Briefing

EU Legislation in Progress

June 2016

European Parliament

Review of 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 which date from 1990. These rules are currently laid out in a directive, which would be repealed and replaced by a regulation.

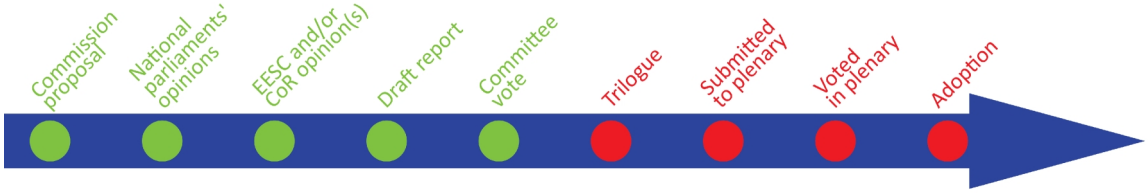
According to the Commission, the need to harmonise the production, marketing and use of medicated feed at EU level results from differences in national implementation that cause difficulties for producers and animal holders and create obstacles in the single market. The revised provisions should also contribute to tackling the problem of antimicrobial resistance. Another aim would be to expand the scope of the regulation to pet animals to facilitate the availability of medicated feed for them.

The legislation on medicated feed is strongly interrelated with the legislation on veterinary medicines. This proposal was therefore presented together with the draft regulation on veterinary medicinal products and legislative work on both acts is being coordinated to assure consistency between their provisions.

On 15 March 2016, the Committee for Agriculture and Rural Development adopted its report on the proposal and decided to open interinstitutional negotiations.

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

Committee responsible:	Agriculture and Rural Development (AGRI)	COM(2014)556 10.09.2014
Rapporteur:	Clara Eugenia Aguilera García (S&D, Spain)	2014/0255 (COD)
Shadow rapporteurs :	Daniel Buda (EPP, Romania) Julie Girling (ECR, UK) Fredrick Federley (ALDE, Sweden) Matt Carthy (GUE/NGL, Ireland) Peter Eriksson (Greens/EFA, Sweden) Giulia Moi (EFDD, Italy)	Ordinary legislative procedure (COD) (Parliament and Council on equal footing (formerly 'co-decision'))
Next steps expected:	Trilogue discussions	



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Author: Beata Rojek-Podgórska

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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. The Commission explains that the rules dating from 1990 need to be modernised and that many provisions are not clear enough, thus allowing differing national implementation. This causes confusion among operators and creates obstacles in the single market. The directive is to be repealed and replaced by a regulation which will harmonise the rules and their implementation at EU level. The proposal is presented in a package together with the proposal for a regulation on veterinary medicinal products. Both acts are strongly interrelated and are being discussed by the co-legislators in a coordinated manner in order to assure consistency of provisions, definitions and approaches.

Context

Medicated feed is a mixture of a veterinary medicinal product (or products) and feed (or feeds) which is ready 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 (a large sector: of ca 800 million farm animals in the EU, ca 140 million are pigs and 450 million laying hens[1]). 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 (ca 200 million, of which 63 million dogs and 72 million cats).[2] 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 (feed mills), on the basis of an approved veterinary medicinal product intended for this purpose (also known as 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, from as low as 0.1% to 9%)[3] and it 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.

The majority of veterinary drugs used in medicated feed are antimicrobials (mostly antibiotics).[4] Usually medicine is administrated 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 which 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). The use of antibiotics as growth promoters to enhance production has been prohibited in the EU since 2006.[5]

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 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.

Existing situation

The conditions for manufacturing, placing on the market and use of medicated feed are laid down in Directive 90/167/EEC (medicated feed directive).[6] This directive provides, among other things, that: medicated feed must be manufactured only with authorised premixes; the manufacturing premises must be approved by national authorities; medicated feed can be supplied to animal holders only against prescription from a veterinarian; the medicated feed manufacturer is responsible for the quality of the products, for the homogeneity of the mix and for preventing contamination of non-target feed; the manufacturer must keep records of the veterinary medicines they used and the feed they produced; when medicated feed is used in animals intended for human consumption, these animals must not be slaughtered before the end of the withdrawal period set for the active substances; Member States may authorise the manufacture of medicated feed on farms; Member States must ensure that there are no obstacles to intra-EU trade in medicated feed.

The directive does not provide, however, for common criteria for the approval of production premises, for the homogeneity of feed and for the carry-over between medicated feed and non-target feed. It does not address anticipated production (which means manufacturing medicated feed in advance, before a veterinary prescription, and storing it until it is ordered). It is also silent on medicated feed for pets.

Being a directive, this legislation leaves Member States free as to how to transpose its provisions into national law. It also offers possibilities which the Member States can apply optionally. In practice, each Member State has its own national system of regulations for medicated feed and these systems differ, sometimes significantly.[7]

While requiring that medicated feed must be manufactured in approved plants, the directive allows a derogation for preparing such feed directly on the farm, with an authorised premix. According to the European Commission's impact assessment, some Member States authorise on-farm mixing, some 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. The directive gives only a general requirement that medicated feed should be sufficiently homogenous. Some Member States implement this provision diligently, by setting up and enforcing target values, while others enforce it to a lesser extent.

As regards carry-over, the directive requires that there be no possibility of undesirable interaction between veterinary medicines and feed. Different approaches have been taken by the Member States. Some have no official value for tolerated carry-over and deal with it on a case-by-case basis, some apply the zero tolerance principle and enforce it either strictly or in a more 'pragmatic' way.

The directive does not address anticipated production. As maintained in the impact assessment, producing medicated feed in advance can help to optimise the manufacturing process, decrease costs, reduce carry-over to non-target feed and ensure quicker delivery to sick animals. Many Member States permit anticipated production, but some impose a prohibition, fearing that this could present an incentive to use the produced medicated feed anyway, even without prescription.

Medicated feed for pets is, according to the impact assessment, available only in three Member States (2014). Many feel unable to authorise these products or are unsure if the directive applies to pets, as its legal base relates to the common agricultural policy.

The industry sees too many regulatory obstacles. The Commission claims that the low availability of medicated feed for pets creates barriers for innovative solutions and prevents comfortable treatment of animals with chronic diseases. However, in the 2010 evaluation it was found that the pet market, although large, is irrelevant regarding the use of medicated feed. Only one of 12 interviewed feed manufacturers' associations and none of 11 producers of veterinary medicines saw a market potential for medicated feed for non-food producing animals.

The scope of the directive and of the proposed regulation covers medicated feed as a ready-to-use product. It does not apply to veterinary medicines used in medicated feed (premixes); these fall under the legislation on veterinary medicinal products. Medicated feed may only be manufactured from medicines authorised under the veterinary medicinal products legislation. Therefore the two proposals are strongly interrelated. For the sake of legal certainty and clarity it is important to ensure coherence between them and to align their corresponding provisions.

Preparation of the proposal

The Commission has been working on the revision of the medicated feed legislation for several years. In 2009 and 2010 an external evaluation of the EU legislative framework in this area was carried out by the Food Chain Evaluation Consortium (FCEC). The report of this evaluation gives a detailed overview of the sector with data at EU and Member States level. Based on this evaluation, as well as on consultations with stakeholders, experts, comitology advisory bodies, Member States and citizens, the Commission published an impact assessment of the proposal in September 2014. Of the analysed options, an EU regulation with detailed rules was considered the best way to achieve the set objectives. Four main problems were identified which would need to be approached 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, it was 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 proposal would bring

The regulation would repeal and replace Directive 90/167/EEC. Most provisions would be retained, many of them clarified. The main changes introduced aim to tackle the problems that were identified during the 2010 evaluation and in the impact assessment.

The problem of **barriers to intra-EU trade** in medicated feed is addressed 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 proposed regulation would be extended to non-food producing animals, to include **medicated feed for pets**. Furthermore, **anticipated production** would be explicitly allowed EU-wide, as would 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 proposed. The **limits for carry-over** of veterinary medicines into non-target feed would be set explicitly. Limits for specific active substances would be established by delegated acts. In the absence of specific values, general limits would 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 would be prohibited. The supply of such feed would be restricted to quantities required for two weeks. **Criteria for the homogeneity** of medicated feed could 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 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 the establishment of concrete criteria for the homogeneity of medicated feed, and inclusion of 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 Committee of Regions decided not to issue an opinion.

National parliaments

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

Stakeholders' views

The European Feed Manufacturers' Federation (FEFAC) welcomed the intended harmonisation of rules, but noted that the two proposals do 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 (like excessive maximum carry-over levels) could make producers stop manufacturing medicated feed.

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 was concerned regarding anticipated production,

considering that this goes against 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 stated that routine use of antimicrobials for prevention should not be permitted as a replacement for good hygiene practices, proper feed and appropriate environment but 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. As for specific provisions, COPA-COGECA called, among other things, for clarification and definition of the 'premix'. It also considered that the administrative requirements are excessive in the case of on-farm mixing. Furthermore, it pointed out that there are too few solutions for minor uses and minor species (bees, rabbits, aquaculture etc.) and that the specificities of these smaller markets should be taken into account.

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.

Legislative process

The Commission proposal was published and submitted to the European Parliament and 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 is based on Article 43 of the Treaty on the Functioning of the European Union (TFEU), the rapporteur prefers to reference only paragraph 2 of this article, which empowers Parliament and Council to establish the common organisation of agricultural markets and other provisions

necessary for the pursuit of the objectives of the common agriculture policy. According to the JURI opinion, of the two paragraphs (2 and 3) of Article 43 which are legal bases, paragraph 2 covers all aspects of the common agriculture policy included in the proposal, therefore this change would be appropriate.

In Council, the proposal is being examined by 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 is 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 on 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.

In Parliament, the AGRI Committee report was adopted on 15 March 2016. Amendments to the proposal concern, 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 shall not apply to finished veterinary medicinal products administered via top dressing or in drinking water, and that the Commission should draw up a separate legislative proposal regulating the administration of veterinary medicines products via 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, unless in exceptional cases. It 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 to issue prescriptions by **other qualified professionals**, in accordance with national law, was clarified by adding this reference in the text.

The AGRI Committee also voted to open interinstitutional negotiations. The trilogues are expected to start after the beginning of interinstitutional negotiations on the proposal on veterinary medicinal products (which, following a partial vote in plenary in March 2016 on amendments, has been referred back to the ENVI Committee).

EP supporting analysis

EPRS Initial Appraisal of the Commission Impact Assessment Medicated feed, Zandersone L., March 2015.

Other sources

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.

[3] Source: European Commission's Impact Assessment, SWD(2014) 271.

[4] Without entering into in-depth discussion, antimicrobials are drugs that kill or stop the growth of living microorganisms (such as bacteria, viruses, fungi and parasites). They include, among others, antibacterials (also called antibiotics, active against bacterial infections), antivirals (against viral infections), antifungals (against fungal infections) and antiparasites.

[5] Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition.

[6] Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feeding stuffs in the Community.

[7] See Commission's impact assessment.

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