

Comments to

DRAFT OPINION
of the Committee on the Environment, Public Health and Food Safety
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
(COM(2014)0556 – C8-0143/2014 – 2014/0255(COD))

The BTK like the rapporteur supports the proposal for a Regulation on medicated feed. A harmonization of the rules on manufacture, placing on the market and use of medicated feed is considered useful. The BTK considers the strong coherence between the regulation on medicated feeds and the new proposal for a Regulation on veterinary medicinal products to be extremely important. Careful use of antibiotics as active ingredients in medicated feed and limitation of carry-over must be ensured. We see as well as the rapporteur, the vets as important players in the use of medicated feed. Medicated feeds must be administered on the basis of examination, diagnosis and prescription by a veterinarian.

We support

- The clarification that the Regulation does not apply to oral medication with finished medicinal products (Amendment 6)
- The definition of "antimicrobials" (Amendment 8) Please note the problems of translation!
- The definition of prophylaxis, therapeutic and metaphylaxis treatment (Amendments 9, 10 and 11)
- The requirement that the substance-specific carry-over limits shall be set by the European Food Safety Authority (EFSA) on the basis of a scientific risk assessment (Amendment 12)
- The clarification of Article 15, paragraph 5, that the examination, diagnosis and prescription does not run from the "prescribing person" but the veterinarian (Amendment 14). Also in Article 15 para. 2 sentence 3, the "person who issued the prescription" should be replaced by "veterinarian".
- That the quantities supplied or mixed for food-producing animals shall not exceed the quantities required for one week (instead of two weeks) in the case of medicated feed containing antimicrobial veterinary medicinal products (Amendment 16). Medicated feed that is approved for a longer application than one week must be excluded however.

In addition, we propose:

- For on-farm mixer the production of medicated feed should be limited to use in their own livestock.

Notes on some amendments:

Amendment 6

Article 1 – Paragraph 1 a (new)

Proposal for a regulation	Amendment ENVI	Comments BTK
	1a. This Regulation shall not apply to finished medicinal products to be orally administered that have been approved for use via feed or drinking water.	This clarification of the scope is to be welcomed, as it is not clearly visible from the regulation text so far.

Amendment 8

Article 2 – Paragraph 2 – Point i a (new)

	(ia) 'antimicrobials': a general term for any compound with a direct action on micro-organisms used for treatment or prevention of infections. Antimicrobials include anti-bacterials/antibiotics, antivirals, anti-fungals and antiprotozoals;	The definition is applicable. But there is a translation problem. The term "antimicrobials" is referred to in the German translation of "antibiotics". Antibiotics are not synonymous with antimicrobial substances. Antibiotics is understood in this country mainly as antibacterial substances. These are indeed the most common active ingredients in medicated feed. One would have to clarify what is meant by the regulation.
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Amendment 12

Article 7 – Paragraph 1 a (new)

	1a. Substance-specific carry-over limits shall be set by the European Food Safety Authority (EFSA) on the basis of a scientific risk assessment.	The proposal is welcomed. A zero tolerance is unworkable, since the magnitude of residues would then depend on the detection limit of the analytical method. Certain carryover is unavoidable and unproblematic. Where the limit is should be determined on a scientific basis. This already happens for the MRLs and the derivation of the withdrawal periods as an absence of residues is also unrealistic.
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Amendment 14

Article 15 – Paragraph 5

5. The prescribed medicated feed may be used only for animals examined by the person who issued the prescription and only for a	5. The prescribed medicated feed may be used only for animals examined by the veterinarian who issued the prescription and only for a	This clarification is welcome. By definition, the veterinarian is the only one who can make a diagnosis and decide on the appropriate treatment.
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<p>diagnosed disease. The person who issued the prescription shall verify that this medication is justified for the target animals on veterinary grounds. Furthermore he shall ensure that the administration of the veterinary medicinal product concerned is not incompatible with another treatment or use and that there is no contra-indication or interaction where several medicinal products are used.</p>	<p>diagnosed disease. The veterinarian who issued the prescription shall verify that this medication is justified for the target animals on veterinary grounds. Furthermore he shall ensure that the administration of the veterinary medicinal product concerned is not incompatible with another treatment or use and that there is no contra-indication or interaction where several medicinal products are used.</p>	<p>In addition, instead of the "person who issued the prescription" should also be replaced by "veterinarian" in paragraph 2.</p>
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Amendment 16

Article 16 – Paragraph 1 – Point b

<p>(b) the quantities required for one month's treatment or two weeks in case of medicated feed containing antimicrobial veterinary medicinal products.</p>	<p>(b) the quantities required for one month's treatment or one week in the case of medicated feed containing antimicrobial veterinary medicinal products.</p>	<p>We agree that medicated feed containing antimicrobial veterinary medicinal products and are intended for use in food-producing animals should only be supplied for a treatment period of one week. Non-food producing animals are not relevant in our view, since such medicated feed is not approved. Addendum: There must be an exception for medicated feed containing antimicrobial veterinary medicinal products and approved for a longer application than one week. These must be available for the approved treatment duration.</p>
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Others:

Article 2, 2 (i)

		<p>For on-farm mixer the production of medicated feed should be limited to use in their own livestock and marketing should be prohibited. A marketing is not the case if a distribution in own animals takes place between different operating parts.</p>
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Berlin, 25 March 2015

The federal chamber of veterinary surgeons (BTK) is a federation of all 17 state veterinary chambers in Germany. It represents the interests of all 37,000 veterinarians, practitioners, official veterinarians, scientists and veterinarians in other occupations in politics, administration and the public at national and EU level.