Brief legal analysis by RA D. Bruhn of 08.09.21: Weaknesses of the draft delegated act and Regulation (EU) 2019/6 with regard to a much-discussed ban on the treatment of individual animals in emergencies

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The German original is available here:
https://martin-haeusling.eu/images/210906_RA_Bruhn_juritische_Kurzanalyse_zu_TAM_VA2019-6_DA_Kriterien_Reserveantibiotika_end.PDF

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Brief analysis

on the European Parliament resolution on the Commission delegated regulation of 26 May 2021 supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council laying down criteria for the designation of antimicrobial agents reserved for the treatment of certain infections in humans

on behalf of Martin Häusling, MEP

On the occasion of many misinformation and irritations, this short analysis shall point out the weak points of the draft delegated act as well as of the regulation (EU) 2019/6 regarding a much discussed ban of individual animal treatment in emergencies. Furthermore, it shall be clarified which adequate demands are put forward in the context of the objection by Martin Häusling (MEP).

Antimicrobial resistance to human and veterinary medicinal products has been identified in the Union and worldwide is a growing health problem, this can be inferred from the list of critically important antimicrobials

in the Veterinary Medicinal Products Regulation (EU) 2019/6.[1] Against this background, the World Health Organization (WHO) has drawn up a ranking list of critically important antimicrobials for human medicine.[2] If these CIAs meet further criteria defined by the WHO, they are classified as "highest priority critically important antimicrobials" (hereinafter HPCIA). According to the WHO, there is an urgent need to take measures to maintain the efficacy of these substances.

The following five classes of active substances, classified by the WHO as HPCIA, are currently authorised for food-producing animals in the EU and are used disproportionately in industrial livestock production:

1. macrolides
2. polypeptides (colistin)
3. fluoroquinolones
4. cephalosporins 3rd generation
5. cephalosporins 4th generation

This is proven in a current study, which at the same time clarifies that in contrast to this, the amount of administration of HPCIA to individual pets is dwindlingly small.[3]

Consequently, the Veterinary Medicinal Products Regulation (EU) 2019/6, which deals with Art. 168(4)(b) TFEU is based solely on the agricultural competence of the EU, the focus therefore point to a significant restriction in the use of (reserve) antibiotics in industrial animal husbandry. In particular, the extensive use of (reserve) antibiotics for prophylactic and metaphylactic group treatment of animals should be curbed.

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[1] Recital (41) Regulation (EU) 2019/6: Antimicrobial resistance to medicinal products for human and veterinary use is a growing public health problem in the Union and worldwide.(...) [It] has become a global public health concern affecting the whole of society and urgently requires coordinated intersectoral action in line with the One Health approach. These actions include strengthening the prudent use of antimicrobial agents, avoiding their routine prophylactic and metaphylactic use, measures to restrict the use of antimicrobial agents in animals that **are critical** for **the prevention or treatment of life-threatening infections in humans**, and promoting and incentivising the development of new antimicrobial agents.

[2] Cf. World Health Organization, World Health Organization Model List of Essential Medicines 21st List (2019) p. 8; for a detailed discussion, see Bruhn, Legal Opinion on the Comprehensive Ban on the Use of Reserve Antibiotics in Food-Industry Animal Husbandry, 2021.

[3] Benning/Strietzel, Recherche zu reserveantibiotika bei Tieren, die der Lebensmittelgewinnung dienen, erstellt im Auftrag von Martin Häusling (MdEP), p. 20, available at https://www.martin-haeus- ling.eu/images/STUDY_Reserve_antibiotics_in_animals_that_serve_food_BENNING_STRIEZEL_sep2021.pdf,

In addition to the provisions already contained in Regulation (EU) 2019/6 on the use of antimicrobial medicinal products (cf. Art. 107 of Regulation (EU) No. 2019/6), the following rules apply, further provisions (Art. 37 of Regulation (EU) 2019/6) were implemented, to reserve the use of certain antimicrobialveterinary medicinal products exclusively for human medicine and to prohibit their use in veterinary medicine to hire. [4]

The draft of the delegated act

The present **draft of the delegated regulation of the Commission**[5] aims to establish the criteria for the designation of such antimicrobial agents reserved for the treatment of certain human infections. The result of this draft is that it raises serious concerns:

- The draft does **not** use the **same criteria as those used by the WHO** to determine the criteria for antimicrobial agents.
- The draft does **not define clear criteria** for the determination of active substances, but operates with terms that are open to interpretation, such as in "Part C" with the "criterion of non-essential need for the Animal Health".[6]
- The EU Commission claims to go further than the WHO with the draft. Against the background of the leeway opened up by the terminology, this does not seem possible in the end.

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[4] Thus, the Commission, by means of a delegated act (Art. 290 TFEU), is first of all entitled, pursuant to Art. 37(4) TFEU, to adopt the following measures
Regulation (EU) 2019/6 allows to establish criteria for the designation of antimicrobial active substances to be reserved for the treatment of certain human infections. By means of an implementing act (Art. 291 TFEU), antimicrobial active substances or groups thereof may then be determined, cf. Art. 37(5) of Regulation (EU) 2019/6. At the same time, these substances/groups will be granted authorisation (Art. 37(3) of Regulation (EU) 2019/6.

[5] European Commission, 2021. ANNEX to the Commission delegated regulation supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council by establishing the criteria for the designation of antimicrobials to be reserved for the treatment of certain infections in hu, Brussels. Available at: https://members. wto. org/crnattachments/2021/SPS/EEC/21_2284_01_e.pdf.

[6] See European Commission, 2021 ANNEX to the Commission delegated regulation supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council by establishing the criteria for the desig- nation of antimicrobials to be reserved for the treatment of certain infections in hu, Brussels. Available at: https://members. wto. org/crnattachments/2021/SPS/EEC/21_2284_01_e.pdf, in particular 'PART C: CRITERION OF NON-ESSENTIAL NEEDS FOR ANIMAL HEALTH; The inconclusiveness of this criterion is illustrated by a response from the EU Commission regarding this criterion: "This criterion aims to ensure that antimicrobial agents are available to treat serious, life-threatening infections in animals which, if left untreated, would have a significant impact on animal health or welfare or on human health. Such diseases can affect food safety and livelihoods of livestock producers, cause excessive suffering of animals and have societal implications considering the important bond between pets and their owners. The paper is available to the author.

- On the contrary, the draft entails the risk that a **group treatment** of animals when applying the intended criteria **with HPCIA still permissible.**
- The EU Commission is currently **not in the position** to name **a single active substance** on the basis of the current draft to be restricted.
- As a result, it is to be feared that the **regulation of the use of reserved antibiotics (HPCIA)** in industrial animal husbandry (group treatment), which is urgently required and intended by the legislator, **cannot be guaranteed** with the current draft.

The prohibition of treatment of individual animals pursuant to Article 107(5) of Regulation (EU) 2019/6

The EU Commission overlooks another problem when it describes the list of antimicrobial agents to be reserved for treatment in humans as *"a living document"*[9] that can always be supplemented or changed. Each and every one of the antimicrobial medicinal products ultimately on that list may no longer be used under any circumstances, that is to say, **not even in the context of individual animal treatment in an emergency**. **This prohibition is laid down in the Regulation in Article 107(5).** The listed antimicrobial medicinal products, for which criteria are to be laid down within the framework of the present legal act, not only lose their authorisation in veterinary medicine (cf. Article 37(3) of Regulation (EU) 2019/6). They are also excluded from the off-label use of (unauthorised) medicinal products in individual emergencies, i.e. in the case of unacceptable suffering of an animal in accordance with the requirements of Art. 112 et seq. VO (EU) 2019/6, excepted.

The EU Commission itself makes it clear that this **ban should also apply to pets without exception.** Such a ban is rightly viewed critically. In order to achieve the objective of the regulation, the use of reserve antibiotics in the group treatment of animals must be prohibited. However, in terms of quantity alone, a ban on the treatment of individual animals in emergencies is neither necessary nor likely to be proportionate in the outcome.

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[7] Cf. in detail Benning/Strietzel, Recherche zu reserveantibiotika bei Tieren, die der Lebensmittelgewinnung dienen, erstellt im Auftrag von Martin Häusling (MdEP), S. 9 ff.

[8] In a paper of the EU Commission on the current delegated act, which is available to the author, it is stated in this regard:
Q.7 Can you give some examples of antimicrobials that will eventually be restricted in the EU?- At this stage it is not possible to give examples.

[9] Paper of the EU Commission on the draft delegated act, available to the author.

The objection to the delegated act

In his objection to the delegated act, Martin Häusling (MEP) has raised both the issue of the insufficiently defined criteria for determining the antimicrobial agents to be reserved for human treatment and the ban on individual animal treatment in emergencies. The objection contains detailed considerations on the criteria now proposed, the WHO criteria and the extent to which the objectives of the Regulation are best served.

The objection aims at a consistent implementation of the Veterinary Medicinal Products Regulation in line with the criteria of the WHO and at the same time demands, with the necessary sense of proportion, that a treatment of individual animals be permitted in extreme cases. It has already been taken into account here, in accordance with the theory of materiality, that such a substantial change to the legislative act as the lifting of this ban cannot be made in the delegated act itself but requires an amendment to the basic act.[10] The motion for a resolution therefore calls on the Commission, in paragraphs 5 to 7, as follows:

> *5. Calls on the Commission to submit a new delegated act in line with the **criteria and recommendations of the WHO** (...)*
>
> *6. Calls on the Commission to **accompany** the new delegated act **with a legislative proposal** amending Regulation (EU) 2019/6 laying down the conditions under which the to lay down rules **for the treatment of individual animals with HRAM** by way of derogation from Article 37(3) of that Regulation*
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> *7. Considers that such a **derogation** should **only** apply **to the treatment of individual animals** with a clinically diagnosed serious, life-threatening disease which, if inappropriately treated, would result in significant morbidity or significant mortality and for which no alternative treatment, alternative management strategy or improved husbandry method/technique is available to prevent, treat or control the disease, and should only apply where an antibiotic susceptibility test is required before treatment; [11]* the recent claim that the objection results in a ban on treatment of companion animals is incorrect.

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[10] Cf. Deutscher Bundestag, Sachstand, Delegierte Rechtsakte der Europäischen Kommission im Framework of the EU Common Agricultural Policy, Ref: PE 6 - 3000 - 76/14.

[11] Unauthorized translation by the author.

Provided that the objection on 16 September 2021 in the EU Parliament has the required majority, this initially means the following:

- In the event of an effective objection, the delegated act adopted shall **not enter into force;**
- the EU Commission is required to submit a **new draft of a delegated** act. This does not necessarily reflect the objection 1:1.
- However, it is to be expected that the new draft will be based on the considerations and demands of the objection as well as on the objectives and contents of the delegation of powers of Regulation (EU) 2019/6 oriented - otherwise there would be a risk of a renewed Objection.
- The **prohibition of the treatment of individual animals** pursuant to Art. 107(5) of Regulation (EU) 2019/6 of (domestic) animals initially **comes to nothing in** the absence of a delegated act and in the absence of a defined list of antimicrobially active veterinary medicinal products based thereon, which are refused an authorisation pursuant to Art. 37(3) of the Regulation.

Conclusion

The objection to the delegated act is to be welcomed and, as a result, calls for nothing other than consistent implementation of what the Union legislator intended. Clearly defined criteria, based on the WHO, with which antimicrobial active substances can be determined, which are then reserved for treatment in humans. In this way, the objection offers the opportunity to effectively counter the ever-increasing threat to human health posed by the development of antibiotic resistance. Only a clear definition of the criteria, based on the WHO, can ensure that a group treatment of animals with the most important reserve antibiotics is denied in the future, as there is no longer any approval for these in veterinary medicine, among other things. At the same time, the objection demands in the result that the prohibition without exception of the treatment of individual animals in emergencies, as provided for in Art. 107 (5) of Regulation (EU) 2019/6, which is laid down in the Regulation, be repealed. There is no apparent reason why it should be necessary and proportionate to implement such a prohibition in a regulation based exclusively on the EU's agricultural competence. This also raises serious concerns with regard to Article 13 TFEU.

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