

MARTIN HÄUSLING (MEP).

Agricultural spokesman for the Greens/EFA Group

Member of the Committee on Agriculture and the Environment in the European Parliament

July 2021



POSITION PAPER:

Criteria for the establishment of reserve antibiotics for Human Medicine - A Response to the Proposal of the European Commission

'If you think Covid 19 is bad, you want nothing to do with antimicrobial resistance'¹

Dr Paul De Barro, head of biosecurity research at Australian government research organisation CSIRO, told The Guardian.

Antibiotic resistance is on the rise worldwide

In the EU alone, 33,000 people die every year because antibiotics no longer work for them. In Germany, the figure is 2,400 people. The global public health consequences of multi-resistant germs are immense when you look at the role antibiotics play today. If antibiotics no longer work, even simple scratches or infections during the birth of a child could lead to death.

The resistances arise because far too many antibiotics are used. In humans, but also - and especially! - in industrial animal fattening. The reserve antibiotic colistin is one of the most used antibiotics in factory farming with 80 tons per year², macrolides follow with 59 tons per year³.

It is estimated that 66% of all antibiotics worldwide are used for farm animals - and not for humans. And almost 90% of the antibiotics administered there are intended for group use⁴, not individual use, with a correspondingly high potential for resistance to develop.

Without a sharp change in the use of antibiotics, the number of deaths from multi-resistant germs will increase dramatically. For Europe, an increase to 400,000 deaths per year is predicted, worldwide to ten million by 2050 - every year. This means that more people would then die from multi-resistant germs than from cancer⁵.

In order to halt the further spread of antibiotic-resistant pathogens, it is of fundamental importance to strictly regulate the use of antibiotics.

For this purpose, the WHO has declared certain antibiotics as "**reserve antibiotics**". More precisely, the WHO speaks of antibiotics of particular importance for humans ("critically important"), and

¹ <https://www.futurezone.de/science/article230381490/Fataler-als-Corona-Forscher-besorgt-durch-multiresistente-Keime.html>

² Ebner, R., Rosenkranz, E. (2021): Pillen vor die Säue. Warum Antibiotika in der Massentierhaltung unser Gesundheitssystem gefährden.

³ <https://germanwatch.org/de/16760>

⁴ <https://www.ema.europa.eu/en/veterinary-regulatory/overview/antimicrobial-resistance/european-surveillance-veterinary-antimicrobial-consumption-esvac#annual-report-on-sales-of-veterinary-antibiotics-section>

⁵ <https://www.aerztezeitung.de/Medizin/Viel-mehr-Tote-durch-multiresistente-Keime-moeglich-250505.html>

MARTIN HÄUSLING (MEP).

Agricultural spokesman for the Greens/EFA Group
Member of the Committee on Agriculture and the Environment in
the European Parliament

July 2021



then further subdivides them into the highest or high priority. Those of highest priority are those that can still act as a last resort in the treatment of widespread and severe bacterial infection. In our opinion, these should be classified as reserve antibiotics. According to the WHO recommendation, these should under no circumstances be used in animal fattening (= treatment of food-producing animals). At the end of 2018, the European Commission, the European Parliament and the European Council also agreed that reserve antibiotics must be reserved for human use in the new EU Veterinary Medicines Regulation.⁶

Commission proposal

However, exactly which antibiotics will be classified as reserve antibiotics has yet to be regulated. From January 2022, the new veterinary medicines regulation is to be applied. And the list of antibiotics that must remain reserved for human medicine should be ready before then. The European Commission has now put a proposal on the table for the criteria to determine the reserve antibiotics as part of a delegated act⁷. However, this proposal contains considerable loopholes which would make it possible to use reserve antibiotics in animal fattening after all. This is unacceptable and for this reason I have objected to this proposal in the European Parliament (right of veto of the European Parliament).

The following is unacceptable in my view:

The Commission proposal lists three criteria that must be met to reserve an antimicrobial active substance for human medicine:

1) the active substance must be of **high importance for human health**

-> totally agree with this criterion.

2) There must be a **risk of resistance transfer** (transfer of bacteria resistant to the antibacterial agent from non-human sources to humans).

-> I also agree with this in principle, of course, however the current delegated legal act states that there must be a *significant transfer of* resistance from animals to humans. However, what is significant is not further specified and offers much room for interpretation. According to the WHO, the *possibility of* resistance transfer alone should be sufficient reason to classify the antibiotic directed against the disease in question as being of critical importance for humans. This is also in line with the European precautionary principle.

3) The antimicrobial active substance has a "non-essential" **importance for animal health**

-> **I completely disagree with this consideration in the classification.** Whether an active substance is classified as a reserve antibiotic - precisely because we want to preserve its efficacy for the treatment of humans - must not be made dependent on the role this active substance plays in veterinary medicine!

⁶ I was the Green negotiator for the Greens, my commentary on the new veterinary medicines regulation at the time can be found here: https://martin-haeusling.eu/images/themen/180614-Briefing-zur-EU-Tierarzneimittelverordnung_Haeusling.pdf

⁷ https://www.europarl.europa.eu/meetdocs/2014_2019/plmrep/COMMITTEES/ENVI/DV/2021/06-28/Commission_Delegated_Regulation_EN.pdf
https://www.europarl.europa.eu/meetdocs/2014_2019/plmrep/COMMITTEES/ENVI/DV/2021/06-28/Annexe_EN.pdf

MARTIN HÄUSLING (MEP).

Agricultural spokesman for the Greens/EFA Group
Member of the Committee on Agriculture and the Environment in
the European Parliament



July 2021

Demands:

I call for the European Commission's proposal to be revised in such a way that antibiotics considered by the WHO to be the most **important globally:**

- are in principle reserved for life-saving measures in human medicine,
- can no longer be used for the problematic group treatment of animals,
- however, individual animal treatment with these antibiotics via the Veterinary Medicines Regulation if the following conditions are met:
 - o Clinical diagnosis of a serious, life-threatening disease, which, if inadequately treated, could lead to serious illness or death
 - o The disease cannot be prevented, treated or controlled by alternative treatment, alternative management strategies or improved animal husbandry
 - o Antibiotic susceptibility testing (antibiogram) has taken place

- **These demands are found in my objection against the current proposals of the European Commission (see points 6 and 7 on page 9)**
- **In establishing the criteria and the list of reserve antibiotics, the WHO-List⁸ should serve as a basis.**

Human physicians also call for ban

Human physicians at the German and European level have also expressed their views. They argue that human health must take precedence over the economic interests of livestock farmers⁹.

- **The Environment and Health Committee of the European Parliament has supported the objection in its vote on July 13.**

What's next?

September 2021: The entire European Parliament votes on the objection. If the majority of MEPs is in favour of the objection, the European Commission must revise the delegated act. Once the criteria for reserve antibiotics have been established, the European Commission will, on the basis of the criteria, draw up a **list** identifying all the antibiotics that will be designated as reserve antibiotics. This will be done by means of an implementing act, which means that the European Parliament will not have a veto on this. That is also why it is so important that the criteria for

⁸ <https://apps.who.int/iris/bitstream/handle/10665/312266/9789241515528-eng.pdf>, Seite 26. Diese werden von der WHO als highest priority critically important antimicrobials bezeichnet (nicht deckungsgleich mit dem, was die WHO als Reserveantibiotika bezeichnet)

⁹ Stellungnahme der Bundesärztekammer: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/11570-Drug-resistance-criteria-for-identifying-antimicrobial-medicines-reserved-for-treating-humans/F2234955_en

Stellungnahme des Ständigen Ausschusses Europäischer Ärzte: https://www.cpme.eu/index.php?downloadunprotected=/uploads/adopted/2021/6/093_FINAL.Letter.MEPs_on_Drug_resistance.Commission.delegated.regulation.pdf

MARTIN HÄUSLING (MEP).

Agricultural spokesman for the Greens/EFA Group
Member of the Committee on Agriculture and the Environment in
the European Parliament

July 2021



reserve antibiotics are correct, they are after all the basis for the list of reserve antibiotics.

The Veterinary Medicines Regulation is applicable throughout the EU, irrespective of the adoption of the list, on 28.1.2022.

Context

Figures on the use of antibiotics in animal fattening

- Although there has been an overall downward trend in antibiotic sales in animal fattening in Europe in the recent years, also for reserve antibiotics (precisely: '*highest priority critically important antimicrobials*' according to the WHO definition)¹⁰, 14 percent of total sales of antibiotics in animal fattening are reserve antibiotics¹¹.
- 87.7 percent of all sales of antibiotics in animal fattening are suitable for group treatment, only 12.3 percent for individual treatment of animals.
- Reserve antibiotics: with the exception of 3rd and 4th generation cephalosporins (individually by injection), all others are almost exclusively available in forms of use suitable for group treatment (oral solution, oral powders, premixes). Group treatment increases the risk of resistance formation many times over.

Background on antibiotics in animal husbandry¹²

Antibiotics have been used in animal husbandry for more than six decades. In Europe they were originally used as a growth promoter. This has been banned in the EU since 2006. According to the OIE, there are still at least 35 countries in the world where antibiotics are used for growth promotion¹³. The share of agriculture in global antibiotic consumption is high and increasing. Overall, agriculture is responsible for over 75% of annual antimicrobial consumption in the EU and the US. Of the 35 classes of antibiotics currently available, only seven classes are used exclusively in agriculture. Tetracyclines, penicillins and macrolides account for over three-fifths of antibiotic use in agriculture. Since no new antibiotics have been developed for more than 40 years, agriculture is using more and more medically "potent" antibiotics. The use of reserve antibiotics in agriculture and consequently the emergence and spread of resistance in e.g. colistin and macrolides is particularly threatening¹⁴.

- Pigs: In intensive farms piglets are weaned at the age of three to four weeks and are given antibiotics as a precaution to avoid the diarrhea that often follows. If piglets are weaned later, their digestive system is stronger and diarrhea is less likely.
- Poultry: Antibiotics are also widely used in poultry farming for the treatment and prevention of respiratory diseases and other bacterial infections. In turkeys and chickens, more than 40 percent use reserve antibiotics¹⁵. Fluoroquinolones, a class of antibiotics used for treatment in *Campylobacter* infections in humans is a commonly used antibiotic.

¹⁰ <https://apps.who.int/iris/bitstream/handle/10665/312266/9789241515528-eng.pdf> (WHO Definition Seite 26) und Tabellen ab Seite 49)

¹¹ https://www.ema.europa.eu/en/documents/report/sales-veterinary-antimicrobial-agents-31-european-countries-2018-trends-2010-2018-tenth-esvac-report_en.pdf

¹² Beispiele von <https://www.saveourantibiotics.org/the-issue/antibiotic-overuse-in-livestock-farming/>

¹³ <https://www.oie.int/app/uploads/2021/03/a-fourth-annual-report-amr.pdf> (Abbildung 14)

¹⁴ Quelle: OECD 2016

¹⁵ <https://germanwatch.org/de/16760>

MARTIN HÄUSLING (MEP).

Agricultural spokesman for the Greens/EFA Group
Member of the Committee on Agriculture and the Environment in
the European Parliament

July 2021



This is often administered via the drinking water to the entire flock of poultry - even if only some animals are affected. A study by Germanwatch shows that every second chicken in Germany from large-scale slaughterhouses is contaminated with antibiotic-resistant pathogens¹⁶.

- Cows: Antibiotics are applied to the udders of dairy cows during the dry period in order to prevent udder inflammation.

There is another way

In organic animal husbandry, significantly fewer antibiotics are used. In organic pig farming, only 13 per cent, but in conventional farming 54.7 percent of herds showed multi-resistant pathogens¹⁷. Demeter has completely banned the use of reserve antibiotics¹⁸.

Imports

Antibiotics that are banned in animal husbandry in the EU may also not be used in imports, e.g. in beef from the USA or Brazil. A strict restriction of antibiotics in European legislation could therefore contribute to a stricter regulation in exporting countries with less stringent regulations¹⁹.

Further information (most of it in German):

Video: Presentation of the delegated act by the European Commission to the Environment and Health Committee of the European Parliament and exchange with MEPs - [ENVI 28.6 at 16.45 o'clock](#)

[Present of the European Commission](#)

[Criteria in Annex](#)

[Documentation "Mehr Tierschutz im Massenstall"](#)

35% of meat samples taken in various EU countries already showed multidrug resistance. Pathogens against reserve antibiotics

¹⁶ <https://germanwatch.org/sites/germanwatch.org/files/2020%20Studie%20%27H%C3%A4hnchenfleisch%20im%20Test%20auf%20Resistenzen%20gegen%20Reserveantibiotika%27%2C%20Germanwatch.pdf>

¹⁷ Fromm, S. et al. (2013): Risikofaktoren für MRSA in der Tierproduktion – eine Metaanalyse. In: Antibiotikaresistenz in der Lebensmittelkette. Es wurden 400 Datensätze ausgewertet: 380 aus Deutschland, 14 aus den Niederlanden und sechs aus Italien.

¹⁸ Demeter-Richtlinien 2021, S. 61

¹⁹ Zum Antibiotikaeinsatz bei landwirtschaftlichen Nutztieren in Brasilien siehe beispielsweise hier: <https://pubmed.ncbi.nlm.nih.gov/32224900/>