

# Mirror Clauses & Antimicrobial Resistance

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# Animal Health Europe: who are we?

12 companies



16 associations  
representing 21 countries

- Belgium
- Czechia
- Denmark
- Finland
- France
- Germany
- Greece
- Hungary
- Iceland
- Ireland
- Italy
- Netherlands
- Norway
- Poland
- Portugal
- Slovakia
- Spain
- Sweden
- Switzerland
- Ukraine
- United Kingdom

Working to ensure a ready availability of  
a wide range of animal health products throughout Europe

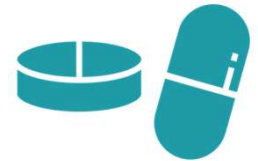
## MISSION

- **Our mission** is to be the voice of the European animal medicines industry
- **Our aim** is
  - to highlight the importance of healthy pets and farm animals and
  - to demonstrate the reliability and value of our solutions to society.By ensuring a ready availability of animal health products throughout Europe, we can help optimise health management and ensure the welfare of animals, while contributing to the sustainability of food production and keeping the companion animals that share our homes free from disease.
- **Our vision** “Healthy animals across Europe and beyond”

# The 2014 revision of our sectorial legislation

The original objectives of the revision were to:

- 1) Increase availability of veterinary medicinal products
- 2) Reduce administrative burden
- 3) Stimulate competitiveness and innovation
- 4) Improve the functioning of the internal market
- 5) Address the public health risk of AMR



# How did a mirror clause come about?

- **September 2014 :**  
Commission **Proposal** for a Regulation revising Directive 2001/82 is published
- **June 2015:**  
Rapporteur MEP Grossetête tables amendment requesting reciprocity on imports
- **2016-2017:**  
Adoption of **EP Report & Council Conclusions** which include reciprocity mention
- **18 May 2018:**  
Political compromise during **trilogues**



- c) *Animals or products of animal origin imported into the Union (Article 122a, EP amendments 264 and 265)*
19. In order to protect the human health against the risk of spread of antimicrobial resistant organisms through imports of animals or products of animal origin and to level the playing field between the animal production within the Union and in third countries exporting to the Union, the Council and the European Parliament have each introduced a new provision to require that certain basic restrictions on the use of antimicrobials on animals set out in this Regulation apply also to animals and animal products imported to the Union. While the European Parliament could accept the Council's approach included in Article 122a (which focusses on the ban of use of antibiotics for growth promotion and of antimicrobials to be reserved for the treatment of certain infections in humans), it firmly insists that the reference in that Article to the compatibility with relevant international agreements should be deleted, as it considers that such a reference is redundant and weakens the political message.
- As the European Parliament has indicated that this point is extremely important for them, the Presidency proposes to accept their request for deletion in Article 122a and to introduce new wording in Recital 39 to underline that the Union obligations under relevant international agreements are fully respected.



# What does a “mirror clause” look like

Article 118  
Regulation 2019/6 on veterinary medicinal products

## *Article 118*

### **Animals or products of animal origin imported into the Union**

1. Article 107(2) shall apply, *mutatis mutandis*, to operators in third countries and those operators shall not use the designated antimicrobials referred to in Article 37(5), insofar as relevant in respect of animals or products of animal origin exported from such third countries to the Union.
2. The Commission shall adopt delegated acts in accordance with Article 147 in order to supplement this Article by providing the necessary detailed rules on the application of paragraph 1 of this Article.



# Article 118 and its legislative implications

1. **Establishment of criteria for antibiotics reserved for human medicine based on the scientific opinion of the European Medicines Agency (EMA)**
  - Delegated act 2021/1760 - article 37.4
2. **List of antibiotics reserved for human medicine**
  - Implementing act 2022/1255 article 107.6
3. **Official controls regulations** modified to include additional controls for entry into the EU of animal goods
  - Regulation 2017/625 modified
4. **Detailed rules on exports from 3rd countries**
  - Delegated act 2023/905 - “article 118”
    - Implementing act adapting official certificates 2024/399
    - Delegated act laying down the list of third countries-ongoing WTO

## Questions around article 118

- Is article 118 **WTO compatible**?
- What impact does article 118 have on **imports and exports** of products to and from the EU?
- Is the **list of countries final**?
- Is the **list of antibiotics** reserved for human list **final**?
- Is article 118 the first of a long series of “mirror clauses” in upcoming EU legislation?

**Any questions on your side?**



# Thank you!



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