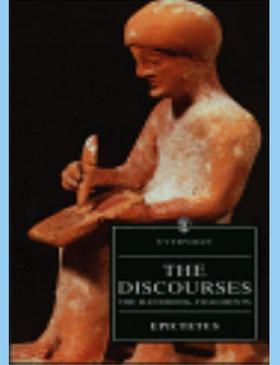


# Risk assessment of biocide and antibiotic resistance Workshop

*“What concerns me is not the way things are, but rather the way people think things are.”*

Epictetus, ca. A.D. 55-135



**Keith Baptiste**

# A timely reality check on silent pandemic of antimicrobial resistance

New evidence shows that, in 2019, AMR was the direct cause of at least 1.27 million global deaths. This number is only set to grow further, unless action is taken.



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Global burden of bacterial antimicrobial resistance in 2019:  
a systematic analysis

THE LANCET

Volume 399, ISSUE 10325, P629-655, February 12, 2022.

DOI:[https://doi.org/10.1016/S0140-6736\(21\)02724-0](https://doi.org/10.1016/S0140-6736(21)02724-0)



# ONE HEALTH

Human health and animal health are interdependent.  
At the same time, both depend on the environment.

Diet



HUMAN HEALTH



Social determinants



Population movements



Note: The associated factors are not exhaustive, they are examples, as there are many elements to consider.

Security food



Antibiotics and other antimicrobials



Climate change



Intensive livestock



ANIMAL HEALTH



Water pollution



Disease vectors



ENVIRONMENT



Air pollution



Biodiversity loss



Deforestation



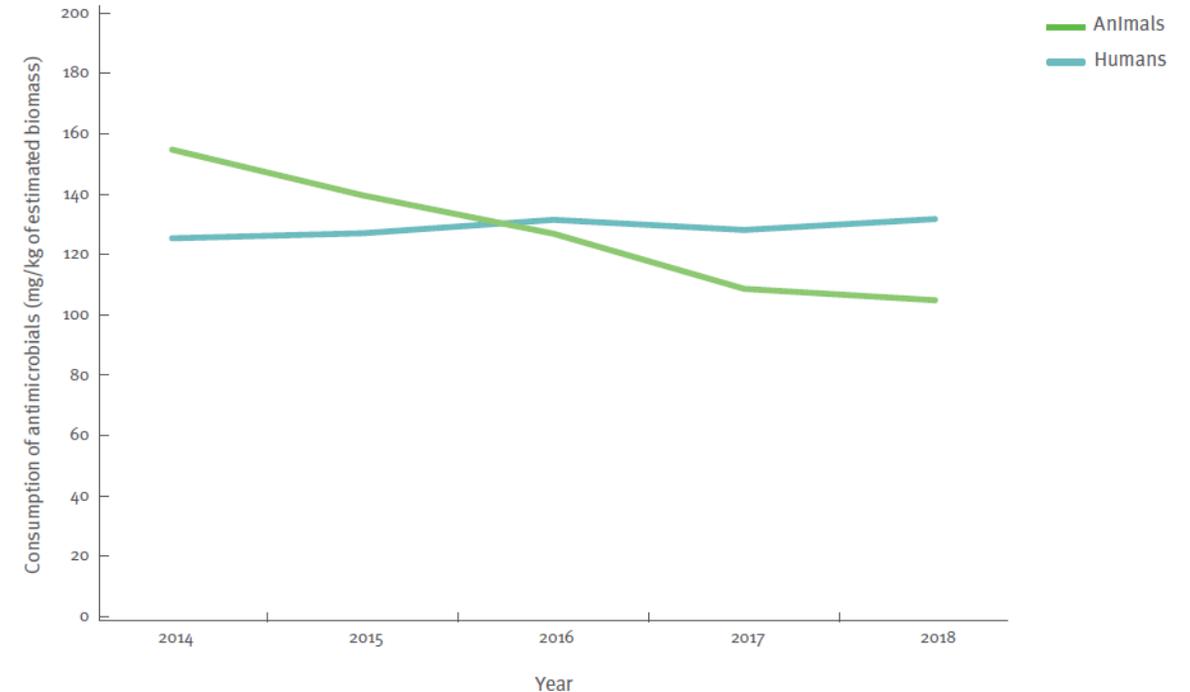
ISGlobal

# Antimicrobial consumption and resistance in bacteria from humans and animals

Third joint inter-agency report on integrated analysis of antimicrobial agent consumption and occurrence of antimicrobial resistance in bacteria from humans and food-producing animals in the EU/EEA

JACRA III  
2016–2018

Figure III: Population-weighted mean of the total consumption of antimicrobials in humans<sup>(a)</sup> and food-producing animals<sup>(b)</sup> in 27 EU/EEA countries<sup>(c)</sup> for which data were available for both humans and food-producing animals, for 2014–2018



# Fundamental differences in Antimicrobial use between Veterinary & Human Medicine

➤ High use in healthy animals (e.g. prophylaxis/metaphylaxis)

➤ Many EU member states allow veterinarians to make profit from the sales/prescription of medicines

➤ High percentage of off-label usage

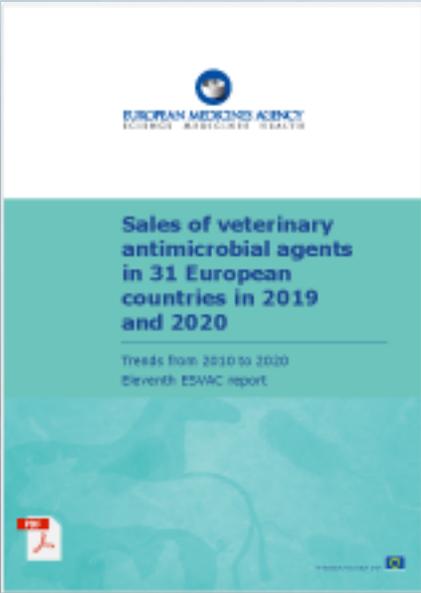
*“The use of a veterinary medicinal product that is not in accordance with the summary of the product characteristics (SPC), including the misuse and serious abuse of the product.”* European Directive 2001/82/EC (Official Journal L -311, 28/11/2004, p. 1 – 66)



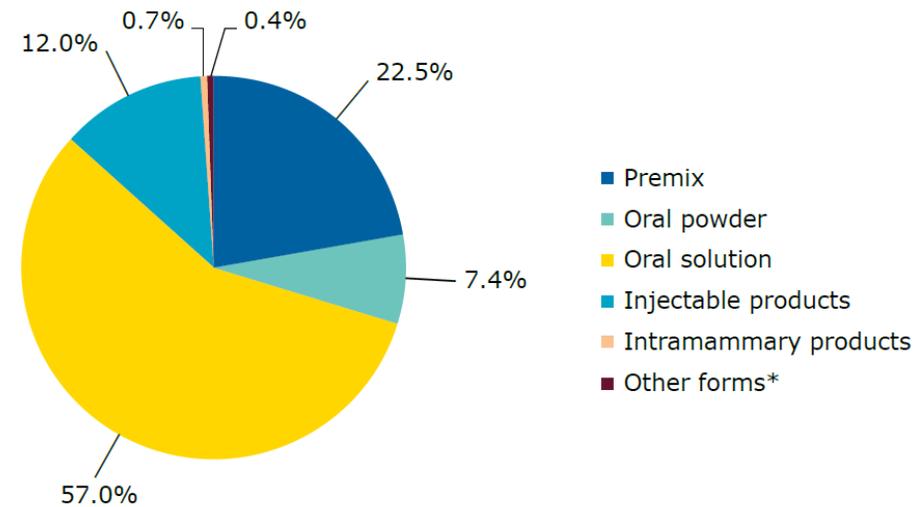


# Antimicrobial Premixes, oral powders/granules for bulk animal feed

European overall sales=5577.8 tonnes of antimicrobials: 86.9% of sales were VMPs either for bulk animal feed or drinking water.



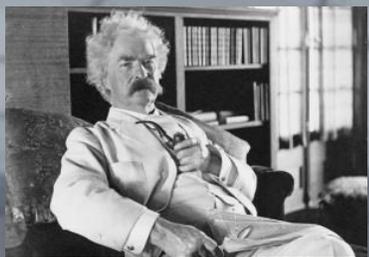
**Figure 8.** Distribution of sales, in mg/PCU, of the various product forms of antimicrobial VMPs for food-producing animals, aggregated by the 31 European countries, in 2020



\* 'Other forms' includes oral pastes, boluses and intrauterine products.



# Antimicrobial Powders/granules, oral solutions for common drinking water



*“It ain't what you don't know that gets you into trouble. It's what you know for sure that just ain't so.”*  
**Mark Twain (1835 – 1910)**

# Highlights of the NVR on antimicrobials in VMPs & MF

## Mass medication bans

- Ban on preventative use of antibiotics in groups of animals.
- Ban on preventative use of antibiotics via medicated feed.
- Re-inforced ban on antibiotics for growth promotion(including third country trading partners).

## Restrictions

- Restrictions on antibiotics for metaphylaxis
- List of antibiotics for human-use only (ban in veterinary medicine)
- Restrictions of specific antimicrobials under ‘Cascade-use’ (off-label)



## Data collection

- Compulsory data collection (EU wide) on sales & use of antimicrobials (animal species level)

# Changes in CVMP Antimicrobial Veterinary Assessments



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Preliminary Risk Profile

- The purpose is to consider the AMR risk to public health from a NEW substance or VMP
- Identify potential need for risk management measures.
- The intended benefit is to provide early stage feedback to applicants and thereby encourage the pharmaceutical industry to develop new antimicrobials for animals.
- Applicants must pay for the assessment.

## Risk Assessment Guideline for Food Animals

- Legally required for applications under Article 8(2), Article 19 (hybrids), Article 62 (variations requiring assessment)
- Used in Referrals addressing concerns over the AMR risk to human health
- The GL does not apply to Article 18 generics.

## TERRESTRIAL ANIMAL HEALTH CODE

- Not specifically developed for AMR
- Easily adaptable
- Relatively simple to understand
- Less frequently updated
- Lacks detail/transparency for complex risk assessments
- Assumptions needed for risk estimate

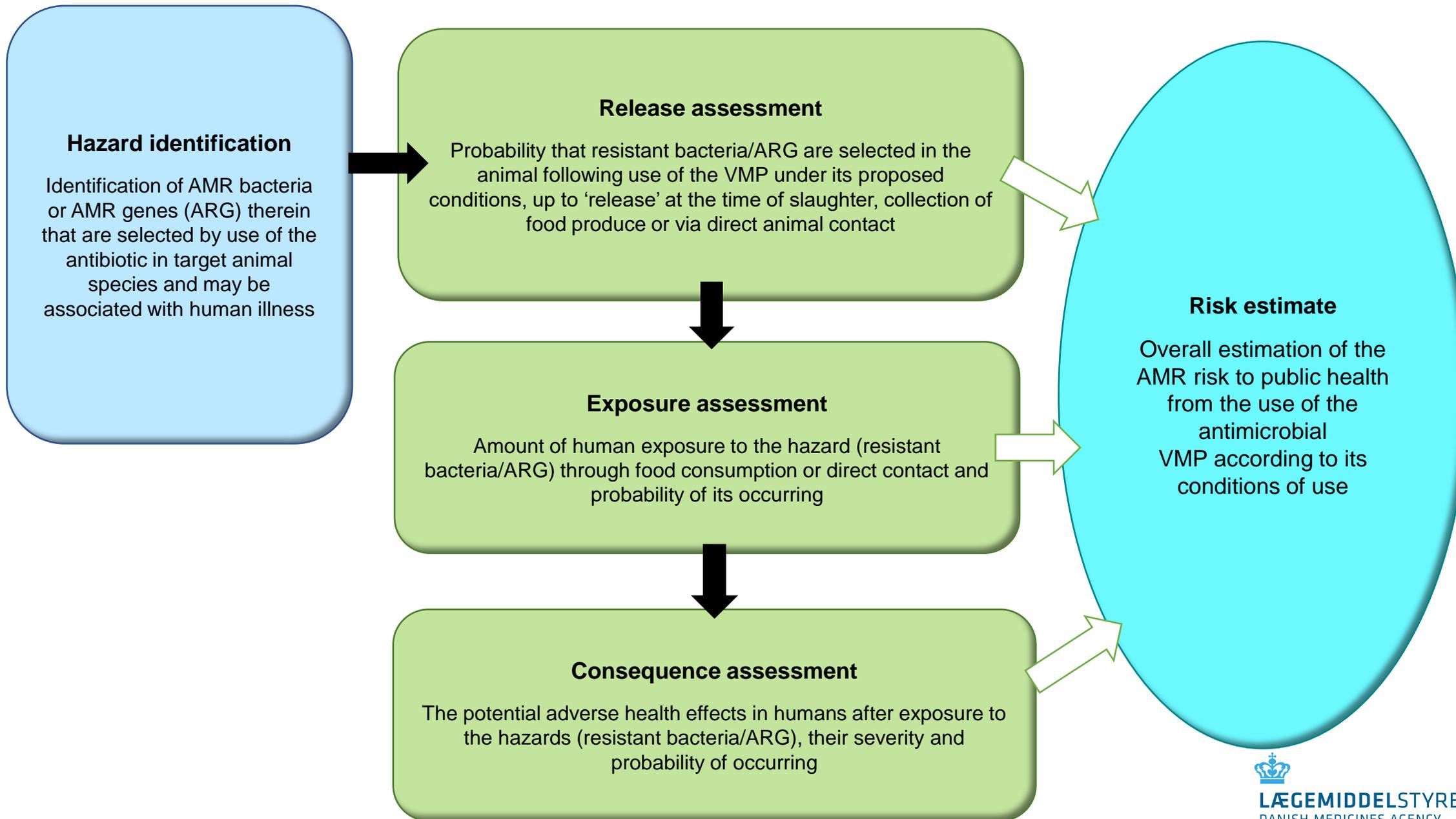
## CODEX ALIMENTARIUS

INTERNATIONAL FOOD STANDARDS

- Specifically developed for AMR
- Not easily adaptable
- Requires training to understand
- Frequently updated
- Very detailed/transparent for complex risk assessments
- No assumptions needed for risk estimate

# Scope of the CVMP Risk Assessment Guideline

- The risk question addresses:
  - Risk to **human health** e.g. loss of treatment options, burden on healthcare services, mortalities (not animal health or the environment)
  - Use of an antimicrobial **VMP** in line with the **intended SPC** (target species, formulation, dosing regimen) (not off-label use)
- **Food-producing species** (not companion animals)
- AMR transfer via **food** and **direct contact** (not environment)
- Risk assessment only (not risk management, communication)



# Thoughts on Regulatory Antimicrobial Risk Assessments



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

- Not fully implemented. Not much experience at this stage.
- Unclear how risks assessments can be objectively evaluated.
  - Biased from the start (based on WHO classification)
  - EU commission also wish to promote availability of VMPs
- Impact of a newly authorised veterinary antimicrobial, that has been through the risk assessment process, will not likely affect population-level antimicrobial resistance for years after authorisation.
- Not designed to take into account the impact of off-label usage
- Not designed to take into account the impact on the environment
- Only designed for food animals (not all species) and not companion animals.

# Følg os

