



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Guideline on the assessment of the risk to public health from AMR due to use of an antimicrobial VMP in food-producing animals

—

## Categorisation of risk factors, risk assessment steps and overall risk estimation

---

Focus group meeting, 19 Sep 2018, London

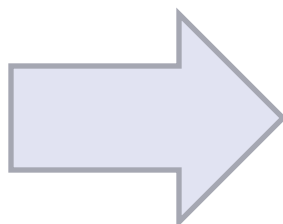
Presented by Christine Schwarz  
Vice-chair of the CVMP's Antimicrobials Working Party





# Risk assessment steps

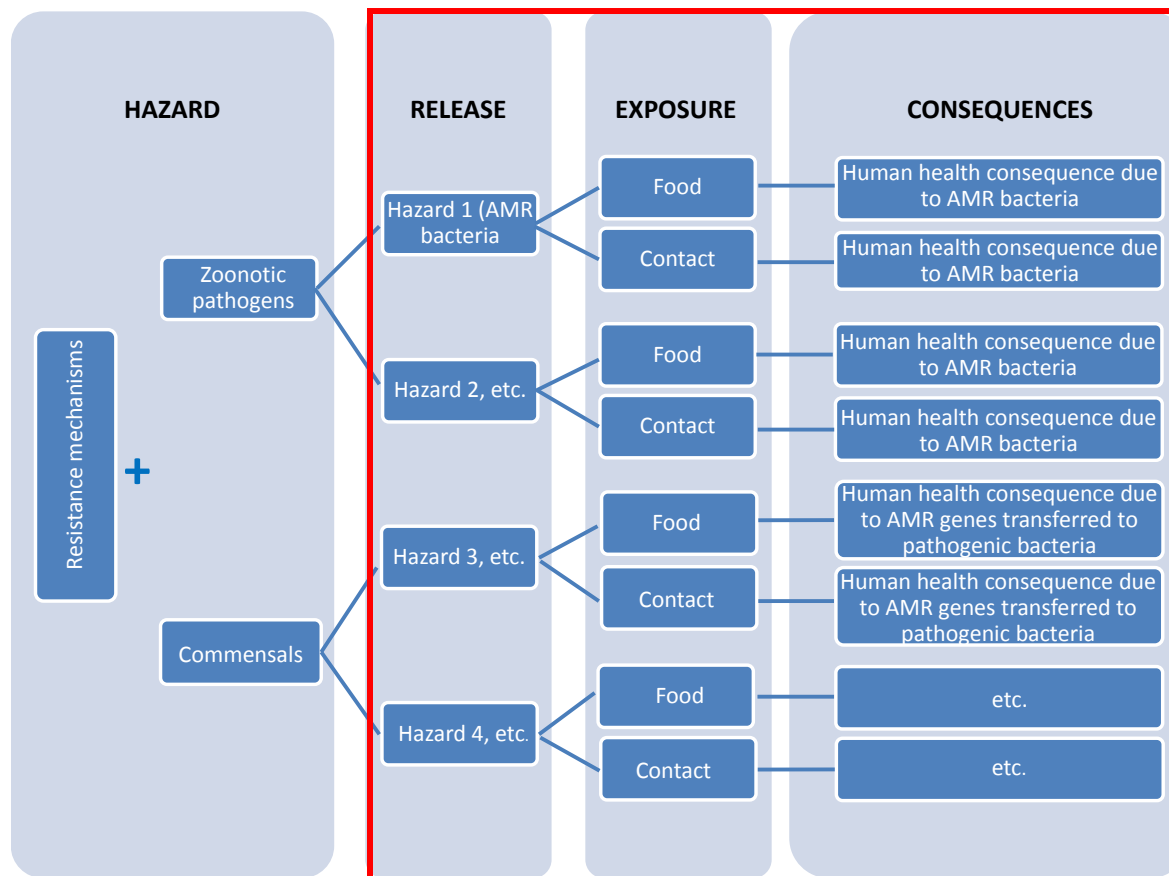
- Hazard identification
- Release assessment
- Exposure assessment
- Consequence assessment



**Risk estimation:** Integration of release, exposure and consequence assessments



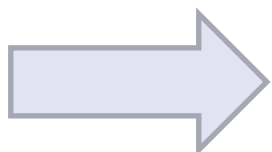
# Mapping of assessment steps





# Categories of risk factors for release / exposure /consequence assessment

very low (VL) – low (L) – medium (M) – high (H)



Ranking of the overall categorization relative  
to the **range of possible outcomes**

... examples for scales of RF are **starting points** that may be refined according to specific conditions of use of the VMP



# Release assessment – Example 1

## Conditions of use, estimate of usage

**higher risk:** common diseases, major species, high level of human contact

**lower risk:** minor species, rare diseases

### **Risk factor:** Target species populations

- **High:** pigs, cattle, poultry
- **Medium:** small ruminants
- **Low:** fish, horses
- **Very low:** rabbits

Resources: e.g. Eurostat, ESVAC



# Release assessment – Example 2

## Resistance selection pressure

**Risk factor:** [Route of administration](#)

**higher risk:** herd/flock treatments, oral, long-acting formulations

**lower risk:** individual animal treatments, local formulations



## Release assessment – Example 3

Prevalence of zoonotic bact./commensals and their resistance rates

**Risk factors:** Proportion of positive samples / Percentage of resistant isolates

- High: >20%
- Medium: >10% to 20%
- Low: >1% to 10%
- Very low:  $\leq 1\%$

Resources: EFSA



# Exposure assessment – Example 4

## Human consumption patterns for food

### Risk factor: Meat

- **High:** >20 kg per capita p.a. - pork, poultry, fish
- **Medium:** >10-20 kg per capita p.a. - beef/veal
- **Low:** >1-10 kg per capita p.a. – sheep
- **Very low:** <1 kg per capita p.a. – other

Resources: EFSA/Eurostat, FAO-OECD





# Categories - overall conclusions

## Release / exposure assessment

- **Very low:** very low probability that release/exposure to occur
- **Low:** low probability for release/exposure to occur
- **Medium:** medium probability for release/exposure to occur
- **High:** significant probability for release/exposure to occur



# Categories - overall conclusions

## Consequence assessment

- **VL** - the antimicrobial is of **very low** importance in terms of **frequency of use** to treat a disease where treatment **alternatives** are available and outcomes are not different.
- **L** - the antimicrobial is of **low to medium** importance in terms of the **frequency of use** to treat a disease for which the **outcomes are more serious** with impact on the individual and on healthcare services.
- **Medium** - the antimicrobial is of **medium to high** importance in terms of the **frequency of use** to treat a disease for which the **outcomes are more serious** with impact on the individual and on healthcare services, **requiring** (possibly prolonged) **hospitalisation**.
- **High** - the antimicrobial is a **last resort treatment** (or one of few alternatives) for a disease for which the **outcome** of treatment failure is **very severe** requiring **lengthy hospitalisation** or resulting in **disability or death**.



## Risk estimation

Integration of release, exposure and consequence assessments

Overall estimate of the risk to PH due to AMR - qualitative approach

The RE should consider:

- entire risk pathway from each of the hazards
- summary of the key influencing data
- uncertainty and variability

Risk matrix? Not included to have greater flexibility



**Final risk conclusion**



# Thank you for your attention

## Further information

---

[zoltan.kunsagi@ema.europa.eu](mailto:zoltan.kunsagi@ema.europa.eu)

**European Medicines Agency**

30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom

**Telephone** +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555

**Send a question via our website** [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact)

Follow us on  **@EMA\_News**



# Conclusions on risk assessment step

Overall conclusions on **release, exposure** and **consequence** assessment expressed as **VL, L, M** or **H** together with

uncertainty of data: **L, M, H**

- **Low** uncertainty: abundant high quality data, consistent conclusions
- **Medium** uncertainty: limited amount of data
- **High** uncertainty: no data available, reliance on expert opinion

variability of data: presented as **best, most common, worst case** scenarios