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 –

Overview

Focus group meeting, 19 Sep 2018, London

Presented by Helen Jukes
Chair of the CVMP's Antimicrobials Working Party

Overview of the guideline

- Scope
- When does the GL apply
- Methodology and data for the risk assessment
- Timelines for GL development

Scope of the guideline/risk assessment

Methodology and data requirements to address the Risk Question:

What is the risk to human health from antimicrobial-resistant bacteria resulting from the intended use of the proposed veterinary medicinal product?

- Risk to human health (e.g. loss of treatment options, burden on healthcare services, mortalities)
- 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)

When does the GL apply?

MA applications for

- New AM substances
- New combinations of AMs
- Any VMP application that will increase extent of use of the AM or the potential risk to public health, e.g. change in dose regimen, major new indication, new target species/production group

Referral procedures for antimicrobial VMPs

Methodology and data for the risk assessment

Adapted from OIE (Terrestrial Animal Health Code)

Also takes note of:

- Codex CAC/GL 77-2011
- Requirements from other jurisdictions (FDA, Heath Canada, APVMA)

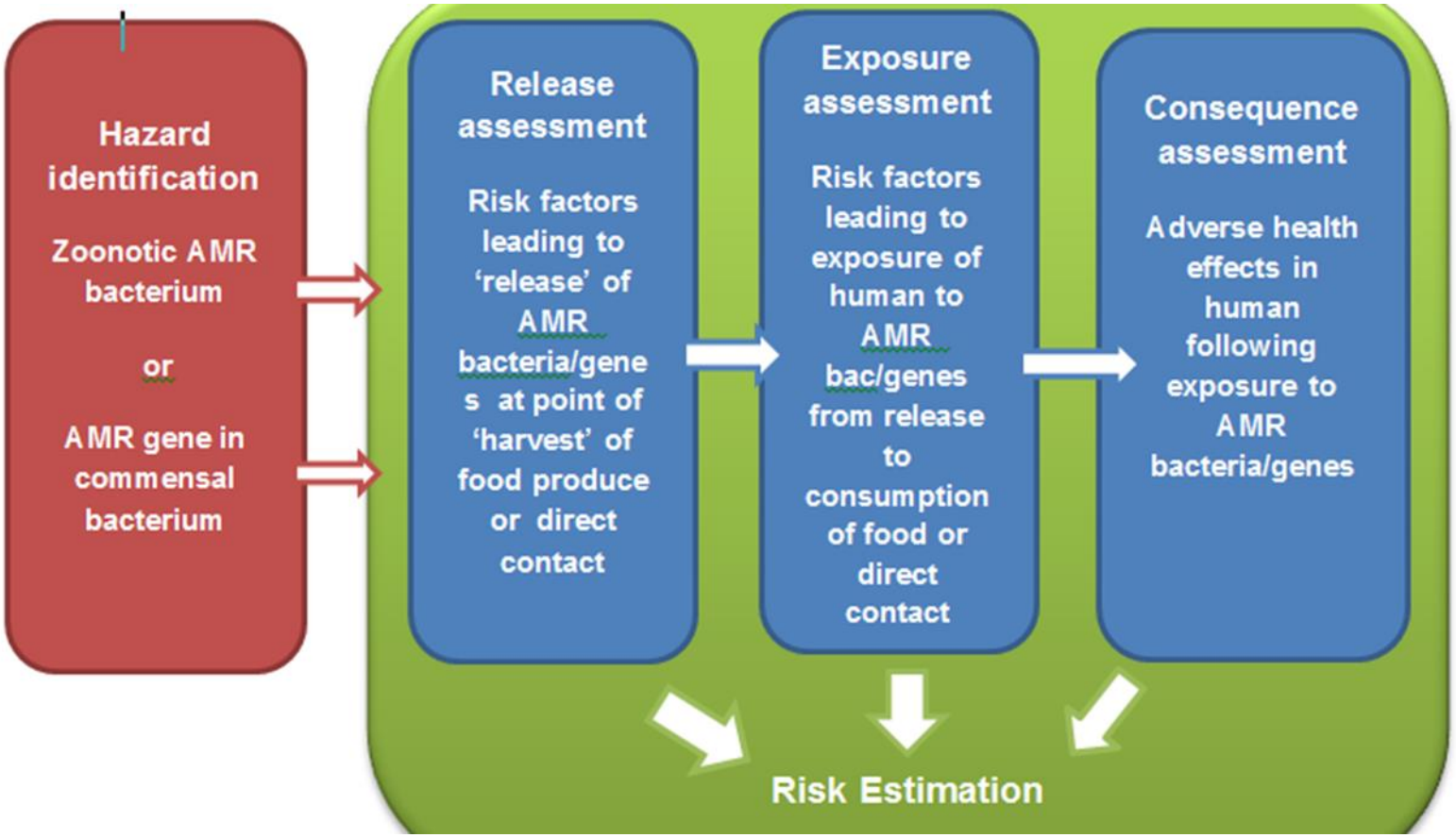
Hazard identification: Identification of zoonotic AMR bacteria or AMR genes in commensal bacteria that are selected by the AM in the target animal and could be involved in a human illness.

Release assessment: Probability (H, M, L, VL) that the hazard will be selected and 'released' following the proposed (SPC) use of the AM VMP

Exposure assessment: Amount of exposure to the hazard through food/contact and the probability of its occurring (H, M, L, VL)

Consequence assessment: Potential adverse health effects of human exposure to the hazards, the severity and probability of those consequences (H, M, L, VL)

⇨ **Risk estimation**: Overall estimate of the risk to public health from AMR resulting from the use of the proposed VMP in accordance with its SPC.



Overview of the AMR risk assessment GL

Data requirements

Data gaps → qualitative risk assessment

Risk factors should be assessed: H,M, L, VL relative to the range of possible outcomes

Uncertainty and variability in data should be discussed

Overall risk estimation: takes into account the entire risk pathway from each of the hazards identified to the unwanted outcomes.

Timelines

First draft released for public consultation from Feb to August 2015

Draft revised according to comments received

Second draft GL and 'Overview of comments + CVMP responses' published July 2018

Second draft released for consultation from July to 31 October 2018

Further revision temporarily suspended under EMA's business continuity plan at least until Q3 2019

Thank you for your attention

Further information

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