



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 –

Key updates after public consultation

Focus group meeting, 19 Sep 2018, London

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

An agency of the European Union





Key updates to the GL after the first consultation

- Risk Question clarified (EU, human health consequences)
- Discussion given on approach to 'uncertainty' and 'variability' in the data
- Direct contact route of AMR transfer: more examples of supporting data given
- Further guidance on hazard identification, and the review of the risk associated with each hazard
- More discussion on the ranking of (H, M, L, VL) of individual risk factors and specific guidance for certain RFs
- More guidance given on the categorisation (H, M, L, VL) of each step (release, exposure, consequence)
- Option for a pragmatic approach to the consequence assessment introduced



Hazard identification and the methodology

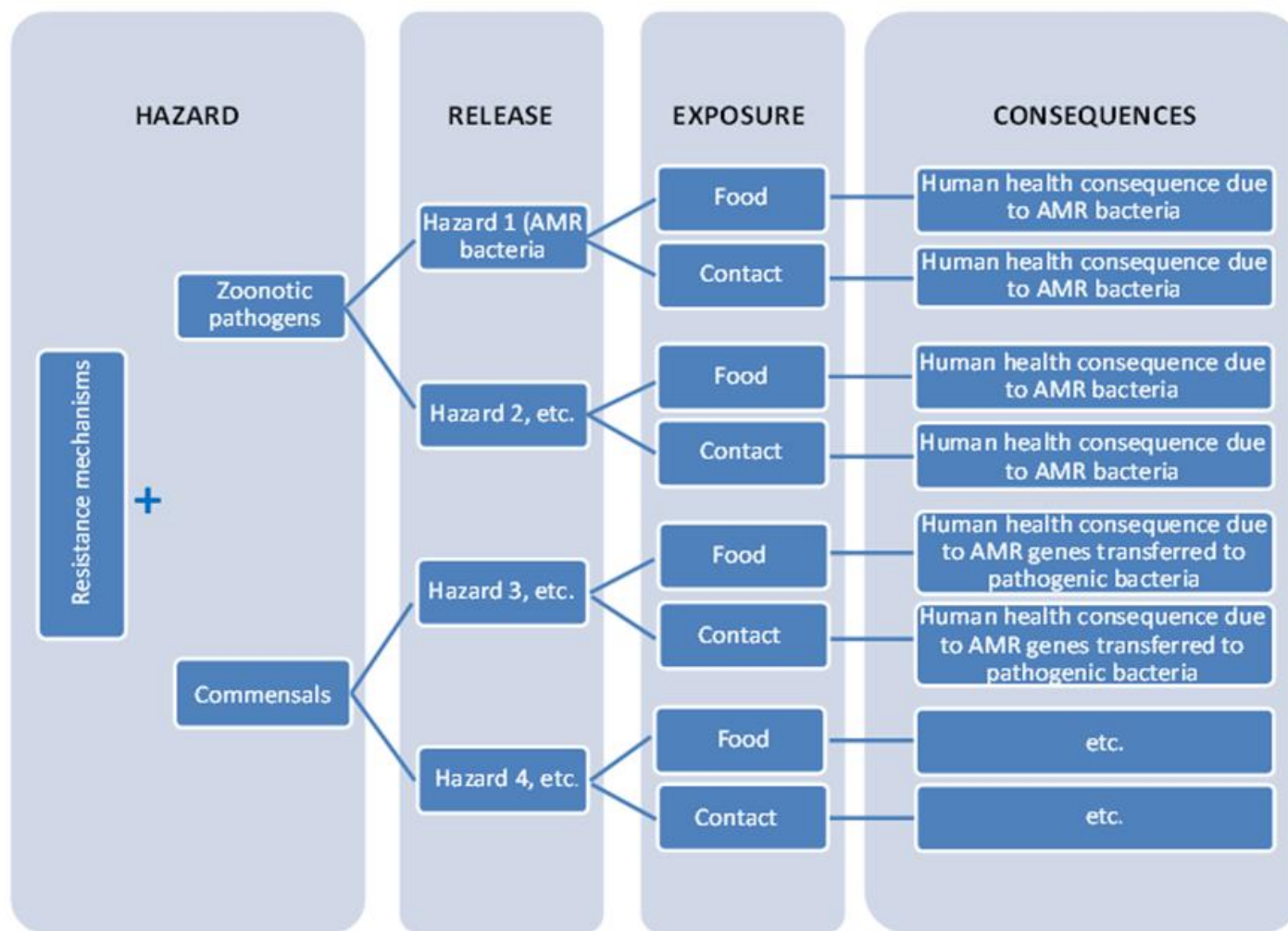
Annex 1

Zoonotic and commensal bacteria present in different food-producing species in which carriage of AMR could be a hazard to human health (non-exhaustive):

Bacterial species	Routes of exposure	Animal species that are possible sources
Zoonotic bacteria		
<i>Campylobacter</i> spp e.g. <i>jejuni</i> , <i>coli</i>	Food (meat, milk) (Contact)	Poultry (<i>jejuni</i>) Pigs (<i>coli</i> , <i>jejuni</i>) Cattle Sheep, goats Fish
<i>Salmonella</i> spp	Food (meat, eggs, milk) Contact	Pigs (Typhimurium) Poultry (<i>Infantis</i> , <i>Enteritidis</i>) Cattle (Typhimurium, Dublin) Sheep, goats



Hazard identification and the methodology (p.12)





Thank you for your attention

Further information

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

Follow us on  **@EMA_News**