



Assessment and listing of animal diseases caused by bacteria resistant to antimicrobials within the framework of Regulation (EU) 2016/429 („Animal Health Law’)

PAFF meeting 30 November 2022

Section AHW, Agenda point A.08.

Part 1: Risk assessment by EFSA

- Key elements of the process
 - Followed a specific methodology
 - Started wide and narrowed down: geographically and content-wise
 - Based on available data: scientific publications and national monitoring data
 - Quality criteria to select data
 - AMR EURL was the data collector
 - 8 groups of animal species covered
 - Dogs/cats, horses, cattle, swine, poultry, goat/sheep, rabbits, aquatic animals

Key elements of findings

- Initial screening: very wide (100s, listed in Appendix A of the SO on methodology)
- Global list: almost 100 diseases, as relevant for the groups of species

Dogs/cats	Horses	Cattle	Sheep/goats	Swine	Poultry	Rabbits	Aquatic
12	11	12	16	16	13	8	4

- Selected for EU relevance

Dogs/cats	Horses	Cattle	Sheep/goats	Swine	Poultry	Rabbits	Aquatic
3	2	2	1	2	3	0	0

- EU relevant list comprised 8 diseases

Staphylococcus pseudintermedius, Rhodococcus equi, Enterococcus ceacorum, Enterococcus faecalis, Brachyspira hyodysenteriae, Pseudomonas aeruginosa, Staphylococcus aureus, Escherichia coli

From initial via global to EU relevance

Animal species/groups	Initial screening list	Global pathogen list	Global vs. 8 EU relevant pathogens
Dogs and cats	43	12	<i>Staphylococcus pseudintermedius</i> , <i>Staphylococcus aureus</i> , <i>Staphylococcus schleiferi</i> , <i>Escherichia coli</i> , <i>Proteus mirabilis</i> , <i>Klebsiella spp.</i> , <i>Enterobacterspp.</i> , <i>Pseudomonas aeruginosa</i> , <i>Clostridium perfringens</i> , <i>Clostridioides difficile</i> , <i>Enterococcus faecalis</i> , <i>Enterococcus faecium</i>
Horses	37	11	<i>Actinobacillus equuli</i> , <i>Dermatophilus congolensis</i> , <i>Enterococcus spp.</i> , <i>Escherichia coli</i> , <i>Klebsiella pneumoniae</i> , <i>Pasteurella spp.</i> , <i>Pseudomonas aeruginosa</i> , <i>Rhodococcus equi</i> , <i>Staphylococcus aureus</i> and <i>Streptococcus dysgalactiae</i> subsp. <i>dysgalactiae/equisimilis</i> , <i>Streptococcus equi</i> subsp. <i>equi</i> and subsp. <i>zooepidemicus</i>
Cattle	76	12	<i>Escherichia coli (non-VTEC)</i> , <i>Klebsiella pneumoniae</i> , <i>Staphylococcus aureus</i> , <i>Streptococcus uberis</i> , <i>Streptococcus dysgalactiae</i> , <i>Pasteurella multocida</i> , <i>Mannheimia haemolytica</i> , <i>Histophilus somni</i> , <i>Mycoplasma bovis</i> , <i>Moraxella bovis</i> , <i>Fusobacterium necrophorum</i> , <i>Trueperella pyogenes</i>
Sheep and goats	50	16	<i>Staphylococcus aureus</i> , <i>Escherichia coli (non-VTEC)</i> , <i>Pseudomonas aeruginosa</i> , <i>Dichelobacter nodosus</i> , <i>Moraxella ovis</i> , <i>Mannheimia haemolytica</i> , <i>Pasteurella multocida</i> , <i>Mycoplasma ovipneumoniae</i> , <i>Mycoplasma agalactiae</i> , <i>Trueperella pyogenes</i> , <i>Streptococcus uberis</i> , <i>Bibersteinia trehalosi</i> , <i>Campylobacter fetus</i> , <i>Mycoplasma mycoides</i> subsp. <i>capri</i> , <i>Mycoplasma capricolum</i> subsp. <i>capricolum</i> , <i>Fusobacterium necrophorum</i>
Swine	35	16	<i>Escherichia coli</i> , <i>Streptococcus suis</i> , <i>Actinobacillus pleuropneumoniae</i> , <i>Pasteurella multocida</i> , <i>Glaeserella parasuis</i> , <i>Bordetella bronchiseptica</i> , <i>Staphylococcus aureus</i> , <i>Staphylococcus hyicus</i> , <i>Brachyspira hyodysenteriae</i> , <i>Trueperella pyogenes</i> , <i>Erysipelothrix rhusiopathiae</i> , <i>Streptococcus dysgalactiae</i> , <i>Mycoplasma hyosynoviae</i> , <i>Mycoplasma hyorhinis</i> , <i>Mycoplasma hyopneumoniae</i> , <i>Brachyspira pilosicoli</i>
Poultry	50	13	<i>Avibacterium (Haemophilus) paragallinarum</i> , <i>Bordetella avium</i> , <i>Clostridium perfringens</i> , <i>Enterococcus faecalis</i> , <i>Enterococcus cecorum</i> , <i>Erysipelothrix rhusiopathiae</i> , <i>Escherichia coli</i> , <i>Gallibacterium spp.</i> , <i>Mycoplasma synoviae</i> , <i>Ornithobacterium rhinotracheale</i> , <i>Pasteurella multocida</i> , <i>Riemerella anatipestifer</i> , <i>Staphylococcus aureus</i>
Rabbits	30	8	<i>Pasteurella multocida</i> , <i>Staphylococcus aureus</i> , <i>Pseudomonas aeruginosa</i> , <i>Escherichia coli</i> , <i>Bordetella bronchiseptica</i> , <i>Clostridium difficile</i> , <i>Clostridium perfringens</i> , <i>Clostridium spiroforme</i>
Aquatic	4	4	<i>Aeromonas hydrophila</i> , <i>Aeromonas salmonicida</i> , <i>Flavobacterium psychrophilum</i> , <i>Flavobacterium columnare</i>



Relevant scientific opinions

- Ad hoc method: <https://www.efsa.europa.eu/en/efsajournal/pub/6645>
- Dogs and cats: <https://www.efsa.europa.eu/en/efsajournal/pub/6680>
- Horses: <https://www.efsa.europa.eu/en/efsajournal/pub/7112>
- Cattle: <https://www.efsa.europa.eu/en/efsajournal/pub/6955>
- Sheep and goats: <https://www.efsa.europa.eu/en/efsajournal/pub/6956>
- Swine: <https://www.efsa.europa.eu/en/efsajournal/pub/7113>
- Poultry: <https://www.efsa.europa.eu/en/efsajournal/pub/7114>
- Rabbits: <https://www.efsa.europa.eu/en/efsajournal/pub/6999>
- Aquatic: <https://www.efsa.europa.eu/de/efsajournal/pub/7076>

Part 2: EFSA findings on listing and categorisation

Outputs

0-33%	33-66%	66-100%
Not listed	Uncertainty about listing	Listed
Any probability range that crosses into the 33-66% zone		

8 Scientific Opinions:

Antimicrobial-resistant bacterium	Animal species	Link	Date published	Outcome of the assessment on listing (probability range)
<i>Staphylococcus pseudintermedius</i>	Dogs and cats	https://efsa.europa.eu/en/press/comm/efsa/efsa/10/2022/efsa-2022-2002	01/02/2022	Uncertain (33-90%)
<i>Rhodococcus equi</i>	Horses	https://efsa.europa.eu/en/press/comm/efsa/efsa/10/2022/efsa-2022-2001	02/02/2022	Uncertain (10-66%)
<i>Enterococcus faecalis</i>	Poultry	https://efsa.europa.eu/en/press/comm/efsa/efsa/10/2022/efsa-2022-2003	21/02/2022	Uncertain (33-66%)
<i>Enterococcus cecorum</i>	Poultry	https://efsa.europa.eu/en/press/comm/efsa/efsa/10/2022/efsa-2022-2004	25/02/2022	Uncertain (33-75%)
<i>Brachyspira hyodysenteriae</i>	Swine	https://efsa.europa.eu/en/press/comm/efsa/efsa/10/2022/efsa-2022-2005	15/03/2022	Uncertain (33-66%)
<i>Pseudomonas aeruginosa</i>	Dogs and cats	https://efsa.europa.eu/en/press/comm/efsa/efsa/10/2022/efsa-2022-2010	03/05/2022	Uncertain (33-90%)
<i>Escherichia coli</i>	Dogs and cats, horses, swine, poultry, cattle, sheep and goats	https://efsa.europa.eu/en/press/comm/efsa/efsa/10/2022/efsa-2022-2011	10/05/2022	Uncertain (33-66%)
<i>Staphylococcus aureus</i>	Cattle and horses	https://efsa.europa.eu/en/press/comm/efsa/efsa/10/2022/efsa-2022-2012	10/05/2022	Uncertain (60-90%)

Relevant scientific opinions

- Staphylococcus pseudintermedius in dogs and cats:
<https://www.efsa.europa.eu/en/efsajournal/pub/7080>
- Rhodococcus equi in horses: <https://www.efsa.europa.eu/en/efsajournal/pub/7081>
- Enterococcus ceacorum in poultry: <https://www.efsa.europa.eu/en/efsajournal/pub/7126>
- Enterococcus faecalis in poultry: <https://www.efsa.europa.eu/en/efsajournal/pub/7127>
- Brachyspira hyodysenteriae in swine: <https://www.efsa.europa.eu/en/efsajournal/pub/7124>
- Pseudomonas aeruginosa in dogs and cats:
<https://www.efsa.europa.eu/en/efsajournal/pub/7310>
- Staphylococcus aureus in cattle and horses:
<https://www.efsa.europa.eu/en/efsajournal/pub/7312>
- Escherichia coli in dogs and cats, horses, swine, poultry, cattle, sheep and goats:
<https://www.efsa.europa.eu/en/efsajournal/pub/7311>

An example for uncertainty

- Staphylococcus pseudintermedius in dogs and cats: skin infections and otitis
 - „Criterion A(v): risk-mitigating measures and, where relevant, surveillance of the disease are effective and proportionate to the risks posed by the disease in the Union”
- Details
 - „The bacterium is a commensal and ubiquitous worldwide, and therefore present in the EU. This makes its risk and the effectiveness of risk-mitigating measures difficult to assess.
 - Treatment (antibiotics) is available, effective and proportionate (considering the disease caused by the bacterium), but can be complicated by multidrug resistance.
 - Other risk-mitigating measures such as surgical antimicrobial prophylaxis, personal hygiene, cleaning and disinfection can be used.
 - Surveillance for AMR *S. pseudintermedius* is sporadic and not harmonised.
 - There are no vaccines or officially/internationally recognised diagnostic tests available.”

Horizontal key problems

- Applicable to all/most animal species and/or pathogens and/or antibiotics
 - Lack of standardised methodology, breakpoints, definitions
 - Heterogeneity or scarcity of information:
 - Infected vs. subclinical vs. clinically affected animals, previous treatments etc.
 - Treatment failure may not be related to microbiological AMR
 - Microbiological AMR may not lead to treatment failure
- National monitoring programs can be of great use

AHL baseline for Category E diseases

- Obligations to be aware, to notify etc.
- Notification and/or annual reporting in accordance with CIR (EU) 2020/2002
- Passive surveillance, no active programme(s)
- Data is collected in ADIS
- Data collection is not co-financed
- Examples: Paratuberculosis, Japanese encephalitis, Equine encephalomyelitis (Eastern and Western), Q fever, West Nile fever, Koi herpes virus disease

Risk management option

Key considerations

- Criteria in the AHL
- Rules for Cat E diseases
- Efficiency and proportionality (burden) of regulation vs. non-regulatory alternatives
- Subsidiarity
- On the basis of EFSA assessment:

no listing of any of the 8 diseases

If MS wish to comment

Send your contribution to either (or both) of the following:

- SANTE-ANIMAL-HEALTH-LAW@ec.europa.eu
- SANTE-CONSULT-G2@ec.europa.eu
- **Deadline: 30 December 2022**