



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

AHAC meeting 28/10/2022

Agenda point 6.

Terms of reference to EFSA

1. Global state of play as regards resistant bacterial animal pathogens that cause transmissible animal diseases

ToR1

1. Summarize the situation in the EU and identify the most relevant bacteria in the EU

ToR2

1. Listing and categorisation of the bacteria that are relevant in the EU in the framework of the Animal Health Law

ToR3

ToR 1

EFSA to perform a **literature review** as follows:

1. Review AMR-related aspects of any bacteria responsible for transmissible animal diseases for which AMR concerns are described both at EU level and globally
2. Target animal species should include **terrestrial and aquatic** food-producing farmed animals, but also include **companion animals**, as there is a lack of data on AMR in those species
3. Bacteria covered by **Directive 2003/99/EC** should be **excluded**
4. Describe the **occurrence** and **prevalence** of AMR in such bacteria, the most relevant **antibiotics** against which resistance has developed and may also include other aspects (**molecular mechanisms**)
5. **Uncertainties and data gaps** also identified and described

ToR 2

Summarize the situation in the EU in terms of the actual or potential impact on animal health of the most relevant bacteria in the EU, indicating those for which sufficient data exists and those for which data is not sufficient

EU relevance is to be understood on the basis of practical considerations, such as actual presence in the EU or presence elsewhere but in animal species, age groups or production systems which are widely used in the EU, or similar elements

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, ToR 3: EFSA findings on listing and categorisation

Outputs

8 Scientific Opinions:

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

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.onlinelibrary.wiley.com/doi/10.2903/efsa.2022.2080	01/02/2022	Uncertain (33-90%)
<i>Rhodococcus equi</i>	Horses	https://efsa.onlinelibrary.wiley.com/doi/10.2903/efsa.2022.2081	02/02/2022	Uncertain (10-66%)
<i>Enterococcus faecalis</i>	Poultry	https://efsa.onlinelibrary.wiley.com/doi/10.2903/efsa.2022.2082	21/02/2022	Uncertain (33-66%)
<i>Enterococcus cecorum</i>	Poultry	https://efsa.onlinelibrary.wiley.com/doi/10.2903/efsa.2022.2120	25/02/2022	Uncertain (33-75%)
<i>Brachyspira hyodysenteriae</i>	Swine	https://efsa.onlinelibrary.wiley.com/doi/10.2903/efsa.2022.2121	15/03/2022	Uncertain (33-66%)
<i>Pseudomonas aeruginosa</i>	Dogs and cats	https://efsa.onlinelibrary.wiley.com/doi/10.2903/efsa.2022.2310	03/05/2022	Uncertain (33-90%)
<i>Escherichia coli</i>	Dogs and cats, horses, swine, poultry, cattle, sheep and goats	https://efsa.onlinelibrary.wiley.com/doi/10.2903/efsa.2022.2311	10/05/2022	Uncertain (33-66%)
<i>Staphylococcus aureus</i>	Cattle and horses	https://efsa.onlinelibrary.wiley.com/doi/10.2903/efsa.2022.2312	10/05/2022	Uncertain (60-90%)

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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

Possible follow-up by stakeholders

Pending and/or regardless of EU regulatory steps

- Those remain to be decided

Beneficial uptake by stakeholders of information already collected by EFSA

- To improve health and welfare of animals
- For prudent use of ABs
- To avoid AMR

To address, reduce uncertainty

- Hitherto missed key data?
- More/different data from stakeholder monitoring initiatives?
- Non-regulatory initiatives (research etc.)

Enhanced cooperation between competent authorities and stakeholders

Summary

- Focus is on animal health
- Have a look and see how you can:
 - use the data to improve health and welfare of animals
 - enhance the quantity and/or quality of available data
- Contribute to national and/or non-regulatory monitoring or other initiatives