

**15 September 2022**

Standing Committee on Plants, Animals, Food and Feed  
Section Animal Health and Welfare



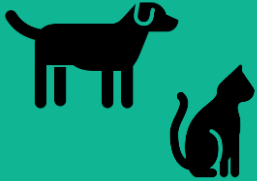
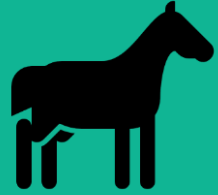

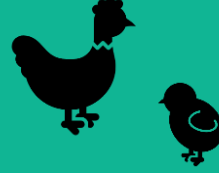


# Listing and categorisation of antimicrobial-resistant bacteria within the framework of Regulation (EU) 2016/429 ('Animal Health Law')

**Lisa Kohnle**

Scientific Officer (EFSA)

Trusted science for safe food

8 'most relevant' antimicrobial-resistant (AMR) bacteria in the EU:

<b>Dogs and cats</b> 	<b>Horses</b> 	<b>Swine</b> 	<b>Poultry</b> 	<b>Cattle</b> 	<b>Sheep and goats</b> 
<i>Escherichia coli</i>	<i>Escherichia coli</i>	<i>Escherichia coli</i>	<i>Escherichia coli</i>	<i>Escherichia coli</i>	<i>Escherichia coli</i>
	<i>Staphylococcus aureus</i>			<i>Staphylococcus aureus</i>	
<i>Pseudomonas aeruginosa</i>	<i>Rhodococcus equi</i>	<i>Brachyspira hyodysenteriae</i>	<i>Enterococcus cecorum</i>		
<i>Staphylococcus pseudintermedius</i>			<i>Enterococcus faecalis</i>		

- **'Fact-sheets'** for each AMR bacterium covering all criteria specified in **Article 7** of Regulation (EU) 2016/429 ('Animal Health Law')
  - (a) disease profile (b) impact of the disease (c) potential to generate a crisis situation and its potential use in bioterrorism (d) feasibility, availability and effectiveness of disease prevention and control measures (e) impact of disease prevention and control measures
- Quantitative instead of categorical approach for the **assessment on listing** (according to criteria specified in **Article 5**) and **categorisation** (according to criteria specified in **Annex IV**) → use of probability ranges to account for uncertainties
- **Lists of animal species** to be considered for listing for each AMR bacterium according to **Article 8**

- 'How certain are you that statement X is true?'

Probability term	Subjective probability range
Almost certain	99–100%
Extremely likely	95–99%
Very likely	90–95%
Likely	66–90%
About as likely as not	33–66%
Unlikely	10–33%
Very unlikely	5–10%
Extremely unlikely	1–5%
Almost impossible	0–1%

**Table 3:** Outcome of the expert judgement on Article 5 criteria

Criteria to be met by the disease: According to the AHL, a disease shall be included in the list referred to in point (b) of paragraph 1 of Article 5 if it has been assessed in accordance with Article 7 and meets all of the following criteria		Outcome			
		Median range (%)	Criterion fulfilment	Number of na	Number of experts
A(i)	The disease is transmissible	90–99	Fulfilled	0	14
A(ii)	Animal species are either susceptible to the disease or vectors and reservoirs thereof exist in the Union	99–100	Fulfilled	0	16
A(iii)	The disease causes negative effects on animal health or poses a risk to public health due to its zoonotic character	66–90	Fulfilled	0	14
A(iv)	Diagnostic tools are available for the disease	95–100	Fulfilled	0	14
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	33–90	Uncertain	0	14
<b>At least one criterion to be met by the disease:</b> In addition to the criteria set out above at point A(i)–A(v), the disease needs to fulfil at least one of the following criteria					
B(i)	The disease causes or could cause significant negative effects in the Union on animal health, or poses or could pose a significant risk to public health due to its zoonotic character	33–90	Uncertain	0	14
B(ii)	The disease agent has developed resistance to treatments which poses a significant danger to public and/or animal health in the Union	66–95	Fulfilled	0	14
B(iii)	The disease causes or could cause a significant negative economic impact affecting agriculture or aquaculture production in the Union	5–33	Not fulfilled	0	14
B(iv)	The disease has the potential to generate a crisis or the disease agent could be used for the purpose of bioterrorism	0–5	Not fulfilled	0	16
B(v)	The disease has or could have a significant negative impact on the environment, including biodiversity, of the Union	5–33	Not fulfilled	0	14

na: not applicable.

- 'How certain are you that statement X is true?'

0–33%	33–66%	66–100%
Criterion not fulfilled	Uncertainty about criterion fulfilment	Criterion fulfilled
<b>Any probability range that crosses into the 33–66% zone</b>		

**Table 3:** Outcome of the expert judgement on Article 5 criteria

Criteria to be met by the disease: According to the AHL, a disease shall be included in the list referred to in point (b) of paragraph 1 of Article 5 if it has been assessed in accordance with Article 7 and meets all of the following criteria		Outcome			
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A(iii)	The disease causes negative effects on animal health or poses a risk to public health due to its zoonotic character	66–90	Fulfilled	0	14
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B(iii)	The disease causes or could cause a significant negative economic impact affecting agriculture or aquaculture production in the Union	5–33	Not fulfilled	0	14
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B(v)	The disease has or could have a significant negative impact on the environment, including biodiversity, of the Union	5–33	Not fulfilled	0	14

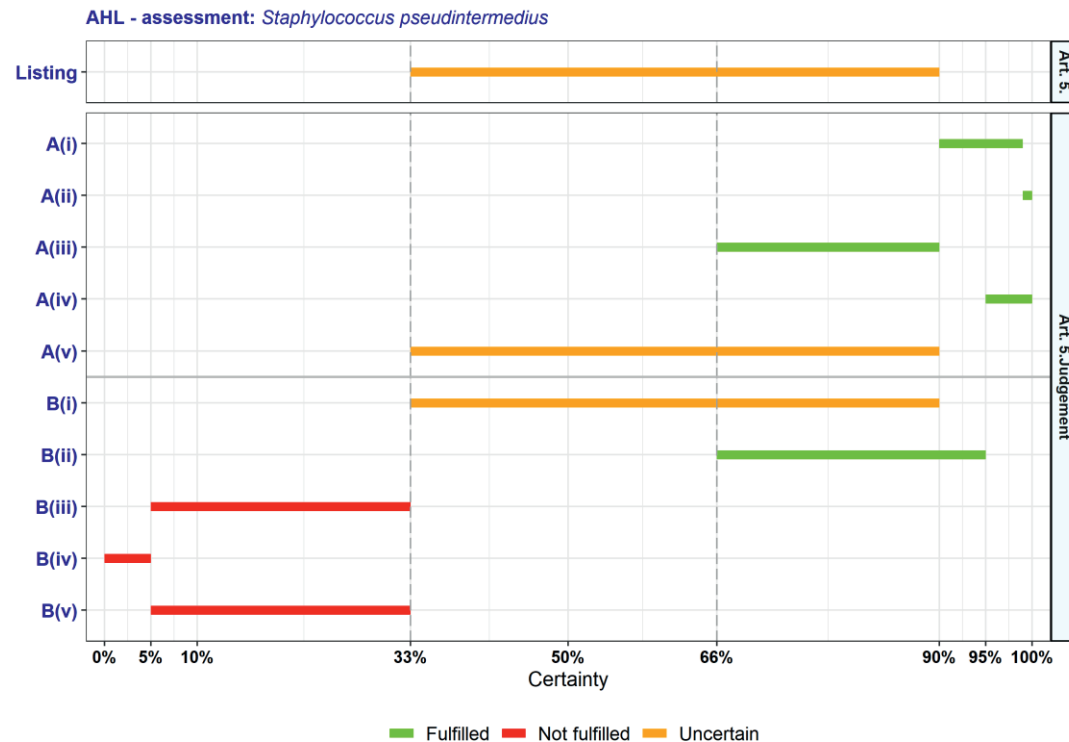
na: not applicable.

<b>0–33%</b>	<b>33–66%</b>	<b>66–100%</b>
Not listed	Uncertainty about listing	Listed
<b>Any probability range that crosses into the 33–66% zone</b>		

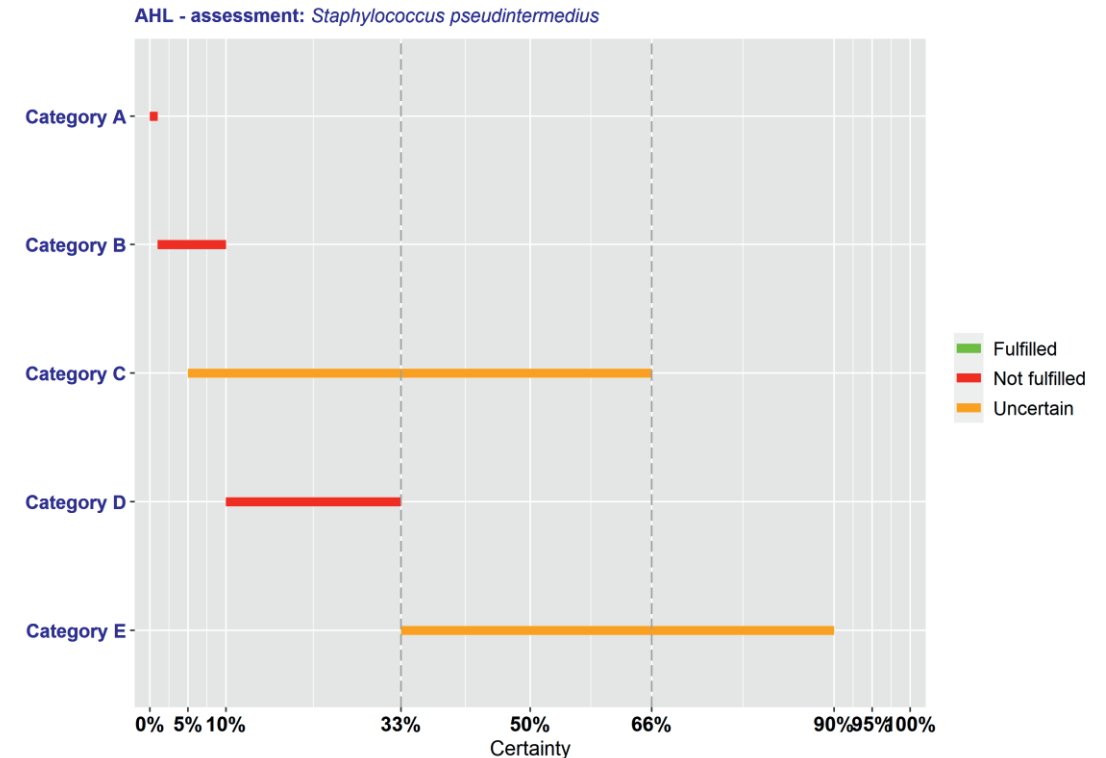
## 8 Scientific Opinions:

Antimicrobial-resistant bacterium	Animal species	Link	Date published	Outcome of the assessment on listing (probability range)
<b><i>Staphylococcus pseudintermedius</i></b>	Dogs and cats	<a href="https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2022.7080">https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2022.7080</a>	01/02/2022	<b>Uncertain</b> (33–90%)
<b><i>Rhodococcus equi</i></b>	Horses	<a href="https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2022.7081">https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2022.7081</a>	02/02/2022	<b>Uncertain</b> (10–66%)
<b><i>Enterococcus faecalis</i></b>	Poultry	<a href="https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2022.7127">https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2022.7127</a>	21/02/2022	<b>Uncertain</b> (33–66%)
<b><i>Enterococcus cecorum</i></b>	Poultry	<a href="https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2022.7126">https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2022.7126</a>	25/02/2022	<b>Uncertain</b> (33–75%)
<b><i>Brachyspira hyodysenteriae</i></b>	Swine	<a href="https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2022.7124">https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2022.7124</a>	15/03/2022	<b>Uncertain</b> (33–66%)
<b><i>Pseudomonas aeruginosa</i></b>	Dogs and cats	<a href="https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2022.7310">https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2022.7310</a>	03/05/2022	<b>Uncertain</b> (33–90%)
<b><i>Escherichia coli</i></b>	Dogs and cats, horses, swine, poultry, cattle, sheep and goats	<a href="https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2022.7311">https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2022.7311</a>	10/05/2022	<b>Uncertain</b> (33–66%)
<b><i>Staphylococcus aureus</i></b>	Cattle and horses	<a href="https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2022.7312">https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2022.7312</a>	10/05/2022	<b>Uncertain</b> (60–90%)

## Listing

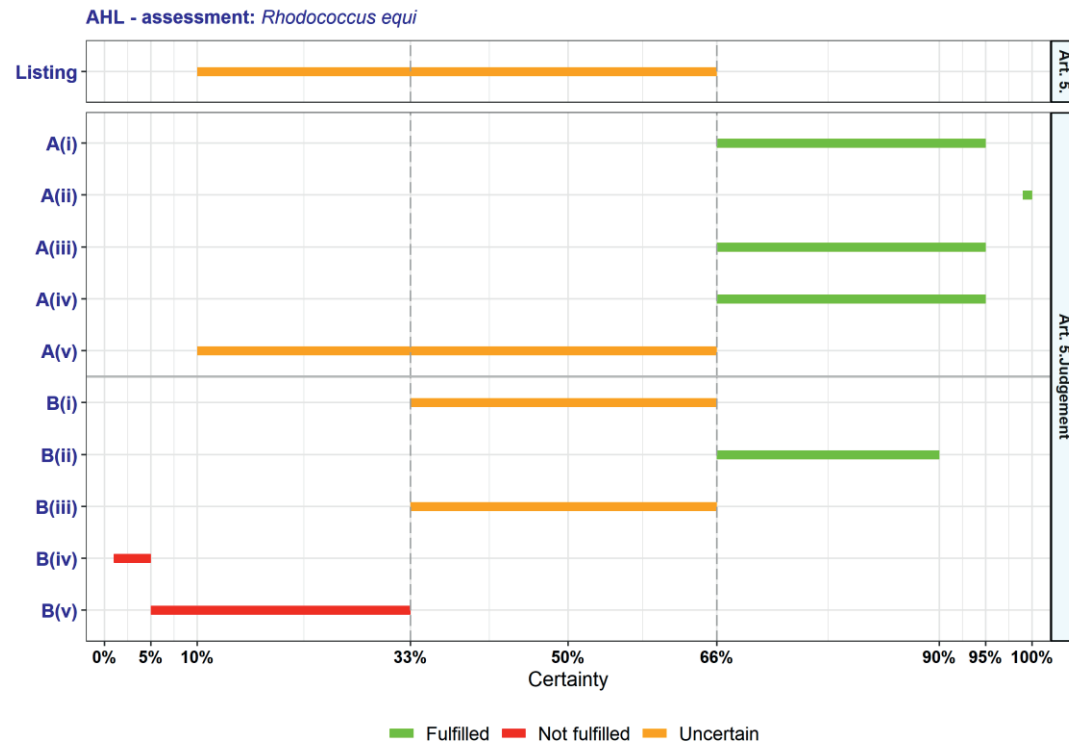


## Categorisation

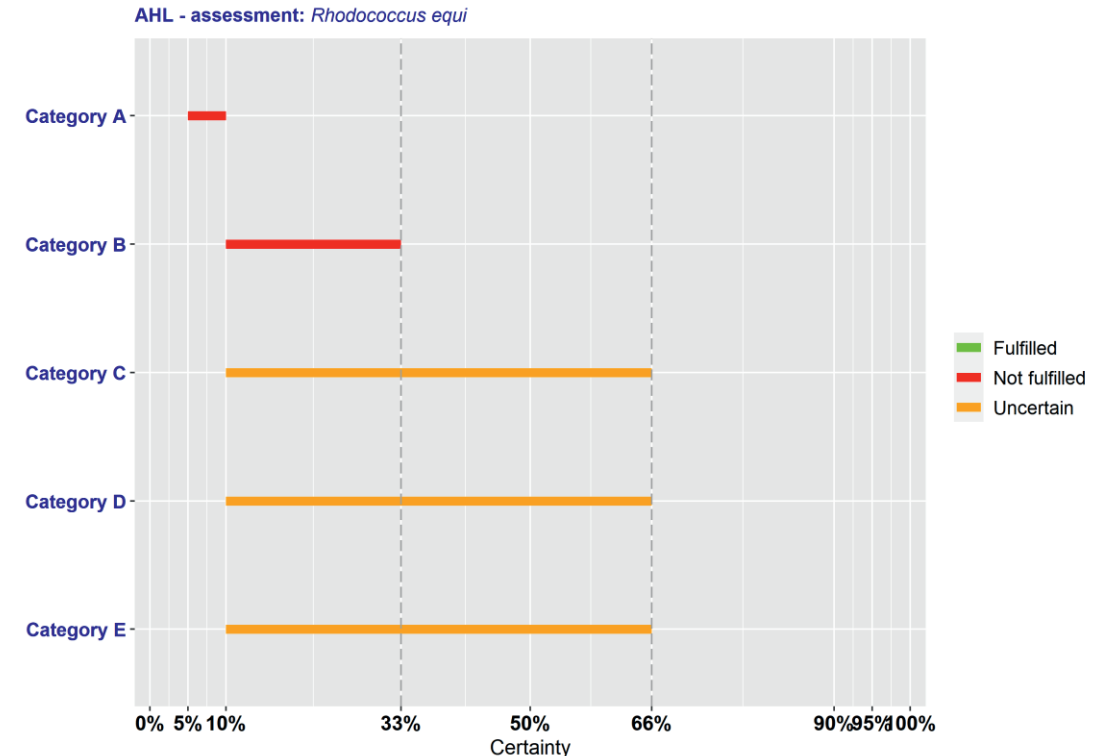


- Ubiquitous and commensal bacterium → effectiveness of risk-mitigating measures and risks posed are difficult to assess
- Surveillance is not harmonised → lack of precise prevalence and incidence estimates
- Among the most important AMR bacteria in small animal medicine → described as 'emerging'
- Opportunistic → only sporadically causes disease
- Disease development is multi-factorial and may be associated with long-term pain and discomfort in dogs

## Listing



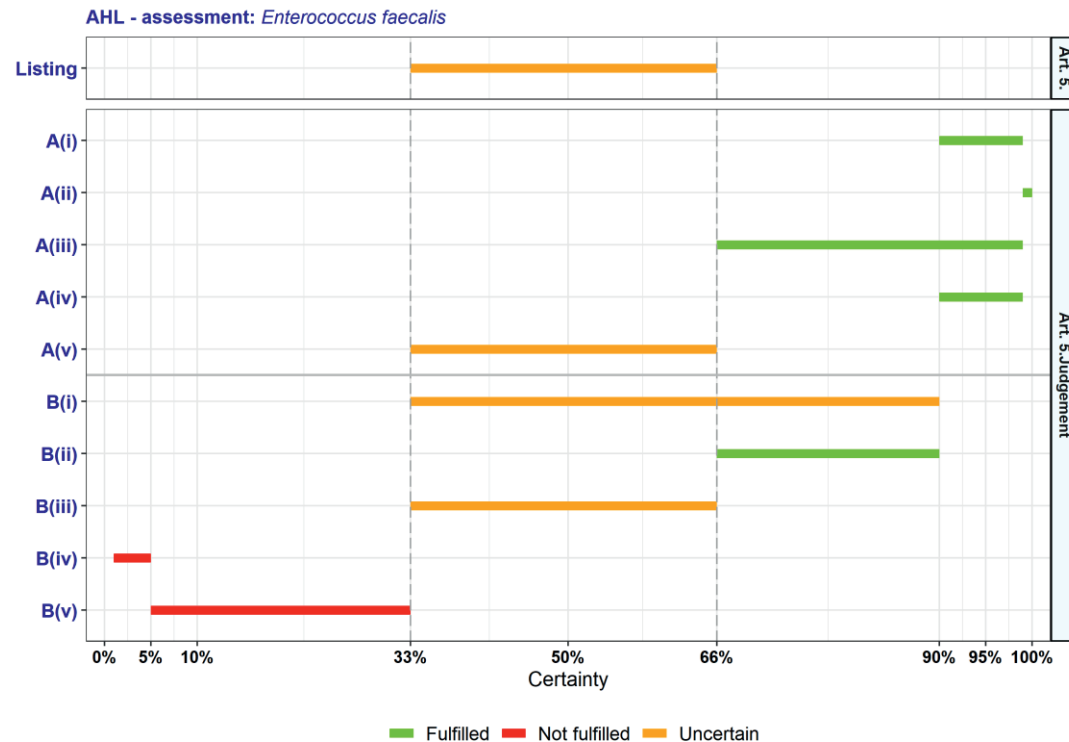
## Categorisation



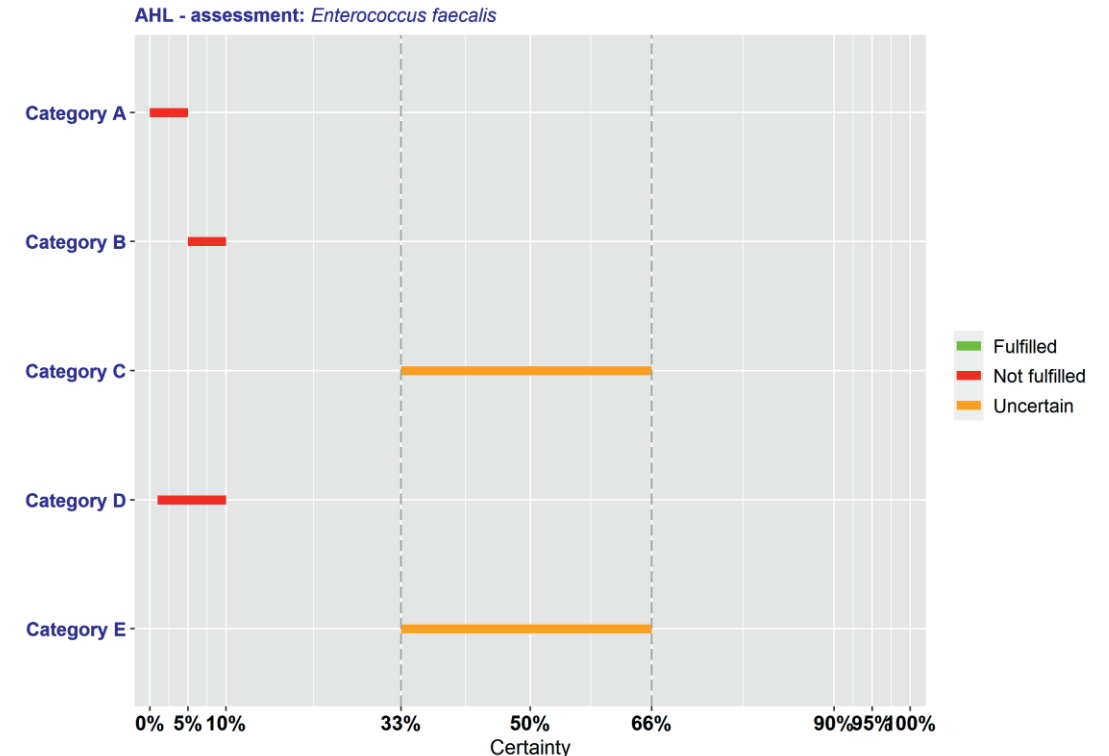
- Ubiquitous in soil
- Surveillance is not harmonised
- Risk-mitigating measures can be considered proportionate to the risks posed, as multidrug-resistant clones are less common in the EU → significant negative effects on animal health may only be seen in some EU Member States
- Impacts mainly horse breeding farms



## Listing

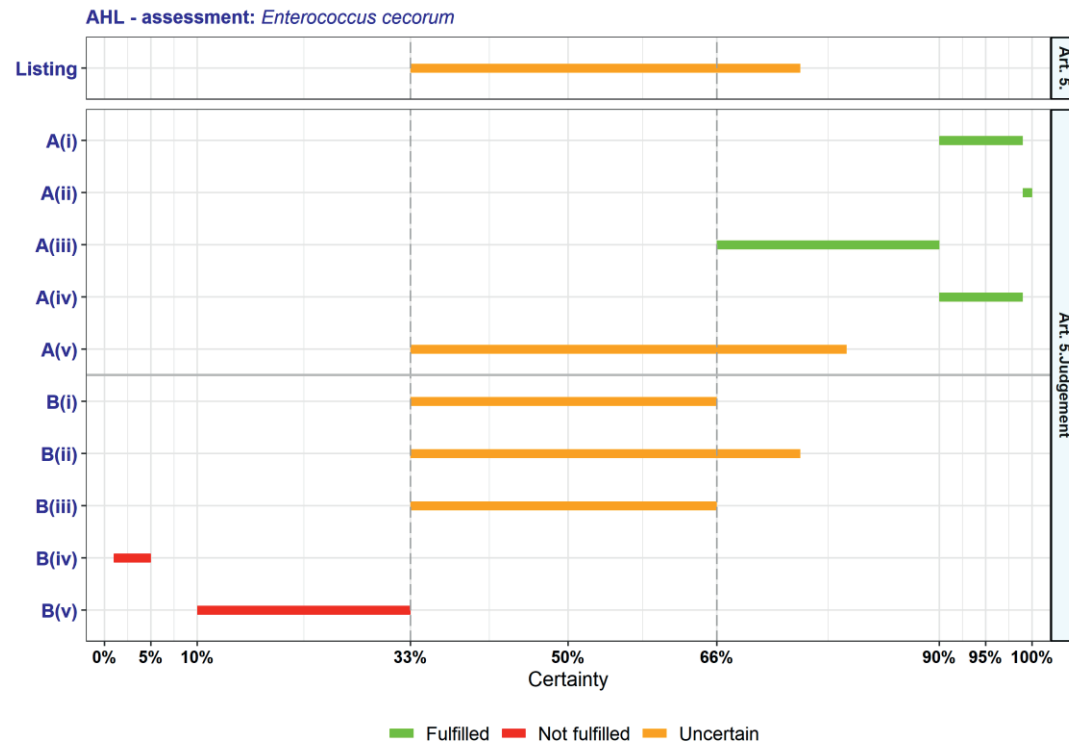


## Categorisation

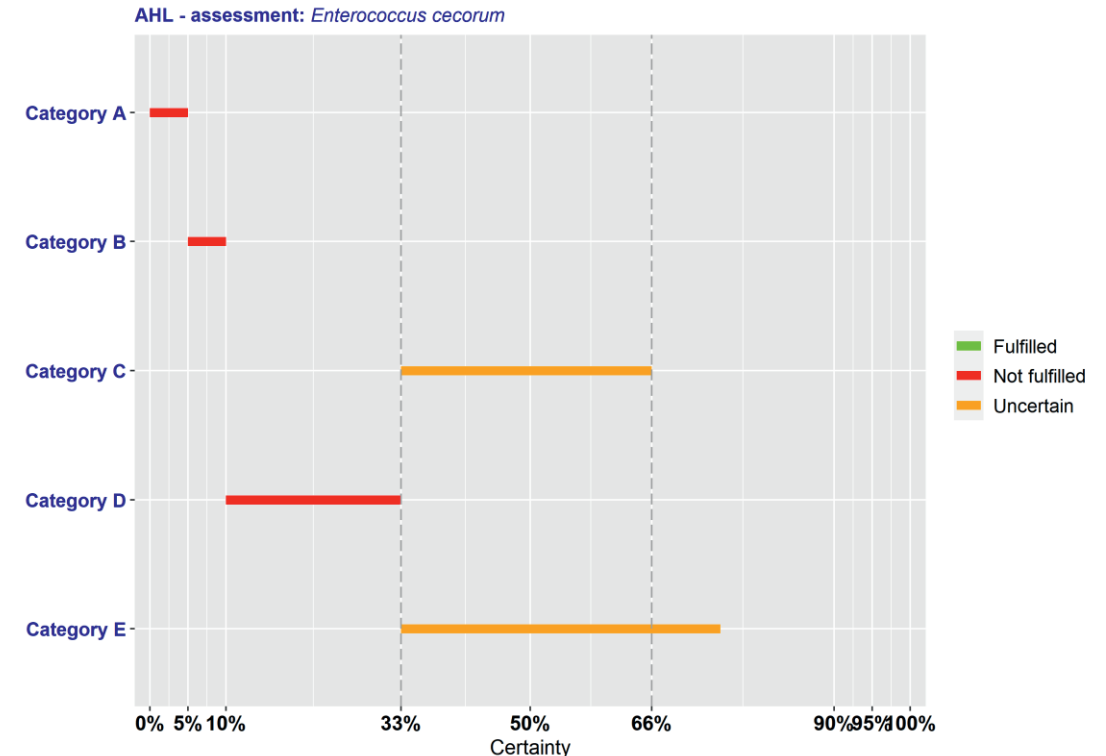


- Surveillance is not harmonised
- AMR clones are widespread in the EU (in all Member States) and extensive use of antimicrobials may further drive such development
- Opportunistic → disease is based on host factors → high morbidity and mortality may be seen in young birds
- Long-term animal health impact is possible

## Listing

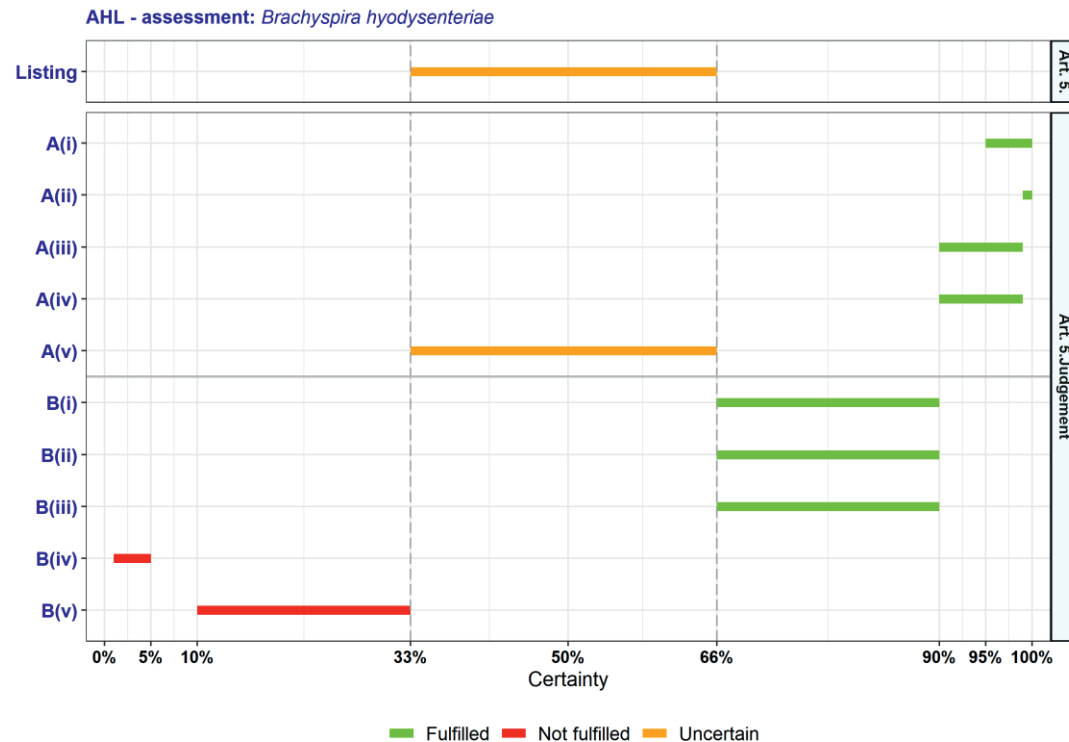


## Categorisation

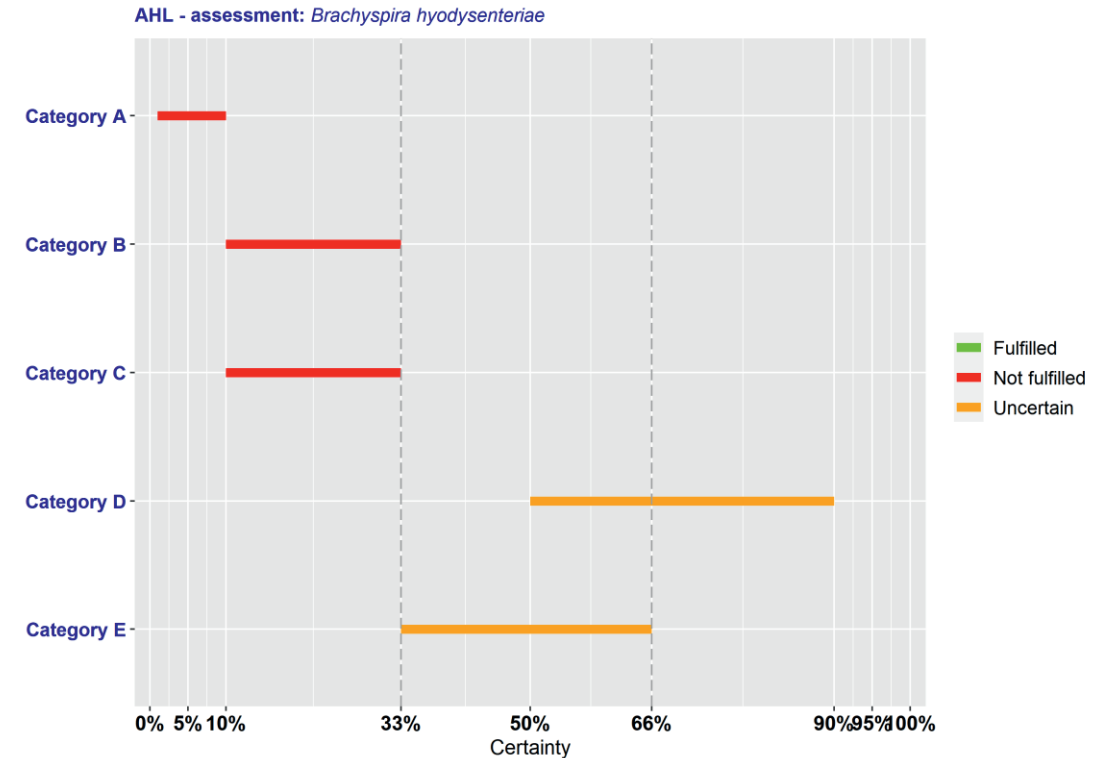


- Surveillance is not harmonised
- Risk-mitigating measures (e.g. biosecurity) are not always effective
- 'Emerging' AMR bacterium (including multidrug-resistant clones) → resistance to critical antimicrobials is currently limited
- Opportunistic → disease is often not remarkable
- May involve skeletal infection and lead to irreversible paralysis

## Listing

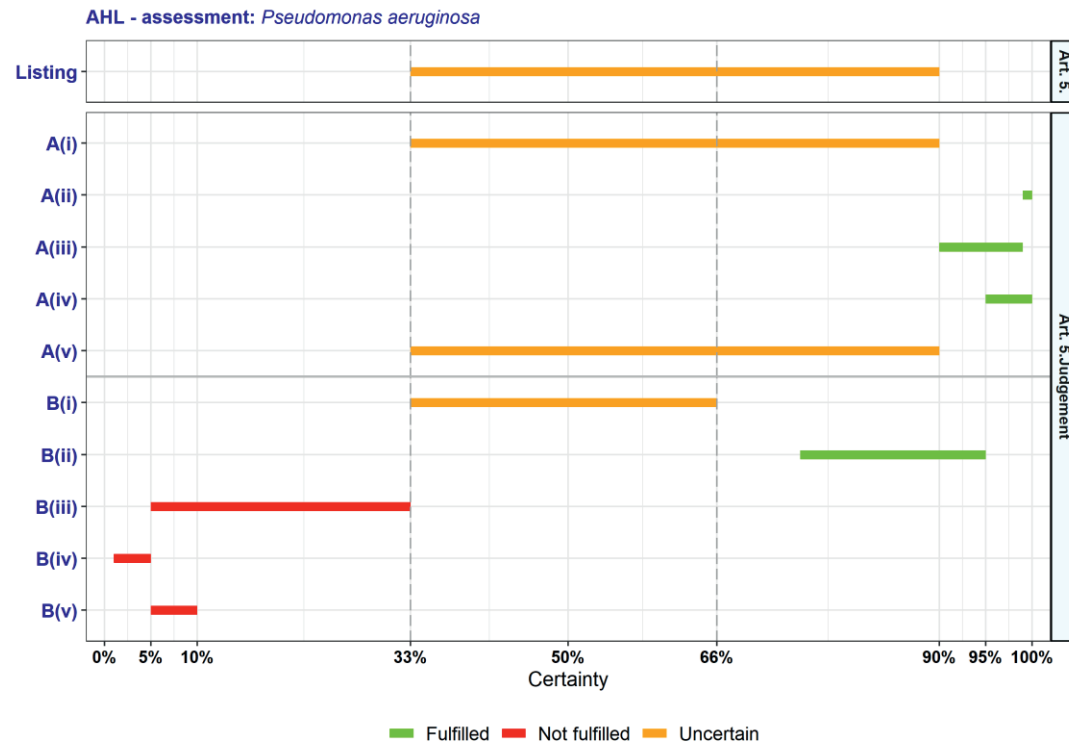


## Categorisation

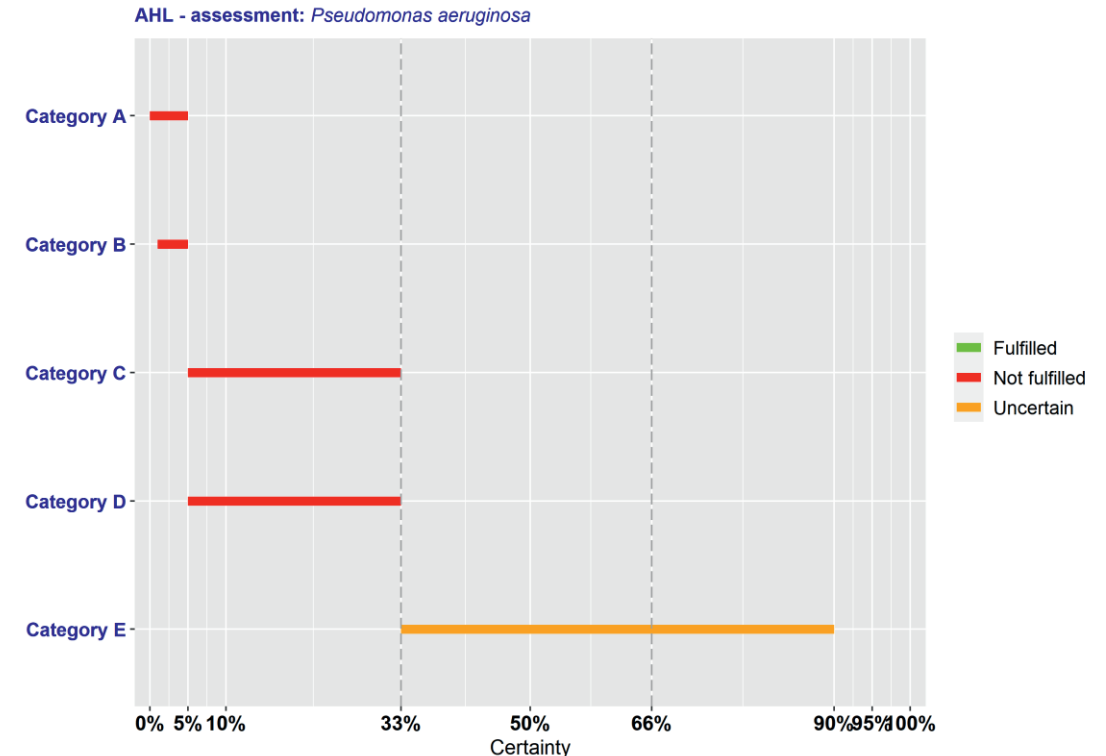


- Surveillance is not harmonised
- Risk-mitigating measures are not always effective → difficult to implement in non-industrialised farming systems
- Can be eradicated → long and expensive effort
- Detection of latent carriers can be challenging
- Resistance is widespread in most EU Member States

## Listing

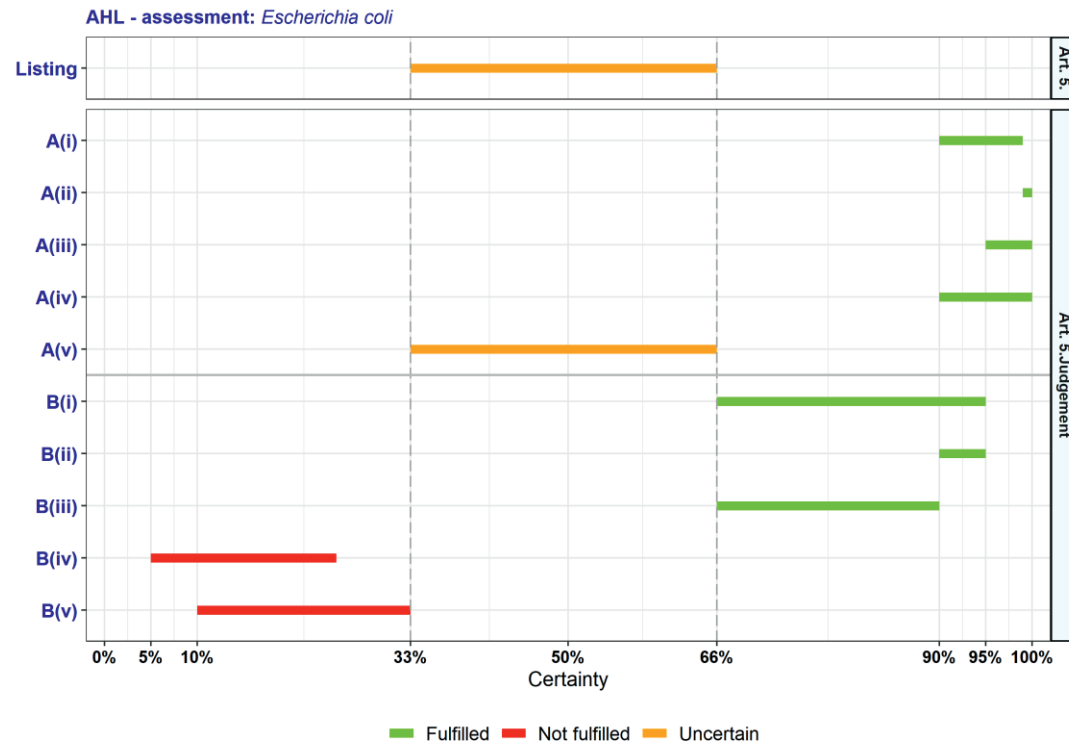


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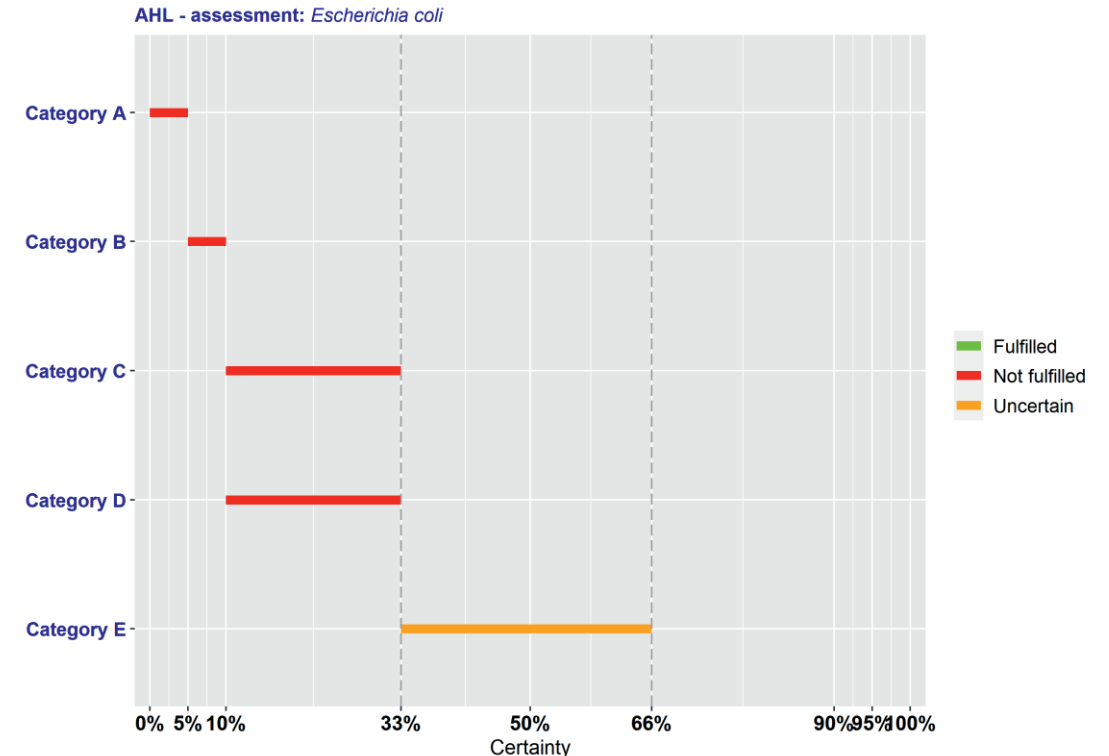


- Mainly indirect transmission through the environment → direct transmission only under certain conditions and considering certain clones
- Surveillance is not harmonised
- Treatment is only partially effective → infections may be difficult to treat (e.g. otitis, UTIs, skin and wound infections)
- Opportunistic but frequent in dogs (among the most frequently reported among clinical cases submitted)

## Listing

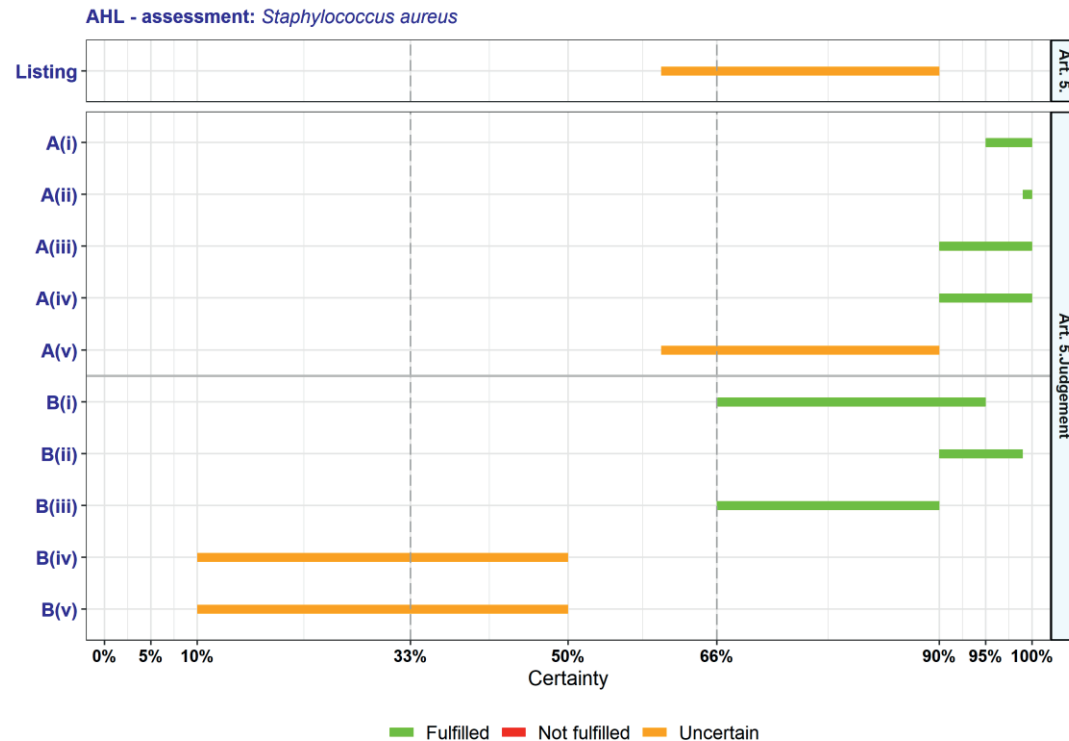


## Categorisation

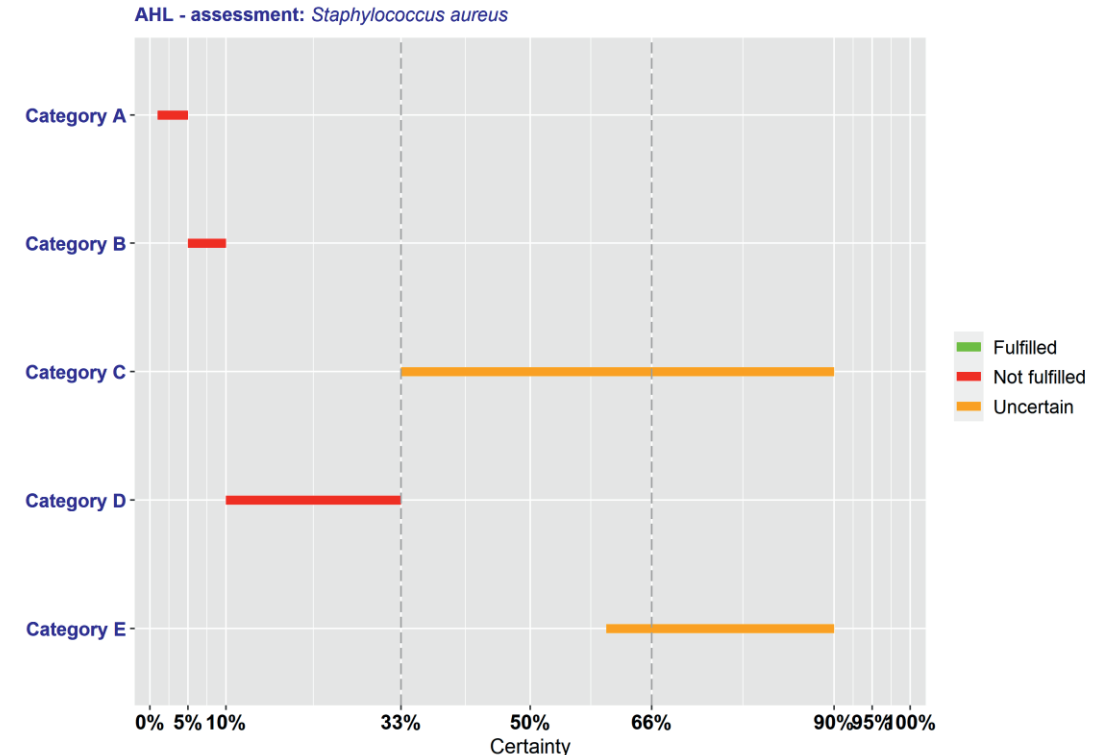


- Ubiquitous
- Surveillance is only in place for VTEC and the commensal bacterium but not for pathogenic *E. coli* clones
- Risk-mitigating measures (e.g. biosecurity, management) are generally effective and proportionate to the risks posed → may not always be well-implemented
- Low efficacy is described for the few available vaccines

## Listing



## Categorisation



- Many risk-mitigation measures exist, but the AMR bacterium still represents a major animal health problem
- Differences in effectiveness and feasibility exist between species and farming systems
- Enterotoxins may be used for bioterrorism
- Already widespread in the EU
- AMR clones have been isolated from several wildlife species

**According to the 'Animal Health Law', a disease shall be included in the list referred to in point (b) of paragraph 1 of Article 5 if it has been assessed in accordance with Article 7 and meets all of the following criteria**

- Criterion A(i) (the disease is transmissible)
- Criterion A(ii) (animal species are either susceptible to the disease or vectors and reservoirs thereof exist in the Union)
- Criterion A(iii) (the disease causes negative effects on animal health or poses a risk to public health due to its zoonotic character)
- Criterion A(iv) (diagnostic tools are available for the disease)
- 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)

**In addition to the criteria set out at points A(i)–A(v), the disease needs to fulfil at least one of the following criteria**

- Criterion B(i) (the disease causes or could cause significant negative effects in the Union on animal health, or poses or could pose a significant risk to public health due to its zoonotic character)
- Criterion B(ii) (the disease agent has developed resistance to treatments which poses a significant danger to public and/or animal health in the Union)
- Criterion B(iii) (the disease causes or could cause a significant negative economic impact affecting agriculture or aquaculture production in the Union)
- Criterion B(iv) (the disease has the potential to generate a crisis or the disease agent could be used for the purpose of bioterrorism)
- Criterion B(v) (the disease has or could have a significant negative impact on the environment, including biodiversity, of the Union)

According to the 'Animal Health Law', a disease shall be included in the list referred to in point (b) of paragraph 1 of Article 5 if it has been assessed in accordance with Article 7 and meets all of the following criteria

- Criterion A(i) (the disease is transmissible)\*
- Criterion A(ii) (animal species are either susceptible to the disease or vectors and reservoirs thereof exist in the Union)
- Criterion A(iii) (the disease causes negative effects on animal health or poses a risk to public health due to its zoonotic character)
- Criterion A(iv) (diagnostic tools are available for the disease)
- 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)

\*apart from AMR *Pseudomonas aeruginosa*

In addition to the criteria set out at points A(i)–A(v), the disease needs to fulfil at least one of the following criteria

- Criterion B(i) (the disease causes or could cause significant negative effects in the Union on animal health, or poses or could pose a significant risk to public health due to its zoonotic character)
- Criterion B(ii) (the disease agent has developed resistance to treatments which poses a significant danger to public and/or animal health in the Union)\*
- Criterion B(iii) (the disease causes or could cause a significant negative economic impact affecting agriculture or aquaculture production in the Union)
- Criterion B(iv) (the disease has the potential to generate a crisis or the disease agent could be used for the purpose of bioterrorism)
- Criterion B(v) (the disease has or could have a significant negative impact on the environment, including biodiversity, of the Union)

\*apart from AMR *Enterococcus cecorum*



- **Ubiquitous** and often **commensal** bacteria
- **Opportunistic** → disease development often multi-factorial
- Risk-mitigating measures are available and mostly effective, e.g.
  - Treatment
  - Vaccines
  - Biosecurity
  - Management
- **Lack of structured and harmonised data** to assess occurrence and frequency of resistance in the EU



**Monitoring** may help to assess their distribution and impacts



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