

The background of the slide features two petri dishes held by hands in blue nitrile gloves. The dishes contain agar with several antibiotic discs placed on the surface. The agar shows varying degrees of bacterial growth inhibition, with some discs having clear, circular zones of inhibition. The lighting is soft, highlighting the texture of the agar and the metallic rim of the dishes.

# Adding antibiotic resistance to Environmental Quality Standards for antibiotics

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## EU Chemical Regulation

- Inconsistencies
- Gaps
  - EDC
  - PMT
  - Grouping
  - Mixtures
  - AMR

# Water Framework Directive

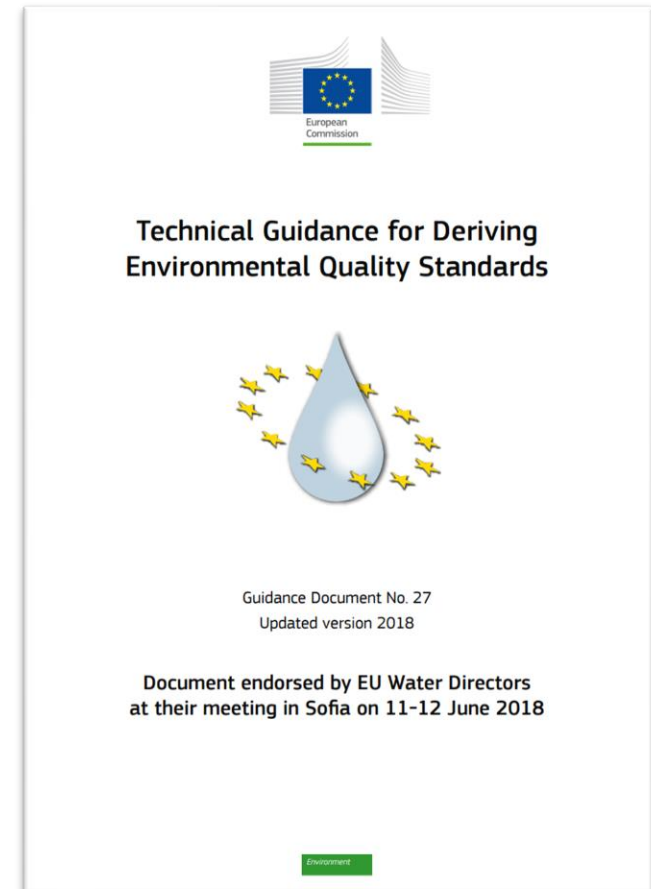
- Key directive when it comes to regulating the quality of European ground and surface water.
- EQS = Environmental Quality Standards (i.e. “safe” concentrations) are defined for pollutants.
  - Based on ecotoxicity studies and uncertainty factors.
  - National and EU level.



# AIM

Analyse if and how the indirect health effects from antibiotics present in the aquatic environment can be considered in the Water Framework Directive.

- From a legal perspective?
- (What method would be most appropriate?)



# Conclusion 1

- The Water Framework Directive aims at maintaining and improving the quality of the *aquatic* environment.
- Still, human health are included and for some substances the *main driver* of the Environmental Quality Standards, e.g. PFOS and mercury.



**No formal obstacle to establishing an Environmental Quality Standards with human health concern as the main driver.**

# Conclusion 2

- The Water Framework Directive is a *minimum* directive, Member States can go further.
- The guidance document is *not legally binding*.



**No formal obstacle to develop Environmental Quality Standards based on data not specified in the guidance document.**

# Conclusion 3

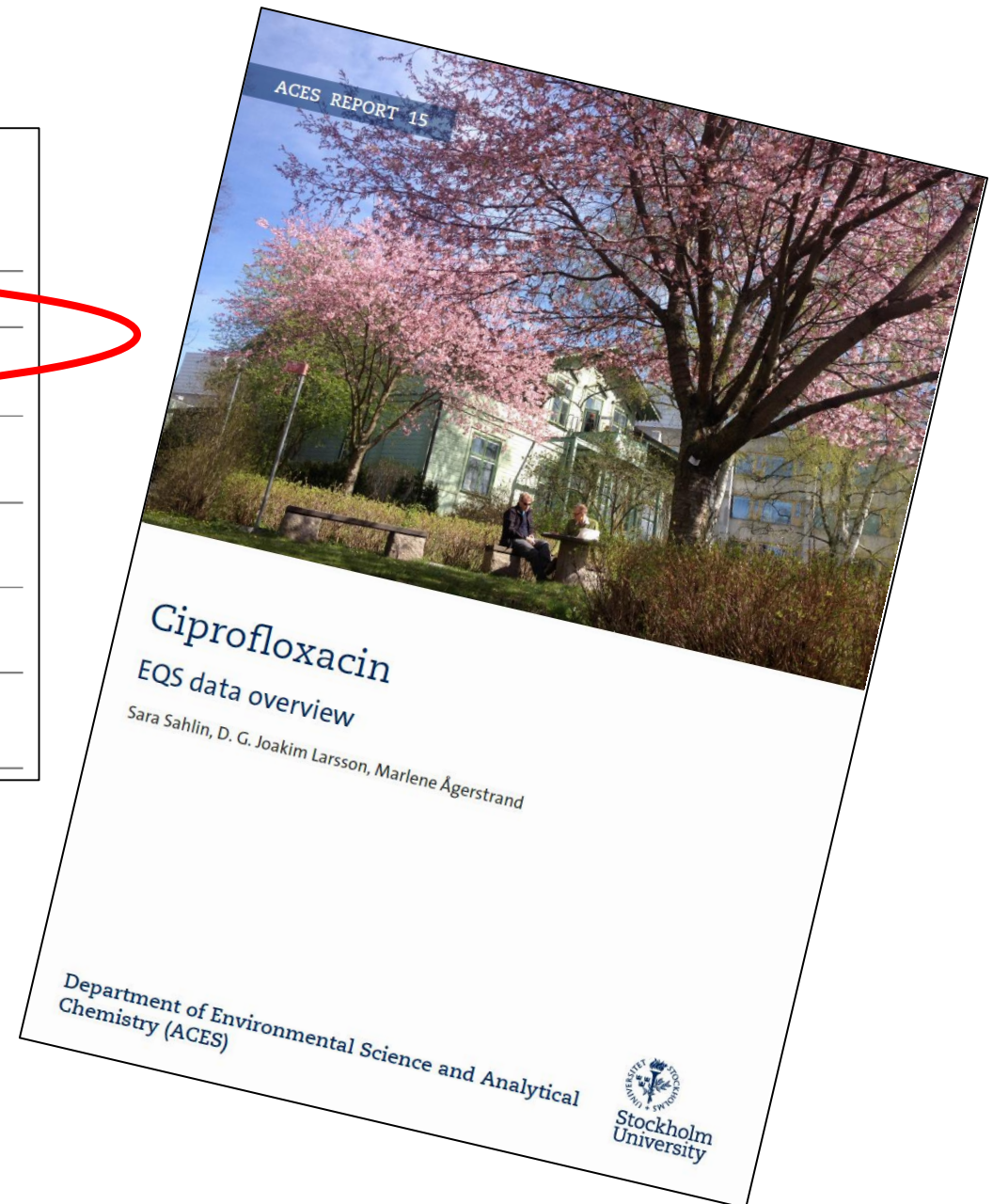
- AMR poses an *indirect* risk to human and animal health if leading to ineffective pharmaceutical substances. In that sense, AMR differs from toxicological effects.
- Pollutant = “*may be harmful to human health*”.



**No formal obstacle to establishing Environmental Quality Standards based on AMR properties.**

#### 4. PROPOSED QUALITY STANDARDS (QS)

	Unit	Value	Comments
Proposed MAC-QS <sub>R</sub> [antibiotic resistance]	[ $\mu\text{g}\cdot\text{L}^{-1}$ ]	0.1	See section 10.2.2
Proposed AA-QS for [conventional pelagic QS]	[ $\mu\text{g}\cdot\text{L}^{-1}$ ]	0.1	See section 10.1.3
Proposed MAC-QS for [conventional pelagic QS]	[ $\mu\text{g}\cdot\text{L}^{-1}$ ]	3.6	See section 10.1.1
Proposed QS <sub>sediment</sub>	Not derived		See section 8.3
Proposed QS <sub>biota sec pois</sub>	[ $\mu\text{g}\cdot\text{kg}^{-1}$ ] <sub>biota ww</sub>	833	See section 11.1





# Water Framework Directive – Watch list

<b>Substance</b>	<b>Freshwater PNEC value (µg/l)</b>	<b>AMR PNEC value (µg/l)</b>
Cephalexin	0.08 <sup>1</sup>	4 <sup>1,3</sup>
Clindamycin	0.1 <sup>1</sup>	1 <sup>1,3</sup>
Ofloxacin	0.026 <sup>2</sup>	0.5 <sup>1,3</sup>

<sup>1</sup> AMR Industry Alliance, 2018. <sup>2</sup> RIVM Letter Report 601711003/2011. <sup>3</sup> Bengtsson-Palme & Larsson, 2016.

# Important regulatory considerations

- Proven to correctly assess the AMR.
- Apply to a variety of substances such as antibiotics, metals, and biocides.
- Rather simple assessment methodology.
- Of sufficient reliability and relevance ([www.scirap.org](http://www.scirap.org)).
- Publicly available data.



Thanks!  
Questions or comments?

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