



Workshop Title	Enhancing environmental risk assessment of antimicrobial resistance across the entire life cycle of antimicrobials
Facilitators and contributors Details of the individuals leading and contributing to the workshop, including: • Workshop facilitators • Guest speakers or contributors • Their roles in the session	Dr Aimee Murray, Senior Lecturer of Microbiology, University of Exeter, UK Dr Joanne Elmoznino, Environmental Risk Assessment, Pfizer Dr Andreas Häner, Environmental Risk Assessment, Roche Mr Steve Brooks, Antimicrobial Resistance Industry Alliance (AMRIA) Advisor Additional Speakers: Dr Isobel Stanton – (UK Centre for Ecology and Hydrology) Prof Ed Topp – <i>to be confirmed</i> (INRAE, France) Additional Facilitators: Dr Laura Murray (University of Exeter, UK) Ms Cara Patel (University of Exeter, UK)
Background An overview of the context and rationale for the workshop, outlining the key issue, challenge, or opportunity it addresses, and why this topic is timely and relevant.	Antimicrobials have been considered as emerging contaminants of concern for several years, with growing evidence that selection for antimicrobial resistance (AMR) can occur at sub-therapeutic concentrations, like those in the environment. Tangible progress has been made in the last decade designing and implementing risk assessment programs for emissions of antibiotics that may arise from antibiotic manufacturing operations. Programs include certification against the AMR Industry Alliance Standard and the WHO's guidance on wastewater and solid waste management. Importantly, such assessments currently do not form part of the environmental risk assessment (ERA) that must be submitted to the relevant regulatory bodies as part of the drug approval process. Furthermore, these approaches currently only consider antibiotics. As part of the marketing authorisation application, the revised EU General Pharmaceutical Legislation (GPL) will require applicants for antimicrobial (antibiotic, antifungal, antiviral and antiprotozoal) drug approval to submit an ERA which evaluates AMR risks in the environment across the entire drug life cycle. This workshop addresses the pressing need to bridge the gaps between scientific research and cross-regulatory practice by facilitating dialogue between researchers and industrial stakeholders to critically discuss current ERA frameworks and future research priorities.
Workshop Aims A description of the purpose of the workshop and its intended focus. This section highlights what participants can expect to explore, learn, or develop during the session.	This workshop aims to critically examine existing ERA frameworks for antimicrobials, with a particular focus on identifying gaps and opportunities for improvement. It will facilitate interdisciplinary dialogue between pharmaceutical industry representatives (AMR Industry Alliance), regulatory experts, and academic researchers. Participants will explore if and how ERAs might be contextualised across different stages of the antimicrobial life cycle (i.e., from production and use to disposal and environmental release). Through structured discussions and breakout activities, participants will develop their understanding of current cross-regulatory landscapes, methodological challenges, and emerging scientific evidence/knowledge gaps. The workshop will also support participants in identifying areas where their research might contribute to more robust, actionable ERA frameworks that better address the environmental dimensions of AMR.
Participant Takeaways	Participants will leave the workshop with improved understanding of the current guidance, standards, and certification processes related to AMR ERA,

A summary of what participants will gain from attending the workshop. This may include new knowledge, practical skills, tools, frameworks, or shared resources, as well as any tangible outputs (e.g. ideas, draft materials, or collaborative outcomes).	as well as the evolving regulatory landscape, including proposed changes to EU's GPL, and the potential global implications. Participants will also have a clearer sense of how their work can inform and influence real-world decision-making in AMR mitigation. It will also provide industrial stakeholders with access to emerging scientific insights that can inform responsible innovation and compliance. The workshop will provide access to shared resources, including summaries of key frameworks, recent policy developments, and current examples of best practice. Those who participate in breakout sessions will have the opportunity to contribute to a collaborative white paper that may be used to inform development of antimicrobial ERA guidance anticipated to be drafted by the EMA in the next 12–18 months. In addition, a critical review or opinion article that will synthesise workshop discussions and identify future research and policy priorities will be submitted to a peer reviewed journal. These two outputs will be finalised post-conference.
Expected Impact An outline of the broader value of the workshop, including how it may: • Influence research, policy, or practice • Support collaboration and knowledge exchange • Contribute to future work or ongoing initiatives	The workshop will enable interdisciplinary collaboration and knowledge exchange at a key moment for AMR policy and regulation. By bringing together stakeholders from academia, industry, and regulatory bodies, it will help align scientific research with emerging legislative priorities, particularly those outlined in the proposed amendments to the EU GPL. The workshop's focus on the full antimicrobial life cycle will encourage participants to consider more holistic, systems-based approaches to AMR mitigation. This could lead to the development of more contextualised and effective ERA tools, that better capture the complexities of environmental exposure and resistance selection. The peer-reviewed opinion piece will serve as a reference point for future work, highlighting key gaps and opportunities in current ERA frameworks. It is hoped the outcomes of this workshop may also inform likely upcoming amendments to regulatory guidance, such as the European Medicines Agency's ERA guidelines, and support the continued development of antimicrobial and environmental stewardship in pharmaceutical manufacturing. In the longer term, the workshop aims to establish a community of researchers and relevant stakeholders around AMR ERA, that will support ongoing dialogue between these groups.
Who should attend? Information on the intended audience for the workshop, including: • Relevant backgrounds, sectors, or expertise • The level of participation expected (e.g. discussion, group work, problem-solving)	We welcome anyone with an interest in translating research for stakeholders and environmental risk assessment, as well as experts in environmental risk assessment, regulation, and policy. All participants will need to bring a laptop or tablet to allow them to access online templates and materials. Active participation will be expected in structured discussions and breakout group work. Those attending breakout sessions in their entirety will be invited to contribute to a draft white paper and/or critical review, with authorship opportunities for those who remain involved post-workshop. All breakout attendees will be credited in the acknowledgements of any publications arising, with opt-out available.
Workshop Schedule and Duration A summary of the structure and flow of the workshop, including: • Key session components • Interactive or breakout activities	This workshop will last approximately 3.5 hours (including break). • Welcome, introduction • Brief, scene setting presentations: - Andreas Häner: State of regulatory environment regarding ERA of antimicrobials - Steve Brooks: Work of the AMR Industry Alliance - Jo Elmozino: ERA of antimicrobials for human use - Isobel Stanton: Antifungal PNECRs

- Ed Topp (TBC): Challenges with AMR ERA

- *Breakout session 1 – mapping the antibiotic life cycle and identifying key challenges, gaps and priorities

BREAK

- *Breakout session 2 – identifying priority areas for ERA research according to different stakeholders. (Interactive)
- ‘Ask Industry Anything’ – panel consisting of Jo Elmoznino, Andreas Häner, Steve Brooks. Informed by breakouts 1 and 2 with option to submit questions throughout the workshop
- Wrap up and close – writing plans and close.