EDAR7 Environmental Dimension of Antimicrobial Resistance — May 26-31 Montréal, Québec

WORKSHOP IN SHORT	
Title of workshop	Mutual understanding between regulatory needs and science-based risk assessment of environmental AMR
Organizers of workshop (2-3) **For each organizer:** - Name - Affiliation - URL - Short bio - Identify two contacts with an Asterix	Thomas Heberer Prof. Dr. Thomas Heberer, Head of Dept. 3 (Veterinary Medicinal Products) at the Federal Office of Consumer Protection and Food Safety and professor for residue analysis and toxicology at the Technical University of Berlin, thomas.heberer@bvl.bund.de Svenja Sander* Dr. Svenja E. Sander Head of Unit 323 (Drug Resistance), Federal Office of Consumer Protection and Food Safety Svenja.sander@bvl.bund.de Sales and use data collection of antimicrobials in veterinary medicine in Germany, specialist veterinarian for pharmacology and toxicology, lecturer of veterinary medicinal law at Freie Universität Berlin Frank Schreiber* Federal Institute for Materials Research and Testing Frank.schreiber@bam.de PhD at Max Planck Institute for Marine Microbiology, Bremen, Germany Postdoc at EAWAG and ETH Zurich, Switzerland PI of biocide resistance research group at Federal Institute for Materials Research and Testing, Berlin, Germany Birgit Walther birgit.walther@uba.de Post doc PI with focus on bacterial adaptation & antimicrobial resistance in an One Health framework at Freie Universität Berlin and Robert Koch-Institute. Head of Unit II 1.4 Microbiological Risks, Berlin, German Environment Agency
Proposed speakers **For each speaker:** - Status (pending invitation, confirmed) - Name - Affiliation - URL	**AMR in the environment - regulatory needs and available risk assessment schemes** Birgit Walther, UBA, confirmed Wastewater-based surveillance of AMR-a perspective Svenja Sander/Thomas Heberer, BVL, confirmed Current and future developments in veterinary AMR regulation Frank Schreiber, BAM, confirmed How to regulate and assess resistance risks of co-selecting agents incl. biocides during application and in the environment Stefan Berggren, Environment and Sustainability Unit and Swedish Knowledge centre for Pharmaceuticals in the Environment, confirmed representative from Regulatory Agencies Global Network against AMR (RAGNA) **Science-based methods for risk assessment of environmental AMR:** David Kneis, TU Dresden, confirmed Implementation and validation of a cost-based approach to predict minimal selective concentrations (MSCs)

	William Gaze, University of Exeter, confirmed Considering risk posed by antimicrobials and AMR in the environment through a Planetary Health lens Joakim Larsson, University of Gothenburg, confirmed WHO Guidance on waste and wastewater management in pharmaceutical manufacturing with emphasis on antibiotic production
Summary (150 words max)	The aim of understanding the environmental dimension of antimicrobial resistance is to deduce mitigation measures from this knowledge. Such mitigation measures may be technological interventions (e.g. special ways of wastewater treatment) or regulatory measures. Regulatory measures resulting in technical interventions or restrictions in the use of antibiotics require knowledge on the presence of particular hazards and exposure routes to the hazards as well as risk assessment schemes that allow to reach tractable decisions. In addition, risks assessment schemes rely on (standardized) methods to provide data for the assessment. Moreover, ideally the impact of an intervention or restriction is measurable to confirm its efficiency and to weigh their costs against the benefits. The aim of the workshop is to create a mutual understanding between regulators, industry and scientists of the regulatory frameworks currently in place and explore how the available science-based risk assessment schemes and methods can help to reach regulatory decisions.
Importance for the EDAR community (100 words max)	This workshop is intended to shed light on scientific and regulatory aspects. Mutual understanding and support is crucial to ensure that scientific findings are taken into account in legal measures and regulations and can be used effectively to protect humans, animals and the environment in line with the One Health Approach. Regulation needs science but science also needs regulation to be effective.
AUDIENCE	
Target audience	Regulators, politics, industry, scientists
Estimated number of participants	max. 60
WORKSHOP CONTENT	
Rationale, objectives and outputs of workshop (300 words max)	Regulatory measures are important to reduce selective pressure on environmental reservoirs to release antimicrobial resistance genes during application of antimicrobial agents (i.e. antibiotics and biocides). Regulatory measures require risk assessment schemes and data from relevant and standardized methods that can be used during risk assessment. Currently, first risk assessment schemes in different sectors and relevant methods are emerging. The aim of this workshop is to provide a forum to exchange between stakeholders from regulatory agencies, industry and scientists with the following objectives: - To identify areas for potential regulatory measures with scientifically predicted hazards and exposure scenarios - To highlight current developments for risk assessment of the environmental dimension of AMR - To feature novel methods that can provide relevant data to inform risk assessment - To discuss methods that quantify the health impact of environmental AMR and the impact of regulatory interventions - To discuss the use of big data and AI for regulatory decision making

	The expected output of the workshop is a policy brief that connects currently available regulatory measures, risk assessment schemes and novel approaches for data generation. In addition, the policy brief should provide a roadmap for improved legal frameworks to allow for efficient regulatory interventions and the types of methods that need to be developed to deliver data for risk assessment and measure the impact of regulatory interventions.
Tentative Schedule	**Part 1:** **AMR in the environment - regulatory needs and available risk assessment schemes** (total 80 min) 4 talks (B. Walther, S. Sander/T. Heberer, F. Schreiber, RAGNA) each 10 min – total 40 min Break out group discussion guided by keynote speakers and workshop chairs - 40 min **Breakout groups:** 1. Wastewater/environment 2. Veterinary antibiotics 3. Human antibiotics 4. Co-selecting agents (biocides) *(depending on the number of participants and their interest, we can cater for multiple breakout groups per topic. There should be no more than 10 persons per group)* <u>Objectives for each breakout group</u> To compile a list of possible regulatory measures (applicable laws worldwide) If no regulatory measures are available; what kind of laws are needed and what would be sensible? To compile a list of risk assessment schemes that would serve the regulatory needs. If no risk assessment schemes are available; what would be the critical steps and data gaps? **Part 2:** **Science-based methods for risk assessment of environmental AMR:** (total 70 min) 2 (to 3) talks (T. Berendonk, W. Gaze, J. Larsson) each 10 min – total 30 min Break out group discussion guided by keynote speakers and workshop chairs - 40 min **Breakout groups:** Wastewater surveillance Minimal selective concentrations and PNECs for selection Other methods To compile a list of scientific methods/endpoints needed for the risk assessment schemes How would those methods need to be modified/standardized to make them applicable for risk assessment? How can the data be collected, retrieved and reused (databases)?

	Part 3: **Cost-benefit and impacts of regulatory measures and workshop synthesis** (total 60 min) Synthesis – panel discussions with keynote speakers and workshop chairs (total 45 min) Short report from breakout group discussions (what was the main theme and outcome of each breakout group?) What is available in terms of laws, risk assessment schemes and methods? What are the regulatory needs? What is feasible in terms of cost-benefit and negative impacts of new regulations? How do we measure the positive and negative impacts of newly implemented regulation? Total minimum 210 min (3.5 h)
What outcome do you expect to result from the workshop (impact) **(200 words max)**	A policy brief published as an OA opinion paper providing a roadmap… - For scientists to work on risk assessment schemes and methods to provide data for risk assessment - For regulators to incorporate state-of-the art knowledge and methods into existing risk assessments - For policy officers to suggest new, efficient regulation - For industry to be informed on the newest development for environmental regulation of their products