

## **Environmental risk assessment of biocides: regulatory requirements, challenges and consequences**

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Biocides are a very diverse group of 22 different product types used to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism. These effects are caused by any means other than mere physical or mechanical action. Harmful organisms in this context are e.g. rodents, algae, fungi, bacteria or aufwuchs. Examples of biocidal products are insecticides, rodenticides, disinfectants or anti-fouling paints for ships. Because they are designed to affect organisms, biocides can also pose risks to humans and non-target organisms in the environment. Thus, they need to be authorized. Their authorization is a complex procedure which is regulated by the Biocidal Products Regulation 528/2012 (BPR) and subdivided in two central areas: the active substance procedure on EU-level and the product procedure on national level. For both procedures extensive data have to be submitted which enable the evaluating member states to conduct a comprehensive risk assessment. This requires, among other things, extensive studies on the influence of the active substance (a.s.) on the environment. Risk has to be determined for every a.s. in the product separately as well as for at least one biocidal product containing the a.s.. Only if the a.s. has passed the evaluation process and is included in the union list of approved active substances, the risks to man and environment posed by the product is assessed in the product procedure. Besides the environmental risk assessment also several other aspects have to be covered like e.g. the assessment of disinfection-by-products (DBPs), endocrine disrupting- and PBT-properties of active substances or the mixture toxicity assessment of products and aggregated exposure assessment. Not for all of these aspects guidance documents or even procedures agreed between the member states are available, making the assessment sometimes complex and requires discussion and coordination between the member states. This session aims to provide an overview of the state of the art in the regulatory environmental risk assessment (ERA) of biocides and associated emerging challenges and possible consequences. We invite scientists from academia, regulatory bodies and industry to present their experiences within the field of the ERA of biocides, and to discuss possible challenges, knowledge gaps or needs for further developments in the regulatory context. Possible topics might be the comparative assessment of biocidal products, the use of bio-pesticides or micro-organisms as biocides or the development of resistance in target organisms. A similar session has been successfully run at the previous SETAC Europe Meeting in Nantes providing an overview on the latest developments in the ERA of biocides including an introductory talk from ECHA, talks on the fate of biocides in the environment and their monitoring as well as the sustainable use of biocides, the mixture toxicity assessment of biocidal products and the effects of anticoagulant rodenticides of non-target animals in the environment. As the feedback from the audience of the previous session was consistently positive, it should be continued at the next SETAC Europe Annual Meeting in 2017 in Brussels.