

Environmental Risk Assessment

of Medicinal Products for Human Use



- Education and training
- Consultancy
- Screening assessment
- Development of test strategy
- Study monitoring
- Hazard assessment
- Exposure assessment
- Risk assessment (EUSES)
- Refinement

Ciba® Expert Services

Ciba® Expert Services is an independent business within the Ciba organization. As a global organization, originating from the chemical industry we offer you consultancy services based on our experience from within the chemical industry. Expert Services are knowledge-based services delivering consultancy on environmental, safety and regulatory issues worldwide.

Ciba® Regulatory Services offers deep understanding of Risk Assessment in general with many years experience of hazard assessment and exposure assessment. Extensive knowledge on the requirements of the Environmental Risk Assessment of Medicinal Products for Human Use is available, both on the studies necessary for hazard assessment and on exposure assessment (EUSES).

Assistance with Environmental Risk Assessments (ERA)

An Environmental Risk Assessment (ERA) accompanies an application for a marketing authorization for a medicinal product for human use.

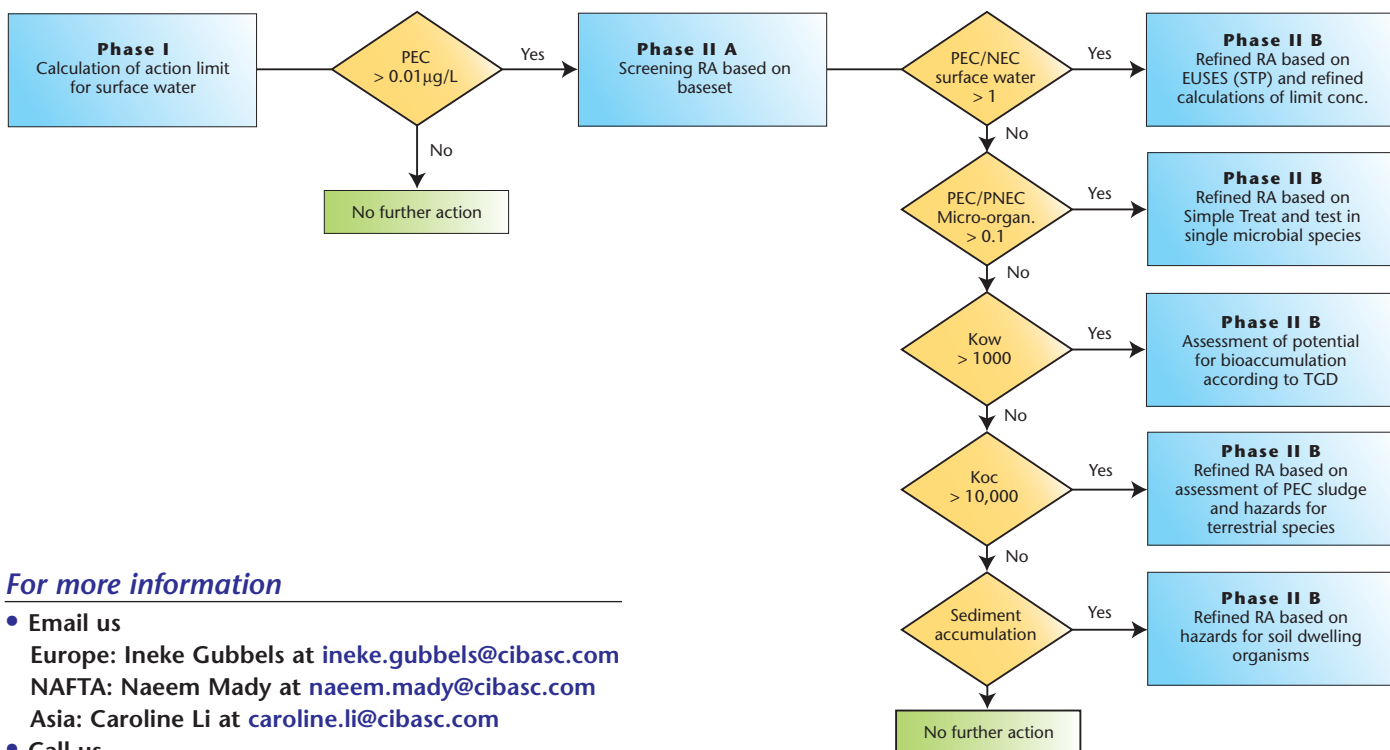
The performance of an ERA is mandatory for:

- all new marketing authorization applications
- type II variations (if there is an increase in the environmental exposure)
- extension applications according to Annex II (if there is an increase in the environmental exposure)

In the flow-diagram a summary of the ERA is depicted. The

first phase is a calculation of the environmental concentration in surface water. The second phase is used to include the result of testing to refine the risk assessment. When a risk is identified, additional testing is required and/or safety measures need to be taken to reduce exposure of the environment where possible.

Ciba® Expert Services can assist you in the initial risk assessment process and further refinement with neutral, science based solutions. We are independent from CRO's and we share our knowledge with you to your advantage!



For more information

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