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Environmental Risk Assessment of Human Medicinal Products

The new guideline from the European Medicines Agency (EMA) on the environmental risk assessment (ERA) of medicinal products for human use, accepted on 15th February 2024 and set to come into force on 1st September 2024, stipulates that an ERA report will be mandatory for all new marketing authorization applications (MAA) of medicines for human use.

The new drug directive currently undergoing EU parliamentary review confirms that an ERA is required for every single drug on the market, including retroactive as well as generic drugs.

For each new pharmaceutical, both a risk assessment and a hazard assessment(PBT/vPvB) are required as part of the ERA.

Key changes to the prior guideline include the introduction of the specific assessment for Endocrine Disrupting Substances (ED), Antimicrobials (AM) and Antiparasitics (AP), and a strengthening of the PBT (Persistent, Bioaccumulative, Toxic) assessment.

Environmental Assessment of the Fate and Effects of Human Medicinal Products

Smithers partners with you by providing a well-defined risk assessment and testing strategy, specific to the unique properties of your product, targeted at the respective environmental compartments of concern.

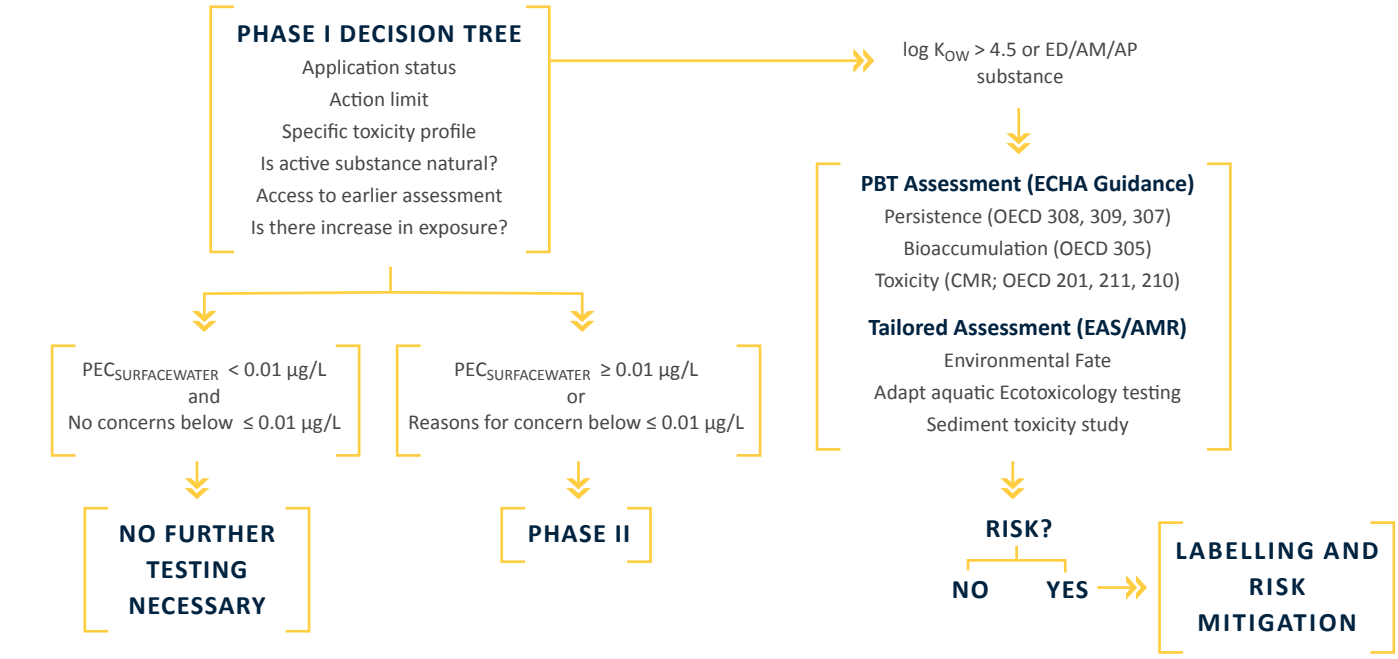
Our extensive experience in environmental safety testing and risk assessment strategy design, coupled with a sound understanding of regulatory requirements, facilitates the avoidance of potential obstacles and saves you time and money.

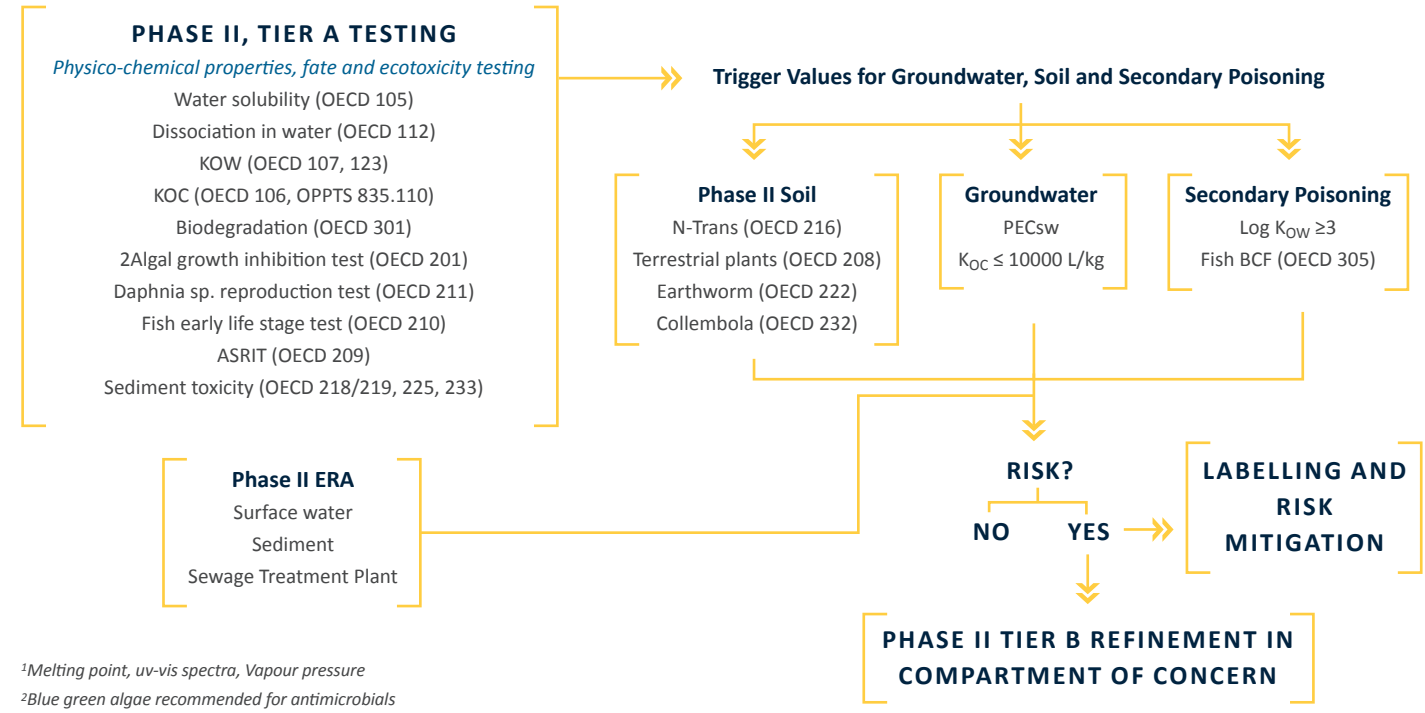
Clients who place an ERA Program with Smithers experience:

- Trust in our track record of successful ERA submissions since the adoption of the guideline in 2006.
- Streamlined communications during your project through a single point of contact.
- Continued support post-submission of the MAA, and for any extended use indications that may result in increased environmental exposure.

ENVIRONMENTAL TESTING

Overview of the Risk and Hazard Assessment:





[1]*Melting point, uv-vis spectra, Vapour pressure*

[2]*Blue green algae recommended for antimicrobials*

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