Integrated assessment strategy for the assessment of aquatic and terrestrial bioaccumulation

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In recent years, a number of New Approach Methods (NAMs) were developed as alternatives to the fish BCF test (OECD TG 305). The revised ECHA PBT guidance integrates the recently developed NAMs in the bioaccumulation assessment and testing strategy, such as *Hyalella azteca* Bioconcentration Test (HYBIT) as invertebrate alternative to fish testing (Figure 1). In vitro methods such as primary hepatocyte assay and liver S9 assay may play a stronger role in the bioaccumulation assessment once more experience with their applicability domain and performance is obtained. Such alternative testing and assessment methods are required and can be useful in several regards: They are meant to minimize the use of animal testing, can enable improved value of information for extrapolation to ecosystems and transferability to species other than those tested. This will result in more reliable estimates based on less data and indicate for which substances or groups of substances further studies are required for a robust assessment. However, the further development of existing screening models, such as IVIVE (in vitro to in vivo extrapolation), PBTK (Physiologically Based Toxicokinetic) and mass balance models that are used for the assessment of bioaccumulation in fish and terrestrial vertebrates, is required in order to identify bioaccumulative substances early and reliably. As part of an UBA funded project the application of the available screening models and alternative methods are currently critically assessed in order to enable their future use as part of the regulatory bioaccumulation assessment of substances within the different EU substance orientated legislations. The limitations of the various screening models (e.g. applicability domain for specific substance properties) and alternative test methods are to be identified.

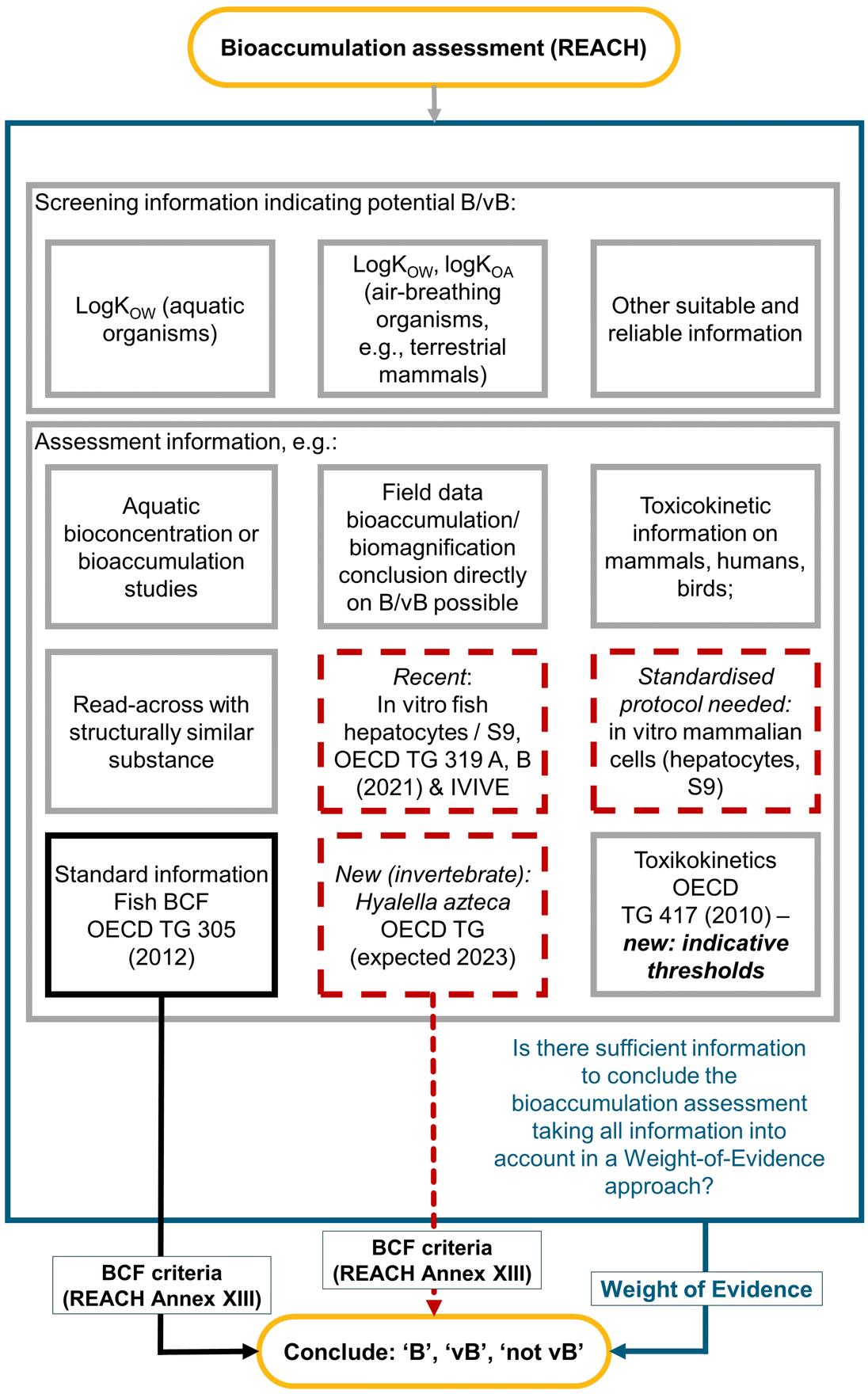

Figure 1: Overview of NAMs (highlighted in red) as bioaccumulation assessment information under REACH.

Critical assessment of screening models and alternative methods for regulatory bioaccumulation assessment

Step 1
Literature search:
- Compilation of available test systems for assessing the bioaccumulation potential of different substance classes and assessment of the respective advantages and disadvantages and areas of application of the respective methods.
- Research and compilation of in silico methods for screening for bioaccumulative substances, usability of physicochemical substance properties, advantages and disadvantages as well as limitations of existing QSAR, read-across and consensus models.
- Compilation of results from laboratory bioaccumulation studies for different classes of substances and their comparison with monitoring data.

Step 2
Based on the test methods researched, evaluated and assessed, a concept for an intelligent crosscutting assessment strategy for bioaccumulation in the context of the prospective assessment of substance regulations, incorporating the findings from previous projects of the UBA, the ECHA and other institutions is presented.

Step 3
Data gaps are closed in order to allow a comprehensive evaluation of the bioaccumulation assessment concept using meaningful case studies. Studies based on the 3R principle are to be performed:
- Test No. 319A: Determination of in vitro intrinsic clearance using cryopreserved rainbow trout hepatocytes / S9.
- HYBIT: *Hyalella azteca* Bioconcentration Test
- Rat model: derivation of lipid-normalized biomagnification factors (BMFL) for neutral hydrophobic organic chemicals based on in vitro biotransformation rates (kr).

Step 4
On the basis of at least 10 case studies, the integrated assessment strategy will be tested for its suitability for use in the regulatory framework.

The project will provide a crosscutting approach for the assessment of aquatic and terrestrial bioaccumulation that can be integrated into the different substance regulations. The suggested approach will be discussed with the regulatory community.

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