Testing Strategies for Environmental Toxicity under REACH

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Introduction

The European REACH (Registration, Evaluation, and Authorisation of Chemicals) legislation is now in force. Although the legislation advocates the use of non-animal methods to provide information for Risk Assessments related to environmental toxicity, it provides little guidance on the scientific approaches to generate this information.

In addition, limited progress has been made with regards to the development and provision of scientific non-animal methods required by the Chemical Industry.

As REACH operates, Regulators will be faced with making decisions based on safety information in Risk Assessments. One major problem is the extent to which traditional animal models can be relied on to generate the information, given the implications for the increase in the numbers of animals used for testing and the cost of successful chemical registration. Another is the timely availability and acceptance of scientific application of alternative approaches to testing strategies.

Methods

Environmental toxicity is the adverse effects caused by exposure to a substance that is harmful to target species in the environment.

FRAME, in collaboration with Liverpool John Moores University (UK) and a UK competent body (DEFRA, the Project sponsor), has reviewed the status of alternative approaches (*in vitro* and *in silico*) in the context of assessing environmental toxicity of chemicals.

In this collaboration the testing strategies have been focused on aquatic toxicity, with live fish as the traditional model, since most substances eventually enter water systems - either by their direct use or by disposal.

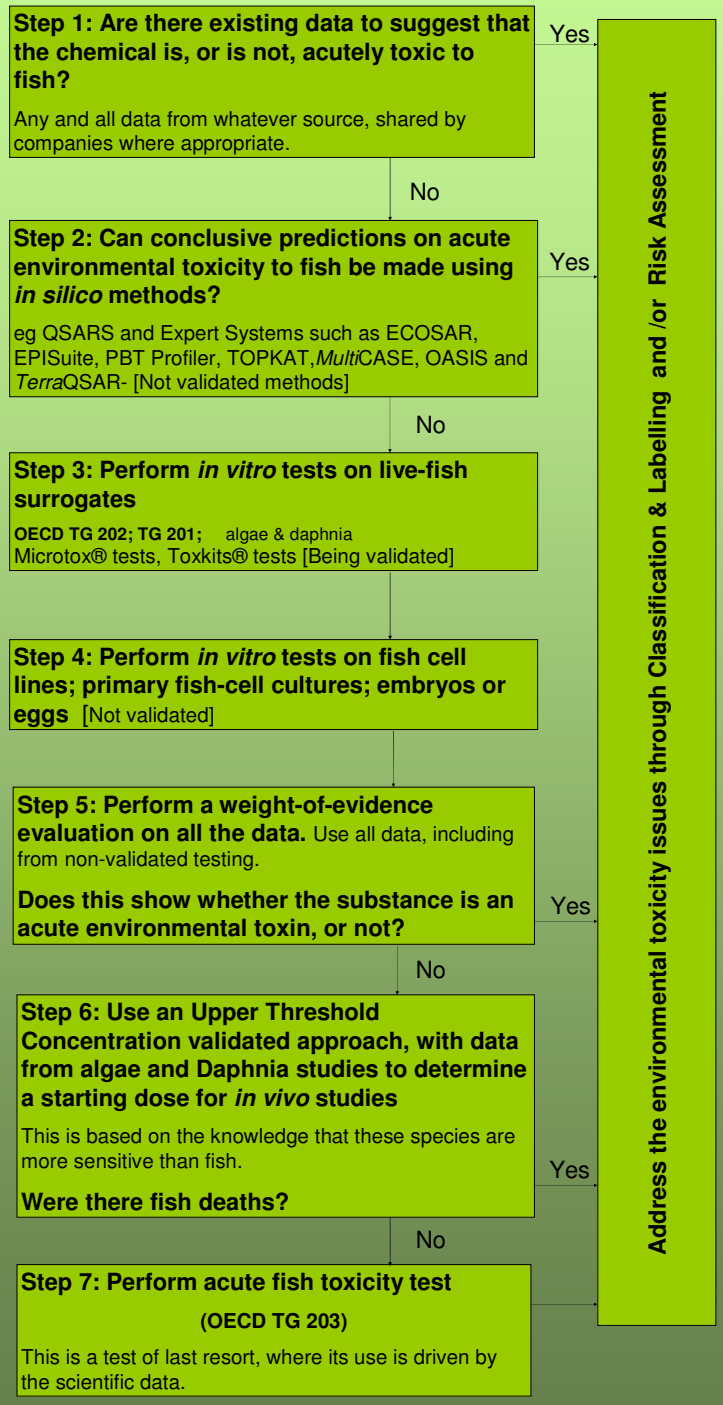
Acute toxicity, mediated by a short term single (often high) chemical exposure is examined herein. Whilst not all alternatives have been rigorously validated, their use integrates within the overall strategy.

Results

A proposed Integrated Decision-Tree Testing Strategy for Aquatic Toxicity is shown opposite. It incorporates various pre-agreed steps where there is an option to exit from the decision tree, and further testing. These decisions and exits are made on the basis that environmental toxicity issues can be dealt with by scientific application of the Regulatory concepts of 'Classification and Labelling' and formal 'Risk Assessments'.

The first step will be a test of REACH procedures since this information may be distributed over more than one business, and they will be expected to co-operate in data sharing. Subsequent steps are designed to use lower organisms and cells to minimise live fish testing but maintain confidence in the safety data.

An Integrated testing strategy for acute environmental toxicity testing



Conclusions

The lack of progress with validated alternatives to live animal testing, in respect of REACH requirements related to environmental (aquatic) acute toxicity testing, is anticipated to be costly and increase animal testing. For the Chemical Industry and Regulators there remains considerable scope to develop and use existing methodologies by scientifically integrating them into decision-tree strategies aimed at providing safety information. Such an approach will reduce registration costs and the anticipated increase in the number of animals used in testing.

The full paper; Integrated Decision-tree Testing Strategy for Environmental Toxicity with respect to the Requirements of the EU REACH Legislation is available in ATLA 34, 651-664, 2006 from FRAME. Poster prepared for the ESTIV2008 Meeting - 15th International Congress on In Vitro Toxicology, 25 to 28 Sept 2008, Stockholm, Sweden