The OECD fish testing framework project: Summary of workshop recommendations

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1. Introduction

An integrated Fish Testing Framework was initiated in mid-2009 as OECD Project 2.30 with the United States as the lead country. The objectives of the project were to review the regulatory needs and data requirements for fish testing and review the currency of existing OECD Test Guidelines. In addition, the project aimed to support animal welfare concerns by identifying unnecessary test methods, minimizing the number of *in vivo* fish tests, and ensuring the optimal use of data derived from *in vivo* studies. A September 2010 workshop with participation from over 40 experts was organized with the goal of producing a Fish Testing Framework guidance document that provides a detailed discussion of issues, relevant endpoints, and the recommendation for a harmonized testing framework for fish.

2. Materials and methods

Over 40 participants from OECD members countries and stakeholder groups participated in the workshop, where various chapters drafted by a project steering team in preparation for the meeting were discussed and revised. In addition to detailed reviews of the individual OECD fish test guidelines, topic areas discussed included general test methods, regulatory needs and data requirements for fish testing, statistical considerations, animal welfare considerations and alternative approaches to testing. General guidance on possible strategies for approaching hazard testing with fish was developed, illustrating broad principles which can then be adapted for specific circumstances and types of chemicals. Numerous preliminary conclusions and recommendations were developed by the participants as a result of the individual chapter discussions.

3. Results and discussion

3.1 Regulatory needs and data requirements for fish testing

Fish tests are the subject of several OECD test guidelines (TGs) and were originally developed at the request of OECD member countries to suit a regulatory need. However, as many of the test guidelines were published several decades ago, it is now worth reconsidering their applicability to modern regulatory requirements and to possible future developments. In addition, more recent guidelines were developed at a time of increased knowledge of fish testing in general leading to a disparity amongst guidelines, A review of the fish testing requirements of a range of regulations in several OECD jurisdictions covering various types of chemicals (pesticides, biocides, industrial chemicals, pharmaceuticals) was performed and discussed.

3.2 Statistical considerations

The statistical methods used to analyze results of regulatory ecotoxicology studies must be consistent with regulatory frameworks, must be statistically robust, and maximize efficiency in terms of animal use, time and cost. Some of the key topic areas discussed included definitions of replicates, biological versus statistical significance, calculation of NOEC, LOEC values, and ECx values, alternate study designs, replicates, use of solvent/carrier controls, and power analysis.

3.3 General test considerations

In addition to the statistical considerations noted above, various general test considerations that are applicable to a wide variety of the OECD fish TGs were addressed. These topic included concentration setting, preparation of test solutions, acclimation and culture maintenance, selection of test species, chemical analysis, water and diet quality criteria, and test acceptance criteria.

3.4 Animal welfare considerations and alternative approaches to testing

Background on and current approaches to replacing, reducing and refining (the "3Rs") the use of animals in testing including social and legal impetus for reducing reliance on animal testing as well as general approaches to the 3Rs were highlighted. During discussion specific examples of 3R approaches from ecological or fish testing were evaluated for their applicability to existing fish TGs and / or integration into a fish testing framework.

3.5 Detailed review of Test Guidelines

All existing OECD Test Guidelines and proposed test guidelines were reviewed by the workshop participants. Specific information that was evaluated includes deliverables (data / information), prerequisites, strengths and limitations, statistical considerations, terminology, concentration setting, quality assurance, animal minimization, delivery or solvent use, and species effectiveness. In addition, general aspects related to clarity or interpretations of TGs were also highlighted.

3.6 Possible fish testing strategies

A generic approach for fish testing was proposed to reflect the latest scientific advances in order to meet risk assessment needs and reduce vertebrate testing. This generic approach provides some general guidance on possible strategies for approaching hazard testing with fish, recognizing that no single approach will be appropriate for all scenarios.

4. Conclusions

Preliminary conclusions and recommendations by the workshop participants focused largely on revisions to existing TGs and/or the need for expert group discussions, workshops, or reviews to address critical issues.

Existing TGs that warrant revision and updating include the 210 (fish early-life stage test) and the 203 (fish acute test); several other TGs (212, 215) may require updating upon completion of the Fish Embryo Test (FET; current a draft TG) validation. TG204 (Fish, Prolonged Toxicity Test: 14-day Study) was recommended for deletion.

Several issues may necessitate expert working groups, workshops, or review papers to sufficiently address the topics before any TG revisions can be made. These include: evaluation of solvent effects (including statistical analysis); choice of test concentrations for fish endocrine screening assays (TG229 and 230); test acceptance and validity criteria; water and nutrition quality; review and analysis of existing fish data to further inform TG229 development; development of high-quality fish chronic data sets; review of practical applications of mode of action and pathways that can help avoid unnecessary testing; assessment of the appropriateness of the various recommended or optional fish species in TGs; and harmonization of definitions across various TGs (e.g., life stages, acute, chronic, spawning status, etc.).

Acknowledgement - The authors thank all of the workshop participants for their active input and critical evaluation.