Abstract Title:
Critical Evaluation of Animal Alternative Tests for the Identification of Endocrine Active Substances

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A significant amount of research is currently targeted to evaluate alternative test methods that may reduce, refine, or replace the use of animals, while ensuring human and environmental health and safety. It is important that the information gained from the alternative tests provide adequate quality and achieve the objectives of the original *in vivo* tests they are intended to reduce or replace. In 2009, the US EPA began implementation of the Endocrine Disruptor Screening Program (EDSP) which includes Tier 1 screening assays in fish and frog species. The Fish Short-Term Reproduction Test and the Amphibian Metamorphosis Assay are EPA Tier 1 in vivo assays that are closely aligned with parallel assays that are part of the Organisation for Economic Cooperation and Development (OECD) test guideline series. However, these assays use a large number of animals and are longer in duration than is ideal for a screening assay. As the intent of these assays is to screen a large number of chemicals for possible endocrine activity and prioritize them for additional testing, shorter-term tests that reduce the animals and time required would be advantageous to the EDSP and to global efforts to screen chemicals for endocrine activity. In order to identify potential alternatives to the current fish and frog screens, a literature search was undertaken and a database assembled with alternative testing methodologies that seemed applicable to the fish and frog test objectives. Data from 1995 to present were collected related to the detection/testing of endocrine active (estrogen, androgen, thyroid) chemicals in the following test systems: cell lines, primary cells, embryos, yeast and bacteria models (if used reporter genes of fish or amphibian origin), cell free systems, and "omics" technologies. Corresponding *in vivo* data were also assembled in order to evaluate the alternative assay performance. A critical analysis was performed to determine the advantages and disadvantages of each of the alternative assays identified and a conclusion regarding chemical specificity, sensitivity, and correlation with *in vivo* data was determined. A summary of the most promising alternative assays with the critical analyses will be presented.

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