

chemicals to be screened and tested: Prevalidation and validation studies on Tier I and Tier II assays; and developing policy and procedures to require endocrine disruptor testing.

1. *Priority setting.* Priority setting is a separate activity from the EDMVS. For the latest information on priority setting of chemicals for testing see **Federal Register** of December 30, 2002, (67 FR 79611) (FRL-7286-6) and docket ID number OPPT-2002-0066.

2. *Validation process.* As a charter member of the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), EPA is following the interagency validation framework outlined in the ICCVAM report "Validation and Regulatory Acceptance of Toxicological Test Methods" for validating the EDSP screening and testing methods. The National Institute of Environmental Health Sciences (NIEHS) established ICCVAM as a standing committee of Federal agencies to coordinate and facilitate interagency validation,

acceptance, and harmonization of toxicological test methods with an emphasis on reducing animal use, refining procedures involving animals to make them less stressful and replacing animals where scientifically appropriate.

The ICCVAM validation process was designed as a flexible, adaptable framework applicable to conventional and alternative methods, and to meet the needs of diverse test sponsors, Federal agencies and regulatory processes. EPA's EDSP is managing the validation process with substantial involvement of ICCVAM personnel.

Although there is widespread interest in EPA's EDSP, the screening and testing methods are being developed and validated with the specific goal of developing test guidelines for EPA regulatory use. The test guidelines will ultimately be used by chemical manufacturers, pesticide registrants, and other entities to develop data for submission to EPA in support of the

Agency's statutorily mandated chemical risk management programs.

In addition to EPA's domestic EDSP validation program, certain screening assays and tests for international use are also being developed by the Organization for Economic Cooperation and Development (OECD) Test Guidelines Program. EPA is an active member of the OECD Test Guidelines Program activities, as well as the latter's Endocrine Disruptor Testing and Assessment Workgroup. EPA will rely upon the OECD mechanism for validating those EDSP screens and tests of international interest. The OECD, EPA, and ICCVAM have also mutually agreed to this administrative arrangement to ensure that all appropriate validation and peer review steps are achieved in both domestic and international efforts.

3. *Status of validation of the assays.* The table below shows the validation process steps that have been initiated on each of the assays.

Screens/Assays	Literature Review	Initial Protocol Demonstration	Prevalidation Studies	Validation Studies
Amphibian metamorphosis	X	X	X	
AR binding	X	X	X	
Aromatase	X	X	X	
ER binding	X	X	X	X
Fish reproductive	X	X	X	
Hershberger	X	X	X	
Pubertal female	X	X	X	
Pubertal male	X	X	X	
Steroidogenesis	X	X	X	
Uterotrophic (Tier ?)	X	X	X	X
Amphibian 2-generation development and reproduction test	X	X		
Avian 2-generation test	X	X	X	
Fish life-cycle test	X			
Mammalian 2-generation test		X	X	
Mysid life-cycle test	X	X	X	

4. *Policy and procedures workgroup.* The Agency has established a workgroup composed of scientists, economists, lawyers, and policy specialists from different EPA offices that is in the process of developing policy and procedures related to requiring endocrine disruptor testing.

List of Subjects

Environmental protection, Endocrine disruption, Endocrine disruptor screening program.

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