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U.S. ENVIRONMENTAL PROTECTION AGENCY

ENDOCRINE DISRUPTOR METHODS VALIDATION COMMITTEE

NATIONAL ADVISORY COUNCIL FOR ENVIRONMENTAL POLICY AND TECHNOLOGY

MISSION STATEMENT

1. **PURPOSE AND AUTHORITY.** This mission statement establishes the Endocrine Disruptor Methods Validation Subcommittee (EDMVS) in accordance with the Federal Advisory Subcommittee Act (5 U.S.C. App. 2 Section 9(c)). The EDMVS is being established as a subcommittee under the auspices of EPA's National Advisory Council for Environmental Policy and Technology. The purpose of the EDMVS is to provide advice and counsel to the EPA on scientific issues associated with the conduct of studies necessary for validation of Tier 1 and Tier 2 assays for the EPA's Endocrine Disruptor Screening Program (63 FR 71542). The EDMVS will provide advice and recommendations regarding: the development and choice of initial protocols; prevalidation study designs; validation study designs; and the integration of prevalidation and validation study results into EDSP Tier 1 and Tier 2 methods documents suitable for external peer review. The EDMVS advice and recommendations will be forwarded to the Agency through NACEPT. Taking into account this advice and recommendations, the EPA will manage and conduct prevalidation and validation laboratory studies.

2. **OBJECTIVES.** EDMVS provides independent advice and counsel to the Agency through NACEPT, on scientific and technical issues related to validation of EDSP Tier 1 and Tier 2 assays including reduction of animal use, refining procedures involving animals to make them less stressful and replacing animals where scientifically appropriate. Following validation of the individual screens, the collective data will be integrated to optimize the configuration of the Tier 1 screening battery. EDMVS may also examine new or innovative assays that may be applicable for inclusion in a second phase of validation. Specific areas for advice and counsel include:

- **Initial Protocol Development** -- The development and/or review of Endocrine Disruptor Screening Program (EDSP) initial protocols based on existing information and experience (past and current research). The initial protocols will serve as the starting point for all subsequent prevalidation studies.

- **Prevalidation Studies** -- The further development and optimization of specific EDSP initial protocols through targeted investigations. The targeted investigations will be designed to address questions necessary for an optimized, transferable protocol suitable for inter-laboratory validation studies.

- **Validation Studies** -- The design and interpretation of comparative inter-laboratory studies to establish the reliability and relevance of the EDSP optimized transferable protocols. Following validation, the optimized transferable protocols will provide the basis for endocrine disruptor test guidelines for regulatory use.

- **EDSP Method Validation Documents for External Peer Review** --All EDSP methods must be peer reviewed prior to approval for regulatory use. All of the study results generated during protocol development, prevalidation and validation will be combined into EDSP method-specific documents suitable for external peer review. External scientific peer review of the EDSP methods will be arranged by EPA through an Agency-approved external scientific peer review panel.

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3. **OBJECTIVE and SCOPE of the ACTIVITY** – The EDMVS and NACEPT will provide a forum for a diverse group of individuals representing a broad range of interests and backgrounds from across the country to consult with and make recommendations to the Agency on matters relating to the validation and external scientific peer review of endocrine disruptor screening and testing methods. The subcommittee will analyze issues, review data and protocols, compile information, make recommendations to the Agency through NACEPT, and undertake other activities necessary to meet its responsibilities.

4. **COMPOSITION** – The EDMVS shall be composed of 26 members approved by the Administrator. EPA appointed a Chair and Vice-Chair for the Subcommittee. Members were selected on the basis of their relevant scientific expertise and diversity of perspectives on endocrine disruptor screening and testing methods and procedures, toxicity test methods standardization and validation, and chemical and pesticide regulatory processes. Members are appointed for two years. Subcommittee members were appointed with balanced representation from the following sectors: the agrichemical and commodity chemical industries; environmental/public interest organizations; public health organizations; animal welfare organizations; Federal Agencies; State, local and tribal governments; academia; consumers, and the public.

5. **MEETINGS** – The EDMVS will hold up to six meeting a year. A regular employee of EPA will act as the Designated Federal Officer who will be present or represented at all meetings and is authorized to adjourn any such meetings whenever the official determines it to be in the public interest. All EDMVS meetings will be called, announced, and held in accordance with FACA and NACEPT rules, which require open meetings and an opportunity for interested persons to file comments before or after meetings, or to make statements during the public meetings to the extent time permits.

Each meeting shall be conducted in accordance with an agenda approved in advance by the Designated Federal Officer. Budgetary support for the EDMVS is provided by EPA's Office of Prevention, Pesticides, and Toxic Substances. The estimated operating costs for the Committee meeting total approximately $400,000 and 3.0 work years of staff support over the two-year anticipated life of the committee.