

Operating Procedures

Of the U.S. EPA

Endocrine Disruptor Methods Validation Advisory Committee

I. NAME

The name of the committee is the **Endocrine Disruptor Methods Validation Advisory Committee (EDMVAC)**.

II. AUTHORITY

The Endocrine Disruptor Methods Validation Advisory Committee (EDMVAC) is established within the U.S. Environmental Protection Agency (EPA) under a charter approved pursuant in accordance with the provisions of the Federal Advisory Committee Act (FACA), 5 U.S.C. App.2 § 9 (c) by the Administrator and by the Office of Management and Budget (OMB).

III. PURPOSE

EDMVAC supports the Environmental Protection Agency (EPA) in its scientific activities related to the validation of assays for the Endocrine Disruptor Screening Program 1996 (63 FR 71542) required by the Federal Food Drug and Cosmetic Act as amended in 1996 by the Food Quality Protection Act (21 U.S.C. § 346a(p)). The EDMVAC is in the public interest and supports EPA in performing its duties and responsibilities.

IV. OBJECTIVES AND SCOPE OF THE ACTIVITY

The Committee provides a forum for a diverse group of individuals representing a broad range of interests and expertise to provide independent advice and counsel to the EPA Administrator on scientific and technical issues related to validation of EDSP Tier 1 screens and Tier 2 tests as they progress through the validation process. The Committee will also consider the reduction of animal use, refining procedures involving animals to make them less stressful and replacing animals where scientifically appropriate. Following validation of the individual screening methods, the collective data will be integrated to optimize the configuration of the Tier 1 screening battery. Specific areas for advice and counsel include:

- **Initial Protocol Development** – The development and/or review of EDSP initial protocols based on existing information and experience (past and current research). The initial protocol serves as the starting point for all subsequent prevalidation studies. It arises from a review of the research literature and/or other relevant sources of information summarized in a detailed review paper (DRP). The

Committee will review and provide advice on any remaining detailed review papers and protocols associated with the assays should the need arise.

- **Prevalidation Studies** – The further development and optimization of specific EDSP initial protocols through targeted investigations. Prevalidation studies are conducted to optimize and standardize the initial protocol(s) for a given assay(s). These studies, conducted by the EPA, will be designed to address questions necessary in achieving an optimized, transferable protocol suitable for intra-laboratory and inter-laboratory validation studies. The Committee will provide advice and input regarding study designs for the prevalidation studies, the data from these studies, and optimization of the protocol.
- **Validation Studies** – Once a protocol has been optimized and standardized, inter-laboratory studies are performed by the EPA to establish the reliability and transferability of the optimized protocols for the assays. The Committee may provide advice and input on the approach for conducting the inter-laboratory validation for the assays. Once the inter-laboratory results are generated, the Committee may provide a recommendation as to the validity of a given assay. The recommendation may include rationales, and the answers to questions posed by the EPA to the Committee concerning the inter-laboratory data, the protocol, and other aspects of the assay(s).

The Tier I screening assays are intended to be a “battery” to screen chemicals for potential estrogen, androgen and thyroid interaction or activity. Once the screening assays have completed validation, the assays that compose the “Tier I Screening Battery” must be determined. The Committee may review the screening assays that have been through the validation process, make a recommendation, and provide a rationale to the Agency on which assays may compose the Tier I screening battery. Selection of a “battery of assays” is not applicable to the Tier II assays.

V. COMPOSITION

The EDMVAC is composed of 20 members approved by the Administrator. Members were selected on the basis of their relevant scientific expertise; diversity of perspectives on endocrine disruptor screening and testing methods and procedures; and standardization and validation toxicity test methods. Members were also selected with balanced representation from various stakeholder sectors. Most members, with the exception of members who are Federal officials, will serve as representatives of non-Federal interests.

Policy Regarding Alternates

The EDMVAC will not seat alternates for the purpose of conducting business. Any member not able to attend an EDMVAC meeting may send an individual, after notifying the DFO, to be seated in close proximity to the table. Individuals attending for a member will not take part in ongoing discussions or decision making recommendations.

Consultants

Consultants may, where necessary, provide specialized information or technical assistance to the EDMVAC Committee. They are not members of the EDMVAC Committee and may not participate in decision-making. Considering the scientific and technical nature of the program, consultants may be invited by the Chair/Co-Chair, the EDSP Team, the Committee or a subcommittee/workgroup, in consultation with the Designated Federal Official.

VI. MEETING PROCEDURES

The EDMVAC will hold up to six meetings a year. A regular employee of EPA will act as the DFO and 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.

- a. **FACA**. The EDMVAC will operate in accordance with all requirements of the Federal Advisory Committee Act (FACA). Such requirements include but are not limited to: publishing notice of meetings in the Federal Register, holding open meetings, taking and distributing minutes of the meetings, and maintaining a public docket. Open meetings must include reasonable opportunity for public comment.
- b. **Open Meetings**. Unless otherwise determined in advance, all meetings of the EDMVAC Committee will be open to the public. Once an open meeting has begun, it will not be closed for any reason. All materials brought before, or presented to, the EDMVAC Committee during the conduct of an open meeting, including the minutes (only after the meeting) of the proceedings of an open meeting, will be available to the public for review or copying at the time of the scheduled meeting. Members of the public may attend any open meeting or portion of an open meeting. All open FACA meetings provide a public comment period to permit public participation by signing up in advance. Members of the public may submit written statements to the EDMVAC at any time.
- c. **Closed Meetings**. Meetings of the EDMVAC Committee will be closed only in limited circumstances and in accordance with applicable law. In addition, requests for closed meetings must be approved by EPA's Office of General Counsel (OGC). Whenever a meeting is to be closed, an advance notice of a closed meeting, citing the applicable exemptions of the Government in the Sunshine Act (GISA), 5 U.S.C. 552b, will be published in the Federal Register. The notice may announce the closing of all or just part of a meeting. Notices of closed meetings will be published in the Federal Register at least 15 calendar days in advance. If, during the course of an open meeting, matters inappropriate for public disclosure arise during discussions, the Chair or Vice-Chair will order such discussion to cease and will schedule it for closed session if it is determined that such a session is warranted.

- d. **Facilitator.** A neutral facilitator(s) may facilitate the EDMVAC Committee meetings and work with all of the members to ensure that the process runs smoothly. The role of the facilitator includes developing draft agendas, focusing meeting discussions, working to resolve any impasses that may arise, preparing meeting summaries, working with the DFO in the location and circulation of background materials and documents the EDMVAC Committee needs or develops, and other functions as the Committee requests.
- e. **Agendas.** Meeting agendas will be drafted by the facilitator in consultation with the EDMVAC Chair, Vice-Chair, and DFO. In developing the agenda, the facilitators will also solicit thoughts from the EDMVAC members. The DFO will approve the agenda for all meetings. A draft agenda will be distributed at least two weeks in advance of each meeting for review by EDMVAC members. EPA will endeavor to distribute all documents to be considered at an EDMVAC meeting to members at least two weeks in advance of that meeting, recognizing that some time-sensitive documents may need updating at the time of the meeting. EPA will publish an outline of the agenda with the notice of the meeting in the Federal Register. The agenda will be reviewed at the beginning of each meeting and refined, if necessary. However, EDMVAC Committee may not substantively change the agenda without approval of the DFO.
- f. **Minutes and Records.** The EDMVAC Committee, DFO and the facilitator(s) will prepare minutes (i.e., a meeting summary) of each meeting and distribute copies to EDMVAC members for approval review approximately within six (6) weeks after the meeting. Committee members present at the meeting being summarized will have two weeks to review the summary and make suggested changes. The facilitators, DFO, and EDMVAC Committee Chair and Co-Chair will attempt to address any comments received and will subsequently develop a final summary for public distribution. Minutes of closed meetings will also be available to the public upon request, subject to the withholding of matters that are exempt from disclosure under the Freedom of Information Act (FOIA). The minutes will include a record of the persons present (including the names of EDMVAC Committee members, names of staff, and the names of members of the public from whom written or oral presentations were made) and a complete and accurate description of the matters discussed and conclusions reached, and copies of all reports received, issued or approved by the EDMVAC.

All documents, reports, or other materials prepared by, or for, the EDMVAC constitute official government records and must be maintained according to EPA policies and procedures. Under FACA, the records, reports, transcripts, minutes, appendices, working papers, drafts, studies, agenda, or other documents which were made available to or prepared for or by the EDMVAC Committee will be included as official records, subject to FOIA requirements. Comments provided by the public at a meeting of the EDMVAC Committee or a work group thereof, or submitted to EPA for consideration by the EDMVAC will be considered part of the official record.

- g. **Subcommittees/Work Groups**. EDMVAC, with EPA's approval, may form subcommittees or workgroups for any purpose consistent with its charter. Such subcommittees or workgroups may not work independently of the chartered committee and must report their recommendations and advice to the EDMVAC for full deliberation and discussion. Subcommittees or workgroups have no authority to make decisions on behalf of the chartered committee nor can they report directly to the EPA. Subcommittee or work group meetings may take place via conference call or in person. All EDMVAC members will be notified of subcommittee or work group meetings, including date and time of meetings and agenda items to be discussed. Summaries of these meetings also will be provided to EDMVAC members.

In accordance with EPA procedures, any subcommittee formed will be conducted in accordance with the Federal Advisory Committee Act. Workgroups will only have a few members and comprised of primarily EDMVAC Committee members. Consultants, researchers and experts having a specialty in the topic area may participate on a limited basis.

- h. **Electronic Communication**. Electronic communication mechanisms will be utilized to the greatest extent possible for the sharing of information outside of EDMVAC meetings, including meeting agendas and summaries. For any EDMVAC Committee member who is unable to participate in electronic communication, others means of communication will be utilized (e.g., fax and mail). All members who have the technical capability to use electronic communication are expected to use it. The purpose of electronic communications is to reduce paperwork, delay and mailing expense.
- i. **Caucus**. Any subset of EDMVAC Committee members may confer privately during or after an EDMVAC meeting as needed. The facilitator may also confer privately with EDMVAC Committee members during or after meetings.
- j. **Attendance at Meetings**. All EDMVAC Committee members must make a good faith effort to attend EDMVAC meetings. The EDMVAC Committee member may be accompanied by such other individuals as deemed appropriate to assist him or her in representing his/her interest. Only EDMVAC Committee members and EPA designees will be permitted to sit at the speakers' table and speak during the meetings, except during designated public comment periods when members of the public will have an opportunity to comment.

VII. DECISION MAKING

- a. **Agreement**. The Committee is anticipated to articulate a range of views in its deliberations. Disparate perspectives and the rationale behind them are of value to EPA. However, when agreement is evident, effort will be made on the part of the Committee to establish and communicate a consensus view to the EPA. Recommendations or other documents can be considered a consensus view if there is no dissent by any member of the EDMVAC.

Another way of stating this is the “all members at the table can live with the decision.” The Committee also may express a view as being “near agreement” with dissenting or alternative views expressed. When formulating recommendations, EDMVAC members should consider all relevant public and private sector perspectives, as well as, majority opinions expressed by the Committee.”

- b. **Product(s)**. Decisions of the EDMVAC Committee on any written document or other product(s) intended for delivery to the EPA will include appropriately authorized signatures from EDMVAC members. Draft materials should not be considered nor characterized as products of the EDMVAC.

VIII. ROLE OF EDMVAC OFFICIALS

- a. **Chair**: The Chair works with the DFO to establish priorities and identify issues, which must be addressed. The Chair also works closely with the EDMVAC membership to achieve the purpose. In addition, the Chair is responsible for certifying the accuracy of minutes or meeting summaries documenting the EDMVAC meetings.
- b. **Co-Chair**: The Co-Chair works with the Chair and DFO in their efforts to fulfill their responsibilities. In addition, the Co-Chair serves as Chair when the Chair is unable to attend meetings.
- c. **Designated Federal Official**: The DFO serves as the government’s agent for all matters related to the EDMVAC activities. The DFO must: (1) approve or call the meeting of the EDMVAC; (2) approve agendas; (3) attend all meetings; (4) adjourn the meetings when such adjournment is in the public interest; and (5) chair meetings of the EDMVAC, when so directed by the Administrator, or her designee.

Record Maintenance

In addition, the DFO is responsible for providing adequate staff support to the EDMVAC, including the performance of the following functions: (1) notifying members of the time and place for each meeting; (2) maintaining records of all meetings, including subgroup or working group activities, as required by law; (3) maintaining the roll; (4) preparing the minutes of all meetings of the EDMVAC deliberations, including working group activities; (5) attending to official correspondence; (6) maintaining official EDMVAC records and filing all papers and submissions prepared for or by the EDMVAC, including those items generated by working groups; (7) acting as the EDMVAC agent to collect, validate and pay all vouchers for pre-approved expenditures; and, (8) preparing and handling all reports, including the annual report as required by FACA.

IX. WORKING RELATIONSHIPS

The EDMVAC members will work collaboratively and cooperatively. In particular, members will:

- Participate and communicate in an open, direct, cooperative, and trusting spirit.
- Address each member's views with respect and work to build common ground when divergent perspectives are expressed.
- Understand the compromises necessary to reach consensus or majority, and when representing colleagues' viewpoints, take care not to misrepresent the views of other parties on any agreement reached or to mischaracterize as final matters still under discussion.
- Seek to reach a consensus in good faith, asking for clarification, offering alternative suggestions, and listening with an open mind to issues under discussion.
- Conduct themselves and their organizations in a manner consistent with the goals and spirit of the EDMVAC.

X. SAFEGUARDS FOR THE PARTIES

- a. **Good Faith**. All parties agree to act in good faith in all aspects of the EDMVAC deliberations. In order to encourage consensus building as well as the free and open exchange of ideas, views and information prior to decision making, members agree not to use specific offers, positions or statements regarding issues under discussion by the EDMVAC that are made by another member outside the context of a recorded statement at an official session of the EDMVAC or a working group thereof, for any other purpose not previously agreed to by the members involved. Personal attacks and prejudiced statements will not be tolerated.
- b. **Right to Withdraw**. Any party may withdraw from the EDMVAC at any time without prejudice. However, it is requested that the member wishing to withdraw communicate the reasons for withdrawal.
- c. **Others' Positions**. Members agree not to characterize the position of any other party in public statements outside of the EDMVAC meetings, or in discussions with the media, even if that party withdraws from the EDMVAC. To the extent feasible, members will refer others to approved meeting summaries for information about the EDMVAC discussions.
- d. **Information**.
 - 1) All parties agree to share all relevant information that is readily available to the maximum extent possible. If a party believes it cannot or should not release relevant information (because of its confidential or proprietary nature), it will provide the substance of the information in some form (such as by aggregating data, by deleting non-relevant confidential information, by providing summaries,

or by furnishing it to a neutral consultant to use or abstract) or a general description of the information and the reason for not providing it directly.

- 2) Parties will provide information called for by this paragraph as much in advance of the meeting at which such information is to be used as is reasonably convenient.
- 3) Information and data provided to the EDMVAC in writing is a matter of a public record and will be maintained according to EPA policies and procedures.
- 4) Any information that qualifies as Confidential Business Information under Exemption b(4) of the Freedom of Information Act may not be discussed by the EDMVAC without prior approval of its owner and may be discussed only in closed session. All EDMVAC members and EPA staff in attendance must agree in writing, prior to its distribution, to protect such information.

XI. EXPENSES AND REIMBURSEMENT

Expenses related to the operation of the EDMVAC will be provided by EPA's Office of Prevention, Pesticides, and Toxic Substances. The estimated annual operating cost for the EDMVAC Committee is approximately \$ 445,000 which includes 1.5 staff-years of support over the two-year anticipated life of the committee. Expenditures of any kind must be approved in advance by the DFO. Federal Government employees serving on the EDMVAC are not eligible for any form of additional compensation. EPA will pay travel and per diem for those non-government members who require assistance in order to attend meetings at a rate equivalent to that allowable for Federal employees.

XII. ADDENDUMS AND AMENDMENTS TO THE OPERATING PROCEDURES

Subject to approval by EPA, the EDMVAC Operating Procedures may be added to, amended, or repealed in whole or in part by consensus action of the members at any regular meeting.