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ECVAM Stakeholder Forum

ESTAF

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ECVAM Stakeholder Forum (ESTAF)

Open Invitation for the Expression of Interest
In Membership in the ECVAM Stakeholder Forum (ESTAF)
(2010/08/20)



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1. Introduction

1.1 Open Invitation for Membership in the ECVAM Stakeholder Forum (ESTAF)

The European Commission's European Centre for the Validation of Alternative Methods (ECVAM) is hosted by the Institute for Health and Consumer Protection (IHCP) of the European Commission's Joint Research Centre (DG JRC), and located in Ispra, Northern Italy.

ECVAM is currently renewing its structures for scientific advice and stakeholder dialogue. This call is addressed to Stakeholder Organisations in the field of Alternative Methods to Animal Testing who would like to be considered for membership in the

[ECVAM Stakeholder Forum \(ESTAF\)](#)

1.2 Background to ECVAM's activities

ECVAM's mission is to support EU policies in the field of consumer protection, environmental protection and animal protection by validating alternative methods for toxicity/safety and efficacy/potency testing of xenobiotic substances (e.g. chemicals, cosmetics, medicinal devices, vaccines and other biologicals).

Alternative methods are empirical test methods and non-empirical approaches that implement the 3Rs (Replacement, Reduction and Refinement of the use of animals in experiments). Alternative test methods (or combinations of such methods) should provide the same or a better basis for safety / risk and efficacy / potency assessments and, ultimately, risk management measures as traditional test methods which are currently mainly in vivo assays (i.e. involving living animals).

Alternative methods in this context include (a) in vitro testing methods, (b) non-testing approaches (e.g. in silico approaches such as expert systems, QSAR based estimation techniques, modelling) as well as (c) integrated testing strategies combining any of these methods and approaches in a defined manner and aiming to provide evidence of defined quality and certainty to serve as a reliable basis for safety and efficacy/potency assessments of xenobiotics.

Moreover ECVAM furthers the development and optimisation of alternative methods (e.g. through participation in research projects, through dedicated workshops and in-house laboratory research), promotes their application in industry (e.g. through expert advice and by maintaining a database service on alternative methods) and supports their acceptance by regulatory authorities on EU and global (e.g. OECD) level. To this end ECVAM, in addition to its other tasks, promotes dialogue between legislators, relevant stakeholders in the field (e.g. academia, industry, regulatory authorities) and serves as a platform for information exchange on topics related to the development, optimisation, proper scientific use and regulatory application of alternative methods.



2. Reason for setting up the ECVAM Stakeholder Forum (ESTAF)

ECVAM's relation with its stakeholders is reciprocal: ECVAM-validated methods help stakeholders comply with regulatory requirements and legislation, provide them with mechanism-based and robust methods to improve their R&D and address the societal concerns regarding animal testing. Equally ECVAM's output depends on the work and input of its stakeholders. Notably, valuable scientific, technical and societal expertise resides within the stakeholder community, which is also the major source of test submissions for ECVAM validation.

To strengthen participatory approaches supporting communication and cooperation with the stakeholder community, ECVAM is now creating the [ECVAM Stakeholder Forum \(ESTAF\)](#).

3. Roles of the ESTAF

The ESTAF will bring together the non-governmental / non-public stakeholders of ECVAM.

In agreement with its composition and taking into account its role of providing technical stakeholder advice to ECVAM, ESTAF's role comprises two main aspects:

- (1) Advocacy / voicing of stakeholder interests.
- (2) Maintaining close dialogue with and between stakeholders in view of sharing and disseminating information on ECVAM's work and that of stakeholders.

These roles are outlined in the following in more detail:

1. **ADVOCACY.** The ESTAF will allow the transparent representation of vested and specific interests (i.e. advocacy of stakeholders) and the transparent voicing of societal concerns (e.g. animal welfare issues, sustainable chemistry etc.).
2. **DIALOGUE:** ESTAF shall support active dialogue with the stakeholder community in view of
 - a) Sharing/disseminating information on ECVAM's activities with/within the stakeholder community.
 - b) Sharing/disseminating information on the activities of individual stakeholder organisations with/within the stakeholder community.



- c) Transparently communicating stakeholder views, interests, perspectives and priorities with regard to the development, optimisation and validation of alternative methods and, in particular, ECVAM's activities. Stakeholder opinions may be used as input into ECVAM's priority setting.
- d) Harvesting stakeholder expertise and opinion with regard to forward-looking aspects of test method development, optimisation, validation and use as well as emerging technologies. This may include the methodology of validation of alternative methods and the utilisation of alternative methods in view of exploiting their full potential with respect to the information they provide (e.g. mechanism of action).
- e) Mutual alerting to urgent and emerging issues and the exchange of relevant information.

Stakeholder input requested by ECVAM may be summarised in position papers which would be published on ECVAM's webpage.

Furthermore, ESTAF will be requested to assess methods suggested for validation for their user relevance. The views of ESTAF will be presented to ECVAM in the form of an ESTAF response template and will be used, together with other considerations, for priority setting regarding validation studies coordinated by ECVAM.

4. Eligibility criteria regarding membership of Stakeholder Organisations in the ESTAF

To be eligible for possible representation in the ESTAF, Stakeholder Organisations need to be able to demonstrate that

- (1) they have a passive or active stake in the area of alternative methods to animal testing, i.e. are affected by or do affect the development / optimisation / validation / use of alternative methods with respect to scientific, technical, societal, ethical or other issues.
- (2) they operate on European (EU) level (exceptions may apply).

Stakeholder organisations that may want to express an interest in membership in the ESTAF include:

- 1 Industry associations from sectors that develop, market and/or use alternative methods for hazard / safety and efficacy /potency assessments of xenobiotic



substances, e.g. industrial chemicals, cosmetic ingredients, pharmaceuticals and biologicals.

- 2 Academic, scientific and research organisations with pronounced interest (non-profit or profit) in the development, optimisation and use of alternative methods.
- 3 Civil society organisations (e.g. so-called non governmental organisations, NGOs) with a clear interest in alternative methods, including inter alia organisations dedicated to animal welfare, environmental protection, consumer protection as well as patient organisations.

5. Representatives to the ESTAF

5.1 Representatives

Stakeholder Organisations fulfilling the Eligibility Criteria may be invited to assign a Representative to the ESTAF. ECVAM reserves the right to select among eligible stakeholder organisations those which it deems most suitable in view of fulfilling ESTAF's role.

Although Representatives are formally participating on behalf of their organisation and not due to personal qualifications, representatives should preferably have the necessary scientific & technical or other expertise to support ESTAF and its role to provide advice to ECVAM. Representatives should be fluent in English, the working language in the ESTAF.

To ensure transparency of the type of advocacy present in the ESTAF, stakeholder organisations represented in the ESTAF, need to make an advocacy statement, i.e. declare their specific (vested) interests and how they conduct advocacy for their stake.

5.2 Other participants to the meetings

The meetings of the ESTAF and its working groups shall be open to Invited Experts.

Invited Experts are external experts who are invited by ECVAM, in agreement with the ESTAF-Chair, to provide specialised input to specified agenda points of ESTAF plenary meetings where required.

Invited Experts shall have full access to meeting documents as Representatives, except in relation to issues that the ESTAF-Chair identifies as confidential or where their participation is excluded.



6. Meetings & Operation

6.1 Meetings and Cost of Meetings

ESTAF will typically meet once a year. The meetings will be organised by the European Commission / JRC / ECVAM. However, travel, hotel cost and subsistence for attending the meetings will normally not be reimbursed by the Commission and are to be carried by the Stakeholder Organisation.

The first meeting is foreseen for spring 2011.

6.2 Written Procedure

Requests, input and collaborative activities will be addressed also through written procedure and using an internet-based forum for document exchange.

6.3 Rapporteurs and ESTAF Working Groups

If necessary, rapporteurs or temporary ESTAF Working Groups may be set up to address specific issues. ESTAF may at any point suggest additional stakeholders for participation

6.4 ESTAFs Input to ECVAM

ESTAF's main input may be summarised in position papers that would be published on ECVAM's website and in the ESTAF response templates for assessing user relevance of alternative methods. [See point 3 above]

7. Procedure for submitting an Expression of Interest

7.1 General issues

All relevant information concerning the submission of an Expression of Interest can be found on ECVAM's website on the ESTAF open invitation

<http://ecvam.jrc.ec.europa.eu/>

Stakeholder Organisations are encouraged to identify their representative already when submitting their expression of interest form.

Expressions of interest can be submitted by

- (1) the person intended to represent the stakeholder organisation in ESTAF in case of selection (=the Representative) or
- (2) any other person entitled to do so by the stakeholder organisation (=the Submitter)

Clearly, Submitter and possible Representative may be identical.



To be admissible, Expressions of Interest must be submitted following the procedure outlined and must be based on the ESTAF Expression of Interest Form.

7.2 Detailed procedure

- (1) Download all documents relevant for the Expression of Interest from <http://ecvam.jrc.ec.europa.eu/>

Downloadable documents relevant for the Expression of Interest in the ESTAF

Nr.	Document	Description
Required for the expression of interest in the ESTAF		
1	ESTAF Submission of Interest Form (WORD DOCUMENT)	To be admissible, expressions of interest submitted to ECVAM must use this form.
2	Open Invitation for the Expression of Interest in the ESTAF (PDF)	Background document outlining the scope of the ESTAF.
Providing additional information		
4	Consent Form (PDF)	Required in case of selection of the Stakeholder Organisation for membership in the ESTAF. Representatives need to give their consent to the processing of their personal information and the publication of their names and other information on ECVAM's website.

- (2) Complete the [ESTAF Expression of Interest Form](#) and send it to JRC-ECVAM-ESTAF@ec.europa.eu