



INFORMAL COMMISSION EXPERT GROUP
EURL ECVAM Scientific Advisory Committee (ESAC)

TERMS OF REFERENCE

1. BACKGROUND

The European Union Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM), hosted by the European Commission's Directorate-General Joint Research Centre (JRC), was formally established under Directive 2010/63/EU on the protection of animals used for scientific purposes¹. According to Annex VII of this Directive, EURL ECVAM is responsible for, amongst other duties, coordinating the validation of non-animal approaches at Union level and promoting dialogue between legislators, regulators and all relevant stakeholders with a view to the development, validation, regulatory acceptance, international recognition, and application of non-animal approaches.

OECD Guidance Document No. 34 on the validation and international acceptance of new or updated test methods for hazard assessment², in turn, specifies that all test methods/approaches should undergo a formal and independent peer review at the end of the validation process, and prior to submission to regulatory authorities for regulatory acceptance consideration. Independent peer-review is, therefore, a mandatory step in the validation of non-animal methods/approaches, and EURL ECVAM coordinates these independent scientific evaluations in order to be able to fulfil its mandate.

The EURL ECVAM Scientific Advisory Committee (ESAC), established in 1991, is charged with providing EURL ECVAM with independent scientific advice. In particular, the ESAC acts as a scientific peer-review body by providing EURL ECVAM with its opinion on the adequacy and outcome of formal validation studies carried out to assess the reliability and relevance of non-animal methods/approaches, typically in the context of regulatory safety assessment. The ESAC may also provide scientific advice on other scientific issues of relevance to the work and mission of EURL ECVAM.

ESAC peer-reviews are formally initiated with a "EURL ECVAM Request for ESAC Advice", which provides the necessary background for the peer-review and establishes its objectives, timelines and the questions to be addressed. Peer-reviews and other work of ESAC are normally facilitated by specialised ESAC sub-groups. At the end of a review, ESAC's

¹ Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes. OJ L 276, 20.10.2010, p. 33–79.

² OECD Guidance Document on the validation and international acceptance of new or updated test methods for hazard assessment. OECD Environment, Health and Safety Publications. Series on Testing and Assessment No. 34, ENV/JM/MONO(2005)14, 18 August 2005.

advice to EURL ECVAM is formally provided as "Sub-group reports" and "ESAC opinions". Adopted ESAC opinions are published on the JRC Publications Repository (<http://publications.jrc.ec.europa.eu/repository/>).

2. TASKS

The ESAC's tasks shall be:

- (a) to assess the scientific validity of non-animal methods/approaches intended for a given purpose;
- (b) to advise on other scientific matters related to the work of EURL ECVAM and the protection of animals used for scientific purposes;
- (c) to share its knowledge and experience on non-animal methods/approaches used in science.

3. MEMBERSHIP

1. The ESAC shall be composed of 9 individual experts appointed in a personal capacity, who shall act independently and in the public interest.
2. ESAC members who are no longer capable of contributing effectively to the ESAC's deliberations, who, in the opinion of the JRC, do not comply with the conditions set out in Article 339 of the Treaty on the Functioning of the European Union or who resign, shall no longer be invited to participate in any meetings of the ESAC and may be replaced for the remainder of their term of office.

4. SELECTION PROCESS

1. The selection of ESAC members shall be carried out *via* a public call for applications, to be published on the Register of Commission expert groups and other similar entities ('the Register of expert groups'). In addition, the call for applications may be published through other means, including on the JRC Science Hub. The call for applications shall clearly outline the eligibility and selection criteria, including the required expertise in relation to the work to be performed. The minimum deadline for applications shall be four weeks.
2. Individuals applying to be appointed as members of the group in a personal capacity shall disclose any circumstances that could give rise to a conflict of interest. In particular, the Commission shall require those individuals to submit a declaration of interests ('DOI') form on the basis of the standard DOI form for expert groups³, together with an updated *curriculum vitae* (CV), as part of their application. Submission of a duly completed DOI form shall be necessary in order to be eligible to be appointed as a member in a personal capacity. The conflict of interest assessment shall be performed in compliance with the Commission's horizontal rules on expert groups ('the horizontal rules')⁴.

³ C(2016) 3301, Article 11 and Annex 4.

⁴ Idem.

3. The members of the ESAC shall be appointed by the Director of JRC Directorate F – Health, Consumers and Reference Materials, from applicants with competence in the areas referred to in Point 2 and who have responded to the call for applications.
4. ESAC members shall be appointed for five years. They shall remain in office until the end of their term of office or until replaced. Their term of office may be renewed.
5. In order to ensure continuity and the smooth functioning of the group, the JRC shall establish a reserve list of suitable candidates that may be used to appoint ESAC members' replacements. The JRC shall ask applicants for their consent before including their names on the reserve list.

5. CHAIR

The ESAC shall elect a Chairperson and Vice-Chairperson from amongst its members by simple majority⁵ of its members.

6. OPERATION

1. The ESAC shall act at the request of the JRC, in compliance with the horizontal rules⁶ or at the request of a simple majority of its members after the JRC has given its agreement. Meetings of the ESAC shall be convened by the Chairperson, with the agreement of the JRC, or at the request of a simple majority of its members after the JRC has given its agreement.
2. In principle, the ESAC shall meet one to two times per year in plenary. The meetings of the ESAC and of its sub-groups shall be held on JRC premises or virtually, depending on the circumstances.
3. The JRC shall provide secretarial services. Commission officials from other departments with an interest in the proceedings may attend meetings of the ESAC and of its sub-groups.
4. In agreement with the JRC, the ESAC may, by simple majority of its members, decide that deliberations shall be public.
5. Minutes on the discussion on each point of the agenda and on the opinions or reports delivered by the ESAC and its sub-groups shall be meaningful and complete. Minutes shall be drafted by the secretariat under the responsibility of the Chairperson.
6. As far as possible, the ESAC shall adopt its opinions or reports by consensus. In the event of a vote, the outcome of the vote shall be decided by simple majority of ESAC members and sub-group members contributing to the specific opinion or report. Members who have voted against or abstained shall have the right to have a document summarising the reasons for their position annexed to the opinions or reports. A member can neither participate in a review nor vote on a specific ESAC opinion or report for which he or she has declared a conflict of interest.
7. When the ESAC initiates a scientific review during the term of office of its members but is not able to conclude the task before the end of that term, the ESAC members

⁵ According to the horizontal rules, simple majority is a majority of the votes of the members.

⁶ C(2016) 3301, Article 13.1.

can finalise that review beyond their term of office. They are also entitled to the reimbursement of meeting expenses and the payment of special allowances in accordance with the provisions of Point 13.

7. ESAC SUB-GROUPS

1. The JRC may set up ESAC sub-groups for the purpose of examining specific questions on the basis of terms of reference defined by the JRC. Sub-groups shall operate in compliance with the horizontal rules and shall report to the ESAC. They shall be dissolved as soon as their mandate is fulfilled.
2. The members of a sub-group that are not members of the ESAC shall be selected via a public, continuously open call for applications, in compliance with the horizontal rules⁷, on the basis of their qualifications/expertise related to the specific question(s) under review. Sub-group members that are not members of the ESAC shall be appointed by the Director of JRC Directorate F – Health, Consumers and Reference Materials in a personal capacity. They must satisfy the same eligibility criteria used in the selection of the ESAC members and shall submit a declaration of interests ('DOI') form in compliance with Point 4.2.
3. Each sub-group must comprise at least one ESAC member who shall chair it, but may be composed of any combination of ESAC members and sub-group members that are not members of the ESAC.

8. INVITED EXPERTS

The JRC may invite experts with specific expertise with respect to a subject matter on the agenda to take part in the work of the ESAC or of a sub-group on an *ad hoc* basis, when considered useful. These invited experts shall not be members of the ESAC or of its sub-groups and as such, they shall not have voting rights and they shall not contribute to the drafting of reports and opinions.

9. OBSERVERS

1. Individuals, organisations and public entities other than Member States' authorities may be granted an observer status, in compliance with the horizontal rules, by direct invitation.
2. Organisations and public entities appointed as observers shall nominate their representatives.
3. Observers and their representatives may be permitted by the Chairperson to take part in the discussions of the ESAC or of its sub-group(s) and provide expertise. However, they shall not have voting rights and shall not participate in the formulation of opinions, reports or other advice of the main group or its sub-groups.

10. RULES OF PROCEDURE

On a proposal by and in agreement with the JRC, the ESAC shall adopt its rules of procedure by simple majority of its members, on the basis of the standard rules of procedure for expert

⁷ C(2016), Articles 10 and 14.2.

groups, in compliance with the horizontal rules⁸. Sub-groups shall operate in compliance with the group's rules of procedure.

11. PROFESSIONAL SECRECY AND HANDLING OF CLASSIFIED INFORMATION

The members of the ESAC and of its sub-groups, as well as invited experts and observers, are subject to the obligation of professional secrecy, which by virtue of the Treaties and the rules implementing them applies to all members of the institutions and their staff, as well as to the Commission's rules on security regarding the protection of Union classified information, laid down in Commission Decisions (EU, Euratom) 2015/443⁹ and 2015/444¹⁰. Should they fail to respect these obligations, the Commission may take all appropriate measures.

12. TRANSPARENCY

1. The ESAC and its sub-groups shall be registered on the Register of Commission expert groups and other similar entities (the "Register of expert groups")¹¹.
2. As concerns the ESAC and the sub-groups' composition, the JRC shall publish the following data on the Register of expert groups:
 - (a) the name of individuals appointed as members in a personal capacity;
 - (b) the name of observers.
3. The JRC shall make available all relevant documents, including the agendas, the minutes and the participants' submissions, *via* a link from the Register to the EURL ECVAM website, where this information can be found. Access to dedicated websites shall not be submitted to user registration or any other restriction. In particular, the JRC shall ensure the publication of the agenda and other relevant background documents in due time ahead of the meeting, followed by timely publication of minutes. Exceptions to publication shall only be foreseen where it is deemed that disclosure of a document would undermine the protection of a public or private interest as defined in Article 4 of Regulation (EC) N° 1049/2001¹².

13. MEETING EXPENSES AND SPECIAL ALLOWANCES

1. The members of sub-groups shall be entitled to the payment of a special allowance (fixed daily rate) of a maximum of EUR 450, in line with the appropriate Commission rules, for each full day of work during a dedicated sub-group meeting. The related preparatory work for these meetings shall not be remunerated.
2. Travel and subsistence expenses incurred by participants in the activities of the ESAC and of its sub-groups shall be reimbursed by the JRC. Reimbursement shall be

⁸ See Article 17 of the horizontal rules.

⁹ Commission Decision (EU, Euratom) 2015/443 of 13 March 2015 on Security in the Commission (OJ L 72, 17.3.2015, p. 41).

¹⁰ Commission Decision (EU, Euratom) 2015/444 of 13 March 2015 on the security rules for protecting EU classified information (OJ L 72, 17.3.2015, p. 53).

¹¹ <http://ec.europa.eu/transparency/regexpert/index.cfm>.

¹² These exceptions are intended to protect public security, military affairs, international relations, financial, monetary or economic policy, privacy and integrity of the individual, commercial interests, court proceedings and legal advice, inspections/investigations/audits and the institution's decision-making process.

made in accordance with the provisions in force within the Commission and within the limits of the available appropriations allocated to the JRC Directorate F under the annual procedure for the allocation of resources.

Done in Ispra, on 17/03/2022.