PRIVACY STATEMENT
for EURL ECVAM Tracking System on Alternative methods towards Regulatory acceptance (TSAR)

1. Description
TSAR is an information system that traces the fate of alternative methods submitted for validation and review to in EURL ECVAM's. It covers all key steps from the submission to EURL ECVAM or to member and observer organisations of the formal International Cooperation on Alternative Testing Methods (the ICATM) until their inclusion into legislation. The system allows the user to see, in a transparent manner, how alternative methods are prioritised, evaluated and translated into legislation or international standards.

2. What personal information do we collect, what is the legal basis, for what purpose and through which technical means?
Identification Data:
The information is collected throughout EURL ECVAM's validation process. This process initiates with the submission of alternative methods to the dedicated functional mailbox JRC- ECVAM-TEST-SUBMISSIONS@ec.europa.eu. The information also originates from organisations collaborating within the ICATM framework provided on a voluntary basis.

Legal Basis of processing:
The establishment and management of TSAR is legally based on 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; art. 48; annex VII(2)(d). OJ L N° 276, 20.10.2010.

EURL ECVAM has a legal mandate for evaluating and promoting alternative methods, which is stipulated in the article 47 of Directive 2010/63/EU of 22 September 2010. As stipulated in the Annex VII of this Directive (2)(a) to (e) and (3), this includes the assessment, validation and promotion of acceptance of alternative methods in international and European regulatory frameworks in order to ultimately contribute to the protection of human health and the environment.
Article 5 (d) of Regulation 45/2001 applies.

Purpose of processing:
The purpose of TSAR is to summarise the progress of alternative methods in validation processes from the (pre)submission step to their use in a regulatory context. The user is thus able to follow the fate of these alternative methods regarding (1) submission to EURL ECVAM (pre- and full submission) or to collaborating organisations and/or validation centres; (2) conduct of validation studies; (3) scientific peer review process and its outcome and (4) situation in the regulatory context. This latter includes Recommendations, Guidance documents, and OECD Test Guidelines and any other relevant documents, deliverables or standards.
Personal information is related to the test submitter's name, address and affiliation with the aim to stay in contact, to exchange and require information necessary for the assessment process.

Technical Information:
The information is collected throughout EURL ECVAM's validation process and from collaborating governmental and regulatory centres. This process initiates with the submission of alternative methods to the dedicated functional mailbox JRC-ECVAM-TEST-SUBMISSIONS@ec.europa.eu or directly from collaborating organisations The address of this mailbox is displayed on the EURL ECVAM website on the webpage named "Test Method Submission" for methods submitted to the EURL ECVAM. Collaborating organisations directly manage their own data. The information undergoes partial manual treatment by the TSAR

manager and scientific staff involved in the assessment processes. The TSAR administrator ensures the technical integrity of TSAR and check of authorised users.

3. Who has access to your information and to whom is it disclosed?

- The information is accessed by either selected EURL ECVAM staff or by collaborators from the ICATM framework (content management) or the public:
  - Regarding the public access, it is possible to consult the fate of alternative methods, at what stage they are in the validation process and their eventual regulatory situation. Names of persons submitting the test method will be displayed only with the agreement of the submitter. Only the organisation is expected to be made accessible. Confidential information on test methods submitted to EURL ECVAM ARE NOT made publically available.
  - Regarding the EURL ECVAM staff access, all documents submitted to EURL ECVAM during the submission process are accessible to the relevant staff. Additionally, EURL ECVAM staff working on test a submission is informed that no information should be publically disclosed.
- During the assessment phases, EURL ECVAM may share the completed presubmission form (including the contact details) and/or the completed Test Submission Template (TST) with its official Advisory Structure, e.g. the EURL ECVAM Scientific Advisory Committee (ESAC), the EURL ECVAM Stakeholder Forum (ESTAF) and the Preliminary Assessment of Regulatory Relevance (PARERE) network (including European regulatory authorities, relevant Commission services and EU agencies like EMA, ECHA and EFSA). In addition the contact details of test submitters/developers are also accessible to governmental validation centres adhering to the official International Cooperation on Alternative Testing Methods (ICATM) for the purpose of evaluations/validation/standardisation/regulatory acceptance. They are however made publicly accessible *via* the TSAR information system only with the agreement of the submitter. Registration is moreover not required for the public consultation of TSAR system.

· Publicly accessible information informing on the progress a method makes during the validation process is accessed by all stakeholder and customer communities as well as by interested scientific and public users (see Notification Recipients section 16; points 1-9)

4. How do we protect and safeguard your information?

Your information is stored on a protected numerical format. This information is accessible to limited staff with prior authorisation for accessing it. Additionally, the use of your information in TSAR has been notified to the Data Protection Officer, as stipulated here http://ec.europa.eu/dpo-register/details.htm?id=35947

5. How can you verify, modify or delete your information?

In case you want to verify which personal data is stored on your behalf by the controller, please contact us by email at **JRC-ECVAM-TEST-SUBMISSIONS@ec.europa.eu** or by phone **+39 0332 78 9725**.

Upon a justified request submitted to the above mentioned functional mailbox, your data will be rectified, modified, frozen or eventually erased in a maximum period of 14 working days.

6. How long do we keep your data?

Personal data will be maintained in the system until the evaluation process is finalized since the

process requires periodical contacts with the test submitters. After conclusion the data subjects will be anonymised in TSAR as well as test method submissions where the process exceeds 5 years before forwarded for peer-review. Thus, for historical records the maximum retention is set to 5 years. .

7. Contact Information.

JRC-ECVAM-TEST-SUBMISSIONS@ec.europa.eu

8. Recourse.

In the event of a dispute, you can send a complaint to:

- the European Data Protection Supervisor: edps@edps.europa.eu