

## Step 1 – The validation study

The validation study is performed according to the OECD Guidance on Validation<sup>5</sup>, following standardized test method protocols and preferably in compliance with GLP principles<sup>6</sup>

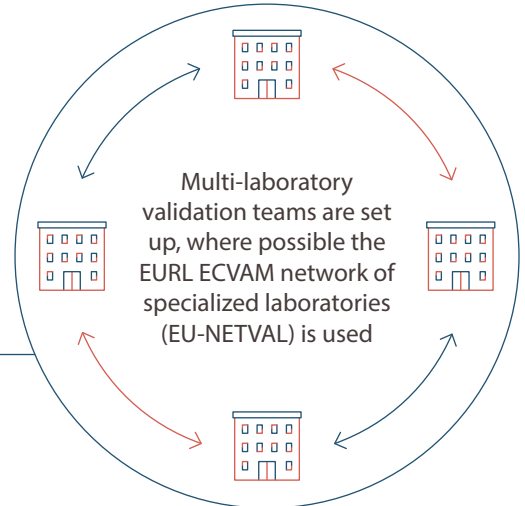
The validation study can also be arranged by the method developer  
An independent scientific peer review is always needed and can be performed by EURL ECVAM

EURL ECVAM plans and designs the validation study  
A public call is used to ensure all relevant information on the method is taken into account

## Step 2 – Scientific peer review



Completed validation studies undergo independent scientific peer review by the EURL ECVAM Scientific Advisory Committee (ESAC)



## EURL ECVAM recommendation

EURL ECVAM can draft a recommendation on the validated test method  
The EURL ECVAM expert and stakeholder panels, the method submitter as well as the general public are allowed to comment before the document is finalized

Submission for uptake in an international guideline or standard

- Assessment
- Commenting
- Peer review

**International acceptance through adoption as OECD Guideline or ISO standard**



OECD and ISO work globally to standardize and harmonize guidelines and ensure reliable data

### OECD

The process to develop or update guidelines is described in OECD Guidance Document No. 1<sup>7</sup>; proposals are submitted to OECD via the member countries

In Sweden, the National Coordinator is located at the Swedish Chemicals Agency

### ISO

The experts in the ISO committees can propose new standards to be drafted to meet a need in the industry; the drafting is based on consensus between members

In Sweden, the national partner is the Swedish Institute for Standards

1. EU Reference Laboratory for alternatives to animal testing
2. Test method submission to EURL ECVAM
3. The Swedish 3Rs Center is the national contact point for the EURL ECVAM Network for Preliminary Assessment of Regulatory Relevance
4. TSAR – Tracking System for Alternative methods towards Regulatory acceptance
5. OECD Guidance Document No. 34 on the Validation and International Acceptance of New or Updated Test Methods for Hazard Assessment
6. OECD Principles of Good Laboratory Practice
7. OECD Guidance Document No. 1 for the Development of OECD Guidelines for Testing of Chemicals