

WG5

Criteria for prioritization

The following criteria were agreed at the WG5 Workshop as important for the prioritization of validation studies in the ECVAM current pipeline:

A – Ethics

- the number of animals used by the animal and the alternative test (impact data) in the overall context of the actual use of the respective methods,
- the level of diminution of the test severity or 3Rs benefit offered
- the increased level of safety introduced

B – Regulatory demand

- Would the test address regulatory needs ?
 - Does the method cover a specific regulatory testing purpose ?
 - Is it strictly applicable ? ie hazard/risk
 - Are there clear agreed rules/ criteria for how test results would be used for decision making : ie Regulatory and/or Safety
 - Would the test offer full replacement for safety assessment or be used in a tiered strategy ?
- Are there legislative timelines ?

C - Industrial incentive

- Does it have a high probability to be accepted by regulators (liability aspects) ?
- the applicability of the test in different sectors,
- the applicability for all chemicals / or for materials of limited range,
- the frequency of use of the method
- method transferability,
- need for special equipment, trained staff, resources (overall cost)
- reduced time
- Could the test be used for screening purposes?(HTS)
- are there patents involved, would the test be commercially available?

D – Development status

- relevant and consistent responses with positive and negative reference materials
- level of advancement of the test, (optimised protocol , standard operating procedures)and of the method (prediction model)
- part of an overall strategy (basic research still missing),
- availability of data (optimization studies , prevalidation , publications),
- Is this test making use of the best scientific knowledge available?
- probability for success