

## ECVAM – The European Centre for the Validation of Alternative Methods

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### 1. Introduction of ECVAM, incl. aims and goals (mission) and sponsor

- ECVAM was created in 1991 in order to support the implementation of the 3Rs in particular through validating alternative toxicological test methods.
- Since then it developed generally accepted principles for the efficient validation of alternative tests, such as pre-validation/validation and the modular approach.
- Validation is only useful if it is deemed trustworthy. Therefore the independent peer review of the validation, for which ESAC is responsible, is an essential element of the process.
- So far ECVAM validated more than 30 test methods, mostly in vitro, and produced 37 ESAC statements.
- Of these ECVAM-validated tests a number is already accepted for regulatory purposes as full replacements, other are in the acceptance process
- Since the 7th amendment to Cosmetics the full replacement of animal tests for the cosmetic endpoints is determining the agenda and progress is made – most topical toxicology endpoints can be tested without using animals.
- The more complex endpoints (in particular reproductive tox, Toxicokinetics, and repeated dose tox) are still far off and require new testing approaches, also because the available animal tests are neither perfect nor cost efficient nor fast.
- REACH is another driver that becomes more and more evident, clearly stating the intention to return to animal testing only as last resort while creating a strong demand for more and reliable data.
- Today ECVAM is a Policy Support Action of the IHCP/JRC, supported primarily by two of its scientific units, the in vitro methods unit and the system toxicology unit. This provides ECVAM with access to stable validation capacities and to much increased laboratory capacities.
- ECVAM is primarily funded by Community funds, mostly directly, e.g. for staff and infrastructure cost, and sometime indirectly, e.g. via co-funded R&D or other projects.

Today ECVAM's mission is:

- We support the EU policies in the field of Consumer protection, Environmental protection and Animal protection
  - by validating alternative methods for safety testing that implement the 3Rs and provide the same or a better basis for risk assessment and risk management as current methods,
  - and by promoting their development, their application in industry and their acceptance by regulators.

### 2. A short statement on the future of the 3 R's in the next decade, e.g. chronic systemic toxicity testing and toxicology in the 21<sup>st</sup> century.

- Sorry, no crystal-ball!
- With growing/continuing economic crisis we might expect a decreasing general public attention for the issue, but
- With increasing allergies, resistances, etc. the public might get more concerned about safety of chemicals and related products, also because with increasing understanding of

the complex physiological pathways in the human body and how chemicals might disturb them, science might ring more alarm bells

- Therefore I expect an increasing demand for better, faster, reliable, and affordable safety testing, also stimulated by REACH, generating a need to screen very fast many chemicals with a high likelihood to catch potential risks.
- If alternatives can successfully respond to this demand, and I believe this is not excluded, the future for the 3Rs will be good, but has to be driven by scientific and technical progress.
- The challenge is to integrate modern science into toxicology and into toxicology testing.
- We will be able to measure more and better at the cell and sub-cellular level – the challenge will be to understand the information. Integrating measurement technology (including those based on biological in vitro test systems) with computational toxicology, in particular modelling will become critical.
- For ECVAM the challenge will be to validate complex testing systems, consisting of building blocks that influence each other (or not). We have to convincingly establish that the generated data are reliable and relevant.

3. Assuming that national 3R centres will be created in the EU Member States. Will ECVAM support a network of European centres on alternatives?

- YES, ECVAM would support these centres by running and managing an effective network.
- For example,
- incoming test methods could be tried out, as part of its potential-assessment, by the centre that has the capacity and expertise. Based on this and other information the validation priorities will be fixed.
- Validation studies could be carried out in the best suited and available laboratories.
- Dissemination activities could be coordinated,...
- As to budgetary support - this depends what the legislator decides. Experience warns to put the expectations too high.