



Interagency Coordinating Committee on the Validation of Alternative Methods

Update on International Collaborations/ICATM and Interactions with ECVAM

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Agency for Toxic Substances and Disease Registry • Consumer Product Safety Commission • Department of Agriculture
Department of Defense • Department of Energy • Department of the Interior • Department of Transportation
Environmental Protection Agency • Food and Drug Administration • National Institute for Occupational Safety and Health
National Institutes of Health • National Cancer Institute • National Institute of Environmental Health Sciences
National Library of Medicine • Occupational Safety and Health Administration

International Collaboration

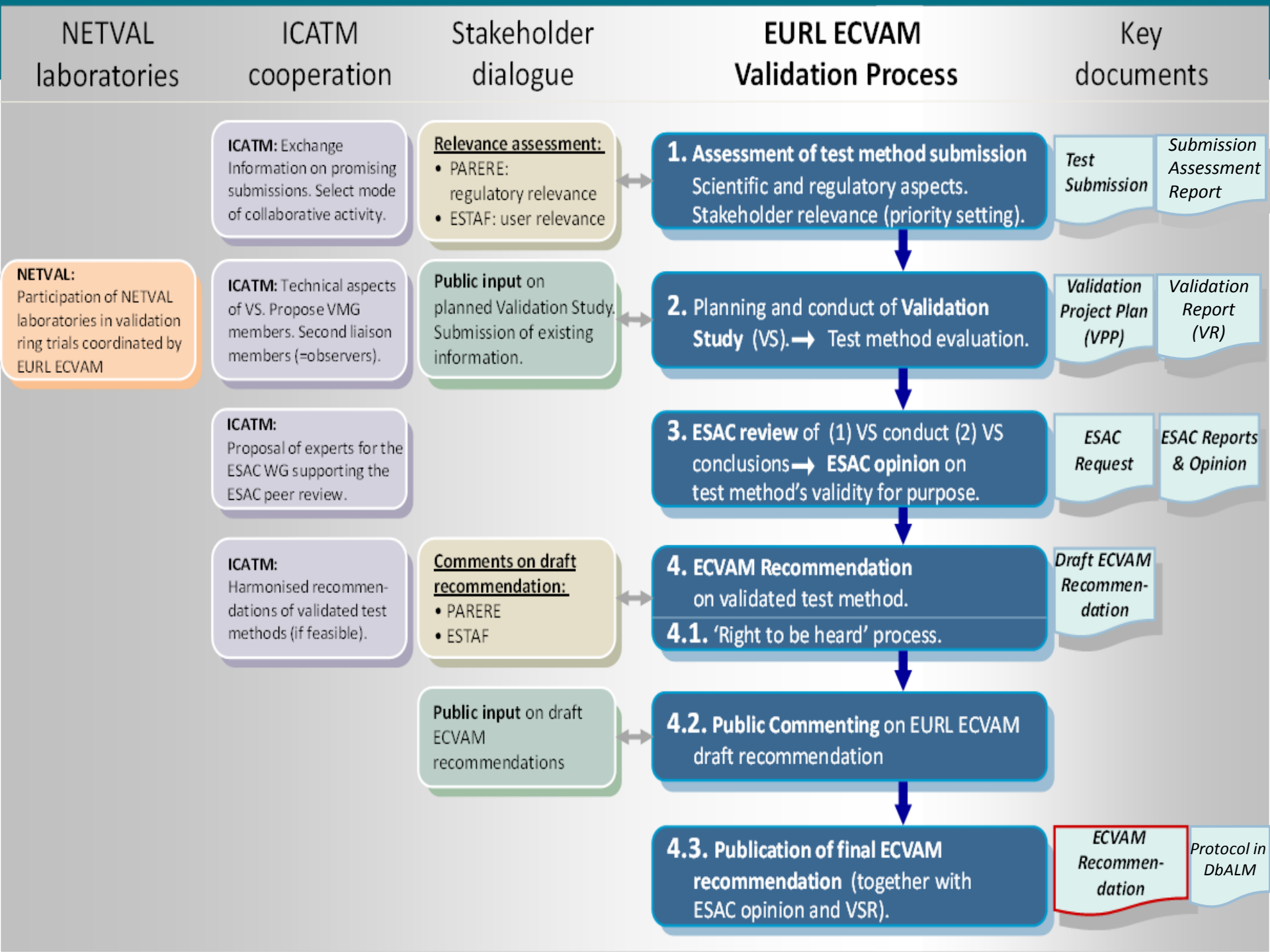
- International collaboration, harmonization, and adoption of alternative test methods are high priorities for ICCVAM.
- OECD Test Guidelines program provides a mechanism for the international evaluation and adoption of alternative methods by its 34 member countries.
- The International Cooperation on Alternative Test Methods (ICATM):
 - provides means to coordinate the validation and adoption of alternative test methods among its member countries: United States, Canada, Europe Union, Japan, and Korea.
 - established to promote international cooperation in the critical areas of validation studies, independent peer review, and development of harmonized recommendations to ensure that alternative methods/strategies are more readily accepted worldwide.
 - "[Alternative Test Method Validation and Regulatory Acceptance Status Report](#)" includes a comprehensive listing of test method evaluation activities undertaken by ICATM partner organizations.

International Collaboration

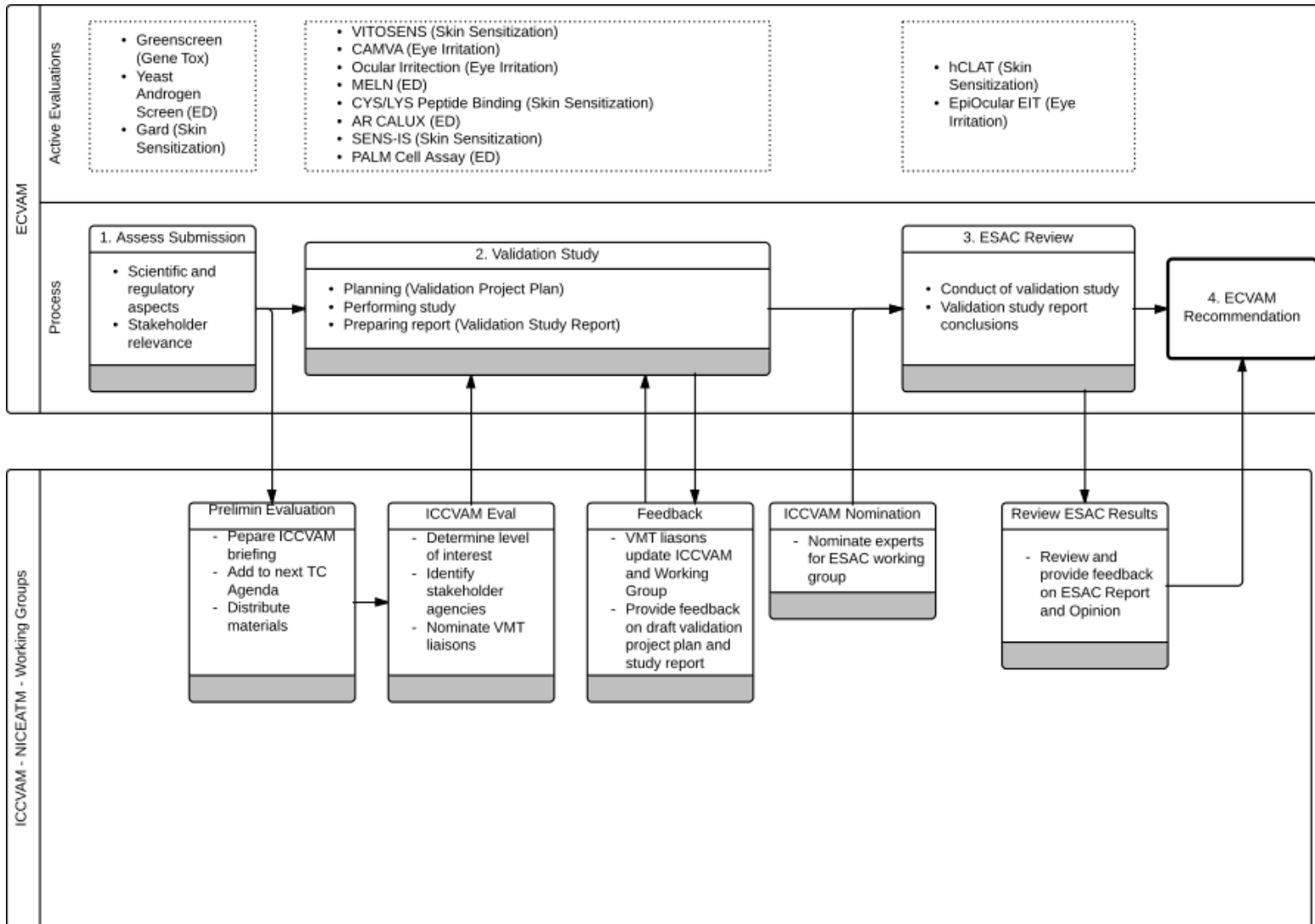
- European Union Reference Laboratory for alternatives to animal testing (EURL-ECVAM):
 - conducts validation study review and approval processes in a manner that meets the needs of US regulatory agencies.
 - has a dedicated budget and a network of laboratory facilities that can accommodate the requisite level of activity needed to produce a robust pipeline of alternative methods.
 - In contrast, to ICCVAM which has no budget & NICEATM which is not budgeted to conduct validation studies.

International Collaboration

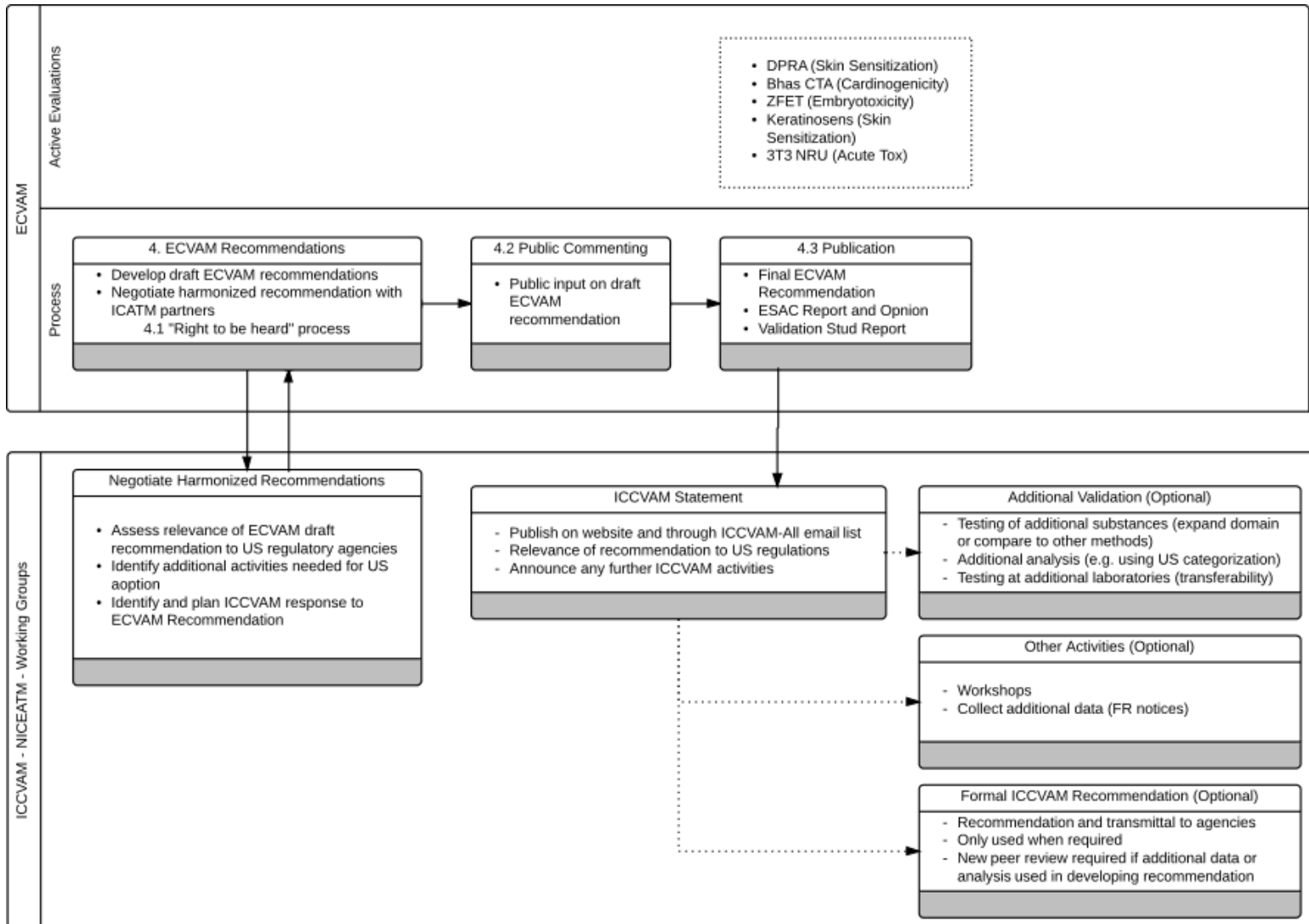
- ICCVAM and NICEATM are working with EURL-ECVAM on a process
 - that will enable US scientists to participate actively in the EURL-ECVAM test method evaluation of the usefulness and limitations of relevant test method and
 - that will increase the transparency of the evaluation.
- U.S. designees will participate in each of the various steps of the evaluation from test method submission, to validation study design, to peer review, to final recommendations.
 - The process will also include opportunities for public comment, inform stakeholders of new methods, that are available, and by ICCVAM working together with ECVAM avoid duplicative reviews that can delay test method acceptance.



ICCVAM Participation on ECVAM Activities (1)



ICCVAM Participation on ECVAM Activities (2)



ICCVAM Responses to ECVAM Recommendations

- Recently, ICCVAM, reviewed the recommendations and, has prepared responses that put the recommendations into context relative to their applicability for U.S. regulatory testing.
 - Direct Peptide Reactivity Assay (DPRA)
 - Zebrafish Embryo Toxicity Test (ZFET)
 - Keratinosens
 - Cell Transformation Assay based on the Bhas 42 cell line
 - 3T3 Neutral Red Update (3T3 NRU) Cytotoxicity Assay for the Identificaiton of Substances not Requiring Classification for Acute Oral Toxicity.

International Coordination

- FY 2015 Goals:
 - Nominate ICCVAM agency experts to international expert working groups, validation management teams, and organizing committees
 - Serve as a forum to communicate updates to ICCVAM agencies on international activities relevant to the 3Rs
 - Nominate methods for interlaboratory validation to the EURL ECVAM network of testing laboratories
 - Continue active participation in ICATM
 - Work with ECVAM on a process for test method acceptance

Charge Questions

- Please comment on ICCVAM's effort toward international evaluation and adoption of alternative methods.
- Please comment on ICCVAM's statements regarding ECVAM's recommendations on the alternative test methods.
- Please comment on ICCVAM's participation on ECVAM Test Methods Evaluations.