Update on International Collaborations/ICATM and Interactions with ECVAM

Background Materials:

- ECVAM Evaluation and Recommendation Process
- ICCVAM Process for Participation on ECVAM Evaluations
- Draft ICCVAM Statements on Recent ECVAM Evaluations

International collaboration, harmonization, and adoption of alternative test methods are high priorities for ICCVAM, given the economic importance of international trade to industries such as cosmetics, industrial and agricultural chemicals, and pharmaceutical products. The OECD, via the 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 another, more direct, and expeditious means to coordinate the validation and adoption of alternative test methods among its member countries: United States, Canada, Europe Union, Japan, and Korea. ICATM was 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. A January 2014 "Alternative Test Method Validation and Regulatory Acceptance Status Report" includes a comprehensive listing of test method evaluation activities undertaken by ICATM partner organizations**.** Of the four ICATM partners, only the 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. Consequently, ICCVAM has placed increased emphasis on interactions with EURL-ECVAM and its processes for validating test methods and assessing their regulatory utility.

International Collaborations with EURL-ECVAM

ICCVAM has no budget and, therefore, does not fund studies related to the adoption of alternative methods. ICCVAM was established to *review* validation study reports and make recommendations to federal agencies on their utility for regulatory testing. NICEATM provides administrative and scientific (data analysis) support for ICCVAM, and is not funded to conduct validation studies. Although these fiscal realities present a challenge to achieving the goal of making more alternative methods available for US regulatory agencies, they do not preclude ICCVAM and NICEATM from making progress towards the 3Rs.

EURL-ECVAM 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. ICCVAM and NICEATM are working with EURL-ECVAM on a process (1) that will enable US scientists to participate actively in the EURL-ECVAM test method evaluation of the usefulness and limitations of relevant test method (see *ECVAM Evaluation Process.pdf*) and (2) that will increase the transparency of the evaluation. Through this process (see *ICCVAM Process.pdf*), 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.

Recently, EURL-ECVAM put into practice this new process and provided ICCVAM recommendations for several alternative test methods. ICCVAM reviewed the recommendations and prepared responses that put the recommendations into context relative to their applicability for U.S. regulatory testing (see *Draft ICCVAM Statements.pdf*).

Charge Questions for SACATM:

- 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.