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Dr. Nicole Kleinstreuer  
Director, NICEATM  
Research Triangle Park, NC 27709  
Submitted via email to: Amber Daniel  
E-mail: [amber.daniel@inotivco.com](mailto:amber.daniel@inotivco.com)

RE: Comments on ICCVAM draft guidance document: Validation, Qualification, and Regulatory Acceptance of New Approach Methodologies

Dear Dr Kleinstreuer,

We appreciate public access to and the opportunity to provide our comments on the draft guidance document noted above. We find this draft to be an excellent update from the 1997 guidance document. It conveys very clearly ICCVAM's collective thinking on a well-considered modern development process for NAMs and the open mindset among the partner agencies to consider new technologies and their applications in ways that go beyond the rigid confines of previous traditional approaches. Our comments are limited to a few small points for additional clarity.

### **The Use of Protected Elements**

Section 3.5, lines 808-810 state: "For NAMs that contain intellectual property, the OECD provides tools to maintain transparency, including reasonable and non-discriminatory terms for licensing commitments (OECD, 2021b)."

The reference cited "OECD, 2021b" reads: "OECD, 2021b. Environment Directorate Joint Meeting of the Chemicals Committee and the 1325 Working Party on Chemicals, Pesticides and Biotechnology [WWW Document]. URL chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV-JM-MONO(2019)14%20&doclanguage=en (accessed 11.3.22)."

The URL included actually points to a google search results page instead of the actual document. The reference might be improved to include the actual document title, "Guiding

Principles On Good Practices For The Availability/Distribution Of Protected Elements In OECD Test Guidelines, Series on Testing and Assessment No. 298", and a more direct hyperlink to the document itself: [https://one.oecd.org/document/ENV/JM/MONO\(2019\)14/en/pdf](https://one.oecd.org/document/ENV/JM/MONO(2019)14/en/pdf)

### **The Process of Engaging with ICCVAM**

Section 5 does a great job of introducing the relevant domestic and international agencies and describing how they interact with each other, but there is no reference or instruction in this section on how private industry NAM developers can identify and approach the correct agency to begin the evaluation process.

This information is, in fact, included elsewhere in the document (indirectly via the initial reference to Table 1), but an additional reference in this section to the document in Table 1, "ICCVAM Guidelines for the Nomination and Submission of New, Revised, and Alternative Test Methods, NIH Publication No. 03-4508" would not only provide clarification but also give the agencies acknowledgement the despite the age of this document (published 20 years ago), it still provides current and accurate information on the engagement process with ICCVAM.

As a small side note, prior to realizing that the engagement process for ICCVAM is contained in the document listed in Table 1, upon a read of the webpage NTP webpage at URL <https://ntp.niehs.nih.gov/whatwestudy/niceatm/resources-for-test-method-developers/submissions>, we find that the link to contact ICCVAM in the sentence opening paragraph 3, "Test method submissions may be made by [contacting ICCVAM.](#)", is a dead link.

We look forward to the timely publication of the final guidance document and thank the authors for considering these comments. Please feel welcome to contact us if any questions arise from these comments.

Yours sincerely,  
(signature redacted)

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