# AGENDA AND CHARGE QUESTIONS FOR NOVEMBER 2ND MEETING

1. Introduction (9-9:45)
    a. Plan for the day – EPA Presentation, Breakout Groups, Expert Comments, Public Comments
    b. OPPT Presentation on Goals/Objectives
    c. Identification of Charge Questions and Overarching Considerations (attached)
2. Breakout sessions (Self-Assigned): (9:45 - 11)
    a. Opportunity for Clarifying Questions Before Starting Breakout Groups (15 min)
    b. GROUP 1: Charge Questions (1-4))
    c. GROUP 2: Charge Questions (5-8)
    d. GROUP 3: Overarching considerations
3. Break (11-11:15)
4. Breakout sessions (11:15 to 12:30)
5. LUNCH – 12:30 – 1:30
6. Bring Back/Plenary (1:30 – 2:30)
    a. 20 min per breakout group
7. Expert Comments (2:30 – 3:30)
8. Break (3:30 to 3:45)
9. Public Comment (3:45 – 4:45)
10. Adjourn

## CHARGE QUESTIONS (Breakout Groups 1 and 2)

1. Review and comment on the draft goals and objectives presented in the draft PowerPoint.
    a. Is there anything missing?
    b. Did the Agency appropriately identify near, mid, and long-term objectives?
    c. Are there additional objectives the Agency should consider important to achieving the goals identified?
2. Regarding the use of NAMs, what should the Agency consider in terms of process and content for "…providing information of equivalent or better scientific quality and relevance that will support regulatory decisions…" (as stated in 4(h)(2)(A) and elsewhere).
3. Please provide ideas for criteria for reliability and relevance of NAMs that may be used under TSCA (4(h)(2)(D); considering the different contexts (regulatory – prioritization, screening risk evaluation, robust risk evaluation; and type of NAM – computer predictions, in vitro, organs-on-a-chip, etc.)
4. Please provide suggestions for which NAMs may be useful to meet our Goal 3 (requirements for a list of NAMs). Are there existing lists that EPA should preferentially draw from? Existing lists that EPA are considering includes those from OECD, ICCVAM and ECVAM[1].
5. Please provide examples of implementation (in a non-regulatory or regulatory setting) of the use of NAMs for the purpose of evaluating risk to human health or the environment. This can be for chemicals, medical devices/products, pesticides, etc.
6. Collaboration and identifying and promoting the use of the new science will be a key to success. What are steps OPPT can take to ensure this happens?
7. As mentioned in TSCA (Sections 4(h)(1)(B)(iii) and 4(h)(2)(A)(viii)), please provide ideas for how to form industry consortia?
8. What research and method development needs remain to achieve long-term TSCA objectives?
    a. What are the best approaches for EPA in identifying gaps in science and encouraging research and development in those areas?
9. How should the Agency ensure that the strategic plan developed is reflected in the development of requirements for testing?

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[1] • List of alternative methods accepted by US agencies through ICCVAM - https://ntp.niehs.nih.gov/pubhealth/evalatm/accept-methods/index.html and list of ICCVAM Guidance Documents: https://ntp.niehs.nih.gov/pubhealth/evalatm/accept-methods/guidance/index-2.html
• List of alternative methods listed as "regulatory acceptance/standards" completed according to the European Union Reference Laboratory for Alternatives to Animal Testing (EURL-ECVAM) through its Tracking System for Alternative Methods towards Regulatory Acceptance (TSAR) - http://tsar.jrc.ec.europa.eu/
• List of alternative methods/strategies presented by health endpoints in the OECD - http://www.oecd.org/chemicalsafety/testing/oecdguidelineapproachbyendpoints.htm

## OVERARCHING CONSIDERATIONS (Breakout Group 3)

1. Understanding the concept expressed throughout the law of implementing NAMs – “to the extent practicable (and) scientifically justified”

2. Identifying and promoting advances in science and NAMs (including training)

3. Fostering collaboration with domestic and international stakeholders inside and outside the government on NAMs

4. Global harmonization

5. Communication and Education of the public

6. The need to identify appropriate information to replace vertebrate animal testing

7. Enhance and harmonize IT systems to maximize the use of existing information and assessments.

8. To develop a new risk evaluation paradigm for human health and the environment for new and existing chemicals in US commerce which uses non-animal alternative test methods and strategies.