



DRAFT AGENDA

HESI UVCB/MCS Workshop

Exploring the Complexities of UVCBs for Testing and Risk Assessment

September 18 – 19, 2023

PURPOSE

Highlight various challenges associated with UVCB risk assessment with a focus on the whole substance vs. representative constituent approach, and persistency evaluation, and initiate multi-sectoral discussions towards resolution and potential consensus for solutions.

OBJECTIVES

1. Engage a broad community of stakeholders to foster the exchange of the latest knowledge and developments in the field
2. Clarify when to test and assess the whole substance, and/or representative constituents
3. Identify the challenges associated with biodegradation/persistency testing and assessment
4. Identify actionable steps to facilitate and improve the general assessment of UVCB
5. Identify emerging science and regulatory questions related to UVCBs
6. Identify gaps in the UVCB assessment and/or testing space, and explore opportunities for potential collaborative solutions.

OUTPUT

One or two manuscript(s) related to the above objectives.

OUTCOME

Help refine the testing and risk assessment of UVCBs.



DAY 1

8:30 – 9:00: LIGHT BREAKFAST

9:00 – 9:15: Welcome, HESI project presentation, and stage setting
Introduction of the HESI UVCB Committee and project

9:15 – 10:00: UVCB Risk Assessment: Regulatory panel
Interview of regulators to highlight key issues associated with UVCBs in their jurisdictions and address regulatory framework questions for P/B and more.

10:00 – 10:20: BREAK

10:20 – 11:20: Rapid fire presentations

- Data compilation challenges
- Difficulty to test UVCBs
- Difficulty to assess UVCBs

11:20-12:15 &

12:45 – 1:30: Whole substance vs. representative constituent approach: which tells the true story?

11:20 – 11:30: Introduction to the break-out exercise on the general challenges associated with whole substance and constituent approach

11:30 – 12:15: Break-out session

1. Whole substance approach. (Groups A&B)
2. Representative constituent approach (Groups B&C)

12:15 – 12:45: PROVIDED LUNCH

12:45 – 1:45: Reporting and discussion

1:45 – 4:00: Combining the two approaches.
Break-out session

1:45 – 1:55: Introduction to break-out groups: problem framing and instructions:

1:55 – 2:45: Break-out session

2:45 – 3:00: BREAK

3:00 – 3:45: Reporting and discussion

4:00 – 5:30: Poster social



DAY 2

8:30 – 9:00: LIGHT BREAKFAST

9:00 – 9:10: Welcome and Introduction

9:10 – 10:10: On persistency and biodegradation
1. Presentation #1: TBD
2. Presentation #2: TBD

10:10 – 10:30: BREAK

10:30 – 12:00: The challenges of persistency evaluation

10:30 – 10:40: Introduction to the breakout session:

10:40 – 11:15 Break-out session

11:15 – 12:00 Reporting and discussion

12:00 – 12:30: LUNCH

12:30 – 12:40: Brainstorm: What other key issues should be addressed?

12:40 – 2:00: Identification of challenges, main takeaways, prioritization of key ideas, and actionable steps

12:40 – 12:50: Introduction to the exercise

12:50 – 1:20: Break-out session

1:20 – 2:00: Reporting and discussion

2:00 – 2:15: BREAK

2:15 – 2:45: Wrap-up

2:45: ADJOURN.