

US-EU Workshop on Endocrine Disruption

6-7 October, 2015

Brussels

OVERVIEW

This workshop was inspired by discussions between EU Commission representatives and the US EPA with the goal of fostering US/EU cooperation on scientific issues related to promoting chemical safety in regard to potential for endocrine disruption. This paved the way for the idea of cooperative work on scientific aspects related to the assessment of chemicals' endocrine disrupting potential, and a workshop on commonalities and differences in the European and US approaches for the screening and assessment of potential endocrine disruption.

The agenda for the workshop addresses the major scientific activities going on in the US and EU on endocrine disruption, with presentations and discussions on screening, priority setting and assessment of endocrine disrupting substances. This 2 day workshop will involve participants from each side, with case studies presented by EU (DG ENV, SANTE, GROW, JRC, ECHA, EFSA) and US (EPA, NIEHS, FDA, CPSC) participants. These case studies will be examined and discussed in order to identify similarities in approaches and possibilities for further cooperation in sharing the scientific basis for the assessment. Whereas the work in US until now has been focused on pesticides, the identification of EDs in Europe has until now only covered industrial chemicals. Taking into consideration available time, experience and resources, pesticides (azole fungicides), phthalates, phenols (nonylphenol/octylphenol) and BPA have all been discussed potential candidate case-studies. The workshop should focus on both commonalities and differences while doing a lot of exploration. Coming out of the workshop, groups could work in subsequent months to prepare workshop summary reports on designated topics. For each case study it should be analysed whether we look at the same data, identified the same endocrine activity and adverse effects, and whether the interpretation of data, dose-response, hazard, exposure and risk is similar. Key findings will be identified in the meeting, forming the basis for the workshop summary reports. Additional questions could be whether the different methodologies for screening and priority setting achieve the same, what are the similarities and differences, and why do they exist. It was agreed that the work should be integrated and attempt to cover both human health and environment which is extremely relevant due to the conservation of the hormonal system across species.

WORKSHOP TOPICS

1. Screening activities and methods to identify potential endocrine disruptors

Description of EU and US approaches and methodologies for screening for endocrine disruption and sharing of data. Comparison and analysis of similarities and differences and possible explanation of differences, if any.

2. Priority setting activities and methodologies to identify substances (potential endocrine disruptors) of concern

Description of EU and US priority setting methodologies to identify potential endocrine disruptors and sharing of work. Comparison and analysis of similarities and differences and possible explanation of differences, if any.

3. Identification of intrinsic hazard of endocrine disruption

Description of EU and US approaches and methodologies to identify inherent endocrine disruptive properties of chemical substances. Comparison and analysis of similarities and differences and possible explanation of differences, if any.

4. Risk assessment

Description of EU and US approaches for risk assessment of endocrine disruptors. Comparison and analysis of similarities and differences and explanation of differences.

PARTICIPANTS

The workshop would be attended by up to 30 participants – 10-15 from each side. US side will be represented by US EPA, FDA, CPSC, and NIH. EU will be represented by the relevant Commission Services and EU Agencies.

U.S. Participants:

- US EPA – [REDACTED] (OSCP); (OPPT); [REDACTED] (OPP); [REDACTED] (OW); (OCHP)
- FDA- [REDACTED]
- CPSC-
- NIH- [REDACTED] (NIEHS)

EU Participants

- DG ENV – [REDACTED]
- DG SANTE – [REDACTED]
- DG GROW – [REDACTED]
- SG – [REDACTED]
- DG RTD – [REDACTED]
- DG JRC – [REDACTED]
- EFSA – [REDACTED]
- ECHA – [REDACTED]
- DK – (.....)
- DE – (.....)
- FR – (.....)

WORKSHOP AGENDA

Both EU and US would present their activities, approaches and methodologies for screening, priority setting, identification and risk assessment as regards endocrine disruptors. Commonalities and differences could be then identified and discussed for each of the topics. Specific examples and case-studies are encouraged. Concluding discussions will focus on possible collaborative work, building from the case-studies or other projects, that will help elucidate similarities, differences and conclusions.

US Presentations:

- “Overview of the US EPA Endocrine Disruptor Screening Program (EDSP)”
([REDACTED] EPA/OSCP)
- “Use of High Throughput Assays and Predictive Models in the US EPA EDSP”
([REDACTED] EPA/OSCP)
- “US EPA EDSP List 1 Tier 1 Screening Level Determinations of Endocrine Activity and Additional Testing for Dose Response and Adversity”
([REDACTED] , EPA/OPP)
- “Phthalates Risk Assessment”
([REDACTED] , EPA/OPPT)
- “Assessing the Risks of Endocrine Disruption from Water-Based Exposures”
(Colleen Flaherty, EPA/OW)
- “BPA Risk Assessment”
([REDACTED] , FDA)
- The Chronic Hazard Advisory Panel on Phthalates (CHAP) Report
<http://www.cpsc.gov/en/Business--Manufacturing/Business-Education/Business-Guidance/Phthalates-Information/>
([REDACTED] , CPSC)
- “CLARITY-BPA Consortium Linking Academic and Regulatory Insights on BPA Toxicity”,
http://www.niehs.nih.gov/research/programs/endocrine/bpa_initiatives/index.cfm
([REDACTED] , NIEHS)

EU Presentations

- Overview of EU activities under the Community Strategy for Endocrine Disruptors
([REDACTED] DG Env)
- Screening for potential endocrine disruptors / work of ECHA's Endocrine Disruptors Expert Group (ECHA ED EG) to identify substances of very high concern due to their endocrine disrupting properties
([REDACTED] , ECHA) ;
- Prioritisation exercise to identify priority substances under Water Framework Directive with the focus on endocrine disruption
([REDACTED] , DG ENV or DG JRC)
- Identification of DEHP and 3 other phthalates as endocrine disruptors under REACH
([REDACTED] , DK/ECHA)
- Identification of phenols (nonyl, octyl and their ethoxylates) as EDs under REACH
([REDACTED] , DE/ECHA)

- Risk assessment of Bisphenol A
(.....,EFSA, ECHA, ANSES)

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Avenue de Beaulieu 9, 1160 Brussels, Room: BU-9 –0A

Draft Agenda

1. Welcome (DG ENV)
2. U.S. and EU policy context
 - a. Overview of EU activities under the Community Strategy for Endocrine Disruptors + distribution of responsibilities among the institutions
(..... DG ENV)
 - b. Regulatory context + distribution of responsibilities among the institutions
(US)
3. U.S and EU screening activities
 - a. “Overview of the US EPA Endocrine Disruptor Screening Program (EDSP)”
(..... EPA/OSCP)
 - b. “Use of High Throughput Assays and Predictive Models in the US EPA EDSP”
(..... EPA/OSCP)
 - c. “US EPA EDSP List 1 Tier 1 Screening Level Determinations of Endocrine Activity and Additional Testing for Dose Response and Adversity”
(..... EPA/OPP)
 - d. Screening for potential endocrine disruptors / work of ECHA's Endocrine Disruptors Expert Group (ECHA ED EG) to identify substances of very high concern due to their endocrine disrupting properties
(....., ECHA)
 - e. Work of JRC on high throughput screening and non-animal approaches
(....., JRC)
 - f. Screening for potential EDs in the Impact Assessment
(....., JRC)
4. Assessing the Risk of Endocrine Disruption for Water Environment
 - a. “Assessing the Risks of Endocrine Disruption from Water-Based Exposures”
(....., EPA/OW)
 - b. Prioritisation exercise to identify priority substances under the Water Framework Directive with the focus on endocrine disruption
(....., DG ENV or DG JRC)
5. Hazard and risk assessment of phthalates

- a. "Phthalates Risk Assessment"
(....., EPA/OPPT)
 - b. The Chronic Hazard Advisory Panel on Phthalates (CHAP) Report
<http://www.cpsc.gov/en/Business--Manufacturing/Business-Education/Business-Guidance/Phthalates-Information/>
(....., CPSC)
 - c. Identification of DEHP and 3 other phthalates as endocrine disruptors under REACH
(....., DK/ECHA)
6. Hazard and risk assessment of Bisphenol A
 - a. "BPA Risk Assessment"
(....., FDA)
 - b. "CLARITY-BPA Consortium Linking Academic and Regulatory Insights on BPA Toxicity",
http://www.niehs.nih.gov/research/programs/endocrine/bpa_initiatives/index.cfm
(....., NIEHS)
 - c. Risk assessment of Bisphenol A
(....., ANSES, ECHA and EFSA)
7. Hazard assessment of octyl, nonyl phenols and their ethoxylates
 - a. Identification of phenols (nonyl, octyl and their ethoxylates) as EDs under REACH
(....., DE/ECHA)
8. Hazard and risk assessment of some pesticides (e.g. azoles)
 - a. US examples of risks assessment as regards ED properties
(US EPA)
 - b. EU examples of risks assessment as regards ED properties
(EFSA)
9. Conclusions