

Ares(2015) 3695320

(ENV)

**From:** [REDACTED]@epa.gov>  
**Sent:** 21 November 2014 22:27  
**To:** [REDACTED] (ENV); [REDACTED]  
**Cc:** [REDACTED] (ENV); [REDACTED] (ENV); [REDACTED]  
**Subject:** RE: following up from 15october  
**Attachments:** Draft Agenda for 2015 Oct Meeting.docx

[REDACTED],

Provided is a very rough draft of ideas for the 2015 meeting. We value your input and look forward to your feedback.

Regards,

[REDACTED]  
[REDACTED]  
Office of Science Coordination and Policy  
Office of Chemical Safety and Pollution Prevention  
William J Clinton (WJC) Bldg-East; [REDACTED]  
202-564-[REDACTED]

-----Original Message-----

**From:** [REDACTED]  
**Sent:** Thursday, November 20, 2014 6:40 PM  
**To:** [REDACTED]@ec.europa.eu  
**Cc:** [REDACTED]; [REDACTED]@ec.europa.eu; [REDACTED]@ec.europa.eu; [REDACTED]  
**Subject:** RE: following up from 15october

[REDACTED]

[REDACTED] will send along a few ideas for the meeting in 2015 tomorrow.  
We got a little caught up with the OECD proposal I sent you earlier today.

Would you prefer I take first stab at minutes from our Oct 15 meeting?  
Could you remind me of names/organizations of all attendees?

Thanks, [REDACTED]

[REDACTED]  
[REDACTED] Office of Science Coordination and Policy Office of Chemical Safety and Pollution Prevention U.S.  
Environmental Protection Agency  
1200 Pennsylvania Ave, NW (7201M)  
Washington DC 20460

Email: [REDACTED]@epa.gov  
Office phone: 202-564-[REDACTED]  
Location: Room [REDACTED]

-----Original Message-----

**From:** [REDACTED]

Sent: Friday, October 31, 2014 4:01 PM

To: [REDACTED]@ec.europa.eu'

Cc: [REDACTED]@epa.gov)

Subject: following up from 15october

Hello [REDACTED]!

Hope you are well. I am getting caught up with things here, and ready to work with you on next steps. Will [REDACTED] be helping us with this?

[REDACTED] will be helping at my end.

Can we start with attendees and minutes from 15 Oct? Do you have that at hand?

Next week, [REDACTED] and I will send along a number of documents and proposals for moving ahead.

And of course, Chemical Watch beat us to the punch- I've attached an Oct 29 report from them.

All the best, [REDACTED]

[REDACTED], Office of Science Coordination and Policy Office of Chemical Safety and Pollution Prevention U.S.  
Environmental Protection Agency  
1200 Pennsylvania Ave, NW (7201M)  
Washington DC 20460

Email: [REDACTED]@epa.gov

Office phone: 202-564-[REDACTED]

Location: Room [REDACTED]

EU and US to draft discussion paper on EDCs Basis for a joint workshop

29 October 2014 / Europe

EU and US officials are to work on a discussion paper, identifying the similarities on screening, priority setting and assessment of endocrine disrupting chemicals (EDCs) over the next six months.

This was the main conclusion of a meeting between officials from the European Commission, Echa and the Joint Research Centre (JRC) with the US EPA director of the Office of Science Coordination and Policy (OSCP), David Dix. The meeting in Brussels on 15 October continued discussions around cooperation on EDCs between the EU and the US (CW 4 September 2014).

"We spent most of the time presenting what each of us was doing on EDCs," Bjorn Hansen, head of the chemicals unit at the European Commission's directorate general (DG) for environment, tells Chemical Watch. "The scientific presentation showed that there is quite a lot of science involved," he adds, explaining that this showed the need for a discussion paper as a next step. The paper will be the basis of a joint workshop between the EU and the US, most likely to take place in October 2015, according to Mr Hansen.

"We will be able to see, after the workshop, what we are doing on both sides, the commonalities, the listing of differences, and then we should be able to recommend whether this forms a good basis for cooperation," he says. When it comes to the assessment of EDCs, the two sides have to compare the chemicals identified on each side of the Atlantic "to see if we have any commonality", Mr Hansen says. "It will be very interesting to look at the same chemicals, but there might not be much commonality; they have assessed mainly pesticides, where we have mainly formally applied the identification to industrial chemicals under REACH, so we may not have so many commonalities on substances," he adds.

Mr Hansen says he does not expect the discussion to address differences in applying the OECD's Extended One Generation Reprotoxicity Study (EOGRTS) as this is something the OECD should monitor, he says. The discussion paper and workshop in 2015 will most likely address questions related to the results of an EOGRTS test in the EU and

the US. "If we have the results of the EOGRTS, will we apply it the same way or not? There are always differences in the way things are done - whether it's a huge problem or not, that's difficult to say right now," he says. Mr Dix confirmed that the next step, after the mid-October meeting, is "coordinated discussions over the next year, involving all relevant EU and US entities, culminating in another face to face meeting demonstrating scientific tools, methods and processes for identifying potential risks for endocrine disruption in humans and wildlife".

-----Original Message-----

From: [REDACTED]@ec.europa.eu [mailto:[REDACTED]@ec.europa.eu]

Sent: Wednesday, October 15, 2014 1:40 AM

To: [REDACTED]

Subject: Re:

Dear [REDACTED]

Sorry for the delay in getting back to you with instructions on getting to my office.

In Gare Medi you need to take the metro - which is located pretty much straight ahead from your arrival track in the station. The metro you take to station Art-loi and from there change to line Hermann-Debroux and get off at stop Beaulieu. Exiting the metro stop you go left, across the intersection with trafficlighs and down the road (Av Beaulieu) to number 5 (left side) where you ask the reception to call my secretary who will pick you up.

Greetings and see you soon

[REDACTED]

Sent from my iPhone

> On 10 Oct 2014, at 22:16, "[REDACTED]" <[REDACTED]@epa.gov> wrote:

>

> [REDACTED]

>

> Looking forward to the 15th.

>

> Attached are 3 slide sets that I think work across the 3 parts of the agenda alright.

>

> Can you refresh my memory on exactly where to go in Brussels and suggestion for the right train/tram/bus once I get off the train from paris?

>

> Cheers, [REDACTED]

>

>

> [REDACTED]

> [REDACTED], Office of Science Coordination and Policy Office of Chemical

> Safety and Pollution Prevention U.S. Environmental Protection Agency

> 1200 Pennsylvania Ave, NW (7201M)

> Washington DC 20460

>

> Email: [REDACTED]@epa.gov<mailto:[REDACTED]@epa.gov>

> Office phone: 202-564-[REDACTED]

> Location: Room [REDACTED]

>

> From: [REDACTED]@ec.europa.eu [mailto:[REDACTED]@ec.europa.eu]

> Sent: Thursday, September 18, 2014 4:35 AM

> To: [REDACTED]  
> Subject: RE: Issues  
>  
> Dear [REDACTED],  
>  
> I have checked the financial frame. Basically we can actually pay for travel for US people, but NOT for EPA (no government staff). So we can pay for the meeting etc and for non-governmental experts but not for your EPA/FDA staff travel and per-diem. As we are talking of quite some number of people (20 at least from COM and I understood 10 at least from EPA) this could easily become the obstacle for the project to move forward.  
>  
> So I think we both need to look at what finances we have to go to the other side of the Atlantic. In any case the Workshop would take place next year as either side cannot find the finances for 2014.  
>  
> Greetings,  
>  
> [REDACTED]  
>  
>  
>  
> From: [REDACTED] [mailto:[REDACTED]@epa.gov]  
> Sent: Saturday, September 13, 2014 9:07 PM  
> To: [REDACTED] (ENV)  
> Subject: RE: Issues  
>  
> [REDACTED]  
> Below and attached is a title and abstract for my presentation Oct 15.  
> Feel free to distribute as appropriate with EU colleagues.  
> I look forward to next steps.  
> [REDACTED]  
>  
>  
> ENDOCRINE BIOACTIVITY AND EXPOSURE-BASED PRIORITIZATION AND SCREENING  
>  
> [REDACTED]  
> US EPA, Office of Science Coordination and Policy, Washington DC  
>  
> The U.S. EPA Endocrine Disruptor Screening Program (EDSP) is using computational toxicology and exposure tools (i.e., high throughput screening (HTS) assays and computational models), along with other data streams to develop an integrated bioactivity and exposure-based approach for prioritization and screening thousands of chemicals. Endocrine bioactivity of chemicals is being quantified using ToxCast HTS in vitro estrogen, androgen, and thyroid receptor assays, along with other potential molecular targets. HTS results are being compared with Tier 1 screening and other in vivo assay results obtained from published peer-reviewed studies. Rapid prioritization and screening of thousands of chemicals allows the agency to focus attention on chemicals with the greatest potential endocrine bioactivity. In addition, high throughput models of human and ecological exposure (i.e. ExpoCast) allows the agency to identify chemicals with the greatest potential for exposures that could result in bioactive concentrations. This pivotal shift in the EDSP framework allows focus to be placed on chemicals that pose the greatest likelihood of exposures leading to endocrine bioactivity in humans or wildlife. EPA's endocrine bioactivity and exposure based approach for ranking EDSP chemicals for further screening and testing will be the subject of an independent external scientific peer review December 2-5 of 2014 (<http://www.epa.gov/scipoly/sap/meetings/2014/>).  
>  
>  
>  
> [REDACTED]  
> [REDACTED], Office of Science Coordination and Policy Office of Chemical  
> Safety and Pollution Prevention U.S. Environmental Protection Agency  
> 1200 Pennsylvania Ave, NW (7201M)

> Washington DC 20460

>

> Email: [REDACTED]@epa.gov<mailto:[REDACTED]@epa.gov>

> Office phone: 202-564-[REDACTED]

> Location: Room [REDACTED]

>

> From: [REDACTED]@ec.europa.eu<mailto:[REDACTED]@ec.europa.eu>

> [mailto:[REDACTED]@ec.europa.eu]

> Sent: Friday, September 12, 2014 9:08 AM

> To: [REDACTED]

> Subject: RE: Issues

>

> Dear [REDACTED],

>

> I tried calling on your mobile and on your fixed phone.

>

> Below a proposed outline for what I could see is a constructive workshop. I may be able to finance such a workshop - hoping to find money to invite say 8 - 10 persons from the US and have it over say 2 days here in Brussels. I could see us using the 15 October to discuss the details of the agenda, persons to come, format of the workshop and to set the dates.

>

> If you get into the office then please call me on my mobile:

>

> +32 460 7[REDACTED].

>

> Greetings,

>

> [REDACTED]

>

>

---

> From: [REDACTED] (ENV)

> Sent: Friday, September 12, 2014 2:13 PM

> To: [REDACTED]

> Subject: Issues

>

>

>

> Dear [REDACTED],

>

> Here are my thoughts for our discussion in an hour:

>

> Cooperation Topics:

>

> 1. Screening methods to identify potential endocrine disruptors

>

> EU Side: ECHA, JRC

> EPA Side

>

> Topic:

>

> Both sides would present approaches to screening methods developed for the aim of identifying potential endocrine disruptors.

> Commonalities and differences are to be identified and discussed to determine why such differences exist.

>

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

>

> EU Side: ECHA, JRC  
> EPA Side  
>  
> Topic:  
>  
> Both sides would present approaches to screening methods developed for the aim of identifying potential endocrine disruptors.  
> Commonalities and differences are to be identified and discussed to determine why such differences exist.  
>  
> 3. Assessment of suspected endocrine disruptors  
>  
> . Hazard Assessment  
> . Risk Assessment  
>  
> EU Side: ECHA, JRC, ENV, ENTR, SANCO  
> EPA Side  
>  
> Topic:  
>  
> Both sides would present actual case studies of assessments performed of suspected endocrine disruptors.  
> Commonalities and differences are to be identified and discussed to determine why such differences exist.  
>  
>  
> I may have money to hold a workshop here in Brussels towards the end of the year to implement this with broader participation.  
>  
> Greeting's,  
>  
> [REDACTED]  
>  
>  
>  
> [REDACTED]  
> [REDACTED]  
>  
> European Commission  
> DG Environment  
> Unit A.3 (Chemicals)  
> BU9 5 [REDACTED]  
> B-1049 Brussels/Belgium  
> Tel: +32-2-296.[REDACTED] Fax: +32-2-296.69.95  
> [REDACTED]@ec.europa.eu<mailto:name.surname@ec.europa.eu>  
>  
>  
>  
><[REDACTED]>  
[REDACTED]  
[REDACTED]

Draft Workplan for EU-US Discussions  
Identifying Specific Chemicals and Priorities for Identifying Risk of Endocrine Disruption  
October 08-09, 2015  
Brussels, Belgium  
Time: TBD

- Review minutes from 15 Oct Meeting
- Approve draft Agenda
- Share updates on our data from high throughput activity and exposure screening, as well as more “traditional” endocrine screening and testing results
- Review approaches and screening methods to identify potential endocrine disruptors
- Priority setting methodologies to identify substances (potential endocrine disruptors) of concern
- Selection of case studies of risk and hazard assessments performed of suspected endocrine disruptors
- Identify differences between EU and US
- Develop a draft proposal
- Review of draft proposal by EC and EDTA
- Presentation of draft proposal to EDTA
- Review and selection of relevant chemicals and case studies
- Develop draft document
- Review draft document by lead organizations
- EDTA review and comment
- Review time for public comment
- Submission of draft document to OECD for declassification

(ENV)

Ares(2015) 3617982

**From:** [REDACTED] (ENV) on behalf of [REDACTED] (ENV)  
**Sent:** 20 January 2015 13:58  
**To:** [REDACTED]@epa.gov; [REDACTED]@epa.gov  
**Cc:** [REDACTED] (ENV); [REDACTED] (ENV)  
**Subject:** FW: Draft minutes and roadmap for EU-US WS on endocrine disruptors  
**Attachments:** [REDACTED]  
[REDACTED] Roadmap for EU-US  
WS20150120\_draft to US.doc

Dear [REDACTED], dear [REDACTED],

First of all, I wish you a Happy New Year! Let's hope the New year will lead to a successful EU-US WS as regards approaches to manage Endocrine Disruptors.

Thanks a lot for sending a draft agenda for the 2015 WS and apologies for this late reply due to a very busy time with the incoming new Commission.

Please find enclosed the minutes of the 15<sup>th</sup> October 2014 meeting for your comments. We agreed that this should be a very short summary, focusing on the planned workshop. Based on the discussion under agenda point 5-8 on the format of the workshop, we have elaborated a bit further on a draft roadmap for the workshop which is also attached for your comments. Further, the EU presentations are attached.

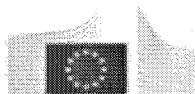
We have focused on the outcome of the work as a description of the EU and US approaches and methodologies for screening, priority setting, identification and risk assessment of EDs, their comparison and analysis of similarities and differences. Then we should develop a template for the case-stories which should be used for 3 relevant substances. The workshop should then work on these cases and analyse similarities and differences and conclude on this. All this work should be documented by a workshop report showing the US and EU approach in general and the outcome when evaluating specific chemical substances. On this background it should be decided whether there is a need for and how to follow-up on this work.

We look forward to your comments on the draft roadmap and the co-operation on this WS. For your information [REDACTED] (in cc.) will be our contact person for the workshop, so please forward your response to her.

Kind regards,

[REDACTED]

[REDACTED]  
Head of Unit



**European Commission**  
DG Environment  
Unit A.3 (Chemicals)

BU9 5/[REDACTED]  
B-1049 Brussels/Belgium  
Tel: +32-2-296 [REDACTED] Fax: +32-2-296.69.95  
[REDACTED]@ec.europa.eu



**Roadmap for preparation of EU-US workshop on  
Approaches for identifying risk of endocrine disruption**

**October 5-7, 2015**

**Brussels, Belgium**

**Time: TBD**

**1. Follow-up on meeting 15 October 2014**

Review and approve minutes from 15 Oct meeting.

**2. Agree on outline for WS**

Discuss and approve draft outline for EU-US workshop.

**3. Establishment of EU/US WS technical working group to prepare the workshop**

**4. Preparation of WS material**

Discuss and approve content and templates for workshop material. Discuss and approve relevant chemicals for case-studies.

Case-studies: prepare case-studies on agreed chemical substances.

Prepare workshop material, e.g. preliminary analysis of commonalities and differences in EU and US approach as thought starter for WS discussions

**5. Arrangement of WS - practicalities**

WS venue, meals, accommodation, travelling etc.

**6. Workshop 5-7 October**

Distribution of WS material at least 1 months before.

**7. WS report and possible follow-up**

Evaluation, preparation and approval of workshop report. Discuss on possible follow-up.

## **Ad 2 -Draft outline for the workshop**

### **PARTICIPANTS**

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

### **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.

### **WORKSHOP AGENDA**

#### **Presentations**

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.

#### **Case-studies**

Group work on case-studies. Discussion of similarities and differences and conclusions.

### **OUTPUT OF THE WORKSHOP**

Summary of EU and US approaches and methodologies for screening, priority setting, identification and risk assessment as regards endocrine disruptors. Analysis of similarities and differences. Possible explanation for these differences, if any. Summary of workshop and case-studies with conclusion.

The more detailed work done by the WS technical working group in preparation of the workshop is reported in an annex to the WS report.