

Parma, 11 February 2013

SCIENTIFIC COMMITTEE

Minutes of the 4<sup>th</sup> meeting of the Working Group on Endocrine Active Substances  
6-7 February 2013

EFSA/SC/1527

Agreed by the WG on by written procedure on 18 February 2013

**Participants**

WG Expert Members	Jan Alexander (Chair), Jacques Auger, Diane Benford, Susy Brescia, Tony Hardy, Karen Ildico Hirsch-Ernst, Susanne Hougaard Bennekou, Robert Luttik, Peter Matthiessen, Wim Mennes, Peter Pärt <sup>1</sup> , Daniel Pickford, Thomas Platzek, Josef Schlatter, Emanuela Testai <sup>2</sup> , Theo Vermeire.
Apologies	Peter Hoet, Gisela Degen.
Observers	Dorota Jarosinska (EEA), Sharon Munn (EC JRC), Gabriele Schöning (ECHA), Jean-Marc Vidal (EMA) <sup>2</sup> , Michael Walsh (EC).
Apologies Observers	Panagiotis Daskaleros (EC).
Hearing Expert	Susan Jobling <sup>3</sup> .
EFSA	Bernard Bottex, Miriam Jacobs, Djien Liem, Reinhilde Schoonjans.

**1. Welcome and apologies**

The Chair welcomed the participants.

**a. Declarations of interest**

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes) and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, EFSA screened the Annual Declaration of Interest (ADoI) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the beginning of this meeting.

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<sup>1</sup> Present on the 7 February only

<sup>2</sup> Participated via conference call

<sup>3</sup> Participation via conference call for agenda item 4 (6 February 2013, Presentation of the UNEP/WHO Report on EDs)

## 2. Adoption of agenda

The agenda was adopted as tabled.

## 3. Approval of the minutes of the 3<sup>rd</sup> working group meeting (17-18 January 2013)

The working group (WG) reviewed the minutes of the 3<sup>rd</sup> meeting (17-18 January 2013) and agreed on them without any further modification. The minutes will be published on the EFSA website: <http://www.efsa.europa.eu/en/sc/scwgs.htm>.

## 4. Presentation of the draft UNEP/WHO Report on Endocrine Disruptors

Prof. Susan Jobling presented the draft UNEP/WHO Report “*State of the Science of Endocrine Disrupting Chemicals – 2012*”, for which she was one of the main editors. The report is an update of the WHO/IPCS 2002 global assessment of the state-of-the-science of endocrine disruptors and provides a comprehensive review of the advances in knowledge on exposure to endocrine disruptors, as compared to 2002. The report is subdivided into main chapters covering the following:

- General aspects of what is endocrine disruption, using the same definition of an ED as developed in IPCS (2002)
- Review of the evidence for endocrine disruption in humans and wildlife: looking at various endocrine systems, functions and disorders.
- Review the Human and wildlife exposure to EDs

The report specifies concluding remarks and future needs e.g. in the area of reducing exposure to endocrine active substances and thereby vulnerability to disease; on identifying endocrine active chemicals; and on methods for developing and evaluating the strength of evidence. Prof. Jobling indicated that the report should be published on 18 February.

## 5. Feedback from the 59<sup>th</sup> SC Plenary meeting (5-6 February 2013, Parma)

The Chair and the Secretariat provided feedback to the participants from the 59<sup>th</sup> Plenary meeting of the Scientific Committee. That meeting was opened to observers<sup>4</sup> and dedicated the time to a detailed review (section per section) of the draft opinion on endocrine active substances.

The Scientific Committee congratulated the members of the working group for the quality of the draft opinion that reads well and answers the questions of the Terms of Reference in a clear manner. The Scientific Committee made a number of suggestions to further improve the text, mostly to highlight or clarify further the positions phrased on the various points of the mandate.

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<sup>4</sup> A free registration was organised online in advance of the meeting on the EFSA website: <http://www.efsa.europa.eu/en/stakeholders/observers.htm?wtrl=01>

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## **6. Draft opinion on the hazard assessment of endocrine disruptors: Scientific criteria for identification of endocrine disruptors and appropriateness of existing testing methods for assessing effects mediated by these substances on human health and the environment**

The working group went through all the sections of the draft opinion version 8.1, considering the comments made by the Scientific Committee to update the document.

A significant part of the meeting was dedicated to the finalisation of the conclusion section, and the identification of recommendations to be added at the end of the document. The secretary was asked to develop the phrasing of the recommendations, to bring the body text inline with the wording as agreed in the conclusions, to provide a proposal for the abstract, as well as for the summary (based on the conclusion section).

## **7. Next steps**

- The Secretariat will provide the working group with an updated version of the opinion (version 9.1) on 14 February 2013. The deadline for comments / last corrections is 19 February 2013; the Secretariat will then prepare the document for the SC.
- The Chair of the working group will be pre-notified with the final version of the document that will then be sent to the Scientific Committee the latest on 22 February 2013.
- Also on 14 February, EFSA will send out an official letter to provide to EFSA's sister agencies (ECHA, EEA, EMA) for information the final draft and ask for final comments through their observers by 25 January 2013 that can be reported to the SC directly at the plenary meeting.

## **8. Next meeting**

Considering the positive feedback from the Scientific Committee on the draft opinion submitted for their review during the 59<sup>th</sup> SC Plenary meeting, and the fact that comments received were mostly editorial / structural but did not urge for reopening discussions on the core contents itself, the decision was made to cancel the working group meeting initially planned on 28 February (starting at 14h00) and on 1 March 2013 (finishing at 13h00).

It is expected that, when reviewing the final opinion for possible adoption, the Scientific Committee will mostly have editorial comments. It was therefore decided that these comments can be addressed by the members of the working group who are also member of the Scientific Committee that convenes on 27-28 in Parma. Those experts will be invited to extend their stay and to convene immediately after the Plenary, i.e. on 28 February afternoon.

## **9. Any other business**

The participants were informed that, following the adoption of the opinion, a meeting will be organised on 20 March 2013 in Brussels to present the outcome of this work. The morning session will consist of a press conference, while the afternoon session will be dedicated to

stakeholders and all interested parties to discuss the recent work done by EFSA and the European Commission on this issue. EFSA will provide an overview of its opinion which will feed into the current review of the EU's strategy on endocrine disruptors. Speakers from EFSA, WHO, OECD, the European Commission's DG Environment and DG for Health and Consumers and the Joint Research Centre, will explain the different roles of European and international bodies in this area. The programme of the afternoon event will be shared with the members of the working group through the EFSA event website (<http://www.efsa.europa.eu/en/events/event/130320a.htm>) as soon as validated. On-line registrations for interested parties will be open on this website until 10 March 2013.

Parma, 24 January 2013

SCIENTIFIC COMMITTEE

Minutes of the 3<sup>rd</sup> meeting of the Working Group on Endocrine Active Substances  
17-18 January 2013

EFSA/SC/1518

Agreed by the WG on 6 February 2013

**Participants**

WG Expert Members	Jan Alexander (Chair), Jacques Auger, Diane Benford, Susy Brescia <sup>1</sup> , Tony Hardy, Karen Ildico Hirsch-Ernst <sup>1</sup> , Peter Hoet, Susanne Hougaard Bennekou, Robert Luttik, Peter Matthiessen, Wim Mennes, Peter Pärt, Daniel Pickford, Thomas Platzek, Josef Schlatter, Theo Vermeire.
Apologies	Gisela Degen, Emanuela Testai.
Observers	Niklas Andersson (ECHA), Trine Husoy (Chair of the EFSA WG on BPA), Dorota Jarosinska (EEA), Sharon Munn (EC JRC), Jean-Marc Vidal (EMA), Michael Walsh (EC).
Apologies Observers	Panagiotis Daskaleros (EC).
EFSA	Bernard Bottex, Miriam Jacobs, Djien Liem, Reinhilde Schoonjans, Antony Smith.

**1. Welcome and apologies**

The Chair welcomed the participants.

**a. Declarations of interest**

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes) and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, EFSA screened the Annual Declaration of Interest (ADoI) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the beginning of this meeting.

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<sup>1</sup> Attended via teleconference

## **2. Adoption of agenda**

Participants were informed that the agenda point regarding the presentation and discussion of the draft UNEP-WHO report on endocrine disruptors was cancelled at the last minute. The updated agenda was adopted.

## **3. Approval of the minutes of the 2<sup>nd</sup> working group meeting (19 December 2012)**

The working group (WG) reviewed the minutes of the 2<sup>nd</sup> meeting (19 December 2012) and agreed on them without any further modification. The minutes will be published on the EFSA website: <http://www.efsa.europa.eu/en/sc/scwgs.htm>.

## **4. Draft opinion on the hazard assessment of endocrine disruptors: Scientific criteria for identification of endocrine disruptors and appropriateness of existing testing methods for assessing effects mediated by these substances on human health and the environment**

The working group went through all the sections of the draft opinion version 6. New contributions received after the 2<sup>nd</sup> working group meeting were discussed and the following action points identified to prepare a new version of the opinion to be discussed at the 5-6 February 2013 Plenary meeting of the EFSA Scientific Committee (SC). Editorial modifications were entered directly in track changes mode during the meeting and are not further reported in these minutes.

## **5. Next steps**

- The Secretariat will provide the working group with an updated version of the opinion (version 7) on 23 January 2013,
- The working group will review the opinion and provide the Secretariat with possible additional suggestions on contents aspects by 25 January noon time at the latest,
- The opinion will be sent to the Scientific Committee on 25 January – end of the day,
- The opinion will be presented and discussed during the SC Plenary meeting (5-6 February 2013),
- The working group will meet on 6-7 February to review the comments made by the SC and update the opinion.

## **6. Next meeting**

6-7 February 2013 – Parma – from 14h00 on the 6<sup>th</sup> to 16h00 on the 7<sup>th</sup>.

## **7. Any other business**

The Secretariat is still trying to invite one of the authors or editors of the UNEP-WHO draft report on endocrine disruptors to present and discuss the document during the next meeting of the working group.

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Parma, 7 January 2013

SCIENTIFIC COMMITTEE

Minutes of the 2<sup>nd</sup> meeting of the Working Group on Endocrine Active Substances

Telemeting, 19 December 2012

EFSA/SC/1512

Agreed by the WG on 17 January 2013

**Participants**

WG Expert Members	Jan Alexander (Chair), Jacques Auger, Diane Benford, Susy Brescia, Tony Hardy, Karen Ildico Hirsch-Ernst, Peter Hoet, Susanne Hougaard Bennekou, Robert Luttik, Peter Matthiessen <sup>1</sup> , Peter Pärt, Daniel Pickford, Thomas Platzek, Josef Schlatter, Theo Vermeire <sup>1</sup>
Apologies	Gisela Degen, Wim Mennes, Emanuela Testai
Observers	Niklas Andersson (ECHA), Sharon Munn (EC JRC), Jean-Marc Vidal (EMA), Gabriele Schöning (ECHA) <sup>1</sup>
Apologies Observers	Dorota Jarosinska (EEA), Michael Walsh (EC), Panagiotis Daskaleros (EC)
EFSA	Bernard Bottex, Reinhilde Schoonjans, Johann Steinkellner <sup>1</sup>

**1. Welcome and apologies;**

The Chair welcomed the participants.

**a. Declarations of interest**

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes) and the Decision of the Executive Director implementing this Policy regarding Declarations of Interest, EFSA screened the Annual Declaration of Interest (ADoI) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the beginning of this meeting.

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<sup>1</sup> Present only at the morning session

## **2. Adoption of agenda**

The agenda was adopted without changes.

## **3. Approval of the minutes of the 1<sup>st</sup> working group meeting (6-7 December 2012)**

The working group reviewed the minutes of the 1<sup>st</sup> meeting (6-7 December) and agreed on them after a couple of editorial modifications. The minutes will be published on the EFSA website: <http://www.efsa.europa.eu/en/sc/scwgs.htm>.

## **4. Report back on External Activities**

Participants were informed by Anne-Laure Gassin, Director of Communications, on the media coverage related to the EFSA activity on endocrine active substances and follow-up actions from EFSA.

## **5. Draft opinion on the hazard assessment of endocrine disruptors (EDs) – Scientific criteria for identification of EDs and appropriateness of existing testing methods for human health and the environment.**

The working group went through all the sections of the draft opinion version 3 and discussed the contributions received after the 1<sup>st</sup> working group meeting. A version 4 of the opinion, reflecting the outcome of the discussion during this 2<sup>nd</sup> meeting of the working group will be circulated together with the list of action points identified to prepare the third meeting of the working group (17-18 January 2013).

Authors of sections are invited to consider comments already inserted in the text and to delete them once they have been addressed. Working Group members who wish to make suggestions on a specific section should address their proposals/suggestions directly to the author of the section, copying the EFSA Secretariat. General comments should be avoided and concrete proposals for rewording have to be provided in track changes.

## **6. Next steps**

Working group members to provide the EFSA Secretariat with updated sections or editorial corrections by 10 January 2013, noontime (not extendable).

## **7. Next meeting**

17-18 January 2013 – Parma – from 9h00 on the 17<sup>th</sup> to 13h00 on the 18<sup>th</sup>.

## **8. Any other business**

The working group agreed to invite one of the authors of the UNEP-WHO draft report on endocrine disruptors to present and discuss the document during the next meeting of the working group.

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Parma, 14 December 2012

SCIENTIFIC COMMITTEE

Minutes of the 1<sup>st</sup> meeting of the Working Group on Endocrine Active Substances

Parma, 6-7 December 2012

EFSA/SC/1506

Agreed by the WG on 19 December 2012

**Participants**

WG Experts	Jan Alexander (Chair), Diane Benford <sup>1</sup> , Susy Brescia, Tony Hardy, Karen Ildico Hirsch-Ernst, Susanne Hougaard Bennekou, Robert Luttik, Peter Matthiessen, Wim Mennes, Peter Pärt, Daniel Pickford, Thomas Platzek, Josef Schlatter, Emanuela Testai <sup>1</sup> , Theo Vermeire.
Observers	Dorota Jarosinska (EEA), Sharon Munn (EC JRC), Jean-Marc Vidal (EMA), Michael Walsh (EC)
EFSA	Bernard Bottex, Djien Liem <sup>2</sup> , Reinhilde Schoonjans <sup>1</sup> , Johann Steinkellner

**1. Welcome and apologies**

The Chair welcomed the participants and made a tour de table to introduce all participants.

Apologies were received from the following working group members: Jacques Auger, Gisela Degen, Peter Hoet, and the following observers: Panagiotis Daskaleros (EC) and Gabriele Schöning (ECHA).

Participants were informed that the working group composition was now completed, with the following areas of expertise represented: general risk assessment (RA), human RA, environmental RA, general toxicology, mechanistic toxicology, immunotoxicology, reproductive and developmental toxicology, ecotoxicology, general endocrinology, human endocrinology, and environmental endocrinology. The composition of the working group was published on the EFSA website on 3 December 2012. If needed, EFSA may invite hearing

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<sup>1</sup> Present only on 6 December 2012

<sup>2</sup> Present only on 7 December 2012

experts to participate in a specific meeting in order to present and explain specific viewpoints or scientific aspects.

## **2. Adoption of agenda**

The agenda was adopted without changes.

## **3. Declarations of interest**

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes) and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>3</sup>, EFSA screened the Annual Declaration of Interest (ADoI) filled in by the experts invited for the present meeting. No conflicts of interest related to the issues discussed in this meeting have been identified during the screening process or at the beginning of this meeting.

## **4. Feedback from DG Environment (DG ENV) activities related to endocrine disruptors**

The Secretariat reported back from the 4<sup>th</sup> meeting of the Expert Advisory Group on Endocrine Disruptors (ED EAG) that took place on 5-6 November 2012 in Arona, and from the 5<sup>th</sup> ad-hoc meeting of the EC Services, EU Agencies, and Member States on Endocrine Disruptors that took place on 30 November 2012 in Brussels.

The DG ENV possible elements for criteria for identification of endocrine disruptors as well as the template for the final report of the ED EAG were provided to the participants. A first draft of the ED EAG report is expected to become available by the end of 2012.

The Secretariat invited the working group to comment on these documents. Comments should be sent to the SC Secretariat who will then forward them to DG ENV.

It was re-iterated to the participants that the Terms of Reference for the EFSA opinion are focussed on scientific aspects of endocrine disruptors and therefore the participants should not discuss risk management related issues.

## **5. Draft opinion on the hazard assessment of endocrine disruptors (EDs) – Scientific criteria for identification of EDs and appropriateness of existing testing methods for human health and the environment.**

The participants discussed the terms of reference received from the European Commission; the opinion needs to address the following issues, taking stock of related work already done by other parties at the National, European and International level:

- Definitions, comparing the WHO/IPCS definition of an ED with the one of the Endocrine Society
- Criteria for the identification of endocrine disruptors
- Testing methods covering the effects of endocrine active substances

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<sup>3</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

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The working group agreed that the opinion should also consider elements for hazard characterisation of EDs, e.g. critical/lead effect, potency, thresholds.

The working group reviewed and discussed the various contributions to the draft opinion received in preparation for the meeting and amendments were made accordingly.

It was agreed to include a short review of the existing provisions for EDs in the European legislation and of related activities on EDs as appendices to the opinion.

## **6. Next steps and timeframe**

Tasks to update the various sections of the opinion according to the outcome of the discussions were distributed among the members of the working group.

The working group will have a conference call on 19 December 2012 to review the progress made and to discuss possible difficulties encountered by members when updating their section. The deadline for identifying issues for discussion at the conference call is 17 December 2012.