[redacted] (ENV)

From: [redacted]@cefic.be> on behalf of [redacted]@cefic.be>
Sent: 17 March 2014 16:32
To: HANSEN Bjorn (ENV); [redacted] (ENV); BEREND Klaus (ENTR); LIEGEOIS Eric (ENTR); [redacted] (ENTR); [redacted] (SANCO); Michael.fluh@ec.europa.eu; [redacted] (SANCO); [redacted] (SANCO); EC CSA; [redacted] @ec.europa.eu.; [redacted] @ec.europa.eu; [redacted] (TRADE); [redacted] (TRADE); [redacted] (TRADE-WASHINGTON); [redacted] (TRADE-WASHINGTON); [redacted] (TRADE); [redacted] @ec.europa.eu; [redacted] (RTD); [redacted] (RTD); [redacted] (RTD); [redacted] (SG); [redacted] (AGRI); [redacted] (AGRI); [redacted] (AGRI); [redacted] @ec.europa.eu; [redacted] @ec.europa.eu; [redacted] (JRC-ISPRA) [redacted] (JRC-ISPRA); [redacted] (SG); [redacted] (SG)
Cc: [redacted] - ECPA (European Crop Protection Association)
Subject: Review of the WHO-UNEP State of the Science on Endocrine Disrupting Chemicals 2012
Attachments: Joint statement from ACC Cefic CLA CLC CLI ECPA on review of WHO-UNEP r....pdf; FINAL Report - Critical Review of WHO-UNEP 2012 State of the Science on ....pdf

Importance: High

Dear Sir or Madam,

Re: Review of the WHO-UNEP State of the Science on Endocrine Disrupting Chemicals 2012

In early 2013 the United Nations Environment Programme (UNEP) and the World Health Organization (WHO) published a report entitled, "State of the Science on Endocrine Disrupting Chemicals – 2012" which was accompanied by a "Summary for Decision Makers". At the time the general chemicals and crop protection products industries both in Europe and the US held significant concerns with the report(s). Our industries therefore jointly commissioned a scientific review of the WHO-UNEP report which has now been published in the scientific journal Regulatory Toxicology and Pharmacology.

Attached is the scientific review and the joint statement prepared the 6 industry associations who supported the review, which includes Cefic and ECPA.

The scientific review highlights a number of significant short comings with the WHO-UNEP report and its conclusions. It particular the review concludes that the WHO-UNEP report does not accurately reflect the state of the science on endocrine disruption. As the European Commission continues to develop its policies on endocrine disruptors, we felt it important to make you aware of the review and its findings. We hope that the Commission will take this publication into consideration in further preparing these policies.

If you have any queries regarding this matter, please do not hesitate to contact us.

Yours faithfully

[redacted]

[redacted]
Programme Product Stewardship
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cefic

March 2014

Joint statement from ACC, Cefic, CLA, CLC, CLI and ECPA on review of WHO-UNEP 2012 report on Endocrine Disruptors

Statement

The 2012 WHO-UNEP report should not be used as the basis for supporting chemicals policy on endocrine disruptors, as the report does not provide an objective assessment of the current state of the science on endocrine disruption. Unfortunately, WHO-UNEP chose not to use a transparent process for selecting authors with recognized expertise and varying perspectives, failed to employ best practices for data collection and evaluation and relied on the authors' judgment/opinion instead of ensuring the use of a transparent weight-of-evidence framework for objectively integrating results for determining cause and effect at relevant levels of exposure.

Background

On 19 February 2013 the United Nations Environment Programme (UNEP) and the World Health Organization (WHO) published a report entitled, "*State of the Science on Endocrine Disrupting Chemicals – 2012*". The report was accompanied by a "*Summary for Decision Makers*". The stated purpose of these documents was to provide the global status of scientific knowledge on exposure to and effects of endocrine disrupting chemicals.

The 2012 WHO-UNEP report was positioned to be an update of the previous report, published in 2002 by WHO in collaboration with the International Programme on Chemical Safety (IPCS)[1]. The 2012 report and summary have since been presented to policy makers internationally, and have been used by some to call for additional precautionary chemicals policy on endocrine disruptors.

ACC, Cefic, CLA, CLC, CLI and ECPA[2], representing the general chemicals and crop protection industries, jointly commissioned a consortium of scientific experts to independently review the 2012 WHO-UNEP report. The review has recently been published

[1] Global assessment of the state-of-the-science of endocrine disruptors (WHO/IPCS/EDC/02.2), 2002

[2] ACC: American Chemistry Council, www.americanchemistry.com/
Cefic: European Chemical Industry Council, www.cefic.org/
CLA: CropLife America, www.croplifeamerica.org/
CLC: CropLife Canada, www.croplife.ca/
CLI: CropLife International, www.croplife.org/
ECPA: European Crop Protection Association, www.ecpa.eu

in the peer-review journal *Regulatory Toxicology and Pharmacology* (available at: http://www.sciencedirect.com/science/article/pii/S0273230014000269).

Why did industry commission the expert review of the 2012 WHO-UNEP report?
At the time it was published, ACC, Cefic, CLA, CLC, CLI and ECPA identified significant shortcomings with the 2012 WHO-UNEP report and the accompanying *"Summary for Decision Makers"*. We were concerned with the selective citation of the literature, the failure to employ best practices for systematic review, and the use of "judgment" and opinion in lieu of a formal weight of evidence analysis. This lack of adherence to basic principles of scientific inquiry for evaluating cause and effect raised considerable doubt about the scientific validity of the report's conclusions and the basis for the serious implications being claimed for human health and the environment.

Additionally, we were concerned with the process employed in preparing the 2012 report and that despite its serious shortcomings it was being used to call for more precautionary chemicals policy.

The chemicals industry is committed to the protection of human health and the environment, and we believe that chemicals policy should be based on a thorough, systematic and objective evaluation of current science. The significant concerns with the 2012 report led ACC, Cefic, CLA, CLC, CLI and ECPA, to jointly commission the expert review, to provide an independent evaluation of the report and the scientific basis for its conclusions.

What are the main conclusions of the expert review?
The review concludes that the 2012 WHO-UNEP report does not provide an objective assessment of the current state of the science on endocrine disruption. The major shortcomings identified are:

- Although the report cites the WHO/ICPS (2002) definition of an endocrine disruptor, its conclusions focus on the potential ability of substances to interact with the endocrine system.
- The 2012 report does not follow the 2002 WHO-ICPS recommended weight of evidence framework for assessing and integrating the available data on endocrine disruption. It relies instead on "*best professional judgement*".
- A formal framework for assessing causation is not employed (i.e. for assessing evidence of whether adverse effects result from chemical exposures).
- Trends in human disease incidence or prevalence are attributed to endocrine disruption, without evidence of their known causes or discussion of other possible causative factors (e.g. diet, lifestyle, physical activity among others).
- There is little discussion of dose-response and potency, and the report often fails to mention the doses at which effects are observed in laboratory animal studies.
- The 2012 report should not be considered an "update" of the 2002 WHO-IPCS report. The report did not refer to the conclusions of the 2002 report, nor was there consideration of whether new information has changed the state of understanding since 2002.
- The process for developing the 2012 report did not attempt to capture the full spectrum of expert views on the issue of endocrine disruption. Instead the report was prepared by a set of authors who represent one side of that spectrum.
- The *Summary for Decision Makers* is not truly representative of the conclusions in the main report and asserts findings not reflected in the main document.

A detailed discussion of these points including specific examples, is included in the review (available at the link given above).

Given the significant shortcomings identified, in our view neither the 2012 WHO-UNEP report nor the *Summary for Decision Makers* should be used as the basis for supporting chemicals policy on endocrine disruptors.

Path forward

Endocrine disruption is an issue of significant public, political and scientific interest, often with diverging points of view. Our industries have made significant contributions to the basic research on endocrine disruption and applied research to develop new standardised and validated tests for assessing substances and potential endocrine related effects. Industry has invested significant resources in the research and development of innovative products and in stewardship projects to ensure products are used safely.

We believe that chemicals policy should be based on a clear and comprehensive evaluation of current science. We support the use of a structured weight of evidence approach to integrate all available information on exposure, (eco)toxicological testing, mode of action and epidemiology in a transparent and objective manner.

The 2002 WHO-IPCS report received wide acceptance as an objective assessment of the state of science on endocrine disruptors. The 2002 report was notable for its process in gathering a group of international experts with varying viewpoints and undertaking a scientifically robust and objective weight of evidence approach to assess the available scientific data. Unfortunately, the authors of the 2012 report inexplicably abandoned this structured approach.

In the future, we urge WHO-UNEP to use a transparent process for selecting experts with recognised experience and varying perspectives, to employ best practices for data collection and evaluation and to ensure that a clear weight of evidence framework is used for objectively integrating results for determining cause and effect. Adherence to these principles should ensure that state of the science reports meet 21st century standards for comprehensive, systematic reviews of the literature when evaluating complex scientific issues.

On the issue of endocrine disruption we believe that an inclusive and collaborative approach should be taken encompassing the broad range of viewpoints and with a genuine commitment to seek consensus and to encourage further dialogue to address outstanding issues of uncertainty or controversy. There should also be broad consensus on critical areas requiring further research, including further developments in testing methods.

Our industries believe that the continued protection of human health and the environment should be founded on scientific and risk-based policy making. We will continue to invest in the research, development and safety evaluation of products, and in the establishment of responsible stewardship practices. We will maintain our support for the work of OECD in developing validated, internationally harmonized test guidelines and assessment procedures which can be deployed by regulatory agencies to evaluate chemicals for their potential to interact with the endocrine system and to cause adverse effects. Results from such high-quality studies can be relied on globally as the best available science and can be used as the scientific basis for risk-based decision-making for protecting human health and the environment.

[redacted] (ENV)

From: [redacted]@cefic.be>
Sent: 16 April 2014 09:30
To: HANSEN Bjorn (ENV); BEREND Klaus (ENTR); [redacted] (ENV)
Cc: [redacted]; [redacted]; [redacted] - Dow Europe GmbH
Subject: Caracal REsponse - Endocrine Disruptors REACH review
Attachments: CARACAL response ED 2014 (final).docx

Gentlemen, Please find attached Cefic comments to the document presented at CARACAL on Endocrine Disruptors and REACH Review for your consideration.
Kindest regards
[redacted]

[redacted]
Programme Product Stewardship
Cefic (European Chemical Industry Council)
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[redacted] 32 (0) 493 [redacted]
Visit our website: http://www.cefic.org

Dr B Hansen DG Environment
Dr K Berend DG Enterprise & Industry

April 2014

Re: 14th CARACAL Meeting - Endocrine Disruptors REACH Review

Dear Sirs,

Cefic offers the following observation on the paper presented under agenda item 10 from the last Competent Authorities for REACH and CLP (CARACAL) meeting, 2-3 April 2014; Endocrine Disruptors REACH Review.

In particular, we are concerned that the paper seeks to bias the scientific determination as to whether a regulatory threshold can be set for an ED substance.

We consider this to be a determination that should be made on the basis of the scientific evidence on a case by case basis. We accept that in some cases it may not be possible to set a threshold for a specific hazard (whether endocrine or non-endocrine related as the paper articulates) based on the available data. However, that can be determined by the appropriate ECHA Committees on the evidence in the particular case.

The above named document defines two specific policy approaches when considering the authorisation of EDs under REACH. These are, i) EDs do not have a threshold, except where it can be demonstrated that a threshold exists; and ii) EDs have a threshold, except where it can be demonstrated that such a threshold does not exist.

It then concludes that, *"it is up to applicants for authorisation to demonstrate the existence of a threshold. Even though this might be particularly difficult for EDs, it cannot be excluded on the basis of current knowledge, that it will ever be possible. "*

Cefic is strongly of the views that a proper, objective and scientific consideration of the evidence for a threshold cannot proceed on the basis that "it cannot be excluded that it will ever be possible". Moreover, we do not see any requirement for the Regulator to choose between the two approaches suggested in the above paper.

Both these approaches introduce a presumption: namely a presumption as to whether EDs do not, or do, have threshold. In practice, it is for the Regulator to decide whether to set a threshold on the basis of the evidence in a particular case. In the circumstances, such a presumption is unnecessary and undesirable and it should be for the applicant to provide sufficient evidence demonstrating the existence of effective thresholds, to the appropriate ECHA committees.

Furthermore, it is important to note that regulatory testing using internationally agreed guidelines does not aim at *all* potential adverse effects but at endpoints deemed sensitive and relevant by the committee that adopted the guideline. If the ECHA committee believes that for a particular substance the threshold for a certain endpoint is not sufficiently addressed based on the available data, this gap needs to be communicated to the registrant in sufficient detail and with plausible arguments. The registrant should then be allowed adequate time to address and close this gap. General reference that a threshold cannot be

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derived, *"except where it can be demonstrated that a threshold exists"* is not acceptable in such a case.

We further believe that by adopting an objective, science based approach, the Commission would be supporting the development of the science around thresholds leading to a better understanding of this complex subject. Regulatory considerations should aim to develop a better understanding based on unbiased case by case approach.

Yours sincerely,

[redacted]

[redacted]
Product Stewardship/Regulatory Affairs Manager

[redacted] (ENV)

From: [redacted]@cefic.be>
Sent: 16 April 2014 10:39
To: HANSEN Bjorn (ENV); BEREND Klaus (ENTR); [redacted] (ENV)
Cc: [redacted]; [redacted]; [redacted] - Dow Europe GmbH
Subject: RE: Caracal Response - Endocrine Disruptors REACH review
Attachments: CARACAL response ED 2014 (final).docx

Sorry, Now without the watermark!
Regards
[redacted]

From: [redacted]
Sent: Wednesday, 16 April 2014 9:30 AM
To: Hansen Bjorn - European Commission (bjorn.hansen@ec.europa.eu); Berend Klaus - European Commission; [redacted] - European Commission
Cc: [redacted]; [redacted]; [redacted] - Dow Europe GmbH
Subject: Caracal REsponse - Endocrine Disruptors REACH review

Gentlemen, Please find attached Cefic comments to the document presented at CARACAL on Endocrine Disruptors and REACH Review for your consideration.
Kindest regards
[redacted]

[redacted]
Programme Product Stewardship
Cefic (European Chemical Industry Council)
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Dr B Hansen DG Environment
Dr K Berend DG Enterprise & Industry

April 2014

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Yours sincerely,

[redacted]

[redacted]
Product Stewardship/Regulatory Affairs

[redacted] **(ENV)**

From: [redacted]@cefic.be>
Sent: 20 October 2014 12:16
To: HANSEN Bjorn (ENV); BEREND Klaus (ENTR); FLUEH Michael (SANCO)
Cc: [redacted]; [redacted]; [redacted]
Subject: Cefic invitation for discussing about a "non-toxic environment strategy" at EU level - Thursday 27 November at 2 pm

To DG Environment (Unit A3), DG Enterprise (Unit F1), DG Sanco (Unit E3)

Dear Sirs,

Since the publication of the 7th Environmental Action Programme at the end of 2013, Cefic has initiated internal discussions on the role and responsibilities of our chemical industry on how to "live well, within the limits of our planet". A particular focus was given to priority objective 3: *"to safeguard the Union's citizens from environment-related pressures and risks to health and well-being."*

By 2018 the Commission has to develop a *"**strategy for a non-toxic environment** which is conducive to innovation and the development of sustainable substitutes including non-chemical solutions, building on horizontal measures to be undertaken by 2015 to ensure: the safety of manufactured nanomaterials and materials with similar properties; the minimisation of exposure to endocrine disruptors; appropriate regulatory approaches to address combination effects of chemicals and the minimisation of exposure to chemicals in products, including, inter alia, imported products, with a view to promoting non-toxic material cycles and reducing indoor exposure to harmful substances"*.

Cefic would like to share its views with you and initiate a debate on what represents a non-toxic environment and how to achieve it in the future, as a long term objective but also as concrete short term actions.

For that purpose we invite you for a 2-hour discussion in **Cefic offices on Thursday 27 November at 2 pm**.
We would be pleased to receive your reply, specifying how many representatives of your department will participate.
A few representatives of our member companies will attend as well.

Thank you in advance and best regards.

[redacted]
Cefic Director - Product Stewardship
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fax: 32 2 676[redacted]
e-mail:[redacted]@cefic.be
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