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Council Secretary

Mr Achim Steiner
Executive Director

United Nations Environment Programme
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22 May 2013

Dear Mr Steiner,

Endocrine Disrupting Chemicals 2012 Report

I wish to bring to your attention some significant shortcomings that we have identified when reviewing the recently published report by the United Nations Environment Programme (UNEP) and the World Health Organisation (WHO): The State of the Science of Endocrine Disrupting Chemicals – 2012. This report has raised some serious irritations in our industry and among some governmental bodies (such as the UK), and in the broader scientific community.

While we see value in having an up to date review of the scientific understanding of this important and complex subject, we found the report to be weak in several critical areas. These include consistency in terminology, the absence of reference to best practices in the scientific community, out of date examples, and research yielding negative causal links. As a result, the report gives the impression that the current chemicals management system is not adequate to identify health impacts and to protect consumers and the environment from harm. When properly implemented, we strongly believe that the existing chemicals management system (such as REACH in the EU) does provide the basis for the protection of consumers and the environment. Additionally, the abandonment of the weight of evidence approach, which was present in the WHO/IPCS report in 2002, is without justification.

Please note that this opinion has also been expressed by the UK Hazardous Substances Advisory Committee. The members of the Committee commented that "despite its length and title, the report was not a blow-by-blow scientific review of primary literature, but an overview which in some cases failed to critically assess important data".

That said, we also recognise that our scientific understanding of chemicals and their safe management is continuously evolving. In the case of Endocrine Disruptors, for example, the chemical industry has supported the progress made at the OECD level to develop testing and assessment approaches as the basis for sound, risk-based decision-making. It should be noted, that the report does not make reference to this substantial body of work.

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Looking forward, we wish to continue to improve our knowledge in the area of endocrine disrupting substances and, for that matter, other classes of substances for which more scientific knowledge is needed to ensure the continued safety of consumers and the environment. To this end, we would welcome the opportunity to discuss possible collaborations between industry-supported research programmes such as the Long-range Research Initiative (LRI) and UNEP in the future.

In the attachment, you will find more specific details where we found the recently published report by UNEP-WHO to be deficient and/or potentially misleading. We trust that you will accept our input in the manner that it is intended to ensure that any potential changes in the way that chemicals are managed in the future will reflect the full scientific knowledge that exists as well as taking into account risk-based approaches to protect society from harm.

Yours sincerely,

Hubert Mandery

Attachment

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Attachment

2012 UNEP/WHO report on Endocrine Disruptors Scientific Shortcomings

The *State of the Science of Endocrine Disrupting Chemicals - 2012* is an update of the scientific knowledge, including main conclusions and key concerns, on endocrine disruptors as part of the ongoing collaboration between the World Health Organization (WHO) and the United Nations Environment Programme (UNEP) to address concerns about the potential adverse health effects of chemicals on humans and wildlife.

Having reviewed the report in detail, we believe that the following are areas in which the report is deficient and/or potentially misleading.

1. A precise terminology is at the heart of good science. The report uses several different ones interchangeably, which mix activity and adversity or disruption. Industry supports the definition given by WHO/IPCS[1].
2. Regarding consumer safety, significant work progress has been made at OECD level to develop testing and assessment approaches as the basis for risk-based decisions by regulators and industry. This major activity is not mentioned in the report, thus giving the impression that endocrine is new and a big threat.
3. It is good practice in the scientific community that, for evaluations of epidemiological data, defined criteria (so-called STROBE[2] criteria) have to be used, before making assessments and reliable evaluations about disease causes and amplifying risk factors. This good practice is missing in the report.
4. Reviews of the existing literature, such as this report, must also take into account data that fails to find statistical associations which are published on the topics discussed. Unfortunately the report is missing such a balanced approach choosing instead a biased selection of studies on associations between purported ED chemicals and health, or highly selected representation of the available epidemiologic research. The report cites only positive associations, but leaves out the multitude of published alternative findings.
5. The vast majority of exposure to endocrine disruptors through food and the environment is that of naturally occurring hormones present on i.e. wheat, beer, tofu. Although not of direct regulatory relevance these exposures have to be taken into account while interpreting epidemiological data, especially under the research aspect.
6. The report does not differentiate between data on mode of actions (activating in vitro) and robust associations to health effects. This leads to "blurred conclusions" open to political, not robust scientific evaluation.
7. The report puts an emphasis on outdated examples. Just 2 examples: 1) The current regulatory system in regions such as Europe has a high level of protection. Many of the chemicals mentioned (like POPs, PCBs) are already subject to stringent risk management. 2) Suggesting that "thyroid toxicity" is a new and unknown phenomenon is at best misleading. The concerns about identifying substances adversely affecting the thyroid have been addressed by the current testing methodologies used in regulatory settings for many years.

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[1] Global Assessment of the State-of-the-Science of Endocrine Disruptors (WHO/IPCS, 2002)
http://www.who.int/ipcs/publications/new_issues/endocrine_disruptors/en/

[2] **ST**rengthening the **R**eporting of **OB**servational Studies in Epidemiology (STROBE)
http://www.strobe-statement.org

Under the banner of the WHO/UNEP this report gives the impression that the current chemicals management system is inadequate to protect consumers and the environment, leaving many health related impacts unidentified. Europe as an example has currently more than 120 regulations related to chemicals and there is no evidence that if correctly implemented these regulations are not protective. Of course new robust scientific findings can lead to modifications of the approach such as test parameters, but before doing so they must meet scientific quality criteria.