March 31, 2014

Mr Achim Steiner  
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Dr. Margaret Chan  
Director-General  
World Health Organization  
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Dear Mr. Steiner and Dr. Chan:

When the WHO-UNEP State of the Science on Endocrine Disrupting Chemicals – 2012 was released in early 2013, our organizations made clear our initial concerns that the report had some significant shortcomings. We identified several of these shortcomings at the time, and noted our interest in continued dialogue and cooperation on this issue; an interest that was reciprocated in Mr. Steiner’s letter to Mr. Mandery dated 18 June, 2013.

The chemicals and crop protection industries are 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. To help further that evaluation, several industry organizations¹ commissioned an independent scientific review of the 2012 WHO-UNEP report. That review has now been published in the peer-reviewed journal *Regulatory Toxicology and Pharmacology*. A copy of the review, whose authors include an editor and a representative on the Steering Committee of the 2002 WHO-IPCS Global Assessment of the State of the Science on Endocrine Disruptors, is attached to this letter.

In short, 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. In particular, it finds that:

- The 2012 report does not follow the weight of the evidence framework recommended in the 2002 WHO-IPCS report for assessing and integrating the available data on endocrine disruption, and instead relies on “best professional judgment”.

¹ The American Chemistry Council; Cefic: European Chemical Industry Council; CropLife America; CropLife Canada; CropLife International; European Crop Protection Association.
The 2012 report does not employ a formal framework for assessing causation (i.e. for assessing evidence of whether adverse effects result from chemical exposures).

The 2012 report attributes trends in human disease incidence or prevalence to endocrine disruption, without evidence of their known causes or discussion of other possible causative factors (e.g., diet, lifecycle, 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 does not refer to the conclusions of the 2002 WHO-IPCS report, nor was there consideration of whether new information has changed the state of scientific understanding since 2002, and therefore should not be considered an "update" of the 2002 report.

The process for developing the 2012 report did not attempt to capture the full spectrum of expert views on the issue of endocrine disruption, and instead the report was prepared by a set of authors who represent one side of that spectrum.

The Summary for Decision Makers suffers from all the deficiencies noted above, is not truly representative of the conclusions in the main report and asserts additional speculative findings beyond those in the main document.

In our view, these shortcomings are significant enough that neither the 2012 WHO-UNEP report nor the Summary for Decision Makers should be used as the basis for further international action or policy development on endocrine disruptors. While endocrine disruption is an issue of significant public, political and scientific interest, we strongly 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 the 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 and UNEP to use a transparent process for selecting experts with recognized 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.

Our industries remain committed to an inclusive and collaborative approach on the issue of endocrine disruption, 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, where the OECD is playing an important role.
Globally, industry has constructively contributed for more than 15 years within the OECD to the development of the validation data sets necessary to establish relevance, reliability sensitivity and specificity of endocrine screening and testing methods for deployment as internationally harmonized OECD test guidelines. In addition, over this same time period, largely through the Long Range Research Initiative of ICCA organizations, we have supported important basic research exploring endocrine mechanisms, dose response and effects.

We welcome the offer from WHO and UNEP to engage in further constructive dialogue to assess current gaps in scientific knowledge and promote a better understanding of the range of scientific perspectives on endocrine disruption. We plan to engage directly with the UNEP Chemicals Branch and the WHO Public Health and Environment Department to take this dialogue forward. Our goal here is to strengthen global efforts to understand and address issues related to endocrine disruption by ensuring that evaluations are based on reliable scientific test methods and a comprehensive assessment of the current state of the science. Such knowledge will provide a solid scientific foundation to guide to risk-based decision making that ensures the protection of human health and the environment.

Sincerely,

Hubert Mandery
ICCA Council Secretary

Howard Minigh
CropLife International President & CEO

cc: Ms. Fatoumata Keita-Ouane
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