12 September

CROPLIFE INTERNATIONAL POSITION FOR ICCM-4
ENDOCRINE DISRUPTING CHEMICALS (EDCs)

Background

Endocrine disrupting chemicals (EDCs) were added as an emerging issue under SAICM at ICCM-3 in 2012. The ICCM-3 mandate was largely restricted to education and information sharing about existing work on EDCs; it also called on UNEP, WHO and OECD to prepare a forward work plan on EDCs. Since ICCM-3, there have been several developments that may influence the discussion on EDCs at ICCM-4: the publication of the 2012 WHO-UNEP State of the Science Report; the adoption of decisions on EDCs at the SAICM Central/South America, Asia-Pacific and Africa Regional Meetings; and the formation of the UNEP Advisory Group on EDCs, and its proposed work program.

CropLife International Position

The CropLife International position on EDCs has several core tenets:

- CropLife International supports the WHO definition of EDCs, which incorporates consideration of adversity (i.e. it is not enough for a substance to interact with the endocrine system; that interaction must have adverse effects).
- The crop protection industry is advocating for a science- and risk-based approach to regulating endocrine active substances and endocrine disruptors that consider both hazard and exposure to ensure farmers worldwide have access to useful crop protection products while protecting human health and the environment.
- Significant work has been undertaken by governments, international organizations, academics and industry to broaden scientific understanding of EDCs, but further work is needed to form a sound basis for public policy. It is essential that efforts to address EDCs adopt a weight-of-the-evidence approach.
- CropLife International is opposed to the development of lists (or collections of lists) of known or suspected endocrine disruptors without appropriate scientific evidence. Compilations of selected substances for priority evaluation can be useful, but the purpose and context of the compilation must be clearly communicated so that the list does not become a de facto classification.
- The “low-dose” hypothesis has significant scientific shortcomings. While further scientific work is needed, regulatory agencies, including U.S. EPA and EFSA, have concluded that suggested “low dose” effects are not reproducibly observed. Without the gold standard of reproducibility, the low-dose hypothesis remains weak at best.
- Sound policy decisions about chemicals that may adversely affect the endocrine system must be based on the following considerations: first, whether a chemical causes endocrine-related activity; second, how this activity relates to realistic levels and means of exposure to the chemical; third, whether this exposure produces adverse effects via an endocrine mechanism; and finally, what steps may be needed to manage possible risks, in order to protect human health and the environment.

Of particular relevance to the discussion on EDCs at ICCM-4:

- CropLife International has strong concerns about using the 2012 WHO-UNEP “State of the Science” report on EDCs as a basis for additional work. The report fails to present an objective, comprehensive and balanced summary of the scientific evidence relating to

EDCs, and its conclusions must be called into question. (see Appendix 1 for more information)

- CropLife International sees the work plan on EDCs requested at ICCM-3, and developed by UNEP, WHO and the OECD, as an appropriate basis for further work. Many of the issues raised in resolutions from SAICM regional meetings are already covered by this work plan, and are therefore redundant.
- The UNEP Advisory Group on EDCs was initially established without a clear mandate. Additional clarity on the purpose and objectives of the Advisory Group is required. The Advisory Group must also work in close collaboration with other IOMC organizations, governments and other stakeholders, and not seek to duplicate existing activities.
- Governments may in particular wish to consider the outputs from the OECD Advisory Group on Endocrine Disrupters Testing and Assessment, and in particular the development of harmonized and validated test guidelines and alternative test methods for the identification of EDCs. The U.S. Environmental Protection Agency has also furthered important work in this area.
- SAICM has an important role to play in promoting information exchange and education on EDCs. Any decision from ICCM-4 on EDCs should center on this role. In particular, activities under SAICM should not seek to duplicate or pre-judge the outcomes of existing work in other fora.
- CropLife International is committed to contributing to international efforts to further scientific knowledge and on EDCs, and looks forward to working with all stakeholders to advance and broaden international understanding on this issue.

Appendix 1: Additional points regarding the WHO-UNEP report

- The 2012 report does not follow the 2002 WHO-recommended weight-of-evidence approach and ignores data quality.
- The main report discusses disease trends without regard to known causes or risk factors, even though disease trends are not suitable for showing that a chemical causes a particular disease.
- The main report ignores real-world exposures for most chemicals discussed.

The following is a list of publicly available documents that have been produced detailing the shortcomings of the report.

- Critical Comments on the WHO-UNEP State of the Science of Endocrine Disrupting Chemicals – 2012 by Lamb et al. published in the Journal of Regulatory Toxicology and Pharmacology 69:22-40.
- A letter by ICCA President Kurt Bock to UNEP Executive Director Achim Steiner about the UNEP and WHO report "The State of the Science on Endocrine Disrupting Chemicals - 2012"
- A joint statement by the EU, U.S. and international chemical and pesticide industry.

In August 2015 the authors of the report published a detailed “rebuttal” of criticisms made by the 2012 Lamb et al. paper. Dr Lamb said in an interview with *Chemical Watch* that he disagrees strongly with the rebuttal article.

- He suggests that the divergence of views comes because: “They are adopting a precautionary principle and hazard-only approach, while we are analysing the issues using a scientific risk-based approach. Using these different methods for reviewing and evaluating data leads to different conclusions.”
- Further, he says: “Our position is consistent with the recent comments [from stakeholders] published by the European Commission on defining criteria for identifying endocrine disruptors, which support a risk-based approach.”
- He adds that the issues of dose-response and potency separate the two groups of authors. “By relying on a risk-based approach, we consider dose-response and potency as critical elements of the analysis of adverse effects. They tend to minimise this issue. We consider that a mistake,” he says.