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**Emerging policy issues and other issues of concern: other
issues of concern: highly hazardous pesticides**

**Paper by CropLife International on its approach to managing
highly hazardous pesticides**

Note by the secretariat

The secretariat has the honour to circulate a paper by CropLife International on its approach to managing highly hazardous pesticides (see annex). The paper is reproduced as received by the secretariat, without formal editing.

* SAICM/OEWG.2/1.

Annex

Crop Life International Approach to Managing Highly Hazardous Pesticides

Introduction

CropLife International and its member companies and associations are committed to the protection of human health and the environment, while providing effective technology solutions and strategies to farmers worldwide to sustainably increase agricultural productivity. The industry has for many years promoted stewardship approaches to product management that maximise the benefits, while minimising the risks of pest management interventions, including use of pesticides. Underlying these approaches is the crop protection industry's support for the International Code of Conduct on Pesticide Management of 2012 (the Code).

The latest version of the Code includes an increased focus on the management of Highly Hazardous Pesticides. CropLife International and its members fully support initiatives that are compatible with the risk management approach that is the basis of the Code and have agreed to adopt a more robust and pro-active approach in managing HHPs on that basis.

Article 7.5 of the Code stipulates that "Prohibition of the importation, distribution, sale and purchase of highly hazardous pesticides may be considered if, based on risk assessment, risk mitigation measures or good marketing practices are insufficient to ensure that the product can be handled without unacceptable risk to humans and the environment".

Building on this understanding, CropLife International has reviewed its position on Highly Hazardous Pesticides (HHPs) and its members have agreed to an approach that is presented below.

The criteria as defined by the FAO/WHO Joint Meeting on Pesticide Management (JMPM) in 2008 were reviewed on the basis of Article 7.5 of the Code and revised criteria were defined. These revised criteria should trigger a risk/use assessment and enable progressive risk management; companies may individually consider voluntary withdrawal of uses¹. An additional and important element of the approach is the commitment of CropLife International to increase capacity building by offering training in risk assessment and responsible use training in developing countries.

The approach promoted by CropLife International on identification and management of highly hazardous pesticides supports the implementation of the International Code of Conduct on Pesticide Management in general, and Article 7.5 in particular. It provides a practical way of identifying HHPs using criteria that follow the definition provided in the Code and which are in accordance with International Conventions. The risk based approach allows for the identification of practical stewardship measures (i.e. progressive risk management, including voluntary withdrawal) to mitigate risks under local use scenarios. We look to other stakeholders to collaborate in the roll-out and promotion of this approach.

The CropLife International Approach

A) **CropLife International Position on Identification and Risk/Use Management of HHPs**

CropLife International proposes an evidence-based approach to understanding the consequences of using a crop protection product and an assessment of those consequences by evaluating the risks and benefits of its intended use in the field.²

Such a "use assessment process" involves characterisation of the product in terms of its efficacy, hazard and exposure, which requires:

- 1) Clearly defined protection goals;
- 2) Data essential to and appropriate for the characterisation of the product;
- 3) Refinements to the assessment or options for mitigating risks as appropriate.

¹ Any such decision will have to be taken on an individual company basis and not by agreement among CropLife International member companies.

² Based on CropLife International's Principles of Regulation.

An evidence- and risk-based approach has always been the hallmark of the Code and remains enshrined in article 7.5 of the 2012 revised version. Therefore, any HHP criteria should trigger a risk assessment due to the hazardous nature of a product. Consequently, CropLife International proposes criteria for identifying HHPs as defined in the Code, which if met, would start a use assessment process under local conditions of use.

B) Definition of HHPs

The definition of HHPs continues to heavily rely on the 2008 JMPM. These criteria have surfaced as a proposed annex to the Code and in an early draft of the FAO's HHP guidelines. The relevant CropLife International committees have reviewed these criteria and used them as the basis for a revised definition of HHPs as follows:

- 1) Pesticide products/formulations classified in the WHO Recommended Classification of Pesticides by Hazard in Classes 1a and 1b for acute oral/dermal toxicity and/or substances/active ingredients identified to have carcinogenic, mutagenic and reprotoxic effects are considered "highly hazardous."
- 2) Pesticide active ingredients and products that meet the criteria in Categories 1A or 1B of C, M or R in the Global Harmonized System, GHS, (i.e. classified as "known" or "presumed" human carcinogens, mutagens or reprotoxins), if the classification has been carried out in accordance with the GHS requirements.
- 3) Pesticide active ingredients listed in the Stockholm Convention, as they have been assessed as meeting all four criteria for a persistent organic pollutant, including high toxicity.
- 4) Pesticide active ingredients that affect the ozone layer and therefore, are listed as prohibited in the Montreal protocol.
- 5) Pesticide products that have been shown to cause a high level of severe³ and/or irreversible adverse incidents under recommended use scenarios and therefore trigger a use assessment. Pesticide products that cause a high level of adverse incidents through non-recommended uses, while not being classified as highly hazardous, will be subject to the same risk review and management options as HHPs.⁴

C) CropLife International Commitment to Risk Management of HHPs

- 1) The use of purely hazard-based criteria deflects from the actual risk likely to be encountered in use and could lead to misconceptions about and rejection of valuable products that support agricultural production and ensure food security.
- 2) CropLife International promotes strict adherence to safe handling instructions with all crop protection products, especially HHPs.
- 3) CropLife International proposes to work with the FAO and other stakeholders in a position to do so to address HHPs with a step-by-step approach based on risk or use assessment and risk mitigation in accordance with the Code, including the following activities by individual companies:
 - a) Identification of potential HHPs based on the above listed five criteria.
 - b) For identified HHPs, assessment of risks under local conditions of use with suitable risk assessment methodologies.
 - c) Risk management based on risk mitigation and effective stewardship measures,⁵ such as restricting access to HHPs and compliance monitoring.

³ This criterion has to be further defined as stated in the report of the 2nd JMPM meeting of 2008: "With respect to this criterion, the JMPM Panel requested WHO, FAO and UNEP to develop workable criteria on how to determine whether pesticide active ingredients and their formulations have shown a high incidence of severe or irreversible adverse effects on human health or the environment." Severity has been defined in "Poisoning Severity Score: Grading of Acute Poisoning" by Persson, Sjoberg, Haines and Pronzcuk Clinical Toxicology 36, 205-213, 1998. A similar scheme needs to be developed for environmental incidents, including livestock.

⁴ In line with the CropLife International 2009 position paper "Guidance Concerning Risk Management and Risk Mitigation of Pesticide Products for Health and/or Environmental Reasons."

- d) Periodic review by individual companies of their individual crop protection products, using the definition of HHPs (section B) to identify any potential HHPs and conduct use assessments on all products that meet one or more criteria.
- e) Based on the use assessment and following progressive risk management (such as voluntary company specific stewardship measures), companies will individually consider voluntary withdrawal of HHP uses. Any such decision will be taken on an individual company basis. Where reliable information leads the product registrant to conclude that risk management and stewardship measures are insufficient to mitigate against the risk arising from product use, the product registrant will consider voluntarily withdrawing that use rather than waiting for formal regulatory action. Any voluntary or regulatory action should take into account the benefits of the HHP and impact of the decision on national agriculture.
- f) Encouraging all stakeholders in a position to do so to put mechanisms in place that help all parties adhere to similar risk management and risk mitigation measures for user and public safety. This may include government regulation or voluntary actions. CropLife International members commit to transparency in the risk management approach, which may include audits by appropriate (third party) auditing organizations using individually tailored protocols.
- g) Committing to capacity-building by providing training on risk and use assessment best practices in developing countries and encouraging other stakeholders in a position to do so, such as the FAO, other appropriate UN bodies and non-governmental organizations, to cooperate in such capacity building activities.

{October 1, 2014}
