

Effective Management of Highly Hazardous Pesticides: Regulating for Risk, Not Hazard

By definition, crop protection products are designed to protect crops from insects, diseases and weeds. They do so by controlling pests that infect, consume or damage crops. Uncontrolled pests significantly reduce the quantity and quality of food production. It is estimated that annual crop losses could double without the use of crop protection products.

All crop protection products are intensively tested and regulated around the world to ensure they don't cause unacceptable adverse effects to humans, non-target wildlife or the environment. Some products are highly toxic in order to control a group of specific pests or highly threatening diseases. Risk assessment and management identify the appropriate uses for crop protection products and promote stewardship measures for their responsible use.

According to the International Code of Conduct on Pesticide Management ("Code"), Highly Hazardous Pesticides (HHPs) are "pesticides that are acknowledged to present particularly high levels of acute or chronic hazards to health or environment according to internationally accepted classification systems such as WHO (World Health Organization) or GHS (Globally Harmonized System) or their listing in relevant binding international agreements or conventions. In addition, pesticides that appear to cause severe or irreversible harm to health or the environment under conditions of use in a country may be considered to be and treated as highly hazardous."

The hazardous nature of these crop protection products alone does not make them HHPs. What really matters

is their risk versus benefits under recommended use conditions. The crop protection industry is committed to ensuring that such risk is appropriately addressed and minimized so a variety of products are available to help protect crops, people and the environment. Besides, the benefits of certain uses of HHPs may outweigh their risks by controlling pests that spread disease or threaten the food supply.

CropLife International supports the Code, which calls for regulating crop protection products based on risk, not hazard. A risk-based approach prevents the restriction or banning of effective, useful products that pose minimal risk under proper use conditions and help farmers feed a growing population.

Based on the Code definition, CropLife International proposes the following criteria to identify HHPs:

- 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 severe¹ and/or irreversible adverse incidents under recommended use scenarios and therefore trigger a use assessment. Pesticide products that cause a high level of 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.²

CropLife International proposes these criteria for identifying HHPs in alignment with the Code, which if met, would start a use assessment process under local conditions of use.

In more simplified terms, these criteria identify HHPs as products that:

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| <ol style="list-style-type: none"> 1 cause serious harm to humans if swallowed or spilled on the skin; 2 contain substances at more than trace levels known to cause cancer in humans, cause damage to genes or adversely affect the development of an unborn child or reproductive system of humans; 3 include active ingredients at more than trace levels that | <ol style="list-style-type: none"> 4 include active ingredients at more than trace levels that have the potential to damage the ozone layer; and/or 5 show credible evidence that their recommended uses cause widespread harm to people or the environment. |
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RISK MANAGEMENT

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.”

CropLife International supports this approach to managing HHPs. It is striving to work with the UN Food and Agriculture Organisation (FAO) and other stakeholders to promote risk-based management of HHPs around the globe. This includes identifying highly toxic products for priority risk assessment per intended use and geography. Any potential unacceptable risks must be mitigated by an action plan or otherwise, the products should not be released or maintained. Risks should be weighed against the need for a product, benefits of its use and availability plus risks/benefits of real alternatives.

Certain uses of HHPs may be desirable when they benefit society by controlling pests that spread disease or threaten the food supply. For example, while no longer used in agriculture, DDT remains an important tool in reducing human exposure to malaria. Removing this major disease control agent from the

market altogether would put people at greater risk. Similarly, substances to control rats and other rodents (rodenticides) protect humans against the spread of diseases.

RISK MITIGATION

The crop protection industry protects people and the environment by following very stringent product development criteria, whereby thousands of chemicals are analyzed and those with potential negative side effects are screened out from the very beginning. Products are then thoroughly tested according to local regulatory requirements and international standards. If they are safe for intended uses, they are delivered to the market responsibly. The industry then offers product support and stewardship training as well as promotes responsible handling practices. These necessary business operations ensure product sustainability and longevity as well as protect society.

Moreover, the crop protection industry supports Integrated Pest Management (IPM), which calls for applying crop protection products only when needed, and conducts farmer training on IPM and responsible product use. In fact, the CropLife International network has carried out many initiatives around the world to promote the responsible transport, storage,

use and disposal of crop protection products. Farmers who follow such guidance and label instructions protect themselves and their farms from adverse effects.

Finally, the industry continuously improves product formulations and packaging with human and environmental protection in mind. For example, it has put in place safety measures to prevent accidental or intentional misuse of products, such as safety seals and vomit-inducing ingredients. Liquid formulas may be switched to gels or microcapsules that don't dissolve in water to prevent spillage and make them difficult to drink. Prominent warnings on labels along with suitably-sized and easy-to-handle containers discourage decanting products into unlabeled, inappropriate containers. Coloring or adding a strong smell to products to avoid mistaken identity, child- or spill-resistant caps and built-in measuring devices also help protect farmers and their families. Finally, products may be restricted in use per application or geography and/or only be sold to professional applicators.

See examples of risk mitigation on the next page.

Examples of Risk Mitigation

PACKAGING



Child-resistant caps



Built-in measuring devices

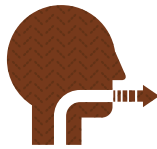


Suitable, easy-to-handle container size

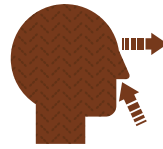
PRODUCT



Changes in formulation to prevent spillage



Vomit-inducing ingredient in case of ingestion



Strong odor or color for identification

RESTRICTED USE



Approved crops



Specific geographic locations



By licensed professional applicators

TRAINING AND EDUCATION



Responsible use of crop protection products



Integrated Pest Management



Proper disposal of empty product containers

REGULATION OF HHPs

Like all crop protection products, HHPs must be regulated by national governments to ensure there are no unacceptable risks to human or environmental health at the local level. The crop protection industry is required to adhere to these regulations. In addition, CropLife International members are voluntarily committed to managing potential risks posed by HHPs by:

- reviewing their product portfolios regularly to identify products that meet HHP criteria;
- conducting use assessments on products/formulations under various conditions of use in specific geographies;
- taking measures to manage any HHP risks, which may include several mitigation measures or individual companies choosing to withdraw a product or use(s);
- encouraging global stakeholders to adhere to similar risk management measures; and
- building capacity for risk assessment in developing countries.

1 This criterion has to be further defined as stated in the report of the 2nd FAO/WHO Panel of Experts on Pesticide Management (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 Pronczuk *Clinical Toxicology* 36, 205-213, 1998. A similar scheme needs to be developed for environmental incidents, including livestock.

2 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."