Guidance concerning risk management and risk mitigation of pesticide products for health and/or environmental reasons

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Introduction

The International Code of Conduct on the distribution and use of pesticides (the ‘Code’; also hitherto colloquially known as “FAO Code”) was established as one of the first voluntary Codes of Conduct in support of increased food security, while at the same time protecting human health and the environment. The basic function of the Code is to serve as a framework and point of reference for the judicious use and sound management of pesticides for all those involved in pesticide matters, particularly until such time as countries have established adequate and effective regulatory infrastructures for the sound management of pesticides.

The members of the crop protection industry represented by CropLife International have “agreed to abide by the FAO Code of Conduct” (Article 4 of the Articles of Association).

Objectives of the Code

The objectives of the Code are to establish voluntary (emphasis added) standards of conduct for all public and private entities engaged in or associated with the distribution and use of pesticides. The Code is designed for use within the context of national legislation as a basis whereby government authorities, pesticide manufacturers and others engaged in trade may judge whether their proposed actions and the action of others constitute acceptable practices.

Inter alia, the standards of conduct set forth in the Code encourage responsible and generally accepted trade practices; promote practices which reduce risks in the handling of pesticides, including minimising adverse effects on humans and the environment and preventing accidental poisoning resulting from improper handling; and adopt the “life-cycle” concept to address all major aspects related to the development, regulation, production, management, packaging, labelling, distribution, handling, application, use
and control, including post registration activities and disposal of pesticides and pesticide containers.

**Risk Reduction in the Context of the Code**

Risk reduction is a central element of the Code culminating in Article 5.2.4 “Even where a (pesticide) control scheme is in operation, the pesticide industry should halt sale and recall products when handling or use pose an unacceptable risk under any use directions or restrictions” (emphasis added); and Article 7.5 “Prohibition of the importation, sale and purchase of highly toxic and hazardous products, such as those included in WHO classes Ia and Ib, may be desirable if other control measures or good marketing practices are insufficient to ensure that the product can be handled with acceptable risk to users” (emphasis added).

The pesticide risk reduction campaign launched by FAO in 2007 as the Highly Hazardous Pesticides (HHPs) Initiative has given renewed prominence to these Articles.

In this context, the FAO/WHO Joint Meeting on Pesticide Management, in expanding Article 7.5, recommended in October 2008 that HHPs should only be registered for use if governments establish a clear need and no alternatives – based on a risk-benefit analysis – are available. The Panel also recommended promoting the substitution principle for HHPs.

Although FAO has somewhat de-emphasised the aim of “progressive banning” as a priority activity to risk reduction from HHPs, the pressure on industry to “**voluntarily withdraw HHPs**” continues to increase. In view of these developments, this document is designed to provide some guidance for decision making concerning voluntary withdrawal of HHPs. This guidance relates to the “beneficial” use of pesticides as covered by the Code. Gross-misuse and abuse of pesticides is outside the scope of this document.

**Guidance concerning “voluntary withdrawal” of HHPs**

Article 5.2.4 of the Code clearly establishes a risk-based approach to the halt of sales and recall of products. Whilst Article 7.5 of the Code appears to call for the prohibition of pesticides based on arbitrary hazard classification, it also embraces ‘risk’ as the ultimate basis for action. It is therefore in keeping with the letter and the spirit of the Code, that this guidance is grounded in a risk-based approach and that a purely hazard-based approach is not justified, but might unnecessarily deprive the farmer/grower of valuable, effective and affordable crop protection tools.

In principle, the granting of registration of a product establishes that the risk to human health of using a given pesticide is acceptable, when used as
recommended and directed (including minor acceptable deviations there from). If actual use appears to be contradicting this prediction, a number of points need to be considered, such as:

1. Collecting and analysing poisoning incidence reports;
2. Segregating accidental and occupational poisoning incidences;
3. Establishing severity of poisonings; minor irritations are less critical than systemic, severe poisoning;
4. Basing mitigation measures on the results of incidence analysis.

**Risk Mitigation – General**

Measures include:

- Promotion of IPM and Responsible Use of pesticides;
- Intensification of education and training programmes and overall stewardship and product support efforts;
- Promotion of appropriate hygiene measures when handling pesticides.

**Risk Mitigation – Accidental Poisoning**

Measures include:

- Prominent warnings against decanting into unlabelled, inappropriate containers, bottles etc. and other “bulk breaking”;
- Reducing the temptation for decanting by providing product in suitably-sized and easy-to-handle containers;
- Colouring, stenching, and embittering of products to avoid mistaken identity;
- Child resistant caps;
- Provision of built-in measuring devices to avoid use of inappropriate means of measuring, such as tea cups etc;
- Safe and secure storage and transport.

**Risk Mitigation – Occupational Poisoning**

Occupational exposure is potentially the major risk when handling and using pesticides. Experience and available data have shown that minor or mild “poisonings” such as skin irritations are much more frequent than severe, systemic poisonings. Whilst it is important to strive for the elimination of all poisonings, it is most critical from a risk mitigation standpoint to reduce/eliminate the more severe incidences.

If risk analysis has established that some action is required, risk mitigation options should employ a decision tree logic, which addresses the conditions
and practical aspects of the case and the alternate crop protection solutions available. Availability of alternatives is an important, but not the primary criterion in this analysis. No approach, including gradual, geography-specific, voluntary withdrawal, should be excluded from consideration, if based on a scientifically valid risk assessment. Risk mitigation measures in hierarchical order could include:

- Labelling changes concerning use recommendations and warnings; specific and detailed advice on actual protective gear required; provision of suitable PPE;
- Change to packaging design;
- Applicator certification;
- Limitation to specific application equipment; closed systems;
- Formulation change to minimise risk to user;
- Use restrictions concerning crops (e.g. no use on tall crops to avoid overhead spraying);
- Geographical restrictions on use;
- Voluntary withdrawal of product, if the risk analysis indicates that lesser risk mitigation measures are unlikely to reduce the risk to an acceptable and manageable level.

Risk analysis, however, should not be used as an excuse to delay decision making.

In adhering to the CropLife International Policy of not dealing with any aspects of individual products of its members, it is not CropLife’s role to make judgement on such individual products nor will any proposal or decision by a member company to withdraw an individual product be communicated or discussed between CropLife member companies who in reaching such decisions will do so at all times in compliance with applicable anti-trust and competition laws. Decision making on risk mitigation and risk mitigation measures is therefore the sole right and duty of the products’ registrants.