Food and Agriculture Organization of the United Nations

World Health Organization

International Code of Conduct on Pesticide Management

Guidelines on Highly Hazardous Pesticides

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Food and Agriculture Organization of the United Nations
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The Inter-Organisation Programme for the Sound Management of Chemicals (IOMC) was established in 1995 following recommendations made by the 1992 UN Conference on Environment and Development to strengthen cooperation and increase international coordination in the field of chemical safety. The participating organizations are the Food and Agriculture Organization of the United Nations (FAO), the International Labour Organization (ILO), the Organisation for Economic Co-operation and Development (OECD), the United Nations Environment Programme (UNEP), the United Nations Industrial Development Organization (UNIDO), the United Nations Institute for Training and Research (UNITAR) and the World Health Organization (WHO). The World Bank and the United Nations Development Programme (UNDP) are observers. The purpose of the IOMC is to promote coordination of the policies and activities pursued by the participating organizations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.
This publication was developed in the IOMC context. The contents do not necessarily reflect the views or stated policies of individual IOMC participating organizations.

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ACRONYMS

ai	Active ingredient
FAO	Food and Agriculture Organization of the United Nations
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HHPs	Highly Hazardous Pesticides
HIC	High Income Countries (previously developed countries)
ILO	International Labour Organization
IPM	Integrated Pest Management
IVM	Integrated Vector Management
JMPM	FAO and WHO Joint Meeting on Pesticide Management
LMIC	Low and Middle Income Countries
LIC	Low Income Countries (previously developing countries)
NGO	Non-Governmental Organizations
OECD	Organization for Economic Cooperation and Development
PPE	Personal Protective Equipment
SAICM	Strategic Approach to International Chemicals Management
UNEP	United Nations Environmental Programme
WHO	World Health Organization

DEFINITIONS

Active ingredient means the part of the product that provides the pesticidal action.

Banned pesticide means a pesticide all uses of which have been prohibited by final regulatory action, in order to protect human health or the environment. It includes a pesticide that has been refused approval for first-time use, or has been withdrawn by industry either from the domestic market or from further consideration in the domestic approval process, and where there is clear evidence that such action has been taken in order to protect human health or the environment.

Co-formulant means a non-active ingredient component of a formulated product.

Exposure to pesticides means any contact between a living organism and one or more pesticides.

Formulation means the combination of various ingredients designed to render the product useful and effective for the purpose claimed and for the envisaged mode of application.

Hazard means the inherent property of a substance, agent or situation having the potential to cause undesirable consequences (e.g. properties that can cause adverse effects or damage to health, the environment or property).

Highly Hazardous Pesticides means 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 or GHS 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.

Integrated Pest Management (IPM) means the careful consideration of all available pest control techniques and subsequent integration of appropriate measures that discourage the development of pest populations and keep pesticides and other interventions to levels that are economically justified and reduce or minimize risks to human and animal health and/or the environment. IPM emphasizes the growth of a healthy crop with the least possible disruption to agro-ecosystems and encourages natural pest control mechanisms.

Integrated Vector Management (IVM) means the rational decision-making process for the optimal use of resources for disease vector control. It aims to improve efficacy, cost-effectiveness, ecological soundness and sustainability of disease vector control interventions for control of vector-borne diseases.

Pesticide means any substance, or mixture of substances of chemical or biological ingredients intended for repelling, destroying or controlling any pest, or regulating plant growth.

Pesticide management means the regulatory and technical control of all aspects of the pesticide life cycle, including production (manufacture and formulation), authorization, import, distribution, sale, supply, transport, storage, handling, application and disposal of pesticides and their containers to ensure safety and efficacy and to minimize adverse health and environmental effects and human and animal exposure.

Risk is the probability and severity of an adverse health or environmental effect occurring as a function of a hazard and the likelihood and the extent of exposure to a pesticide.

Severely restricted pesticide means a pesticide virtually all use of which has been prohibited by final regulatory action in order to protect human health or the environment, but for which certain specific uses remain allowed. It includes a pesticide that has, for virtually all use, been refused for approval or been withdrawn by industry either from the market or from further

consideration in the domestic approval process, and where there is clear evidence that such action has been taken in order to protect human health or the environment.

1. INTRODUCTION

1.1 Background

The understanding that some pesticides are more hazardous than others is well established. Recognition of this is reflected by the World Health Organization (WHO) Recommended Classification of Pesticides by Hazard, which was first published in 1975. The document classifies pesticides in one of five hazard classes according to their acute toxicity. In 2002, the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) was introduced, which in addition to acute toxicity also provides classification of chemicals according to their chronic health hazards and environmental hazards.

Broad international concerns about health and environmental hazards led to the establishment of the Stockholm Convention on Persistent Organic Pollutants and the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade. The Stockholm Convention agrees on the phasing out of persistent pesticides and other chemicals listed under its Annex A. The Rotterdam Convention promotes shared responsibility and cooperative efforts in the international trade of certain hazardous chemicals in order to protect human health and environment. It facilitates information exchange on final regulatory actions taken by countries and on severely hazardous pesticide formulations that have been reported to cause problems under conditions of use in low or middle income countries.

In 2006, the FAO Council endorsed FAO participation in the Strategic Approach to International Chemicals Management (SAICM) and noted that the International Code of Conduct on the Distribution and Use of Pesticides[1] was to be considered as an important element of the SAICM process. The Council suggested that the activities of FAO could include pesticide risk reduction, including the progressive banning of Highly Hazardous Pesticides (HHPs)[2]. This request resulted in the formulation of criteria that define HHPs by the Joint FAO\WHO Meeting on Pesticide Management (JMPM)[3] and also led to a definition for HHPs and specific references in the International Code of Conduct on Pesticide Management (further referred to as the Code of Conduct) when it was revised in 2013. The criteria and definition encompass a broader range of pesticides than those addressed by the Conventions. HHPs then became a special focus area in the programme of work for the FAO Pest and Pesticide Management Group.

In 2015, the SAICM International Conference on Chemicals Management adopted a resolution that recognized HHPs as an issue of concern and called for concerted action to address HHPs, with emphasis on promoting agro-ecologically based alternatives and strengthening national regulatory capacity to conduct risk assessment and risk management[4]. Stakeholders were encouraged to align efforts and, in order to ensure coherence, be guided by the definition of HHPs in the Code of Conduct and by these guidelines.

[1] The title was changed into "Code of Conduct on Pesticide Management" at its revision in 2013. [FAO/WHO 2014]
[2] Report of the Council of FAO, Hundred and Thirty-first Session, Rome, 20-25 November 2006
[3] Report of the 2nd FAO/WHO Joint Meeting on Pesticide Management and 4th Session of the FAO Panel of Experts on Pesticide Management, Geneva, 6-8 October 2008
[4] SAICM/ICCM.4/15 – Annex I - Resolution on highly hazardous pesticides (IV/3).

These guidelines expand upon the articles that address HHPs in the Code of Conduct (Box 1) with the objective of helping countries to interpret and apply these articles effectively in order to reduce risks posed by HH

Ps. Countries are encouraged to identify the HHPs in use, to assess the risks involved and to decide upon appropriate measures to mitigate these risks.

Box 1: Articles related to Highly Hazardous Pesticide in the FAO/WHO International Code of Conduct on Pesticide Management

3.6 Pesticides whose handling and application require the use of personal protective equipment that is uncomfortable, expensive or not readily available should be avoided, especially in the case of small scale users and farm workers in hot climates.

5.1.6 Governments should utilize all possible means for collecting reliable data and maintaining statistics on health effects of pesticides and pesticide poisoning incidents, using harmonized tools where available, and submit, where appropriate, the Rotterdam Convention Human Health Incident Report Forms on Severely Hazardous Pesticide Formulations (SHPF), to the relevant designated national authority. Suitably trained personnel and adequate resources should be made available to ensure the accuracy of information collected.

6.1.1 Governments should introduce the necessary policy and legislation for the regulation of pesticides, their marketing and use throughout their life-cycle, and make provisions for its effective coordination and enforcement, including the establishment of appropriate educational, advisory, extension and health-care services, using as a basis FAO and WHO guidelines and, where applicable, the provisions of relevant legally binding instruments. In so doing, governments should take full account of factors such as local needs, social and economic conditions, levels of literacy, climatic conditions, availability and affordability of appropriate pesticide application and personal protective equipment.

7.5 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.

9.4.1 All entities addressed by this Code should support the process of information exchange and facilitate access to information on matters including pesticide hazards and risks, residues in food, drinking water and the environment, the use of pesticides in or on non-food products, IPM/IVM, pesticide efficacy, alternatives to highly hazardous pesticides and related regulatory and policy actions.

1.2 Issues related to HHPs

Hazards

Pesticides can be considered highly hazardous if they present particularly high levels of acute or chronic hazards to human health or the environment.

High acute human toxicity refers to product properties that can cause immediate health effects. Pesticides with high acute toxicity can affect people who are preparing, mixing or using pesticides, but also by-standers, people entering treated fields, consumers eating treated produce too soon after application, etc. Other handling during which such pesticides can pose risk include storage, cleaning and storage of application equipment, disposal of empty containers and contaminated materials such as gloves.

Besides acute risk of occupational poisoning, several countries documented a broad problem of use of acutely toxic pesticides for self-harm purposes. In several countries, it has been demonstrated that prohibiting or restricting access to such products significantly reduces fatalities due to suicide. WHO therefore recommends that products frequently used for suicide are made less accessible[5].

Chronic human toxicity refers to product properties that may cause any adverse effect as a result of repeated or long-term exposure. Such adverse effects could for instance include cancers or developmental disorders.

Hazards to the environment include contamination of water resources and soils, and acute or chronic toxicity to non-target organisms that may lead to disruption of ecosystem functions, such as pollination or natural pest suppression.

HHPs often are older generation, off-patent, products that are relatively cheaply available[6]. Products that have been taken off the market in High Income Countries (HICs), frequently remain registered in Low and Middle Income Countries (LMICs). Contributing factors may include:

- Poorly functioning registration schemes that are affected by limited human and financial resources and have inadequate capacity for risk assessment,
- Perceptions that poor farmers should have access to cheap pesticides,
- Lack of knowledge about alternatives

Furthermore, production of HHPs from older product generations is increasingly being shifted from HICs to LMICs.

In some cases, HICs may maintain the registration of certain HHP uses, but control these through strict risk mitigation measures. Such measures are often less likely to be implemented or enforced in LMICs because of limitations in capacity.

Use context

[5] Preventing suicide: a global imperative, World Health Organization 2014

[6] Economic aspects of pesticide selection are elaborated in section 3.2

It should be noted that there is a significant difference between pesticide users in HICs and those in Low Income Countries (LICs). In HICs the percentage of the population working in agriculture is typically below 5%[7]. In LICs the percentage of the population working in agriculture is often much higher (typically above 40%). The average for Sub-Sahara Africa for instance is about 60%. Poverty, limited education, distances, and ineffective extension systems are amongst the factors that affect the feasibility of reaching all farmers with training and advice on pesticide use in LICs. Furthermore, the institutional capacity to train farmers and enforce pesticide legislation tends to be less in LICs.

Personal Protection Equipment (PPE) for highly hazardous pesticides, as prescribed on the label or by training programmes, is often not available or not used in LMICs because it is too expensive or too uncomfortable to wear in hot, humid climates. In many LICs, the available PPE in rural pesticide shops is often of inadequate quality or not suitable for protection against many formulations of highly hazardous pesticides (e.g., household gloves and simple dust masks).

Commonly used application equipment in LMICs (mainly knapsack sprayers) tends to be less sophisticated compared to that used in HICs. Application equipment is often not regulated in LMICs, which may affect specifications and quality. Cost factors often prevent timely replacement. Maintenance and safe cleaning and storage is often a challenge. Leaking or poorly calibrated equipment and improvised application methods can further increase risks.

Other factors affecting proper use of pesticides may include: limited user knowledge about pests and pest management options, available products and their risks; users not being able to read or understand labels (low literacy levels in certain areas); incomplete labels; labels not available in the local language; relatively high cost of following label instructions (e.g. buying recommended PPE and application equipment), etc.

For these reasons , there is often a significant gap between the common conditions of use in LMICs and the prescribed instructions on the label, potentially leading to high human and environmental exposures and consequently to risks exceeding estimated levels based on the assumption that label instructions are followed.

In LMICs, incidents related to use of HHPs often remain undetected due to a lack of adequate monitoring and reporting systems for health and environmental impacts of pesticides. Absence of poisons information centres and limited medical facilities to diagnose, treat and report pesticide poisoning are further factors.

In cases where HHPs continue to be used, there may be a lack of knowledge about less hazardous alternatives. Particularly for biological alternatives there may also be limitations related to the availability and distribution of such products and to knowledge about their use.

1.3 Purpose of this document

These guidelines are intended to help national or regional pesticide regulators with limited resources to design a process to address HHPs that follows the three steps of identification, assessment and mitigation. They also aim to underscore the importance of adequate pesticide legislation, and risk and needs assessment as part of the registration process.

[7] ILO Key indicators of the labour market, 2011

1.4 Scope

These guidelines apply to all pesticides, including agricultural, public health, household, amenity and industrial pesticides.

The information in this document is supplemented by other guidelines and tools on the FAO webpages on pest and pesticide management. These include the FAO/WHO Guidelines for the Registration of Pesticides [2010], the FAO/WHO Guidelines on developing a reporting system for health and environmental incidents resulting from exposure to pesticides [2009], the FAO/WHO Guidelines on pesticide legislation [2015] and the FAO Pesticide Registration Toolkit, which provides guidance on risk assessment (Annex II).

1.5 References

These guidelines contain many references to other documents. To facilitate access to these documents, hyperlinks have been included at many places within the text of this document. For those using a hardcopy, the main references with their full internet addresses are listed in the section on Further Tools and References.

FAO and WHO are interested to receive suggestions or comments that you may have after using these guidelines as these may help further improve future editions. Please send your suggestions or comments to pesticide-management@fao.org

2. IDENTIFICATION

2.1 Definition

The FAO/WHO International Code of Conduct on Pesticide Management [2013] defines Highly Hazardous Pesticides as:

P*esticides 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 the World Health Organization (WHO) or the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) 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*.

2.2 Criteria

The FAO/WHO Joint Meeting on Pesticide Management [2008] recommended that highly hazardous pesticides should be defined as having one or more of the following characteristics:

- **Criterion 1**: Pesticide formulations that meet the criteria of classes Ia or Ib of the *WHO Recommended Classification of Pesticides by Hazard*;
  or
- **Criterion 2**: Pesticide active ingredients and their formulations that meet the criteria of carcinogenicity Categories 1A and 1B of the *Globally Harmonized System on Classification and Labelling of Chemicals* (GHS);
  or
- **Criterion 3**: Pesticide active ingredients and their formulations that meet the criteria of mutagenicity Categories 1A and 1B of the *Globally Harmonized System on Classification and Labelling of Chemicals* (GHS);
  or
- **Criterion 4**: Pesticide active ingredients and their formulations that meet the criteria of reproductive toxicity Categories 1A and 1B of the *Globally Harmonized System on Classification and Labelling of Chemicals* (GHS);
  or
- **Criterion 5**: Pesticide active ingredients listed by the *Stockholm Convention* in its Annexes A and B, and those meeting all the criteria in paragraph 1 of Annex D of the Convention;
  or
- **Criterion 6**: Pesticide active ingredients and formulations listed by the *Rotterdam Convention* in its Annex III;
  or
- **Criterion 7**: Pesticides listed under the *Montreal Protocol*;
  or
- **Criterion 8**: Pesticide active ingredients and formulations that have shown a high incidence of severe or irreversible adverse effects on human health or the environment.

Further and more detailed technical information regarding these criteria is provided in Annex I. International research into hazards of pesticides continues and other criteria may be added later by FAO and WHO[8] as international consensus develops. Current focus areas of international research for instance include endocrine disruption and toxicity to pollinators.

2.3 Identifying HHPs in use

In order to identify HHPs in use, the list of registered pesticides should be examined against the criteria for HHPs as provided in Section 2.2. This could be done by the pesticide registration authority or, for instance, by a specially established inter-ministerial working group.

For criteria 1-7 there are reference lists and related guidance that can be found on the internet. Annex I provides an overview of information sources for easy reference.

Assessment as to whether an active ingredient or formulation would fall under Criterion 8 is more complex as this depends on the actual situation in individual countries. The following indicators could be taken into consideration:

- Surveillance indicates relatively high incidences of poisoning or environmental impact;
- Surveillance of pesticide use practices indicates high exposure risks under common conditions of use. Comparison of label instructions for relatively hazardous products with actual use practices consistently indicates a significant gap between precautions that should be taken and precautions that are actually taken. Examples include: required PPE is not available; pesticides which are highly toxic to aquatic organisms are broadly used in irrigated rice; products being broadly used on crops for which they are not approved, etc. In such cases, targeted surveys should be conducted to establish whether the use of a product qualifies under Criterion 8.

Countries that do not have effective surveillance schemes could use information about products identified as HHPs under Criterion 8 in other countries with comparable pesticide use situations, as pointers to potential problems. The use for these products should then be investigated through targeted surveys in order to determine whether or not these products cause problems under the circumstances of use in the country, and consequently, whether or not they should be regarded as HHPs. Such information from other countries could include:

- Countries with comparable pesticide use situations that have taken regulatory measures for certain pesticides in response to health or environmental incidents.
- Surveillance, research or incident reporting data from countries with comparable pesticide use situations, indicate significant health or environmental issues for certain pesticides;

For countries where the pesticide registration scheme is not effectively enforced, the list of registered pesticides should be supplemented by lists of imported pesticides or findings from pesticide use field surveys. If such lists are not available then it would be important

[8] This would follow the same review process by the FAO/WHO Joint Meeting on Pesticide Management that developed the current criteria.

to conduct such surveys. One should also be aware that certain products may have remained registered, while in practice their use has ended.

3. ASSESSMENT

After it has been identified which HHPs are used in the country, the next steps are to assess the risks that these products are posing to human health and the environment under the conditions of use in that country and to review the needs for these products, taking into consideration available alternatives.

3.1 Risk assessment

The FAO Pesticide Registration Toolkit (Annex II) provides practical guidance on conducting risk assessments for pesticide registration or review of existing registrations. For countries with limited capacity for risk assessment, it also contains guidance on the use of risk assessments from other countries and on bridging such information to national use conditions.

To conduct a risk assessment it is important to understand the concept of risk (Box 2).

Box 2: The concept of Risk

Risk is a function of **Hazard** and **Exposure:** $R = f(H \times E)$

The hazard of a product is determined by the intrinsic toxicological properties of the active ingredient. Risk reduction can thus be achieved in two ways: Reduction in hazard or reduction in exposure.

Reduction in hazard would generally involve choosing a less hazardous alternative. This could be a non-chemical approach to pest management, a different chemical compound or a different formulation of the same compound.

Reduction in exposure can be achieved in a variety of ways (discussed below).

Exposure

As a high hazard has already been established, exposure is the main factor to consider for risk assessment of HHPs. The following types of exposure may be relevant:

Human exposure

Human exposure includes both direct exposure and dietary exposure.

Direct human exposure scenarios include occupational exposure (operators and workers), and bystander and residential exposure. Exposure can be oral, dermal or through inhalation and result from mixing, application, spray drift, re-entry or contact with treated crop or contaminated equipment and materials

Dietary exposure includes exposure through contaminated food or water. It generally involves consumption of treated agricultural produce. Cumulative and synergistic effect of multiple exposures may need to be taken into consideration.

For both direct human exposure and dietary exposure, the potential health effects can be more severe for certain vulnerable groups, such as pregnant or breast-feeding women, infants and children, immune compromised persons, malnourished persons, etc.

Exposure scenarios for children may include mothers taking children into the fields with them, hand to mouth behaviour in residential settings, exposure through breast-feeding or during pregnancy. Special consideration should be given to areas where children are involved in agricultural work[9].

Exposure of livestock, domestic animals and wildlife

Pesticide use could expose livestock and domestic animals, as well as other non-target organisms such as pollinators and other beneficial insects, aquatic organisms, birds and other wildlife, including endangered species.

Environmental exposure

High levels of environmental exposure can result in contamination of ground or surface water, soils, air and/or plant material. This may affect soil organisms, beneficial insects and other organisms that provide ecosystem functions. Some pesticides accumulate through the food chain.

Unintentional exposure of crops

Unintentional exposure of crops, usually resulting from drift or overflow, may affect crop health and food safety. Concerns include drift of herbicides that could damage crops in neighbouring fields and drift of insecticides and fungicides that may affect food safety of neighbouring crops.

Exposure context

The local circumstances of use are an important factor that is to be taken into consideration when determining the exposure risk. Examples of local circumstances that may increase pesticide exposure include:

- Non-availability of prescribed PPE, limited access to it, or limited use of it.
- Non-availability of appropriate application equipment or limited access to it.
- Limited ability to safely store pesticides.
- Limited ability to maintain and safely clean and store application equipment.
- Poor advice and knowledge about pesticide use and risks.
- Not respecting prescribed re-entry intervals and pre-harvest intervals.
- Risk of occurrence of spray drift.
- Lack of disposal options/facilities for obsolete stocks, left-over product or empty containers.

[9] This also is emphasized in article 6.1.2 of the Code of Conduct and the relevant ILO Conventions.

Assessment of exposure levels

Assessment of exposure levels is a key element of the risk assessment. This can be done through actual exposure assessment or through indirect assessments. Examples of different approaches are provided in Box 3. Combining different types of assessments may provide the most solid results.

Box 3 Examples of different approaches to exposure assessment

Surveillance of actual impacts

This could involve collection of available data on poisoning incidents for a specific compound or product, which, for instance, could be collected from poisons information centres, hospital or health clinic records or from reporting by extension officers, decentralised plant protection staff or vector control programme staff. Where desirable, such data can be supplemented by specific targeted community-level surveys whereby one would look specifically at poisoning incidents within communities where the product is used by a relatively large proportion of the people.

Assessment of degree to which necessary precautions are followed

This would involve assessment of abilities and willingness of users to follow label instructions regarding necessary protection of personal and public health and the environment. Such an assessment would take into consideration the local context factors that may increase exposure, as well as the actual practices. Differences between required precautionary measures and actual practices and working conditions would provide an indication of exposure and risk. Having clear and complete labels would be a pre-requisite for this approach. If these are lacking, labels from comparable countries that do have proper labels, or other information such as health and safety guides for pesticides might serve as reference.

Models for exposure assessment

Models have been developed to help assess occupational and environmental exposure. These vary from relatively simple to fairly complex. The FAO Pesticide Registration Toolkit (Annex II) provides examples and guidance on their use.

Actual exposure measurements

In some cases, actual exposure to an HHP can be measured. This can be done through direct exposure monitoring (analysing the pesticide on the body of a person when handling the product) or biomonitoring (analysis of the pesticide or one of its metabolites in blood, urine or breastmilk). Exposure measurements tend to be rather complex and expensive studies, and are therefore not often conducted in LMICs.

3.2 Needs assessment

The needs assessment serves to establish to what extent the product is actually needed for its current uses, what specific benefits it provides and whether effective less hazardous alternative pest management approaches or products that pose less risk might be available.

The approach to pesticide risk reduction as described in the FAO Guidelines on Pest and Pesticide Management Policy Development [2010] comprises three main steps (Box 4). The first step involves an assessment of needs.

Box 4 Steps in pesticide risk reduction

1. Reduce reliance on pesticides. Determine to what extent current levels of pesticide use are actually needed and eliminate unjustified pesticide use. Make optimum use of non-chemical pest management practices in the context of sustainable intensification of crop production and integrated vector management.
2. Select pesticides with the lowest risk. If use of pesticides is deemed necessary, select products with the lowest risk to human health and the environment from the available registered products of those that are effective against the pest or disease.
3. Ensure proper use of the selected products for approved applications and in compliance with national regulations and international standards.

A needs assessment involves the following:

- Stock-taking of the uses of identified HHPs and the reasons why they are being used.
- Identification of possible alternatives that are effective and pose less risk, and might substitute for HHPs.
- Review of the need for identified uses of HHPs taking into consideration the available alternatives and economic aspects.

Availability of alternatives

There may often be a perception that HHPs need to remain available because there would be no good alternatives. This can prove to be a misconception that may persist because of user habits or advice based on limited knowledge or by persons with interest in the products concerned. In the majority of cases, there are alternatives that pose less risk. These may include suitable biopesticides or non-chemical pest management approaches, less hazardous chemicals, or different formulations that pose less risk. Pest and vector management based on Integrated Pest Management (IPM) and Integrated Vector Management (IVM) would be preferred. The same applies to other agro-ecologically[10] based production systems, such as organic agriculture.

[10] FAO describes agro-ecology as the science of applying ecological concepts and principles to the design and management of sustainable food systems; Agroecology for food security and nutrition – Proceedings of the FAO International Symposium on Agroecology, 2014, Rome, Italy

Box 5: IPM and IVM Definitions

The Code of Conduct defines IPM as the careful consideration of all available pest control techniques and subsequent integration of appropriate measures that discourage the development of pest populations and keep pesticides and other interventions to levels that are economically justified and reduce or minimize risks to human and animal health and/or the environment. IPM emphasizes the growth of a healthy crop with the least possible disruption to agro-ecosystems and encourages natural pest control mechanisms. A similar definition of IVM is also provided in the Code of Conduct.

A useful approach can be to look at crop protection methods in other countries with similar agronomic conditions that have cancelled the use of certain HHPs. This may provide useful information about the availability and viability of alternatives for these HHPs. Within countries, there may also be areas where alternatives have been successfully introduced and that can serve as examples for other areas.

Nevertheless, there may remain specific cases for which there are no good alternatives to current uses of HHPs. This also may involve certain limited and restricted roles in resistance management strategies. In other specific cases it may be desirable to keep the option open for future use by having a fall back option if alternatives were to lose their effectiveness and there are no other options for control of pests of public health concern or economic significance. If such situations occur, the exceptions should be temporary, whilst new alternatives are being identified.

Economic aspects

Many HHPs are found in the market segment of cheap generic products. Higher prices of less hazardous alternatives are often mentioned as an impediment to their use[11]. The concern being that farmers could not afford the alternatives and be deprived of affordable pest management options, should access to certain HHPs be limited. It is therefore important to understand and carefully consider the costs and benefits of cases where continued use of HHPs is requested.

In order to understand the full costs of HHPs, one should not only look at their purchasing price (taking into account the number of applications needed) but also at all other direct and indirect costs[12]. Direct private costs include the purchasing of appropriate PPE and possible direct health costs for the applicator, including medical expenses and loss of labour time if poisoning occurs. Indirect private costs include the costs of long-term health effects. Indirect public costs include long-term health costs to farming communities and consumers, and environmental costs associated with water contamination and loss of biodiversity, including pollination functions[13]. IPM and IVM tend to reduce the public

[11] Less hazardous alternatives does not only refer to other compounds, but could also include different (often more expensive) formulations that are less hazardous, such as microencapsulated products or water soluble packages, as described in 4.1.3.

[12] For further information on cost factors see Guidance on Pest and Pesticide Management Policy Development [2010].

[13] The UNEP report "Costs of inaction on the sound management of chemicals [2013]" provides indications of the magnitude of long term public costs of inaction in regulating chemicals.

costs. It is the responsibility of governments to balance short term private benefits against long term public costs.

Another factor is the effect of residues on the value of the crop. Residues of highly hazardous pesticides are more likely to render crops unsuitable for consumption or export and as such would pose an income risk to farmers. More expensive low-toxicity products may lower this risk. Consistent application of IPM may even attract a premium on the price of crop or its produce.

Costs of HHPs tend to be under-estimated because of lack of information on health and environmental impacts, which may represent significant public costs. Likewise, benefits tend to be over-estimated due to a lack of information about effective alternatives. To consider the full costs of HHPs one needs to assess the health and environmental costs, the effects on the economic value of crops, and the availability of alternatives and their costs and benefits. The analysis should comprise both private and public costs.

4. MITIGATION

This section outlines the options for mitigating risks of HHPs currently in use and for possible new HHPs. As further explained below, the main lines for risk mitigation are ending, restricting or changing formulations or uses. Selection of the most appropriate option will vary from case to case and depend on risk levels and needs, but also on policies and adequacy of institutional infrastructure for pesticide management.

4.1 Mitigation options

Ending use

For cases where HHPs pose high risks that are difficult to reduce while effective, less hazardous, alternatives are available; the most effective option to mitigate such risks will often be to end its use through regulatory action. This can be done through banning or through cancelling or withdrawing registration, or not extending registration.

Banning is a final regulatory action to prohibit all uses of an active ingredient or product in order to protect human health or the environment. It is usually done for an active ingredient. Once an active ingredient or product is banned, it cannot be registered again, unless the ban is overturned. Cancelling or withdrawing registration prohibits the use of a product, but does not rule out new registrations in the future. This option may be preferred if one would want to retain the possibility to temporarily re-introduce a product, for instance if resistance issues were to arise for the main alternatives, while research into new alternatives is ongoing.

Restricting use

In cases where viable alternatives that pose less risk are not available it may be desirable to restrict the use of the concerned HHP instead of ending it with a regulatory decision. Restrictions can involve the type of users (e.g. only certified users who have received training and possess the correct PPE and application equipment), areas of use (e.g. not close to water bodies), type of use (e.g. only as seed dressing or as stem injection; prohibiting aerial or backpack application; etc.) or type of crop (only for specified crop/pest combinations under strictly controlled circumstances). In practice, it will often be a combination of these types of restrictions. A product could for instance only be permitted for a certain crop/pest, applied in a certain manner by a certified applicator.

Restricting can include severely restricting, which means that virtually all uses of a pesticide are prohibited by regulatory action in order to protect human health or the environment, but that certain specific uses remain permitted.

The effectiveness of restrictions is strongly dependent on the ability to enforce these. Restricting may thus be a less viable option if enforcement capacity is weak.

Changing formulations, packaging or use

Changing formulations, packaging or use can be considered at the level of manufacturer or regulator. It may be possible to change the formulation or packaging in order to reduce the hazard or the exposure risk. Changing formulations can for instance involve lower concentrations or different formulations for different application methods. Examples include: replacement of foliar sprays by granules or seed coatings; microencapsulated formulations to reduce acute toxicity; water soluble packages to avoid handling powdered

or liquid concentrates when mixing; adding co-formulants to make the product less risky; etc. Changing packaging may involve smaller package sizes to avoid storage or package design that reduces risk during mixing.

Usually such changes by the manufacturer require an amendment of the registration. Likewise, registration authorities can use cancellation or withdrawal of registration of certain formulations to change the type of products that are being permitted for use. This way, formulations of a certain ai that pose less risk may be maintained, while others of the same ai that pose higher risk may be terminated. The same applies to amending registrations to change the purposes for which a product is registered or the conditions under which it can be used.

Policy or administrative measures:

Besides regulatory measures, there is a range of policy or administrative measures that can be taken, to directly or indirectly reduce pesticide risks. Users may change practices as a result of awareness raising, training or incentive schemes.

Examples of policy or administrative measures to enhance sustainable pest management that poses less risk:

- Promote IPM and IVM through investment in training, communication and further research, and monitoring of their effectiveness;
- Improve the availability and distribution of low risk biological alternatives;
- Use good agricultural practice schemes and other non-regulatory options to promote substitution of HHPs by pest management approaches and products that pose less risk;
- Consider using financial incentives (e.g. subsidy or taxation instruments) to favour low risk products, such as biological control agents and most biopesticides, over high risk products;

Examples of measures to promote proper use and disposal of pesticides:

- Provide training programmes for pesticide retailers and users in proper selection and use of pesticides. However, it should be noted that long-term effects of farmer training in proper use of pesticides can be limited[14]. One should not rely on such training as a mitigation measure without carefully monitoring its effect. The hierarchy in the three steps in pesticide risk reduction (Box 4) should be taken into consideration.
- Ensure availability of appropriate PPE and application equipment, and support development or introduction of new application technologies that pose less risk;
- Develop schemes whereby pesticides are only available on prescription from a plant protection officer;
- Encourage the development of professional pesticide application services to prevent application by individual farmers. Such schemes may require safeguards against unnecessary applications.

[14] Safe and effective use of pesticides – Use of crop protection products in developing countries, Edited by J. Atkin and K. M .Leisinger, CABI Publishing, 2000.

- Introduce procedures to limit environmental exposure (e.g. timing of application, buffer zones, etc.);
- Work with industry to develop disposal plans for empty containers and, where relevant, obsolete stocks of HHPs.

Examples of policy measures to strengthen regulatory control of pesticides, which will help prevent problems with HHPs:

- Strengthen pesticide legislation and/or ensure its effective implementation and enforcement,
- Strengthen pesticide registration with particularly attention to risk assessment in the registration process (The FAO Pesticide Registration Toolkit -Annex II- can be useful in this respect),
- Establish, monitor and enforce maximum residue limits,
- Institutionalize monitoring of pesticide use and related health and environmental aspects.
- Enhance information sharing with other countries on: incidents with pesticides; regulatory actions taken, experiences with alternatives to HHPs, etc.

For most of the above points, specific guidance is available from the FAO webpages on pest and pesticide management.

Procedure for ending the use of an active ingredient or formulated product

Banning an active ingredient, or cancelling a product registration, usually follows a gradual phasing-out process to allow for phasing in alternatives and to deplete stocks in order to prevent accumulation of stockpiles of obsolete products. The steps typically include:

1. End manufacturing and importation
2. End distribution and sale
3. End use

However, an immediate ban or cancellation may be considered in rare cases when new information indicates unacceptable risk that requires an immediate response. In such cases, arrangements would need to be made for the recall, collection and disposal of remaining stocks.

It is common practice to announce the phasing-out process when a ban is declared. This should involve the time periods granted for phasing out of sales and use. These time periods should be sufficient to clear all stocks from manufacturers and importers before ending distribution and sale, and to clear all stocks at retail level before ending use. They also should be used to inform farmers about alternatives. During phase-out specific risk mitigation measures may be required to minimize risk. This could for instance include restrictions on the use of the pesticide concerned. An effective communication mechanism will be important to inform importers, distributors and users. Informing users about specific risk mitigation measures during phase-out may require targeted efforts. Inspections will be needed to monitor compliance and to prevent illegal importation.

4.2 Selecting a mitigation option

Once a country has an adequate picture of the risks of, and needs for, a specific HHP, the next step would be to carefully consider the pros and cons of the use of that product and the available mitigation measures. Such considerations will be different for each product and each use situation, and thus need to be assessed on a case-by-case basis. In some cases, different uses of one product may need to be considered separately.

When selecting a mitigation option, attention should be paid to the practicality and effectiveness of the proposed mitigation option as some may be less feasible under the conditions of use in the country concerned. The FAO Pesticide Registration Toolkit provides useful examples of criteria for determining the effectiveness of mitigation measures.

Some of the questions and factors to consider include:

1. Is the identified HHP still being used? In some countries, certain HHPs may still be registered while they may have been unavailable and unused for a considerable time. If such products are no longer needed then there may be no reason to maintain their registration.

However, in some specific cases it may be desirable to retain the option to allow use a product at a later time should a specific emergency develop that deems such use necessary. In such cases, a restriction may be preferred over ending use.

2. What is the reason the product concerned qualifies as a HHP? In cases where pesticides qualify as HHP because the active ingredient is listed under the Stockholm Convention or Montreal Protocol, there is an international obligation to reduce the risk by eliminating the use if the country is a Party.

3. Does the country have established criteria or policy on what it considers unacceptable risk? There may be provisions in the pesticide, health, environmental or labour legislation that provide such criteria. Some countries, for instance, would consider any exposure to carcinogenic (causing cancers), mutagenic (causing damage to genes) or teratogenic (disrupting the development of the embryo or foetus) products as unacceptable and consider these as "hazard cut-off criteria" which means that they are eliminated on the basis of intrinsic hazard and that further risk assessment is not needed. Countries that do not have unacceptable risk criteria are recommended to establish protection goals and associated unacceptable risk criteria based on the specific requirements of the country and the local situation. The FAO Pesticide Registration Toolkit (Annex II) provides guidance in this respect.

4. How broad is usage, who are the users, what are the current use practices and are nation-wide improvements feasible in the short term? If it is not considered feasible to reduce risk through exposure reduction in a manner that can be implemented by large groups of users throughout the country in the short term, then that may limit the choice of mitigation options to cancellation or restriction. For many countries, the objective will be to phase out access to HHPs by users who are not in a position to handle these products within risk margins that are considered as acceptable.

5. Are less hazardous alternatives available that provide effective pest management and are cost-effective? A possible outcome could be cancellation of registrations for HHPs if

effective, less hazardous, alternatives are available. It could also lead to recognition that certain HHPs remain needed because they provide specific benefits, while adequate alternatives are not yet available. In the latter case, restrictions and strict risk mitigation measures would need to be considered. In addition, specific research or policy towards identification and implementation of alternatives may be initiated. This may include incentives to encourage development of alternatives.

5. PLANNING

5.1 Designing an action plan

Efforts to address HHPs can best be stream-lined by designing a plan of action that includes the main steps as described above and summarised below:

- Identify which registered pesticides are to be considered HHPs,
- Take stock of the current uses of these HHP and the reasons for their use,
- Determine to what extent their use is actually needed (taking into account the availability of possible alternatives),
- Determine risks, taking into account the conditions of use,
- Select and implement mitigating measures,
- Monitor and review the effectiveness of the mitigation measures.

Further it should:

- Identify the main actors and other stakeholders (who),
- Assign tasks and responsibilities (what),
- Establish a time frame (when),
- Establish a coordination mechanism. This could for instance involve an inter-departmental working group and/or a stakeholder platform,
- Establish an outreach and communication strategy.

Besides following these steps to specifically address HHPs, the action plan may also consider broader interventions to strengthen pest and pesticide management as listed above under policy and administrative measures. Such measures would help prevent further issues with HHPs.

5.2 Communication and stakeholder involvement

Effective communication is important to raise awareness about risks associated with pesticides and mitigation measures, including alternatives for agricultural pesticides, this should not only be aimed at growers, but also at food retailers and consumers to enable them to make informed choices.

Identification, reporting and communication of issues related to HHPs under field use situations is important to develop an understanding of issues and products that require attention from regulators and policy-makers. Regulators may want to consider providing special schemes or arrangements for incident reporting involving pesticides.

Communication is also important to prepare all entities in the pesticide supply chain for changes if regulatory or other changes are made concerning HHPs, which could involve cancellations or changes in usage to mitigate risk.

Communication needs to be clear and credible and information thus needs to be accurate and appropriate. In order to ensure this, countries may wish to establish a specific communication strategy in relation to HHPs[15].

Articles related to communication in the Code of Conduct on Pesticide Management

Governments and the pesticide industry should cooperate in further reducing risks by: (Article 5.3.5) raising awareness and understanding among pesticide users about the importance and ways of protecting health and the environment from the possible adverse effects of pesticides.

Article 5.4: Entities addressed by the Code of Conduct consider all available facts and should promote responsible information dissemination on pesticides and their uses, risks and alternatives.

Further, there are international communication requirements for Parties to the Rotterdam Convention to report regulatory actions for health or environmental reasons and to report major incidents.

Broad stakeholder involvement in needs and risk review of HHPs will contribute to balanced decisions. Involving growers, researchers, input suppliers and civil society organisations in needs assessments will help find viable alternatives or other risk mitigation measures if viable alternatives are not yet available. For public health pesticides, such reviews should involve epidemiologists.

[15] Useful guidance is provided by the OECD Guidance document on risk communication for chemical risk management [OECD 2002] and the European Chemicals Agency in Guidance on the communication of information on the risks and safe use of chemicals [ECHA 2010]

6. PREVENTION

6.1 Registration

To prevent future problems with HHPs, the registration system for pesticides may need to be revised . This may involve:

- Defining protection goals and unacceptable risks in the pesticide legislation.
- Strengthening of registration procedures and in particular the assessment of risk.
- Adding registration considerations based on the HHP criteria. This could, for example, include not registering products that fall under GHS Category I, or adding restrictions or conditions of approval that ensure products whose handling and application require the use of PPE that is uncomfortable, expensive or not readily available, are not accessible to small scale users and farm workers in hot climates.
- Requiring the periodical review of registered pesticides and initiating a registration review where monitoring, field surveillance, new scientific information, or new information from comparable countries indicates high risks, e.g.,because of relatively high numbers of adverse incident.
- Pro-actively favouring registration of products that pose less risk where such alternatives are viable and available. In this respect, particular attention should be given to encouraging the use of biological control.

For further guidance on strengthening pesticide registration reference is made to the FAO/WHO Guidelines for the Registration of Pesticides [2010] and the FAO Pesticide Registration Toolkit (Annex II).

6.2 Enforcement

Enforcement of pesticide legislation may need to be strengthened to prevent illegal production, importation, trade and use. If withdrawals or restrictions are used as a mitigation measure, then there would need to be an effective monitoring and enforcement system to ensure compliance. The Guidelines on compliance and enforcement of a pesticide regulatory programme [2006] provide further guidance.

6.3 Training

Extensive training programmes for pesticide retailers and pesticide users on correct selection of products and proper use, including use of protective equipment, will help reduce risk. Of particular importance is training in IPM and IVM, or other agro-ecological based pest management approaches that reduce reliance on pesticides.

6.4 Surveillance

Surveillance systems need to be put in place to monitor use of HHPs and the effectiveness of risk mitigation measures. Guidance on setting up such monitoring systems is provided in the WHO/FAO Guidelines on Developing a Reporting System for Health and Environmental Incidents Resulting from Exposure to Pesticide [2009]. Entities that could play a role in monitoring and reporting include: agricultural extension staff, decentralised crop protection staff, NGOs working with communities in rural areas, vector control programme staff, rural health posts and provincial hospitals, etc. If the effectiveness of a

chosen risk mitigation measure is found to be insufficient, other mitigation measures would need to be considered. This is particularly the case when administrative or policy based mitigation measures have been chosen, such as for instance training in proper use. In some cases, where new, less hazardous, products are introduced as alternatives, plant protection staff may also need to monitor the effectiveness of these.

FURTHER TOOLS AND REFERENCES

Tools

FAO aims to make available further tools to assist with the implementation of these guidelines. These will be posted on the FAO webpage on technical guidelines in support of the Code of Conduct. Envisaged tools include:

I The FAO Pesticide Registration Toolkit for guidance on risk assessment.

II Reference lists for the identification of HHPs

III Case studies on phasing out of HHPs

Key references

ECHA [2010] Guidance on the communication of information on the risks and safe use of chemicals [ECHA 2010]

FAO/WHO [2015] Guidelines on pesticide legislation, Food and Agriculture Organization and World Health Organization of the United Nations.

FAO/WHO [2013] International Code of Conduct on Pesticide Management. (Revision of the earlier Code of Conduct on the Distribution and Use of Pesticides). Food and Agriculture Organization and World Health Organization of the United Nations.

FAO [2010] Guidance on pest and pesticide management policy development, Food and Agriculture Organization of the United Nations.

FAO/WHO [2010] Guidelines for the registration of pesticides, Food and Agriculture Organization and World Health Organization of the United Nations.

FAO/WHO [2009] Guidelines on developing a reporting system for health and environmental incidents resulting from exposure to pesticide, Food and Agriculture Organization and World Health Organization of the United Nations.

FAO/WHO [2008] Report of the 2nd FAO/WHO Joint Meeting on Pesticide Management (which established the HHP criteria)

GHS [2015] Globally Harmonized System of Classification and Labelling of Chemicals (GHS). 6th Revised edition. Part 3 – Health hazards. United Nations, New York and Geneva.

OECD [2002] OECD Guidance document on risk communication for chemical risk management, Paris, Organisation of Economic Co-operation and Development.

UNEP [2013] Costs of inaction on the sound management of chemicals. United Nations Environmental Programme. Geneva. [accessed 4 October, 2013]

UNEP [2013] Stockholm Convention on Persistent Organic Pollutants

UNEP/FAO [2013] Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade. []

WHO [2010] WHO classification of pesticides by hazard and Guidelines to classification , 2009. World Health Organization, Geneva.

List of hyperlinks embedded in the text of this document:

FAO webpages on pest and pesticide management	http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/code/list-guide-new/en/
FAO/WHO International Code of Conduct on Pesticide Management [2013]	http://www.fao.org/docrep/meeting/027/mg095e.pdf
FAO Guidelines on Pest and Pesticide Management Policy Development [2010]	http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/Code/Policy_2010.pdf
FAO/WHO Guidelines for the Registration of Pesticides [2010]	http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/Code/Registration_2010.pdf
FAO Pesticide Registration Toolkit	http://www.fao.org/pesticide-registration-toolkit/tool
Guidelines on compliance and enforcement of a pesticide regulatory programme [2006]	http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/Code/Compliance.pdf
WHO/FAO Guidelines on Developing a Reporting System for Health and Environmental Incidents Resulting from Exposure to Pesticide [2009]	http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/Code/Incidentreporting09.pdf
OECD Guidance document on risk communication for chemical risk management [2002]	http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono%282002%2918&doclanguage=en
Globally Harmonized System of Classification and Labelling of Chemicals [2015]	http://www.unece.org/fileadmin/DAM/trans/danger/publi/ghs/ghs_rev06/English/03e_part3.pdf
Stockholm Convention	http://chm.pops.int/
Rotterdam Convention	http://www.pic.int/
Montreal Protocol	http://ozone.unep.org/en/handbook-montreal-protocol-substances-deplete-ozone-layer/44
ECHA Classification and Labelling Inventory	https://echa.europa.eu/information-on-chemicals/cl-inventory-database
EU common registration system	http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.selection&language=EN
ECHA Guidance on the communication of information on the risks and safe use of chemicals [2010]	https://echa.europa.eu/documents/10162/13639/risk_communications_en.pdf
IARC monographs on the evaluation of carcinogenic risks to humans	http://monographs.iarc.fr/ENG/Classification/index.php
USEPA National Pesticide Information Center	http://npic.orst.edu/chemicals_evaluated.pdf
UNEP Costs of inaction on the sound management of chemicals [2013]	http://www.unep.org/chemicalsandwaste/Portals/9/Mainstreaming/CostOfInaction/Report_Cost_of_Inaction_Feb2013.pdf

ANNEX I: FURTHER DETAILS AND REFERENCE SOURCES REGARDING THE HHP CRITERIA

Criterion 1: Acute Toxicity

The main reference is the WHO Recommended Classification of Pesticides by Hazard:

It is important to note that the hazard classification should concern the formulated product. The classification of the formulated product can be estimated if it is not provided by the manufacturer. The main tables in the above mentioned document provide the hazard classification for active ingredients, which then needs to be adjusted for the actual concentration of the formulated product concerned. Conversion tables in its Annex can then be used to establish the actual hazard classification of the formulated product concerned.

Criteria 2/4: Chronic Toxicity

The main reference is the Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

The table below provides an overview of the relevant GHS classifications

	Category		Description	Hazard statement
Carcinogenicity	1		Known or presumed human carcinogen.	
		1A	Known to have carcinogenic potential for humans; the placing of a substance is large based on human evidence.	May cause cancer
		1B	Presumed to have carcinogenic potential for humans; the placing of a substance is largely based on animal evidence.	May cause cancer
Mutageneicity	1		Substances known to induce heritable mutations or to be regarded as if they induce heritable mutations in the germ cells of humans.	
		1A	Substances known to induce heritable mutations in germ cells of humans.	May cause genetic defects
		1B	Substances which should be regarded as if they induce heritable mutations in the germ cells of humans.	May cause genetic defects
Reproductive Toxicity	1		Known or presumed human reproductive toxicant	
		1A	Known human reproductive toxicant	May damage fertility or the unborn child
		1B	Presumed human reproductive toxicant	May damage fertility or the unborn child

Unlike the WHO hazard classification, the GHS does not provide lists of pesticides and their classification. This information needs to be found elsewhere. The table below lists some of the main information sources:

	Carcinogenicity	Mutagenicity	Reproductive toxicity	Provide GHS classification
International Chemical Safety Cards (WHO\ILO)	×	×	×	indirect
Pesticide Database of the European Union	×	×	×	×
European Chemicals Agency (ECHA) – Classification and Labelling Inventory	×	×	×	×
OECD e-Chem Portal	×	×	×	×
IARC Monographs (WHO)	×			
US-EPA National Pesticide Information Center	×			

The **International Chemical Safety Cards (ICSC)** are available from an online database that is maintained by the WHO and ILO. The database aims to provide the GHS classification for all pesticides, but this may still be missing for some of the older pesticides that have not yet been re-evaluated. The ICSC database does not provide the GHS carcinogenicity Category for 1A and 1 B, but rather the hazard statements for those classes (See table above).

The **Pesticide Databases of the European Union** provides information on plant protection products that have been reviewed through the EU common registration system. This includes information on the GHS classification. Information about pesticides not reviewed, or not registered, is not included in this database. That information can be found in the ECHA CL (see below), which also provides classification of biocides (i.e. not plant protection products).

European Chemicals Agency (ECHA) – Classification and Labelling Inventory (C&L) provides the hazard classification of chemicals, including pesticides, which have been reviewed in the EU (even if these are not authorized). The ECHA Classification and Labelling Inventory consistently follows the GHS. The FAO Pesticide Registration Toolkit (Annex II) explains how information can be found in the ECHA\C&L.

The **OECD e-Chem Portal** can be used for many of the above sources, and has recently initiated a special search modality for GHS classifications in the participating databases.

The following sources provide information about carcinogenicity, but do not use the GHS classification.

The **IARC Monographs.** These monographs on the evaluation of carcinogenic risks to humans are prepared by the International Agency for Research on Cancer (IARC), which is part of WHO.

The **Integrated Risk Information System of the US-EPA** also provides information on carcinogenicity of pesticides, but is more difficult to use as it assigned different classifications and criteria for different review periods. It does not use the GHS classification. The results of reviews for carcinogenicity are published in the List of

Chemicals Evaluated for Carcinogenic Potential. This list is made available on the website of the National Pesticide Information Center

Criterion 5: Stockholm Convention

Pesticides listed in Annexes A and B. The criteria of what may constitute a POP are listed in Annex D.

Criterion 6: Rotterdam Convention Pesticides listed in Annex III

Criterion 7: Montreal Protocol Pesticides listed under the Montreal Protocol. Up to the time of publication of these guidelines, the only listed pesticide was methyl bromide.

Criterion 8: High incidence of severe or irreversible adverse effects

Whether a product falls under this criterion is at the discretion of the national regulatory authority and will vary from country to country, depending on the use circumstances and the availability of reliable data.

ANNEX II: THE FAO PESTICIDE REGISTRATION TOOLKIT

The FAO Pesticide Registration Toolkit is a decision support system for pesticide registrars in lower and middle-income countries. It assists registrars in the evaluation for authorization of pesticides and review of registered pesticides.

The Toolkit can best be considered as a web-based registration handbook intended for day-to-day use by pesticide registrars. It supports and facilitates informed decision-making by registrars, but is not an automated system that suggests decisions for registrars.

Registrars can use the Toolkit to support several of their regular tasks. With respect to highly hazardous pesticides (HHPs), the Toolkit can be used as an aid to implement the three steps described in these guidelines: Identification, Assessment and Mitigation. The Toolkit for instance provides methods and resources for:

- **Conducting risk assessments,** both for human health and environmental effects, using broadly accepted methods or existing assessments from reputable registration authorities. [see the *Assessment Methods* tool in the left column of the screen shot below]. It aims to provide assessment methods at different levels of complexity. These range from generic methods requiring limited resources, to more locally specific risk assessment methods.
- **Finding pesticide-specific information**, such as registration status of pesticides in other countries, scientific reviews, hazard classifications and pesticide properties. [See the *Information Sources* column in the screenshot below)]
- **Decision making on risk mitigation options,** including practical guidance on how to take local conditions into consideration. (See the Toolkit Column in the screenshot below)

The FAO Pesticide Registration Toolkit can be accessed at:
http://www.fao.org/pesticide-registration-toolkit/tool