International Code of Conduct on the Distribution and Use of Pesticides

Guidelines for the Registration of Pesticides

World Health Organization

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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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Abbreviations

CBI	Confidential Business Information
CILSS	Comité Permanent Inter Etats de Lutte contre la Sécheresse au Sahel (Permanent Interstate Committee for Drought Control in the Sahel)
CRA	Comparative Risk Assessment
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
IPM	Integrated Pest Management
IVM	Integrated Vector Management
JMPR	Joint Meeting on Pesticide Residues
NAFTA	North American Free Trade Agreement
OECD	Organization for Economic Co-Operation and Development
PRD	Proprietary Rights Data
SAICM	Strategic Approach to International Chemicals Management
UN	United Nations
WHO	World Health Organization
WHOPES	World Health Organization Pesticide Evaluation Scheme

Definitions

Active ingredient means the biologically active part of the pesticide.

Applicant means the party (producer, importer or their representative) that makes an application for registration of a pesticide to the Responsible Authority.

Banned pesticide means a pesticide for which all uses have been prohibited by final regulatory action, in order to protect human health or the environment. The term 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.

Equivalence means the determination of the similarity of the impurity and toxicological profile, as well as of the physical and chemical properties, presented by supposedly similar technical material originating from different manufacturers, in order to assess whether they present similar levels of risk.

Formulated pesticide product means any formulation containing one or more active ingredients.

Formulation means the combination of various ingredients designed to render the product useful and effective for the purpose claimed; the form of the pesticide as purchased by users.

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 human and animal health, the environment or property).

Minor uses are those uses of plant protection products in which either the crop is considered to be of low economic importance at national level (minor crop), or the pest is not important on a major crop (minor pest)

Pesticide[1] means any substance, or mixture of substances, or micro-organisms including viruses, intended for repelling, destroying or controlling any pest, including vectors of human or animal disease, nuisance pests, unwanted species of plants or animals causing harm during or otherwise interfering with the production, processing, storage, transport, or marketing of food, agricultural commodities, wood and wood products or animal feeding stuffs, or which may be administered to animals for the control of insects, arachnids or other pests in or on their bodies. The term includes substances intended for use as insect or plant growth regulators; defoliants; desiccants; agents for setting, thinning or preventing the premature fall of fruit; and substances applied to crops either before or after harvest to protect the commodity from deterioration during storage and transport. The term also includes pesticide synergists and safeners, where they are integral to the satisfactory performance of the pesticide.

Pesticide Board (sometimes referred to as Pesticide Registration Board, Pesticide Council or Pesticide Committee) is the officially or legally appointed body that takes the final decision on the request for registration.

[1] For the purpose of this guideline, the definition of pesticide provided in the Manual on development and use of FAO and WHO specifications for pesticides [11] is used, rather than the definition in the Code of Conduct, as the former better reflects all the different types of pesticides that a registration procedure should comprise.

Pesticide industry means all those organizations and individuals engaged in manufacturing, formulating or marketing pesticides and pesticide products.

Pesticide registration means the process whereby the responsible national government or regional authority approves the sale and use of a pesticide following the evaluation of comprehensive scientific data demonstrating that the product is effective for its intended purposes and does not pose an unacceptable risk to human or animal health or the environment.

Product (or pesticide product) means the pesticide active ingredient(s) and other components, in the form in which it is packaged and sold.

Registration dossier means the set of data that is submitted by applicants, in a structured manner, in support of their application for registration.

Responsible Authority means the government agency or agencies responsible for regulating the manufacture, distribution or use of pesticides and, more generally, for implementing pesticide legislation.

Risk is a function of the probability of an adverse health or environmental effect, and the severity of that effect, following exposure to a pesticide.

Severely restricted pesticide means a pesticide for which virtually all use 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 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.

1. Introduction

Registration of pesticides is the process whereby the responsible national government or regional authority approves the sale and use of a pesticide following the evaluation of comprehensive scientific data demonstrating that the product is effective for its intended purposes and does not pose an unacceptable risk to human or animal health or to the environment.

Registration is an important step in management of pesticides as it enables authorities primarily to determine which products are permitted to be used and for what purposes, and also to exercise control over quality, use levels, claims, labelling, packaging and advertising of pesticides, thus ensuring that the interests of end-users as well as the environment are well protected.

It is emphasized that registration also involves regular or unscheduled review of already registered pesticides to determine whether they still meet the requirements, for instance after relevant new information has become available or when criteria are being adjusted. Registration criteria should take full account of local circumstances and needs, social and economic conditions, levels of literacy, climatic conditions and availability of appropriate and affordable pesticide application and protective equipment.

Governments should introduce the necessary legislation for the regulation of pesticides. This should include the establishment of a registration procedure and the principle that the sale and use of pesticides that have not been registered are prohibited. Furthermore, governments should make provision for effective monitoring and enforcement of pesticide regulations, including the establishment of licensing and inspection schemes for importers and retailers.

The *International Code of Conduct on the Distribution and Use of Pesticides* [1] (further referred to as the Code of Conduct) describes the shared responsibility of many segments of society, including governments, industry, trade and international institutions. The Code of Conduct, originally adopted in 1985 by the Food and Agriculture Organization of the United Nations (FAO) Conference and revised in 2002, promotes sound pesticide management practices that minimize potential risks to human health and the environment. The revised Code of Conduct includes the life-cycle approach to pesticide management and calls upon all private and public entities to support its implementation. The Code of Conduct provides a framework for management of all pesticides, including those intended for use in agriculture and public health.

The purpose of this document is to provide general advice on principles and process as well as requirements for registration of pesticides, including institutional and administrative organization. The guidelines highlight the vital role of intersectoral and intrasectoral collaboration in the registration of pesticides and highlight the important collaborative role of the health, environment and agriculture sectors in this effort. These guidelines are not intended to give in-depth technical guidance on most of the registration requirements; separate guidelines have been developed or are under development for this purpose by FAO [2] and/or the World Health Organization (WHO) [3]. These guidelines also constitute an important contribution towards the work of the Strategic Approach to International Chemicals Management (SAICM).

The increasing complexity of evaluation and assessment of pesticides and their management requires substantial resources and adequate national infrastructure, which includes well-trained personnel in the various fields of pesticide management. The guidelines therefore

promote the establishment of a single national authority for registration of all pesticides to optimize the use of limited resources available in most countries.

The guidelines also promote transparency and exchange of information in the pesticide registration process as well as in monitoring and evaluation post-registration in order to, among other things, prevent duplication of efforts by other regulatory authorities as well as to inform all stakeholders about the risks of pesticides. Furthermore, the guidelines promote the advantages of establishing harmonized (by region or subregion) pesticide registration requirements, procedures and evaluation criteria.

A well-developed and managed legislation on pesticides, of which pesticide registration forms a key part, is crucial in the proper and effective management, regulation and control of pesticides in a country. Such legislation should include provisions for the management of the different aspects of pesticides throughout their life-cycle and include aspects related to manufacture, import, export, sale, storage, quality control, residues, licensing of pesticide vendors and professional pest control operators, advertising, quality control, packaging, disposal and use [4].

An effective and efficient pesticide registration scheme should ensure that only approved pesticides are sold and used in the country. Poor-quality pesticides should also be prevented from entering the local market through effective enforcement of the legislation.

A well-defined and structured registration scheme will also identify procedures for the collaboration of all relevant stakeholders in the registration and management of pesticides.

Governments should design procedures suited to their own specific requirements and need not necessarily adopt all the elements of a comprehensive regulatory scheme as operated in countries with extensive resources. These guidelines therefore also contain a section on guidance to countries with limited human and financial resources. However, all countries in which pesticides are used should have in operation an effective scheme for registering, managing and controlling pesticides. Such a scheme can assist governments in ensuring that pesticide use does not result in unreasonable risk to human health, livestock and the environment.

2. Pesticide registration

2.1 Scope of the guidelines

These guidelines are intended to cover the registration of all types of pesticides, as defined in the Definitions section, used in various sectors including agriculture, public health, forestry, animal husbandry and fishery. They also encompass the principles of registration, both legislative and administrative, as w ell as the technical requirements for introducing and managing an efficient registration scheme.

2.2 Objective of registration

The objective of pesticide registration is to ensure that pesticides imported, manufactured and placed on the market are effective for their intended purpose and do not pose unacceptable risk to human or animal health or the environment.

The outcome of the registration process may be provisional or full registration, with or without restrictions or conditions, or refusal of registration. Equally important is that registration can be cancelled if new information warrants such action.

Legislation should have provisions for issuance of permits by the responsible authority for experimental as well as emergency use of pesticides.

2.3 Responsibilities

Various sectors of the community have varying responsibilities in the registration of pesticides as well as related post-registration activities, including as follows:

Governments should:

(a) establish a legal system for the management (including registration) of pesticides. In so doing, they should take full account of local needs, social and economic conditions, levels of literacy, climatic conditions and availability of appropriate pesticide application and personal protective equipment;

(b) create the technical and administrative infrastructure to manage applications for registration;

(c) maintain a dialogue with the applicant on all matters related to registration, e.g. when additional information is required;

(d) grant or refuse registration in a timely and transparent manner;

(e) set up systems that allow for appropriate checks and balances in decision making, including appeal procedures, during registration;

(f) conduct risk evaluations and make risk management decisions based on all available data or information, as part of the registration process, taking into account potential needs to protect sensitive groups and ecosystems or important environmental resources such as drinking-water reservoirs;

(g) establish and implement appropriate enforcement systems;

(h) establish and maintain a system for monitoring of pesticide use under actual conditions ("post registration surveillance");

(i) establish a re-registration procedure to ensure the periodic review of pesticides, so that prompt and effective measures can be taken if new information or data on their performance or risk indicate that regulatory action, which may include the cancellation of registration, is required. The procedures may vary from country to country depending on needs and available resources;

(j) conduct unscheduled review of registered pesticides if new information about actual use practices or health or environmental risks warrants such a review, thus ensuring that prompt and effective measures can be taken if new information or data on performance or risks indicates that regulatory action is needed;

(k) detect and control trade in illegal and counterfeit pesticides;

(l) as far as capacity permits, collect and record data on the import, export, manufacture, formulation, quality, quantity and use of pesticides in order to assess the extent of any possible adverse effects on human health or the environment, and to follow trends in pesticide use for economic and other purposes;

(m) promote the advantages of, and cooperate with other governments in, the establishment of harmonized (regionally or by groups of countries) pesticide registration requirements, procedures and evaluation criteria, taking into account appropriate, internationally agreed technical guidelines and standards and, where possible, incorporate these standards into national or regional legislation;

(n) comply with the requirements of relevant multilateral agreements to which the country has agreed, or use such multilateral agreements as guidance for the control and management of chemicals. Examples may include the Rotterdam and Stockholm Conventions and the Montreal Protocol.

Pesticide industry should:

(a) apply for registration, supplying all information as specified by the responsible authorities ("registration dossier");

(b) provide an objective pesticide data assessment, together with the necessary supporting data on the product, including sufficient data to support risk assessment and to allow a risk management decision to be made;

(c) provide the responsible authorities with any new or updated information of a pesticide that may have a bearing on the registration, for review of its registration status as soon as such information becomes available;

(d) ensure that the active ingredient(s) and other ingredients of a pesticide product correspond in identity, quality, purity and composition to the substances tested, evaluated and cleared for toxicological and environmental acceptability;

(e) ensure that the active ingredient(s), and formulated pesticides for which international specifications have been developed, conform with the relevant FAO specifications for agricultural pesticides and with WHO pesticide specifications for public health pesticides;

(f) refrain from putting any product, subject to registration, on the market prior to the approval by the responsible authorities to do so;

(g) strictly comply with the conditions, as specified in the registration, as granted by the responsible authorities;

(h) provide draft labels and other forms of information, such as safety data sheets, which are fully consistent with all registration requirements and legislation;

(i) provide all relevant information to vendors and users;

(j) provide all relevant information to inspection services, customs and other authorities and follow carefully the requirements specified in the regulations;

(k) set up or participate in supply chain responsibility schemes, including forms of product stewardship. This may include schemes operated jointly and collectively by all stakeholders (including private waste disposal companies) designed to take back surplus pesticides and empty containers for safe disposal;

(l) provide their national responsible authorities with data on export, import, manufacture, formulation, sales, quality and quantity of pesticides;

(m) take voluntary corrective action when problems occur and, when requested by governments, help find solutions to problems.

Pesticide vendors should:

(a) ensure that they supply only registered pesticides to users;

(b) inform buyers about any restrictions that may apply to the use of the product;

(c) strictly follow all instructions as specified in the registration, in particular the label and other relevant documents such as safety data sheets;

(d) ensure that all instructions specified in the pesticide legislation about storage and sale are followed while the pesticide is in their custody;

(e) keep records of sale, if required;

(f) fully inform customers of the proper use and handling, as specified on the label, and on disposal of containers and other safety precautions for pesticides in their custody;

(g) ensure that registered pesticide products are not re-packaged or re-labelled;

(h) participate in product stewardship programmes as may be developed by industry, importers or other stakeholders.

Pesticide users should:

(a) adhere to restrictions related to the use of the product and use it only for its purposes as specified on the label;

(b) strictly follow instructions for storage, use, precautions and disposal as specified on the label or other information documents such as safety data sheets;

(c) strictly apply the pesticide according to label instructions, including observing correct dosage, safety precautions and use of personal protective equipment;

(d) ensure that proper personal and environmental precautions are followed during application;

(e) notify the responsible authority of any adverse effects such as poisoning incidence during the application of pesticide;

(f) maintain records and report use of restrictive pesticides as required under the law;

(g) safely dispose of any surplus pesticide or empty container as advised on the label or stipulated by local regulations while in their possession.

Academia and Research Institutes should:

(a) where in the position to do so, carry out research to:

- better understand the health and environmental risks under circumstances of use in the country concerned;
- identify lower risk alternatives for higher risk products;
- improve use practices to reduce quantities applied and risks;
- include official trials to support the appropriate use of pesticides

(b) ensure that studies are adequately and effectively performed using recognized procedures and test methods.

Organizations of Civil Society should:

(a) collaborate with other stakeholders such as the government and pesticide industry in promoting pesticide use and risk reduction. Careful selection of pesticides and their proper use are an important element of this;

(b) monitor the use and effects of the use of pesticides and report results to the responsible authority.

International Organizations should:

(a) provide information on specific pesticides (including guidance on methods of analysis) through the provision of criteria documents, fact sheets, training and other appropriate means;

(b) within available resources, consider assisting in the establishment of analytical laboratories, or strengthening existing laboratories, in pesticide importing countries, either on a national or a regional basis. These laboratories should adhere to sound scientific procedures and guidelines for good laboratory practice, should possess the necessary expertise and should have adequate analytical equipment and supplies of certified analytical standards, solvents, reagents and appropriate, up-to-date analytical methods.

3. Principles of pesticide registration

Responsible authorities, in managing their national or regional registration schemes, should follow a number of important principles that are practised internationally. The acceptance and use of these principles will ensure greater efficiency, transparency and optimal use of resources in the registration process. They include the following:

- comprehensive, harmonized and clear registration requirements and criteria;
- use of all available information and mutual acceptance of data;
- transparency and exchange of information;
- science-based assessment to determine whether precautionary approaches are warranted;
- consideration of hazard;
- risk assessment and mitigation based on the local situation;
- risk–benefit analysis, taking into consideration the availability of alternatives;
- post-registration monitoring and evaluation;
- mechanisms for periodic and unscheduled review in order to respond to new information that may affect the regulatory status;
- protection of intellectual property rights of the application.

The evaluation of the data submitted in the registration dossier should follow internationally accepted and agreed evaluation standards and procedures in as much as these are available.

These standards should be regularly updated to ensure conformity with current scientific developments.

It is essential that all steps in the registration process are transparent, based on sound and published criteria and guidance documents, with full information shared with the applicant on the outcomes of the various steps in the registration procedure. Responsible authorities should ensure that the criteria and requirements for registration are comprehensive and clearly defined. The same applies to the standards for acceptance of data, for the quality of data, for the acceptability of formulated pesticide products for specified uses and users, or for the criteria for degradability or accumulation.

Governments should facilitate exchange of information between responsible authorities through national institutions, international, regional and subregional organizations as well as public sector groups. They should develop legislation and regulations to permit information exchange to the public about pesticide risks and benefits as well as to facilitate the participation of the public in the management of pesticides in the country.

Responsible authorities should, whenever possible, make use of data that have been released publicly, and that preferably have been peer-reviewed, when considering an application for registration. In this way, duplication of work and inefficient use of resource can be minimized. Mutual acceptance of data by several regulatory authorities on topics such as efficacy and residues, among others, is recommended whenever a sound basis can be established to ensure that the data is relevant to the situation being considered..

In addition, hazard assessments are generally applicable globally and are available from published sources, including the peer-reviewed assessments of the FAO/WHO Joint Meeting on Pesticide Residues (JMPR). These may be used in the evaluation of a dossier, as long as data propriety is adequately taken into account.

Countries should fully evaluate pesticide efficacy, behaviour, fate, hazard and risk with regard to the various anticipated conditions of use in their country. Any registration procedure should include evaluation of the potential risks related to the use of the pesticide for which registration is sought. The instructions for use, as given on the label, should cover these risks and prescribe measures for proper application, storage, handling and disposal to mitigate such risks. In doing so, the responsible authorities should also ensure that these measures could be realistically adopted by the user for whom the product is intended. Consideration should also be given to specific requirements under national policies for Integrated Pest Management (IPM) [5] and Integrated Vector Management (IVM) [6].

The responsible authority should also use risk–benefit analysis as one of the principles in the consideration for registration of a pesticide. Under certain circumstances, this analysis may have to include evaluation of the potential impact of using the pesticide compared with that of not using it, or comparison of potential risks and benefits of the product under evaluation with other already registered pesticides or locally available pest management options.

The registration system may also incorporate innovative approaches that can contribute to risk reduction and greater efficiency in the registration process. Examples may include comparative risk assessment to ensure that lower risk products are selected, substitution to favour lower risk product registration, fast tracking for products known to be low risk and equivalence to permit diversification of products in the market place that can be considered identical in their chemistry. These approaches and others are described in more detail in section 8.

A pesticide registration scheme should also include an effective post-registration monitoring and evaluation programme, as it plays a very important role in ensuring that the main

objective of registration to prevent unacceptable risk to human health and the environment is achieved. It involves follow-up monitoring activities to assess whether the registered product is used for the approved purposes and is properly handled, distributed and of good quality. Post-registration monitoring should also provide information on the occurrence of any adverse effects on human health or the environment, inadequate efficacy, resistance development or non-compliance with maximum residue limits. It provides a means of measuring the validity of predictions, based on registration data, regarding human and environmental safety and efficacy of a particular pesticide.

Governments should establish a re-registration procedure to ensure periodic review of active ingredients and formulated pesticide products. The level of detail of periodic review may vary, however, and will depend in part on available resources. In addition, there should be a possibility of unscheduled review if new information warrants such a review, thus allowing for prompt and effective measures to be taken in response to (i) concerns based on data and information from post-registration monitoring of the real situation in practical use and from other sources, (ii) new scientific insights about the hazard of products to human health or the environment, (iii) regulatory action taken in other countries regarding the permitted use or permitted residue levels, and (iv) inclusion in relevant annexes of the Rotterdam and Stockholm Conventions.

4. Outline of the pesticide registration process

The registration process includes the following major steps for the first-time registration: (i) preparation and submission of the dossier by the applicant; (ii) initial administrative actions by the responsible authority; (iii) completeness check; (iv) technical and scientific evaluation; (v) preparation of summaries and conclusions; (vi) risk management and registration decision; (vii) publication and dissemination of registration decision; and (viii) label extension.

Besides first-time registration, the registration process also involves:

- further review if amendments to uses, use instructions or label are proposed;
- reconsideration of registration status at the end of the period for which initial registration was granted;
- unscheduled review of registered pesticides if new information warrants such a review;
- cancellation of registration for a variety of reasons, as elaborated below.

The description of the registration process below concerns a comprehensive registration scheme. Many countries will not have the human and financial resources to establish such a scheme in the short term. Chapter 12 provides guidance on the phased introduction of pesticide registration for countries with limited resources. In any case, the actual elements and stages of the registration process applicable in a given country should be published by the responsible authority.

4.1 Registration process

4.1.1 Preparation and submission of the dossier by the applicant

The applicant, if necessary, should consult the responsible authority on the legal and other requirements prior to the submission of the application for registration.

Certain registration schemes may permit applicants to submit a pre-application, a limited dossier that indicates the major issues that are relevant for the specific product, in order to obtain more specific guidance on whether the product could be registered. The responsible authority may at that stage inform the applicant that the product for which the registration is sought may not fulfil the criteria for registration, based on experience or based on certain set criteria (e.g. pesticides of certain class of toxicity would not be permitted for a specific group of users in the country).

The applicant should submit the application for registration according to the format and conditions as specified by the responsible authority. The responsible authority may consider requesting an electronic dossier to facilitate storage and retrieval of the data.

The application for registration should include a full and objective summary of all data as well as the conclusions from the applicant. The relevant general requirements for the dossier should be made publicly available and any specific requirement should be made available from the responsible authority upon written request. The applicant should fulfil all technical and financial requirements as specified in the registration regulations of the country.

4.1.2 Initial administrative actions by the responsible authority

Upon receipt of the application for registration, the responsible authority should create a unique file for this application and ensure that all correspondence is properly filed and can be easily retrieved.

The responsible authority should, upon receipt of the application for registration, send an acknowledgement of receipt to the applicant within a reasonable time frame. In case a fee is required for submission of the application for registration, verification of receipt of the fee should also be carried out as part of the completeness check.

Confidential data on pesticide products should be handled by authorized staff only. Such documents should be held in a secure location at all times. Measures against loss (fire, theft, damage by water, etc.) should be taken. A duplicate dossier should be stored safely in a physically different location.

4.1.3 Completeness check

The responsible authority should check, in a timely manner, whether the dossier is complete with respect to the requirements and specified criteria. The check should also include consideration of any request for waivers from the applicant.

Based on the completeness check, the responsible authority should request the applicant to supply any missing or incomplete information in the dossier. If the gaps in data submitted are considered essential for their evaluation, the responsible authority should inform the applicant that further processing of the application is postponed, pending the submission of these additional data. After the check of completeness the responsible authority and the applicant should discuss a work plan that includes expected timelines for the regulatory decisions.

4.1.4 Technical and scientific evaluation

The registration dossier, including any data generated at the request of the responsible authority, should be submitted to qualified experts in relevant fields including efficacy, human health and environmental effects for technical evaluation of the data. These experts could either be part of the office of the responsible authority or experts from academia or research institutions. They should perform the evaluation, whenever possible, making use of internationally agreed methodologies and criteria. Care should be taken to ensure that these experts are indeed independent, that no conflict of interest is declared with respect to the data they are evaluating and that the dossier is treated confidentially.

After receipt of the evaluation of the data in the relevant fields, the responsible authority should, if necessary, request the applicant to submit any additional data that are deemed essential by the evaluators. Any requests by the applicant for a data submission waiver should, in principle, be treated at this stage. The responsible authority should also specify a time period within which these data should be submitted as well as indicate that further processing of the application for registration is postponed until receipt of these data. If and when appropriate, the responsible authority may also take note of expert opinion from other competent regulatory authorities when evaluating data.

4.1.5 Preparation of summaries and conclusions

Reviewers should submit their conclusions to the responsible authority within a reasonable and agreed time frame and provide a summary listing of the data and assessments that formed the basis of their conclusions.

Based on the evaluations and recommendations of the experts, the responsible authority should prepare a comprehensive summary of all relevant data and the conclusions from the experts for consideration by the pesticide board if it is of the view that review of the data is complete and ready for a decision.

4.1.6 Risk management and registration decision

The pesticide board will take the final decision on the registration of the pesticide, taking into account the review prepared by the responsible authority, and possibly the outcome of the public review procedure.

The decision of the pesticide board may be provisional or full registration, with or without restrictions and/or conditions, or refusal. The Board may also decide to suspend a decision, and request further data or assessments to be provided.

Use of a pesticide is generally approved only for specific applications, e.g. for control of specific pest(s) on certain crops or specific applications for control of nuisance pests or vectors of diseases. These approved purposes should be incorporated in the registration decision.

Effectiveness of the product to control specific pests, and risk of residues on the crop concerned, are among the factors that play a role in decisions to limit approval to certain crop–pest combinations.

In cases of elevated human health or environmental risk, the use of certain pesticides may be severely restricted. Such severe restrictions may, for instance, specify that the product can be used only by licensed applicators for very specific purposes.

However, restricting the use of pesticides as a form of risk management is only effective if the restrictions are actually adhered to and are being enforced. The Code of Conduct therefore stipulates that prohibition of the importation, sale and purchase of highly toxic and hazardous products 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 the user.

In case the Board concludes that a registration may be granted, the responsible authority should assign a unique registration number linked to the specific registration from the specific applicant. If the registration of a pesticide is refused, or if the use of pesticide is severely restricted, specific additional post-registration actions may need to be taken in order to protect human health or the environment.

The responsible authority may publish its summary and proposed registration decision and invite third parties to provide comments. Care should be taken that any public review period does not unreasonably delay the registration process.

4.1.7 Publication and dissemination of registration decision

The responsible authority should inform the applicant of the decision of the pesticide board. In cases where registration is granted, the responsible authority should inform the applicant of all relevant conditions linked to the registration, including the labelling and marketing conditions and the registration number.

The responsible authority should then take the necessary actions to publish the decision in the governmental or official gazette for the product to be legally registered. The information contained in the gazette should include: name of registrant, registration number, trade name of product, active ingredient(s) as well as its concentration(s), formulation and usage. Only registrants of registered products should be allowed to import and/or manufacture the products for sale. The responsible authority may also make this information available on the Internet.

The responsible authority should also inform all key representatives of relevant governmental agencies and institutions, including enforcement agencies, customs departments, plant protection services or public health services as well as experts who participated in the evaluation of a positive decision. Enforcement agencies and experts may also receive information regarding refused applications.

4.1.8 Label extension

Industry should provide additional data to the responsible authority to support new uses (label extension). If these additional label claims are approved by the authorities, they would then be included on the label.

4.2 Post-registration process and activities

4.2.1 Archiving

The responsible authority should ensure that decisions made, including summaries, assessments, deliberations and conclusions of the Pesticides Board, written communications (including e-mails) and data, are properly documented and stored for future reference. Adequate facilities should be provided to store such confidential information, which should be accessible to authorized personnel only.

4.2.2 Post-registration monitoring and evaluation

Post-registration monitoring and evaluation provide a means of measuring the validity of predictions, based on registration data, regarding the efficacy, safety and environmental effects of a particular pesticide product. Post-registration monitoring and evaluation may reveal that a product is no longer effective as a result of the documented development of pesticide resistance to a level of field performance failure, that the product is of poor quality or that it has caused unacceptable risks to human health or the environment. Widespread abuse of the pesticide concerned or non adherence to restrictions are factors that should also be taken into consideration. The responsible authority may make use of the findings of post-registration monitoring and evaluation to take the necessary corrective actions such as the amendment of recommendations on use and dosage, restriction on use or, if necessary, withdrawal of the registration of the product.

The Code of Conduct calls upon governments to periodically review the pesticides marketed in their country, their acceptable uses and their availability to each sector of the public, to conduct special reviews when indicated by scientific evidence and to carry out health surveillance programmes of those who are occupationally exposed to pesticides and investigate, as well as document, poisoning cases.

There should be provision for a mechanism for reporting adverse effects caused by pesticides as well as for collecting and analysing such data. Governments should collect and record data on the import, export, manufacture, formulation, quality, quantity and use of pesticides in order to assess the extent of any possible effects on human health or the environment and to follow trends in pesticide use for economic and other purposes. The development of track-and-trace systems of pesticides will facilitate such data collection, and should be encouraged whenever feasible.

Post-registration monitoring or evaluation may also consider other information sources such as publications regarding health or environmental problems related to the pesticides concerned in other countries, in particular when such data can be extrapolated to the local situation in an appropriate manner.

4.2.3 Re-registration and unscheduled reviews

The Code of Conduct calls upon governments to establish a re-registration procedure to ensure the periodic review of registered pesticides, thus ensuring that prompt and effective measures can be taken if new information on product performance or risks indicate that regulatory action is needed. Such re-registration procedures may take different forms, depending on national legislation and available resources.

A registration would normally be granted for a limited period of time, the length of which depends on national circumstances and capacity for re-registration review. Before the end of the registration period, registrants should submit an application for re-registration of their product based on the requirements and conditions set by the responsible authority of the country. The application should include any new information about the product that has become available in the intervening period. The responsible authority should then proceed to evaluate the application for re-registration, taking into consideration any new data or information as well as the standard of science and knowledge and any update of requirements that have occurred since the previous registration. If no request for re-registration is submitted at the end of the registration period, the pesticide should be removed from the pesticide register and its continued use should not be allowed.

Since periodic complete re-evaluations of a pesticide are highly resource-intensive, other options for periodic review are available to a responsible authority. They include data call-ins

for specific parts of the dossier, partial reviews for those assessments for which important changes of insight have occurred, or reviews of feedback from monitoring programmes.

Explicit provisions should be made for unscheduled review of registered pesticides when new information becomes available that may affect the efficacy or risk assessments that were carried out previously. Such information may include data on resistance development, adverse health or environmental effects, or changed maximum residue limit requirements for export crops. In such cases, the pesticide registration may need to be reviewed before it formally expires.

4.2.4 Administrative arrangements for minor changes

Minor changes in the registration dossier, such as changes to company address or telephone number or in distributors, which do not affect the content of the registration decision, may be handled by a simple administrative arrangement, although they would have a consequence for the labelling of the product.

It is recommended that any minor changes made to the registration be reflected in the registration number, for example by adding a suffix at the end of the number. This will facilitate traceability of the product in relation to the originally registered product.

4.2.5 Administrative arrangements for major changes

Major changes in the registration, such as changes to the label or adding new uses (crops, pests or vectors), will require full or partial review of the data package submitted by the registrant and, where necessary, additional data would be requested and evaluated before approval of the request.

4.2.6 Appeals procedure

If the registration of a pesticide is refused, or if restrictions apply, the applicant should be allowed to appeal against the decision. A formal appeals procedure should be included in the pesticide regulations, stipulating the full procedure, the conditions of appeal and time limits to all steps in the procedure. The responsible authority should communicate this information to the applicant where applicable. However, the appeals procedure explicitly should not allow questioning of the validity of criteria.

4.2.7 Litigation

Depending on the national legal system, an applicant may take its case to court if it is not satisfied with the outcome of the appeals procedure. Third parties, including public interest groups, depending on the national legal system, may also have the opportunity to contest in court the decision to register or not to register a pesticide. The pesticide board should therefore keep records of all its decisions and deliberations.

4.2.8 Notification to the Rotterdam Convention

For Parties to the Rotterdam Convention, the responsible authority should inform the designated national authority of the Convention (if it is not itself that authority) of any final regulatory action it has taken to prohibit or severely restrict the use of a pesticide in order to protect human health or the environment. Such decisions are considered as a ban or a severe restriction under Article 2 of the Convention, that also covers a pesticide that has been refused approval for first-time use or has been withdrawn by industry either from the domestic market of from further consideration in the domestic approval process, where there is clear evidence that such action has been taken in order to protect human health and the environment. In line with Article 5 of the Convention, the designated national authority is required to notify the

secretariat of such final regulatory actions within 90 days after the regulatory action has taken effect.

When a chemical is listed in Annex III of the Convention, it is subject to the prior informed consent, or PIC procedure. Under this procedure, Parties are required to inform the Secretariat whether or not they consent to the future import of these chemicals. Parties to the Convention are legally bound to respect these decisions. In line with article 10, a decision not to consent to future import should be accompanied by prohibition of (i) the import of the chemical from any source and (ii) domestic production of the chemical for domestic use. Prohibition of the import and domestic production of a chemical would warrant cancellation of its registration.

More information on the notification of final regulatory action as well as the operation of the PIC procedure, and on other provisions of the Rotterdam Convention, can be found on its web site [7].

4.3 Experimental permits

Governments should have in place regulations for the importation of limited quantities of unregistered pesticides for the purposes of research, education or registration. Such regulations would enable the responsible authority to issue an experimental permit to any party that is able to comply with the conditions of the regulations to import a limited quantity of pesticide for any of the above purposes.

The regulations would, among others, require applicants to provide some basic information on the pesticide (such as the code name, common name, type of pesticide, chemical group, percent active ingredient, acute oral and dermal LD_{50}, inhalation toxicity, fish toxicity), the purpose of the import, the quantity to be imported, and particulars on where and when and by whom the experiment will be carried out. The responsible authority would then evaluate the application and decide whether an experimental permit should be issued and, if so, the conditions attached to its issuance. The conditions of the permit would, among others, depend on the stage of development of the chemical, the quantity of pesticide permitted for importation, the requirement to destroy the crops after the experiment (if relevant), the location of the experiment and provision of information on the date of the experiment for inspection by the responsible authority.

4.4 Fast-track registration procedure and pesticides for emergency use

4.4.1 Fast-track registration procedure for low/reduced risk products

Responsible authorities may decide that for certain types of pesticides that have been shown to be of low risk, a fast-track registration procedure can be followed, in which case submission of a limited set of data may suffice for evaluation. This evaluation should be carried out on an accelerated timetable. Such a fast-track procedure should be based on clear and published requirements and criteria. If such a procedure is established, it is important to carefully define what groups of products are eligible in order to avoid discussion on whether a product is low risk or not.

4.4.2 Procedures for use of pesticides in emergency situations

Provisions should be made to allow certain pesticides that are not registered to be used in emergency situations to control certain pest outbreaks in agriculture or public health under

exceptional circumstances. Proper procedures should be in place regarding the approval for the use of such pesticides in these situations. It should be made clear as to who has the authority to declare an emergency and request the pesticide board to approve emergency use. Generally, the quantity of the pesticide that may be used, the duration of use and the authorized user(s) will be limited and specified. Special monitoring may be required. The office of the responsible authority should serve as the administrative unit dealing with all aspects of these situations. Subsequent to the emergency use of the pesticide, consideration should be given to registering the pesticide following the normal procedure to ensure that it is available, if necessary, for the control of future pest outbreaks.

4.5 Cancellation of registration

Cancellation of registration is an important part of the registration process. Registration can be cancelled for the following reasons:

- banning of a pesticide;
- active cancellation of registration after review by the Registration Board prior to the end of the registration period;
- decision not to extend after expiration of registration period;
- expiration of registration period without request for renewal (passive cancellation);
- voluntary withdrawal by a company.

Banning would involve the prohibition on the use of the pesticide in the country to protect human health and the environment. This means that no application for its registration would be entertained. The registration of a pesticide could be cancelled as a result of the availability of new information showing that the continued registration of the pesticide is undesirable or as a result of the contravention of legal requirements by the registrant. If registrants are unable to comply with the requirements of the responsible authorities, the registration of their products may not be extended after their expiry. Sometimes registrants, for commercial reasons, do not request for the extension of the registration period of their products, in which case the products will no longer be registered once the registration periods are over. Registrants have also on occasions voluntarily withdrawn the registration of their products as a result of safety concerns or for commercial reasons.

5. Data requirements and the registration dossier

The responsible authority of a country should specify clearly and comprehensively the types of data that are required for the registration of a pesticide. The format as well as the number of copies of the dossier that are required should be stated. The responsibility to generate or supply the data to support an application for registration of pesticides is with the applicant. Data provided in support of registration should reflect the conditions in the country or region where the pesticide is intended for use.

5.1 Data quality

The data provided by the applicant should be of high quality and reliability and, whenever possible, be based on internationally recognized testing guidelines and methods, such as those published by FAO, WHO and the Organisation for Economic Co-operation and Development (OECD) [8], among others.

Data should be generated in accordance with sound scientific and experimental procedures and follow the principles of good laboratory practice, whenever applicable.

If requested by the responsible authority, full reports should be submitted. Summaries should equally be of high quality, and fully reflect the findings of the studies. Applicants should ensure that proposed use patterns, label claims and directions, packages and technical literature truly reflect the outcome of scientific tests and assessments.

5.2 General outline of data requirements

Data required to support an application of a registration should cover all relevant aspects of the product during its full life-cycle. They should include the identity and physical and chemical properties of the active ingredient and formulated pesticide product, analytical methods, human and environmental toxicity, proposed label and uses, safety data sheets, efficacy for the intended application or use as well as residues resulting from their use, container management and waste product disposal. FAO and WHO assessments of pesticides should be included, when available.

Efficacy data, where practical, should be generated against the target pest or vector species and in ecological conditions representing areas in which the pesticide is intended for use. Data generated in another country that has similar ecological or epidemiological conditions should be accepted, whenever relevant, if the national requirements for testing have been met [9]. The WHO Pesticide Evaluation Scheme (WHOPES) assessments of public health pesticides, where available and relevant, should be considered [10].

Data requirements may differ depending on various aspects, among them:

- the nature of the pesticide (synthetic chemical pesticides, microbial pesticides, etc.);
- the intended use pattern (e.g. agricultural pesticides for field use, pesticides used in greenhouses, vector control pesticides, domestic use pesticides, wood preservatives);
- whether the product is an active ingredient or a formulation;
- whether the product is based on a new active ingredient or a generic one;
- whether the product will be used on a large scale or be of minor use;
- whether the product is (closely related to) a recognized low-risk pesticide.

The responsible authority should therefore define data requirements for the above, and rules for data waivers, in order to avoid unnecessary data generation, and as a result reduce the costs for the applicant.

Efficacy trials may not be required for pesticides based on technical grade active ingredients registered by equivalence as long as the intended use is the same as the approved use of similar products already on the market.

5.3 Tiered approach to data requirements

Increasingly, responsible authorities apply tiered or step-wise approaches to evaluation and data requirements.

In a tiered approach, a more limited data set is required in a first submission by the applicant. If, on the basis of this limited data set, the assessment of efficacy, residues, and human and environmental risk show that the product is acceptable for registration, no further data need to be submitted. If, however, the limited data set does not allow for a conclusive assessment, additional data are requested from the applicant for the areas that need further evaluation (e.g. more specific toxicity studies, more precise exposure data, or larger-scale efficacy trials). This process of step-wise or tiered assessment may be repeated several times until a final decision on the registration is taken.

The advantages of tiered assessments and data requirements are that costs for the applicant are limited to the absolutely necessary, and that the responsible authority only evaluates the data needed to come to a final decision. However, efficient communication between the applicant and responsible authority is required for the approach to be effective and not delay the registration process.

5.4 Country-specific data requirements

Countries may require data that are not generally required in other registration schemes. This may particularly be the case if conditions of use are different in that specific country or region, where the pests, modes of application, or exposure due to climatic conditions are different.

5.5 Data protection and confidentiality

Pesticide registration authorities will receive many documents, materials and a wide range of data from companies wishing to register their products. Companies submitting such data for registration of a pesticide have an interest in ensuring that this information which is costly to generate, and which may be used unfairly by competitors, is suitably protected. At the same time, good public policy and national legislation strive to reconcile competing interests, and, provide sufficient incentives for such data to be generated in the first place, ensuring that follow-on producers have reasonable opportunities to enter the market and providing for the possibility of making all or part of the data concerned accessible to the public.

Many different types of data exist, for which there are different mechanisms and levels of protection also exist. There is also wide variability in the way in which individual countries protect such data as a separate category of intellectual property rights (IPRs) in their domestic legislation. For Members of the World Trade Organization (WTO), the protection of undisclosed information is mandatory under the Agreement on T rade-Related Aspects of Intellectual Property Rights (TRIPS), contained in Annex 1C of the Agreement Establishing the World Trade Organization (WTO).

In an attempt to achieve a balance between competing interests, and to promote public interest in the development of such data by firms and reference to them by regulatory authorities, WTO Members are required to provide for two forms of protection of undisclosed test or other data pursuant to Article 39.3 of the TRIPS Agreement. The first is against unfair commercial use, where:

- the data have to be submitted as a condition of marketing approval for pharmaceutical or agricultural chemical products;
- those products utilize new chemical entities;
- the origination of the data involves considerable efforts; and
- the data is undisclosed.

The second form of protection of test data is against disclosure, except where necessary to protect the public, or unless steps are taken to ensure the data are protected against unfair commercial use.

The TRIPS Agreement remains silent about how protection against unfair commercial use should be implemented by WTO Members. Some form of protection of test data has generally been implemented into national legislation. For example, a number of WTO Members provide for a fixed period of exclusivity during which neither regulatory authorities nor third parties can rely on the data submitted by the originator company for regulatory approval purposes without the originator's consent. Other WTO Members have implemented approaches to data protection that do not provide for a specific period of exclusivity.

Countries may take different approaches as to which government authorities should be responsible for data protection. However, for data on agricultural or public health pesticides, the pesticide registration authority is usually responsible for developing and administering pertinent national legislation, including its adherence to international obligations on intellectual property rights. Where appropriate, pesticide authorities should consult the national office with general responsibility for intellectual property rights, in order to ensure a consistent approach regarding the protection, handling and access to registration data, materials and documents.

For WTO Members, it can be expected that relevant national laws and regulations, and their administration, reflect the minimum standards established by the TRIPS Agreement as set out above. Countries that are not members of WTO may have legislation on intellecural property or rules in place that should be adhered to. Where no such legislation or rules exist, pesticide registration authorities are advised to use the TRIPS Agreement, and the specific choices taken by different WTO Members, as a point of reference. Details of the diverse national approaches of many countries to implementing TRIPS standards on data protection have been notified to WTO and are available upon request from the Secretariat.

6. Evaluation of the registration dossier (data review)

6.1 Assessment of the submitted registration dossier

The responsible authority should take the following steps as summarized below.

- *Verification of authenticity:* The responsible authority should ensure that an applicant has the rights to submit the registration dossier and the data submitted are authentic.
- *Completeness check:* The responsible authority should ensure that data in the submitted dossier is complete and in conformity with the officially published data requirements for the intended use of the pesticide.

- *Waiving request:* The responsible authority should ensure that if there is a request for a waiver from certain data requirements, reasons given are acceptable based on the criteria set.
- *Assessment of data quality:* The responsible authority should ensure that the data submitted are of acceptable quality and that they comply with the standards required.
- *Assessment of registration status in other countries:* The responsible authority should ensure that the information is provided and includes information about restrictions.
- *Assessment of all technical data:* The responsible authority should ensure that the data support the registration for the intended use.
- *Risk assessment:* The responsible authority should ensure that the risks of using the pesticide according to the proposed label are acceptable.
- *Relevance of data*: The responsible authority should ensure that all data provided is relevant to the conditions under which the product will be used and to the crops and pests/diseases to which it will be applied.

6.2 Request and assessment of additional data

If the responsible authority should conclude that data submitted are incomplete or that the outcomes of certain studies require more detailed information, it should request the applicant to submit additional data to enable a more complete assessment to be made. Different scenarios may apply:

(a) the data set is incomplete to allow for an assessment and the registration process is suspended until receipt of the additional data required;

(b) the data set is complete for an assessment leading to a provisional registration under certain restrictive conditions for a limited period of time, such as provisional registration;

(c) the data is complete when compared to the requirements, but certain aspects require further study. The responsible authority may decide to grant registration for a period that is long enough to allow for these additional studies to be carried out.

6.3 Use of existing evaluations of the same active ingredient and/or product

In case the applicant has the ownership of the data or can fully justify the right to use the data for his application for registration, elements of existing registrations can be used for new applications based on the same active ingredient. However, if the data were to be owned by a different owner and the applicant could not justify his right to use these data, the responsible authority should not use the data and evaluation from the first registrant for approval of the product of the second applicant.

7. Decision making

This is one of the most important steps in the registration process and should be carried out by qualified experts and based on well-established criteria and procedures relevant to the intended use of the pesticide. It is important that applicants provide quality data to support their applications to enable the responsible authority to make informed decisions that would ensure that products registered would perform as intended and not cause unacceptable adverse effects to man and the environment.

The pesticide board should take its decisions to register a pesticide, or refuse registration, based on criteria which have been legally defined. This will increase transparency and independence of decision-making.

7.1 Risk–benefit analysis

In considering the need for a pesticide, the responsible authority should weigh the benefits against the risks the pesticide would pose if it were to be used under local conditions. Relevant questions that should be considered are whether: the pest(s) for which the pesticide is to be used against is a problem; suitable (non-chemical) or lesser toxic and cost-effective chemical alternatives are available; there is a need for its use in resistance management; or the use of the pesticide is compatible with IPM or IVM. Besides human health and environmental risks there also may be economic risks, for instance if maximum residue limits for certain pesticides on export crops have been set at detection level in the country of destination.

7.2 Efficacy assessment

Efficacy assessment in the registration of a pesticide should be carried out, where applicable, to ensure that pesticides approved would be efficacious for its intended use. The assessment would provide the responsible authority the necessary information to decide and include the appropriate statements on the recommendation for use on the label. Guidelines on the Efficacy Evaluation for the Registration of Plant Protection Products are available from FAO [9]. Guidelines for testing of and evaluation of certain public health pesticides are available from the WHO [3]. WHO efficacy assessment and evaluation of certain public health pesticides are available from WHOPES [10] and Governments should make use of such assessments where relevant to avoid duplication of efforts and minimize the local testing of the product.

Efficacy assessment does not always necessarily involve local trials. In some cases it may suffice to review the results of trials conducted in neighbouring countries that have equal agro-ecological conditions and the same pest species.

7.3 Quality assessment

The quality of a pesticide submitted for registration is of prime importance and a quality assessment should be carried out. Applicants should provide certification to prove that their product is of good quality and where applicable, complies with international specifications

such as those of FAO and WHO. Responsible authorities on the other hand should have access to analytical facilities to verify the quality of the pesticide prior to as well as post-registration. In the absence of such facilities, a certificate of analysis from an independent certified laboratory can be requested

7.4 Residue assessment

For all uses of pesticides on food and feed crops, the applicant should provide the necessary residue data generated in accordance with *Codex Alimentarius* [12] and FAO guidelines on good analytical practice and on crop residues data [13], for assessment by the responsible authority. Residue assessments do not always need to be based on local residue trials, however. In some cases it may suffice to review the results of trials conducted in other countries on similar crops, using relevant agricultural practices under comparable climatic conditions.

The use of maximum residue limits defined by the *Codex Alimentarius* is recommended whenever applicable to the national situation. The responsible authority in collaboration with other relevant national agencies should also use the assessment to set national maximum residue limits for food, in particular for situations that have not been covered by the *Codex Alimentarius.*

7.5 Health and environmental hazard assessment

Applicants for registration of pesticides should submit a full assessment of hazards for human health and the environment. Such assessment should include acute oral, dermal and inhalation toxicity; skin and eye irritation, skin sensitization, as well as toxicity based on repeated administration (from sub-acute to chronic) and studies such as reproductive and developmental toxicity, genotoxicity, carcinogenicity, metabolism in animal and plants, etc. Ecotoxicological profile of the product based on toxicity to aquatic and terrestrial organisms as appropriate to the intended use, and information of persistence and bioaccumulation is also necessary.

For acute health or environmental hazards, both the active ingredient and the formulation should be considered. For long term or chronic effects, however, the assessment would normally involve the active ingredient only, unless there is a need to assess the other compounds in the formulation for long term effects.

The responsible authority should carry out an objective assessment of the data submitted and request for additional data where necessary. Where applicable, the responsible authority, in order to avoid duplication and a waste of resources, should also use the peer-reviewed hazard assessment for pesticides that have been carried out and published by the FAO/WHO or other reputable national or regional registration authorities.

7.6 Health and environmental risk assessment

Applicants for registration of pesticides should provide data on exposure resulting from the intended use under actual conditions of use. Applicants should also make an assessment of human health and environmental risks under the conditions the pesticide is proposed to be used and provide it to the responsible authority for evaluation. Responsible authorities should,

where applicable, use the WHO peer-reviewed, generic models of assessment of certain public health pesticides (available from WHOPES) in their assessment.

In the case of the re-registration of a pesticide, any relevant information about its use practices and associated health and environmental risks in the country concerned should be taken into consideration. This may include full epidemiological studies, but anecdotal information about problems with pesticides should also be assessed. The latter may provide a valid reason for further investigation into the local circumstances of pesticide use and its impact.

7.7 Pesticide classification

All products should be classified according to their hazard, in accordance with the Globally Harmonized System for Classification and Labelling (GHS) [14]. As long as this system is not fully implemented, products can be classified according to the WHO hazard classification [15] or any national regulation. Responsible authorities particularly in developing countries should consider the use of colour bands, warning statements and pictograms to reflect the different hazard classes of pesticides to minimize risks posed by pesticides.

7.8 Resistance management

Resistance to pesticides is a major concern in control of vectors and pests of public health importance as well as in the agricultural sector. The responsible authority should assess the potential risk of resistance development of the product. Applicants should provide information in the dossier about cases of resistance development in other countries. A risk assessment of resistance development should be made against any national policies and guidelines on the judicious use of pesticides in the context of integrated pest and vector management and national resistance management policies, if they exist [2]

Responsible authorities, in collaboration with other relevant organizations, should establish systems for regular monitoring of resistance and to develop resistance management strategies to prolong the useful life of valuable pesticides and reduce the adverse effects resulting from resistance. Applicants should inform the responsible authority about evidence of resistance as soon as it is detected, including after registration of their product.

7.9 Pesticide labelling

Draft labels submitted by applicants should be evaluated based on the requirements and criteria set for registration and should include clear information on the permitted use of the product, dosage and other use recommendations, warning and precautionary statements and description of required personal protection, hazard class, warning statement against the reuse of containers, and instructions on safe disposal or decontamination of empty containers. The responsible authority should also ensure that the approved labels are written in the major language(s) of the country and also include the registration number, lot or batch number, warning and precautionary statements, date of release of lot (month and year) [2]

7.10 Pesticide packaging

The responsible authority should evaluate the packaging to ensure that it is suitable for the pesticide product and for transportation and climatic conditions in the country before approval. The packaging should also be of appropriate size for the intended use and should conform to the relevant national regulations and United Nations (UN) guidelines on packaging [16].

8. Specific issues

8.1 Pesticide mixtures

Products containing two or more active ingredients are assessed according to the same procedures as for single active ingredient pesticides. The active ingredients are assessed each individually, while the evaluation of the formulation is done for the pesticide product (i.e. the mixture).

Of specific importance for mixtures is the possibility that the active ingredients may interact, either with respect to efficacy but also regarding toxicity (e.g. synergism, antagonism). Furthermore, responsible authorities should assess whether using the mixture is in line with national IPM or IVM strategies and does not adversely affect resistance management policies, when compared to using the active ingredients separately and consecutively.

8.2 Formulants

A formulant is a substance other than the technical grade active ingredient that is intentionally incorporated in a pesticide formulation to improve its physical characteristics, e.g. ease of use or application, solubility or stability. When a formulated product is assessed for registration, the product as a whole is being evaluated and hence any change of the formulants could change the characteristic and property of the product. Responsible authorities should therefore ensure that there are provisions in their regulations to require the registrant to inform the authority of changes in formulants of the approved product and to submit evidence (e.g. efficacy, storage stability and hazard data) if such changes would require submission of a new application for registration.

8.3 Equivalence determination

Equivalence determination is the evaluation of whether the impurity and toxicological profile, as well as of the physical and chemical properties, presented by supposedly similar technical material originating from different manufacturers is indeed similar, in order to assess whether they present the same levels of risk. Equivalence determination can be used as a step in the registration of generic pesticides.

Responsible authorities should establish national principles and criteria for determination of equivalence of pesticide products from different manufacturers to avoid wastage of resources

and to facilitate market access of products of acceptable standards. Governments should use the principles described in the *Manual on development and use of FAO and WHO specifications for pesticides* [17] for determining such equivalence. The Manual also stipulates data to be provided for equivalence assessment.

Efficacy, residue, health and environmental hazard and risk assessments are normally not required when the technical grade active ingredient of the pesticide being registered has demonstrated its equivalence to an already registered technical grade active ingredient and the intended use of the formulated product based on the equivalent technical grade active ingredient is the same as that of the product already on the market.

8.4 Minor use

Minor uses apply to pesticide used on a small scale, which may not provide sufficient economic incentive for a registrant to support initial or continuing registrations. Governments should develop criteria and procedures for registration of such products that will on the one hand allow for an acceptable efficacy and risk assessment while on the other reduce the data requirements for applicants.

Procedures for the registration of minor use products are generally based on extrapolation of efficacy and residue data from one country to another, or between pests and/or crops. Mutual acceptance of data is an important principle that responsible authorities should adopt to allow for effective minor use registrations.

If the active ingredient or product has already been registered in the country on another crop or against another pest, a label extension, with the agreement of the registrant, may be considered an appropriate way to register a minor use product.

Any residue data that are generated for minor uses/specialty crops should be made available for the establishment of Codex maximum residue limits in order to facilitate the trade of agricultural products.

8.5 Lists of banned or severely restricted pesticides

The responsible authority, in addition to publishing and making available to the public, a list of registered pesticides, should also provide a list of banned or severely restricted pesticides. The purpose of a list of banned pesticides is to indicate that certain pesticides will not be considered for registration. The purpose of severely restricting pesticides is to keep certain pesticides available for very specific purposes, only to be handled by specialists, while acknowledging that hazards are such that they should not be freely available.

8.6 Microbial pest control agents, semiochemicals, insect growth regulators, pheromones and plant extracts (botanicals)

As any other pesticide product, microbial pest control agents, semiochemicals, insect growth regulators, pheromones and plant extracts (botanicals) should be registered before they are allowed for use. The general procedures for registration of these products are the same as for other pesticides, however, the data requirements and the assessment of the data may be different [2, 18].

8.7 Comparative risk assessment (CRA)

Comparative risk assessment (CRA) can be defined as the regulatory process that considers and ranks the risks of different active ingredients or products within a group of similar products.

The objective of CRA is to identify, within a group of products, the one posing the lowest risk for health and the environment taking into account national conditions of use and crop protection or public health needs. As such, it goes beyond the application of fixed criteria to determine whether a product should be restricted or not. CRA encourages precautionary approaches to pest/vector management in agriculture and public health. Ideally, a CRA system would identify products that present significantly less risk to health or the environment and that would be equally effective in controlling the target pest or organism as well as taking into consideration the risk of development of resistance.

8.8 Substitution principle

Substitution principle involves the process of replacing high risk products with lower risk alternatives. Substitution should be based on comparative risk assessment, which should demonstrate that another product available for the same use presents significantly less risk to human or animal health or the environment.

The alternative product should also be sufficiently effective and could be used without unreasonable economic or practical disadvantageous for the user. In adopting the substitution principle governments would need to develop a process that would continue to encourage registration of less hazardous products and to review all registrations on a regular basis.

9. Institutionalization and administrative organization

9.1 Legislation

The pesticide registration procedure should have a sound legal basis in the national pesticide legislation, for it to be effective and enforceable. In particular, provisions should be included to define the mandate of the responsible authority and the pesticide board (including composition), describe the pesticide registration procedure, specify data requirements, define the criteria for the authorization of pesticides, and outline an appeals procedure. Furthermore, a description of penalties should be included in case of violation of the pesticide registration provisions defined under the legislation [4].

The legislation should in principle cover all types of pesticides and allow for a tiered/stepwise or a regional approach, if needed.

9.2 Types of pesticide registration bodies

The responsible authority is the legal entity or statutory body which is responsible for the implementation of the pesticide legislation, generally including the pesticide registration scheme. Various options are available for countries to choose the type of pesticide registration body, among them:

- a government department or agency, or a unit placed under it;
- an independent national statutory body, or a unit placed under it;
- a regional statutory body.

9.2.1 National registration schemes

In the first case, pesticide registration is administratively part of the overall responsible authority for pesticide legislation, control and management (e.g. an administrative unit of a Ministry). This is presently the practice in most countries. But pesticide registration may also be placed under one ministry, while the responsible authority for other pesticide regulatory tasks (e.g. licensing, inspection, enforcement) are under one or more other government ministries.

Increasingly, pesticide registration is carried out by independent statutory bodies, which may be accountable to various ministries simultaneously. This tends to provide more independence in decision making.

Regional pesticide registration bodies are still relatively rare, but are likely to become more common since they are intended to make better use of limited resources for evaluation of pesticides.

If the authority responsible for registration is not an administrative part of the overall responsible authority (or authorities) for pesticide management and regulation, it is essential that effective day-to-day communication channels and collaboration procedures are established.

Although some countries have separate registration authorities for agricultural pesticides and other types of pesticides, the approach recommended in this guideline is to have the same authority to register all types of pesticides. This would not only make better use of often limited human and financial resources in many countries, but would also reduce the cost of operating the scheme, ensure more efficient use of combined expertise and experience and facilitate close collaboration between stakeholders. Furthermore, it may reduce the cost of registration to the applicant and hence the cost of pesticides to the user. Finally, since many pesticides may be used in different sectors (e.g. in agriculture and in public health), separate registration schemes could result in inconsistencies regarding authorized uses of a pesticide product.

9.2.2 Regional cooperation and registration schemes

It is increasingly recognized that there are advantages to regional cooperation and work sharing in registration as compared to registration on a purely national basis. These advantages include:

- a stronger expertise base;
- more efficient use of scarce financial resources (work sharing to improve efficiency and to minimize duplication of work);
- lower operating cost;

- less vulnerable to outside pressures;
- harmonized approach, which will help facilitate implementation and enforcement, and may help combat illegal importation; and
- broader peer review leading to more robust conclusions and greater uniformity in regulatory decision-making.

When a government chooses to cooperate on a regional basis, it is important to ensure that there is a good consensus among the major ministries (Health, Agriculture, Environment and Trade) related to pesticides. The government should initiate the process of negotiations for regional registration cooperation through existing regional groupings or through the proper diplomatic channels. Existing regional schemes in other areas could provide useful information in the preparatory process. The process for development of such a regional cooperation scheme would in general be more complex as there is a need to also look into how responsibilities and resources should be shared.

For countries that have very limited human as well as financial resources, a well implemented regional cooperation scheme is a viable option to assist them in addressing resource constraints. An example is the Committee for Drought Control in the Sahel (CILSS), where the nine member countries in West Africa share resources in operating a common registration scheme for pesticides. Developed countries have also been active in regional cooperation in pesticide registration, particularly to minimize duplication of work as well as improving efficiency in the registration process. Examples include the European Union (EU) (for active ingredients) and the North American Free Trade Agreement (NAFTA).

9.3 Structure of the pesticide board and the responsible authority

The pesticide board is the generic term used in this guideline for any legally appointed body that takes the final decision on the application for registration of a pesticide. It should consist of highly qualified independent experts who together cover all the relevant fields of pesticide evaluation and management. Members could be drawn from government, academia or may be independent experts, and should cover at least the sectors of agriculture, health and environment.

In some legal systems, the pesticide board will take the final decision to register a pesticide, i.e. it "signs the registration". In others, the accountable responsible authority may need to administratively formalize the registration decision.

The responsible authority serves as the secretariat to the pesticide board. It deals with all matters related to the implementation of the pesticide registration scheme, such as receipt of applications, evaluation of registration dossiers, preparation of summaries and draft decisions for the pesticide board, correspondence with applicants, and archiving and maintenance of the Register.

The responsible authority may rely entirely on its own staff to execute these tasks, or it may call upon external expertise for part of it. External expertise will most likely be needed for the evaluation of registration dossiers when chemists, entomologists, plant pathologists, weed scientists, toxicologists environmental scientists and other specialists may be called upon from other governmental agencies, academia or the private sector.

All those who have access to the pesticide registration dossiers should sign a confidentiality declaration in which they are obliged not to disclose any confidential proprietary pesticide

data, and the potential for conflict of interest with their other roles should be explored and avoided.

9.4 Infrastructure and equipment

The responsible authority should be provided with adequate number of qualified staff for the tasks legally entrusted to it. If only limited permanent staff can be funded, provisions should be taken to assign or contract external experts for dossier evaluation.

The responsible authority should also be sufficiently equipped with computers, documentation, secure storage facilities for the registration dossiers, as well as adequate working space and rooms for meetings and discussions. Absolutely essential is the access to good communication facilities, particularly Internet and email which should in principle be available to all administrative and technical/scientific staff.

The responsible authority should furthermore have access to technical support services such as laboratory facilities for pesticide quality and residue analysis, pesticide field-testing facilities, and post-registration monitoring mechanisms.

10. Coordination and collaboration

10.1 National level

10.1.1 Governments

Coordination and collaboration are essential for effective pesticide registration. In implementing the pesticide registration scheme, the responsible authority will need to coordinate with other government ministries or bodies that are responsible for setting human health and environmental legislation, criteria or standards. If such legislation or standards apply to chemicals or pesticides, they will need to be taken into account in the registration decision-making process.

Furthermore, the responsible authority will likely need to rely on external expertise for dossier evaluation. Such expertise may come from specialized ministries, such as those responsible for agriculture, health, environment or labour. Members of the pesticide board should be able to help identify such expertise within their ministries.

In addition, responsible authorities rely on effective collaboration with and feedback from government bodies and other public organizations that carry out post-registration monitoring and surveillance. Information collected in monitoring exercises needs to come back to the responsible authority so that it can be used for re-registration reviews.

Regular information exchange between the responsible authority and designated national authority for the Rotterdam Convention, and the focal point for the Stockholm Convention is essential for effective pesticide registration and national implementation of these Conventions, in countries where these Conventions have been ratified.

Implementation and enforcement of pesticide legislation and registration require the expertise of personnel in many fields. It is therefore crucial that there is adequate provision in the legislation for the active participation and collaboration of relevant ministries and government agencies such as the ministries of agriculture, health, environment and trade. The Pesticides Board mandated under the legislation should comprise members from these ministries and agencies as well as other statutory research institutions for proper assessment and evaluation of pesticides. It is important to ensure that Board members do not have any conflict of interest in relation to their responsibilities to the Board and the pesticide industry. The responsible authority should in collaboration with the private sector and civil society make efforts to implement the provisions of the Code of Conduct.

10.1.2 Academia and research institutions

Scientific assessment of pesticides requires close collaboration with national research institutions. This may include efficacy testing of pesticide products against target pest and vector species in different ecological settings as well as environmental impact assessments, pesticide residue analysis and quality control of pesticides.

Academia or research institutions may also be involved in post-registration monitoring as well as civil society organizations, consumer groups, farmer organizations, community health organizations and other relevant groups.

Academia and research institutions with the support of the government should carry out research in the development of alternatives that pose fewer risks including biological control agents and techniques, non-chemical pesticides and pesticides that are, as far as possible or desirable, target-specific, that degrade into innocuous constituent parts or metabolites after use and are of low risk to humans and the environment.

10.1.3 Regulated community

There should be regular dialogues between the responsible authority and the regulated community including the pesticide industry, pesticide vendors, professional pest control operators, pesticide advertising agencies and the general public from time to time to receive feedback and suggestions on the implementation and enforcement of pesticide registration in the country. The responsible authority should encourage the pesticide industry in the development of reduced risk pesticide products as well as in product stewardship activities.

10.1.4 Civil society

The responsible authority may have regular dialogues with representatives of civil society to discuss issues related to the registration of pesticides in the country. Civil society groups may in particular be important to provide feedbacks on the use of pesticides and actual and potential problems that may occur.

10.2 Regional and/or international levels

The responsible authority should establish and strengthen collaboration with other countries as well as regional and international institutions in registration of pesticides, including exchange of information on scientific, technical, economic, regulatory and legal issues and, where possible on toxicological, environmental and safety data. The collaboration may also include development of low or reduced-risk cost-effective alternative control measures, tools and application technologies as well as resistance management strategies. Responsible authorities could hold regional meetings on a r egular basis to discuss issues related to

pesticide management and identify areas of collaboration. A collaborative plan of action could then be developed and implemented. A regional network of responsible authorities could be formed and information of common interest on pesticides management posted on the Internet for the benefit of the responsible authorities, the Industry and the general public.

Responsible authorities should be fully aware of the requirements of the Rotterdam Convention, the Stockholm Convention and the Montreal Protocol, as well as the national implementation of these Conventions, and ensure that registration decisions are in compliance with these Conventions, if they are ratified. Furthermore, pesticide registration authorities are encouraged to make use of information on individual pesticides provided under these Conventions, and under the *Codex Alimentarius*, when making registration decisions.

OECD countries should collaborate with developing countries in capacity strengthening, especially training personnel in pesticide evaluation. They should also promote maximum availability to, and use by developing countries of, appropriate international assessments and evaluations of pesticide hazards and risks.

International organizations should provide information on specific pesticides (including guidance on methods of analysis) through the provision of criteria documents, fact sheets, training and other appropriate means to assist responsible authorities in the registration of pesticides.

Where such agreements are in place, countries may operate mutual recognition schemes, whereby a formulated pesticide product already registered in country A may be granted a "fast-track" approval in country B. Such schemes involving authorization under existing national schemes are already in operation in the EU between certain of its member states.

11. The pesticide register

There should be adequate provisions in the pesticide legislation for pesticides that have been approved for registration by the Pesticides Board to be officially published in a government gazette or publication. This is essential to ensure that the pesticide is legally registered. The government gazette may contain other information not related to registration of pesticides, and may not be easily available to the public; therefore, a pesticide register that is the compilation of all pesticide products registered by the responsible authority is necessary.

The pesticide register should contain the trade name/trade mark/commercial name of the product, the registration number, the name of the active ingredient(s) and their concentrations, the authorized uses, the name of the registrant and the period of registration. Other information including the following may also be included: the label instructions, conditions of use, possible restrictions to certain types of users, classification and all other relevant information.

The register should be kept up-to-date on a regular basis, preferably at least once a month. It should be easily accessible and, if possible, internet-based but with hard copies distributed to enforcement bodies and other relevant parties on a regular basis.

A separate list containing the pesticide products that are banned or severely restricted in the country or region is desirable.

12. Phased development of a pesticide registration scheme

Countries developing or strengthening their pesticide registration scheme should not only consider the establishment of an appropriate regulatory framework but also the available resources, both financial and human (professional and scientific capacity), necessary for operating such a scheme.

Depending on the resources available, a country should choose the degree of complexity of the registration procedure that suits it best. Countries with limited resources may initially choose a registration scheme requiring less staff or funding. As experience is gained with the evaluation of pesticide registration dossiers, expertise and infrastructure will be built up and the scheme can progressively be strengthened and tailored to the specific conditions of use in the country.

Two stages of the pesticide registration process are particularly resource-intensive. First, the generation of data for the registration dossier, which is carried out mainly by the applicant but which may also involve public research institutions. Second, the evaluation of the dossier, which is primarily done by the pesticide registration body. Phased development of a registration scheme, when resources are limited, therefore tends to focus on optimizing the use of funds and personnel during these two stages.

There are various approaches to the phased development of a pesticide registration scheme, which all have their particular advantages and disadvantages. They include, among others:

- *acceptance of registrations in other countries*. If a pesticide has been authorized in a country with a reputable registration system, the responsible authority may decide to register that same pesticide for the same uses based on only a limited evaluation of the dossier;
- *use of existing risk assessments*. If risk assessments exist from reputable pesticide registration bodies in other countries or international organizations, the responsible authority may use such assessments as a starting point for the risk evaluation of a pesticide that has been submitted for registration under comparable use conditions. This is sometimes referred to as a "bridging approach" to risk assessment;
- *mutual acceptance of data*. If relevant data of good quality have been generated in other countries, the responsible authority may waive the requirement for local data generation. This is particularly relevant for efficacy trials, residue data and environmental field studies, all of which likely require the involvement of national (public) research institutions;
- *prioritize specific groups of pesticides*. In the early stages of development of the registration scheme, the responsible authority may focus on more in-depth evaluation of pesticides which are either likely to be used in high volumes, or by many different groups of users, or on high-value crops that may pose moderate-to-high risk to human health or the environment. This approach would also valuable for the prioritization of pesticides for re-registration;
- *prioritize specific protection goals*. When evaluating a pesticide for registration, its risk for many groups of non-target organisms (e.g. fish, birds, soil organisms) and

several human exposure conditions (e.g. consumer, applicator, worker, bystander) is assessed. In the early stages of development of the registration scheme, the responsible Authority may limit data requirements and/or more thorough evaluation to protection goals that are considered high priority for the country;

- *set up fast-track registration channels*. For certain groups of pesticides, (temporary) fast-track registration channels may be set up, which either limit the data requirements or simplify and shorten the dossier evaluation process. The responsible authority may, for instance, temporarily allow fast-track registration for pesticides that have been used on a large scale in the country, and for a long time, without adverse effects or insufficient efficacy having been reported; for pesticides expected to pose very low risk (see 4.4); for minor use products (see 8.4); or for active ingredients or products that already have been authorized in the country on another crop or for another use (see 8.3).

These options for phased development of a registration scheme are not mutually exclusive, and in practice several of the above approaches are generally implemented at the same time. As expertise is built up over time, or as more resources become available, the registration procedures can be further strengthened, data requirements better tailored to local conditions, efficacy and risk evaluations improved and the coverage of the scheme made more comprehensive.

It is generally better to operate a pesticide registration scheme effectively with recognized, but politically accepted, limitations, than to set up a complex system intended to cover all eventualities, which cannot be implemented with the available resources.

13. Funding of pesticide registration

Pesticide registration is a resource-intensive activity and therefore requires adequate funds and qualified personnel for its full implementation. It generally is also a legal obligation for governments to ensure an effective and efficacious registration procedure.

The costs of pesticide registration and post-registration monitoring and evaluation are integral to the cost of using pesticides. Such costs are sometimes termed “externalities”, along with other factors such as health care for pesticide-affected populations, decontamination of land and water that has been contaminated by pesticides, pesticide storage facilities, public information and other activities.

Resources could be secured from a variety of sources. Certain countries would consider this as part of the services provided by the government, which would bear the full cost of implementation. However, most countries have introduced systems for partial or total cost recovery from applicants for the costs involved in the registration.

Sources for cost recovery could include the following:

- registration application fees;
- annual registration maintenance fees;
- licensing and permit fees;

- specific administration fees;
- analysis fees.

The fees imposed should be based on the cost of the services provided as well as incentives to be given for the registration of certain groups of products (such as reduced-risk chemical pesticides), but the criteria should be clearly spelt out and published.

It is strongly recommended that any funds generated through the pesticide registration process are also used for pesticide registration. It will generally facilitate acceptance by applicants for imposing fees when they see t hat such fees are being used to strengthen and speed up pesticide registration. Conversely, dependence on income from pesticide registration fees to finance the registration system should not become an incentive to register more pesticides.

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