

THE POLICY FOR THE HARMONIZATION OF PESTICIDES REGISTRATION IN AFRICA;

**Elaborated during the experts meeting on 11-13 June, 2012
Alexandria-Egypt and validated in Addis Ababa-Ethiopia.**

INTRODUCTION

Regulation 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, labeling, packaging and advertising of pesticides, thus ensuring that the interests of end-users, consumers, as well as the environment are well protected.

Governments should introduce and/or strengthen 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.

Themes to be adopted in the document preparation:

- Regional integration
- Importance of sharing information, work-sharing and harmonization of regulations
- Definition of harmonization in the text.

I. Situation Analysis

Africa like the rest of the world in consolidation of its efforts in economic and development has formed the Africa Union in 1999.

This forms a major market for the member countries and bargaining tool in the international trade.

African countries are agricultural dependant in their GDPs and with modern agriculture and climate change have become PCP dependant for pests and diseases management in their production systems.

However African countries have varied capacities and competences in the regulation of those keys productions inputs.

Over the years countries have instituted mechanisms for PCPs regulations that are varies in capacity and capabilities to manage that benefits while safeguarding their health and the environment.

In Africa, Regional Economic Communities (RECs) have been formed in order to benefit the economies of the member states.

Harmonization efforts in these regions have achieved significant benefits such as custom union.

With globalization, pests have no borders and the effect of non authorized PCPs continue to challenge effective pests' control, while posing unacceptable level of risks to health and environment in the continent.

The African Union, while appreciating the need to support their members in pesticide management, envisioned that MS need to harmonize regulation and management of PCPs in order to facilitate trade and assure safety to man and environment.

References consulted

- AU: mandate
- Regions & their efforts
- Regional Integration.

I. GNERAL PROVISIONS,

Conventions & Treaties

National legal frameworks for regulating pesticides

- a) [Basel Convention, Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal](#), Basel, 1989.
- b) [Convention on Civil Liability for Damage Caused during Carriage of Dangerous Goods by Road, Rail, and Inland Navigation Vessels \(CRTD\)](#), Geneva, 1989.
- c) [Bamako Convention, Convention on the ban of the Import into Africa and the Control of Transboundary Movements and Management of Hazardous Wastes within Africa](#), Bamako, 1991.
- d) [Convention on the Transboundary Effects of Industrial Accidents](#), Helsinki, 1992.
- e) [Rotterdam Convention Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade](#), Rotterdam, 1998.
- f) [European Agreement Concerning the International Carriage of Dangerous Goods by Inland Waterways \(AND\)](#), Geneva, 2000.
- g) [European Agreement concerning the International Carriage of Dangerous Goods by Road \(ADR\)](#), Geneva, 1957.
- h) [FAO International Code of Conduct on the distribution and use of Pesticides](#), Rome, 1985.

- i) [Stockholm Convention Stockholm Convention on Persistent Organic Pollutants](#) Stockholm, 2001.
- j) [Waigani Convention Convention to Ban the Importation into Forum Island Countries of Hazardous and Radioactive Wastes and to Control the Transboundary Movement and Management of Hazardous Wastes within the South Pacific Region](#), Waigani, 1995.
- k) [Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter](#) (London Convention), London, 1972.
- l) [International Convention for the Prevention of Pollution from Ships](#), 1973, as modified by the Protocol of 1978 relating thereto (MARPOL 73/78), London 1973 and 1978.
 - Regions: ECOWAS, ECCAS, SADC, COMESA, UMA
 - Guidelines from FROM: FAO, WHO, OECD, EPPO, GHS etc.

II. PESTICIDE REGULATIONS

1) Registration

- a) Application: application form that contains the a.i., country of origin, trade name, manufacturer, formulant, formulation , agent, chemical & physical properties.
- b) Dossier: Annex (a)
- c) Preliminary Dossier evaluation by the authority.
- d) Issuance of testing permit by the authority
- e) Submission of representative Sample for QC, which will be used as a reference.
- f) sample for efficacy testing shall be submitted, as required
- g) Residue Analysis & PHI and withdrawal intervals (where required).
- h) Final Evaluation & Recommendation.

2. AUTHORIZATION: (if approved).

3. Labelling, packaging & advertising

Labelling:

Label should be written in official language

3.1 A description of the content:

3.1a Trade name

3.1b name and content (% , g/kg or g/l) of a.i.

3.1c type of pesticide

3.1d type of formulation

3.1e rate of application

3.1f net content of the product expressed in international units;

3.2 A clearly visible indications of the hazard.

3.3 Concise indications for precautions to be taken.

3.4 Concise indications for first aid treatment in case of intoxication

3.5 Indications on the proper use of the product:

- 3.5a how, when and where to use the product;
- 3.5b contra indications
- 3.5c PHI and re-entry interval, if required;
- 3.6 Name and address of the manufacturer;
- 3.7 Country of origin;
- 3.8 Name and address of national or regional distributor;
- 3.9 Registration number;
- 3.10 Date of manufacture or formulation and expiry
- 3.11 Lot / batch number
- 3.12 Storage conditions
- 3.13 Telephone number of poison control center or emergency number of the applicant
- 3.14 Information about disposing of empty packages and leftovers.

Packaging

- The packaging shall preserve all its qualities throughout the transportation and storage of the pesticide
- The material chosen shall be perfectly adapted to the physico-chemical properties of the content according to the local storage conditions, particularly in order to avoid corrosion and changing the composition.
- Where the content is intended to be used at very small doses particularly for liquid products, the existence of a measure-stopper shall constitute an additional requirements for proper dosage and safety in use.
- The unit volume of the packaging shall, where possible, be adapted to the area unit to be treated, so that all of the content should be used once.
- Secondary packaging, especially in cartons, shall be as strong as possible to facilitate transportation and storage.
- Transportation indications shall be printed on the secondary packaging and coarse packaging in conformity with international symbols adopted for air, sea, railway, and road transport.
- The applicant shall specify:
 - nature of the packaging materials;
 - net/ gross weight;
 - dimensions of the packaging, in addition to diameter of openings and closing mechanism.

Advertising

- Pesticide advertisements promote the sale and use of pesticides by print and electronic media, signs, displays, demonstrations, or word of mouth.
- Advertisements can strongly influence users' decisions on which pesticide to use, when and how.
- It is a powerful means of influencing purchasing decisions and building recognition of / or loyalty for a brand or product name.
- It is therefore important that governments exercise some control on advertisements for pesticide products.

- Advertisements must be consistent with the conditions of registration, specifically with the approved label, in addition to the advertising guidelines recommended by the FAO.
- Advertising guidance is set out in Article 11 of the International code of conduct on the distribution and use of pesticides (Annex b).
- When promoting pesticides, it is important to present accurate product information and emphasize the importance of user competence.
- The pesticide industry is called upon to adhere to these standards and governments are urged to put in place appropriate regulations or legislation to enforce advertising standards.

Standards, compliance and regulation

- All advertising should be legal, decent, honest and truthful.
- All advertisements should comply with the requirements of any applicable legislation and adhere to any other applicable standards.
- They should not appear to approve or encourage actions that contravene or infringe national laws and regulations, or non-observance of standards or self-regulatory codes, and they should follow generally accepted standards of environmentally responsible behavior.
- The purpose of regulations and standards are to ensure that information in advertisements is conveyed correctly and fairly, is not misleading, and that use instructions are communicated appropriately.
- These guidelines focus both on voluntary standards or codes of practice (in chapters 4 and 6, Annex b) and legally binding national legislation on advertising (in chapter 5 of the code of conduct).

III. IMPORTS AND EXPORTS CONTROL:

QC of the pesticide is one of the most important pre-requisites for ensuring that the pesticides marketed in a country are of acceptable quality. Therefore, sampling of all pesticide shipments at the port of entry is of a paramount importance to ensure conformity with the registered product.

Since the bulk of the technical materials are imported, governments should control the importation of pesticides to ensure compliance with registration policies.

No pesticide should be allowed entry without an appropriate permit from a competent government authority. In addition to requirements by other departments such as trade and industry, the following are important considerations for allowing an importation:

- (i) the importer must be a licensed company;
- (ii) the pesticide product and active ingredient must be registered, or covered with an appropriate experimental use permit; and
- (iii) the quality of the import must be assured.

IV. TRANSPORT, HANDLING & STORAGE

TRANSPORTATION

- Pesticides should not be shipped or transported in the same container or compartment with cargo that could become a hazard if contaminated, such as food, drugs, toys, clothing, cosmetics or household furnishings.
- This is particularly so with trucks transporting pesticides, fertilizers, and farm produce to /or from the farm.
- Pesticides should not be carried in passenger compartments of transport vehicles.
- Care must be taken to ensure that persons travelling on the same vehicle with a cargo of pesticides are not subjected to exposure to the chemicals or their vapours.
- Vehicle-attendants should not ride with a pesticide cargo.
- Vehicles transporting pesticides should carry "hazard warning or cautionary notices", prominently displayed.
- Pesticides should at all times during transport be kept tightly secure and covered.
- Accident and damage during transportation (to be added).

HANDLING

Storage

Improper pesticides storage can be hazardous to human health and the environment.

Safety recommendations:

- i. Do not stockpile; reduce storage needs by buying only the amount you will need in the near future or during the current season when the pest is active;
- ii. Follow all storage instruction on the pesticide label;
- iii. Store pesticide high enough so that they are out of reach of children and animals;
- iv. Keep all pesticides in a locked store in a well ventilated utility area or shed;
- v. Never store pesticides in a place with or near food, animal feed, or medical supplies;
- vi. Store flammable liquid outside living areas and far away from an ignition source;
- vii. Always store pesticides in their original containers which include the label, direction for use and first-aid steps in case of accidental poisoning;
- viii. Never transfer pesticides to soft drink bottles or other containers;
- ix. Use child-resistant packages and close the container tightly after using the product;
- x. Do not store pesticides in place where flooding is possible or
- xi. In places where they might spill or leak into wells, drains, groundwater or surface water.

V. DISTRIBUTION AND SALES (LICENSING)

Licensing of the distribution chain provides the Government with an assurance that the persons are aware of the hazardous nature of the products they are dealing with and requires that they take the responsibility of complying with the legislation in force. There should be provision in the legislation to enable licensing of manufacturers, formulators, repackers,

operators and retailers to be undertaken. This may require regular training programmes, inspections, examinations and spot checks to be made.

1. Licensing of Pesticide Companies

Licensing pesticide companies including formulators, provides the government with an assurance that the company representatives are aware of the hazardous nature of the products they are dealing with and requires that they take the responsibility of complying with regulations; regarding pesticide registration, trade, production and use. In addition to commercial requirements for companies, the following are needed for a license to operate a pesticide company:

- (a) The premises must be inspected to check that all safety precautions are met. For manufacturing and formulation plants, anti-pollution devices are required. A quality control laboratory or provisions for quality control must be available. A staff doctor or nurse must be employed, who has undergone training on the management of pesticide poisoning. Managers must be aware of the nearest poison control centers, clinic or hospital. Governments are encouraged to establish or strengthen centres capable of treatment of poisoning cases.
- (b) The managers and staff must undergo training on safe use and handling of pesticides.
- (c) The government authority must approve the product stewardship guidelines of the company.
- (d) The necessary safety equipment must be available for use of all workers handling pesticides.
- (e) The appropriate antidotes and first aid treatments must be available.
- (f) All products handled must first obtain prior registration.

2. Licensing of Pest Control Operators

Pest control operators are entities engaged in commercial application of pesticides. Pest control operators normally handle the more toxic formulations and applications are done in or around houses. The licensing scheme for the pest control operators is designed to:

- (i) ensure safety of the applicators and their clients;
- (ii) generate awareness on the inherent risks of indiscriminate use and misuse of pesticides; and
- (iii) enable the early recognition of pesticide poisoning.

The following should be considered when licensing pest control operators:

- (a) Each office and branch must have at least one applicator that has taken a prescribed training course on safe application and use of pesticides, and has received the necessary accreditation from an authorized government institute.
- (b) The duly accredited applicator must have the responsibility to supervise and train those working in the same company.

- (c) Pest control contracts must specify the use of pesticides registered for such purposes.
- (d) Offices must be equipped with the required safety equipment and protective clothing for the applicators. There must be an occupational health program for the workers exposed to pesticides and a maintenance program for the spray equipment.

3. Licensing of Retail Shops

Pesticide retail shops are those privately owned or appointed by pesticide companies and distributors to sell their products to the end user. Licensing these shops, by the regulatory authority, would facilitate enforcement of regulatory measures related to pesticide registration. In addition to the requirements for pesticide companies, retail shops should comply with the following:

- (a) The owner or supervisor should attend regular prescribed training courses on pesticides.
- b) A list of sold pesticides should be kept and made available by retailers upon the request by the regulatory authority.
 - (b) The premises must be inspected by competent authorities, to check the storage facilities, display of pesticides, and safety equipment and conformity to other regulatory requirements.

PESTICIDE APPLICATION, APPLICATION EQUIPMENT AND USE (CERTIFICATION)

1) Operator training

Operators of pesticide application equipment must receive suitable training before handling and applying pesticides. Training should be provided by a recognized provider and courses are frequently offered by local training groups, agricultural colleges, government extension departments, spray equipment manufacturers and the chemical industry. The satisfactory completion of a course may result in a recognized certificate of competence to cover:

- safe product handling,
- delivery of the product to the target
- instruction on using the relevant spray equipment.

It is important that as technology moves forward, field applicators are kept up to date with new methodology to help ensuring that pesticides are safely used. In some countries where spray operators are licensed, they can only renew their operator's license if they attended regular refresher courses. Operator training is best organized and provided through sustainable permanent national structures.

2) Application equipment selection

The selection of appropriate and suitable application equipment is essential for safe and effective pesticide use. International and national equipment testing schemes have been established in many countries where after thorough testing under laboratory and field situations, application equipments are given certificates of approval. Where testing is not in place equipment manufacturers can be required to confirm that the equipment complies with the requirements in countries where testing is mandatory or the equipment meets the appropriate FAO guidelines.

Equally important when selecting application equipment is access to spare parts, service and support facilities.

Ideally, equipment selection should not be based primarily on cost. Safety, design, comfort and ease of use must be major considerations, and ease of maintenance must be a high priority. Knapsack sprayer maintenance should require only simple tools.

The combination of operator training to a recognized standard, combined with the selection of appropriate application equipment will contribute to improving the accuracy of pesticide delivery as well as protecting health and the environment

3) Using pesticides correctly

Pesticides should only be used if there is an economically important need and all pesticides must be used strictly in accordance with their label recommendations. Product selection must assess the potential exposure hazard of the selected formulation and determine what control measures and dose rates the label recommendations advocate.

4) Managing operator exposure

The use of Personnel Protective Equipment (PPE) is essential for protecting operator health and advice on its use will be found on the product label. Effective health monitoring records will be able to provide early warnings and identify changes in operator health, which may be attributed to working with pesticides.

As well as the workers handling and spraying pesticides the public must be safeguarded, both during, and after spraying, for example where they might have access to a treated area. Livestock also ought to be prevented from re-entering treated areas immediately after de application. For such reason marks indicating that the area was treated with pesticides should be posted.

DISPOSAL

- Products and left-overs and wastes that can no longer be used are to be disposed off in a safe and environmentally-sound manner.
- In case of Organochlorine Pesticides (OCPs), the recommended method is high temperature incineration. This technology is not available in number developing countries. Therefore, such waste is usually shipped to countries that are willing to accept the waste for incineration.
- Obsoletes and expired but not POPs pesticides shall be collected by the makers/ distributors for proper destruction.
- The best way to dispose of small amounts of excess pesticides or pesticide preparation is to use them- apply them; according to the label directions.
- Containers of pesticides shall be washed after using the last portions and the wash shall be added to the spray tank.
- The best way to dispose of the empty containers and the contaminated articles is to collect them by the producer / distributor where they can be recycled, reused or destructed in a proper way.
- Methods such as chemical treatment or land filling after solidification may sometimes offer solutions for relatively small quantities of specific groups of pesticides.
- Pesticides should never be disposed off by burying or open burning.
- For detailed information concerning disposal options, reference should be made to the *Guidelines* on disposal of bulk quantities of pesticides in

developing countries (UNEP/FAO/WHO). Safe and environmentally sound disposal of pesticides can be very expensive (appen.C).

VI. INSPECTION

- Quality control should continue as the product goes through the market chain.
- Random sampling and monitoring of product quality from retail outlets should be encouraged.
- Regulatory authorities must be vested with the power to enter retail outlets and take samples for analysis.
- Products that do not meet approved specifications must be confiscated. Subsequent action will depend upon the individual case and regulations; such actions may include relabeling for another use, reformulating or disposal.
- At least one laboratory assigned by the government should be charged with monitoring the quality of pesticides.
- To ensure effectiveness of quality control programs, appropriate legal sanctions must be imposed on violations.

VII. RE-EVALUATION, POST REGISTRATION SURVEILLANCE

- The safe and effective use of the product will depend on the user's understanding of complete, clear statements on the label.
- This monitoring activity can yield information which can be used to adjust and improve the label.
- Monitoring compliance with label directions and warning is important and can form the basis for enforcement actions and other regulatory controls.
- These programs must be carried out in conjunction with extensive information campaigns and training on the importance of reading and understanding the label.
- When monitoring for label compliance, the following are useful considerations:
 - (a) Monitoring should start at retail outlets. Only pesticides for general use should be allowed for sale in retail outlets. Restricted-use pesticides should not be sold in these outlets.
 - (b) Field surveillance is important to accurately monitor that the product is used for the specific crop and pest and in a manner consistent with the label. This should be carried out with the help of extension workers and industry representatives and supported with the necessary information programmes

(c) Distributors must be properly informed of the label directions and required to disseminate the same information to their outlets.

- Efficacy and resistance development is another element of monitoring approved uses. The regulatory agency should not usually expend major effort in this area, but can rely on extension and farmer reports to a large extent.
- Data submitted for registration allow the prediction of impacts of pesticide use in the environment. After a pesticide is used for some time, it is desirable to confirm that the predictions about environmental effects made at the time of registration, are valid. Doubts on the validity of previous predictions indicate a need for field surveillance and monitoring of residues and possible biological effects. Surveillance should be made of the residue levels in the various parts of the environment to provide information on the distribution pattern of the chemical and to identify suitable indicators for monitoring its fate and possible effects.
- The data provided for registration allows the regulatory authority to provide advice on the proper and safe use of the product. Misuse and mishandling of pesticides may result in poisoning. Monitoring these poisoning cases will provide useful information regarding the necessity of other regulatory controls /actions that may be embedded in the registration system.
- Monitoring these poisoning cases will provide information on hazards posed by the pesticide under conditions of field use, and must be accompanied by necessary training on pesticide poisoning symptoms and information campaign to instill awareness of the hazards posed by pesticide use. Recording of poisoning cases and regular reporting to the regulatory authority should be necessary components of such programs. Proper and accurate monitoring of pesticide poisoning cases can form a strong basis for appropriate policy decisions and control measures on pesticide use in the country.