

GUIDELINES ON

**POST-REGISTRATION
SURVEILLANCE
AND OTHER ACTIVITIES
IN THE FIELD OF PESTICIDES**



FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

**GUIDELINES ON POST-REGISTRATION SURVEILLANCE
AND OTHER ACTIVITIES IN THE FIELD OF PESTICIDES**

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
Rome - October 1988

TABLE OF CONTENTS

1.	INTRODUCTION.....	1
2.	MONITORING ACTIVITIES.....	2
2.1	Monitoring Quality of Pesticide Products.....	3
2.2	Pesticide Use in Accordance with Approved Label.....	3
2.3	Pesticide Residues in Food.....	4
2.4	Environmental Monitoring.....	5
2.5	Accidental Poisoning Due to Pesticides.....	5
3.	TRAINING PROGRAMMES ON SAFE USE OF PESTICIDES.....	6
3.1	Training of Farmers.....	6
3.2	Training of Retail Shop Personnel.....	7
3.3	Training of Government Extension Workers.....	7
3.4	Training of Doctors and Medical Practitioners.....	8
4.	LICENSING OF PESTICIDE HANDLERS.....	8
4.1	Licensing of Pesticide Companies.....	8
4.2	Licensing of Pest Control Operators.....	9
4.3	Licensing of Retail Shops.....	9
5.	ENFORCEMENT AND OTHER CONTROL MEASURES.....	10
5.1	Control of Imports.....	10
5.2	Control of Advertisements.....	10
5.3	Control of Labelling and packaging.....	11
6.	INFORMATION EXCHANGE.....	11

1. INTRODUCTION

Registration is the process of evaluation and acceptance by a statutory authority of extensive documented proof submitted in support of all claims for efficacy and safety made for the proposed product. The purpose of registration is to ensure that pesticides, when used according to directions for use, warnings and precautions contained on the approved label, will be effective for their intended purpose, while not posing unacceptable risks to users, consumers of treated food, and wildlife or other non-target organisms.

Registration involves a number of activities undertaken before a pesticide product is introduced in the market. A well-devised and operated registration scheme does not stop at this pre-market evaluation stage. It incorporates post-registration surveillance to ensure enforcement and monitoring of the actual use of the product to ascertain that the goals of registration are met. Post-registration activities provide the needed follow-up to ensure that the registered product is properly handled, distributed, and used safely and in accordance with applicable rules and regulations.

Post-registration activities provide a means of measuring the validity of predictions based on registration data, regarding efficacy, safety and environmental effects of a particular pesticide. If results of field surveillance raise doubts as to the effectiveness or safety of a product's use, further studies may be required or appropriate regulatory sanctions imposed. On the other hand, if despite potential adverse effects predicted, safety in use of a product is demonstrated, previous regulatory controls may be adjusted.

Post-registration activities are equally as important as the registration process. These activities should be basic components of any law regulating the trade, production and use of pesticides. The FAO Second Government Consultation on Harmonization of Pesticide Registration Requirements, Rome, October 1982, discussed the importance of post-registration surveillance as a needed support to registration. The Second Regional Consultation on Harmonization of Pesticide Registration Requirements, RENPAF, Manila, December 1986, recommended the need to develop guidelines to assist governments in effective monitoring of pesticide use. These guidelines have been developed to address this need and ensure that the registration objectives are adequately met. The guidelines evolve from common post-registration practices in many countries, especially the following:

- Various monitoring activities
- Training programmes on safe use of pesticides
- Licensing schemes for pesticide handlers and companies
- Enforcement of regulations and suitable control measures
- Information exchange

2. MONITORING ACTIVITIES

Surveillance or monitoring activities are designed to assure implementation of registration policies. Various monitoring activities may be initiated for various purposes:

- Quality of formulations in the market
- Pesticide use in accordance with the approved label
- Pesticide residues in food
- Environmental impacts of pesticide use
- Accidental poisoning due to pesticides

2.1 Monitoring Quality of Pesticide Products

A registration is granted on the basis of approved specifications of a product, which provide assurance that the data submitted were produced using a chemical sufficiently similar to that proposed for registration. In order to be consistent with registration policies, the product marketed should conform with the specifications approved for registration.

Temperature changes, storage conditions, packaging and other factors affect pesticide product quality. Any change in the product can result in unacceptable hazards or alter its effectiveness. It is therefore important to regularly monitor the quality of formulations in the market to ensure that the products will perform their intended purposes when used as stated in the label.

2.1.1 Quality of Technical Material

When technical materials are either produced locally or imported, such materials should conform to the specifications submitted during registration. These specifications should be based on FAO or WHO specifications if available. A valid certificate of analysis must accompany each sale of the technical material.

If there is any doubt regarding the quality of a shipment, it is appropriate to subject a sample for analysis by a Government laboratory or to require the exporter to obtain an analysis from a competent independent laboratory.

2.1.2 Quality of Imported Formulated Products

Formulated products normally have shorter shelf life than technical materials. When importing formulated products, it should be borne in mind that the time elapsed from formulation to actual receipt and repacking in recognized facilities in the country of destination may reach 60 to 90 days. The quality of these products must be carefully ascertained before acceptance by the importer. The following are some safeguards that may be followed:

- (a) The lot should be checked by a sworn sampler prior to shipping.
- (b) One sample should be analyzed by a reliable and well-equipped laboratory in the formulating country. An official body in that country should confirm the status of the laboratory.
- (c) One sample should remain in the manufacturing country and two should be sent to the receiving country. One of the latter may be used for analysis by an accepted laboratory in the recipient country, and the other should be kept as a reference sample in case of a dispute.
- (d) The importer should be personally responsible for ensuring compliance with the above procedures, and if the government itself is the importer, one official should be made responsible.
- (e) Only on the written confirmation of the laboratory in the manufacturing country that the lot meets the required standard should the goods be released for unloading.

2.1.3 Quality of Local Formulations and Repacked Products

Most pesticide products are either locally formulated or repacked. The same standards of quality must be maintained, i.e., the product must conform with the specifications submitted during registration. It is important that governments encourage formulation and repacking plants to maintain their own quality control capability, including their own, or access to other laboratories. The function of government will then be to randomly monitor that these plants produce quality products. The above safeguards for quality control of imported products should also apply for local formulations.

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 withdraw samples for analysis. Products that do not meet approved specifications must be confiscated. Subsequent action will depend upon the individual case; such actions may include relabelling for another use, reformulating or disposal. At least one official government laboratory should be charged with monitoring the quality of pesticides, especially local formulations. To ensure effectivity of quality control programs, appropriate legal sanctions must be imposed on violations.

2.2 Pesticide Use in Accordance with Approved Label

In countries operating a registration system, the accepted label is the legal proof of registration. It contains information on directions for use, warnings and precautions, obtained as a result of a lengthy process of evaluation of scientific data submitted for registration. The label is the main medium for instructing users in correct and safe use of pesticides. 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.

Full value should be taken from the FAO Guidelines on Good Labelling Practice for Pesticides. Failure to ensure adequate labelling and compliance with label directions can render fruitless all other efforts to regulate pesticides.

Monitoring compliance with label directions and warning is important and can form the basis for enforcement actions and other regulatory controls but it is difficult to accomplish in practical terms. These programmes 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 pesticides should not generally be sold in these outlets.
- (b) Field surveillance is important to accurately monitor that the product is used for the specific crop 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.

2.3 Pesticide Residues in Food

Experience over many years in those countries conducting market basket surveys has shown that residues rarely exceed the maximum residue limits (MRL's), established by the Codex Alimentarius procedures, and are usually much lower. In addition, where good agricultural practice (GAP) is followed, residues should not exceed MRL's. Nevertheless, regulatory authorities should exercise some monitoring and control over residues in food after the registration of the product, for the protection of the consumers and to facilitate international trade.

Data on residues remaining in food provided for registration will have allowed a reasonable estimate to be made of the level of residues remaining in the crop when the produce has been applied according to good agricultural practice. Once the pesticide is available in the market it is desirable for the competent authority to confirm that the estimate made during registration is valid. To do this, residue levels must be monitored, by taking samples of the crops at the point of harvest, where the pesticide has been used. For crops treated during storage, samples in warehouses should be taken. Analyses of these samples should show if revision of the estimated maximum residue limit is necessary.

Monitoring residues on food commodities can provide useful information to assess the safety to consumers of treated food, detect residues from improper use of pesticides, and protect

the credibility of exporters with their customers. Such residue monitoring data can also provide the basis for modifying use patterns, restricting or cancelling registered uses, or taking enforcement action against pesticide misuse.

At least one government laboratory should be responsible for analysis of residues on food and the environment, and report findings routinely to the regulatory authority. If practicable, the laboratory should be under the control of the regulatory agency.

2.4 Environmental Monitoring

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 biological effects of a pesticide on the environment may be assessed by monitoring changes in populations of key indicator species, of a susceptible species or of one vulnerable because of its position in the ecosystem. Biological monitoring is also possible by assessing changes in species diversity in ecosystems or by studying physiological and behavioural parameters.

If field surveillance and monitoring data give rise to doubts on the validity of predictions regarding environmental effects of the use of a particular product, its continued use or the conditions for use have to be reconsidered. Monitoring of the environment therefore provides an indication of residue movement and potential contamination which may affect fish, wildlife and other non-target organisms. Results of such monitoring can form the basis for appropriate regulatory actions.

2.5 Accidental Poisoning Due to Pesticides

The data provided for registration allows the regulatory authority to provide advise on the proper and safe use of the product. However carefully the precautions for the use of the pesticide product are written and however clearly they appear on the labels there are still cases of pesticide misuse. Misuse and mishandling of pesticides may result in poisoning. Monitoring these poisoning cases will provide useful information regarding the effectiveness of the registration system, its training and information programmes.

It is not possible to monitor each and every user of pesticide. A practical approach is to obtain statistical samples of farm level users of pesticides. This can be done in cooperation with government extension workers and industry field representatives. In some cases, hospital records may also be useful sources of poisoning data, but doctors and paramedics must be properly trained to recognize the symptoms of poisoning due to pesticides.

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 cases and regular reporting to the regulatory authority should be necessary components of such programmes. 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.

3. TRAINING PROGRAMMES ON SAFE USE OF PESTICIDES

The importance of training users on the proper application and handling of pesticides cannot be overemphasized. The wide use of pesticides even in remote areas, emphasizes the need to ensure that safety information reaches the individual users. The text of the product label contains handling information and warnings on misuse, but careful reading and observance of these is unfortunately not universal. Therefore, local education and training on safe use of pesticides are necessary after a product is registered.

Training and information programmes should include all sectors handling and using pesticides. Aside from farmers, the pesticide retail store owners and attendants, the government technicians and extension workers, the pest control operators and commercial pesticide applicators, and even the doctors, nurses and paramedics should be trained on the safe use of pesticides. Different training modules should be developed for each group.

A modular course on the safe use of pesticides is available from WHO. The course is divided into more than 100 modules, each with a text and a visual aid, from a which selection, appropriate to the level and experience of the group under instruction, may be made. Films, slides, and other information materials are available from industrial firms which, with local language commentaries, may be useful for instruction purposes.

3.1 Training of Farmers

Where there is good network of extension officers, the training of farmers and others in the correct method of storing pesticides, in the choice of the most appropriate product, in the application techniques and in safe disposal of unwanted pesticides and empty containers could be part of their regular duties. Faulty application equipment, particularly knapsack sprayers, are a common cause of contamination, and therefore farmers need instructions on the proper maintenance and repair of farm equipment. All possible methods of communication with the farming community should be used. These should include radio, television, films, slides, literature, and posters on relevant subjects. In countries where the majority of the population is involved in agriculture, there is justification for the inclusion of lessons on pesticide safety in the school curricula.

The training course should include advice on:

- (a) Importance of reading and understanding the label
- (b) Importance of skin absorption as a route of poisoning
- (c) Potential of some pesticides for cumulative effects
- (d) Importance of minimizing exposure to chemicals because of long-term effects
- (e) Proper handling of pesticide concentrates

- (f) Symptoms of poisoning, precautionary measures, first aid treatments and availability of medical assistance
- (g) Proper application techniques
- (h) Protection of the environment, including neighbours, mammals birds and fish and groundwater

3.2 Training of Retail Shop Personnel

Retail shops for pesticides are important channels of information to farmers concerning the safe handling and effective use of pesticides. Because farmers come to such shops when their crops are threatened by pests and because they have to pay for pest control products, they normally are well motivated to ask advice and listen to suggestions on pesticide use. However, many of these shop owners and staff have limited knowledge about the pesticides they sell and the hazards involved in their use. Training of these shop owners and staff will go a long way in ensuring safe use at farm level. The training module should include advice on:

- (a) Recognition from the label of the hazard category of formulations
- (b) Appropriate methods of storage
- (c) Proper display of pesticide containers
- (d) Knowledge of relevant regulations on pesticides, particularly regarding restrictions on purchase and sales
- (e) Hazards of pesticide use, and first aid measures
- (f) Proper transport of pesticides

3.3 Training of Government Extension Workers

Training programmes of this type are important to instill awareness on these workers, of the hazards posed by pesticides and to promote consciousness in the efficient use and safe handling of the products. The extension workers in turn are responsible for training the farmers on the subject,

3.4 Training of Doctors and Medical Practitioners

Doctors and paramedics should be trained in the recognition and management of pesticide poisoning cases. Since the subject is normally not part of medical school curriculum, there are very few doctors trained in pesticide poisoning. Information of the mode of action of pesticides, their effects on human health, and their toxicity and their treatment are important components of the module. Poison control centers can play an important role in this process, particularly as a source of information.

4. LICENSING OF PESTICIDE HANDLERS

A system of licensing the handlers of pesticides can be useful in ensuring proper enforcement of registration policies and other pesticide regulations. Many regulatory systems already incorporate a licensing scheme. In these systems, no person or entity is allowed to import, manufacture, formulate, repack, distribute or sell pesticides without first obtaining a license from the registration authority. Handlers of pesticides may be classified into:

- Pesticide companies engaged in the business of importing, formulating, manufacturing, and distributing pesticide products
- Pest control operators or commercial applicators of pesticides
- Pesticide retail shops

Each of these categories would have different requirements for licensing.

4.1 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. A clinic or hospital must be located near the premises.
- (b) The managers and staff must undergo training on safe use 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.

4.2 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.

4.3 Licensing of Retail Shops

Pesticide retail shops are those authorized by pesticide companies and distributors to sell their products to the end user. Licensing these shops 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 a prescribed training course on pesticide safety.
- (b) A list of the companies represented and the products sold should be provided to the regulatory authority on a regular basis. Only registered pesticides allowed for general use should be sold in retail shops.
- (c) The premises must be inspected by competent authorities, to check the storage facilities, display of pesticides, and safety equipment.
- (d) The FAO Guidelines on Retail Distribution of Pesticides with Particular Reference to Storage and Handling at the Point of Supply to Users in Developing Countries should be strictly followed and compliance monitored on a regular basis.

5. ENFORCEMENT AND OTHER CONTROL MEASURES

The effectiveness of pesticide regulations depend on the practical implementation and enforcement of the law. The law must require that only pesticides that have been cleared through the registration process can be sold and used in the country. Registration authorities should have the power to confiscate unregistered products and hold the distributor, trader, retailer and user responsible for any violation of the law.

Monitoring activities are designed to form the basis for any enforcement action. When violations are discovered, appropriate penalties must be imposed. All regulations should have penal provisions which are necessary to ensure effective implementation of regulations.

There may be other control actions that may be exercised to ensure compliance with registration policies. Among these are the control of imports, labelling, packaging and advertisements of pesticides.

5.1 Control of imports

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 if a licensing scheme exists in the country; (ii) the pesticide product and active ingredient must be registered, or covered with an appropriate experimental use permit if a registration scheme exists; and (iii) the quality of the import must be assured.

5.2 Control of advertisements

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 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, the guide to advertising under the FAO International Code of Conduct on Distribution and Use of Pesticides should be followed by industry and government.

5.3 Control of Labelling and Packaging

It is necessary for Government to be able to monitor whether labelling and packaging by the companies meet the standards agreed to and accepted by the regulatory authority. Regulations should provide for the power to allow stocks which do not meet these requirements to be withdrawn from sale. The FAO Guidelines on Good Labelling Practices for Pesticides and Guidelines on the Packaging and Storage of Pesticides should form the basis for action taken by the regulatory authority on these aspects.

6. INFORMATION EXCHANGE

Registration officials must continually reappraise pesticides after registration in light of new data and information. Information regarding actions taken by other governments, trade in banned or severely restricted pesticides and new analytical data on pesticides received by other governments is an important source for such reappraisal.

Governments of pesticide-exporting countries should, under the FAO Code of Conduct, OECD and UNEP guidelines, inform all other nations of action taken to ban or severely restrict the use or handling of a pesticide and the reasons for such action. In addition, any other country which takes such an action should advise other governments of the nature and reasons for such action.

Pesticide-exporting governments are also expected to advise the country of receipt on exports of banned or severely restricted pesticides prior to the first shipment annually.

Such notice may be sent directly to other nations or directed through the International Registry of Potentially Toxic Chemicals (IRPTC). Experience of some countries indicate that it is preferable to make such notices directly to regulatory authorities. But in any case, an information copy should be provided to IRPTC and to FAO.

Exporting countries should be prepared to provide further information and technical assistance if requested to help importing countries determine the significance of the action under its use conditions.

Importing country governments should establish such systems as necessary to utilize the information received to make their own regulatory decisions. They should ensure that an up-to-date contact point is maintained and is made known to other nations, FAO and IRPTC.

In addition to information on banned or severely restricted pesticide, governments of exporting countries should provide information and technical assistance on any other pesticide when requested by an importing country.

Attention is drawn to the provisions of Article 9 of the FAO Code of Conduct on the importance and need for information exchange.