



International Code of Conduct on the Distribution and Use of Pesticides

Guidelines for Quality Control 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.

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Abbreviations

AOAC	Association of Analytical Communities, International
CAN	Comunidad Andina de Naciones (Andean Community)
CILSS	Comité Inter-Etate pour la Lutte contre la Sécheresse au Sahel (Permanent Inter-State Committee for Drought Control in the Sahel)
CIPAC	Collaborative International Pesticides Analytical Council
EPA	Environmental Protection Agency (United States)
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
OECD	Organisation for Economic Co-operation and Development
SEARCH	South East Africa Regulatory Committee on Harmonisation
WHO	World Health Organization

Definitions

The definitions given below apply to the terms as used in these guidelines. They may have different meanings in other contexts.

Adulterated pesticide

A pesticide any component of which has been substituted wholly or in part, or any constituent of which has been wholly or in part abstracted, added or modified in quantity compared with the regulatory specification on record.

Chain-of-custody

The ability of the inspector to guarantee the identity and integrity of the enforcement sample from seizure, custody, transport, storage and analysis to reporting of test results.

Compliance

The full implementation of legal requirements [6].

Counterfeit pesticide

A pesticide made by someone other than the approved or registered manufacturer, by copying or imitating an original product without authority or right, with a view to deceive or defraud, and then marketing the copied or forged product as the original.

Enforcement

The set of actions that governments or others take to achieve compliance by the regulated community with pesticide regulatory requirements and/or to halt situations that may endanger public health or the environment. Government enforcement usually includes activities such as investigations, negotiations and legal actions [6].

Inspector

An officer who is authorized under the pesticide law of the country to enforce the provisions of the law, including taking pesticide samples from the market and taking prosecution actions in cases of non-compliance.

Official analyst

A chemist who is authorized under the pesticide law of the country to carry out analysis and issue reports on the analysis of samples submitted by inspectors for use as evidence in court.

Pesticides Board (sometimes referred to as Pesticide Registration Board, Pesticide Council or Pesticide Committee)

The officially or legally appointed body that takes the final decision on the request for registration [8].

Quality control of pesticides

The inspection by the responsible authority of pesticide products imported, manufactured and/or available in the market to check whether they meet the desired requirements, including of labelling, packaging and specifications, as well as to identify the cause for non-conformities and take the necessary corrective actions.

Responsible authority

The government agency or agencies responsible for regulating the manufacture, distribution or use of pesticides and, more generally, for implementing pesticide legislation [2].

Sampling report

The standard report form completed by the inspector at the time of sampling and countersigned by the person designated to be responsible for the batch at the time the sample is taken [9].

Substandard pesticide

A pesticide the physical-chemical properties of which do not meet the minimum quality standard.

Violations Noncompliance with a requirement [6].

Guidance for Quality Control of Pesticides

1. Introduction

Pesticides, when properly used, can be important to the production of many agricultural crops as well as for the protection of human health. Successful control of pests and vectors relies on effective pesticide products of acceptable quality that do not cause any unacceptable effects when used as recommended. The use of substandard products can have serious adverse effects on human health and the environment. In addition, their use in quarantine situations could have serious repercussions, such as introducing a pest or a disease into an area previously free of that pest or disease. It can also result in not only ineffective pest or vector control operations thus leading to increasing application rates and cost, but also loss of crops and even human lives. It may also lead to the development of pest resistance to pesticides and aggravate any such existing problem. In addition, it may increase the risk to users and the environment as substandard formulations may contain impurities or chemicals which can increase the toxicity of the product to mammals and other non-target species.

In 2001, the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) [1] estimated that around 30 percent of pesticides marketed in developing countries with an estimated value of US\$ 900 million annually did not meet internationally accepted standards of quality. When the quality of labelling and packaging is also taken into account, the proportion of poor-quality pesticide products in developing countries is even higher. High incidences of substandard pesticides have also been reported to FAO and WHO by national pesticide quality control laboratories of developed countries, emphasizing the significance of the problem.¹ The possible causes of low-quality pesticides can be attributed to a range of factors that include poor production technology and quality control, production of counterfeit products, adulteration of products (see Definitions) and poor storage prior to marketing. Insufficient enforcement by regulatory authorities as a result of financial, infrastructure and human resource constraints can create an environment that enables such practices to expand.

The *International Code of Conduct on the Distribution and Use of Pesticides* (2) (hereafter referred to as the Code of Conduct)² describes the shared responsibility of many segments of society, including governments, industry, trade and international institutions. The Code of Conduct provides a framework for management of all pesticides, including those intended for use in agriculture and public health. The Code of Conduct emphasizes the importance of ensuring quality control of pesticides, and that is mainly the responsibility of government and industry to ensure that pesticides being traded are of assured quality.

FAO and WHO establish and publish specifications for technical material and related formulations of agricultural and public health pesticides [3, 4] with the objective that these specifications may be used to provide an international reference point against which products

¹ In reports of the FAO/WHO Joint Meeting on Pesticide Specifications available at <http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmps/meetjmps/en/> and at http://www.who.int/whopes/quality/fao_who_meetings/en/

² The International Code of Conduct on the Distribution and Use of Pesticides (revised version) was adopted by the 123rd Session of the FAO Council in November 2002.

can be judged either for regulatory purposes or in commercial dealings. Member countries are encouraged to use these specifications whenever they are available.

Quality control of pesticides is a crucial and integral part of pesticide management and also in the implementation of the Code of Conduct by the various stakeholders. These guidelines have been prepared to assist Member States, particularly those that have constraints in the setting up of an effective pesticide quality control system in their countries. Governments may find that their existing laws are inadequate to implement some of the proposals contained in these guidelines and should consider making relevant amendments to their laws as the way forward.

2. Scope of the guidelines

These guidelines cover the legislative, administrative, organizational and infrastructure (facilities and trained human resources) requirements to implement a scheme of regulatory quality control of pesticides in Member States. Guidance on sample selection and sampling procedures is also included. They do not include quality assurance practices of pesticide quality control laboratories, which are covered in another set of guidelines developed by the Collaborative International Pesticides Analytical Council (CIPAC), FAO and WHO [5].

3. Objectives of the guidelines

The objectives of these guidelines are:

- (i) to provide guidance to responsible authorities, the pesticide industry, retailers, users and civil society on legislative, administrative, organizational and infrastructure requirements and procedures for quality control of pesticides; and
- (ii) to enhance the quality of pesticides in the market, thus minimizing risks to human health and the environment, crop losses and ineffective control of pests of public health importance

4. Responsibilities

The main responsibilities for ensuring the quality of pesticides marketed in the country have been identified in the Code of Conduct. They include the following issues.

4.1 Governments should:

- (a) introduce the necessary legislation for the regulation of pesticides and make provisions for its effective enforcement;
- (b) strive to establish pesticide registration schemes and infrastructures under which products can be registered prior to domestic use and ensure that each pesticide product is registered before it can be made available for use;
- (c) possess or have access to facilities to verify and exercise control over the quality of pesticides offered for sale or export, to establish the quantity of the active ingredient or ingredients and the suitability of their formulation, according to FAO or WHO specifications, when available;
- (d) use the principles described in the *Manual on development and use of FAO and WHO specifications for pesticides* [9] for determining equivalence of pesticides;
- (e) improve regulations in relation to collecting and recording data on import, export, manufacture, formulation, quality and quantity of pesticides; and
- (f) detect and control illegal trade in pesticides.

4.2 Industry should:

- (a) supply only pesticides of adequate quality, packaged and labelled as appropriate for each specific market;
- (b) take all necessary steps to ensure that pesticides entering international trade conform at least to relevant FAO, WHO or equivalent specifications (where such specifications have been developed);
- (c) endeavour to ensure that pesticides manufactured for export are subject to the same quality requirements and standards as those applied to comparable domestic products;
- (d) ensure that pesticides manufactured or formulated by a subsidiary company meet appropriate quality requirements and standards. These should be consistent with the requirement of the country and of the parent company;
- (e) provide, at the request of a country, methods for the analysis of any active ingredient or formulation that they manufacture, and provide the necessary analytical standards;
- (f) ensure that the active ingredient and other ingredients of pesticide products being marketed correspond in identity, quality, purity and composition to the substances tested, evaluated and cleared for toxicological and environmental acceptability;
- (g) ensure that active ingredients and formulated products for pesticides for which international specifications have been developed conform with the relevant FAO specifications for agricultural pesticides and with WHO specifications for public health pesticides;
- (h) verify the quality and purity of pesticides offered for sale;
- (i) use labels that identify each lot or batch of the product in numbers and letters that can be understood without the need for additional code references and labels should clearly show the release date (month and year) of the lot or batch and contain relevant information on storage stability of product;
- (j) retain an active interest in following their products to the end-user, keeping track of major uses and the occurrences of any problems arising from the use of their products, as a basis for determining the need for changes in labelling, directions for use, packaging, formulation or product availability; and

- (k) provide advice and assistance in the training of technical staff involved in the relevant analytical work.

4.3 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; and
- (b) within available resources, consider assisting in the establishment of new analytical laboratories, or strengthening capacity and capability of 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.

4.4 Government and industry should:

- (a) in establishing production facilities of suitable standards in developing countries, cooperate to maintain quality assurance procedures to ensure compliance with the relevant standards of purity, performance, stability and safety; and
- (b) ensure that all pesticides made available to the general public are packaged and labelled in a manner which is consistent with FAO guidelines on packaging and labelling and appropriate national regulations.

5. Pesticide quality control – legislation, organizational setup, and administrative requirements and resources

5.1 Legislation

Comprehensive legislation for the control of pesticides (including microbial pesticides) is one of the most important prerequisites to ensure that pesticides marketed are of acceptable quality. The legislation should include, among others, provisions for the control of registration, licensing, manufacturing including packaging and re-packaging, labelling, use, advertisements, transport, disposal and enforcement (including offences, penalties and inspection). FAO has published a comprehensive set of guidance [7] on how and what are required in designing national pesticide legislation.

An effective system for the control of the quality of pesticides would first of all require that legislative, administrative, technical and financial support is in place for the registration of pesticides. This is essential, as pesticides should be thoroughly evaluated before they are allowed to be imported, manufactured and marketed to ensure they are of acceptable quality, effective and would not pose any unacceptable risk to human health and the environment when used as approved. Many developing countries face challenges in developing and sustaining an

effective registration system given the lack of expertise and financial resources. A set of guidelines for the registration of pesticides has been prepared and published by FAO and WHO to assist these countries [8].

During the registration process, the responsible authority should ensure that products approved are of good quality. In cases where FAO and WHO have already published specifications [3, 4] for the pesticide products, responsible authorities should make it a requirement that approved products conform to the above specifications. However, in cases where no such specifications have been developed, responsible authorities could depend on their national standards, on standards set by developed countries, if available, or use their discretion to accept the standards provided by the companies with modifications, where appropriate, until such time as FAO and WHO have developed specifications for these products.

Specifications have been developed as trade standards. Products that do not meet the relevant specifications should not be traded. However, meeting specifications is not necessarily the only criterion regarding whether old pesticide stocks still can be used or should be disposed of. Old stocks that are out of specification should be reviewed on a case-by-case basis to determine whether they still could be used. In some cases, where there are toxic break-down components, continued use is not an option, while in other cases it may be possible to adjust the dosage rate to account for the reduced concentration or potency of pesticide active ingredients. In view of the high costs of disposal, it would be important to adopt such a case-by-case approach for large stocks instead of automatically declaring all products that are out of specification as obsolete. Such reviews require specialist advice.

Packaging and labelling constitute a part of the pesticide product marketed. Hence, in the evaluation and approval of a pesticide product the responsible authority should ensure that the packaging of the product is of good quality and would be able to withstand the rigours of handling, transportation and storage under local climatic conditions. Poor packaging could not only adversely affect the quality of the product but may also result in leakages causing unexpected human exposure and environmental pollution. Approved products should also conform to the national labelling requirements to ensure that users obtain correct information about the product.

Other aspects of the legislation such as licensing for sale and manufacturing could also have an impact on the quality of pesticides. Licensing retailers and manufacturers would impose greater accountability on them to sell and manufacture pesticides of assured quality. Contravention of the law by selling or manufacturing substandard or unregistered products could result in the withdrawal of their licences.

While an effective registration system will be the first important step in ensuring that only high-quality pesticides are permitted to be imported, manufactured and marketed, post-registration activities such as surveillance, education and enforcement are equally important, particularly in some developing countries where poor quality and counterfeit products have frequently been encountered.

Although enforcement is not the only tool to enhance the quality of pesticides marketed, it is, however, important and essential, particularly in countries where substandard and counterfeit pesticides are frequently encountered. For effective enforcement, the pesticide legislation and supplementary regulations should include the following provisions for:

- taking enforcement actions relating to poor-quality, unregistered and banned as well as counterfeit pesticides;
- specifying the procedure for taking samples, including the methodology, number of samples to be taken and by whom; where samples should be analysed; timeframe for

analysis; personnel qualified to carry out the analysis; who may advise on the results of the analysis; and actions in the event of a challenge to the results of the analysis;

- specifying the procedure for seizure of products;
- imposing adequate penalty to act as a deterrent for non-compliance;
- formulating regulations on licensing for the manufacture or formulation, and distribution and sale of pesticides;
- officially appointing officers to take enforcement samples as well as carry out prosecution of offenders;
- officially appointing official analysts; and
- allowing (or permitting) the party (company) from whom the samples are taken (or the manufacturer or supplier if different) to challenge the results of analysis if they differ from the results of analysis provided by the enforcement officer.

5.2 Organizational setup

It is important that the authority responsible for control of pesticides in the country should be clearly stipulated in the pesticide law. The organizational set-up of the responsible authority will vary from country to country depending on the local situation. The various options for setting up such an authority are discussed in *Designing national pesticide legislation* published by FAO [7] and *Guidelines for the registration of pesticides* published by FAO and WHO [8]. Whichever type of organizational set-up is adopted, it is beneficial from the viewpoint of cost as well as the better utilization of limited human and technical resources, that all pesticides are controlled by a single authority.

It is common practice that there is provision in the law for the formation of a Pesticide Board (sometimes referred to as a Pesticide Committee or Pesticide Council) with members representing the relevant sectors that would be responsible, among others, for making the final decision on a request for registration as well as for making policies on pesticide regulation and management, and the implementation of the law on pesticides.

At the same time, there should also be provisions in the law to appoint a department or agency which would act as the responsible authority to carry out the day-to-day activities in the implementation of the law. The responsible authority should be provided with the funds to employ technically competent officers skilled in the various aspects of pesticide management. Funds should also be provided to set up laboratory and administrative facilities capable of supporting the Board in the implementation of all the provisions of the Act.

The law should also provide the Pesticides Board with the powers, among others, to carry out its duties, including the promulgation of supplementary regulations, appointment of relevant officers, collection of data and collection of fees.

Depending on the local situation, the supporting services such as the analytical laboratories and enforcement services for the control of quality of pesticides may or may not come under the direct administration of the responsible authority. For situations where the laboratories and the enforcement personnel are under the administration of other agencies, it is imperative that their appointments are provided for under the law.

5.3 Administrative requirements and resources

Enforcement is an important and essential aspect of pesticide management, particularly so in countries facing challenges to control the quality of pesticides marketed. Enforcement has often been weak and neglected in many countries. Any law is only as good as how well the authorities are able to enforce it. While adequate punitive action for non-compliance is important, it should not be the only option used. For minor offences, enforcement agencies may opt to issue warnings on the condition that corrective actions are taken within a specified timeframe by the offenders.

It is often not realized the extent to which a country stands to lose through the lack of enforcement. Through the use of substandard products, the public may not be protected against pests and vector-borne diseases, farmers may lose their crops or suffer significantly lower yields, and users and consumers may be at risk due to exposure to highly toxic impurities.

There are different scenarios on how quality control of pesticides may be implemented, depending on the local situation and available resources. Some common scenarios are the following.

5.3.1 Responsible authorities with access to local pesticide analytical laboratory facilities

Countries with local pesticide analytical laboratory facilities are in a better position to implement quality control programmes compared with those that do not have such facilities. Pesticide analysis is highly specialized and requires not only the laboratory to have suitable infrastructure and to be adequately equipped with the appropriate instrumentation but also analysts should be specifically trained in this field of analysis. Other than the requirements of adequate analytical facilities and skilled analysts, another important aspect which is part and parcel of quality control is enforcement, which permits the taking of legal samples in the market for analysis, submitting the samples for analysis and finally using the analytical report on the samples for follow-up action, including prosecution if necessary.

It is crucial to ensure that requirements for enforcement under the law have been complied with prior to taking enforcement actions, and this may include the following:

There should be provisions in the pesticide law for appointment of inspectors with powers to take pesticide samples and initiate prosecution in the court if necessary. Before officers are appointed, normally through gazetting, they should be given comprehensive training on enforcement requirements under the Act. A standard operating procedure for carrying out enforcement activities regarding quality control should also be developed and followed.

The integrity of any legal sample is of utmost importance for it to be of use in any prosecution case. Hence, it is crucial that there is provision for a store under the control of the enforcement agency to allow the secure storage of enforcement samples so that the sample integrity would not be compromised.

It should be highlighted that taking of enforcement actions requires well-trained officers who are not only conversant with the law to ensure that actions taken are in compliance with the law but are also sufficiently competent to safely handle and secure toxic pesticides during their sampling and transportation.

It is also important that official analysts who carry out analysis to verify the quality of pesticide samples taken by inspectors should also be officially appointed under the law. This is to ensure that only competent analysts are entrusted to carry out quality control analysis.

In addition, it is important that analytical facilities are well maintained and, preferably, accredited under a reputable laboratory quality assurance programme. Similarly, gazetted analysts should also be well trained in the techniques and methodologies of pesticide analysis. It should be pointed out that the analytical laboratory may be any competent government or independent analytical laboratory in the country that has been gazetted under the pesticide law of the country.

The capability and capacity of a quality control laboratory would depend on the needs and availability of national financial and human resources. The cost in the establishment and operation of quality control laboratories is high, and serious considerations should be made before any attempt is made for the setting up of such laboratories. Requirements for setting up such quality control laboratories as well as aspects of management and quality assurance have been adequately covered in *Quality control of pesticides products: guidelines for national laboratories* [5]. Quality assurance is an important consideration in the operation of such a laboratory and, in general, accreditation according to ISO/IEC 170251 through a national body seems to respond better to the specific needs of an official quality control laboratory than the quality assurance scheme under Good Laboratory Practice (*OECD series on principles of good laboratory practice, and compliance monitoring* [11]), which is mandatory for the elaboration of studies necessary for national registration in countries of the Organisation for Economic Co-operation and Development (OECD) [5].

5.3.2 Responsible authorities without access to local pesticide analytical laboratory facilities

Many developing countries do not have the privilege of having analytical facilities for pesticide quality control. This will pose a big challenge to the responsible authority of the country to implement an effective quality control programme. However, other options should be explored and could include the following:

The responsible authority should impose a requirement for licensed importers of pesticides to provide reports of analysis issued by an accredited or certified laboratory to verify the quality of the consignment imported.

The responsible authority should, on a random basis, send samples of imported pesticides, at the cost of the importer if possible, to an accredited laboratory overseas (preferably to an accredited laboratory in the region of one of the WHO collaborating laboratories) to verify the accuracy of the reports of analysis submitted by importers. Bilateral or regional arrangements could also be made to assist in the analysis of products.

When local financial resources for the establishment and maintenance of a quality control laboratory become available, the responsible authority may wish to consider building their capacity to carry out their own pesticide quality control analysis. It is crucial to ensure that prerequisites for continuity of laboratory services have been critically evaluated before set up. Laboratories are costly to maintain and it may be a major challenge to sustain the operation of the laboratory in the long term. Countries establishing such a laboratory should therefore carefully consider the operating costs and potential for cost recovery in order to determine the economic viability and to make a business plan if the government is not in a position to fully finance the operation of the laboratory.

If it is not feasible to establish a laboratory specifically for pesticide formulation analysis due to financial and human resource constraints, it may also be possible to enhance the capacity and capability of an existing chemical laboratory that is serving other needs of the country to carry out pesticide formulation analysis. Collaboration between an international laboratory specialized in pesticide analysis and a local non-specialized laboratory that is to assume the responsibility

of pesticide analysis is highly recommended given the operational knowledge and know-how that would need to be obtained by the local laboratory

It would be useful to request for foreign aid to help establish a pesticide formulation laboratory to check the quality of pesticides in the country; however, it is very important that there should be government commitment to ensure continuity of laboratory services on completion of the project. Steps should be taken to develop a mechanism, even before the establishment of the pesticide formulation laboratory, to ensure continuation of operations at the termination of foreign support, taking into account in particular the high costs of operating and maintaining analytical laboratories.

5.3.3 Pesticide manufacturers or formulators

Pesticide manufacturers or formulators have the responsibility to ensure that the pesticides they produce are of good quality. They should source their raw materials from reliable sources. They should also establish an in-house quality control department equipped with the relevant testing equipment and adequate human resources to monitor the quality of raw materials as well as pesticides produced and those sold by them in the market. Steps should also be taken so that such laboratories are accredited under a reputable laboratory quality assurance programme. Records of analysis and a copy of test reports for every batch of pesticide manufactured or formulated should be made available when requested by the responsible authority. These records should be kept for a period of not less than five years from the date of manufacture/formulation of the pesticides. The responsible authority should ensure that manufacturers have the required quality control systems in place and adequate technical expertise before licenses are issued to them.

5.3.4 Pesticide importers

Developing countries in general import most if not all of their pesticides. In some of these countries, however, some formulation activities are carried out. Pesticide importers are often traders with very limited technical resources and expertise. They should be required to establish a system to ensure that their imported products are sourced from producers who will be considered acceptable to the responsible authority as well as to the responsible authority of the exporting countries and in compliance with the regulatory specification on record. In addition, they should ensure that every consignment is accompanied by a quality control report for that batch issued by an accredited laboratory for the product. To further ensure that the products they are marketing are of good quality, they should develop and implement a mechanism to constantly verify the quality of their products.

6. Practical considerations for regulatory quality control of pesticides

Control of the quality of pesticides should be an ongoing activity, but it is costly and therefore requires careful planning and implementation to optimize the use of limited resources. Regulatory authorities should make efforts to implement realistic cost recovery mechanisms to ensure the sustainability and continuity of quality control systems. The quality control process should involve pesticides submitted for registration, pesticides imported and manufactured as well as those marketed. Quality control laboratories should be equipped not only to analyse the

active ingredients of pesticides but also to conduct the tests required to check compliance with all physical and chemical properties, including impurities as specified in the specifications.

6.1 Products submitted for registration

Registration can be considered as the first line of defence to prevent the entry of substandard pesticides into the country. It should be part of the registration process to require that applicants for registration provide comprehensive information on the composition of the product and a sample of the pesticide product for evaluation of quality together with a sample of certified analytical standard for the active ingredient and/or relevant impurities. In addition, the specification and method of analysis of the product should also be submitted. It is the responsibility of the responsible authority to evaluate the quality of the product submitted for registration using collaboratively tested methods such as those published by CIPAC and by the Association of Analytical Communities International (AOAC) if available. If such methods are not available, methods submitted by the company should be evaluated internally and, if found acceptable, could be used until such time as internationally collaboratively tested methods become available.

It is therefore crucial that during the registration process appropriate procedures are established and followed to:

- ensure that products submitted for registration comply with FAO/WHO specifications for pesticides, national standards or other standards where applicable;
- ensure that the quality of the product be verified (including active ingredient and relevant impurities content and physico-chemical properties of the product) during the registration process using internationally collaboratively tested methods such as those published by CIPAC or AOAC. In the absence of CIPAC or AOAC methods, other methods such as methods in national standards or company methods may be used after their validation;
- ensure that the labelling and packaging of approved pesticides comply with set standards;
- request for a report of analysis from an accredited or certified laboratory, as part of the registration requirements;
- send samples to accredited laboratories outside the country for verification of quality in the absence of laboratory facilities in the country; and
- make compliance to the set standards or specifications be a prerequisite for registration.

6.2 Post-registration surveillance of pesticide products in the market

Many agricultural pesticides in developing countries are used by small-scale farmers whose livelihood and well-being are very much affected by the quality of pesticides that they use. They could lose their crops to pests if the pesticides used are not efficacious due to poor quality. These farmers are the source of very useful information on the performance and quality of pesticides available in the market. Similarly, plantations of agricultural crops also use substantial amounts of pesticides and should also be in the position to provide information on the performance of pesticides used by them.

However, in the public health sector, pesticides are mainly used by the Ministries of Health or municipalities. Hence, they would be the best source of information regarding the performance

of the pesticides used by them. In addition, professional pest control operators who use public health pesticides could also provide useful information on the performance of such products.

It is prudent, therefore, that the responsible authority should, with the collaboration of the major stakeholders such as the Ministries of Agriculture, Ministries of Health and Ministries in charge of municipalities, develop and implement a scheme to address the problem of substandard pesticides. The scheme could entail a reporting mechanism involving ground-level staff of the relevant ministries who are in regular contact with the users. A reporting system should be developed to enable rapid reporting of incidences of substandard pesticides to the responsible authority for further investigation and action.

Proper management of complaints, including timely interventions by relevant authorities regarding poor-quality pesticides in the market, is one of the keys to address the problem. Farmers and consumers should have easy access, such as through ground officers of the Departments of Agriculture and Health who should have the facilities to rapidly report to the responsible authority any pesticide incident including non-efficacious pesticide products. Standard formats for reporting such incidents should be developed, widely publicized and disseminated. A typical flowchart for such a system is as shown in Annex 1.

Based on the report received, the responsible authority should take the necessary actions to investigate in a timely manner, including enforcement actions such as taking samples for quality evaluation as well as seizure of goods if necessary. To optimize the use of available resources, it would be prudent to increase sampling of brands that are regularly found to be substandard and at the same time decrease frequency of sampling for brands that are consistently found to be in compliance with registration requirements. Prompt and effective follow-up enforcement actions are fundamental for ensuring that substandard and banned or illegal pesticides in the market are minimized.

Other than acting on complaints, routine inspections should also be carried out. This would include the inspection of premises selling and manufacturing pesticides.

6.2.1 *Non-enforcement samples*

Sometimes, samples are taken from the market for analysis to obtain information on the general status of their quality. Such samples are taken not for enforcement purposes, but the results of analysis could provide useful information for subsequent corrective actions to be taken.

It would be prudent, based on information received as well as experience, to develop a sampling strategy including the types, source and number of pesticide samples to be taken bearing in mind the availability of local resources. Such samples need not be taken by inspectors, and the results of analysis are not meant for enforcement purposes, but the outcome of the analysis would provide information for the taking of enforcement samples as well as for further investigations and necessary corrective actions.

Another source of non-enforcement samples are those submitted by other government departments (agriculture, health, local authorities, etc.) to check for the quality of the products bought and used by them. Results of analysis for such samples can also provide very useful information for planning subsequent enforcement actions. Given the high cost involved in analysis, samples should be taken judiciously.

6.2.2 *Enforcement samples*

Taking of enforcement samples is more elaborate and complex compared to that for non-enforcement samples. Enforcement samples should be taken only by inspectors (officers designated under the law) in accordance with standard operating procedures based on provisions

of the law. It is important that inspectors present their credentials or identifications to the management of the premises upon entry to inform them of the intention to carry out inspections or sampling.

Samples including formulated and technical products should be taken from retailers as well as formulators or manufacturers and be based on an accepted standard operating procedure. The procedure may vary from country to country depending on local regulations and requirements but should include the main aspects as stated in section 6.3 of these guidelines.

Other than analysis to verify the chemical and physical properties for compliance to accepted specifications, the labels and packaging of the samples should also be examined for compliance.

It is imperative that samples are taken following the chain-of-custody procedure to ensure the integrity of the samples so that the test results would be admissible as evidence in the court of law.

A typical flowchart for the above processes is as shown in Annex 2. The details in the process may vary from country to country depending on local regulations and practices, but the flowchart shows the main aspects in the enforcement process.

6.3 Sampling

An official sample of a pesticide product may be required for use as evidence in court for an enforcement action. Hence, samples taken must conform to the provisions of the law regarding admissibility of evidence to support the enforcement's case that a violation has occurred.

In general, a properly collected, prepared and documented sample includes the following:

- sufficient amount of pesticide from a batch for laboratory analysis;
- copies of shipping and transaction records or correspondence, where appropriate;
- acknowledgement of receipt of subsample(s) and relevant document(s) by the party from whom the samples are taken.

The subject of taking samples for analysis has been comprehensively dealt with in the *FAO/WHO Manual on development and use of FAO and WHO specifications for pesticides* [9]. Topics covered include safety precautions, general principles of sampling, preparations for sampling, monitoring the properties of pesticide packages, sampling for testing physical and chemical properties. The Environmental Protection Agency of the United States of America (EPA) has also provided a comprehensive set of guidelines on the subject in the *Federal Insecticide, Fungicide and Rodenticide Act inspection manual* [10].

For the purpose of this guideline, it is important to note the following points when taking samples for enforcement purposes. Countries may use the guidelines to develop their own procedures. References to the above two documents should be made for further details on the subject.

6.3.1 Preparation for sampling

Before inspections are made, it is essential to ensure that appropriate logistic arrangements and sampling apparatus including the following are available during inspection:

- sampling apparatus, for example, 50–100 ml pipettes; 3-way pipette fillers; siphon-and-lift hand-pumps, dip tubes; sample triers, scoops; sample bottles (preferably glass

containers with caps that can be tightly closed); plastic bags (without ventilation holes); plastic sheets; tools for opening pesticide containers; containers for pesticides where the original containers are to be emptied;

- portable balance with a suitable weighing range;
- labels which can be firmly glued or otherwise attached to the sample containers;
- sealing tape and wax seal, or official printed tape to certify the authorized opening of containers;
- personal safety devices, for example, appropriate gloves (suitable for handling drums, cans packages, sampling devices and sample containers), aprons, dust masks, an effective respirator where necessary, safety goggles, tissue paper, first aid kit, soap, towel and a supply of water for washing;
- case for sampling equipment and sample containers which enables them to be carried and transported safely;
- absorbent material (e.g. vermiculite or similar material) for filling the space around sample containers.
- newspaper, polystyrene granules or wood wool are not satisfactory absorbents.
- a sufficient number of relevant forms;
- writing and marking pens;
- a valid identification document or authorization of the inspector;
- vehicle for carrying sampling personnel, equipment and samples; and
- transportation for the samples to the laboratories.

6.3.2 *Sampling procedure*

Official samples of pesticide formulations are normally taken from materials that are packaged, labelled and ready to be marketed. This could also include counterfeit products which are being sold. However, in developing countries, it is not uncommon to encounter smuggled or repackaged pesticides which are unregistered being sold together with other products. Such products should be officially seized and appropriate legal action taken as provided for under the law. Depending on the local regulations, inspectors may have to pay for the samples taken for analysis.

For liquid products packed in containers of up to 1 litre or less and intended for retail distribution, three whole packages should be taken randomly from the same batch. If the content of each package is less than 200 ml, enough packages should be taken to make up a minimum of 200 ml (e.g. if each package contains only 100 ml, then each of the three samples should have 2 x 100 ml package.)

Similarly for solid products packed in containers of up to 2 kg or less, three whole packages should also be taken randomly from the same batch. If the content of each package is less than 600 g, enough packages should be taken to make up a minimum of 600 g (e.g. if each package contains only 200 g, then each of the three samples should have 3 x 200 g package).

For packages larger than stated above (1 litre for liquids and 2 kg for solids), subsampling is usually recommended to facilitate handling as well as to avoid disposal problems on completion of the analysis. It is important to ensure the samples are thoroughly mixed before three subsamples are taken. The subsamples (200 ml for liquid and 600 g for solids) should preferably be stored in glass containers with Teflon or polyethylene-lined caps that can be tightly closed. The amount taken for each subsample may be increased, depending upon the tests required.

Depending on the type of pesticides and size of packages, sampling apparatus used could include pipettes, 3-way pipette fillers, siphon-and-lift hand-pumps, dip tubes; and sample triers and scoops. To avoid cross-contamination of samples, different sets of sampling apparatus should be used or they should be cleaned thoroughly and dried before each use and reuse.

Samples should be taken from original, previously unopened packages. If more than one batch or lot number is present, samples shall be taken from the predominant batch. If it is necessary to sample more than one batch or lot, all lots and batches shall be written on the receipt of samples to identify the lots or batches.

Immediately following the collection of a sample, the sample should be identified in the inspector's own handwriting with a unique reference number, date as well as his/her initials. It should then be officially sealed and recorded. The sampling report (Annex 3) and the chain-of-custody record (Annex 4) should be completed and signed by the party from whom the samples are taken as well as the inspector who received them. The first subsample should be given to the party from whom the sample has been taken and is meant to enable him to send it to a laboratory officially recognized by the responsible authority for analysis in case he doubts the outcome of the test. The inspector should then arrange for all the samples taken to be transported and kept in the designated store of the enforcement agency. The inspector should then send the second subsample within a week to the designated laboratory for analysis by the official analyst together with the form requesting for analysis (Annex 5). The analyst should also be requested to sign the chain-of-custody record. The analyst should be given a timeframe to complete the analysis (normally within a month). The third subsample should be kept by the inspector for use as a back-up sample in case a dispute arises regarding the results of analysis of the first two subsamples.

6.3.3 *Shipping and transaction records*

Documents including invoices, bill of lading, freight bill and delivery order that record the movement of pesticides provide important information that enables the inspectors to trace the source of substandard products, allowing appropriate actions to be taken against the offending parties. It is thus important that during enforcement operations such records are scrutinized and, where relevant, copies should be obtained for follow-up investigation as well as providing them as evidence in court. The inspector should not remove the record if it is the only copy available but should have it photocopied, photographed or hand-copy all the necessary details. He should have the dealer sign and initial the copies of the records obtained to prove that he/she provided them on the date of the inspection. All copies of the records should be identified with the sample reference number and the identification of the inspector in his own handwriting.

6.3.4 *Seizure of goods*

During the inspection of the retailers, inspectors should also scrutinize for unregistered pesticides and products in leaking containers as well as those that have long passed the dates of release or manufacture. In cases where the inspector decides to seize the goods due to very obvious contraventions, he should prepare the necessary documents (Annexes 3 and 4) for the retailer to confirm, by signing in the appropriate forms, the type and amount of pesticide handed over to the inspector. The inspector, in addition, should seal and record the samples taken as previously described for follow-up enforcement actions to be taken.

6.4 Transparency in process of quality monitoring

Information on the rules and regulations related to enforcement, including enforcement procedures, offences, penalties and right to appeal, should be made readily available to the

public. Given the limited available resources for quality control in many developing countries, it is crucial that sampling should be done judiciously so that vulnerable sections of manufacturers or formulators and retailers are sampled. It should be based on the database or information available from the responsible authority as well as reports received. Information provided by the officers responsible for the registration of products based on their evaluations would be useful to target the samples to be taken. To ensure that sampling has been carried out by the inspectors fairly in a transparent manner, it is very important that a mechanism is put in place for the responsible authority to constantly review the enforcement activities carried out. Any complaints regarding the quality monitoring process should be immediately investigated and addressed by the authority.

6.5 Coordination of enforcement

Good collaboration between the inspectors and other relevant agencies such as the Customs Department, Police Department and Ministry of Trade is crucial to ensure effective enforcement of the law. A system for coordination of enforcement involving the above agencies should be formally established and, at the same time, steps should be taken to train enforcement officials (including customs officers) in the identification of suspected substandard and illegal products. The Customs Department, in particular, is in the forefront to ensure that only registered pesticides are allowed to be imported into the country, and hence constant communication with the responsible authority would be essential to prevent the entry of any unregistered and substandard products. It should be provided with the current list of registered pesticides their approved sources of import as well as banned and withdrawn pesticides. Steps should also be taken, if not already done so, to link the Customs Department and the responsible authority electronically to facilitate the importation only of pesticides that have been registered. Industry very often has good information on the substandard and counterfeit products in the market and in particular on products that affect their own market. Close collaboration between the responsible authority and industry could be a key factor to address issues on such pesticides.

It is also crucial that there is close collaboration with good exchange of information between the analyst and the responsible authority if the analyst works in a laboratory which is not in the same organization as the responsible authority. There is a need to establish a system of collaboration where the analyst would be able to refer to the registration dossier (including collaboration with the responsible authority in an exporting country where necessary) to obtain detailed information on the product which, among others, includes chemical and physical properties, impurities and method of analysis of the product. The responsible authority should provide, if necessary, certified analytical standards, a sample of the technical material from which the product is formulated as well as a sample of the registered product. This would facilitate examination of the identity of the sample (i.e. to verify if the composition of the sample corresponds with the composition of the product that has been registered).

6.6 Control of manufacture (including formulation, repackaging, re-labelling) and sale of pesticides

Other aspects of regulatory control which would have an impact on the quality of pesticides marketed are the licensing of pesticide manufacturers and retailers. Licensing of manufacturers and retailers would provide greater accountability in ensuring products manufactured and sold by them meet with required quality standards. There is an urgent need, particularly in some developing countries, to train retailers on the importance of not selling counterfeit products as well as not repacking pesticide products by themselves (except where legally permitted for specific situations).

7. Quality control of pesticides in international trade

During recent decades, FAO and WHO have been actively involved in assisting Member countries and industry in the life-cycle management of pesticides, including addressing issues related to pesticide quality. As stated in section 4 of these guidelines, the Code of Conduct has identified the responsibilities of the various parties in ensuring the quality of pesticides in international trade. The FAO and WHO specifications for pesticides provide an international point of reference against which products can be judged, either for regulatory purposes or in commercial dealings, and thus help to prevent the trading of substandard products. They define the essential chemical and physical properties that may be linked to the efficacy and risk associated with use of a product. The FAO and WHO publications on pesticide specifications are of importance in ensuring that pesticides in international trade meet acceptable standards. Industry and governments should, as far as possible, ensure that pesticides produced, exported and registered meet the above specifications. In the case of exports, pesticide products should meet the specifications required by the importing country if they differ from those of the FAO and WHO specifications.

8. Non-compliant pesticides

In the course of checking for the quality of pesticides, one of the issues often faced by responsible authorities is what actions should be taken in cases where the samples examined have been found to be not in compliance with the required standards. There are various options on actions that could be taken, depending on the purpose for which the samples are taken.

8.1 Registration samples

If, during the course of analysis, the sample submitted together with the application for registration was found to be non-compliant with respect to specification, the responsible authority could reject the application for registration or discuss further with the applicant any corrective actions that need to be taken if the deviation from the specifications is minor. The product should not be registered unless the responsible authority is convinced that the product supplied after registration would be of good quality.

8.2 Non-enforcement samples

Depending on the source of the samples, different courses of actions could be taken. If samples were taken for the survey on the quality of pesticides in the market, the results of the analysis of non-compliant samples could be used to plan future enforcement actions. However, if the samples submitted by other government departments have been found to be non-compliant, the results could be used by the relevant department to reject consignments supplied to them as well

as follow-up actions by enforcement. The responsible authority, on the other hand, should follow up with further investigations and, where necessary, enforcement actions could be taken.

8.3 Enforcement samples

If products taken by inspectors for enforcement purposes have been found not to be in compliance with specifications and labelling and packaging requirements, corrective actions, including prosecution in court, should be taken. At the same time, the responsible authority could also withdraw the registration status of the product. Warnings, with conditions for corrective actions to be taken within a certain timeframe for minor contraventions, could also be acceptable. Proof of disposal of non-compliant material via legal waste disposal routes should be required as part of any corrective action. Such proof could be in the form of official destruction certificates issued by licensed hazardous waste disposal facilities.

Enforcement agencies have often faced problems with the disposal of pesticides on completion of court cases, particularly when the quantities of seized pesticides are large. Violators should be required by law to pay for the costs of the disposal of the pesticides at the conclusion of enforcement actions.

9. Regional cooperation

In recent years, there has been a trend towards greater regional cooperation on matters related to pesticide management, including legislation and registration. Examples include the European Union (EU), the Permanent Inter-State Committee for Drought Control in the Sahel (Comité Inter-Etate pour la Lutte contre la Sécheresse au Sahel [CILSS]), the South East Africa Regulatory Committee on Harmonisation (SEARCH) and the Andean Community (Comunidad Andina de Naciones [CAN]). Such regional cooperation has several advantages, including facilitation of trade, sharing of limited information and resources, and enhancement of Member countries in complying with international obligations related to pesticides.

While most countries have some form of legislative control of pesticides, there is however, a lack or absence of quality control of pesticides in many of the developing countries. This is due to the absence or limit of resources (human, financial and analytical facilities). It has been shown in recent years that some countries that have established pesticide analytical laboratories with foreign or international aid have not been able to sustain the operation of laboratories on the completion of the projects as a result of financial constraints and lack of human resources. Such a waste of resources should be avoided and alternative options such as regional collaboration pursued to address this problem.

Regional organizations as well as international organizations could play a major role in facilitating the establishment of regional pesticide analytical laboratories. Member countries of regional organizations that have adequate resources could provide assistance to other Member countries that need analytical services, with the support of international aid, if necessary.

In addition to collaboration in pesticide analysis, there is also a need to promote the establishment or strengthening of networks for information exchange on pesticides through national institutions, international, regional and subregional organizations and public sector

groups to facilitate the exchange of information to address the issues of substandard, counterfeit and illegal pesticides. Information on counterfeit pesticides or substandard pesticides marketed could be shared among countries in the network to address the problems posed by such products, including assisting them to take appropriate corrective actions. Other areas of collaboration among national regulatory authorities in the region could also include matters regarding analytical methodologies, inter-laboratory cross-checks and exchange of certified pesticide analytical standards.

10. Education and public awareness

It is important to note that legislation alone is not adequate to address the issue of substandard pesticides. Other aspects of pesticide management should be brought into play to complement legislation. There is a need to develop and implement programmes to educate users on the importance and need to use good-quality pesticides and report incidences of ineffective or poor-quality pesticides to the relevant authorities to investigate and take the necessary corrective actions. Users should be educated about the consequences of using poor-quality pesticides, consumers and non-governmental organizations also have a major role to play in minimizing the availability of substandard pesticides in the market. The responsible authority should, in collaboration with all relevant stakeholders such as the Ministries of Agriculture, Health and the Environment, develop a reporting system whereby products that have not performed as claimed could be reported and investigated. Such a system should be widely publicized for it to achieve its objective of minimizing substandard pesticides in the market.

The responsible authority, on the other hand, should collaborate with international organizations such as FAO and WHO to train their own staff as well as assist the local pesticide industry to enhance the quality of their products through training workshops on subjects such as FAO and WHO specifications for pesticides and the importance of compliance with these specifications.

11. Funding

Financial constraints are one of the major issues faced by many responsible authorities in the enforcement of pesticide laws in their countries. Enforcement of the law would necessitate that various provisions of the law, including provisions such as quality of approved products, licensing of premises selling and storing pesticides, and licensing of manufacture, have been complied with. Enforcement is not only weak but also almost non-existent in some countries and is an area often overlooked and neglected. There is a need to carry out advocacy with national policy-makers on the importance of enforcement and the costs of its neglect. It is crucial that responsible authorities place greater importance in enforcement and explore options for greater collaboration among enforcement agencies in the country as well as funding to enhance pesticide enforcement activities.

One of the most common funding mechanisms for quality control is through funds provided by the government for the establishment and maintenance of pesticide analytical laboratories,

including the employment of qualified staff. Depending on the local situation, the laboratory could be in the same organization as the responsible authority or a laboratory under the jurisdiction of another government agency or department, provided that there is no conflict of interest and that it has been certified as being adequately equipped and competent as well as gazetted as the designated laboratory under the pesticide law of the country. Through such an arrangement, countries with limited resources could share the facilities of a central chemical laboratory to optimize the use of resources in the country. The government could impose fees, among others, for the registration, issuance of import permits and licensing. The fees collected could be used to supplement the implementation of the various provisions of the law. Some governments have also imposed taxes for the importation of pesticides. In some developed countries, users are taxed based on the amount of pesticides used. Taxes collected could then be channelled to implement pesticide management activities.

Many developing countries with the aid of foreign funding have successfully established pesticide quality control systems in their countries. This involves establishing laboratories with relevant equipment and training of staff during the project. The countries themselves would then take over the operation of the laboratories on completion of the project using funds provided by the government.

In some countries, the responsible authorities are partially supported with funds provided by the government. They are expected to generate funds through services provided (including registration, licensing, imposition of cess, and import permits) for the operation of their organizations. It is, however, imperative that there should not be any conflict of interest in the process of generating such funds.

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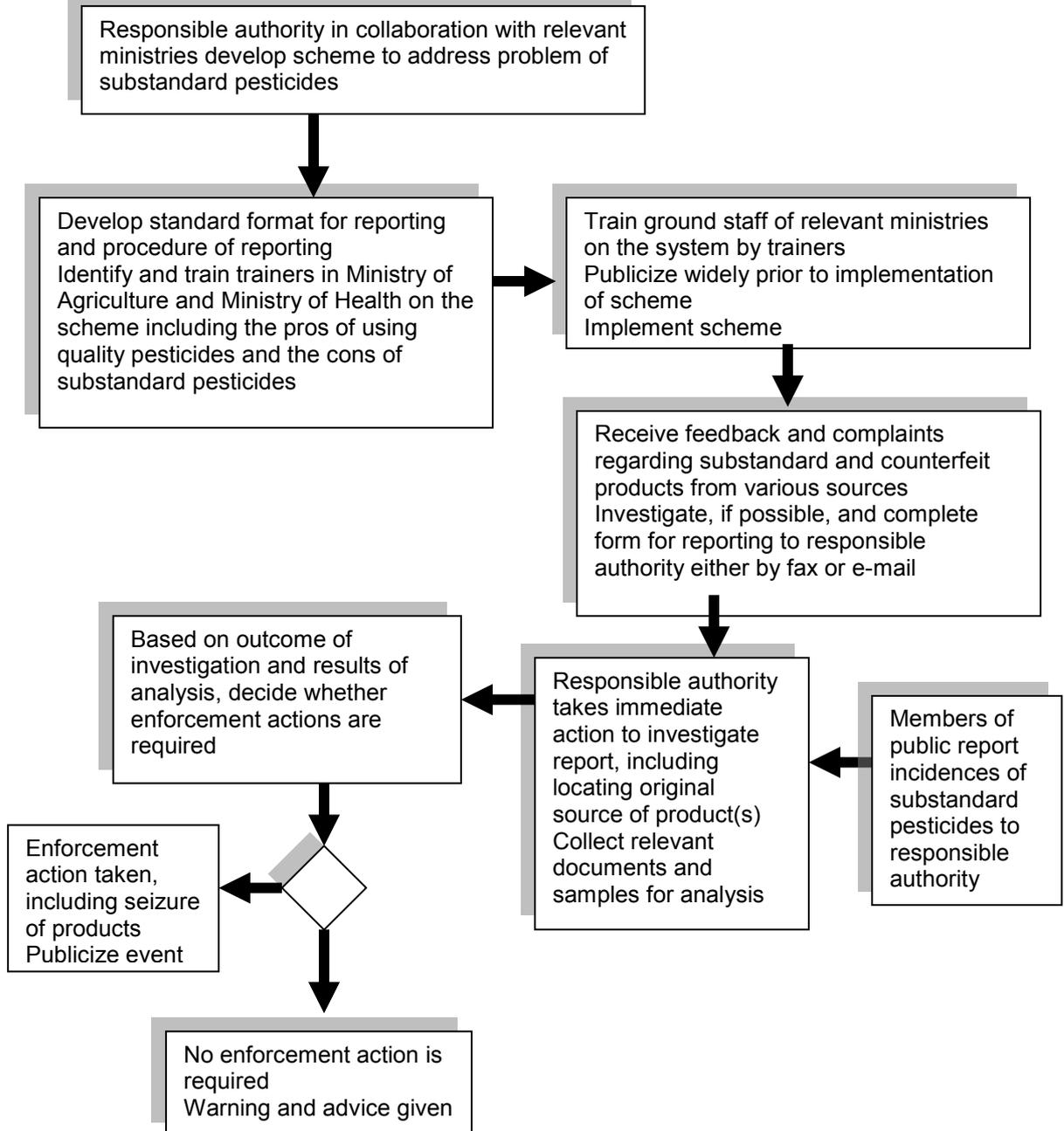
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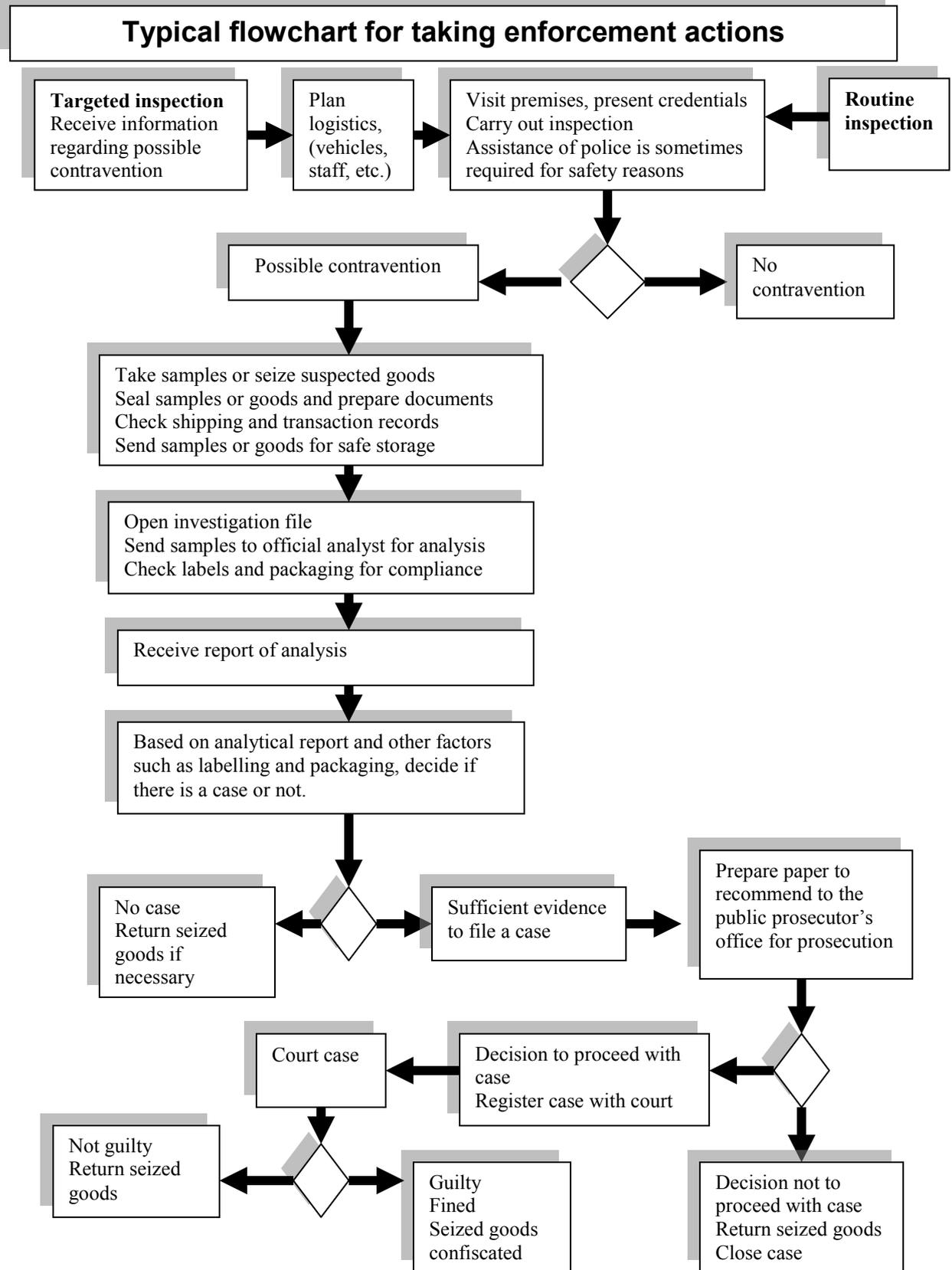
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Annex 1

Typical flowchart for scheme to receive and investigate feedback and complaints regarding substandard, counterfeit and banned or illegal pesticide products



Annex 2



Annex 3

Typical sampling report <i>(to be completed in four copies: one copy to accompany each set of subsample(s) and a fourth copy to be retained on file)</i>
Name and address of retailer/wholesaler/manufacturer:
Name of owner of premises or staff present when samples were taken:
Date (dd/mm/yy) and time of inspection/sampling/seizure:
Name of inspectors/officers who were present during the inspection and taking of the samples:

List of pesticides taken			
No.	Details of pesticides	Sample reference no.	Quantity taken

Confirmation by retailer/wholesaler/manufacturer:	
I confirm that I have received one (1) copy of the list of pesticides taken for analysis as well as a subsample for each of the pesticides listed above.	
Signature:	
Name:	
Date (dd/mm/yy):	
Time:	Company or official stamp

Inspector:
Signature:
Name:
Date (dd/mm/yy):
Time:

Annex 4

Typical chain-of-custody record			
Name and address of source of sample:			
Description of sample (including the condition of packaging): Registration no. (if applicable): Sample reference number:			
	Quantity	Handed over by: Signature: Received by: Signature:	Date (dd/mm/yy) and time
	Quantity	Handed over by: Signature: Received by: Signature:	Date (dd/mm/yy) and time
	Quantity	Handed over by: Signature: Received by: Signature:	Date (dd/mm/yy) and time
	Quantity	Handed over by: Signature: Received by: Signature:	Date (dd/mm/yy) and time
	Quantity	Handed over by: Signature: Received by: Signature:	Date (dd/mm/yy) and time

Annex 5

Typical format for request for analysis of pesticide sample(s)
(to be completed in duplicate)

	Description of pesticide (including reference number)	Quantity	Types of analysis required
1			
2			
3			
4			
5			

The results of analysis are required by:
(dd/mm/yy)

<p>Sample(s) submitted by inspector:</p> <p>Signature: Name: Date (dd/mm/yy): Time:</p>	<p>Samples(s) received by official analyst:</p> <p>Signature: Name: Date (dd/mm/yy): Time:</p>
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