



International Code of Conduct on Pesticide Management

Guidance for inspection of pesticide producers, importers, distributors and retailers



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Foreword

In recent decades, countries on all continents and at all stages of development have adopted laws and regulations on pesticides to protect human health and the environment while assuring the availability of products for food production and public health. Ensuring compliance with these laws and regulations can, however, be difficult, and violations are frequent in many countries. This is a serious problem. As noted in the FAO *Guidelines on compliance and enforcement of a pesticide regulatory programme* (1),

even the best designed and most comprehensive regulatory systems cannot accomplish their purpose unless there is real, meaningful compliance with their requirements. Mere paper requirements can create a false sense of security.

The guidelines continue:

Compliance requires competency and expertise, involves costs, and comes only when regulated entities have a willingness and even a commitment to invest the resources and efforts necessary to comply. This will almost always require the involvement of government and the establishment of government enforcement programmes. Governments face considerable challenges in finding ways to motivate compliance successfully, and generally have to establish an approach to compliance and enforcement using a variety of tools and over a period of time. There is no single effective formula for achieving compliance. There is only trial, evaluation and feedback, and attention to what works and what does not work in each specific situation. Getting started with enforcement programmes can be a discouraging task, and it is important to consider that some enforcement is better than no enforcement, and that every government has to start somewhere and build from available structures and tools.

The guidance provided in this publication is on enforcing compliance by on-site inspection of companies involved in pesticide production, import, distribution and retail sale. The publication is intended to be a practical, hands-on tool, with checklists that inspectors can use to prepare and conduct inspections at various sites and impose fines or penalties if deficiencies are found. It proposes a format for the report that inspectors submit to the responsible authorities after an inspection and that is filed for future reference.

The guidance was prepared with the support of the FAO/WHO Joint Meeting on Pesticide Management, which advises FAO and WHO on producing guidance to promote compliance with the International Code of Conduct on Pesticide Management. The document was reviewed by experts of the Working Groups on Biocides and Pesticides of the Organisation for Economic Co-operation and Development, and their contributions are gratefully acknowledged.

The International Code of Conduct

The *International Code of Conduct on pesticide management* sets out a framework and voluntary standards of conduct that should be followed in any activity related to pesticide management. Endorsed by FAO, WHO, governments, pesticide producers, nongovernmental organizations and other stakeholders, the Code of Conduct emphasizes stakeholders' shared responsibility for promoting best practice and risk reduction throughout the life cycle of a pesticide. The Code of Conduct thereby establishes the commitment and moral obligation of stakeholders to comply with the agreed standards of conduct and to assume their respective responsibilities.

Specific articles of the Code of Conduct relate to specific aspects of pesticide production, import, distribution and sale, e.g. Article 5.5.3 on the siting of pesticide manufacturing and formulating plants, Article 8 on distribution and trade and Article 10 on storage and disposal.

FAO and WHO welcome feedback

FAO and WHO consider this guidance a living document that could be improved. They therefore welcome any feedback and comments from readers. They would value examples of how the guidance is used.

Please send your suggestions, comments and examples to pesticide-management@fao.org, indicating the title of the guidance and the relevant section and page.

Introduction

Background

Inspection is an essential part of pesticide regulation. Inspections at production sites can ensure that facilities have safety systems in place, that they follow procedures to provide a safe working environment and that their products meet required standards. Inspection of importers and distributors can prevent the entry and distribution of prohibited pesticides, such as products that are banned, have not been registered, are not properly packaged or labelled or whose shelf-life has expired. Inspection of retailers and other places where pesticides are sold can help ensure vendors' compliance with legal provisions. Inspection of pesticide producers, importers, distributors and retailers can contribute to identifying deficiencies in the pesticide market.

Objectives and targeted audience

The guidance is intended to be a practical, hands-on tool to assist government inspectors in preparing, conducting, recording, reporting and following-up on inspections of pesticide producers, importers, distributors and retailers. The guidance:

- reviews the legal and regulatory framework for inspection;
- provides advice on the management and coordination of inspections;
- presents an approach to designing an inspection scheme; and
- provides checklists of the materials to be collected and the procedures to be followed before, during and after inspections at various sites.¹

This guidance is intended for national regulatory authorities, especially in low- and middle-income countries, in inspecting pesticide producers, importers, distributors and retailers, to ensure their compliance with the country's legal obligations for pesticide management.

Scope

The document addresses both chemical and biological² pesticides, professional and amateur use products and plant protection and public health products, including substances identified as "biocides" in the European Union (4).

The guidance includes inspection of premises for the production, import, distribution and sale of pesticides (but not on-line sales). It does not cover border inspections or inspection of pesticide users, as these and other areas are addressed in the following documents, which provide further information and guidance on compliance and enforcement of pesticide regulations:

- The FAO/WHO *Guidelines on pesticide legislation* (5) provide the legal and administrative framework for Member States to use when inspecting different establishments.
- The FAO/WHO *Guidelines for quality control of pesticides* (6) outline the administration, organization and infrastructure required to implement a quality control scheme and provide guidance on sample selection and procedures during inspection.
- The Organisation for Economic Co-operation and Development *Guidance on pesticide* compliance and enforcement best practices (7) supports regulators in promoting and monitoring compliance and in assessing and mitigating the risks of non-compliance.

¹ The checklists in this guidance are compiled from various sources in the public domain, principally the pesticide management inspection manuals of the United States Environmental Protection Agency (2) and the Permanent Interstate Committee for Drought Control in the Sahel (3).

² Including microbial, botanical and semiochemical pest control agents.

- The FAO *Guidelines on compliance and enforcement of a pesticide regulatory programme (1)* set out core principles and building blocks for a national compliance programme, with examples of how countries in different situations can build and implement an effective programme.
- The FAO Guidelines for retail distribution of pesticides with particular reference to storage and handling at the point of supply to users in developing countries (8), set out conditions for pesticide storage, display and transport.

1. The legal framework for inspection

The legal framework for inspection is generally specified in national pesticide law and regulations. As elaborated in the FAO/WHO *Guidelines on pesticide legislation* (5), a framework for inspection should:

- designate the national authority (or authorities) responsible for inspection, and, if several authorities are involved, establish clear mechanisms for coordination;
- provide for the appointment of qualified inspectors;
- define the powers of inspectors, and ensure that they are adequate for them to fulfil their duties;
- provide procedures and criteria for inspections;
- provide procedures and requirements for taking samples and for designating official laboratories for sample analysis;
- provide clear, effective procedures for addressing irregularities found during inspections;
- maintain a list of offences and the procedures and penalties associated with each; and
- ensure funding of inspection, which is usually included in funding for the pesticide regulatory programme, through public (government) funds, including registration fees when applicable.

The guidelines explain the importance of a national pesticide law to establish the mandate of inspectors and the procedures for inspection. They note that inspectors must have the power to enter various locations, including private premises, in order to ascertain that all aspects of the law are being complied with. As these powers may be similar to those of the police and may affect personal liberty, a pesticide law should clearly outline the parameters of the inspectors' powers. If not, inspections may have limited effect.

The guidelines also address inspectors' power to take samples, seize equipment, products and documentation, ask questions, request and review purchase and sales records, take photographs, shut down operations and, in some countries, issue on-the-spot fines (charged immediately during the inspection). The law may also include penalties for inspectors who abuse their power or accept money informally.

It is highly recommended that countries that wish to strengthen or create a national inspectorate review these guidelines. A review of the FAO/WHO *Guidelines for quality control of pesticides* (6), which provides guidance on sample taking and analysis, is also recommended, to ensure that samples taken during an inspection can be properly admitted and used in a court of law.



2. Management and coordination of inspections

Management and coordination of inspections are likely to be straightforward if a single national service is responsible for inspection of pesticide producers, importers, distributors and retailers. This is, however, often not the case, and many government authorities and levels of government may have a role in pesticide regulation. As a result, different inspection activities may be conducted locally, provincially or nationally. Usually, on-site inspections, investigations of allegations, responses to violations and other law enforcement are conducted by local or provincial agents, whereas product registration, import and export controls and licensing of companies involved in pesticide distribution and sale are overseen by national pesticide regulatory authorities. Other regulatory authorities, such as those responsible for workers' health and safety or environmental protection, may also be involved. In addition, customs and law enforcement will be involved in detection of illegal and counterfeit products, which are a significant problem in many countries, and collaboration between importing and exporting countries and among neighbouring countries is necessary when there are international trade deficiencies.

Given the multiplicity of actors, it is important to plan, prioritize and coordinate inspections and follow-up enforcement actions. Senior management of the national pesticide authority and/or the service or services responsible for inspection have key roles, as elaborated in Annex 5 of the 54th report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations (9). As explained in the report, senior management should:

- make a formal commitment to inspection;
- define the scope and objectives of inspection, and ensure that they are aligned with regulatory requirements;
- set targets and objectives for inspection, and ensure that resources are adequate to meet them;
- ensure that inspection has an organizational structure, the necessary resources (e.g. financial, human, equipment and facilities) and documented procedures that allow it to perform its functions satisfactorily to meet its objectives;
- assign a quality control manager (or, if necessary, more than one manager) with direct access to senior management to ensure the quality and consistency of inspections;
- include all relevant inspection bodies in planning, and establish procedures for them to exchange information on their respective activities and to coordinate site visits and other inspection work; and
- ensure that impartiality and independence are safeguarded in inspections.



3. Designing an inspection scheme

3.1 **Documentation**

In view of the legal and sometimes contentious nature of inspection, the responsible national authority must maintain clear, detailed records of all inspection activities. The country's inspection work plan, records of the inspectorate's activities and functions, inspection reports and records of any complaints received and the actions taken by the inspection authority should be in an approved format and should be kept on file for a defined period. It is also advisable to keep on file a description of the standard operating procedures that define the responsibilities, processes and actions of the inspection service(s). Annex 5 of the 54th report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations (9) provides detailed guidance in this area, and Annex 1 of this document provides a sample format for an inspection report.

3.2 Qualifications of inspectors

Inspection systems should be designed to ensure that inspectors have the necessary powers and expertise to perform their duties. As previously discussed, the "powers" are the inspectors' legal authority, established by national law and/or regulations, to enter a company's premises, to inspect the company's products and procedures, to interview employees and to impose fines or other measures if deficiencies or violations are identified. The inspectors' expertise, as elaborated in Annex 5 of the 54th report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations (9), should encompass:

- knowledge of the inspection process and subject acquired through education, training and experience;
- knowledge of the national legislation, regulations, standards and guidelines that they have been appointed to enforce; and
- ability to make professional judgements about whether an inspected company conforms to the relevant requirements and to best practice.

Given the broad scope and legal nature of the work, it is advisable for new inspectors to work with a mentor for up to a year before they take on all aspects of the work independently. In addition, it is advisable that all inspectors have continuous training in administrative, regulatory and technical topics to maintain their knowledge of industry practice, technological advancements and regulatory changes. Responsibility for appointing inspection officers should be specified in national pesticide legislation or related regulations. Some countries may require inspectors to be certified by an authorized certification body.

3.3 Targeting for efficiency and effectiveness

The efficiency and effectiveness of inspection programmes can be increased by targeting pesticide producers, or "primary suppliers", in routine inspections, for several reasons. First, there are generally fewer production sites than other sites to be inspected. Secondly, some aspects can be checked only at production sites, such as whether the product is indeed made with the formulation specified in the product registration. Thirdly, producers will be well-informed about all aspects of their products, as they are the authors of the product labels and the safety data sheets that describe the products' physical and chemical properties.

Information about the hazards and handling of products must be correct from the beginning of the supply chain, as it will follow the pesticides down the chain until the products are sold to users. For this reason,

inspection of labels to ensure that they conform to product registrations is an important part of the inspection of producers and importers and also of distributors and retailers, who provide advice based on the label to users. Application of new technology and tools, such as databases and a digital national inspection information system, is encouraged to improve efficiency and effectiveness.

3.4 Prioritizing inspections

An inspection scheme should establish criteria for prioritizing inspections and for taking immediate action when necessary. Table 1 lists factors that would raise the priority of inspection. Table 2 identifies cases that require immediate action.

Table 1. Prioritizing inspections of pesticide producers, importers, retailers or distributors

Type of facility	Factors that increase priority for inspection
Producer and formulator facilities	Production or formulation of highly toxic pesticides
	History of accidents or non-compliance
	High production volumes
	Complaints about pesticide quality and/or toxicity, spills or odour.
	History of not reporting correct data on production and/or formulation
	Complex product manufacturing process
	Change in management
	New product applications
	Results of formulation analysis, if available
Storage facilities	Storage of a large quantity of pesticides
	Storage of highly toxic pesticides
	Storage of flammable or explosive products
	History of accidents or non-compliance
	History of not reporting correct data on storage
	Complaints about pesticide quality and/or toxicity, spills or odour
Distribution outlets, shops,	Storage of a large quantity of pesticides
salespersons	History of non-compliance
	Scale of operation
	Sale of highly toxic pesticides
	Complaints about pesticide quality and/or toxicity, spills or odour
	Complaints by neighbours about spills or odours
	History of not reporting correct data on products, storage, sales and/or use

Table 2. Urgent cases that require immediate action

Product or event	Action to be taken
Products identified that present a serious risk	Products to be withdrawn from the market because risk identified
	Alert users, producers, distributors and retailers about associated risk
Serious accidents or incidents reported to authorities	 Accidents/incidents should be investigated as soon as possible Inspectors should identify the main causes of the accident or incident, e.g. whether it occurred because of non-compliance with working instructions and risk management policies or of a lack of specific instructions or policies. Inspectors should check the consequences of the accident. For
	accidents that also involved the surrounding environment, inspectors should confirm whether there is pesticide residue in the surrounding agricultural crops, soil, surface water and even groundwater, depending on the size of the accident.

3.5 Types and levels of inspection

The types and levels of inspection carried out depend on the situation and available resources. Inspections may be regular, scheduled, ad hoc or "surprise". Regular and scheduled inspections are generally those done regularly or to follow up on an earlier inspection to confirm that the necessary corrections were made. In both cases, the company will be prepared for the inspection. Ad hoc or surprise inspections, for which the company is not prepared, might be necessary to determine a facility's typical practice, to follow up on a previous inspection if there are doubts about whether the corrections have been made or to investigate complaints or confirm suspicions about faulty practice.

Table 3 illustrates two levels of inspection, from the least to the most thorough and resource-intensive, and a third level to follow up on an earlier inspection.

Table 3. Levels of inspection of a pesticide producer, importer, retailer or distributor

Level	Type of inspection
1	Routine
	Routine inspections are conducted periodically as per the inspection plan. The time spent on site will depend on the information obtained.
	Routine inspections are generally limited to a quick survey of the facility and confirmation that it is licensed. Inspectors simply walk through the facility, for example to check that there is safety equipment, to observe work practices and housekeeping, to verify that there is a records repository and to check or take examples of labels of products. These inspections establish an enforcement presence and can also serve for screening, to identify facilities that should be targeted for more intensive inspection.

Level	Type of inspection
2	Compliance or concise inspections
	These involve a thorough inspection of the facility. In addition to the visual observations made in level 1, they include evaluation of records, interviews with facility personnel, evaluation of the facility's self-monitoring methods, instruments and data, and collection of evidence of non-compliance, including labels and sample of products.
	Systematic control of retailers would also include inspection of the routines at the shop and the competence of the personnel to fulfil legal requirements for pesticide management. This generally requires discussion with a person who is well-acquainted with the operation and knowledgeable about purchasing routines and product placement in the shop. Open questions should be asked to give the person interviewed the opportunity to describe the routines as well as possible.
	Background information should be collected on the number of products sold and the suppliers. The inspector should also confirm the details of the establishment, the owners or responsible parties and the physical address.
	Tips for securing as much information as possible:
	 Assign at least two inspectors to conduct an inspection to ensure a witness in the event of a dispute.
	• Collect documented evidence of all cases of non-compliance identified.
3	Follow-up
	This level includes the procedures in levels 1 and 2 and investigation of any corrective action the site has taken since the previous inspection.

4. Inspection procedures

The three steps in an inspection of pesticide producers, importers, distributors and retailers are:

- preparation before the inspection;
- on-site inspection; and
- follow-up after the inspection.

4.1 Preparation before the inspection

An inspection is also prepared in three steps:

- review of background information about the facility to be inspected;
- preparation of an inspection plan; and
- collection of materials and documentation to take to the inspection.

4.1.1. Review of background information about the facility

Preparation for an inspection should begin with a thorough review of background information about the facility. This will help the inspectors to ask the right questions and verify critical information during the inspection. It will also save time at the inspection site, both for the inspectors and for staff at the establishment. Table 4 provides a checklist for a background review of the four types of facilities covered in this guidance.

Table 4. Checklist for a pre-inspection background review of a pesticide producer, importer, retailer or distributor

Objective	Information to be reviewed
Become familiar with the size, activities and physical layout of the facility	Site master plan, which will include: maps showing the location and its situation in the surrounding area physical lay-out and size of the facility names and telephone numbers of facility owners or representatives organizational structure special entry requirements previous and present levels of operation, production or sales reports prepared by the facility safety equipment and health and safety training requirements

Objective	Information to be reviewed
Establish the compliance history of the facility	 previous inspection reports (if available) certified applicator records compliance history
	 previous enforcement actions intelligence from local authorities familiar with the company
Clarify technical and legal issues	legal texts or technical standards that apply to the type of facility, establishment or operation

4.1.2. Preparation of an inspection plan

An inspection plan should lay out the objectives, tasks, resources and schedule for the inspection. A detailed plan for each inspection should be prepared according to the standard operating procedures of the inspectorate's quality management system. The inspection plan should be concrete and precise but sufficiently flexible to allow inspectors to adapt it to any unanticipated situation. Table 5 provides a checklist for preparation of an inspection plan.

Table 5. Checklist for preparing an inspection plan for pesticide producers, importers, distributors and retailers

Objectives	Notes
♦ What is the purpose of the inspection?	
♦ What is to be accomplished in the inspection?	
Tasks	
◆ What information should be reviewed before starting the inspection? For instance:	
- pesticide sales license or permits	
- pesticide production, formulation or repackaging licences	
- previous inspection reports	
- information on the facility's history of compliance or violations	
- type of pesticides stored at the facility	
♦ What coordination is required? For instance, with:	
- a pesticide analysis laboratory	
- a microbiology laboratory	
- a pesticide chemist and a specialist in biopesticides	
- the environmental or health authorities	
- the customs service	
- local authorities	
- the police or other legal or law enforcement agencies	
♦ What information should be collected during the inspection? For instance:	

pesticide import, production, storage or sales data - pesticide samples - facility lay-out and equipment, including controlled temperature storage facility for biopesticides - organization of safety procedures - identity of operators involved and their training records **Procedures** ♦ What procedures will be used? For instance: - general observation - sampling (for biopesticides, unopened containers should be sampled) - interviews - inspections of books and statistics ♦ Will the inspection be announced in advance (in which case, an appointment should be made to ensure that the appropriate people will be present) or unannounced? Resources ♦ What equipment will be needed, for example to transport any samples? Will any have to be obtained externally (for example, appropriate (cold) temperature for transporting biopesticide samples)? ♦ What is the sample custody procedure for identifying each person involved (i.e. who will collect each sample, who will take it to the laboratory, who will analyse it, and who will record the results), to ensure that all the samples analysed can be correlated with those that were taken?

4.1.3. Collecting materials and documentation for the inspection

Preparation of an inspection concludes with collecting the materials and documentation to be taken to the inspection. Those generally required are listed in Table 6.

Table 6. Materials and documentation required for inspections

Basic equipment

- Field notebook
- Clipboard
- Waterproof pens and markers
- · Cell phone
- Camera, film and flash equipment
- Pocket calculator
- Tape measure
- Sample bag
- Official letterhead of the inspection agency

Personal protective and emergency equipment in the event that the site does not provide them

- Splash-resistant apron
- Chemical-resistant gloves
- Safety glasses or goggles
- Face shield
- Hard hat
- Cotton hat or cap
- Protective footwear
- Workwear (long-sleeved shirt and long trousers or coveralls)
- Respirator (and cartridges)

Other emergency equipment and materials in the event that the site does not provide them

- Emergency telephone numbers (nearest hospital or doctor)
- First aid kit
- Fire extinguisher
- Airtight containers for storing samples
- Soap or waterless hand cleanser and a towel or rolls of tissue paper
- Jerry can with clean water
- · Eye-wash kit

Sampling equipment

If the inspection is likely to include sampling, the necessary equipment should be collected and checked to confirm that it is in good operating condition.

Petty cash

Depending on national legislation, inspectors may not be able to seize the required number of samples but are required to pay for the products sampled.

Forms, checklists and other relevant documentation

Various forms and documents should be brought to the inspection. The type of inspection will dictate which are necessary. They may include:

- Official credentials of the inspector
- Entry warrant
- Notice of inspection
- Receipts for samples or documents that are collected
- Investigation summary forms
- Official letterheads or seals
- Copies of applicable laws and regulations.
- A checklist of information to be collected during the inspection, tailored specifically to the company

Notice of Inspection

Before conducting an announced inspection, the inspection team should notify the site in advance (1 day to 3 months) through a Notice of Inspection on official letterhead that states the objective of the inspection, the date and time of the inspection and the names of the inspectors. The Notice of Inspection might also have to be presented to the owner of the establishment or another person in a position of authority, with the inspectors' authorization, when the inspection team arrives at the inspection site.

4.2 Conducting the inspection

On-site inspections of pesticide producers, importers, distributors and retailers have elements in common but also elements that are unique to the different types of facility. In addition, every inspection should be tailored to the individual company inspected, its size and activities, and its history.

4.2.1. Introductions and overview of the company

The on-site inspection should begin with introductions and a general review of the company and its product portfolio. Table 7 provides a checklist of procedures for this phase of the inspection.

Table 7. Introductions and overview of pesticide producers, importers, distributors and retailers

Date, place and purpose of the inspection

Before arriving at the inspection site, the inspector(s) should note:

- the date
- the company name and address
- · the type of facility
- the size of the facility
- the purpose of the inspection
- whether it is a regular/scheduled or a surprise/ad hoc inspection

Introduction of inspector(s)

The inspector(s) should:

- introduce themselves and give a brief overview of their agency, the authority for which they are carrying out the inspection and the standards and guidelines against which the inspection will be conducted;
- show supporting credentials or other authorization to conduct the inspection;
- indicate the purpose of the inspection;
- explain the inspection process.

Introduction of company personnel

The inspector(s) should ask the company personnel to introduce themselves and to give a short overview of the company operations, organogram, products manufactured or handled on site, including hazardous substances, any changes implemented since the previous inspection (if applicable), any recent inspections by any other regulatory authority, critical suppliers, any activity conducted or contracted off-site, waste management and complaints handling procedure.

The inspector(s) should then request any additional information required to c follows.	complete the checklist that
Company name	
VAT number (or similar)	
Address	
Telephone number	
Chief executive officer or equivalent	
NameEmail	
Principal officers, partners or owners and person in charge of day-to-day running of the facility	
Name(s)Email (s)	
Address of site if different from original, if relevant	
Establishment number	
(or equivalent)	
Contact person	
Name(s)Email(s)	
Company representative(s) attending the inspection:	
Credentials	
Inspector(s):	
Name(s)Email (s)	
Inspection registry no. (or similar)	
Purpose of inspection	
Commence of the commence of th	
Company operations	
Type of site or company	

Number of employees at the facility and names of key personnel with job titles (i.e. personnel in charge of chemical safety, worker safety and environmental protection)	
Contract suppliers	
• Name	
• Address	
Warehouse, if any:	
• Location	
Capacity	
 Contact person, job description, email(s) 	
Transport arrangements	
Facility and storage safety, emergency procedures and equipment	
Waste management and recycling company	
Address	
- Madicob	

4.2.2. Inspection of pesticide producers, importers and distributors

After the introductions, inspections of pesticide producers, importers and distributors should address the product portfolio, inventory and records, with the checklists in Tables 8 and 9. It may be useful to request some time alone to examine the product information and company records. After review of these documents, the inspection should proceed to visual observation of the facility and storage areas.

If deficiencies are encountered, actions to correct them should be discussed and deadlines agreed. The inspection report should identify any instances of non-compliance, with the corrective and preventive actions to be taken by the company and the timelines for completing them. The inspector(s) may conduct a follow-up inspection to verify implementation of the corrective actions. If any instance of non-compliances has not been addressed within the agreed time, the authority could take more forceful action as per legislative provisions, such as imposing a fine, issuing a notice of concern, imposing a quarantine on products or preventing sales of a product.

Table 8. Checklist for inspection of pesticide producers

Items to be checked	Notes	Corrections required and deadlines
Routines for classification and labelling of pesticides		
Routines for producing and updating safety data sheets		
Routines for distributing safety data sheets to clients		

Items to be checked	Notes	Corrections required and deadlines
Production of pesticides and active ingredients		
• brand name		
• registration number		
• quantities produced per batch		
Production of devices containing pesticides:		
• brand name		
• registration number		
• quantities produced per batch		
Research data		
• all raw data, interpretations, evaluations and reports supporting a product registration or tolerance petition		
Experimental use permit number		
Any modifications to registration		
Any transfers of registration		
Labelling and label information:		
• legibility		
• durability		
 information on net content and ingredients 		
• use instructions		
• safety warnings		
• instructions for disposal of contents and packaging		
• language(s)		
Approval and quality of child-resistant packaging		
Description and labelling of unit packaging		
Reporting of adverse effects		
Annual production reports		
Disposal		
• item disposed of (pesticide or active ingredient, device or containers containing pesticides, etc.)		
 method of disposal 		
 dates of disposal 		

location of disposal sites or routes of disposal, e.g. container management programme				
deviation from normal practice				
Records and documents	Records maintained?		No. of years	Corrections required and deadlines
	Yes	No	records are kept	
Inventory of stocks				
 identity and amount of pesticides or active ingredients in stock 				
 identity and quantity of pesticide- containing devices in stock 				
 identity and quantity of stored pesticides with cancelled or suspended registrations 				
 identity and quantity of obsolete or out-of-date products in stock 				
Identity and annual production of each pesticide and device produced				
 brand name of pesticide or device or common or chemical name of active ingredient 				
• registration number				
 quantity produced annually, including amount per batch and batch identification number 				
Domestic and foreign shipping records				
brand name of pesticide or device or common or chemical name of active ingredient				
• copy or photograph of product labels, including bilingual labelling				
 name and address of consignee (buyer) 				
• name and address of shipper				
 name and address of carrier 				
• signed foreign purchaser contracts				
 specifications and instructions provided to purchasers 				
• exporter certification				
• copy of any guarantees given				
 restrictions, special exemption or special local need 				

 date shipped or delivered for shipment 		
 quantity shipped or delivered for shipment 		
Advertising		
 copy of all domestic advertising 		
 sales promotion instructions sent to pesticide distributors, dealers, retailers 		

Table 9. Checklist for inspection of pesticide importers and distributors

Records of receipt of pesticides and de	evices co	ntaining	pesticides	
Items to be checked		Notes		Corrections required and deadlines
Brand name of pesticide or device, or co or chemical name of active ingredient	ommon			
Registration number (Only registered or authorized products are permitted for importation or distribution. Importation distribution of unauthorized products is	or			
Safety data sheet				
For pesticides not registered nationally a to be sold or used in the country but only produced and/or transported through the country, if national legislation permits:	y to be			
• confidential statement of formula				
• product's destination				
• information on why the product is negistered nationally	ot			
Verification of correct and appropriate l in line with national requirements and lo language(s)				
Verification of durable, legible and child packaging	d-safe			
Name and address of supplier				
Name and address of shipper				
Name and address of carrier				
Date received				
Quantity received				
Shipping records and documents	Maint	ained?	No. of years	Corrections required and
	Yes	No	records are kept	deadlines
Brand name of the pesticide or device				
Copy of product or device and unit labels				

Name and address of consignee (buyer)				
Name and address of shipper				
Name and address of carrier				
Date shipped or delivered for shipment				
Quantities shipped or delivered for shipment				
Restrictions, special exemption or special local need				
Guarantees and advertising:				
• copies of all domestic advertising				
 sales promotional instructions sent to pesticide dealers and retailers 				
 copies of any guarantees given 				
Information for foreign exports				
 copy of any specifications or instructions for production of pesticides, devices or active ingredients 				
 copy of product labels and labelling 				
 copy of any additional safety or 				
use information supplied				
use information suppliedcopy of signed purchase				
use information suppliedcopy of signed purchase acknowledgement statements	Mainta	nined?	No. of years	Corrections required and
 use information supplied copy of signed purchase acknowledgement statements copy of exporter certification 	Mainta Yes	nined?	No. of years records are kept	Corrections required and deadlines
 use information supplied copy of signed purchase acknowledgement statements copy of exporter certification 				
use information supplied copy of signed purchase acknowledgement statements copy of exporter certification Other records and documents Inventory (identity and quantity) of pesticides and active ingredients, devices and containers containing				
use information supplied copy of signed purchase acknowledgement statements copy of exporter certification Other records and documents Inventory (identity and quantity) of pesticides and active ingredients, devices and containers containing pesticides in stock Inventory (identity and quantity) of stored pesticides and devices with				
use information supplied copy of signed purchase acknowledgement statements copy of exporter certification Other records and documents Inventory (identity and quantity) of pesticides and active ingredients, devices and containers containing pesticides in stock Inventory (identity and quantity) of stored pesticides and devices with cancelled or suspended registrations Disposal of outdated stocks and				
use information supplied copy of signed purchase acknowledgement statements copy of exporter certification Other records and documents Inventory (identity and quantity) of pesticides and active ingredients, devices and containers containing pesticides in stock Inventory (identity and quantity) of stored pesticides and devices with cancelled or suspended registrations Disposal of outdated stocks and containers				
 use information supplied copy of signed purchase acknowledgement statements copy of exporter certification Other records and documents Inventory (identity and quantity) of pesticides and active ingredients, devices and containers containing pesticides in stock Inventory (identity and quantity) of stored pesticides and devices with cancelled or suspended registrations Disposal of outdated stocks and containers method of disposal 				
use information supplied copy of signed purchase acknowledgement statements copy of exporter certification Other records and documents Inventory (identity and quantity) of pesticides and active ingredients, devices and containers containing pesticides in stock Inventory (identity and quantity) of stored pesticides and devices with cancelled or suspended registrations Disposal of outdated stocks and containers method of disposal date of disposal				
use information supplied copy of signed purchase acknowledgement statements copy of exporter certification Other records and documents Inventory (identity and quantity) of pesticides and active ingredients, devices and containers containing pesticides in stock Inventory (identity and quantity) of stored pesticides and devices with cancelled or suspended registrations Disposal of outdated stocks and containers method of disposal date of disposal location of disposal sites type of pesticide, device, active				

4.2.3. Inspection of pesticide retailers

Inspection of a retailer comprises the storage, display, labelling, packaging and promotion of pesticide products; the routines and competence of the staff; and communication with customers about their pest problems and about pesticide risks and use. Inspectors should also ask whether the shop has a role in the collection of empty pesticide containers, as required by law in some countries.

The inspection should begin with a general scan of the shop to observe how products are stored and displayed. A sample of products should be quickly checked to confirm whether their packaging, labelling, display and storage are acceptable. Any products that do not appear to comply with national requirements should be set aside for further examination and possible testing. The number of products inspected depends on the number of products sold and stored in the shop, the overall conditions of storage and display, the time available for inspection and the estimated complexity of the assessment. Products that do not appear to comply with national requirements or are questionable with regard to quality or legitimacy (e.g. potentially fraudulent products) should be removed from the shop for further examination and possible testing.

It is preferable if shop owners voluntarily correct any problems and remove deficient products from their shelves. If they do not agree to do so, official measures should be taken to correct the problem or stop sale of the products. Examples of official measures to correct problems include the following.

- If counterfeit products or products that are not approved are found, they should be taken off the shop shelves immediately, inventoried and securely stored for later disposal or removed to prevent further distribution.
- If serious packaging or labelling deficiencies are found, such as absence of use instructions, lack of
 pictograms for hazardous products, labelling not in a local language or packaging in reused or leaking
 containers, strong measures may be required. Sales of the product should be stopped, and the products
 should be taken off the shop shelves immediately, inventoried and securely stored for later disposal
 or removed to prevent further distribution.
- If retailers do not appear to provide information to their customers about exposure to and risks of pesticides, inspectors may recommend that the retailers provide and/or display information about the routes of exposure to pesticides. Inspectors may also recommend that they stock and sell personal protective equipment, pesticide application equipment and spare parts.

A checklist for inspection of pesticide retailers is provided in Table 10.

Table 10. Checklist for inspection of pesticide retailers

Inspection of products					
Items to be checked	Notes	Corrections required and deadlines			
Product registration, packaging and labelling					
 Product brand name Registration number Is the product authorized in the country? (No banned pesticides should be sold or stored by retailers.) Is use of the product restricted? Is a permit required to sell such products? Does the label comply with national requirements and product approval? Is the label in the appropriate language? Is the label easy to read? 					

Inspection of products					
Items to be checked	Notes	Corrections required and deadlines			
 Does it have instructions for use? Does it list the net contents and ingredients? Does it have instructions for disposal of leftover product and packaging? Does it have Globally Harmonized System of Classification and Labelling of Chemicals classification, pictograms, signal words, hazard and safety statements, mode of action, restrictions on use, name of producer and weight/volume if these are enforceable? Does the label include all information required by law? Does it provide other information that is desirable but not 					
 obligatory, such as "good agricultural practice"? Is there any suspicion that the label is wrong? Does the packaging comply with the approved product packaging and labelling requirements? Is the retailer aware of any poisoning incidents? (If so, the inspector should record information for later follow-up.) 					
 Pesticide products should be in their original packaging (unless repackaging is allowed), which should be secure, durable and child-proof. Opening and closing devices should be sealed and undamaged. Pesticide containers should not resemble food containers, to avoid any confusion. 					
 Product storage and display Pesticides should be stored and displayed in such a way as to avoid risks to people and the environment. If the country's legislation recommends that products be displayed and sold with the necessary protective equipment, compliance with this recommendation should be checked. 					
 Questions to be considered: Is the product stored and displayed safely? Are products stored according to their storage conditions and displayed away from direct sunlight, heat, moisture, food, medicine, toys, clothing and other such products? 					

Inspection of products				
Items to be checked	Notes			Corrections required and deadlines
 Is "first-in, first-out" adhered to, so that stock is rotated regularly and out-of-date and damaged containers are removed? Are products displayed out of the reach of children (e.g. high up or in closed or locked cupboards)? 				
 Are safety advice and advice on personal protective equipment displayed? 				
• Are other products (e.g. fertilizers or other types of products) stored with pesticides?				
Routines and procedures				
The following should be determined:				
 Licenses and permits Suppliers and/or distributors Staff training and competence Information and advice provided to clients Sale of restricted products Maintenance of product registers Any advertising posted Distribution of safety data sheets 				
Records and documents	3		No. of years records are kept	Corrections required and deadlines
	Yes	No	•	
 Product or device brand name Registration number Copy of label Name and address of supplier, shipper and carrier Date and quantity received and invoice Copies of all advertising Copies of any guarantees 				

4.2.4. Sampling

Physical samples of pesticides and devices should be collected if the inspector suspects that a pesticide product or device has been adulterated or that its composition differs from that specified in its registration. Samples should always include photographs of the label and labelling on the pesticide as well as on the cases or container in the batch or shipment. Photographs of personal protective equipment and spray equipment should also be taken to check whether they comply with relevant standards.

The inspector should:

• Issue a receipt for any samples taken and give the receipt to the person who received the Notice of Inspection as well as to the company director or other person of authority.

- Collect the sample in the presence of the company representative, and ask the representative to sign the receipt. Keep a copy of the receipt in the records.
- When taking the sample, request a statement from the company documenting information about the sample (e.g. its origin, reformulation, repackaging).
- Establish a chain of custody for the sample, identifying who will collect, transport and analyse it, and record and report the results.
- Submit the sample to the appropriate laboratory, and ask the laboratory to expedite the analysis.
- Inform the government authority that requested the inspection that a sample has been collected and sent for analysis, specifying the name of the laboratory.
- Exchange telephone numbers and email addresses with all persons involved to facilitate communication about the results of the analysis and further action.

Detailed guidance on pesticide quality control and sampling is provided in the *Guidelines for quality* control of pesticides (6).

4.3 Concluding the inspection

At the end of the inspection, the inspectors should notify the company that they will receive a formal inspection report listing any instances of non-compliance identified during the inspection. A sample format for the report is attached in Annex 1. If any corrective measures are needed, the inspectors should:

- explain the deficiencies or violations found, corrections required and fines or penalties to be imposed, such as temporarily stopping the company's operations if the corrections are not made by the deadline set. If possible, the explanation should be provided both orally and in writing. It is advisable to do this in the presence of a person in a position of authority at the company;
- send a written notice to the pesticide authority (depending on national procedures, this may or may not be the same as the report to the company); and
- schedule a post-inspection meeting or re-inspection to confirm that the corrections have been made.

An inspection report should be drafted as soon as possible after the inspection and sent to the company and to relevant national enforcement bodies, if applicable. The report should include all relevant information recorded in the inspection checklists and should reiterate any corrections required. Depending on the type of deficiencies or violations, it may also be necessary to send the company a police or prosecutor's report. The report should be securely archived and indexed for future consultation. Relevant laws concerning data protection should be respected.



5. Post-inspection follow-up

Once the corrections have been made, the inspected company should send a written report to the inspection team and authorities with proof that the deficiencies or violations have been corrected. The inspection team should review the company's correction and prevention plan, and, if it concludes that the corrective actions should be verified, should conduct a follow-up inspection. The inspection report, the company's response and a report of the follow-up visit should be kept on file for reference.



References

- 1. FAO & WHO. 2006. *Guidelines on compliance and enforcement of a pesticide regulatory programme*. Rome. (http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/Code/Complia nce.pdf, accessed September 2020).
- 2. United States Environmental Protection Agency (USEPA). 2019. Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) inspection manual. Washington, DC (https://www.epa.gov/sites/production/files/2014-01/documents/fiframanual.pdf, accessed September 2020).
- 3. FAO & CILSS. 2011. Pesticides Inspection and Control A manual for government agents in the Sahel. Draft. Rome
- 4. European Chemicals Agency (ECHA). Undated. *Product-types*. Helsinki. (https://echa.europa.eu/regulations/biocidal-products-regulation/product-types, accessed September 2020).
- 5. FAO. 2015. *Guidelines on pesticide legislation*. Rome (http://www.fao.org/3/a-i5008e.pdf , accessed September 2020).
- 6. FAO & WHO. 2011. *Guidelines for quality control of pesticides*. Rome. (http://www.fao.org/3/a-bt477e.pdf, accessed September 2020).
- 7. Organisation for Economic Co-operation and Development (OECD). 2012. *Guidance on pesticide compliance and enforcement best practices*. Paris. (http://www.oecd.org/env/ehs/pesticides-biocides/oecdguidanceonpesticidecomplianceandenforcementbestpractices.htm, accessed September 2020).
- 8. FAO. 1988. *Guidelines for retail distribution of pesticides with particular reference to storage and handling at the point of supply to users in developing countries.* Rome. (http://www.fao.org/3/a-bt482e.pdf, accessed September 2020).
- 9. WHO. 2020. *Quality management system requirements for motional inspectorates*. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-fourth report. WHO Technical Report Series, No. 1025. Geneva, Switzerland. (https://www.who.int/publications-detail/978-92-4-000182-4, accessed September 2020).



Annex 1. Sample format of an inspection report

Report on establishment inspection to determine compliance with national law

Establishment name

Address (city, state or province, postal code, country

[Mailing address if different]

Date of inspection (day, month, year)

Performed by:

Inspection No.

- I. Company information
 - Name
 - Establishment license or registration number
 - Responsible official
 - Type of ownership
- II. Date of inspection (day, month, year)
- III. Participants
 - Company
 - Inspector(s) and their affiliation(s)
- IV. Objectives

To inspect/investigate/follow-up on ...

- V. Company background
- VI. Inspection results
 - Opening meeting
 - Report of inspection results
 - Closing meeting

Inspector's name

Inspector's title

Signature

Date (day, month, year)

