



GUIDELINES FOR PROCURING PUBLIC HEALTH PESTICIDES



**World Health
Organization**



Guidelines for procuring public health pesticides

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DEFINITIONS

- *Active ingredient.* Biologically active part of a pesticide formulation
- *Analytical portion.* Portion of a suitably prepared, appropriately homogenized laboratory sample to be analysed or tested; also known as a *test portion*
- *Batch.* Identifiable quantity of an active ingredient or formulation that has been manufactured, processed and stored under conditions presumed to be uniform
- *Bulk sample.* Combined total of primary samples taken from a batch
- *Consignment.* Quantity of one or more materials delivered at one time. A consignment of pesticides may consist of one or more batches or parts of batches.
- *Dangerous co-formulant.* Any substance present in a pesticide product at a concentration that triggers classification of the formulation
- *Equivalence.* Determination of the similarity of the impurity and toxicological profile and physical and chemical properties of supposedly similar technical material originating from different manufacturers; used to assess whether they present similar levels of risk
- *Formulation.* The combination of active ingredient(s) and formulators intended to facilitate application of a pesticide and make it effective for the purpose claimed
- *Indoor residual spraying.* Spraying of the interior walls of dwellings with an insecticide to kill mosquitoes that spread malaria
- *Inspector (sampling officer).* Person who has been properly trained in reliable, safe sampling and who is authorized by the responsible authority to examine pesticides and take samples for controlling their quality and packing
- *Insecticide-treated net.* Mosquito net that repels, disables or kills mosquitoes that come into contact with the insecticide on the netting material. There are two categories: conventionally treated and long-lasting insecticidal nets:
 - *Conventionally treated net.* A mosquito net that has been treated by dipping it in a WHO-recommended insecticide. To ensure its continued insecticidal effect, the net should be re-treated after three washes, or at least once a year.
 - *Long-lasting insecticidal net.* A factory-treated mosquito net made of netting material with insecticide incorporated within or bound around the fibres. The net must retain its effective biological activity without re-treatment for at least 20 WHO standard washes under laboratory conditions and 3 years of recommended use under field conditions.

- *Label*. Written or graphic information on or attached to the immediate container of the pesticide and its external packaging, if any
- *Laboratory sample*. The portion of material obtained by the specified sampling procedure, which is sent to a laboratory for testing
- *Obsolete pesticides*. Stocked pesticides that can no longer be used for their intended purpose or any other purpose and must therefore be disposed of
- *Packing*. The container and the protective wrapping used to transport pesticides by wholesale or retail distribution to users
- *Packing unit*. An individual container containing pesticide or a retail package containing a number of smaller packages or containers (each usually <2 l or 2 kg) of a pesticide
- *Pesticide product*. The active ingredient(s) and other components in the form in which it is packed and sold
- *Pictogram*. A graphical composition that may include a symbol and other elements, such as a border, background pattern or colour, intended to convey specific information (Globally Harmonized System of Classification and Labelling of Chemicals)
- *Precautionary statement*. A phrase that describes measures that are recommended to be taken to minimize or prevent adverse effects resulting from exposure to a pesticide or improper storage or handling of a pesticide (Globally Harmonized System of Classification and Labelling of Chemicals, amended)
- *Primary sample*. Quantity of material, loose or packaged, taken with or without a sampling tool from a single sampling position in a container or batch
- *Procurement*. Obtaining goods and services by preparing and processing a requisition through to receipt and approval of the invoice for payment. It commonly involves purchase planning, standards determination, specifications development, supplier research and selection, value analysis, financing, price negotiation, making the purchase, supply contract administration, inventory control and stores and disposal and other related functions.
- *Procurement entity*. The entity (body) that procures pesticides
- *Professional pest management pesticides*. Pesticides used by certified professional pesticide applicators to control pests, including termites and structural pests in houses, commercial and industrial premises and public areas
- *Public health pesticides*. Pesticides used to control pests of public health significance, including vector control pesticides, household insecticides and professional pest management pesticides
- *Referee analysis*. An analysis performed in an independent laboratory staffed by suitably experienced personnel, agreed by the parties to a dispute, in order to certify the quality of a disputed sample
- *Sampling report*. Standard report form completed by an inspector at the time of sampling and countersigned by the person responsible for the batch at the time the sample is taken
- *Technical material*. Material resulting from a manufacturing process, comprising the active ingredient and associated impurities
- *Testing laboratory*. Laboratory authorized by the responsible authority to test pesticides for their compliance with quality specifications
- *Tender*. Invitation for bids in the procurement of goods and services (including pesticides)
- *Triangulation*. Arrangements in which a donor funds the repacking and movement of a stock of pesticides from a country that has an excess stock to a country in direct need of the product.



1. INTRODUCTION

Pesticide procurement is a highly specialized and complex subject. Expertise is required to ensure that appropriate high-quality pesticide products are procured rapidly, efficiently, economically and in a fair and transparent manner. It also requires the existence of national policies and guidelines, with clear and transparent procedures supported by appropriate legal provisions and controls.

Large quantities of public health pesticides are procured annually through national or international tender procedures. It is estimated that an average of 4429 tonnes of active ingredient of organochlorines, 1375 tonnes of organophosphates, 30 tonnes of carbamates and 414 tonnes of pyrethroids were used annually for global vector control during the period 2000–2009 in WHO's six regions (1). Indoor residual spraying programmes to control malaria vectors in Africa have expanded significantly in recent years: the number of people protected in sub-Saharan Africa increased from 13 million in 2005 to 75 million in 2009. In addition, by the end of 2010, approximately 298 million long-lasting insecticidal mosquito nets (LNs) were delivered to the African Region for malaria prevention. The burden on public health due to nuisance pests is significant, leading to the use of considerable volumes of pesticides for personal protection, although comprehensive statistics on pesticides used for this purpose are not available.

Pesticide products of appropriate quality, which are suitably packaged and labelled, and an efficient procurement system are therefore crucial to the control of vector-borne diseases and nuisance pests.

Procurement of public health pesticides differs from that of agricultural pesticides. The former is usually done by government agencies, international organizations or aid agencies, while agricultural pesticides are usually procured by the private sector. In outbreaks of agricultural pests, however, governments and international organizations are involved in the procurement of pesticides.

The Food and Agriculture Organization of the United Nations (FAO) has published provisional guidelines on tender procedures for the procurement of pesticides (2), mainly for agriculture. These guidelines also provide useful information for the procurement of public health pesticides. The World Health Organization (WHO) published guidelines for the purchase of public health pesticides in 2000 (3). The present document is an expanded, updated version of that document and replaces it.

These guidelines promote procedures and regulations to increase transparency, accountability, fairness and integrity in pesticide procurement and for implementation of the International Code of Conduct on the Distribution and Use of Pesticides (4). As procurement procedures vary by country and international procurement entity, these guidelines are also intended to harmonize practices.



2. OBJECTIVES AND SCOPE

The objectives of the guidelines are to provide guidance on the procurement of appropriate, good-quality public health pesticide products. The guidelines promote fairness, transparency, integrity, accountability and quality assurance in procurement. Their aim is to assist Member States and other stakeholders in preparing their own standard operating procedures and to harmonize them.

These guidelines cover the basic principles and stages that are important in the procurement of public health pesticide products (*Figure 1*). They include planning, selection of appropriate high-quality products, procurement, legal and technical requirements, quality control and administrative requirements.

While it is recognized that most pesticide products used for public health purposes are insecticides, other types are also used, such as repellents, rodenticides and molluscicides. Therefore, the more generic term ‘public health pesticide products’ is used throughout these guidelines, rather than ‘public health insecticide products’. Public health pesticides include those used for vector control, household pesticides and professional pest management pesticides (that is pesticides used by pest control operators). LNs are a pesticide product.

The target audience includes procurement officers, managers of national vector-borne disease control programmes, health officers and supply chain managers in international aid agencies, institutional buyers, nongovernmental organizations and United Nations organizations. The document should also be valuable to national pesticide regulatory authorities, the pesticide industry and laboratories involved in controlling the quality of pesticides.

FIGURE 1. Stages in procurement of public health pesticides

		SECTION
Choose an appropriate product		3
Estimate need		4
Prepare procurement documents		7
Solicit tenders	Solicit restricted/limited tender or quotation	7
Process procurement documents		8
Award contract		8
Purchase product		8
Product quality control		9

3. CHOOSING AN APPROPRIATE PESTICIDE PRODUCT

WHO promotes integrated vector management, which is a rational decision-making process for the optimal use of resources for vector control (5). Its aim is to improve the efficacy, cost-effectiveness, ecological soundness and sustainability of interventions for the control of vector-borne diseases. In an integrated vector management approach, account is taken of the available health infrastructure and resources, and all chemical, biological and environmental cost-effective measures are integrated. Judicious use of pesticides and pesticide resistance prevention and management¹ are promoted in integrated vector management.

In selecting a pesticide and an appropriate formulation, consideration should be given to:

- the biological effectiveness of the pesticide (including residual activity where appropriate) against the target pest or vector;
- the susceptibility of the target species to the insecticide and its role in the prevention and management of resistance to pesticides;
- the method(s) of application;
- risks to human health and the environment;
- national registration status of the product;
- existence of WHO Pesticide Evaluation Scheme (WHOPES) recommendations for the intended use;
- existence of adequate capacity for safe handling, application and life-cycle management (e.g. distribution, storage and disposal);
- obligations under international conventions, e.g. the Stockholm Convention with regard to DDT; and
- operational cost, which should be determined from the cost of the product as applied or delivered and not strictly on its purchase price. The criteria for comparing the operational cost and 'value for money' of different products for the intended application(s) should be set at the onset. For indoor residual spraying, the criteria for comparison can be the 'cost per unit surface area (m²) sprayed for a certain time, preferably for 1 year' (*Table 1*). For LNs, the criteria for comparison can be 'cost per median year of net life under local conditions of use'.

¹ For example, the Global plan for insecticide resistance management in malaria vectors (GPIRM) (http://whqlibdoc.who.int/publications/2011/9789241501095_eng.pdf).

WHO recommendations on public health pesticides and publications of WHOPES should be considered in selecting appropriate pesticide products. The following documents are especially useful:

- reports of the WHOPES working group (6), which contain evaluations, reviews and recommendations on public health pesticides submitted to WHOPES for evaluation;
- Malaria vector control – decision-making criteria and procedures for judicious use of insecticides (7), which provides useful information on the safe, effective use of insecticides in malaria vector control;
- Pesticides and their application for the control of vectors and pests of public health importance (8), which gives personnel involved in operational vector and public health pest control programmes practical information on the safe, effective use of pesticides and information on the use of chemicals for individual and household protection from insect and rodent pests; and
- The use of DDT in malaria vector control – WHO position statement (2007) (9).

The list of pesticide products recommended by WHOPES, including insecticides for indoor residual spraying, insecticides for treatment of nets, LNs and mosquito larvicides is available on the WHO site at <http://www.who.int/whopes/en>. WHO policy and strategies on the use of insecticides and vector control interventions for malaria control are available at <http://www.who.int/malaria/en/>.

WHO Pesticide Evaluation Scheme

The WHO Pesticide Evaluation Scheme (WHOPES) was established in 1960 to promote and coordinate the testing and evaluation of pesticides for public health. It involves the participation of representatives of governments, manufacturers of pesticides and pesticide application equipment, WHO collaborating centres and research institutions, as well as other WHO programmes, notably the Global Malaria Programme and the International Programme for Chemical Safety.

In its present form, WHOPES comprises a four-phase testing and evaluation programme for studying the safety, efficacy and operational acceptability of public health pesticides and for preparing specifications for quality control and international trade. WHOPES procedures and criteria for testing and evaluating public health pesticides are based on WHO guidelines (<http://www.who.int/whopes/guidelines/en/>) established and periodically reviewed and revised, in consultation with research institutions, industry and national programmes.

WHOPES recommendations are intended to facilitate the registration and use of evaluated products by WHO Member States. A full or interim recommendation for a product means that it has been evaluated by WHO in laboratory and field trials and that it was found to meet WHO's criteria and requirements.

For LNs, WHO may, pending the completion of long-term studies that may be required to evaluate the LNs fully and subject to certain conditions being met, issue an interim recommendation for the use of the LNs for malaria prevention and control.

WHO recommendations on the use of pesticides in public health are valid only if linked to WHO specifications for their quality control (<http://www.who.int/whopes/quality/en/>)

TABLE 1. Guidance for estimating and comparing the cost of applying different insecticide products for indoor residual spraying for malaria control

Insecticide product	Concentration of active ingredient (%)	Application dose of active ingredient (g/m ²)	Approximate duration of residual effect on common surfaces (months)	Number of applications required in 1 year	Total amount of formulation required per m ² per year	Cost per kg or litre of pesticide product (US\$)	Cost per 1000 m ² per year (US\$)	Cost of transport and storage for amount needed to spray 1000 m ² per year (US\$)	Cost of application per 1000 m ² per year (US\$)	Total cost per 1000 m ² per year (US\$)	Cost ratio, W being the lowest cost
	a	b	c	d = 12/c	e = (b x d)100/a	f	g = (e x (f/1000)) x 1000	h	i	j = g + h + i	
A	75	2	6	2	5.3	8	42.4			W	1
B	50	2	3	4	16	15	240			X	X/W
C	10	0.03	4	3	0.9	70	63			Y	Y/W
D	25	0.025	4	3	0.3	200	60			Z	Z/W



4. ESTIMATING REQUIREMENTS

Estimating the correct quantity of pesticides to be procured is an important step in procurement. The steps comprise quantification and forecasting and should be guided by information from a logistics management and information system. This would include records of existing stocks and their location, accurate estimates of the population to be covered, disease incidence, past consumption figures, a sound distribution plan and documented experience in managing the vector(s).

Overestimation of the quantity required could result in problems of storage, particularly for bulky products such as LNs, as well as the creation of stocks of obsolete pesticides, the environmentally sound disposal of which requires substantial resources. Underestimation of the quantity could result in loss of lives because of a shortfall in effective vector control coverage. FAO has devised a 'pesticide stock management system' (<http://psms.fao.org/psms/about.htm>) to help countries manage pesticides efficiently by proper recording, monitoring and use, with the aim of reducing the accumulation of obsolete pesticides. Member States could adopt the system for managing stocks of public health pesticides.

Large sums of money are involved in pesticide procurement. As a result, parties with vested interests might try to influence decisions on pesticide procurement. Therefore, quantities of pesticide products should not be acquired in excess of actual requirements.

5. ASSURING GOOD PRODUCT QUALITY

Good product quality (i.e. products that comply with acceptable quality standards) is essential both for effective use and for safety. Applying products with a content of active ingredient that is lower than that declared could result in application of a sublethal dose, which can lead to ineffective control, the development of resistance and wasted funds and resources. Products or formulations with inferior physicochemical properties can also result in inadequate application and possibly increase the risk for exposure of application personnel. Impurities formed during the manufacture and storage of the pesticide or by interaction in unstable formulations can increase its toxicity to humans and the environment. It is therefore of prime importance to identify and specify the quality of pesticide products during procurement. It is also important to ensure that the products supplied meet the quality standards specified.

WHO has established specifications for pesticides with the objective of promoting the manufacture, distribution and use of pesticides that meet basic quality requirements. One way to identify good-quality public health pesticide products is therefore to ensure that they meet WHO specifications, when available. A list of specifications for public health pesticide products is available on the WHOPES website (<http://www.who.int/whopes/quality/en/>). The evaluation reports that are an integral part of the WHO specifications include the names of manufacturers whose products have been assessed and recommended.

WHO specifications for public health pesticides

WHO establishes and publishes specifications for technical material and related formulations of public health pesticides, which can be used as an international point of reference against which products can be judged, either for regulatory purposes or in commercial dealings.

Since 2002, the establishment of WHO specifications has followed a new procedure, described in the *Manual for development and use of FAO and WHO specifications for pesticides* (10). The new procedure consists of a formal, transparent evaluation, including the minimum data package, the procedure and the evaluation used by WHO and experts in the FAO/WHO Joint Meeting on Pesticide Specifications.

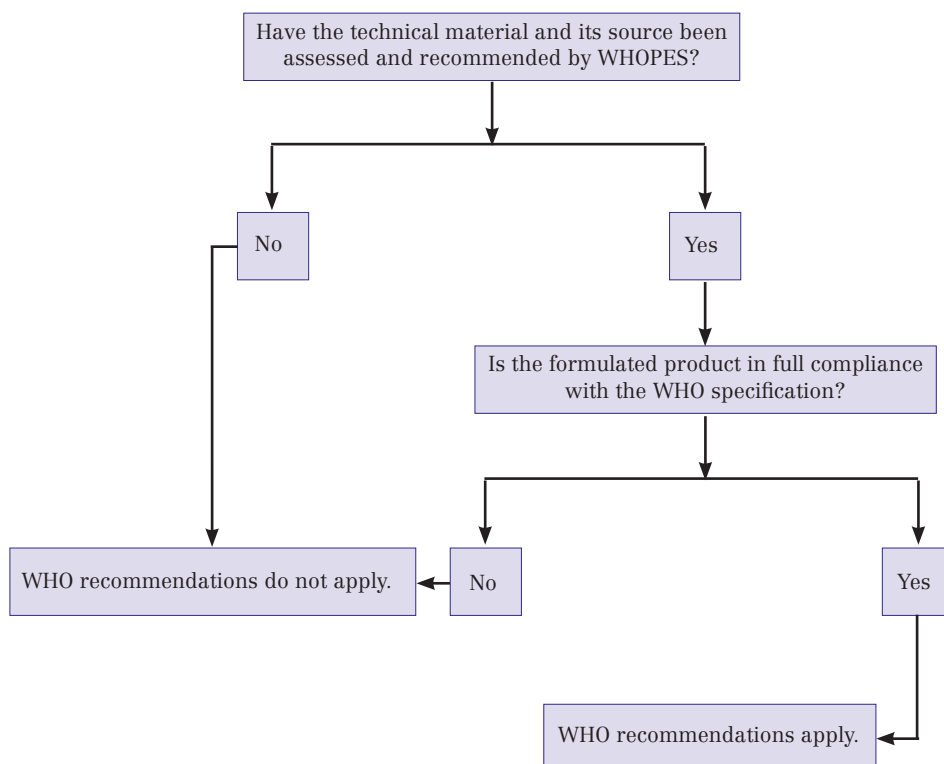
WHO specifications for technical material, prepared under the new procedure, do not necessarily apply to nominally similar products of other manufacturer(s) nor to those in which the active ingredient is produced by other routes of manufacture. WHO can extend the scope of the specifications to similar products, but only when the FAO/WHO Joint Meeting on Pesticide Specifications is satisfied that the additional products are equivalent to those that formed the basis of the reference specification (see definition of 'equivalence').

WHO specifications for formulations under the new procedure, unless otherwise stated, encompass the products of all formulators who can legitimately certify that their products contain only active ingredient from a manufacturer to whom the WHO specification for the technical material applies. Buyers and regulatory authorities should demand such certification and ensure both that it is valid and that the products fully comply with the physical and chemical requirements of the WHO specifications for formulated pesticide products (Figure 2).

WHO specifications are available only on the WHO home page on the Internet. Specifications may be revised, and additional evaluations may be undertaken. Use of current versions can be checked by consulting www.who.int/whopes/quality/en.

It is equally important that procurement entities have access to quality control laboratories, to ensure that the pesticide products procured are of acceptable quality. Many developing countries, however, still do not have such facilities. One option would be to seek, through WHOPES, the assistance of the WHO Collaborating Centre for Quality Control of Pesticides¹

FIGURE 2. Algorithm to verify compliance of a pesticide product with relevant WHO specifications



¹ Walloon Agricultural Research Centre, Agriculture and Natural Environment Department, Plant Protection Products and Biocides Physico-chemistry and Residues Unit, Rue du Bordia, 1, B-5030 Gembloux, Belgium. (For further information refer to <http://cra.wallonie.be/>.)

6. NATIONAL REGULATIONS

Procurement of public health pesticide products involves not only large sums of money but also complex technical issues to minimize opportunities for illicit influences on procurement and to promote transparency and fairness. It is crucial that there be adequate safeguards, such as legislation, to regulate the procurement of products. Most countries have their own laws and regulations for government procurement of goods and services; often, however, these are not written specifically for the procurement of public health pesticide products. In general, laws related to public procurement of goods and services include provisions for:

- establishment of administrative structures, including a tender committee, and rules for the composition, functioning and powers of the committee;
- making rules for procurement, including different methods, such as open tendering, restricted or limited tendering, direct procurement and requests for quotations and various stages of procurement;
- administrative review of procurement proceedings to address appeals and complaints;
- establishment of an authority with powers to ensure compliance; and
- imposition of penalties, including debarment from participating in procurement proceedings for offending suppliers.

Such laws and regulations for public procurement of goods, if sufficiently comprehensive and efficiently enforced, provide a good basis for proper procurement of public health pesticides. The process can be further strengthened by comprehensive guidance on issues in the procurement of public health pesticide products, to complement the law and regulations. The documents should include the elements related to public health pesticide procurement mentioned in this document.

National regulations should include provisions to safeguard the integrity of the supplier and the procurement entity by requiring suppliers to sign an undertaking that they are not involved in any bribery practices. Any contraventions of the terms of the undertaking by the supplier should result in imposition of a penalty. The Organisation for Economic Co-operation and Development adopted the *Convention on combating bribery of foreign public officials in international business transactions* (11) in 1997, which obliges signatory countries to make bribery of a foreign public official a crime under their laws.



7. SELECTING THE PROCUREMENT METHOD AND PREPARING TENDER DOCUMENTS

7.1 Procurement planning

Relevant information and realistic timetables are needed to ensure successful procurement planning. Selection of the type, quantity and quality of pesticides to be procured should be based on the criteria and procedures discussed under sections 3 and 4 of this document. Depending on the administrative and bureaucratic system of the country, planning should begin not less than 6 months but preferably 12 months before the anticipated delivery. More time may be needed, especially if many countries are on a similar implementation cycle, to give suppliers sufficient time to deliver the products.

The delivery places and schedules should be planned in advance, taking into account the availability of local storage and transport. This is particularly important for products such as mosquito nets, which are bulky and require large storage spaces.

7.2 Procurement methods

The aim of good practice in the procurement of high-quality pesticide products is to ensure the principles of transparency, fairness and competition and to achieve the best possible value for money.

Various methods can be used to procure pesticide products. The choice of method depends on the total value, the availability of the products and the source of funding. National procurement agencies and international aid agencies have their own requirements for the procurement of goods and services.

Depending on the value and availability of the product, the tendering process can be open, restricted or limited. National regulations or the funding agency usually stipulate a threshold value, above which open tendering is mandatory and below which restricted or limited procurement is acceptable.

The aim of procurement is to secure the best value for money for quality-assured products, to ensure the reliability of suppliers in terms of both quality and service, to maintain transparency and to minimize opportunities for illicit influences on procurement.

The three procurement methods are:

- open tender, open to all suppliers; also called ‘competitive’ or ‘public’ tender;
- restricted or limited tender, in which only short-listed suppliers with a good record in terms of quality and delivery are invited; and
- direct procurement, in which the product is purchased directly from a single supplier at the quoted price.

To avoid dependence on a single supplier, some procurement entities award a bid for a proportion of the required quantities to two or more suppliers. Such ‘split tender’ systems minimize the risk for supplier default but are likely to raise prices.

Countries may consider appointing an appropriately qualified external agency to assist them in sound, fair procurement of public health pesticides products.

International organizations and agencies, such as the United Nations Children’s Fund (12), the World Bank (13) and the Global Fund to Fight AIDS, Tuberculosis and Malaria (14), have their own requirements and procedures for the procurement of public health pesticide products.

7.3 Tender requirements

7.3.1 Tender documents

Tender documents should be prepared on the basis of legal provisions on the procurement of goods and services in the country, including any that may be specific to pesticides. The format of the tender document will vary from country to country but usually consists of three sections:

- Section 1 provides information on the procurement procedure, including instructions to tenderers, conditions of tenders and technical specifications and requirements of the products being procured (see guidelines in *Annex 1*).
- Section 2 contains the schedule of requirements, such as time, quantity and place of delivery.
- Section 3 usually describes the contract for procurement.

Instructions to tenderers inform them about the procurement process and the actions they must take to comply with the requirements. The instructions are based on the legal requirements for procurement of goods and include the scope of the tender, procedures for tender submission, opening and evaluation and award of a contract. The principles of sound public procurement must be followed by giving potential suppliers accurate technical information and specifications for the products to be procured.

Open tenders are often invited in advertisements in newspapers or international journals or on the Internet to promote competition and allow procurement entities to obtain pesticides at the best possible price.

The tender documents include the technical specifications and other requirements that define the commercial and logistic framework for procurement. They include:

- pesticide specifications (without specifying trade names);
- technical specifications and documentation to be submitted in support of compliance requirements for outer packaging and shipping, which include compliance with norms,

dimensions, volumes, stacking requirements, materials, crush resistance, padding and external marking;

- quantities and delivery schedules, required delivery terms (e.g. Incoterms: 'free carrier', nearest main sea- or airport) and ordering procedures;
- applicable terms and conditions that will form the basis for selection;
- the deadline for submission of bids, which should not be so short as to restrict competition;
- timetables for orders and delivery (bidders should be alerted to any anticipated delays, for example if the pesticides have still not been authorized for use in the destination country);
- procedures for awarding tenders;
- any special conditions in adjudicating tenders, such as preference for products recommended by WHOPES;
- request for a statement of the supplier's administrative and legal status and its link with the product; and
- a standardized proposal form, stating delivery times, expected delivery date, gross weight of the order, personnel involved and contact details, and a quotation for the total amount, including any discounts.

Other information in the document should include the name and address of the procurement entity and the place of delivery of the goods. When registration or authorization for importation of the pesticide or LNs in the country of use is a prerequisite for acceptance of a product for procurement, this information should be included in the tender specifications.

Tender documents can also contain other administrative requirements, such as insurance requirements, percentage of advance payment, payment schedule, interest for payment delays, and bond for satisfactory completion of contract. These are not, however, within the scope of this document.

7.3.2 Pesticide specifications

Procurement of a high-quality pesticide begins with a definition of the correct specifications for the intended purpose. The personnel responsible for drawing up the specifications of the pesticides to be procured must have the appropriate expertise and experience.

On the one hand, the specifications should not be unnecessarily restrictive (e.g. restricting competition to one product). On the other hand, many problems associated with pesticide use arise from incomplete or inappropriate specification in tenders and procurement documents. In general, the specifications of pesticides to be procured should include:

- the common name of the active ingredient(s), or, in the absence of a common name, the chemical name; use of trade names should be avoided;
- the content of active ingredient and the acceptable limits (*Table 2*) in the product, expressed in g/kg for solids and g/l for liquids;
- the formulation of the product (e.g. wettable powder, emusifiable concentrate, suspension concentrate);
- relevant chemical and physical properties and their acceptable limits;
- maximum permissible levels of relevant impurities;
- storage stability requirements at low or elevated temperature, as appropriate;

- whether the product should comply with WHO specifications for pesticides and its specification number, if applicable; and
- whether the product has been recommended by WHOPES for the intended purpose, if applicable.

TABLE 2. Typical acceptable tolerance values of active ingredients of formulated products

Declared content in g/kg or g/l at 20 ± 2 °C	Tolerance
≤25	± 15% of declared content for homogeneous formulations (e.g. emulsifiable concentrates, aqueous suspension concentrates) ± 25% for heterogeneous formulations (e.g. granules, water-dispersible granules)
>25–100	± 10% of declared content
>100–250	± 6% of declared content
>250–500	± 5% of declared content
>500	± 25 g/kg or g/l

Each range includes the upper limit.

In the case of LNs, not only the identity and content of the active ingredient(s) but also the fibre and filament type, denier, impregnation technology, colour, size, shape, active ingredient retention index, seam stitching (number and location), netting mesh size and shape, dimensional stability of netting to washing, bursting strength and storage stability at elevated temperature should be specified. WHOPES-recommended LNs are identified by a range of WHO specifications, each with its own combination of these characteristics. In order to ensure that all such products are eligible, the tender should refer to each specification.

For other pesticide uses, several products with different specifications may be suitable for the intended purpose (e.g. indoor residual spraying). In this case, the tender should include reference to all these specifications.

For pesticide formulations packaged in sealed water-soluble bags, the requirements for their dissolution and other appropriate physical tests and limits should be specified (10).

7.3.3 Other technical specifications

Packaging requirements: Tender documents should also specify the packaging type, thickness of materials used (where appropriate), size and durability to suit the local use and climatic conditions. The packaging should also comply with United Nations recommendations for the transport of dangerous goods (15). Specifying appropriate packaging size will both facilitate field application and minimize incidents of poisoning. While purchasing pesticides in bulk may be more economical, this practice should be weighed against the risks of spillage, inaccurate dosing and exposure of pesticide applicators and handlers during field application.

LNs should be packed individually in sealed plastic bags that are sufficiently strong to prevent damage during transit. The label statements specified below should be printed on the bag or inserted in a transparent plastic bag inside the bag. Rectangular nets should usually have six hanging loops made of reinforced fabric or netting material. Conical nets should have a non-rusting ring. In order to reduce the cost of transport of LNs, manufacturers are requested to bale them, usually with 50, 40 or 25 per bale. The bale should have a secondary outer packaging that protects the LNs and should be properly strapped (minimum of four straps) and labelled.

Tenderers should be required to provide evidence that the packaging will be in accordance with national requirements. In the absence of such standards, they should provide evidence that the packaging will be sufficiently robust to preclude leakage and breakage during shipment and local transport.

Labelling requirements: Good labelling is essential to ensure that pesticides are used properly, to avoid misuse and undesirable incidences such as poisoning and contamination of the environment. Hence, tender documents should be explicit in defining the labelling requirements. Tenderers should comply with any national labelling requirements, which should include the language(s) to be used. The labelling requirements should also be in line with the International Code of Conduct on the Distribution and Use of Pesticides and the FAO guidelines on Labelling of Pesticides (16). The labels on procured products should be approved by the pesticide regulatory authority of the country. When such requirements are lacking, the conditions of the tender should include the condition that the products supplied should bear labels in the specified language(s) and the following information:

- product brand or trade name;
- product category (e.g. insecticide, rodenticide);
- type of formulation;
- name of active ingredient;
- content of active ingredient (g/kg for solids and g/l for liquids);
- name, identity and concentration of dangerous co-formulants (i.e. all substances in the formulation that contribute to its hazard classification), if any;
- net content of unit pack (e.g. litre, gram, kilogram);
- batch number;
- registration number, if any;
- hazard and safety information;
- precautionary pictograms;
- hazard colour band (based on the WHO classification of pesticides by hazard), printed on the lower part of the label;
- first aid and medical advice;
- product or user category (e.g. professional use, restricted use, household use);
- directions for use;
- storage and disposal of product and packaging;
- supplier identification (local distributor or supplier name, address and telephone number), often also the holder of registration approval of the product in the country. If the approval holder and the local distributor or supplier are different, contact details for the approval holder may also appear on the label.
- manufacturer's name and company logo;

- date of release¹ of the product; and
- shelf-life for products with a shelf-life of <2 years from the date of release.

LN's should be packed individually in plastic bags and baled. Their labelling should include:

Printed (in indelible ink) on the label attached to the net

Brand or trade name
Name of registration holder (if applicable) or manufacturer
Registration number (if relevant)
Name of active ingredient
Concentration of active ingredient
Size of the net
Fibre composition
Batch number
Date of release
Standard pictograms for washing: five pictograms according to ISO 3758, indicating: gentle wash at no more than 30 °C, no bleaching, no use of a drying machine, no ironing and no dry cleaning



Printed on the bag or as a leaflet inside the transparent bag

Brand or trade name
Name of registration holder (if applicable) or manufacturer
Registration number (if relevant)
Name of active ingredient
Concentration of active ingredient
Size of net
Fibre composition
Batch number
Date of release
Standard pictograms for washing: five pictograms according to ISO 3758, indicating: gentle wash at no more than 30 °C, no bleaching, no use of a drying machine, no ironing and no dry cleaning



Filament count
Fabric weight (g/m²)
Linear density of fibres
Flammability
Use instructions
Care and washing instructions
Any other information required by national regulations (e.g. disposal advice)

Printed on the bale

Brand or trade name
Name of registration holder (if applicable) or manufacturer
Registration number (if relevant)
Name of active ingredient

¹ Pesticide product labels must be marked with the release date (month and year) of the lot or batch. The date shown on the label must be the start date from which the supplier guarantees the quality of the formulation. The term 'release date' should be used rather than 'formulation date', which may lead to confusion between supplier and buyer (10).

7.3.4 Conditions relating to suppliers

The responsibilities of successful suppliers go beyond the supply of pesticides; they may also include product stewardship and support, with provision of information and other materials, training and disposal of empty containers.

Tender documents should require suppliers to provide documentary evidence:

- that they are a bona-fide company with the legal and financial requirements and experience in trading in the pesticides to be procured;
- that they have the technical and management expertise to provide technical support for the pesticides they offer, including training on proper use and provision of advice and antidote in cases of poisoning related to their pesticide;
- of long-term viability to ensure continuity of after-sales service; and
- of their ability to produce products that comply with national or WHO specifications, as relevant.

When suppliers are local companies that obtain pesticides from manufacturers abroad, they should provide evidence that the products are from producers that have the capability and capacity to provide the required quantity and quality.

7.3.5 Schedule and place of delivery

Both the schedules and the places of delivery of the pesticide must be specified in the tender document.

To facilitate evaluation of the tender, the document should include a table showing the volume, price, international commercial terms (Incoterms), place of delivery and lead time (see *Annex 2*).

7.3.6 Other conditions

Several safeguards should be built in at the stage of procurement, such as specifying the appropriate conditions and requirements to ensure that the procurement entities obtain a fair deal and to enable them better to manage the pesticides procured. Depending on the local situation and requirements, several conditions could be stipulated in the tender documents:

- The supplier should ensure that the products delivered have an acceptable remaining shelf-life, specifically, that, at the time of delivery, they still have a shelf-life of X months (to be specified in the contract, depending on the product and Incoterms).
- The procurement entity has the right to examine, take samples from and analyse the products supplied. The supplier should facilitate the examination and collection of samples.
- In the event that the product supplied is found to be of unacceptable quality or inappropriately packaged or labelled, the supplier should take the consignment back at its own cost and replace, within a specified time, the rejected consignment with one that meets the requirements of the contract. Failing this, the supplier should refund to the procurement entity all the expenses incurred in procuring the product. In addition, the bid bond provided as a guarantee of satisfactory completion of the contract should be forfeited.
- The procurement entity should have the right to compensation when part of the consignment has been used and it is subsequently found that the consignment was not in compliance with the agreed specifications.
- When samples have to be sent outside the country for quality control in an accredited or recognized laboratory, the supplier should bear the cost.

The following conditions, subject to mutual agreement between the procurement entity and the supplier, may also be considered:

- The supplier will collect all empty pesticide containers for proper disposal, according to national regulations.
- The supplier will take back products that remain unused after a specified time.
- The supplier will provide protective gear, material safety data sheets, antidotes and cholinesterase test kits for monitoring exposure of applicators to the procured pesticides, when required.
- The supplier will provide training in proper handling and use of the pesticides supplied.

8. PROCESSING OFFERS: ORGANIZATIONAL REQUIREMENTS, EVALUATION, SELECTION & AWARD

The procedures for processing offers should be in line with the legal requirements for public procurement of goods and services in the country, where applicable, and be supported by national legislation for regulation and registration of pesticides.

In countries that have a pesticide registration scheme, any public health pesticides procured should be registered by the national pesticide regulatory authority in order to ensure that they have been evaluated and found acceptable for the intended use. Countries without a registration scheme should use products recommended by WHOPES. If there are no national registration or relevant WHOPES recommendations, countries may refer to a valid registration (for the same intended application) in countries with high registration standards.

Organizational requirements are usually specified in legislation on public procurement of goods and services but may vary from country to country. There is generally a provision for the establishment of a 'tender committee' responsible for planning, processing and making procurement decisions and for compliance with the public procurement law, in order to ensure transparency, fairness and integrity. The structure of the committee will vary by country, but it is typically composed of senior officers with sufficient expertise in the legal requirements of procurement and in the technical aspects. The tender committee considers two independent evaluations of each bid and assesses its technical and financial proposals, which may be prepared by a technical subcommittee and a financial subcommittee.

To safeguard the integrity of the tender committee, members should officially declare that they do not have any vested interest in the supply of pesticides.

The technical evaluation includes consideration of:

- the completeness of the offer;
- a review of the technical specifications of the products offered;
- an evaluation of whether the requirements have been met;
- an evaluation of the product's shelf-life;
- a review of pertinent documentation (e.g. certificates of analysis, compliance, origin, authorizations);
- proven experience in the pertinent field;
- lead time; and
- technical support and after-sales service offered.

The technical officers evaluating the tender must verify the integrity of the information on the products and the tenderers. For example, a claim that the product offered meets WHO specifications must be supported by documentary evidence, including a certificate of analysis of the product and the source of the technical material used in the formulated product. Tenders containing false or incomplete information should be recommended for disqualification.

The financial evaluation includes consideration of:

- the completeness of the offer;
- an administrative analysis of the bidder's profile;
- a financial analysis of the bid submitted;
- proven experience in the pertinent field;
- assurance that the bidder can supply the product;
- evaluation of the information supplied against the defined evaluation criteria;
- unit price; and
- value for money (see *section 3*).

In order to obtain the best possible value for money, the technical subcommittee should, for example in the case of indoor residual spraying products, provide the necessary information on the amount of each product required to maintain the insecticidal effectiveness of 1 m² of wall during all periods of transmission of the targeted disease over 1 year. The financial subcommittee should calculate the cost of the different products offered on the basis of the above information. For LNs, the criteria for comparison could be 'cost per median year of net life under local conditions of use'.

The tender committee will evaluate the recommendations from the financial and technical subcommittees and combine the technical and financial measures to arrive at a 'value for money estimate' before awarding a contract proposal. Evaluation of the tender should take no more than 4 weeks.

The award proposal should be submitted to a senior office who is not directly involved in the tender process for endorsement or to the donor for a 'no objection'. The result should then be conveyed to all bidders. A contract department will initiate the procurement contract.

Decision-making criteria at all stages must be clear, justifiable and objective, especially in the evaluation and comparison of bids. In each case in which the tender committee rejects a submitted recommendation which was to procure the operationally most cost-effective product meeting the criteria established by the Committee, the reason(s) for rejection of the recommendation should be clearly stated, endorsed by the Committee and documented.

9. QUALITY CONTROL: PRESHIPMENT AND ARRIVAL INSPECTION

Quality control of pesticides is essential to minimize risks associated with their handling and use and also to guarantee their efficacy and stability during storage. Poor-quality pesticides can result in inadequate application of the product, increase the risk for users and the environment and lead to ineffective control and potential development of resistance.

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 prevent the trade of substandard products. They define the essential chemical and physical properties associated with the efficacy and the risk of use of a product.

All public health pesticides offered for sale should meet the WHO specifications, when they exist. When WHO specifications do not exist, any other relevant internationally accepted or national specifications should be considered. The bidder must provide evidence that the product offered complies with the relevant specification. A certificate of analysis should be provided by the supplier for each batch of product at the time of delivery. The independent control of the quality of the product has to be determined through independent analysis by the procurement entity.

Quality control involves: choosing an independent certified or accredited laboratory, random sampling of appropriate samples, shipment of samples to the selected laboratory, quality control and reporting by the selected laboratory. To guarantee the transparency of procurement, the sampling agent and the laboratory must be independent of the supplier.

Preshipment analysis ensures that the product offered meets the relevant specifications before shipment, thereby avoiding subsequent problems if the product delivered is of poor quality. Quality control on arrival or after shipment may be required if the traceability of the product cannot be guaranteed, if the product appears to have been tampered with or if it is known to have been exposed to unacceptable shipping and storage conditions.

9.1 Choosing an independent certified or accredited laboratory

The selected laboratory should be independent of the manufacturer or supplier and have all the infrastructure, equipment and human resources to perform physico-chemical analysis of pesticide samples. The laboratory should have a quality assurance system in place, according to the ISO 17025 accreditation standard or to the Organisation for Economic Co-operation and Development principles

of good laboratory practice, in order to ensure the traceability of analysis and to provide accurate, reliable results. This involves designating a quality assurance manager; writing a quality assurance manual and standard operating procedures for all operations performed by the laboratory, from receipt of samples until the final report; writing standard operating procedures for all the equipment; a detailed description of the analytical methods; validation of analytical methods (specificity, linearity of detector response, accuracy, repeatability and reproducibility, limit of quantification for impurities); verification of the performance of the method during analysis of samples; writing raw data in laboratory notebooks or on forms; organizing management reviews; training personnel; safely archiving raw data; and writing study plans, contracts and comprehensive reports of the analysis. Participation in proficiency tests or collaborative trials is highly recommended.

The selected laboratory should have a solid infrastructure, including separate facilities for different activities (sample receipt, sample preparation, chromatographic determination, storage of reagents and solvents, offices), appropriate work tables and fume hoods. The laboratory should have all the necessary resources, including equipment to perform physico-chemical testing of pesticides according to the methods of the Collaborative International Pesticides Analytical Council (CIPAC) (17) and WHO specifications. The laboratory should also have all certified analytical standards, reagents and solvents necessary to perform the required analysis.

The selected laboratory should have sufficient qualified scientists and technicians. Regular training and participation in workshops on modern analytical techniques, such as gas chromatography and high performance liquid chromatography, are recommended. Training in quality assurance is also recommended. The laboratory should be competent in analytical methods for quality control of pesticides. The methods referenced in the pesticide specifications should be applied exactly as described in order to obtain reliable results. The laboratory should have access to WHO specifications, guidelines on pesticide analysis (available on the websites of FAO, WHO, the Organisation for Economic Co-operation and Development and the European Union) and the analytical methods of CIPAC and the Association of Official Analytical Chemists).

In general, accreditation according to ISO 17025 through a national body meets the needs of an official quality control laboratory better than the quality assurance scheme under good laboratory practice, which is mandatory for the studies necessary for national registration in countries of the Organisation for Economic Co-operation and Development. The guidelines on quality control of pesticide products for national laboratories (18) provide general guidance for the establishment or strengthening of national pesticide quality control, irrespective of whether the product is used for public health or agriculture. Although the use of a product may differ, the quality control schemes are similar, and a laboratory that analyses products for both areas might be synergistic and allow rational use of resources. This document focuses on laboratories for the analysis of pesticide products, to ensure that the data generated are of a sufficiently high standard to withstand external scrutiny. Reference is also made to laboratories engaged in pre-registration testing of products. These guidelines are not restricted to quality control in conducting specific analyses but extend to the full range of management in the operation of a laboratory, including organization, staff, procedures and facilities.

The WHO Collaborating Centre for Quality Control of Pesticides¹ can be requested by procurement entities to perform the quality control of pesticides that they procure.

¹ Walloon Agricultural Research Centre, Agriculture and Natural Environment Department, Plant Protection Products and Biocides Physico-chemistry and Residues Unit, Rue du Bordia, 11, B-5030 Gembloux, Belgium.

9.2 Sampling

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

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

Guidelines on sampling for the quality control of technical-grade active ingredients of pesticides and formulated products are published in Appendix A of the Manual on the development and use of FAO and WHO specifications for pesticides (10). The topics covered include safety precautions, general principles of sampling, preparations for sampling, monitoring the properties of pesticide packages and sampling for testing physical and chemical properties. The Environmental Protection Agency of the United States of America provides comprehensive guidelines on the subject in the Federal Insecticide, Fungicide and Rodenticide Act inspection manual (19).

9.2.1 Preparation for sampling

Before sampling, an independent sampling officer should be selected. It is important to ensure that appropriate logistic arrangements and sampling apparatus are available. Appropriate, clean equipment and containers should be used to take and retain samples in order to avoid contamination from outside sources, to ensure that contamination of the sampling officer is minimized and to enable the analyst to analyse the submitted material satisfactorily.

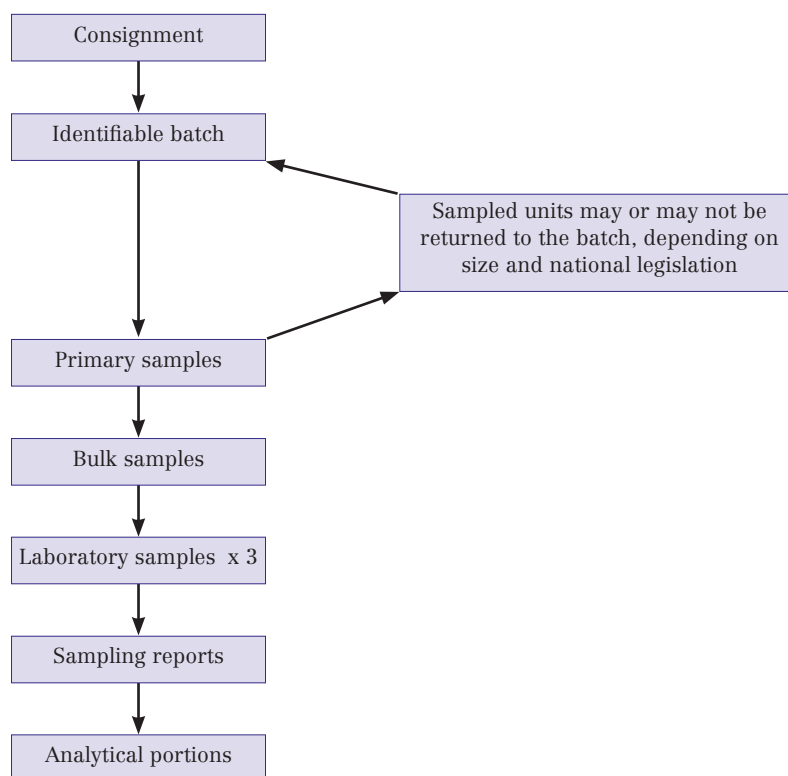
Apparatus and logistic arrangements recommended for sampling

- sampling devices, including 50–100-ml pipettes, three-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 when the original containers are to be emptied;
- portable balance with a suitable weighing range;
- labels that can be firmly glued or otherwise attached to the sample containers;
- sealing tape and wax seal or official printed tape to certify authorized opening of containers;
- personal safety devices, for example appropriate gloves (suitable for handling drums, tins, packages, sampling devices and sample containers), aprons, dust masks, an effective respirator when necessary, safety goggles, tissue paper, first-aid kit, soap, towel and a supply of water for washing;
- case for sampling equipment and sample containers that allows 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 or sampling officer;
- vehicle for carrying sampling personnel, equipment and samples; and
- transport for the samples to the laboratories.

9.2.2 Sampling procedure

Samples of pesticide formulations are usually taken from materials that are packaged, labelled and ready to be marketed. The general sampling protocol for laboratory testing is shown in *Figure 3*. Although it is preferable to sample material from positions in a batch chosen in a statistically random manner (20), in practice the positions may be limited by accessibility and safety. If random sampling is not practicable, the method of selecting primary samples should be noted in the sampling report. When applicable, the samples for laboratory testing may be taken from packing units selected for on-site examination.

FIGURE 3. General sampling protocol for laboratory testing



It is crucial to the success of the testing that samples be collected and forwarded to the testing laboratory by an inspector or sampling officer, who must be well trained in sampling procedures. In all cases, the sampling technique must ensure that the samples taken allow the analyst to provide results that are representative of the material sampled. The inspector or sampling officer must therefore follow established procedures for sampling, handling and packaging.

Formulated pesticides may be checked before distribution at the manufacturing, formulating and packing plant or, in the case of imported formulations, at central depots or stores.

The bulk sample should be thoroughly mixed and divided into three equal laboratory samples: for the testing laboratory, for the organization agreed by both parties that will retain referee samples (e.g. the procurement entity) and for the person responsible for the batch at the time of sampling (e.g. the

manufacturer or supplier). A sampling report (*Annex 3*) should be completed in a minimum of four copies; one copy should accompany each laboratory sample, and the last copy should be retained by the inspector.

Appendix A of the *Manual on the development and use of FAO and WHO specifications for pesticides (10)* gives detailed instructions on the sampling procedure for technical-grade active ingredients, liquid formulations and solid formulations. These instructions are summarized below.

Sampling of packages in small volumes

For liquid products packed in containers of ≤ 1 l 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 1 l, enough packages should be taken to make up a minimum of 1 l (e.g. if each package contains only 100 ml, each of the three samples should comprise 10 x 100-ml packages).

Similarly, for solid products packed in containers of ≤ 2 kg, three whole packages should be taken randomly from the same batch. If the content of each package is less than 1 kg, enough packages should be taken to make up a minimum of 1 kg (e.g. if each package contains only 200 g, each of the three samples should comprise 5 x 200-g packages).

Sampling of bulk quantities

For packages larger than stated above (1 l 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. The samples must be thoroughly mixed before three subsamples are taken. The subsamples (1 l of liquids and 1 kg of solids) should preferably be stored in glass containers with Teflon or polyethylene-lined caps that can be tightly closed.

Sampling LNs and other products

For LNs, three entire nets in their packages should be taken randomly from the same batch. The sampling procedure for mosquito coils, vaporizing mats, liquid vaporizers and aerosol dispensers is described in the specification guidelines for pesticides formulated as devices in the *Manual on the development and use of FAO and WHO specifications for pesticides (10)*.

The amount taken for each subsample may be increased, depending on the tests required in the specification. *Table 3* gives the minimum quantity of laboratory sample required to perform all physical and chemical tests specified in the WHO specifications for tests on fresh samples and after accelerated storage (excluding the quantities needed for the supplier and the procurement entity).

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

In general, each batch should be tested for compliance with the specification. The number of batches and the number of samples per batch to be tested depend on the degree of confidence required by the buyer or the procurement entity regarding compliance with the specification and the quality of the product. For liquid formulations, a minimum of one sample from each batch should be tested. If the size of the batch exceeds 10 000 l, at least one sample should be tested for each 10 000 l. For solid formulations, a minimum of one sample from each batch should be tested. If the size of the batch exceeds 5000 kg, at least one sample should be tested for each 5000 kg. For LNs, the number, frequency and distribution of nets within and between batches and consignments to be tested for compliance with the specification must be decided by the buyer or the procurement entity, according to the required balance between cost and risk (21). A method for determining sampling frequency on the basis of probability is given in *Annex 4*. Sampling of LNs can also be based on the sampling procedures for 'inspection by attributes' of the standards of the ISO 2859 series (22).

TABLE 3. Minimum quantities of laboratory samples required to perform all physical and chemical tests in the WHO specifications

Formulation	Fresh	Fresh and accelerated storage
Solid formulations for direct use		
Dustable powders	0.3 kg	0.5 kg
Granules	1.5 kg	2.5 kg
Solid formulations for dispersion		
Wettable powders	0.3 kg	0.6 kg
Water-dispersible granules	0.8 kg	1.3 kg
Simple solutions		
Ultra-low-volume liquids	0.7 l	1 l
Solutions for dispersion		
Emulsifiable concentrates	0.6 l	1 l
Emulsions		
Emulsions, oil in water	1.5 l	2 l
Suspensions		
Aqueous suspension concentrates	2 l	3 l
Capsule suspensions	3 l	4 l
Pesticides formulated or prepared as devices		
Long-lasting insecticidal nets or netting	One entire net	One entire net

Immediately after a sample is collected, it should be identified in the inspector's handwriting with a unique reference number, the date and his or her initials. It should then be officially sealed and recorded. The sampling report (*Annex 3*) and the chain-of-custody record (*Annex 5*) should be completed and signed by the party from whom the samples are taken as well as by the inspector who received them. The first subsample should be given to the party from whom the sample was taken to allow him or her to send it to a laboratory for analysis if he or she doubts the outcome of the test. The inspector should then send the second subsample within a week to the designated laboratory for analysis with the form requesting an analysis (*Annex 6*). The analyst should also be asked to sign the chain-of-custody record. The analyst should be given a deadline to complete the analysis, usually within 4 weeks for tests on fresh samples or within 6 weeks for tests including accelerated storage. This timeframe can be longer for testing that includes longer accelerated storage (e.g. 8 weeks at 40 °C). The third subsample should be kept by the procurement entity for use as a back-up in case a dispute arises about the results of the analysis of the first two subsamples.

9.2.3 Delivery and shipment of samples

Great care must be taken to avoid spillage, leakage or deterioration of samples during packaging and transport. Pesticide samples that are packed improperly and broken during transport can endanger the health of both transport handlers and laboratory staff.

Examples of procedure that could be adopted when packing and shipping pesticide samples are:

- Place each sealed sample container, clearly marked with a number that corresponds to that on the accompanying sampling report, in a plastic bag and seal with tape.
- Line a robust container of about 4-l capacity (e.g. a plastic or metal tin with a securely fitting lid) with a suitably large plastic bag.
- Half-fill the plastic-lined container with absorbent material to immobilize the sample bottles and to absorb any leakage from broken bottles.

- Place the sampling reports in a separate plastic bag, seal it and place it in the container. Fill the remainder of the container with absorbent material.
- Close the container and seal its lid. Securely attach labels showing:
 - the name and address of the shipper;
 - the address of the testing laboratory and the name of the contact unit or person;
 - the appropriate hazard classification of the pesticide (United Nations number, class or division, packing group, packing instruction, as appropriate); and
 - arrow(s) indicating the 'up' position of the samples.

The samples must be accompanied by a 'material safety data sheet', when available, a document for declaring dangerous goods and a non-commercial proforma invoice for customs clearance, as appropriate.

Offering and transporting dangerous goods can expose the shipper, carrier, general public and environment to the risks inherent to these materials. When pesticide samples are transported, the regulations of the International Civil Aviation Organization and the International Maritime Organization and the International Regulations concerning the Carriage of Dangerous Goods by Rail or the International Air Transport Association must be applied (23). These regulations state mandatory procedures for moving these materials. Packaging and shipping dangerous goods correctly in accordance with the applicable regulations can eliminate risks for incurring liabilities.

9.3 Independent quality control and reporting

The samples taken at preshipment or on arrival should be analysed by an independent certified or accredited laboratory to check compliance of the product with the WHO or any other relevant specification.

9.3.1 Performing quality control

A contract should be established between the laboratory and the party requesting the analysis. This contract should specify all the relevant information for quality control.

Typical content of a contract for analysis

- the contract or study number;
- the contract or study title;
- information on samples to be analysed (e.g. number of samples, trade name, declared active ingredient content, batch number);
- the experimental protocol (reference to the WHO specification or other relevant specification and list of tests to be performed);
- the analytical methods to be used (as specified in the WHO specifications, e.g. CIPAC methods; and where required clear indication of tests to be performed according to ISO 17025 or good laboratory practices requirements.
- detailed information on the sponsor and study monitor;
- detailed information on the responsible analyst or laboratory manager;
- the proposed test completion date;
- a clause of confidentiality and any particular information;
- the cost of the testing; and
- a clause for archiving raw data and samples after analysis.

Collaborative International Pesticides Analytical Council (CIPAC)

CIPAC is an international, non-profit, nongovernmental organization to promote:

- international agreement on methods for the analysis of pesticides and physicochemical test methods for formulations and
- inter-laboratory programmes for evaluation of test methods.

The methods are proposed by companies and are tested by laboratories all over the world. After evaluation of the results and adoption, the methods are published in CIPAC handbooks.

CIPAC provides most well-known methods for testing the compliance of physical and chemical properties of pesticide products. WHO specifications recommend use of CIPAC methods for quality control of pesticides. <http://www.cipac.org/index.htm>

The contract must be signed by the responsible analyst or laboratory manager and agreed by the party requesting the analysis.

The pesticide samples should be analysed according to the terms of the contract. The analysis should not be limited to the active ingredient content but include all the physical and chemical properties specified in the WHO specifications or other relevant specifications.

The time to complete the analysis is usually 4 weeks after receipt of samples for tests on fresh samples or 6 weeks after receipt of samples for tests including the classical accelerated storage for 2 weeks at 54 °C. The time can be longer for simultaneous testing of a large number of samples or for testing including longer accelerated storage periods (e.g. 8 weeks at 40 °C).

WHO specifications define the minimum acceptable criteria for good-quality products, and samples should be tested for compliance with all the specified clauses and limits. Omission of more expensive or time-consuming tests from quality control might seem financially attractive but increases the risk for accepting poor-quality products and is therefore not recommended. In exceptional situations, some tests can be omitted, but this must be agreed between the laboratory and the party requesting the analysis. For example, in emergency situations in which the pesticide products are required for use immediately after delivery, the test for accelerated storage stability can be omitted.

9.3.2 Reporting results of analysis

The laboratory should give the party requesting the analysis a complete, clear, comprehensive report of the analysis. The report should include as a minimum:

- the contract or study number;
- the contract or study title;
- detailed information on the party requesting the analysis;
- detailed information on the responsible analyst or laboratory manager;
- a confidentiality clause;
- a clause for archiving raw data and samples after analysis;
- information on the pesticide samples analysed (e.g. number of samples, trade name, declared active ingredient content, supplier, manufacturer, batch number, receipt date and storage conditions at the test facility);

- the experimental protocol (reference to the WHO specification or other relevant specification and list of tests performed, with number of replicates per test);
- the analytical and test methods used and the conditions of application (e.g. concentration rates, temperature, as appropriate) and tests performed according to ISO 17025 accreditation or good laboratory practice standards;
- the detailed results of the analysis;
- a summary of results and conclusions on compliance with the WHO or any other relevant specification; and
- any information that would facilitate interpretation of the results.

The report of the analysis should be signed by the responsible analyst or laboratory manager and sent to the party requesting the analysis.



10. PENALTY FOR NONCOMPLIANCE WITH TENDER CONDITIONS

National regulations for the procurement of goods and services usually include provisions for imposing appropriate measures for submission of noncompliant offers as well as supply of noncompliant products. Bidders submitting offers containing incomplete, false or misleading information should be disqualified. Further legal action might be taken, depending on the gravity of the offence, possibly leading to a fine or incarceration, in accordance with the stipulations of the applicable national law. The bidder might further be debarred and excluded from participation in future calls for tender for a given time.



11. CUSTOMS CLEARANCE

Before awarding a contract, international procurement entities should be thoroughly familiar with the local customs procedures and requirements for importation of pesticides. In countries with operational pesticide registration systems, customs clearance of registered pesticides usually requires close collaboration between the pesticides regulatory authority and customs. Customs offices often have information on the products that are registered and should be given advance notice of the impending arrival of a shipment of the pesticide products. If this kind of coordination is weak or if the pesticide is not yet registered in the country, customs clearance may require importation to be authorized by another competent authority. In either case, it is useful to specify in the purchase contract the list of documents that must be provided by the supplier in order for the shipment to clear customs.

12. EMERGENCY PROCUREMENT

In an outbreak of vector-borne disease, pesticides are often required for control of the vector. When there are insufficient stocks of the required pesticide, legal and administrative provisions should be in place for its procurement on short notice. The pesticide legislation of the country should have provisions for unregistered public health pesticides (subject to any specified conditions and procedure) to be imported for emergency use, with the permission of the competent authority.

Triangular arrangements (see definition) for emergency supply of pesticides from one country to another have been successfully used for the control of locusts in some African countries (24). Such arrangements provide another option by which countries facing outbreaks of vector-borne diseases can rapidly procure the necessary pesticides for emergency use. This is particularly effective when there is a severe shortage of the pesticide on the market. In addition, it can help prevent the accumulation of obsolete pesticides. Steps should be taken, however, to prevent abuse of the arrangement (such as disposal of obsolete stocks). These could include:

- repacking into new containers with labels specified by the recipient country;
- a certificate of analysis by an independent laboratory to be submitted to the recipient country before shipment of the stock; and
- provision of samples to the recipient country for quality checking, before shipment of the stock.

When relevant, the provisions of the Basel and Rotterdam Conventions must be observed.



13. TRACEABILITY

A system must be in place to record the main steps in distribution of the procured pesticides, so that they can be traced to local warehouses after they have been distributed. This system should allow recording of information on the products received, distributed and used. This is critical in the event that products are found to be noncompliant after they have been delivered and distributed and must therefore be recalled while they are still in stock in local storage centres. It is also a useful means of preventing diversion of pesticides for unauthorized use and for good management.

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ANNEXES

Annex 1. Documentation for inviting tenders for the supply of pesticides

Subject: Supply of pesticide(s) [brief description of product(s)] to [name and address of organization]

Reference no. of tender:

Documentation reference:

Name and address of organization inviting tenders for supply of pesticides

Date of supply: commencing [date] until [date]

Closing date of tender [local time on date]

Tenders are hereby solicited for the supply of pesticides, in accordance with the specifications and conditions listed, during the period from [date] to [date] to [organization] in [name of country].

Interested eligible tenderers may obtain further information from [name of procurement entity] at [address] from [office hours]. The fee (non-refundable) for each set of documents is [amount].

Tenders submitted, with supporting documentation and undertakings, must be in a sealed envelope with the reference number of the tender clearly marked on the envelope. Tenders must be delivered to the [location and address of office] at or before [time], local time, on [date] and be placed in the box reserved for that purpose. Tenders received later than the specified time will not be accepted and will be returned unopened to the tenderer.

General conditions:

1. The tenderer shall complete the tender documents and the appropriate price schedule, which are obtainable from the procurement entity [name and address of office].
2. The [procurement entity] shall not be responsible for any loss arising as a result of any tender document being delayed or lost in the post.
3. Tenders for each product to be purchased will be evaluated separately.
4. Tenders submitted must be supported by sufficient data, documentation, evidence, information, statements and undertakings to demonstrate compliance with the required specifications and conditions.

5. Prices quoted must be for a product of the quality specified and include the cost of packaging and labelling in accordance with the requirements specified, as well as the cost of insurance, transport and delivery to the specified store(s) according to the attached schedule.
6. In view of the requirements for the pesticides relating to quality, effectiveness, price, registration status in the country, manner and ease of use, storage life, safety to humans and the environment, packaging, labelling, delivery constraints, technical support and after-sales service offered, and other condition(s) mentioned in the tender, contracts may not be awarded to the bidders providing the lowest quotations.
7. Tenders shall remain valid for the period specified after the date of tender opening prescribed by the procurement entity. A tender valid for a shorter period shall be rejected.
8. The tenderer shall bear all costs associated with the preparation and submission of its tender, regardless of the outcome of the tendering process.
9. Representatives of tenderers will be invited to witness the opening of tenders. The tenderers' representatives who are present shall sign a register to record their attendance.
10. The tenderer's name, tender prices and other details such as the presence or absence of the requisite tender security will be announced by the procurement entity at the tender opening session.
11. No tenderer shall contact the procurement entity on any matter relating to its tender, from the time of the tender opening to the time the contract is awarded. The tenderer may if it wishes submit additional information in writing to the procurement entity.
12. Any attempt by a tenderer to influence the procurement entity in evaluating and awarding the tender may result in rejection of the tenderer's tender.
12. The procurement entity reserves the right to accept or reject any tender, to annul the tender process and to reject all tenders at any time before awarding the contract.
13. The procurement entity will reject a proposal for award if it determines that the tenderer recommended for the award has engaged in corrupt or fraudulent practices in competing for the contract in question.
14. Contracts may be awarded for certain items for which tenders were invited or for all such items and, in the case of individual items, for all or part of the quantity concerned.
15. The procurement entity reserves the right to place a contract for supply of the full amount for which a quotation is offered or, when the supplier can deliver it, for more than that quantity.
16. As soon as a contract is offered to a supplier, it will be required to submit a bond guaranteeing satisfactory completion of the contract. The bond must be in the form of a bank guarantee and shall be returned within a specified time after the contract obligations have been satisfactorily discharged.
17. A tenderer that fails to sign a contract after one has been offered or that withdraws a tender any time after it has submitted it will not be allowed to submit any tender to the procurement entity for a period of 2 years from the date of withdrawal or refusal.
18. Successful tenderers shall not use the award of tender for purposes of advertising their products.
19. Disputes arising from the tendering procedures, awarding of contracts and discharge of contractual obligations shall be heard only in the [name of court].
20. The procurement entity reserves the right to examine, take samples from and analyse products being procured. Successful tenderers shall facilitate such examination and sampling.
21. Should any inspected or tested products fail to conform to the required specifications, the supplier shall remove any unacceptable product from the premises and replace it with products that meet the agreed specifications. The supplier should dispose of the substandard product in an environmentally acceptable manner if it is unable to reformulate the product to meet the required specifications. The

supplier shall bear all expenses incurred in such removal or disposal. If the supplier is unable to supply a product of the agreed specification, it shall be required to refund to the procurement entity all expenses incurred in procurement of the product. The procurement entity may also require the tenderer to replace, within a specified period, the rejected product with a product of acceptable quality, suitably packaged and labelled. In all such cases, the bond provided as a guarantee of satisfactory completion of the contract for the product concerned shall be forfeited.

22. The tenderer warrants that use of the goods offered or supplied against a contract does not infringe any patent, design, trade name or trade mark. In addition, the supplier shall, pursuant to this warranty, indemnify, defend and hold the procurement entity harmless from any actions or claims brought against the procurement entity pertaining to the alleged infringement of a patent, design, trade name or trade mark arising in connection with the goods sold under this tender or contract.

23. The tenderer or supplier shall not, except after obtaining the written consent of the procurement entity, assign, transfer, pledge or make other disposition of the contract, or any part thereof, or any of the tenderer or supplier's rights or obligations under this contract.

24. Should the tendered or supplier become insolvent or should control of the tenderer or supplier change by virtue of insolvency, the procurement entity may, without prejudice to any other rights or remedies, immediately terminate the contract by giving the supplier notice of termination.

Annex 2. Examples of price and delivery schedules

Pesticides

Tender reference number: _____				
Product description				
Active ingredient	Identity			
	Concentration (g/kg or g/l)			
Formulation				
Packing size				
Quantity ^a				
Unit of measurement				
Unit price				
Incoterm 2010 ^b				
Other charges (specify)				
Total price				
Lead time				

Long-lasting insecticidal nets

Tender reference number: _____				
Product description				
Size (W x L x H)				
Deniers				
Colour				
Active ingredient	Identity			
	Concentration (g/kg or g/l)			
Unit of measurement				
Quantity ^a				
Unit price				
Incoterm 2010 ^b				
Other charges (specify)				
Total price				
Lead time				

^a Price is understood to be valid for the quantity requested $\pm$ 20%.

^b E.g. EXW, Stockholm, Sweden; FOB, Le Havre, France; DA,P Ouagadougou, Burkina Faso <http://www.iccwbo.org/Incoterms/index.html?id=40772>

Annex 3. Typical sampling report

(To be completed in four copies: one copy to accompany each set of subsample(s) and a fourth to be retained on file.)

Name and address of retailer, wholesaler or manufacturer:	
	Name of owner of premises or staff present when samples were taken:
	Date (dd/mm/yy) and time of inspection, sampling or seizure:
Names of inspectors or officers who were present during inspection and taking of samples:	

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

Confirmation by retailer, wholesaler or manufacturer:

I confirm that I have received one (1) copy of the list of pesticides taken for analysis as well as a subsample of 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. Sampling of long-lasting insecticidal nets

TABLE A4.1. Sampling rate based on probability of detection and frequency of noncompliance

Actual frequency of noncompliant nets in the batch (%)	Minimum number of samples per batch required to detect a noncompliant net with a probability of:		
	90%	95%	99%
20	11	14	21
15	15	19	29
10	22	29	44
5	45	59	90
1	231	299	459

Example: A buyer who requires 90% confidence for detecting noncompliance occurring at 10% frequency would have to collect and test 22 nets per batch.

TABLE A4.2. Probability of detecting a noncompliant net by testing eight nets per batch

Actual frequency of noncompliant nets in batch (%)	Probability of detecting a noncompliant net by testing eight nets (%)
44	99
31	95
25	90
10	57
5	34
1	8

The probability values given in *Tables A4.1* and *A4.2* are based on the assumption of either random sampling, random distribution of noncompliant nets or both. The values are calculated from:

$$1-p = (1-i)^n$$

where p is the probability of detecting a noncompliant net (expressed as a fraction, not %); i is the incidence of noncompliant nets in the batch (expressed as a fraction, not %) and n is the number of nets in the batch tested.

Annex 5. Typical chain-of-custody record

Name and address of source of sample:		
Description of sample (including 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

Annex 6. Typical format for requesting analysis of pesticide samples

(To be completed in duplicate.)

No.	Description of pesticide (including reference number)	Quantity	Types of analysis required
1			
2			
3			
4			

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

Sample(s) submitted by inspector: Signature: Name: Date (dd/mm/yy): Time:	Samples(s) received by official analyst: Signature: Name: Date (dd/mm/yy): Time:
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World Health Organization
Department of Control of Neglected Tropical Diseases
WHO Pesticide Evaluation Scheme
&
Global Malaria Programme
Vector Control Unit

