



Briefing Note

Pre-Shipment Sampling, Testing and Reporting Results for Insecticide-treated Nets (ITNs)

Allocation Period 2023-2025

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Note: Any comments, proposed changes or amendments to this Briefing Note should be directed to the Quality Assurance team at HealthProductQualityAssurance@theglobalfund.org

1. Overview

Background

As per the [Guide to Global Fund Policies on Procurement and Supply Management of Health Products](#) (the “PSM Guide” published in June 2021), Principal Recipients (PRs) of Global Fund grants are authorized to procure vector control products including Insecticide Treated Nets (ITNs) only when those products are:

Pre-qualified under the WHO Prequalification Programme.

Recommended for use by the World Health Organization Pesticide Evaluation Scheme (WHOPES); and are compliant with specifications indicated in WHOPES.

Acceptable for procurement using grant funds, as determined by the Global Fund based on the advice of the Expert Review Panel (ERP).

Within the WHOPES, quality control was considered essential to ensure that products meet specifications and provide the best efficacy. Review functions for these products, previously carried out by the WHOPES within WHO’s Control of Neglected Tropical Diseases department, have been transferred to the WHO Prequalification team (PQ) to ensure that the approach to evaluation of these products is aligned with other health products and follows a product lifecycle approach. WHO is evolving its approach to supporting the development, evaluation and adoption of new vector control products and tools.

While maintaining quality control is important, implementing this upstream quality assurance in design and manufacturing is equally critical. WHO product specifications for pesticides continue to provide an international point of reference against which products can be judged and thus prevent the procurement of poor-quality product under the grants.

In addition to quality control activities performed at pre-shipment stage, testing products upon arrival of the goods in country (i.e., post-shipment sampling and testing) may be required in specific circumstances, in particular when the products are suspected to have been exposed to unacceptable shipping and/or storage conditions. To avoid such cases, products should be transported and stored as per the manufacturers or suppliers’ specifications and the conditions documented. In circumstances where PRs are made aware of any incident, they should liaise with the Global Fund Quality Assurance (QA) team as soon as practicable to discuss additional risk mitigations activities such as pro-actively dedicated monitoring activities.

This Briefing Note outlines a risk-based approach to pre-shipment testing.

Purpose

This Briefing Note supports the implementation of the Global Fund quality assurance requirements. It contains guidance for performing pre-shipment sampling, physical and chemical testing and release of ITNs procured with Global Fund grant funds in order to ensure a consistent approach to Quality Control (QC) testing, as required by the PSM Guide.

As per Section 6.4 of the [PSM Guide](#), to ensure that vector control products procured with Global Fund funding comply with Global Fund quality assurance requirements, PRs or the procurement services agent (PSA) acting on their behalf shall perform randomized pre-shipment sampling and testing. The following principles must be implemented:

- Sampling and randomization performed according to WHO Guidelines for procuring public health pesticides¹.
- Sampling conducted by an independent sampling agent.
- Testing conducted by an independent ISO 17025-accredited or Good Laboratory Practices (GLP) certified laboratory with the specific testing methods within its scope of accreditation.
- Testing conducted according to WHO approved product specifications.
- Testing methods based on the Collaborative International Pesticides Analytical Council (CIPAC, if adopted as final by the council) unless the specification identifies a different method.

This Briefing Note also provides additional information on the reporting requirements, as stated in the PSM Guide Section 6.10.

The PSM Guide requests PRs to perform sampling and testing at the pre-shipment stage. Some PRs may opt for parallel shipment to quality control testing, leading greater risk to manufacturer and the PR in case the product doesn't comply to specifications, requiring the manufacturer to carry out reverse logistics and PR having to procure another product. The Global Fund QA team does not recommend parallel shipment except in exceptional circumstances where the program is likely to be heavily impacted if the products do not arrive on time. In this case, the PR or the PSA is required to engage the Global Fund QA team for approval.

Scope

This Briefing Note is applicable to all brands of ITNs currently recommended by WHOPES, WHO Prequalification or ERP products and procured with Global Fund grant funds.

Requirements for sampling for pre-shipment visual inspection for labelling, measurements, quantity and workmanship and appearance are detailed in a separate [Briefing Note for visual inspection](#).

¹ <https://www.who.int/publications/i/item/9789241503426>

Durability monitoring of approved products/suppliers is also not part of this Briefing Note. This is covered under the WHO Guidelines for monitoring the durability of long-lasting insecticidal mosquito nets under operational conditions².

Responsibilities

For ITNs procured through PPM, the PSAs oversee the implementation of the procedures outlined in this Briefing Note.

For ITNs procured with Global Fund grant funds but not through the PPM, PRs are responsible for implementing the procedures outlined in this Briefing Note or are requested to instruct their PSA (if applicable) to implement similar procedures providing the same level of assurance.

This Briefing Note should be sent to all inspection agents performing services for PSAs. It is to be used by the inspection agency representative as supporting information and guidance for any inspection and sampling of ITNs.

2. Description of Activities / Procedure

2.1 Testing strategy depending on the regulatory pathway

Sampling and testing can take some time. The PR or the PSA are advised to factor in sampling and testing timelines in their procurement. Quality control testing can take up to one month or more, depending on the lab and testing being undertaken.

a) Basic principles

ITNs procured with Global Fund grant funds can be classified in two categories based on the different regulatory pathways:

Prequalified ITNs: Products which have been prequalified by the WHO Prequalification Program having satisfactorily completed the whole spectrum of assessment and review planned for WHO prequalification.

ITNs acceptable for procurement using grant funds, as determined by the Global Fund based on the advice of the Expert Review Panel (ERP).

The list of prequalified ITNs can be found in the WHO Prequalification Program websites for vector control products³.

² <https://apps.who.int/iris/handle/10665/44610>

³ <https://extranet.who.int/pqweb/vector-control-products/prequalified-product-list>

Depending on the regulatory pathway of a product in question, different sampling and testing procedures should be applied.

- **For newly prequalified ITNs or newly relisted prequalified ITNs**

The testing strategy consists of testing as per the full approved specifications⁴ of the first five batches procured by the PR or PSA.

In case of non-compliance or out-of-specification (OOS) in these first five batches, the procurement will be initially halted pending the outcome of the investigations performed by the supplier, as agreed with Global Fund QA team. Resuming of the procurement will depend on the satisfactory implementation by the supplier of a plan of corrective and preventive actions (CAPA).

If no OOS is identified, one out of ten batches (1:10) procured will be tested but no less than one batch per consignment, as per a subset of the approved specifications.

In case an OOS is raised in relation to one batch, the randomization process should be stopped. Because all product non-compliance should be notified to the Global Fund QA team as per Section 6.10 of the PSM Guide, further advice can be provided by the Global Fund QA team during the investigations.

In the absence of any procurement by the PR or PSA from the supplier for any ITNs for more than one year, the randomization process should be stopped and the testing strategy for newly prequalified or newly relisted prequalified ITNs should apply.

- **For existing prequalified ITNs**

The testing strategy considers the historical results obtained in the previous testing practices.

The PR or the PSA acting on its behalf is advised to perform a reconciliation of the historical results. If analysis show no non-compliance/OOS results for the last five batches procured, the randomization scheme should then be applied.

For this reconciliation, the PR or the PSA can rely on historical results made available to the public or ask the Global Fund QA team for advice – see also section on consolidation of testing results.

In this case, the randomization is performed to test one out of ten batches procured, but no less than one batch per consignment, as per a subset of the approved specifications.

In case an OOS is raised in relation to one batch, the randomization should be stopped. Because all product non-compliance should be notified to the Global Fund QA team, further advice will be provided by the Global Fund QA team during the investigations.

In the absence of any procurement for more than one year by the PR or PSA, the randomization process should be stopped and the testing strategy for newly prequalified or newly relisted prequalified ITNs applies.

⁴ Approved specifications refer to the WHO specifications as published and updated from time to time OR the suppliers' specifications approved by the WHO prequalification team.

- **For a new manufacturing site of existing ITNs**

The testing strategy consists of testing as per the subset of approved specifications⁵ the first five batches procured by the PR or PSA. After satisfactory completion of testing for the first five batches, the randomization process of the applicable category should be implemented.

- **ITNs acceptable for procurement using grant funds, as determined by the Global Fund based on the advice of the Expert Review Panel (ERP)**

For ERP products, the pre-shipment inspection and testing specific activities should be implemented as per the risk mitigations activities recommended by the ERP, if deemed appropriate.

b) Exceptional circumstances

In exceptional situations, some tests can be omitted subject to prior agreement between the laboratory and the party requesting the analysis. In such cases, the Global Fund QA team must approve the change before implementation.

In emergency situations, quarantine shipment can be organized in parallel to the testing activities to take advantage of time during transportation and the on-going analysis. In such cases, a specific contractual agreement should be established between the supplier, PSA and PRs. Please refer to the Global Fund Operational Policy Note⁶ available within QA team for further advice.

For WHO-declared pandemic situations, the Global Fund has set up a mechanism to deviate temporarily from certain specific Quality Assurance requirements; please refer to the Global Fund QA team for further advice on this matter.

c) Publication of QA Information Notice

The Global Fund QA team from time to time publishes Quality Information Notices which provide information on specific corrective/preventive actions for which quality control testing activities can be recommended. It is the responsibility of PRs to consider such notices and the extent to which they will impact their procured products.

2.2 Sampling for testing purposes

a) Sampling by an independent sampling agent

Before sampling, the PR or PSA should select an independent sampling agent and establish a written contract. The sampling agent is responsible for the operational and logistics arrangements for sampling – see detailed guidance in WHO Guidelines for procuring public health pesticides.

⁵ Approved specifications refer to the WHO specifications as published and updated from time to time or the suppliers' specifications approved by the WHO prequalification team.

⁶ OPN on Specific requirements for allowing parallel shipment to quality control testing organized by Quality Assurance team.

b) Request for sampling and testing

The request for sampling and/or testing is to be issued by the PR or the PSA acting on behalf of the PR to a sampling agent. The instructions and documentation should include:

- Request to withdraw a specific number of samples per batch;
- Methods and tools for sampling;
- Methods for expedition to dispatch to a nominated testing laboratory;
- Compliance with importation requirements for samples into the country where the testing laboratory is located;
- Certificate of analysis (CoA);
- Purchase Order (PO);
- Packing list.

c) Sampling method

The samples are to be drawn and handled as indicated in the WHO Guidelines on procurement for public pesticides. Samples should not be taken from products previously opened for inspections. Only products in original packaging should be sampled either as a single packaged net or nets packaged in a bale.

The packaging integrity of the bales and of the nets should be verified and recorded by the inspectors during pre-delivery inspection (PDI) using the requested template – see [Briefing Note on pre-shipment visual inspection](#).

d) Sampling procedure

The sampling agent should have a specific procedure for sampling, visual inspection and documenting inspection conclusions. For information on sampling, refer to the WHO Guidelines for procuring public health pesticides.

The sampling should consider separately each manufacturing batch identified within a consignment. In the case of continuous manufacturing (e.g., production of a large scale or several lots which make a batch and/or per order placement), the sampling agent should select samples taken for different bales distributed equally within the same batch on as many bales as possible.

e) Sample size

The sample size for testing purposes is defined based on the scope of testing performed and the need for keeping two other set of samples for further investigations until expiry date.

The WHO Guidelines for procuring public health pesticides under sampling (Section 9) advises to sample three entire nets in their package which should be taken randomly from the same batch.

However, based on experience and the need to keep some samples in case of further investigations, the sampling size recommended should be based as per the laboratory requirement to ensure enough quantity to carry out two more analyses if needed.

f) Sampling strategy

The same batches from the same manufacturer should not be sampled several times if procured by the same PR or PSA acting on its behalf.

For batch sizes greater than 500,000, one set of sample needs to be taken for each increment of 500,000 nets. For example:

- One set of samples for batches from 1 to 500,000.
- Two sets of samples for batches from 500,000 to 1,000,000.

g) Sampling record

The information to be collected at each sampling step is recorded in a sampling report, which can be combined with the pre-shipment inspection report. The bale number for each sample taken should be recorded, if available.

In case an individual identification number is attached to each individual ITN, this number should be recorded.

The environmental storage conditions under which ITNs are kept for storage at the time of sampling should be described in the reports for each location.

A typical sampling report is provided in the Annex 4 of the WHO Guidelines for procurement of public health pesticides.

h) Sample transportation and delivery

Appropriate logistics arrangements should be available prior to the sampling. More guidance is provided in the WHO Guidelines for procuring public health pesticides under Section 9.

The logistics arrangements should be organized as per the manufacturer's requirements mentioned on labelling and packaging requirements for the nets to avoid deteriorations. More advice is provided in WHO Guidelines for procuring public health pesticides.

2.3 Quality control testing

a) Selection of quality control laboratory

Testing should be performed by a laboratory that is independent of the manufacturer or supplier. The laboratory should have a quality assurance system in place according to ISO 17025⁷ accreditation standard or the Organization for Economic Co-operation and Development (OECD) principles of Good Laboratory Practices (GLP).

Ideally, all methods requested for testing the specifications should be within the scope of accreditation of the laboratory. If this is not possible, the COA should clearly state which tests were performed out of the scope of accreditation/certification.

⁷ <https://www.iso.org/ISO-IEC-17025-testing-and-calibration-laboratories.html>

The list of laboratories historically identified by the Global Fund QA team as acceptable for quality control testing of vector control products is available under the Quality Assurance [webpage](#)⁸.

b) Contractual agreement

A contract should be established between the accredited laboratory and the party requesting the testing (e.g., PR, PSA), signed by the responsible analyst or laboratory manager and agreed by the party requesting the analysis. The contract should consider/refer to the current standard operating procedures (SOPs) established by both parties.

The typical contents of the contract for analysis are provided in the WHO Guidelines for procuring public health pesticides under Section 9. To maintain confidentiality and independence, the independent sampling agent should not disclose the lab(s) where samples are sent for analysis.

c) Testing specifications

Under current practices, the sample analysis should not be limited to the active ingredient content. It should also include all the physical and chemical specifications such as:

- Per the WHO specifications and evaluations for public health pesticides published by the WHO Prequalification Program for Vector Control, from time to time in their report⁹.
- Supplier's specifications, as reviewed and agreed between the Global Fund QA team and suppliers.

As per the "Testing strategy" section, two sets of specifications can be implemented:

- Full set of specifications.
- Subset of approved specifications which does not involve storage stability testing.

A list of eligible ITNs and their applicable specifications is published and updated from time to time by the Global Fund Quality Assurance team. The PR or the PSA acting on its behalf can refer to its last version which is made available on the Global Fund's website.¹⁰

In case of a change in the specifications of prequalified ITNs or new prequalified ITNs for which specifications are not yet published, please liaise with the Global Fund QA team to validate the specifications which must be implemented.

d) Testing method

Except if a specific directive is given to the testing laboratory by the PR or PSA acting on its behalf, the testing method should be performed according to the methods of CIPAC¹¹.

⁸ <https://www.theglobalfund.org/en/sourcing-management/quality-assurance/other-products/>

⁹ <https://extranet.who.int/pgweb/vector-control-products>

¹⁰ <https://www.theglobalfund.org/en/sourcing-management/quality-assurance/other-products/>

¹¹ <https://www.cipac.org/index.php/guidelines>

Testing method verification and/or validation should be performed as per quality control laboratory's internal procedure. Before performing any testing method, the laboratory should consider the labelling and packaging requirements and envisage to what extent this can affect the results of the testing activities.

e) Testing report

The laboratory should provide for analysis a complete and comprehensive report of the results in the form of a COA, which must be signed by the responsible person. The content of a COA is provided in the WHO guidelines for procurement of public health pesticides under Section 9¹².

3. Review of Manufacturer Certificate of Analysis

Aside from the testing activities, the PR or the PSA acting on its behalf is requested to routinely review the correctness of the COA provided by the supplier, even if no quality control testing is undertaken such as verification of suppliers' name, reference to approved product specifications or results in line with approved specifications.

The physical and chemical testing reports should be crosschecked with the COA provided by the manufacturer to ensure compliance with the WHO approved product specifications available in the WHO Prequalification website¹³.

4. Decision for Release

The decision to release the products rests with the PR. However, delegation can be organized under specific contractual arrangements with the respective PSA.

The final decision to release should be made by an authorized person, preferably the Head of Quality Assurance for the PR or PSA or a person under their direct supervision.

The reports for both visual inspection and physical and chemical testing should comply with the approved specifications to allow for the final release. In some circumstances, products which do not comply with product specifications can be released using risk-based approaches. An example is use of Health Product Risk Committee (HPRC) within Global Fund which can release non-compliant products upon request by the PR.

In case of full compliance, the authorized person records the decision and may allow the release of the batches as per the planned arrangements with the PR or PSA.

¹² <https://www.who.int/publications/item/9789241503426>

¹³ <https://extranet.who.int/pgweb/vector-control-products>

5. Management of Non-Conformities and Poor-Quality Control Practices

Any non-conformities highlighted in the testing reports issued by the quality control laboratory should be recorded by the PSA and forwarded within five working days upon receipt of the report, with an appropriate message calling for attention of the PR.

In case of product non-compliance, the PR or the PSA acting on its behalf is required to notify the Global Fund QA team within five working days on receipt of the non-complying testing report using QA team email:

HealthProductQualityAssurance@theglobalfund.org

Investigations must be performed by the supplier in line with the contractual arrangement. Impacted products should be maintained under quarantine conditions by the supplier until the end of the investigations performed by the supplier in collaboration with the PR or PSA, who should provide a regular update to the Global Fund QA team for further guidance or advice.

PRs and PSAs are requested to notify within five working days to the Global Fund QA team any suspicion of poor-quality control practices (in particular related to data integrity/data manipulation from the laboratory) from the date it is brought to their attention.

PR and PSA, in consultation with the Global Fund QA team, will coordinate investigative work with the contracted laboratory and/or at the suppliers until root causes or probable root causes have been established. Further release decisions after investigation closure must be agreed upon with the Global Fund QA team. PR/PSAs will summarize a proposed course of action and provide detailed information at the request of Global Fund QA team.

The Global Fund QA team will assist in timely decision-making on the affected materials and keep trend information on quality control experiences for suppliers/products for QA purposes. Where needed, trend information will be fed back to the WHO-PQ team or ERP, as applicable.

6. Reporting Results

a) Communication of inspection reports and test results

As per Section 6.10 of the PSM Guide, PRs are required to submit inspection reports and test results of all quality control testing of vector control products to the Global Fund QA team by uploading them on the PQR as per the [Quick Guide to the Price and Quality Reporting System \(PQR\)](#).

PRs shall ensure that the necessary arrangements exist between the PSA and the quality control laboratory, so that a documented procedure is in place and implemented to ensure the adequate communication of these results. As per Section

6.10 of the PSM guide, PRs shall ensure that the Global Fund is authorized to use these results.

b) Consolidation of the test results and trend analysis

The Global Fund QA team will create a repository with other product categories, the list of ITNs, corresponding batch numbers and related COAs tested on behalf of the Global Fund.

This repository is considered a reliable source to manage the randomization in case of newly prequalified or relisted ITNs – see above Section 2.1 on Testing strategy.

The Global Fund will perform a trend analysis on the results collected from the various quality control laboratories every year. If a trend exists, such analysis should be communicated to the relevant parties.

7. Record Keeping

All records related to the activities described above should be archived by the PR or the PSA acting on its behalf for at least seven years. Records should be made available to the Global Fund upon request.

8. Cost Related to These Quality Control Activities

As per Section 6.9 of the PSM Guide, the cost of conducting quality control activities of vector control products may be included in the grant budget to be paid with grant funds, as part of the procurement and supply management cost.

9. Acronyms & Abbreviations

CIPAC	Collaborative International Pesticides Analytical Council
COA	Certificate of Analysis
ERP	Expert Review Panel
FAO	Food and Agriculture Organization
GLP	Good Laboratory Practices
ISO	International Organization for Standardization
ITN	Insecticide-treated net
OOS	Out-of-specification
OECD	Organization for Economic Co-operation and Development
PDI	Pre-delivery inspection
PPM	Pooled Procurement Mechanism
PQ	Prequalification
PR	Principal Recipient
PSA	Procurement Service Agent
PSM	Procurement and Supply Management
QA	Quality Assurance
QC	Quality Control
SOP	Standard operating procedure
WHO	World Health Organization
WHOPES	World Health Organization Pesticide Evaluation Scheme

10. Glossary of Terms

Active ingredient

Active ingredient means the part of the product that provides the pesticidal action (WHO/FAO Guidelines Rev3).¹⁴

Authorized person

Dedicated staff from Principal Recipients or delegated staff of the Procurement Service Agent having the formal responsibility to release the batch procured with Global Fund grant funds.

Batch

A defined quantity of material produced in a single series of operations (WHO/FAO Guidelines Rev3). Manufacturers may have different mechanisms to define their own batches.

Consignment

Quantity of one or more products shipped at one time to a destination country. A consignment of pesticides may consist of one or more batches or parts of batches.

Lot

Part or all of a consignment that may comprise part of all of one manufacturing batch (FAO/WHO Manual on Development of Specifications).¹⁵

Non-conformity

Non-fulfilment of a specified requirement as per ISO 2859-1.¹⁶ For the purposes of this Briefing Note, the term “defect” means non-conformity.

Request for inspection / Testing

The specific document issued by each Procurement Service Agent to initiate the inspection or testing process.

Specification

The parameters and criteria defining the physical appearance and physical and chemical properties of technical and formulated pesticides linked with hazard and risk profiles.

Subset specifications

Subset of approved specifications which does not involve storage stability testing.

WHO specifications

Specifications developed by the World Health Organization with the basic objective of promoting, as far as practicable, the manufacture, distribution and use of pesticides that meet basic quality requirements¹⁷.

¹⁴ <https://www.fao.org/3/i5713e/i5713e.pdf>

¹⁵ <https://www.fao.org/3/cb8401en/cb8401en.pdf>

¹⁶ <https://www.iso.org/obp/ui/#iso:std:iso:2859:-1:ed-2:v1:en>

¹⁷ <https://extranet.who.int/pqweb/vector-control-products/who-specifications-pesticides>

11. References

- Guide to Global Fund Policies on Procurement and Supply Management of Health Products-June 2021.¹⁸
- WHO Guidelines for procuring public health pesticides (2012).¹⁹
- Manual on the development and use of FAO and WHO specifications for pesticides (2016).²⁰
- [Briefing Note for sampling for pre-shipment visual inspection](#), measurements, quantity and workmanship and appearance.
- Operational Policy Note on specific requirements for allowing parallel shipment to quality control testing (March 2017).

¹⁸ https://www.theglobalfund.org/media/5873/psm_procurementsupplymanagement_guidelines_en.pdf

¹⁹ <https://www.who.int/publications/i/item/9789241503426>

²⁰ <https://www.fao.org/3/cb8401en/cb8401en.pdf>