

# WHO Guideline for the prequalification assessment of insecticide-treated nets

## Implementation plan

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- The WHO Guideline for prequalification assessment includes requirements for additional studies and more detailed information pertaining to the formulation, manufacturing, and physical chemical characteristics of ITNs.
- Hence, **updated product dossiers are required.**
- It is imperative that the information submitted, including previously submitted/reviewed studies are **relevant to the current manufacturing process and formulation.**

## Implementation plan (2)

- For prequalified products and those products which are under assessment or nearing submission, the following categorization and requirements for submission within the identified timelines applies:
  - **Prequalified products**
    - Not based on a claim of equivalence – Submit **Module 3, 4, 5 requirements** for assessment by **31 December 2024**
    - Based on a claim of equivalence - Submit a **complete product dossier** for assessment by **31 December 2025**
  - Proposed **products currently under assessment or submitted before 30 June 2025** - Applications will be screened based on the previous requirements. However, updated forms/templates should be submitted providing all required information which does not require the generation of data. During the assessment of the application, any data gaps in the dossier which are linked to the new guideline may be required to be filled during the assessment or included as Post-PQ Commitments, depending on the nature of the data gap.
  - Proposed **products submitted after 30 June 2025** - Submitted product dossiers are expected to comply with the new guideline.

# Prequalified products not based on equivalence

Manufacturers of products which fall into this category will be required to submit the following for assessment by **31 December 2024**.

## Module 3

1. Declaration of current formulation and manufacturing process
2. Phys/chem analysis on 5 batches (including additional physical tests)
3. Regeneration Study
4. Wash Resistance Study (using a wash interval based on the regeneration study)
5. Real-time storage stability (Interim results: minimum 6 months)

## Module 4

6. Risk assessment based on current GRAM and/or citation of the available GRAs

# Prequalified products not based on equivalence (2)

## Module 5

1. No explicit requirement for generation of new semi-field studies.
2. Additional semi-field studies may be necessary. For each available semi-field study, the available phys/chem data (available from chemical analyses and/or QC data on production batches) of the test materials should be compared to the updated Module 3 data to justify the inclusion of the semi-field study in the updated submission
3. NOTE: Based on the results of the wash regeneration study, an analysis will be required to understand if semi-field trials are representative or if additional data are needed
4. If community studies have not been submitted, they are required by **31 December 2028**.

# Prequalified products not based on equivalence (3)

## Module 5

### 1. Summary table of information for semi-field studies

1. Study ID
2. Study Title
3. Year
4. Location
5. Batch numbers of ITNs used
6. Wash interval used for sample preparation
7. Mean AI content for each batch (Unwashed)
8. Mean AI content for each batch (20x Washed)
9. AI Retention per wash
10. Justification for inclusion

## Prequalified products based on equivalence

- Manufacturers of products which fall into this category will be required to submit a complete product dossier for assessment by **31 December 2025**.

## Proposed products currently under assessment or submitted before 30 June 2025

- Applications will be screened based on the previous requirements
  - Allows applications to be accepted for assessment despite not necessarily fulfilling all data requirements as presented in the new guideline.
- Manufacturers are expected to rely on the updated forms/templates and provide all required information which does not require the generation of data.
- On a case by case basis, products may be prequalified in advance of receiving additional data and in such situations, the specific requirements would be included as Post-PQ Commitments.
- If a prequalification decision cannot be determined without additional data, a Request for Information (RFI) letter will be issued.



## Proposed products submitted after 30 June 2025

- For proposed ITNs which are submitted after 30 June 2025 - Submitted product dossiers are expected to comply with the new guideline