

WHO Prequalification of Vector Control Products

WHO specification for source material

New applications and extensions

PURPOSE

This document describes the application process for requesting a specification for vector control product (VCP) source material. WHO service codes for this process are PQ400 for a new specification, and PQ401 for extension of an existing specification. The process for these two services is identical, but the data requirements differ. [The Manual on development and use of FAO and WHO specifications for pesticides](#) provides the information on data needed to successfully apply for specification.

SPECIFICATION FOR SOURCE MATERIAL

A specification establishes and communicates specific physical and chemical characteristics of the source ingredients, active and synergists, used in the formulation of end-use products, as well as of the end-use products themselves. WHO specification includes: the physical appearance of the material; its content of active ingredient(s) and any relevant impurities; physical and chemical properties; and stability in storage. The specifications do not include: the chemical characteristics of the formulants, except where they influence the physical characteristics (including pH, acidity and alkalinity) or clauses which define the fundamental properties of the active ingredient.

WHO requires that active ingredient and synergist source materials be assessed and, at minimum, found in compliance with established specifications in order to be acceptable for used in the formulation of prequalified vector control products. In many cases, the source material of active ingredients and synergists included in the formulation of a vector control product is in the technical material (TC) or technical concentrate (TK) form. In certain cases, the production of the vector control product may rely on source ingredients in other forms; in such cases, the intermediate or formulated source material must have been assessed for the purpose of establishing new specifications or confirming compliance with existing specifications.

The PQ400/PQ401 process takes an estimated 12 months from submission of an application. To ensure the most efficient processing of an application, manufacturers are encouraged to inform the WHO Prequalification Unit Vector Control Product Assessment team (PQT/VCP) as early as possible of the target submission date, enabling PQT/VCP to include the projected submission on the workplan for the Joint Meeting on Pesticide Specifications (JMPS).

Additional resources to facilitate the application process include:

- [WHO specifications webpage](#);
- [List of WHO service codes](#);
- [Specifications list – new procedure](#);
- [Specifications list – old procedure](#);
- [Manual on development and use of FAO and WHO specifications for pesticides](#);
- [PQT/VCP website](#).

Manufacturers interested in requesting a WHO specification of vector control product source material, or the extension of an existing WHO specification, are also invited to contact PQT/VCP at pqvectorcontrol@who.int with any questions or for additional information.

DEVELOPMENT OF SPECIFICATIONS

PROCESS

Application submission

The manufacturer is responsible for generating the necessary data and compiling the complete dossier for specification.

The *Manual on development and use of FAO and WHO specifications for pesticides* provides the necessary guidance on dossier development for submission of an application to establish or extend a TC/TK specification for an active ingredient.

Information to include in the submission:

1. [PQ400/401 application form](#);
2. cover letter identifying the requested service code and describing the submission;
3. [proposed specification](#);
4. [proposer data entry form](#) (for TC and TK);
5. supporting physical/chemical study reports;
6. description of manufacturing process.

If an applicant produces the material at multiple sites, then a supporting 5-batch study, conducted in accordance with good laboratory practices (GLP), must be submitted presenting quality and consistency of the production at each site. Additionally, the applicant must identify the primary manufacturing site, from which the 5-batch will serve as the reference profile for the applicant.

The completed dossier must be submitted to PQT/VCP at jmps@who.int with copy to pqvectorcontrol@who.int with a cover letter requesting the [service code](#):

- PQ400 - for new specification; or
- PQ401- for extension of existing specification.

Screening

Once the product dossier has been received by WHO, it will be assigned to an expert assessor and screened for completeness before being reviewed. Any deficiencies in the documentation submitted and/or in the data that are identified in the product dossier review will be communicated in writing to the manufacturer by WHO. The manufacturer may be informed that an incomplete application has been received and requested to provide the necessary information to complete the dossier. If deficiencies in the product dossier are critical in nature, WHO may issue a screening failure letter, effectively cancelling the review of the submission. If a screening failure letter is issued, the applicant may resubmit the application once the identified deficiencies have been addressed.

NOTE: Only complete applications will be accepted for assessment.

Assessment by WHO

Upon an application having been determined to be complete, following the screening process, the assessment will be initiated. Any deficiencies in the documentation and/or in the data submitted will be communicated in writing to the manufacturer for clarification or revision. The assessment cannot be completed until the manufacturer provides all of the required information to WHO.

Upon receipt and assessment of all required information, if the assessment confirms that the submission meets WHO requirements for specification (PQ400 – new specification), or complies with the established specification (PQ401 – extension of existing specification), the manufacturer will be informed of WHO's acceptance. The manufacturer, with identification of the manufacturing sites, will be included in the list of manufacturers for the specified ingredient after the source material is accepted for specification.

DEVELOPMENT OF SPECIFICATIONS

Inspection by WHO

WHO will plan and coordinate, in accordance with established standard operating procedures and based on quality management principles, the performance of inspections of the site(s) of manufacture of the VCPs, and where needed, site(s) of manufacture of source materials and contract research organizations. The following factors will be considered when planning inspections:

- results of previous inspection(s) by WHO or a national regulatory authority, and history of compliance of the company or facility with WHO-recommended standards;
- outcome of the assessment of data submitted to WHO;
- complexity of the site, processes and product;
- number and significance of known quality defects (e.g. complaints, recalls);
- major changes to the manufacturing or research facility (e.g. buildings, equipment,
- processes, key personnel); and
- site experience with manufacturing and testing of a product.

If serious or critical nonconformities of public health concern are identified in connection with an inspection, WHO reserves the right to use, publish, issue, share with relevant authorities of WHO Member States as well as with United Nations agencies and other relevant intergovernmental organizations, and/or make publicly available (in each case, pursuant to the provisions of WHO standards and published documents, including provisions regarding the protection of any commercially sensitive confidential information of the manufacturer) any outcomes, reports and/or results – whether in draft or final form, and whether positive or negative – arising from or relating to the prequalification assessment process. This includes, without limitation, any WHO notices of concern, WHO notices of suspension and WHO information notices for users.

REQUEST FOR ASSISTANCE

Manufacturers with questions on specification requirements or extension of specification for vector control product source material can contact PQT/VCP via email or request a meeting and/or teleconference by submitting the [pre-submission meeting request form](#).