WHO Prequalification of Vector Control Products

Overview of the WHO assessment of vector control active ingredient products

October 2025

World Health Organization

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Contents

1. Abbreviations

AI	active ingredient
FAO	Food and Agriculture Organization
JMPS	Joint Meeting on Pesticide Specifications
NRA	national regulatory authority
PQT/VCP	Vector Control Products Assessment in the Prequalification Unit
SOP	standard operating procedure
VCAI	vector control active ingredient
VCP	vector control product
WHO	World Health Organization

2. Purpose of these procedures

The purpose of this document is to describe the procedures through which the World Health Organization (WHO) assesses applications for active ingredient (AI) source materials, intended for use in the formulation of public health pesticides, submitted by manufacturers to demonstrate compliance with WHO-recommended quality standards and therefore acceptable for use in the formulation of vector control products (VCPs) which have been or are proposed to be evaluated by WHO for the purpose of prequalification.

Ensuring compliance of source materials with the established specifications is a critical component which directly impacts the quality, safety and efficacy of end use pesticides used in vector control activities to protect the health of at-risk populations around the world from vector-borne diseases.

In addition to the described purposes for setting of pesticide specifications, WHO relies on the Joint Meeting on Pesticide Specifications (JMPS) scientific assessment of manufacturer submitted data/information pertaining to the production process and physical chemical characteristics to confirm that a vector control active ingredient (VCAI) is compliant with the WHO specification and therefore acceptable for use in the formulation of prequalified VCPs.

The quality, safety and efficacy of a VCP is dependent on the quality of the AIs used for its production. The manufacturer of the VCP is responsible for the finished product, which includes the choice of the suppliers and manufacturers of the ingredients. In the context of globalization, AIs are sourced in a worldwide market and there is therefore a risk of sourcing substandard or contaminated products. A proper system of assessment of suppliers can promote the regular sourcing of AIs of appropriate quality and thereby safeguard public health interests. To this end, WHO Vector Control Products Assessment in the Prequalification Unit (PQT/VCP) relies on the JMPS assessment of VCAI products to establish and/or assess compliance with WHO specifications for public health pesticides, on a per product basis.

WARNING/DISCLAIMERS. Those VCAIs and their declared manufacturing sites which are found to meet the quality standards recommended by WHO may be included in a list of VCAIs confirmed to comply with WHO specifications and therefore are found as an acceptable source, in principle, for use in the formulation of VCPs which have been or are proposed to be evaluated by WHO for the purpose of prequalification (the "Listed VCAIs"). It remains the ultimate responsibility of the manufacturer of the VCP to ensure that the source material, as accepted in principle, is suitable for the manufacture of the specific product.

The use by manufacturers of Listed VCAIs in the formulation of future VCPs does not guarantee and shall not create any expectation among manufacturers that such VCPs (using the Listed VCAIs) will be found to meet the WHO standards pursuant to the *Overview of the WHO prequalification assessment of vector control products* and be listed as prequalified VCPs by WHO. For more information on the prequalification assessment of VCPs, please visit the PQT/VCP website.

Further, the listing of VCAIs by WHO pursuant to these procedures does not imply any approval by WHO of such VCAIs and/or their respective manufacturing site(s). Moreover, such listing does not constitute any endorsement or warranty by WHO of the fitness of any product for a particular purpose, including its safety, quality or performance.

3. Introduction

Since 2001, WHO and the Food and Agriculture Organization (FAO) have worked in a harmonized manner under a memorandum of understanding for the development of specifications for pesticides to be used as points of reference for international quality standards. The alignment of the two organizations was recommended by the respective expert committees at the time, noting that for technical materials, i.e. those source materials used in the formulation of end use pesticide products, joint specifications should be pursued to ensure consistency of quality standards for those pesticidal AIs used in agriculture and public health.

In their assessments of manufacturer submitted applications, FAO and WHO are responsible for establishing specifications and evaluating those applications from manufacturers to confirm compliance with the established specification(s). These assessments are conducted through the JMPS. JMPS refers to the joint meeting of experts convened by FAO and WHO to develop recommendations to both organizations on the adoption, extension, modification or withdrawal of specifications.

The FAO and WHO work closely through different so called "joint meetings" on pesticide related topics. The three meetings are the Joint Meeting on Pesticide Residues, the JMPS and the Joint Meeting on Pesticide Management. These bodies were established in 1963, 2001 and 2007 respectively, with the purpose of promoting global standards and good practices with the overall goal of protecting human health and the environment and promoting agriculture development.

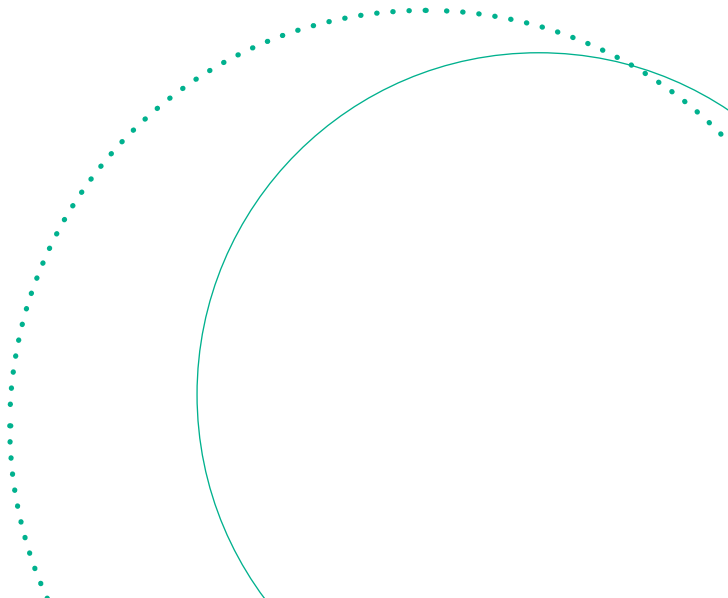
- The Joint Meeting on Pesticide Residues provides scientific advice to Codex Alimentarius, the world's food standard setting body, on maximum residue limits for pesticides in food and feed.
- The primary functions of the JMPS are to produce recommendations to FAO and WHO on the adoption, extension, modification or withdrawal of pesticide specifications and to develop guidance and procedures in establishing pesticide specifications.

The Joint Meeting on Pesticide Management advises FAO, WHO and United Nations Environment Programme on the *International code of conduct on pesticide management* and the development of its technical guidelines. For WHO, the scientific assessment of pesticidal AIs by JMPS and the recommendations therefrom are of particular importance in that only those source materials which have been assessed and confirmed to comply with the established specifications are eligible for use in the formulation of WHO prequalified VCPs.

3.1. International harmonization of standards and guidance for pesticides

PQT/VCP acts as the WHO Secretariat for JMPS, jointly with FAO. The Secretariat for JMPS supports the evaluation of pesticidal AIs, including VCAIs, for the following core purposes:

- establish international point of reference for pesticide quality (establishment of specifications);
- assess compliance of additional manufacturers of an AI (extension of specifications);
- support Member States through promoting recognition and reliance mechanisms for registration of AIs.



3.2. Categorization of pesticides and differentiation of uses

The term "pesticide" is used following the definition provided in the Article 2 of the *International code of conduct on pesticide management*: "Pesticide means any substance, or mixture of substances of chemical or biological ingredients intended for repelling, destroying or controlling any pest, or regulating plant growth" (FAO and WHO, 2014).

The term is usually associated with materials intended to kill or control pests (insecticides, fungicides, herbicides, etc.). It also encompasses those materials used to modify the behaviour or physiology of pests (e.g. insect repellents and synergists) or of crops during production or storage (herbicide safeners, germination inhibitors).

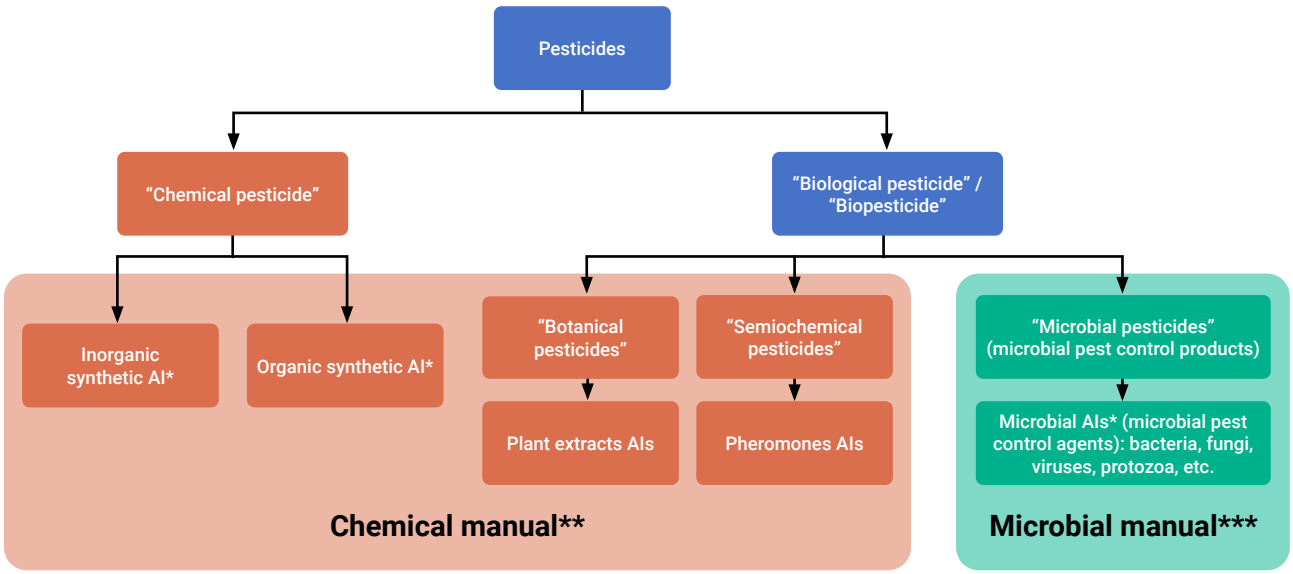
For the purposes of setting specifications, pesticides developed from biological or synthetic process are considered separately to reflect different characteristics which are critical for identification and quality control/assurance.

The term "chemical pesticide" is considered to encompass inorganic and organic synthetic AIs in any form, irrespective of whether, or to what extent, they have been formulated for application.

The term "biopesticide" is considered to encompass microbial pesticides, botanicals (plant extracts) and semiochemicals (pheromones).

The term "microbial pesticide" is considered to encompass microbial AIs (bacteria, fungi, viruses, protozoa, etc.) in any form, irrespective of whether, or to what extent, they have been formulated for application. The terms "microbial pest control agents" and "microbial pest control products" are used to differentiate these kinds of pesticides from other biopesticides and from the synthetic chemical ones ("pesticides" in general).

Figure 1. Pesticide types and appropriate FAO/WHO reference manual to be used for the purposes of developing specifications, in order to reflect different characteristics which are critical for identification and quality control/assurance.



*in any form, irrespective of whether, or to what extent, they have been formulated for application

***Manual on development and use of FAO and WHO specifications for chemical pesticides*

****Manual on development and use of FAO and WHO specifications for microbial pesticides*

Note: Additional manuals may be developed in the future.

3.3. Purpose of FAO/WHO specifications

In general, specifications may be used:

- as part of a contract of sale, so that a buyer may purchase a pesticide with some guarantee of the quality expected; or
- by the competent authority to check that the quality of the products on the market is the same as that registered.

FAO/WHO specifications are intended to enhance confidence in the purchase and use of pesticides and thus to contribute to human and environmental safety, as well as to more sustainable agricultural production and improved public health. FAO/WHO specifications may be used by national authorities as an international point of reference but are not intended to replace national or international registration requirements.

The specifications encompass the physical appearance of the material, its content of AI and any relevant impurities, and its physical and chemical properties, and stability in storage.

The specifications do not encompass the chemical characteristics of the formulants, other than where they influence the physical characteristics (which are taken to include characteristics such as acidity and/or alkalinity or pH range).

The specifications do not include clauses which define the pesticidal properties of the AI, for example, the intrinsic efficacy of the pesticide.

3.4. Purpose of JMPS

The JMPS is composed of scientists collectively possessing expert knowledge of the development of specifications. Their opinions and recommendations to FAO/WHO are provided in their individual expert capacities, not as representatives of their countries or organizations. The JMPS is a statutory body of FAO and WHO whose panel members are appointed by the two organizations.

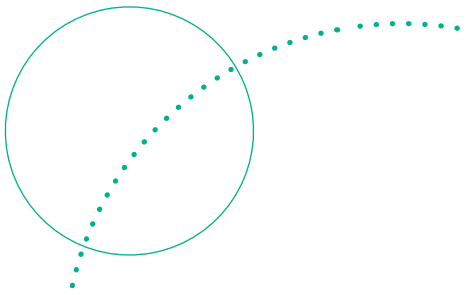
The primary function of the JMPS is to develop recommendations to FAO and/or WHO on the adoption, extension, modification or withdrawal of specifications based on the scientific evaluation of the applicable data. The resulting publications from the evaluations of JMPS have two parts:

- Specifications – Establishment of quality standards for technical materials and end use formulation types (norms and standards).
- Evaluation reports – Manufacturer/product specific evaluations which support the establishment of specifications and provide the public assessment report of applications which have been submitted by responsible applicants.

The established roles and responsibilities of JMPS, the secretariats, members and chairs were developed based on the foundational document *FAO/WHO framework for the provision of scientific advice on food safety and nutrition*. This document and preceding reports established the following:

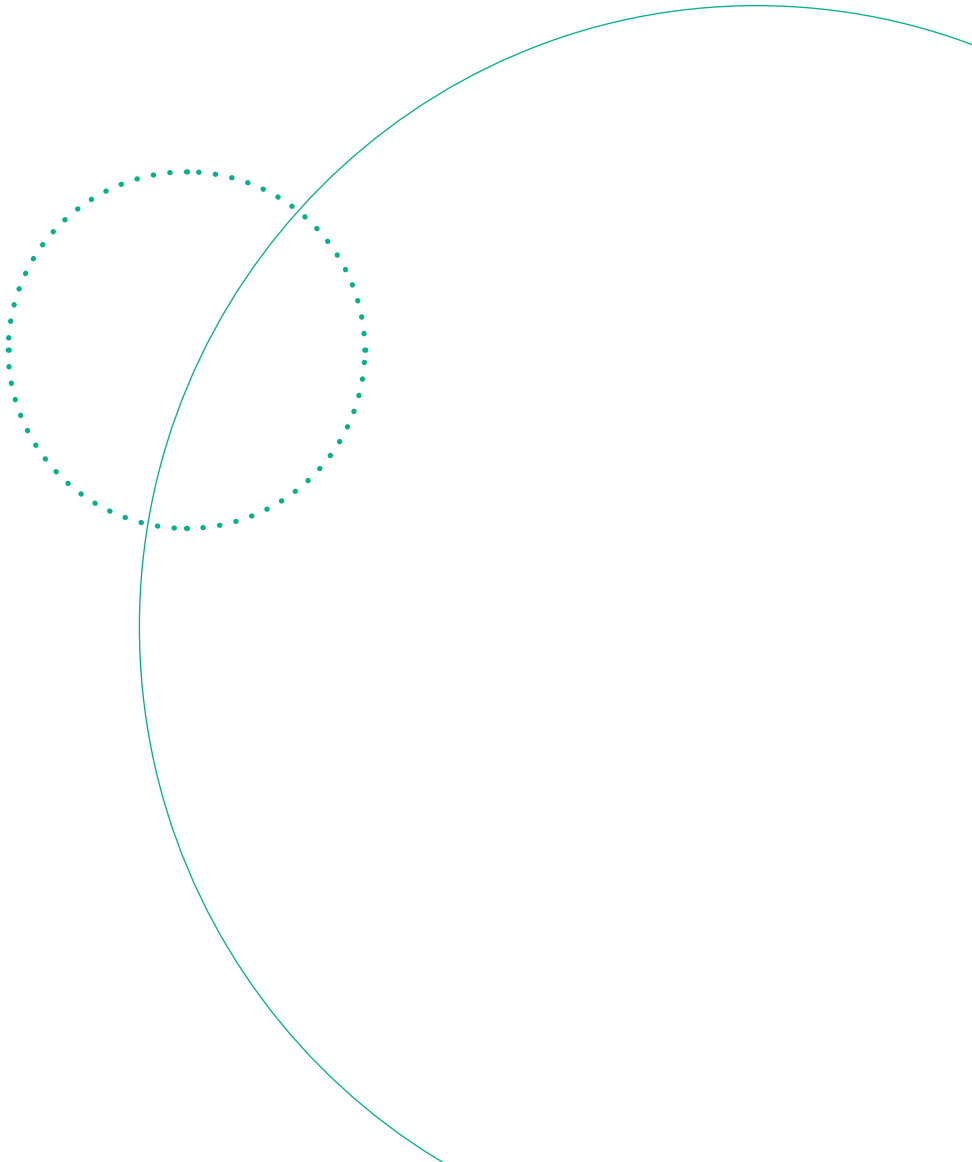
> *Scientific advice is defined as "the conclusion of a skilled evaluation taking account of the scientific evidence, including uncertainties. It may comprise an appraisal of the consequences of one or more options based on an analysis of the available scientific knowledge and on scientific judgement. Such advice should include explicit recognition of any uncertainty either in the current state of knowledge or in the adequacy of the available data. If necessary, it should include any alternative interpretations of the data."*

The joint FAO/WHO secretariats comprise professional staff members from FAO and WHO, who are responsible for the preparation, organization and advancement of outcomes of expert meetings. Each organization designates one staff member as a fully responsible joint secretary; other staff members are members of the joint secretariat.



The secretariats are responsible for:

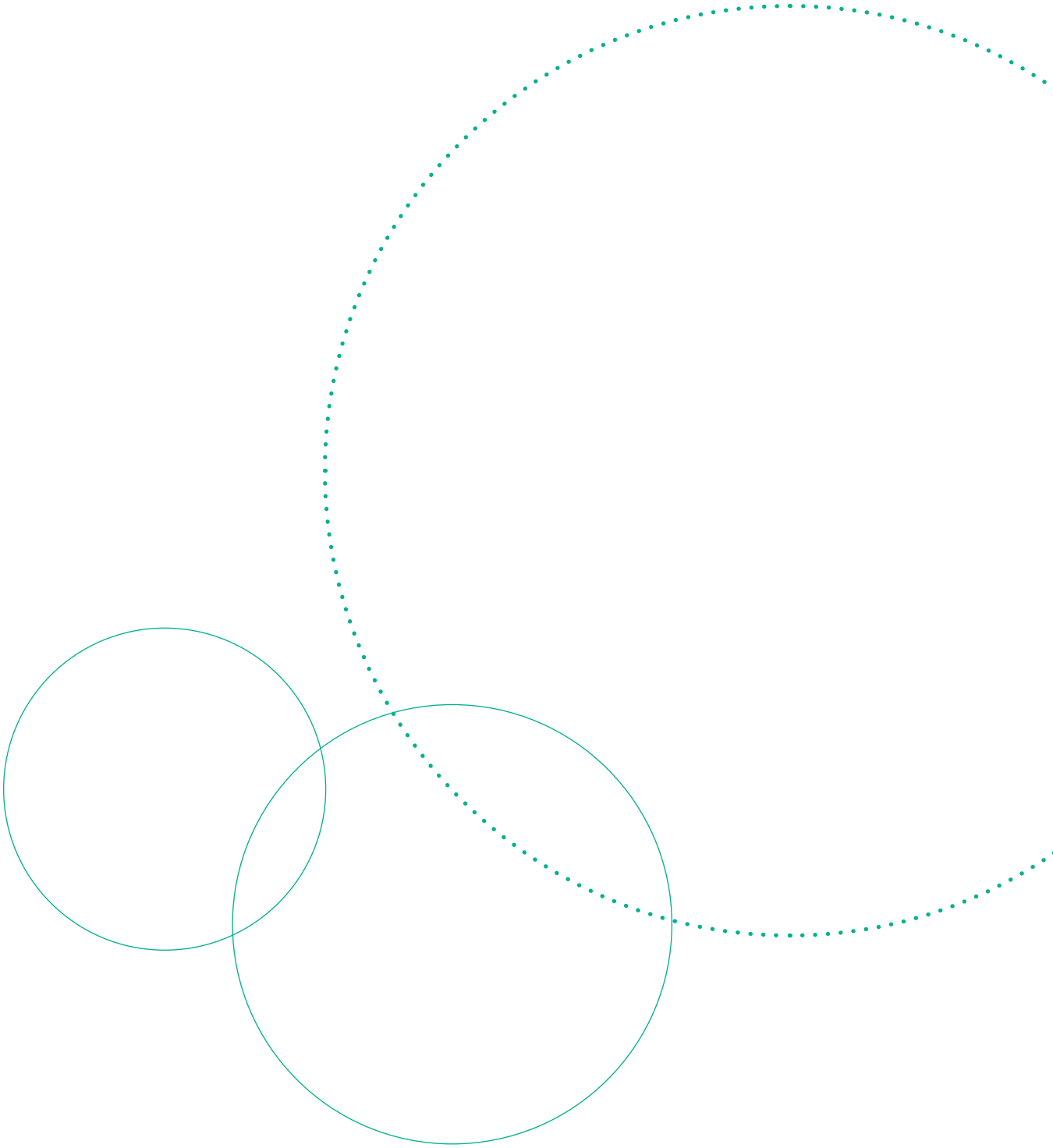
- designating appropriate technical staff as focal points on all aspects covered by the memorandum of understanding;
- participating in the preparation and conduct of joint, mutually agreed upon, technical meetings relevant to the development of the pesticide specifications in accordance with the terms of the memorandum of understanding;
- engaging in the development of the specifications applicable for use in agriculture and public health;
- proceeding to joint publication of the pesticide specifications, once they have been agreed upon, subject to terms and conditions and modalities to be determined by a separate agreement between the Parties, on the understanding that each Party maintains its existing intellectual property;
- prioritizing and engaging in the revision and/or improvement of the pesticide specifications, as the Parties may from time to time agree to be required for the benefit of users of pesticide in agriculture and public health, and proceed to joint publication of such revisions and/or improvements, once they have been agreed upon, subject to terms and conditions, and in accordance with modifications, to be negotiated by the Parties.



4. Intended audience

The intended audience of this document are manufacturers of VCAIs interested in establishing specifications and being eligible for use in the formulation of prequalified products.

This document has been developed to provide manufacturers with an overview of the WHO assessment process for VCAI compliance with WHO specifications. Manufacturers wishing to apply for WHO assessment of their VCAI product(s) should read this document before applying so that they can be aware of and prepared for all aspects of the assessment process.



5. Assessment of VCAIs: process overview and outcomes

WHO assessment of VCAI(s) ensures that source materials comply with specifications thereby contributing to the quality, safety and efficacy of VCPs. Facilitating access to improved quality prevention-focused VCP tools primarily benefits populations most affected by vector-borne diseases. The vector-borne diseases include malaria and neglected tropical diseases such as dengue, chikungunya, Zika, Chagas disease, lymphatic filariasis, leishmaniasis, human African trypanosomiasis, onchocerciasis and schistosomiasis.

The products which should be submitted for WHO assessment of VCAIs include, at a minimum, those formulants which provide the pesticidal action as well as those which may elicit a synergistic effect in combination with the AI(s). WHO may identify other formulants in VCPs which require additional assessment and as such would be assessed in accordance with these procedures, to the extent applicable. WHO requires that AI and synergist source materials be assessed and, at a minimum, found in compliance with established WHO specifications in order to be acceptable for use in the formulation of prequalified VCPs. In many cases, the source material of AIs and synergists included in the formulation of a VCP is in the technical material or technical concentrate form.

In certain cases, the production of the VCP may rely on source ingredients in other forms. Intermediate or formulated source materials may include, for example, suspension concentrates used in the coating of insecticide treated nets or polyethylene based masterbatches used in the formulation/extrusion process of incorporated insecticide treated nets. Intermediates may be purchased by the VCP manufacturer or produced "in house" as part of the formulation of the particular VCP. Intermediates which are purchased from a third party must have been assessed by WHO in accordance with these procedures for the purpose of establishing new specifications or confirming compliance with existing specifications. Intermediates which are formulated "in-house" are assessed as part of the *WHO prequalification assessment procedures*.

The WHO process for assessment of a VCAI's compliance consists of the following steps:

1. Applicant submits a dossier to WHO which includes data and information to support the quality and safety requirements appropriate to the formulation type and generated according to good laboratory practices of the VCAI concerned.
2. Submission is screened by WHO for completeness. Only complete applications are accepted for assessment of VCAI's compliance.
3. Once an application is determined to be complete by WHO, two parallel activities will commence:
   - assessment of the application by experts as part of the JMPS; and
   - inspection of the manufacturing facilities to ensure compliance with WHO-recommended quality standards (as needed).

Once WHO is satisfied that the assessment process is complete for the relevant VCAI product, that the product meets WHO requirements, and that the product is compliant with the existing WHO specifications, the VCAI, as manufactured at the declared manufacturing site(s), will be included in the WHO list of VCAIs confirmed to comply with specifications. The duration of the validity of the status of a product is dependent on the manufacturer's fulfilment, within the applicable deadlines, of its post-assessment obligations and requirements, including:

- fulfilling VCAIs' compliance commitments;
- reporting of changes;
- post-market surveillance obligations;
- receiving inspections/re-inspections (if/when required); and
- continued compliance with established WHO specifications.

In identifying pesticidal source materials for use in the formulation of end use public health pesticides, manufacturers are encouraged to refer to this list in addition to any and all applicable regional, national and local regulations and requirements.

For WHO prequalified VCPs, the use of VCAIs not included in this list in the formulation of the VCP is prohibited and may result in the removal of the product from the list of WHO Prequalified VCPs, as expressed in the *Overview of the WHO prequalification assessment of vector control products*.

Additionally, manufacturers of end use pesticides, including WHO prequalified VCPs, using information from the WHO assessment of VCAIs process should not rely exclusively on the WHO assessment and should make their own assessment before purchasing VCAI products included in the WHO list of VCAIs, including but not limited to steps such as ensuring the supplier's financial stability and standing, the ability to supply the required quantities of the product, security of the supply chain, quality control testing and other relevant aspects.

5.1. Applicants and their obligations

5.1.1. Legal manufacturer

Applications to WHO for the assessment of VCAIs are accepted only from the legal manufacturer of the product. The legal manufacturer of the VCAI is the entity which is entirely responsible for the manufacturing of the submitted VCAI. Legal manufacturers are required to ensure that all product dossier information on file with WHO is current and correct, including authorized points of contact. The legal manufacturer is ultimately responsible for ensuring that the product having been confirmed to comply with WHO specifications is manufactured in accordance with the information provided to WHO to support the assessment. This responsibility extends beyond the manufacturing of the product in facilities owned by the legal manufacturer and includes all contractual or toll manufacturing facilities. Legal manufacturers are also required to submit and maintain current information on the rebranding or supplemental distribution of their products to WHO.

5.1.2. Use of authorized agents

Legal manufacturers of VCAIs may rely on an authorized agent to submit applications for assessment to WHO and/or communicate with WHO on their behalf. The legal manufacturer must provide a Letter of Authorization identifying the authorized person(s) with whom WHO may communicate and the specific product(s) or application(s) to which the authorization applies.

In order to ensure that written and meeting engagements with legal manufactures and their agents are handled in accordance with the procedures for the WHO assessment of VCAIs, the following should be adopted by the responsible individuals and organizations.

- In all written communication with PQT/VCP, agents are required to:
  - identify the legal manufacturer on whose behalf they are communicating with WHO;
  - include the appropriate point of contact of the legal manufacturer in copy.
- For all meetings, in-person and virtual, it is preferred that when agents may be leading the meeting on behalf of the legal manufacturer, that participation include direct representation of the legal manufacturer as well. If participation of the legal manufacturer is not possible, verification of the status of the agent should be included with the meeting request form (or in advance of the meeting).

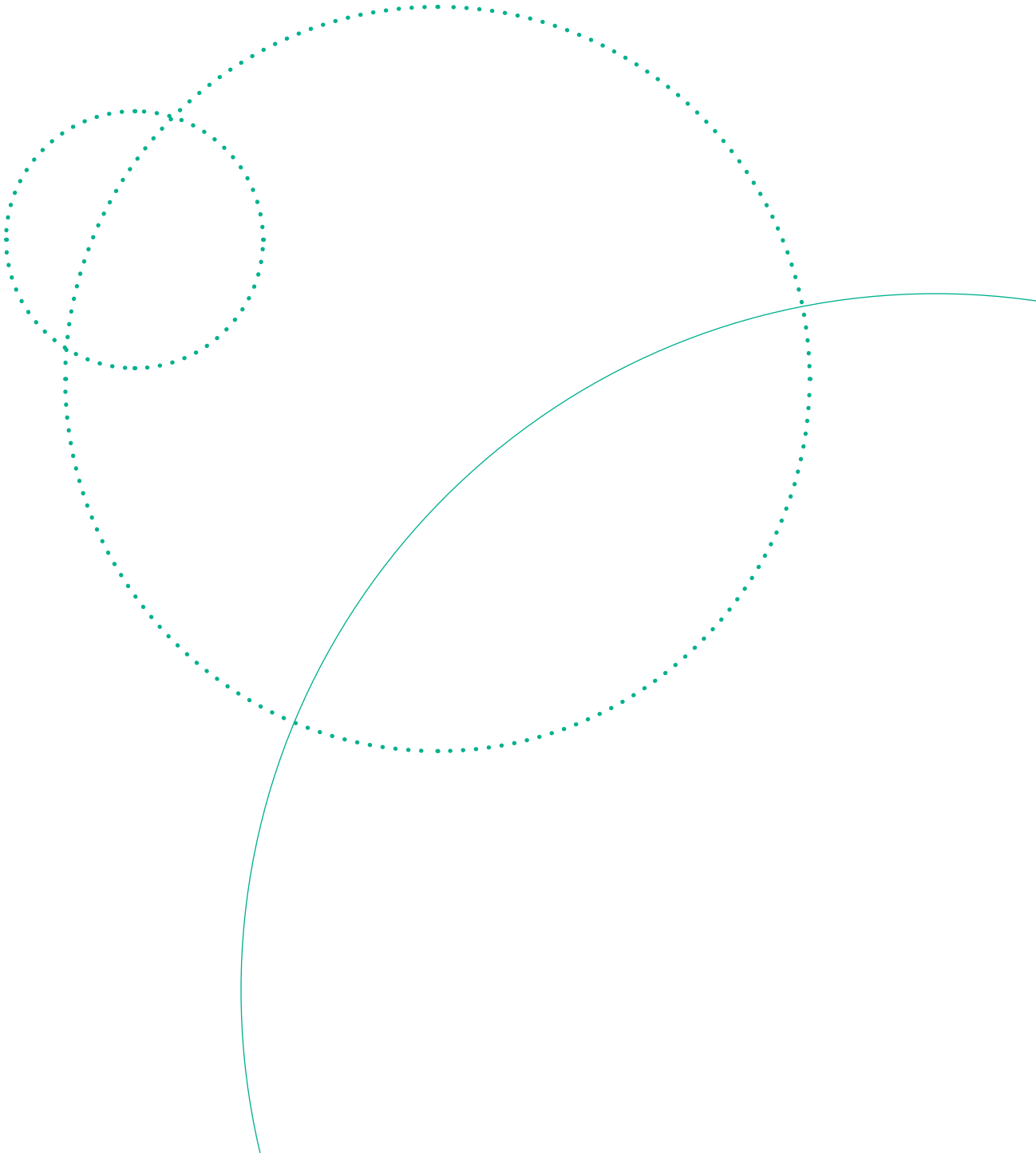
5.2. Eligibility for participation in the WHO assessment process

All VCAIs for which there is a public health use when formulated as VCPs are eligible for submission.

6. Dossier development and pre-submission activities

WHO requires that VCAI product dossiers be developed using the current guidance available on the website.

Manufacturers interested in submitting a VCAI are invited to contact PQT/VCP prior to the submission of their application. PQT/VCP offers pre-submission meetings to ensure clarity and understanding of the assessment process and data requirements, either generally or within the context of a particular proposed application.



7. Applying for WHO assessment of VCAIs

To ensure that WHO can assess VCAIs as efficiently as possible, manufacturers should be fully prepared for the assessment process when they apply for WHO assessment. Applications should be submitted to WHO in a manner to ensure the security (secure data transfer) and clear organization of the information (clear reference to paths/folders/files for the data to be reviewed) of the submission.

Following the established procedures and timeliness for the JMPS meetings, applicants should consider the following for inclusion of their dossier in the JMPS workplan for the following year:

- 31 May – Deadline for notifying WHO of the applicant's intent to submit an application
- 31 October – Deadline for submitting the complete application and product dossier

WHO cannot guarantee inclusion of the application in the JMPS workplan for the following year, if submissions are made after the aforementioned deadlines. Complete applications containing the product dossier are welcome to be submitted any time in advance of the deadline.

Only complete applications will be accepted for assessment of VCAIs' compliance with WHO specifications. Once the product dossier has been received by WHO, it will be screened for completeness and assigned to an expert assessor for its review. This screening is aimed at ensuring that all requisite sections of the product dossier have been submitted; it does not take into consideration the technical appropriateness of the information provided in the product dossier. 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 found to be of critical 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. The new application will be considered without prejudice.

Upon an application having been determined to be complete, following the screening process, the application will be accepted for assessment and WHO will inform the manufacturer in writing. Additionally, and before the assessment of a VCAI product may commence, manufacturers must deliver to WHO a signed and completed Letter of Agreement, which will serve: (i) as an agreement between WHO and the manufacturer on the participation of the product in the WHO assessment process of VCAI's compliance with WHO specifications, and (ii) as the manufacturer's acceptance of and commitment to comply with the provisions of the assessment process. After an application has been accepted for assessment by WHO, it will be published on the PQT/VCP website in the pipeline of VCAI applications under assessment for compliance.

7.1. Assessment of VCAIs

For applications which have been accepted for assessment of compliance with existing specifications and/or supporting the establishment of new WHO specifications, the information submitted in the application will be assessed by external experts (assessors) appointed by WHO. Assessors involved in the dossier review must have appropriate qualifications and expertise in the relevant fields and must comply with the confidentiality and conflict of interest rules of WHO. The assessors will act as temporary advisers to WHO. The assessment of VCAI product dossiers will be conducted in accordance with standard operating procedures (SOPs) established by WHO for that purpose to ensure uniformity in evaluation and timeliness of assessment activities.

The assessment of VCAI applications will be conducted as per the following criteria:

- Quality – assess source material production, manufacturing process, physical/chemical characteristics for the establishment or extension of WHO specifications as needed;
- Safety – assess relevant toxicology information related to the relevance/non-relevance of impurities identified in the source material production.

Any deficiencies in the documentation submitted and/or in the data that are identified in the VCAI product dossier review will be communicated in writing to the manufacturer by WHO for clarification or revision. WHO may request that a corrective action plan detailing the amendments needed to correct the deficiencies (i.e. responses to comments, documentation and/or data that is missing) and target times for their submission be provided by the manufacturer to WHO.

The VCAI assessment procedure is usually suspended (WHO will not undertake any further action) until a complete response has been submitted by the manufacturer. The assessment cannot be completed until the manufacturer provides all of the required information to WHO. In certain cases, WHO may agree, in its sole discretion, to permit the manufacturer to correct specific deficiencies after a VCAI product has been confirmed compliant, provided that the manufacturer commits in writing to correct them by an agreed upon deadline. Such a commitment will be reflected in the WHO public assessment report and will be monitored for completion. Failure to comply with established commitments within agreed deadlines may result in suspension of the VCAI product or delisting from the WHO list of VCAIs confirmed to comply with specifications. The manufacturer may request a hearing or meeting with WHO to clarify issues identified during the assessment of the VCAI. If the VCAI product/application successfully meets WHO assessment requirements for compliance, a summary of the assessment will be included in the WHO public assessment report.

If the product dossier does not meet WHO assessment requirements or if any of the other conditions outlined under section 8.3 (Cancellation of the application) are met, the application will be cancelled.

7.2. Inspection

WHO will plan and coordinate, in accordance with established SOPs and based on quality management principles, the performance of inspections of the site(s) of manufacture of the VCAIs, and where needed, site(s) of manufacturer 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 (NRA) 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 this document, 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 assessment process. This includes, without limitation, any WHO Notices of Concern, WHO Notices of Suspension and WHO Information Notices for users.

7.2.1. Manufacturing sites

The inspections of the manufacturing site(s) are conducted to assess compliance with WHO-recommended quality standards (ISO-9001:2015). The initial inspection of the manufacturing site will be performed in two stages. The stage 1 inspection, usually a desk audit,[1] will evaluate the documentation related to the quality management system to ensure readiness for the stage 2 inspection. General information about the documented quality management system (including the quality manual and manufacturing processes, organigram, workflows, critical suppliers and floor plan)[2] will be reviewed during the stage 1 inspection to establish the readiness of the manufacturer's quality management system and to prepare for an on-site visit. Any issues of concern will be communicated to the manufacturer.

The stage 2 inspection will comprehensively evaluate the effective implementation of the quality management system and production processes through an on-site(s) inspection(s). The inspection team is composed of WHO staff, external experts (inspectors) appointed by WHO as well as, potentially, interpreters and observers. The inspectors involved in the on-site(s) inspection(s) should have appropriate qualifications and expertise in the relevant fields, must comply with the confidentiality and conflict of interest rules of WHO and will act as temporary advisers to WHO. Representatives of the NRAs and/or additional WHO employees may accompany the inspection team to the manufacturing site(s) as observers or for training purposes.

If time allows, a preliminary nonconformance report detailing issues of concern (if any) will be provided to the manufacturer on the final day of the inspection. A final inspection report, including the graded nonconformities will be issued to the manufacturer after the inspection of the manufacturing site(s).

All nonconformities must be corrected by the manufacturer through suitable corrective actions addressing the root cause of each nonconformity. Depending on the nature and number of nonconformities, objective evidence of the effective implementation of proposed corrective actions may be required. WHO will assess the information provided and decide whether the corrective action plan can be accepted. Conformity with compliance with WHO specifications requirements will be established based on assessment of such information. In some instances, the number and criticality of nonconformities may require that the effective implementation of proposed corrective actions be verified in a follow-up inspection before the nonconformities can be closed off.

A summary of the findings of the inspection of the manufacturing site(s) will be included in the WHO public inspection report, if the VCAI product successfully meets WHO requirements. In certain cases, WHO may agree, in its sole discretion, to permit the manufacturer to correct specific nonconformities after VCAI product has been confirmed compliant, provided that the manufacturer commits in writing to address them by an agreed upon deadline. Such a commitment will be reflected in the WHO public assessment and/or inspection report and will be verified during the re-inspection. Failure to comply with commitments within agreed deadlines may result in the suspension of the VCAI product or delisting of the product from the WHO list of VCAIs confirmed to comply with specifications. If the manufacturer does not meet WHO requirements or if any of the other conditions outlined in section 8.3 (Cancellation of the application) are met, the application will be cancelled.

1 The stage 1 inspection may also be performed on-site.

2 See site master file guidance.

8. Outcome of the assessment of VCAIs

8.1. Reporting and communication of the results of the assessment

As part of the assessment process, WHO may share the manufacturer's application and related information with interested NRAs, subject to WHO entering into an appropriate confidentiality undertaking with each such NRA. Furthermore, the outcome of any joint review of information by WHO and NRA(s) may be used by WHO, at its discretion, as part of the assessment process.

Upon receipt and assessment of all required information, each assessment report (including WHO specifications) and manufacturing site(s) inspection report will be finalized according to the relevant SOPs and format established by WHO, describing the findings and including requests and recommendations to the manufacturer. The assessment reports will be communicated in writing to the manufacturer. If the assessment confirms that the submission meets WHO requirements for specification development (PQ400 – new specification), or complies with the established specification (PQ401 – extension of existing specification), the manufacturer will be informed of WHO's decision. If any additional information is required, or if corrective action has to be taken by the manufacturer, WHO will postpone its decision on the compliance of the VCAI product and/or manufacturing site(s) concerned until, as applicable: (i) such information has been provided by the manufacturer, assessed and found satisfactory by WHO, and/or (ii) such corrective action has been taken by the manufacturer and found satisfactory by WHO, in light of the specified standards.

As WHO is responsible for the assessment process, the ownership of the reports arising from or relating to the assessment process lies with WHO. Thus, WHO shall be entitled to use and publish such reports subject to the protection of any commercially sensitive confidential information of the manufacturer.

Confidential information in this context means:

- confidential intellectual property, know-how, and trade secrets (including formulas, processes or information contained or embodied in a VCAI product, unpublished aspects of trademarks, patents, etc.); and
- commercial confidences (e.g. structures and development plans of a company).

Subject to the protection of commercially sensitive confidential information, WHO will publish on the WHO website and make publicly available the following information in connection with the assessment process:

- names of VCAI products submitted for assessment, associated manufacturer(s) and the status of each application;
- certain attributes depending on the VCAI product type, for the purpose of identifying specific VCAI product characteristics;
- manufacturing sites associated with the production of the VCAI;
- WHO public assessment report summarizing the findings of the assessment; and
- any negative outcomes of the assessment, including product alerts such as WHO Information Notices for users, WHO Notices of Suspension and/or WHO Notices of Concern.

Notwithstanding any of the foregoing, 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, in accordance with the provisions of this document, including provisions regarding the protection of any commercially sensitive information of the manufacturer) any outcomes, reports, notices and/or results, whether in draft or final form, and whether positive or negative, of the assessment process. This includes, but is not limited to, the assessment and/or manufacturing site inspection, and includes any confidential information to which WHO may gain access in the course of the assessment process.

8.2. VCAI compliance

Once WHO is satisfied that the assessment process is complete for the relevant VCAI product, and that the VCAI meets WHO assessment requirements, the VCAI, as manufactured at the declared manufacturing site(s), will be included in the WHO list of VCAIs confirmed to comply with specifications. The WHO list of VCAIs confirmed to comply with specifications will be compiled in accordance with an SOP established by WHO for final decision-making on inclusion in that list. The list will be published on the WHO website and will specify the VCAI, relevant product attributes/characteristics, the manufacturer's name, the manufacturing site(s), the date of compliance and the current assessment status.

The manufacturer will receive a letter from WHO informing on WHO's confirmation of compliance as outcome of the overall assessment of the VCAI product. Once the VCAI is included in the WHO list of VCAIs confirmed to comply with specifications, 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 confirmed to comply with specification, and the manufacturer will be responsible for:

- fulfilling established commitments;
- reporting of changes (i.e. change in manufacturing process, declared characteristics for VCAI product(s) confirmed to comply with specifications or new manufacturing site(s) for VCAI product(s) confirmed to comply with specifications);
- post-market surveillance obligations;
- receiving inspections/re-inspections; and
- continued compliance with established WHO specifications.

The decision to include the VCAI in the WHO list of VCAIs confirmed to comply with specifications is made based upon information available to WHO at the time of the assessment, including information obtained as a result of the VCAI product dossier submitted in the application and the inspection of manufacturing site(s) conducted by WHO. This decision is subject to change on the basis of new information that may become available to WHO.

NOTE: If serious or critical nonconformities or concerns (including with respect to quality and/or safety are identified in connection with the assessment of a VCAI product and/or a listed VCAI product confirmed to be compliant with specifications, 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 this document, including provisions regarding the protection of any commercially sensitive information of the manufacturer) any outcomes, reports, notices and/or results, whether in draft or final form, and whether positive or negative, arising from or relating to the assessment process and/or listed VCAI product confirmed to comply with specifications. This includes, without limitation, any WHO Notices of Concern, WHO Notices of Suspension and WHO Information Notice to end users. Consequently, WHO may delist the VCAI product after evaluation of the evidence and risk-benefit assessment or may suspend the VCAI product until results of further investigations become available and are assessed by WHO. WHO may re-list the VCAI product only after the aforementioned evidence, risk-benefit and other assessments, and investigation results are considered acceptable by WHO.

USE OF WHO NAME AND/OR EMBLEM

Manufacturers must understand and agree that it is not WHO's mandate to issue any approvals, certificates or licences for VCAIs. This responsibility lies with the NRA of each country. Furthermore, WHO does not, as a matter of policy, endorse any specific commercial product over others. As mentioned above, the purpose of this procedure is to provide relevant United Nations agencies and relevant authorities of WHO Member States, with advice on the confirmation of compliance, in principle, of AI source materials which are found to meet WHO-recommended quality standards. In this regard, the results of the assessment, participation in the WHO assessment process, inclusion of any VCAI product in the WHO list of VCAIs confirmed to comply with specifications, and/or the WHO name and emblem MAY NOT BE used by manufacturers or any other party for commercial and/or promotional purposes. WHO will not accept any liability or responsibility whatsoever for an injury, death, loss, damage or other prejudice of any kind that may arise as a result of or in connection with the procurement, distribution and use of any VCAI product as to which WHO has published the assessment results for compliance and/or that is included in the WHO list of VCAIs confirmed to comply with specifications.

8.3. Cancellation of the application

WHO reserves the right to cancel the application for a specific VCAI product at any time or stage of the assessment procedure if:

- the VCAI product dossier does not contain all of the required information or does not meet WHO assessment requirements; and/or
- the manufacturer is not able to, or fails to, provide the required or requested information within a specified deadline; and/or
- the VCAI product does not meet the standards for assessment; and/or
- the manufacturer is not able to, or fails to, implement any corrective actions which WHO may require within a specified deadline; and/or
- the information supplied is inadequate to complete the assessment in a timely manner.

After cancellation, the manufacturer may re-apply for WHO VCAI product assessment once the issues have been addressed.

8.4. Withdrawal from the assessment

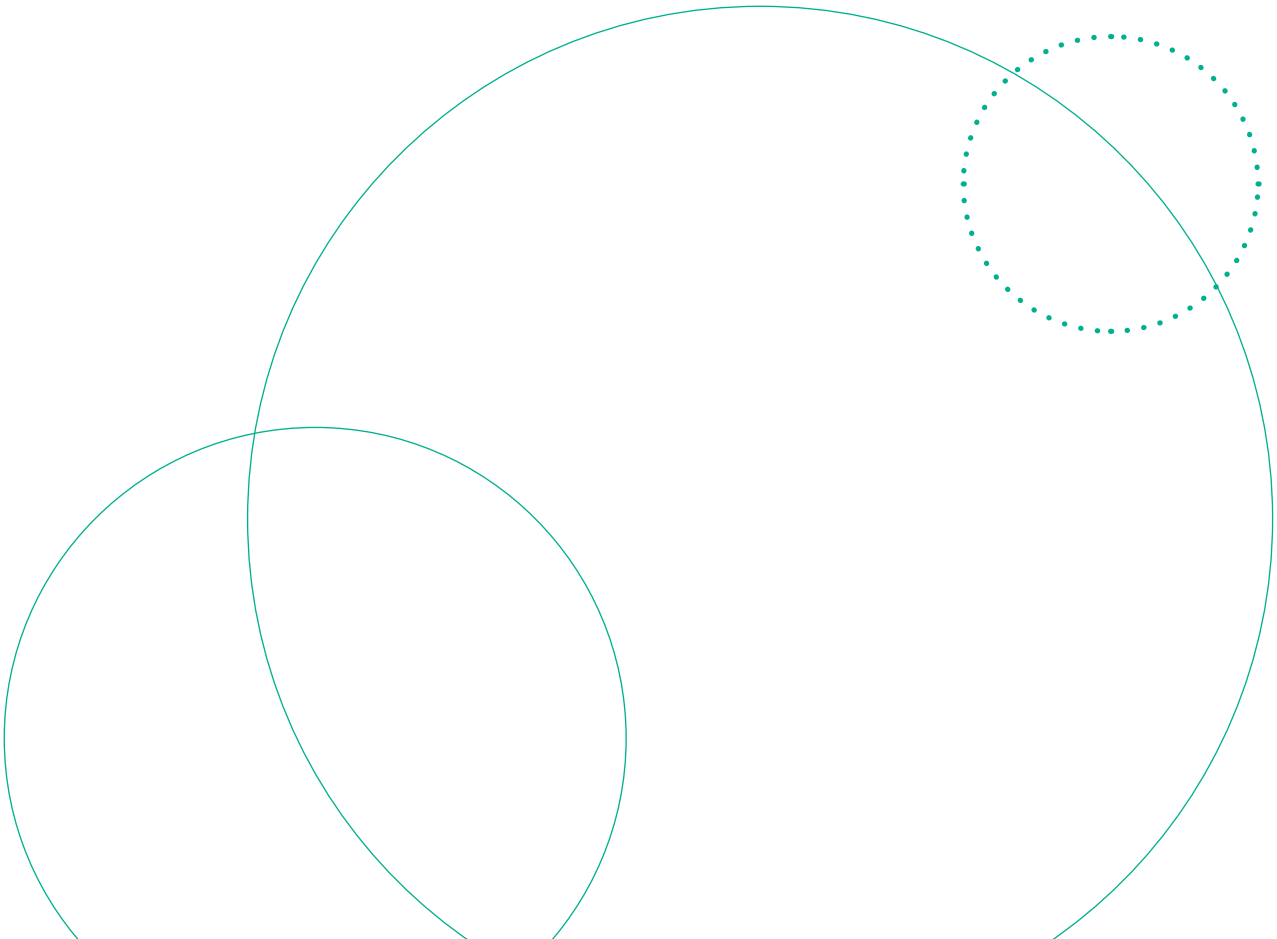
WHO provides the manufacturer with the right to withdraw its application for VCAI product assessment at any time. To exercise this right of withdrawal, the manufacturer must provide WHO with written notice specifying the VCAI product(s)/ application(s) to be withdrawn. After withdrawal, the manufacturer may re-apply for WHO VCAI product assessment at any time.

8.5. Reporting and communication of outcomes after withdrawal or cancellation of an application

The cancellation or withdrawal, at any time and for any reason, of an application for assessment of a specific VCAI product will not prejudice or otherwise affect WHO's rights 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 in accordance the provisions of this document, including provisions regarding the protection of any commercially sensitive information of the manufacturer) any outcomes, reports, notices and/or results, whether in draft or final form, and whether positive or negative, arising from or relating to the VCAI product assessment process, including without limitation any WHO Notices of Concern, WHO Notices of Suspension and/or WHO Information Notices for users.

8.6. Reporting and communication of outcomes after delisting or suspension of a VCAI product

If the VCAI assessment and/or listed VCAI product confirmed to comply with specifications is suspended or delisted, at any time and for any reason, such suspension or delisting will not prejudice or otherwise affect WHO's rights 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, in accordance the provisions of this document, including provisions regarding the protection of any commercially sensitive information of the manufacturer) any outcomes, reports, notices and/or results, whether in draft or final form, and whether positive or negative, arising from or relating to the VCAI product assessment process, including without limitation any WHO Notices of Concern, WHO Notices of Suspension and/or WHO Information Notices for users.



9. Assessment fees

Currently there are no fees required to be paid by the manufacturer in association with the submission of an application.

10. Post-assessment activities

10.1. Fulfilment of commitments

Established commitments must be fulfilled by the manufacturer within the agreed deadlines in order to maintain the compliance status of the VCAI product. Failure to meet established commitments within the agreed deadlines may lead to suspension or delisting of the VCAI(s) from the WHO list of VCAIs confirmed to comply with specifications.

10.2. Changes

The manufacturer of VCAI(s) included in the WHO list of VCAIs confirmed to comply with specifications are obligated to report to WHO changes related to the quality and/or safety of the listed VCAI product or its manufacture.

For all reportable changes to a VCAI product confirmed to comply with specifications, the manufacturer must submit to PQT/VCP a change application including the supporting information/data, as applicable. The manufacturer must communicate to WHO its intent to introduce a change well in advance (i.e. early in the process of designing and validating the change) to allow sufficient time for WHO to assess the change before its implementation. WHO will not approve any changes without due assessment. Depending on the type of change, the assessment may also include an inspection of the manufacturing site(s).

Once the change application is received by WHO, it will be screened for completeness and, provided all the required information has been supplied, will undergo assessment by WHO. If any aspect of the supporting documentation is incomplete, the manufacturer will be informed in writing and requested to complete it within a specified deadline set by WHO.

WHO will inform the manufacturer in writing of the outcome of its assessment of the change. The manufacturer will also be notified if WHO deems (based on the nature of the change), that an inspection of the manufacturing site(s) is also required, or if a new VCAI product application may be necessary depending on the significance of the change.

Once WHO is satisfied that the change assessment of a VCAI is complete and provided that the overall findings demonstrate, as determined by WHO, that the VCAI continues to meet all WHO's compliance requirements, then the WHO list of VCAIs confirmed to comply with specifications will be updated, as necessary, to reflect the relevant change accepted by WHO. If the submitted documentation supporting the change does not meet WHO's requirements or if all the requested information is not provided by the manufacturer within the specified deadline, WHO will reject the change. The impact of such a decision on the status of the listed VCAI product will be communicated to the manufacturer in writing by WHO.

Failure to submit a change to WHO, which may impact the quality and/or safety of a listed VCAI product, may lead to suspension or delisting of the VCAI product(s) from the list of VCAIs confirmed to comply with specifications.

10.3. Routine re-inspections

Routine re-inspections may be conducted, to ensure continued compliance with WHO requirements. Routine re-inspections may take place every three years, and up to five years, after confirmation of compliance of a VCAI product unless an earlier re-inspection is deemed necessary by WHO.

10.4. Post-market surveillance

10.4.1. Handling of complaints

In the case of a complaint, WHO will verify the validity of the information submitted and may request the manufacturer to provide further information relating to the complaint, including details regarding the investigation undertaken and any preventive and corrective actions taken. When necessary, WHO will conduct an investigation in relation to the complaint(s), which may include use of established procedures for assessment and/or inspection. Based on the findings of the investigation, WHO may determine that it is necessary to issue a suspension of the listed VCAI product(s) until the identified issues are addressed or VCAI product is brought into compliance. Alternatively, WHO may determine that the VCAI should be delisted and removed from the WHO list of VCAIs confirmed to comply with specifications. WHO may also notify, depending on the nature of the complaint, NRAs, relevant authorities of any interested Member States and/or interested United Nations agencies of the complaint.

Depending upon the severity of the complaint(s), WHO may determine that it is necessary to issue a suspension of the listed VCAI product(s) pending the outcome of investigation.

10.5. Compliance with established WHO specifications

Manufacturers are expected to maintain compliance with the relevant WHO specifications for the source materials, as appropriate. Compliance with the established WHO specifications may be verified during inspection/re-inspection and/or post-market or quality assurance testing by a third party. Failure to comply with the relevant WHO specifications will require the manufacturer to take corrective actions to ensure compliance or submit the necessary application/information to establish new/revised specifications. Such noncompliance may lead to suspension of the listed VCAI product(s) until the product is brought into compliance or delisting of the VCAI(s) from the WHO list of VCAIs confirmed to comply with specifications.

10.6. VCAI product review

At WHO's discretion, a VCAI product review may be initiated related to a subset of VCAI products which share certain attributes. A VCAI product review process includes:

- identification of the relevant VCAI products based on the issue;
- review of existing information;
- identification of new information/data gaps to be addressed;
- applicant submission of information based on the identified needs; or
- evaluation of VCAI product integrating new information.

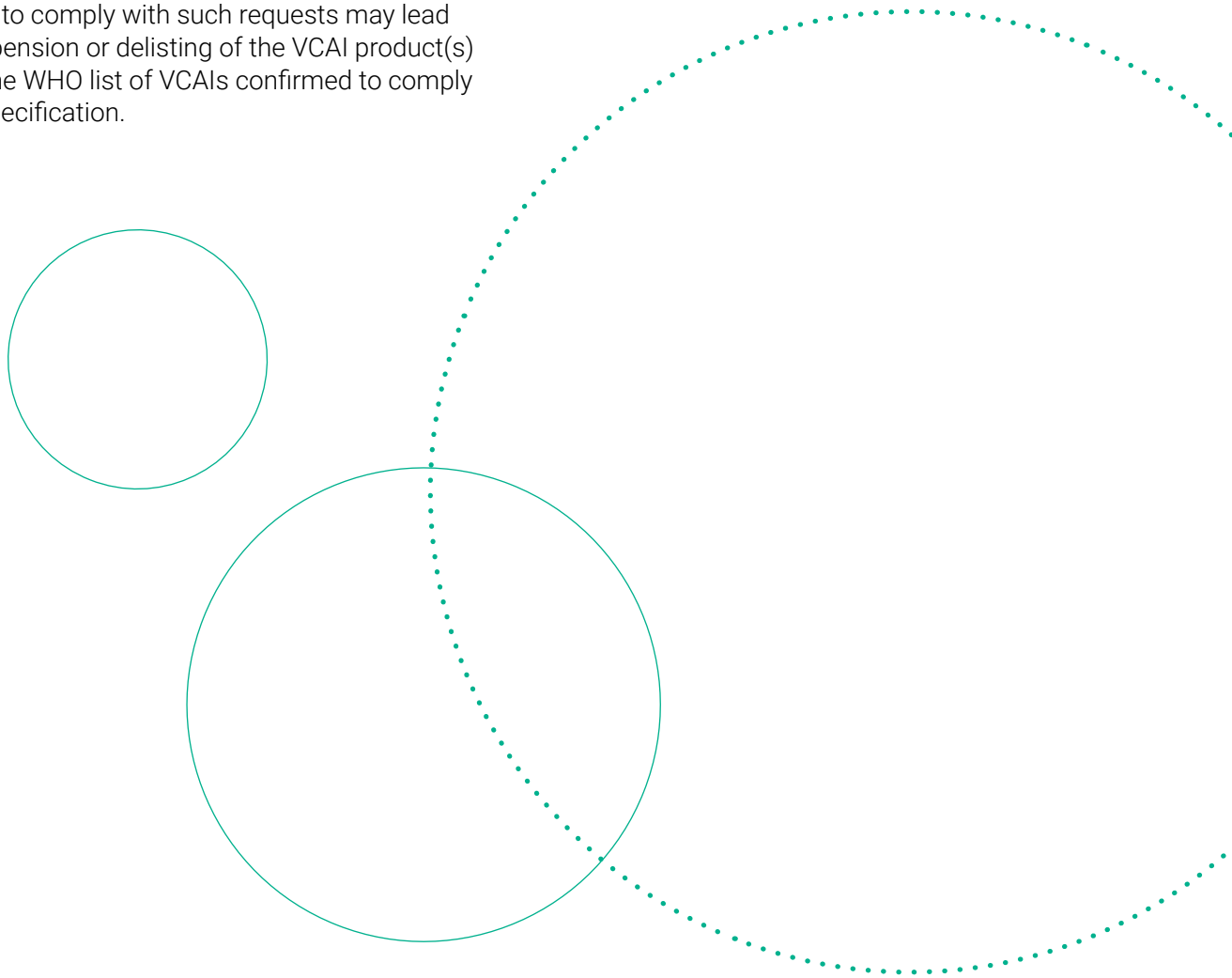
Manufacturers are required to provide all requested information within specified timelines. Failure to comply with such requests may lead to suspension or delisting of the VCAI product(s) from the WHO list of VCAIs confirmed to comply with specification.

10.7. VCAI product re-assessment

WHO may initiate a partial or complete re-assessment of a single VCAI product, resulting from:

- conclusions of a VCAI product review;
- submission of complaints and/or suspension of the listed VCAI product(s);
- inspection findings; or
- other relevant criteria.

Manufacturers are required to provide all requested information within specified timelines. Failure to comply with such requests may lead to suspension or delisting of the product(s) from the list of VCAIs confirmed to comply with specifications.



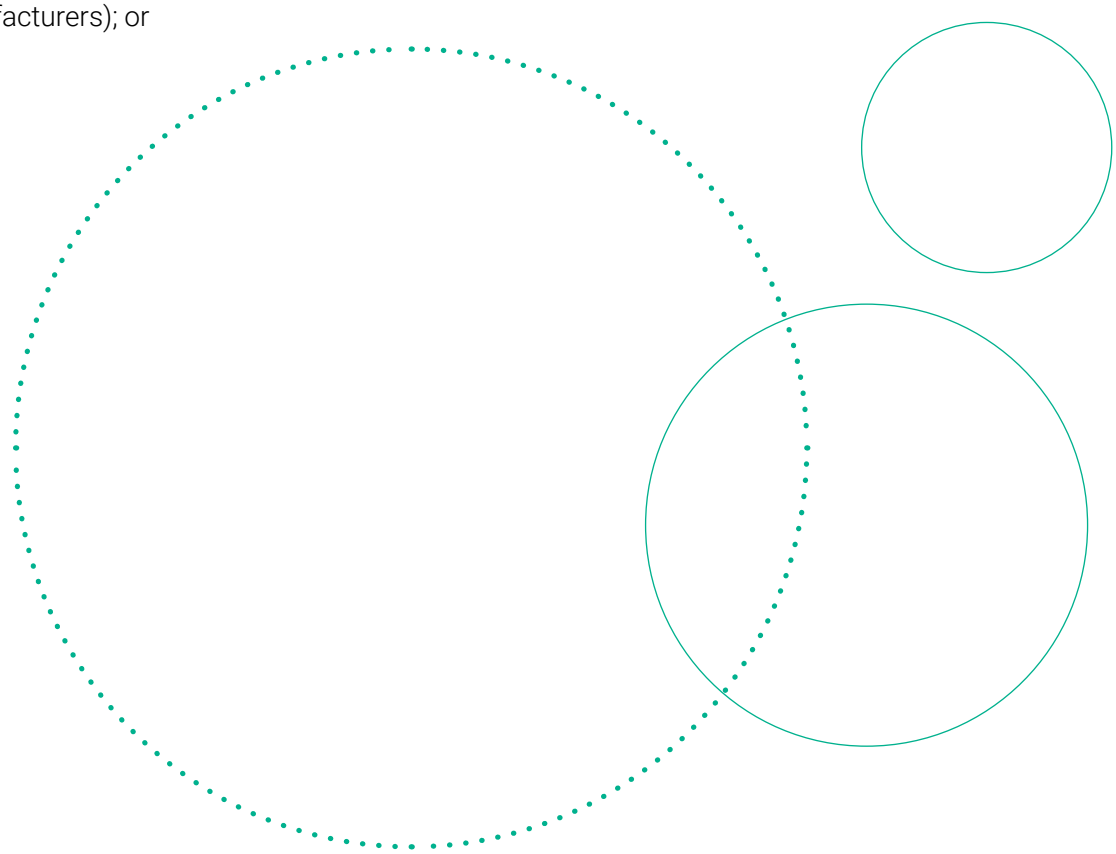
11. Confidentiality

WHO assessors, inspectors and the designated evaluating sites will treat all information to which they will gain access during the assessments and inspections, or otherwise in connection with the discharge of their responsibilities in regard to this assessment procedure, as confidential and proprietary to WHO or parties collaborating with WHO in accordance with the terms set forth below. WHO assessors and inspectors will take all reasonable measures to ensure that confidential information:

- is not used for any purpose other than the assessment and inspection activities described in this document; and
- is not disclosed or provided to any person who is not bound by similar obligations of confidentiality and non-use as contained herein.

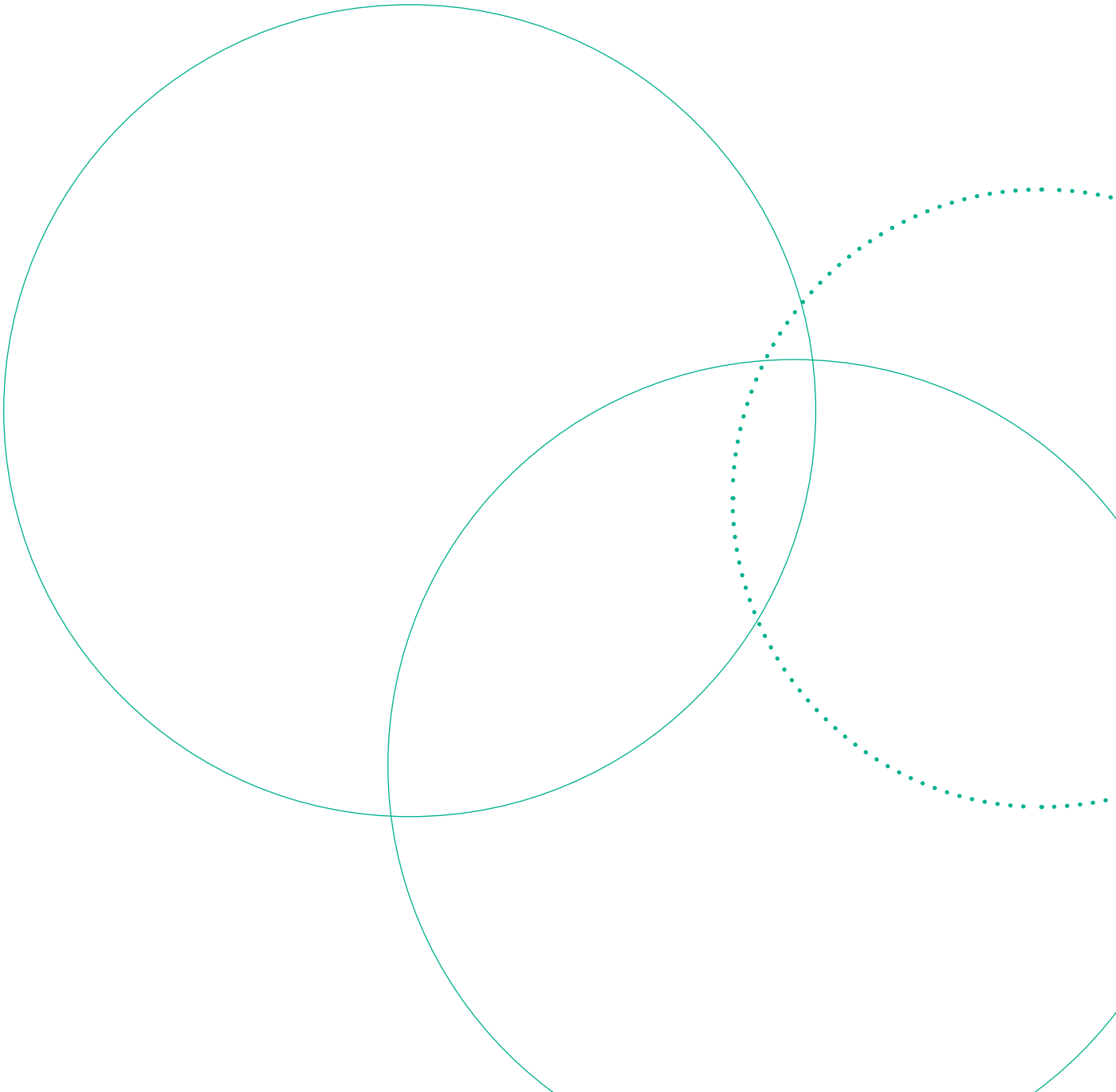
WHO assessors and inspectors will not, however, be bound by any obligations of confidentiality and non-use to the extent they are clearly able to demonstrate that any part of the confidential information:

- was known to them prior to any disclosure by or on behalf of WHO (including by the manufacturers); or
- was in the public domain at the time of disclosure by or on behalf of WHO (including by the manufacturers); or
- has become part of the public domain through no fault of theirs; or
- has become available to them from a third party not in breach of any legal obligations of confidentiality; or
- was subsequently and independently developed by or on behalf of WHO, as shown by written records, by persons who had no knowledge of such confidential information; or
- is required to be disclosed by law, provided that WHO shall in such case immediately notify the manufacturer in writing of such obligation and shall provide adequate opportunity to the manufacturer to object to such disclosure or request confidential treatment thereof (note, however, that nothing contained herein shall be construed as a waiver of the privileges and immunities enjoyed by WHO and/or to submit WHO to any national court jurisdiction).



12. Conflict of interest

Before undertaking the work, each external inspector and assessor will also (in addition to the above-mentioned confidentiality undertaking) be required to complete and sign the WHO Declaration of Interests Form. If, based on the above-mentioned declaration of interests, it is felt that there is no risk of a real or perceived conflict of interest (or it is felt that there is only an insignificant and/or irrelevant conflict of interest), and it is thus deemed appropriate for the assessor or inspector in question to undertake the work, then he/she will discharge his/her functions exclusively as adviser to WHO. In this connection, each assessor and inspector is required to confirm that the information disclosed by him/her in the declaration of interest is correct and complete, and that he/she will immediately notify WHO of any change in this information.



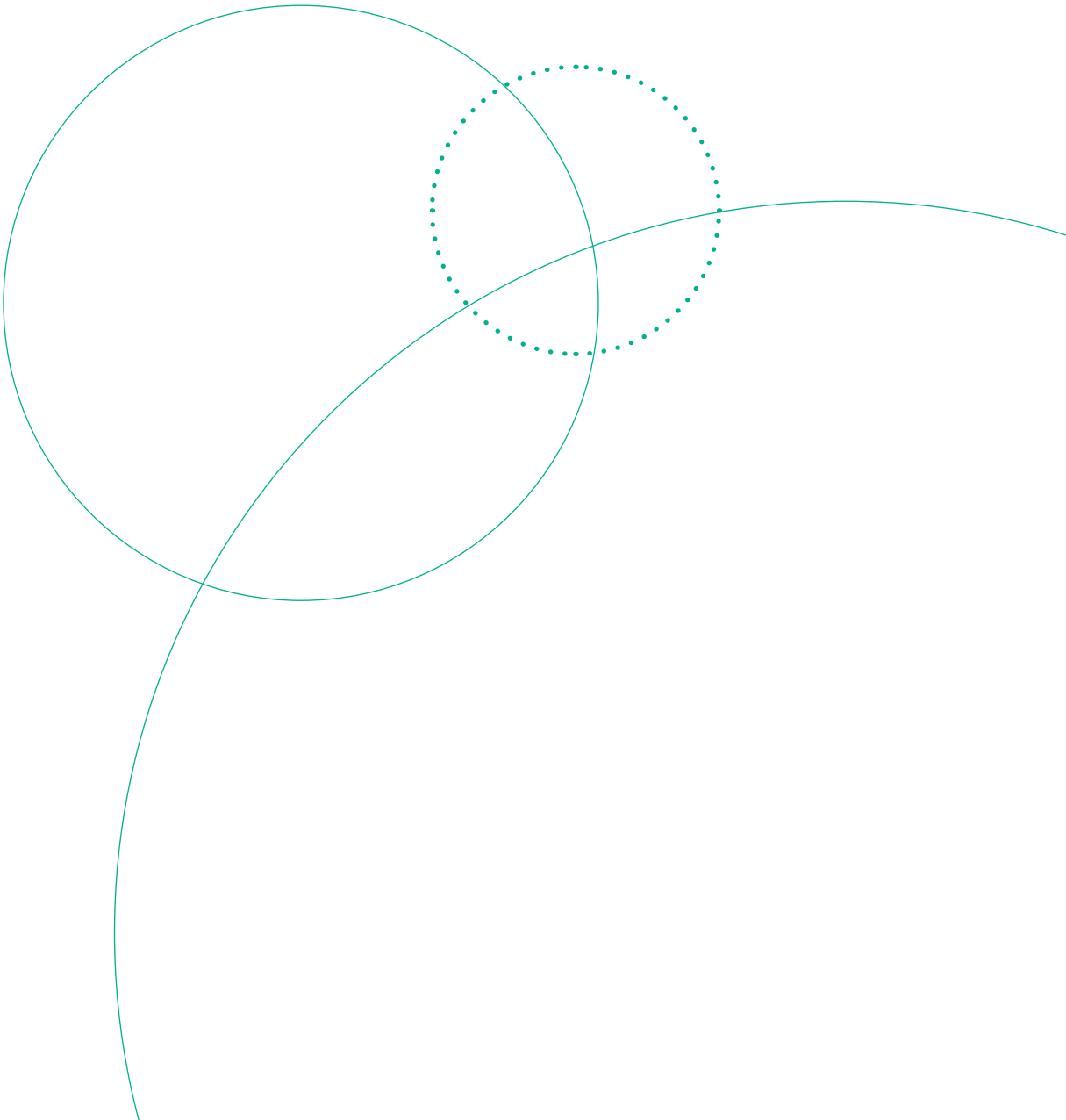
13. Disputes – privileges and immunities of WHO

In the event of any dispute or disagreement between the manufacturer and WHO arising from or relating to the assessment process, an SOP established by WHO for the handling of such disputes and disagreements will be followed to discuss and resolve the issue. By virtue of WHO's status as a specialized agency of the United Nations, WHO, its officials and experts performing missions for WHO (including for example, the prequalification assessors and inspectors) enjoy privileges and immunities under national and international laws and conventions, including the Convention on the Privileges and Immunities of the Specialized Agencies, adopted by the General Assembly of the United Nations on 21 November 1947 (the 1947 Convention). Nothing contained in or relating to this document or the assessment will constitute or be deemed as a waiver of any of the privileges or immunities which WHO, its officials and/or experts performing missions for WHO enjoy pursuant to the 1947 Convention or otherwise under any national or international law, convention or agreement, and/or as submitting WHO, its officials and/or experts aforesaid to any national court jurisdiction.

14. Further information

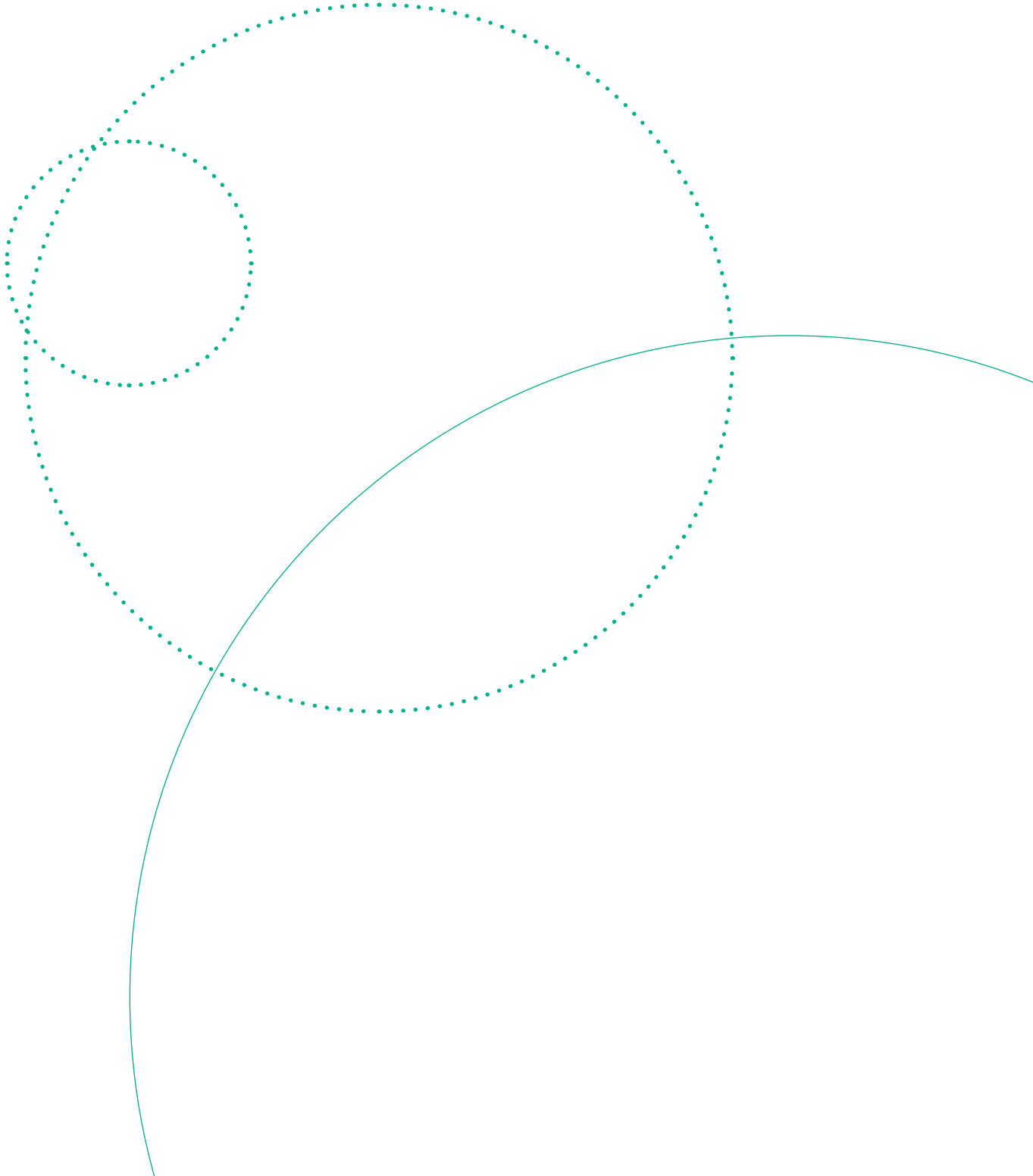
For further information about applying for assessment of VCAIs' compliance or prequalification of VCPs, the assessment process or PQT/VCP, please visit the following websites:

- WHO Prequalification: WHO specifications for pesticides
- WHO Prequalification: List of WHO service codes
- WHO Prequalification: Specifications list – new procedure
- WHO Prequalification: Specifications list – old procedure
- WHO Prequalification: Specification templates for proposers
- Manuals on development and use of FAO and WHO specifications for pesticides
- WHO Prequalification: Advice to manufacturer series
- WHO Prequalification: Vector Control Products



15. Contact information

Any enquiries regarding WHO assessment of VCAI compliance, specification requirements or extension of specifications for VCP source material(s) should be addressed to: pqvectorcontrol@who.int.



16. Definitions

Active ingredient (AI)	The ingredient of a product formulation providing the pesticidal action.
Applicant	The party who submits an application for VCAI assessment.
Contract research organization	An organization (commercial, academic, or other) to which an applicant may transfer some of its tasks and obligations in relation to the conducting of studies to generate data for the product dossier.
Good laboratory practices	A quality system concerned with the organizational process and the conditions under which nonclinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported.
Manufacturer	Any party with responsibility for the production of a VCAI with the intention of making the VCAI available for use in the formulation of VCPs, under the party's name, whether such a VCAI is designed and/or manufactured by that party or on behalf of another party.
National regulatory authority (NRA)	The government agency or agencies responsible for regulating public health pesticides and/or VCPs.
Pest	Any destructive organism (including insects and other arthropods, molluscs, plants, etc.) that acts as a vector of human or animal disease, creates nuisance conditions or causes harm to or otherwise interferes with the production, processing, storage, transport or marketing of food, agricultural commodities, wood and wood products or animal feed stuffs.
Pesticide	Any substance, mixture of substances, microorganism (including viruses), biological agent or device intended to repel, destroy or control a pest.
Screening	A systematic process to ensure all sections of the dossier/application have been submitted.
Site master file	A site-specific dossier provided by the manufacturer detailing information necessary for inspections of the manufacturing facility.
Synergist	The ingredient of a product formulation providing the synergistic effect to enhance the efficacy of the active ingredient(s).
VCAI dossier review	Review and assessment of documentation, including data, protocols, reports, procedures, etc., submitted to support the VCAI product for the purpose of WHO assessment.
VCAI inspection	Inspection (where needed) of the manufacturing site(s) of manufacture of a VCAI source material(s) undergoing or having undergone assessment.
Vector control active ingredient (VCAI)	Active ingredient(s) and/or synergist(s) used in the formulation of VCPs. VCAIs are generally technical materials or technical concentrates. In some case formulated intermediates (e.g. soluble concentrates) may be considered VCAIs.
Vector control product (VCP)	A product used to control vectors of disease, which has undergone all stages of manufacture, including packaging and labelling.

World Health Organization
Avenue Appia 20
1211 Geneva 27
Switzerland

WHO Prequalification of Vector Control Products:
https://extranet.who.int/pqweb/vector-control-products