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WHO Prequalification of Vector Control Products

Procedures for the Pilot of the WHO programme for Quality Assurance of Modified Mosquito Production

July 2026

1. Introduction

In recent years there have been significant advancements in the field of mosquito modification aimed to prevent or interrupt the transmission of mosquito-borne diseases. A variety of intentional modifications have been developed resulting in such examples as mosquitoes which carry a bacterial infection, sterilized mosquitoes, and those mosquitoes which carry alterations of their genetic code.

Considering the spectrum of potential products, which may range from continuous/seasonal releases to those which could result in complete population replacement or eradication from a single release, Member States will look to WHO for guidance well in advance of epidemiological data and full WHO recommendations becoming available. As such, there is an inherent need for WHO to consider an approach that would enable the assessment of the quality and capability for performance of products in advance of the demonstration of the potential epidemiological impact.

2. Proposed WHO Quality Assurance Mechanism for Modified Mosquito Production

The WHO Quality Assurance Mechanism for Modified Mosquito Production (QAM) is a proposed regulatory mechanism specifically developed to address growing needs for quality assessments and manufacturing site audits of modified mosquito products which may be intended for use in public health programs to reduce the transmission of vector borne diseases.

The purpose of the QAM is to establish an independent assessment by WHO of modified mosquito products (MMPs) and their manufacturing facilities to support Member States and other UN bodies.

It has been determined that the WHO prequalification team responsible for the assessment of vector control products is uniquely positioned to address the global need

for quality assessments and manufacturing site compliance audits in relation to the production of modified mosquitoes.

The QAM differs from the established procedures for prequalification of vector control products in two distinct ways.

- Whereas the prequalification assessment of VCPs results in a prequalification listing of the proposed product, the QAM results in a certification of the declared manufacturing site supported by the finalized quality assessment and inspection reports. These reports provide public disclosure by WHO that the declared manufacturing site has demonstrated the ability to produce the declared product in a consistent manner in accordance with the declared quality standards.

- Whereas the prequalification assessment of VCPs includes a full evaluation of quality, safety, and efficacy of a proposed product, the QAM is solely focused on the quality and manufacturing controls of the proposed modified mosquito product (MMP) as produced at the declared manufacturing site(s).

  The quality assessment is supported by an on-site inspection for the review of the quality management system (QMS) established in accordance with GMP, or other standard, as deemed appropriate based on the type of modification and regional, national, and/or local requirements.

  The QAM does not include an assessment of the safety nor efficacy of the product in operational deployment.

3. Intent of the pilot

In the development and advancement of a new regulatory mechanism and new regulatory requirements, a pilot of the proposed programme is a common approach across regulatory bodies which enables the responsible organization to test the approach before officially launching a new programme.

The pilot of the QAM will enable WHO to engage with prospective commercial manufacturers of modified mosquitoes and validate the proposed assessment and inspection requirements as well as the potential outcomes of the procedures.

In implementing this pilot, WHO does not intend to publish any assessment reports, nor officially certify any manufacturing sites. However, WHO may rely on its assessments and reports, as well as the information submitted by manufacturers to support the certification of manufacturing sites if, based on the outcomes of the pilot, the QAM is fully implemented as a programme within the Prequalification Unit of WHO.

4. Procedures for the QAM pilot

4.1. Open call for applications

WHO will announce a call for Expressions of Interest (EoIs) to be submitted by the legal manufacturer who are interested in voluntarily participating in the pilot of the QAM programme. The EoI will establish the manufacturer's anticipated participation and in the pilot and the target date for submission of a complete application with supporting dossier.

The call for EoIs will remain open for 12 months from the date of initiation. As determined by WHO, the duration of the call for EoIs may be extended.

4.1.1. Legal manufacturer

An EoI and application for the pilot QAM is accepted only from the legal manufacturer of the MMP. The legal manufacturer of the MMP is the entity which is entirely responsible for the manufacturing of the MMP.

It is recognized that there are organizations/entities developing MMPs which do not intend to become the commercializing entity of the MMP. In the context of the pilot of the QAM, these organization/entities, as the current legal owner and producer of the product, are eligible and encouraged to participate in the pilot as their engagement would ultimately support the regulatory knowledge base of those entities to which the MMP(s) ownership is transferred for commercialization.

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 MMP is manufactured at the declared manufacturing site and in accordance with the information provided to WHO to support the assessment.

4.1.2. Use of authorized agents

Legal manufacturers of MMPs may rely on an authorized agent to submit EoIs and applications to WHO for the pilot of the QAM 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 application(s) to which the authorization applies.

4.2. Eligibility for participation in the pilot QAM

All manufacturers of MMPs are products intended for use in public health programmes are eligible to submit an EoI to WHO. Based on the information provided in the EoI, WHO will determine if the proposed MMP and manufacturing site are eligible for inclusion in the pilot. This determination will be dependent upon the type of modification, intended mechanism and impact of the MMP, stage of product development, target timeline to application submission, and any other criteria as determined by WHO upon receipt of the EoI.

4.3. Invitation to submit an application

Upon determination of eligibility to participate in the pilot based on the WHO review of the EoI, WHO will officially invite the legal manufacturer to submit a complete application and dossier. The invitation will include the target date of submission as proposed by the manufacturer in the EoI.

The target timeline for submission may be amended at the request of the manufacturer.

WHO reserves the right to, at any time, withdraw the invitation for submission of an application. If the invitation is withdrawn, WHO will inform the manufacturer and provide an explanation for the decision.

Prior to the submission of the application, the manufacturer may request a pre-submission meeting(s) with WHO for further guidance on the generation of supporting information and compilation of the dossier based on the available published guidance.

Where applicable, the manufacturer may also submit a PQ200 Protocol Review Application for studies of relevance to the product dossier. WHO will review the proposed protocol(s) and provide advice to be considered by the manufacturer. Note: WHO does not approve testing protocols. The manufacturer may choose to incorporate the feedback provided, if appropriate. The review of testing protocol(s) and considerations provided do not have any impact on the review of the data/information generated using the reviewed protocol. The review of submitted protocol(s) does not guarantee, nor have any bearing on the acceptability of any generated data/study reports, nor the assessment of the product.

4.4. Submitting an application

The manufacturer is required to contact WHO prior to submission of their application to ensure that the application is submitted in a manner which protects the confidentiality and sensitivity of the information being transmitted to WHO.

In the context of the QAM pilot, WHO will accept rolling submissions. In such cases, the manufacturer must provide clear information about the outstanding dossier requirements and timelines for the missing information to be submitted.

4.5. Dossier Assessment

Once the product dossier has been received by WHO, it will be screened for completeness by WHO staff before being reviewed. This screening is aimed at ensuring that all requisite sections of the product dossier have been submitted and if dossier requirements are missing that a clear timeline is provided for their submission. The screening does not take into consideration the technical appropriateness of all the information provided in the product dossier.

If the application is incomplete, the manufacturer may be informed in writing that an incomplete application has been received and be requested to provide the necessary information to complete the dossier. Alternatively, in cases where 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 must provide a new target timeline for submission of the application. As per section 4.3 WHO reserves the right to withdraw the letter of invitation if it is determined that a viable dossier cannot be submitted in a timely manner. A new application will be considered without prejudice.

If an application is found to be complete, the application will be accepted for assessment, and WHO will inform the manufacturer in writing. Additionally, and before the assessment of a 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 QAM pilot assessment process, and (ii) as the manufacturer's acceptance of and commitment to comply with the provisions of the pilot QAM assessment process.

For applications which have been accepted for assessment, the information submitted in the application will be assessed by WHO staff and 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 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. If needed, WHO may provide training to the assessors.

The assessment of prequalification applications will be conducted as per the criteria outlined in the document, "Data requirements and technical considerations for a quality assurance mechanism for modified mosquitoes" and the available supporting implementation guidance documents.

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. WHO may request that a corrective action plan that details 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 prequalification assessment procedure is usually suspended (WHO will not undertake any further action) until a complete response has been submitted by the manufacturer.

The manufacturer may request a hearing or meeting with WHO to clarify issues identified during the assessment.

For the purposes of the pilot, WHO will share its assessment reports with the manufacturer. The manufacturer is not authorized to share or distribute the WHO assessment report without prior written consent from WHO. WHO will not publish its assessment reports.

4.6. Manufacturing site 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 MMP(s). The following factors will be considered when planning inspections:

- results of previous inspection(s) by WHO or an NRA and history of compliance of the company or facility with WHO-recommended standards;
- outcome of the assessment of the dossier 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.

The inspections of the manufacturing site(s) are conducted to assess compliance with WHO-recommended quality standards identified as Good Manufacturing Practices (GMP), or other standard, as deemed appropriate based on the type of modification and regional, national, and/or local requirements. The initial inspection of the manufacturing site will be performed in two stages. The stage 1 inspection, usually a desk audit, 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) will be reviewed during the stage1 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 in writing.

The stage 2 inspection will comprehensively evaluate the effective implementation of the quality management system and production processes through an on-site(s) inspection.

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.

For the purposes of the pilot, WHO will share its inspection report, including the graded nonconformities, with the manufacturer. The manufacturer is not authorized to share or distribute the WHO inspection reports without prior written consent from WHO. WHO will not publish its inspection reports.

Manufacturers are expected to respond to the inspection report by indicating suitable corrective and preventative actions addressing the root cause of each nonconformity, as well as any other actions taken as a result of the WHO inspection.

4.7. Closure of the application in the QAM pilot

Upon completion of the assessment and inspection processes, and after sharing the WHO reports with the manufacturer, WHO will schedule a closing meeting with the manufacturer. During the closing meeting, WHO and the manufacturer will have the

opportunity to present their findings from the QAM procedures, data and dossier requirements, assessment and inspection processes, and overall feedback.

This meeting will constitute the closing of the application case.

The feedback provided by the manufacturer and experience of WHO will be included in the WHO evaluation of the pilot of the QAM procedures and requirements. This evaluation will support the determination for advancement and launch of a full QAM process, as well as amending the procedures and requirements.

5. Cancellation of the QAM application

WHO reserves the right to cancel an application at any time or stage of the pilot QAM assessment procedure if:

- the dossier does not contain all of the required information or does not meet WHO prequalification 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 information supplied is inadequate to complete the assessment in a timely manner.

After cancellation, the manufacturer may request to re-apply if WHO has not withdrawn the invitation for submission of an application as per Section 4.3.

After cancellation, WHO may request a closure meeting as described in Section 4.7. Manufacturers, having submitted an application, are expected to participate in the closure meeting.

6. Withdrawal from the QAM assessment procedures

WHO provides the manufacturer with the right to withdraw its application for the QAM pilot at any time. To exercise this right of withdrawal, the manufacturer must provide WHO with written notice specifying the application(s) to be withdrawn.

After withdrawal, the manufacturer may request to re-apply if WHO has not withdrawn the invitation for submission of an application as per Section 4.3..

After withdrawal, WHO may request a closure meeting as described in Section 4.7. Manufacturers, having submitted an application, are expected to participate in the closure meeting.

7. Confidentiality

WHO assessors and inspectors 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 QAM 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).

8. 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.

9. 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 prequalification 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 UN, 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 prequalification 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.