Current requirements to support Quality component of the PQ vector control product application

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FAO/WHO Definition of specification

• “The parameters and criteria defining the physical appearance and physical and chemical properties of technical and formulated pesticides”.

Source:
Reference Specification

- The current published specifications for a pesticide adopted according to WHO/FAO evaluation process.

- Reference specifications are subject to review.
Consideration for TC/TK Specifications

• Minimum purity of the AI in a technical grade active ingredient together with the identity and maximum concentration of all impurities –including unknowns-.
• Impurity limits range 0.1 to 1 g/Kg
• Impurity profile should be representative of the production process
• Minimum purity of AI and relevant impurities concentration are published in the specification
• The information on non relevant impurities and production process is kept confidential
Methods:

- Use certified and validated methods
- CIPAC/AOAC/MT/ISO methods
- Methods must be peer-validated, all supporting information must be provided
- Multiple batch replicates are required for physical chemistry data
- Data from GLP laboratory
Formulated Products:

- Description of the product and formulation type
- Confirmation of source AI from WHO/FAO certified
- Active ingredient content
- Physico-Chemical data based on formulation type
- Relevant impurities
- Storage Stability
Submission to JMPS:

- WHO PQT VC is the single point of entry for JMPS FAO/WHO specification evaluation process.
- Submission should be done through MedNet.
- PQT VC is responsible for screening the JMPS submissions.
- PQT VC is responsible for communicating information from JMPS evaluation to manufacturers (e.g. request for additional data or final decision).
WHO Specifications following the New Procedure

https://www.dropbox.com/sh/5gf6dirqt2c1yfn/AADvA8188fTNJwvFM4Q-Pyyla/WHO%20Specifications%20following%20the%20New%20Procedure?dl=0&subfolder_nav_tracking=1
Questions