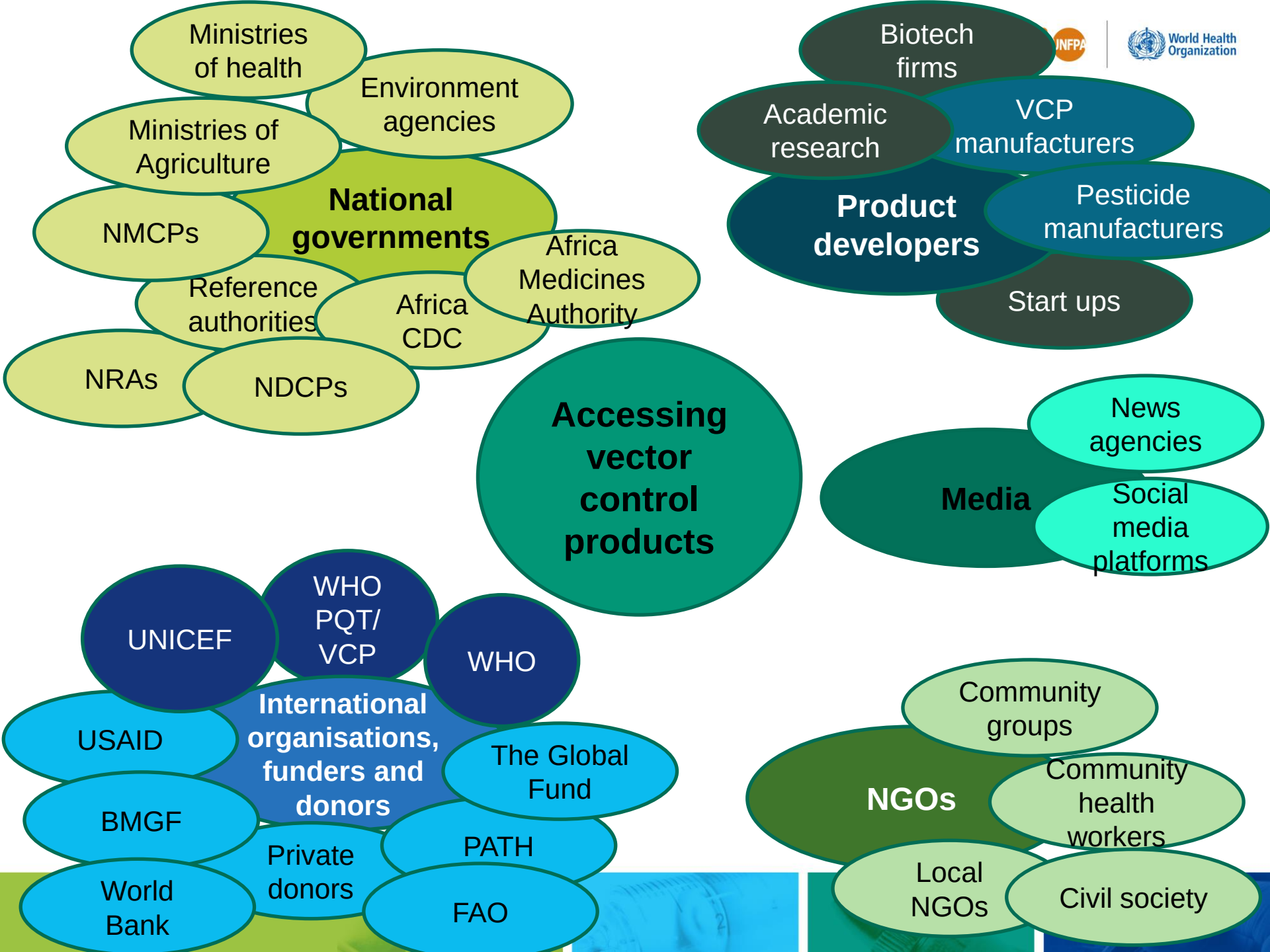
PQT/VCP Updates for the Joint UNICEF-UNFPA-WHO Meeting with Manufacturers and Suppliers

3 December 2024

Vector Control Product Assessment Team
World Health Organization

Partnerships

Ensuring Health Equity: Partnerships For Accessible Quality Products


Ministries of health
Environment agencies
Ministries of Agriculture
National governments
NMCPs
Reference authorities
Africa CDC
Africa Medicines Authority
NRAs
NDCPs
Biotech firms
Academic research
VCP manufacturers
Product developers
Pesticide manufacturers
Start ups
Accessing vector control products
News agencies
Media
Social media platforms
UNICEF
WHO PQT/ VCP
WHO
USAID
International organisations, funders and donors
The Global Fund
BMGF
PATH
Private donors
World Bank
FAO
Community groups
NGOs
Community health workers
Local NGOs
Civil society

Agenda

- General Updates, Submissions and KPIs, Prioritization of guideline development, Workplan for 2025
- Who does what!? - Mapping assessment and advisory groups in VC
- PQ Dossiers - Partnerships, reliance, and recognition before and after
- ePQS Portal – Status of pilot and development of guidance

General updates

Accomplishments 2024

Team, assessments, and communication

- ✓ Staffing
- ✓ Two vector control products assessors (ASVCP) meetings in 2024 (March and November), next planned for March 2025.
- ✓ Open call for applications and expansion of ASVCP roster
- ✓ Continued to engage the best experts in the field
- ✓ Open call for applications for TAG-VCPR
- ✓ Managed submission workload and timely advancement of assessments
- ✓ Continuation of communication tools and approaches
- ✓ Internal launch of ePQS, pilot for submission portal, preparation for external "Go Live" rollout
- ✓ Expansion of Departmental, Unit and Team QMS

Accomplishments 2024

Guideline and guidance

- ✓ WHO Guideline for prequalification assessment of ITNs and corresponding implementation guidance – mid-term and long-term goals
- ✓ Expansion of Advice to Manufacturer Series (AMS)

Joint Meeting on Pesticide Specifications (JMPS)

- ✓ One online panel session (end of year) and one in person session (June) to progress with the evaluation schedule
- ✓ 16 active ingredient specification documents published in 2023 and 9 more published/to be published in 2024, including new specifications, new sources (extensions), multiple change applications (new sites and transfer of ownership), and other updates.

Accomplishments 2024

- ✓ Publication of the chemical manual and translated versions
- ✓ Publication of the microbial manual, translated versions coming
- ✓ Publication of revised specification templates for technical materials (chemical and microbial), formulated chemical and formulated microbial products
- ✓ Development of operations manual (live internal document)
- ✓ Renewed MoU FAO-WHO. Joint FAO/WHO TORs for JMPS (in progress).
- ✓ Preparation for Open Call for JMPS experts (wide expertise, geographic distribution)
- ✓ Overview of the WHO Assessment of Vector Control Active Ingredients (in preparation) to be implemented such as Overview of the WHO Prequalification Assessment of Vector Control Products

Accomplishments 2024

Collaborations with countries and partners

- ✓ CIPAC – Joint open meeting
- ✓ Collaborative Registration Procedures (CRP) pilot interest and kick-off meetings
- ✓ AUC, ALMA, NEPAD, i2i – Joint Vector Control Registration Consultation meeting
- ✓ RBM - Vector control working group
- ✓ Engagement with Regions : PAHO - Meeting with PAHO, ANVISA, Brazil Ministry of Health

Assessment session for vector control products (ASVCP)

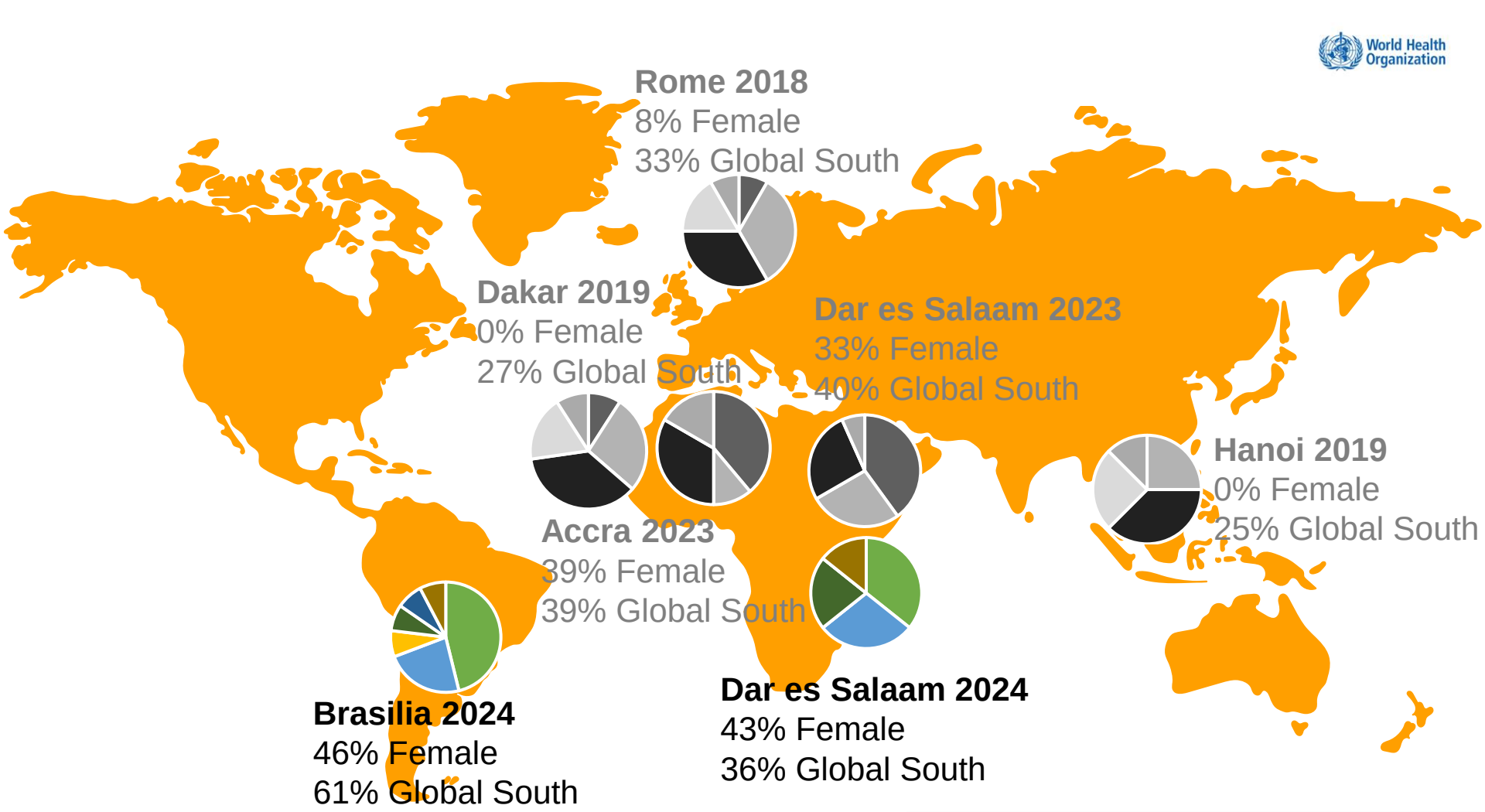
- 2 assessment sessions held in 2024: March (Dar es Salaam, Tanzania), November (Brasilia, Brazil)
- New strategy for ASVCP meetings – rotation among WHO offices

Regional rotation of ASVCP meetings

- Engage with regional offices to plan ASVCP meetings
  - 2024 – AFRO, AMRO/PAHO
  - 2025 – WPRO, EMRO
  - 2026 – SEARO, EURO
- Generate opportunities for engagement with regional/country offices and local authorities

Regional rotation of ASVCP meetings

- 2024.2 ASVCP in Brasilia – Engagement day
  - Eighteen participants - Representation from PAHO Washington DC, OPAS Brazil country office, ANVISA, Brazilian Ministry of Health
  - Outcomes:
    - Increased awareness of
    - PQT/VCP purpose, processes, and requirements
    - ANVISA supporting legislation, processes, and requirements
    - MoH VC programs, implementation strategies/challenges, pursuit to deploy novel strategies (e.g. modified mosquitoes) all within the social/environmental contexts and disease pressures/burden in Brazil
    - PAHO/OPAS role in procurement and support to MoH in supply of VCPs and QA mechanisms



WHO regional representation 2019 - 2023

AFRO AMRO
EMRO EURO
SEARO WPRO

WHO regional representation 2024

AFRO AMRO
EMRO EURO
SEARO WPRO

Image by Freeimages.com

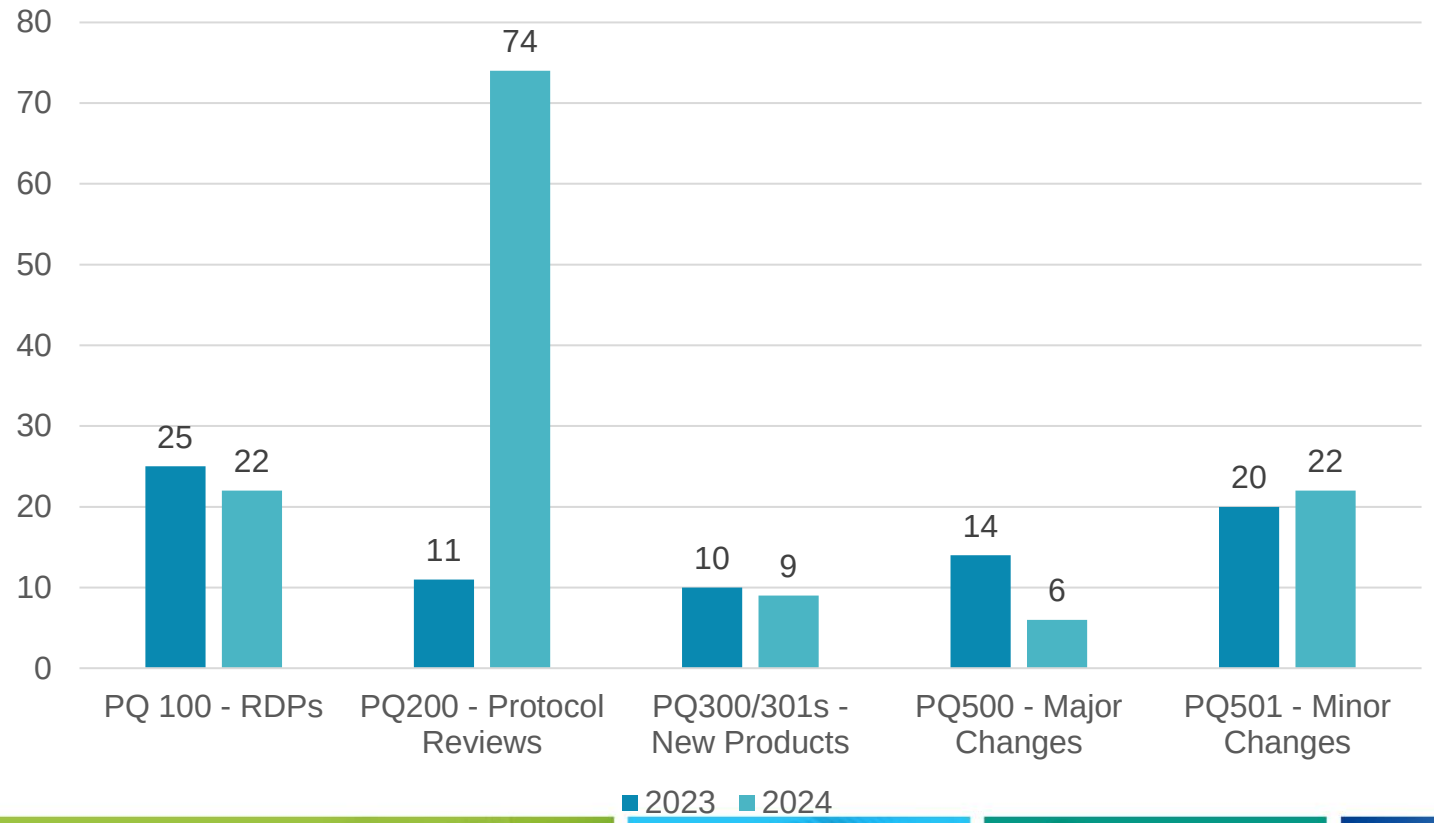
Assessor statistics (%)			
Female assessors	43	Global South	48

Image by Freeimages.com

Submission Statistics and KPIs

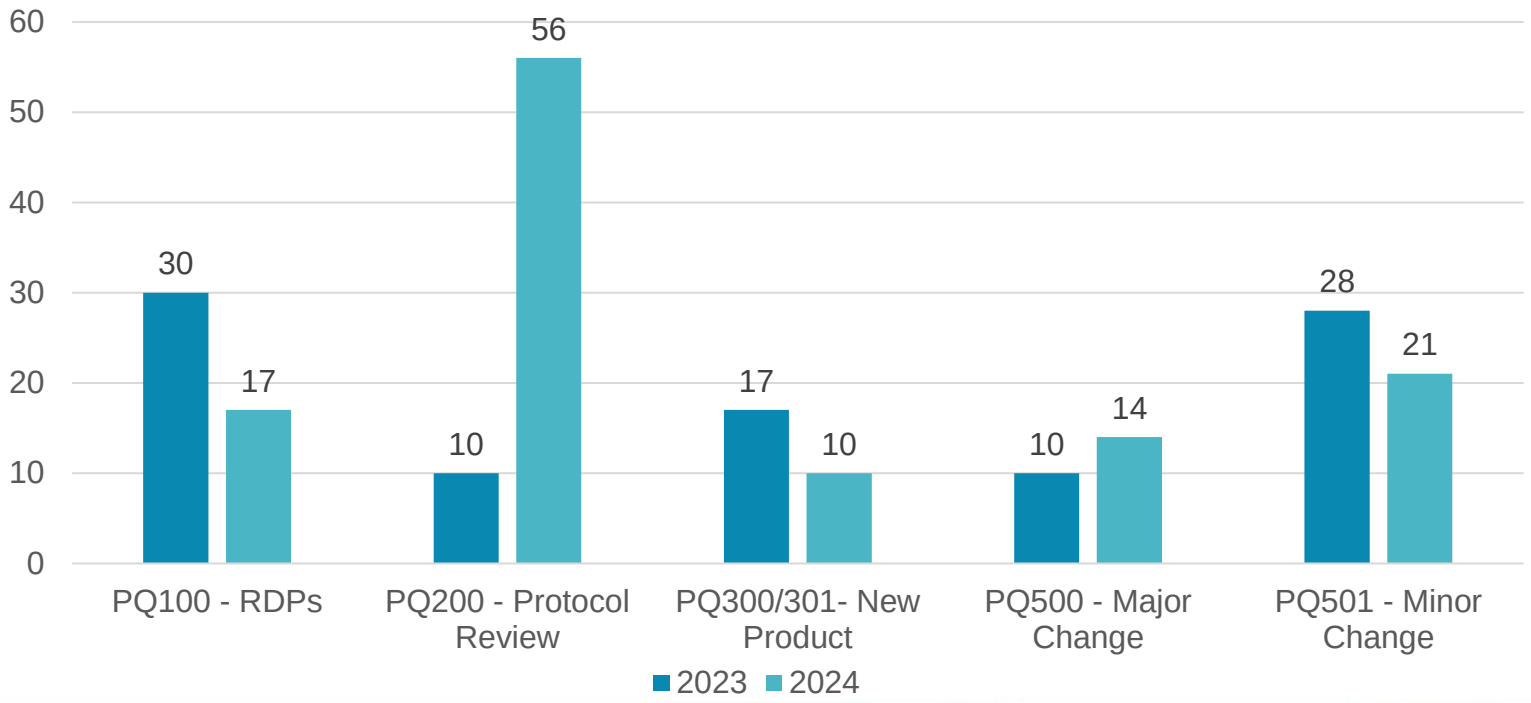
Submissions Received

80 applications received in 2023 and 133 in 2024 (as of 26 Nov)



Applications Closed in 2023-2024

95 applications closed in 2023 and 118 in 2024 (as of 26 Nov)



Key Performance Indicators – New product assessments

- Submission cohort based on date accepted for assessment:
  - 2023/2024 – 3 products prequalified (avg 209 days)

- Decision cohort:
  - 2023 – 4 products prequalified (avg 443 days)
  - 2024 – 6 products prequalified (avg 359 days)

<u>Increasing decisions and decreasing timelines</u>

Key Performance Indicators

- Dossiers **screened** in specified KPI timelines:
  - 11 dossiers submitted in 2024, 100% screened in target timeline (60 days)

- Assess **changes** to prequalified products:
  - 21 minor changes closed in 2024 – 100% met KPI of 90 days (avg 19 days)
  - 16 major changes closed in 2024
    - 7 accepted - 100% met KPI of 90 days
    - Backlog cleared – 7 withdrawn, 2 accepted

Key Performance Indicators

- Proportion **VCP PQed** ≤ WHO target time (365 days)
  - Decision cohort closed in 2024 – 50%
  - Submission cohort (2023/24) closed in 2024 – 100%
  - Increased from 25% in 2023

- Proportion of **VCP PQed 1st actions** ≤ target time (180 days)
  - Decision cohort 2024 – 83%
  - Increase from 75% in 2023
  - Pending product submitted 2023/24 – 100%

Key Performance Indicators

- Proportion of **Determination of Pathway submissions** completed ≤ WHO target time (90 days)
  - Decision cohort closed in 2024 – 62%
  - Submission cohort (2024) closed in 2024 – 92%
  - Increase from 48% in 2023 based on process improvement and PQT/VCP support to NTD and GMP

- Proportion of **Study Protocol submissions** completed ≤ WHO target time (90 days)
  - Decision cohort 2024 – 93% (Avg time 43 days)
  - 2023 – 6 applications received/closed
  - 2024 – 74 applications received to date, 56 closed
  - 1,133% increase in applications due to ITN guideline implementation plan

Discussion points

- Opportunities for improving quality of submissions, e.g.:
  - Complete and up-to-date Table of Contents
  - Finalized documents (e.g. internal notes/track changes removed)
- PQT/VCP is not your technical adviser nor consultant
- Resubmission of protocol reviews (PQ200)
- Communication between Mfr and CROs can be strengthened – Mfr ownership and accountability of submissions
- Assessment phase vs decision phase in the PQ process
- Capacity building - Opportunities for engagement in open fora
- ePQS portal – will give additional visibility to status, e.g. phase of process
- Clear commercial strategy

Prioritization of guideline development

Guideline(s) plan(s) – WHO Guideline for the prequalification assessment of insecticide treated nets

- Community studies protocol:
  - Designed to provide the necessary information for applicants to conduct studies previously conducted by WHOPES (Phase III)
  - Changes/additions from WHOPES protocol
    - Sample size calculations based on attrition as primary endpoint
    - Semi-field study for estimation of entomological efficacy
    - Reduced sampling timepoints
    - WRI/Surface AI estimation as part of quality testing
  - Circulated on PleaseReview platform

Guideline(s) plan(s) – WHO Guideline for the prequalification assessment of indoor residual spraying products

- Preliminary data assessment complete
- Call for information issued to manufacturers of prequalified IRS products August 2024
- Product review planned Q1 and Q2 2025
- Convening of working group planned for July 2025
- Expected publication December 2026

Information to include in response:

1. Cover letter

   - Indication of submission in response to this letter to support the WHO PQT-VCP Product Review for IRS Products

2. Declaration of Labelling

   - The labelling information submitted to WHO in support of the evaluation of a product is referred to as the Declaration of Labelling (DOL). A guidance document and example DOLs can be found here: https://www.who.int/pq-vector-control/resources/en/

   - In addition to existing guidance on the Declaration of Labelling, applicants are encouraged to include the following information for each surface type intended to be treated (substrate) on their submitted DoLs:
     - Surface Type (including characterization such as porous/non-porous)
       - Target application rate (mg/m^2)
       - Spray mix concentration (mg ai/mL)
       - Volume of spray mix to be applied ($ml/500m^2$)
       - Residuality
       - Any other relevant information

3. Information pertaining to the development and design of IRS products which may be considered when identifying target substrates on which the product is intended for use (e.g. selection of formulation type [WP, SC, CS, WG] and formulants):

   - Data on the impact of the physical and chemical properties of substrates on product performance
   - Data on the impact of physical and chemical variations within substrate types on product performance

4. Details of any bioassay methods developed to support the demonstration of characteristics of product performance.

5. Details of any chemical analysis methods developed to characterise the availability/presence of active ingredient(s) on surfaces.

Guideline(s) plan(s) – WHO Guideline for the prequalification assessment of aircraft disinsection products

- Planning underway; awaiting outcome of expert consultation
- Expected publication December 2025

Guideline(s) plan(s) – WHO Guideline for the prequalification assessment of larvicide products

- Experts identified
- Expected publication December 2026

Looking ahead to 2025

2025 – Focus of workplan

- Prequalification applications
- TAG-VCPR
- Guidelines
- Vector Control Active Ingredients (VCAIs)
  - VCAI Overview document – Procedures for WHO
- JMPS
  - Submissions
  - Joint Terms of Reference
  - Open call for experts
  - Operations Manual
- Supporting expansion of CRP
- ePQS – full implementation
- Continued communication and advocacy

2025 Events and meetings – where to find us

- February – ASVCP Quality convening (Switzerland)
- March - RBM – Vector control working group (VCWG, Benin)
- March – Vector Control Advisory Group (VCAG, Virtual)
- March – ASVCP meeting (Manila)
- April – Gender mainstreaming consultation (Switzerland)
- June - Joint Meeting on Pesticide Specifications (JMPS, Ireland)
- September/October – VCAG (Switzerland)
- October – ASVCP meeting (EMRO)

Fee for service (FFS) analysis

- PQ-wide initiative to look at fees structure
- No timeline established for implementation of fees for VCP
- Opportunity to develop and analyze different models which could be appropriate FFSs for VCP

- With the potential of application fees in the horizon, VCP will be:
  - Reviewing service codes – Relevance, clarity, granularity
  - Developing clear guidance on pre-submission activities and screening procedures to support strong dossiers

Update of procedures and service codes

- With the fees analysis, we will revisit our service code structure to better serve the type of submissions we are seeing and expect to see in the coming years
  - P500 series – Change Applications – redefine change applications which involve significant scientific assessment such as a new application rate or use pattern
  - P200 – Protocol Reviews – add a “resubmission of protocol” code to be used for infrequent reviews of protocols where significant reworking was necessary based on initial comments

Update of procedures and service codes

- - Discussion –
- Which manufactures are familiar with regulatory FFS systems? Impression? Benefits/Limitations?
- What would you see as opportunities within a FFS for VCPs?
- What would you see as challenges within a FFS for VCPs?

Agenda

- General Updates, Workplan for 2025, Prioritization of guideline development
- Who does what!? - Mapping assessment and advisory groups in VC
- PQ Dossiers - Partnerships, reliance, and recognition before and after
- ePQS Portal – Status of pilot and development of guidance

Advisory groups

Advisory Groups

- Groups of individual experts convened by the WHO Secretariat to provide technical and/or scientific and/or strategic advice to WHO.

- AGs are established by the WHO Secretariat and composed of external experts acting in a personal capacity (and not representing any external entity, authority or government). They generally advise WHO on technical and/or scientific matters on an identified subject matter, but in some cases, may also provide strategic advice.

Advisory Groups

- Different from:
  - WHO expert committees Groups
  - Hearings, consultations or other meetings with representatives of non-State actors
  - One-off meetings for exchange of information involving individuals, and/or representatives of non-State actors, and/or representatives of Member States to exchange views on a particular topic.
  - Networks, communities of practice, conferences, etc.
  - Internal consultative or coordination mechanisms within the WHO Secretariat or the UN System

AGs of relevance to prequalification of VCPs

- Technical/disease departments
  - Malaria Policy Advisory Group
  - Standing Technical Advisory Group (STAG for NTDs)
  - Vector Control Advisory Group
- Department of Regulation and Prequalification
  - Technical Advisory Group for Vector control product regulation (TAG-VCPR)
  - Joint Meeting on Pesticide Specifications (JMPS)
- Related
  - Joint meeting on pesticide residues (JMPR)
  - Joint meeting on pesticide management (JMPM)

- *ASVCP is not an advisory group*

VCAG

Functions:

- To support WHO in guiding applicants, via the WHO Advisory Group Secretariat, on study designs for the generation of epidemiological data intended to enable assessment of the public health value of new vector control interventions;
- To support WHO in evaluating the public health value of new vector control intervention classes, based on epidemiological studies submitted to WHO;
- To advise WHO (i.e. the relevant technical departments) on whether public health value has been demonstrated for a new vector control intervention

Vector Control Advisory Group (VCAG) (who.int)

TAG-VCPR

Functions:

- To provide regulatory advice on the procedures related to the assessment of VCPs and VCAIs
- To provide advice on the development, revision and adoption of policies, guidelines and guidance in response to advancements of technologies in VC and the progression of the PQT-VCP activities, e.g.
  - Regulatory frameworks for existing and novel products
  - Guidelines and guidance, including data requirements, for pre-market assessment
- To provide advice on the workplan and prioritization of activities/initiatives within the scope of prequalification of VCPs, and other related activities.

Call for experts | 27 June | 2024 - EXTENDED TO 31 DECEMBER 2024

JMPS

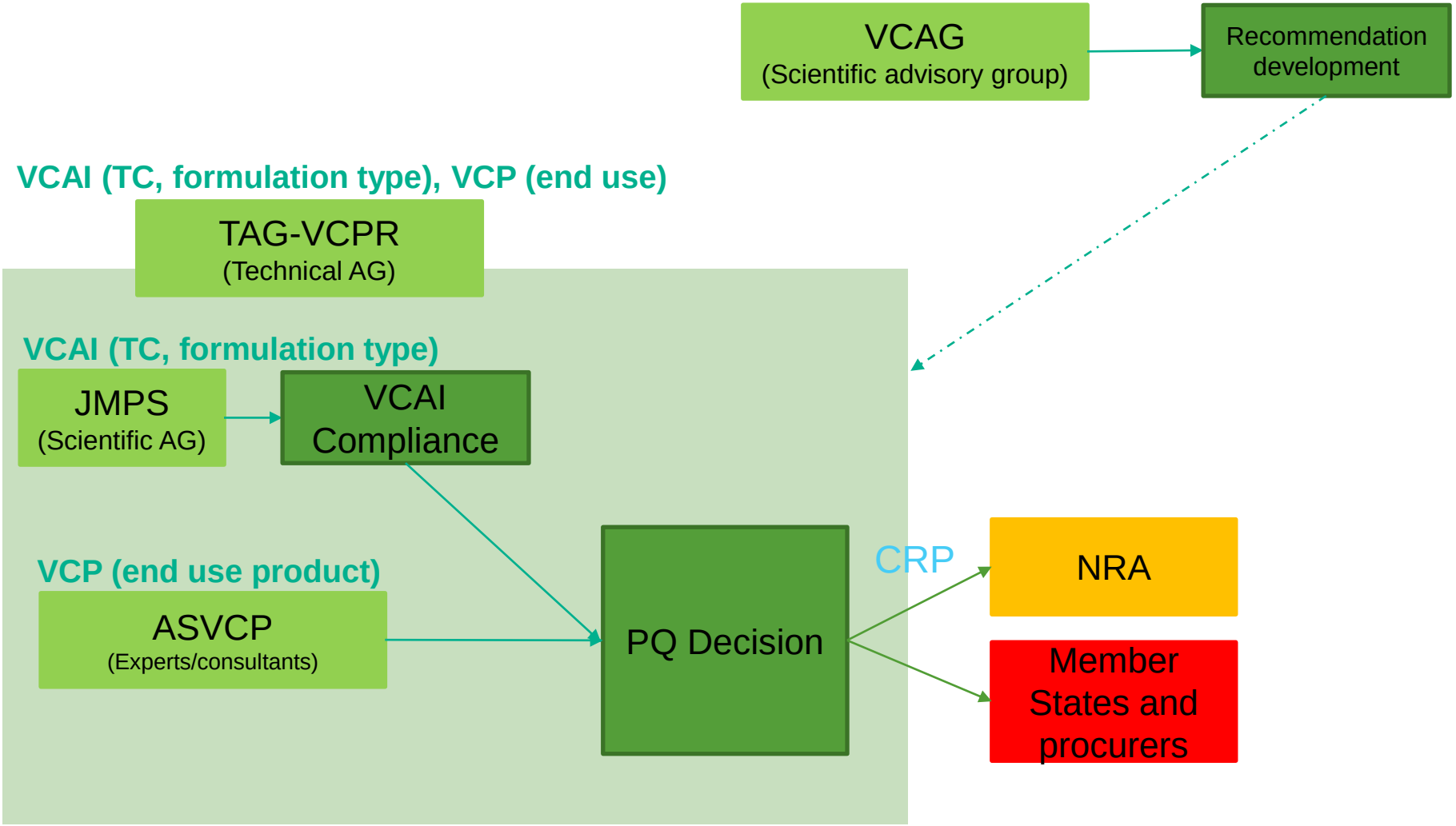
Functions:

- 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.

Note:

- The specifications establish the norms and standards for identification and quality control of pesticide active ingredients
- Assessments are triggered by submissions from industry

Advisory and assessment groups related to PQT/VCP



JMPS Updates

FAO/WHO Manuals on specifications for pesticides

Chemical Manual, Second Edition
→ Published in May 2022 (EN, ES, FR, CH)

Materials to kill or control pests
- Inorganic active ingredients
- Synthetical active ingredients

Materials to modify the behaviour or physiology of pests or of crops during production or storage
- Insect repellents, synergists
- Herbicide safeners, germination inhibitors

→ Technical materials
and formulated products

FAO/WHO Manuals on specifications for pesticides

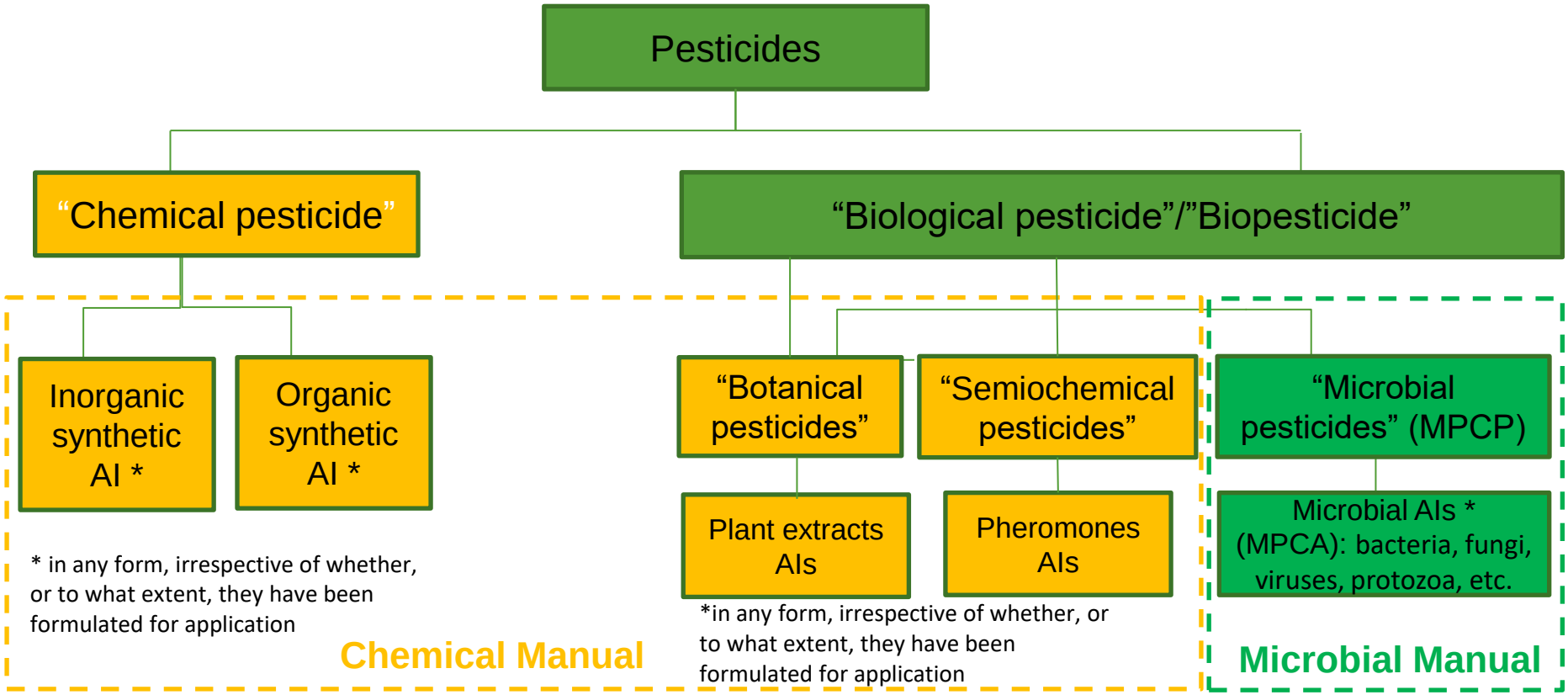
Microbial Manual, First Edition
→ Published in April 2024 (EN)

Microbial active ingredients
Bacteria, Fungi, Viruses, Protozoa …

Microbial pest control agent (MPCA)
and microbial pest control product (MPCP)
Different from synthetic chemical types,
botanicals (plant extracts) and semiochemicals
(pheromones)

→ Technical materials and formulated products

FAO/WHO Manuals and categories of pesticides



Standardization of WHO processes related to JMPS

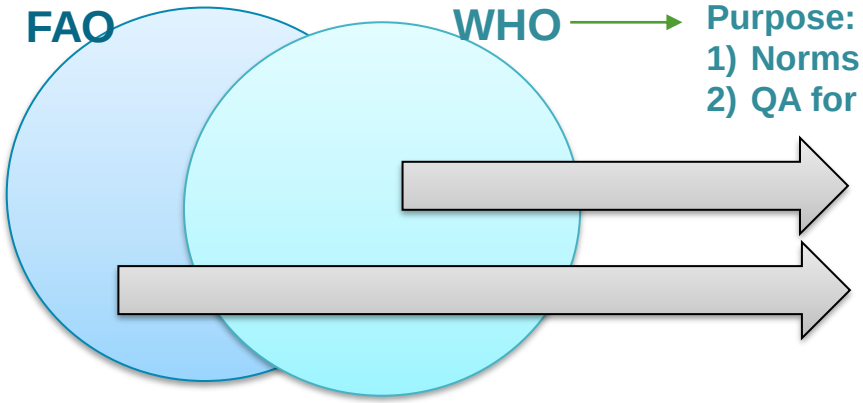
- *Overview of the WHO Assessment of Vector Control Active Ingredients* under development.
  - Correlate to *Overview of the WHO Assessment of Vector Control Products*

- Establish clear understanding of the roles and responsibilities of WHO and applicants in the submission and handling of applications and use of assessments by WHO for publicly conveying the confirmation of compliance with WHO specifications for source materials used in formulation of VCPs

- Includes use of a Letter of Agreement to be implemented for all existing source materials and future applications

TC/TK specifications vs public health product specifications

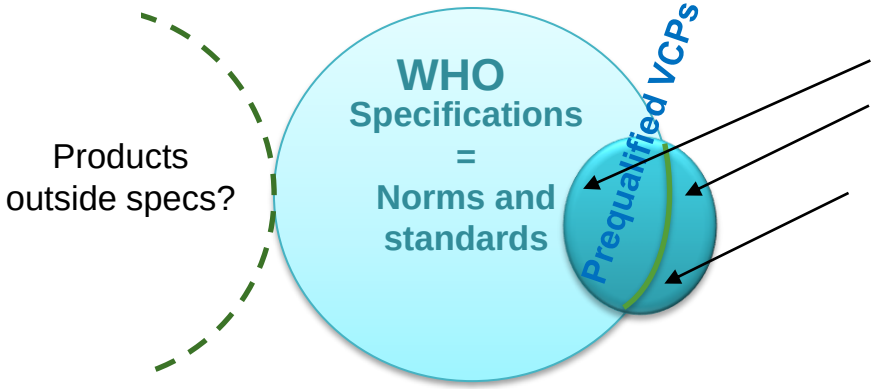
TC/TK/formulated intermediates specifications (Vector Control Active Ingredients -VCAIs)



Purpose:
1) **Norms and standards for AIs related to public health**
2) **QA for source materials**

HOW DO COUNTRIES USE THIS?
- Registration
- Others

Formulated product specifications (e.g. Vector Control Products - VCPs)



Products aligned with WHO specifications

e.g. ITNs

e.g. non-compliant clauses with WHO specifications, but demonstrated product quality, safety and efficacy

JMPS: updated publications

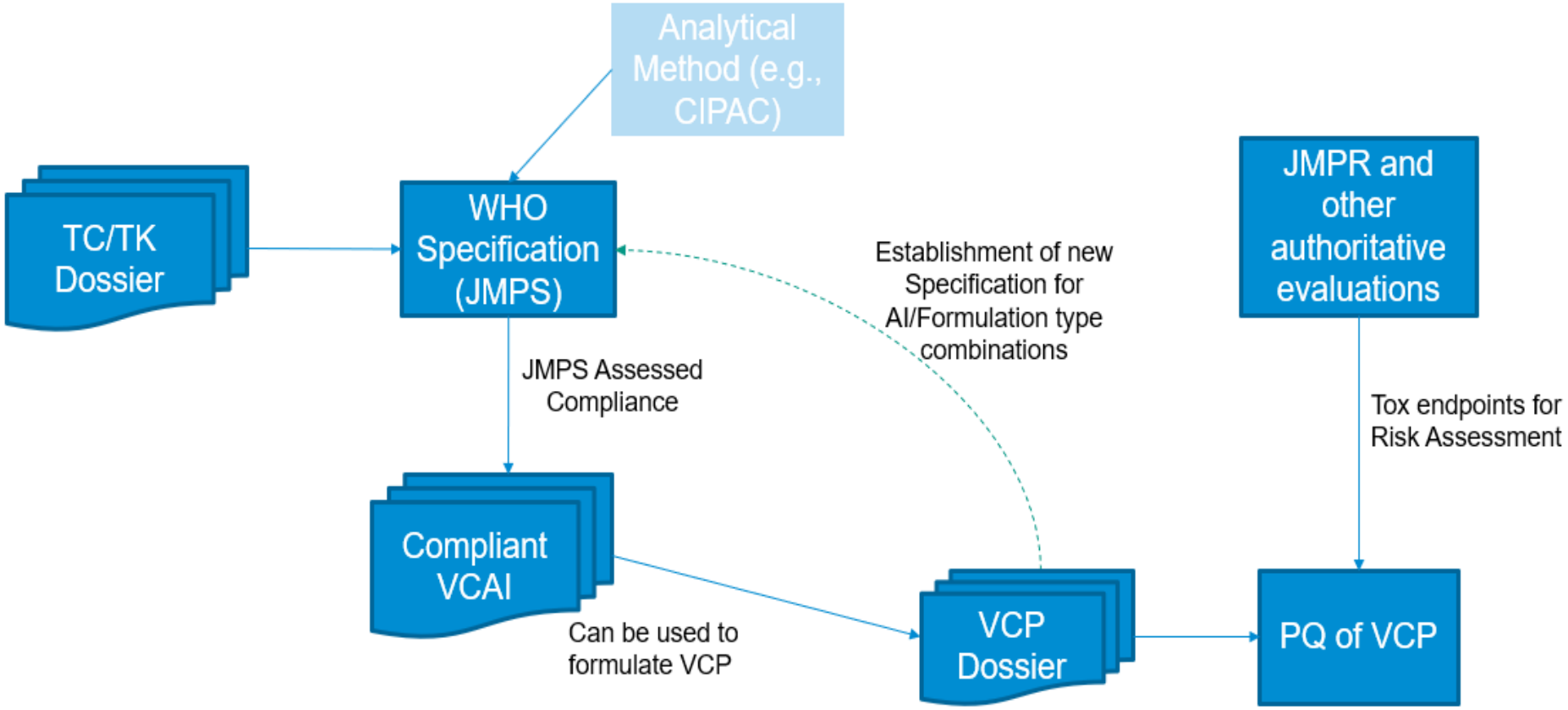
Summary of actions taken from the 22nd JMPS meeting (June 2023)

16 Updated specifications (WHO and Joint)

- Alpha-cypermethrin SC
- Bendiocarb TC
- Bifenthrin TC
- Broflanilide TC
- Chlorfenapyr SC
- Chlorfenapyr - New Site
- Chlorfenapyr TC
- Chlorfenapyr TC
- Deltamethrin TC
- Flupyradifurone
- Flupyradifurone + Transfluthrin
- Lambda-cyhalothrin TC
- Malathion TC, EW
- Piperonyl Butoxide TC
- Pirimiphos-methyl TC
- Transfluthrin TC

Agenda

- General Updates, Workplan for 2025, Prioritization of guideline development
- Who does what!? - Mapping assessment and advisory groups in VC
- PQ Dossiers - Partnerships, reliance, and recognition before and after
- ePQS Portal – Status of pilot and development of guidance


Analytical Method (e.g., CIPAC)
TC/TK Dossier
WHO Specification (JMPS)
JMPR and other authoritative evaluations
Establishment of new Specification for AI/Formulation type combinations
JMPS Assessed Compliance
Tox endpoints for Risk Assessment
Compliant VCAI
Can be used to formulate VCP
VCP Dossier
PQ of VCP

Agenda

- General Updates, Workplan for 2025, Prioritization of guideline development
- Who does what!? - Mapping assessment and advisory groups in VC
- PQ Dossiers - Partnerships, reliance, and recognition before and after
- ePQS Portal – Status of pilot and development of guidance

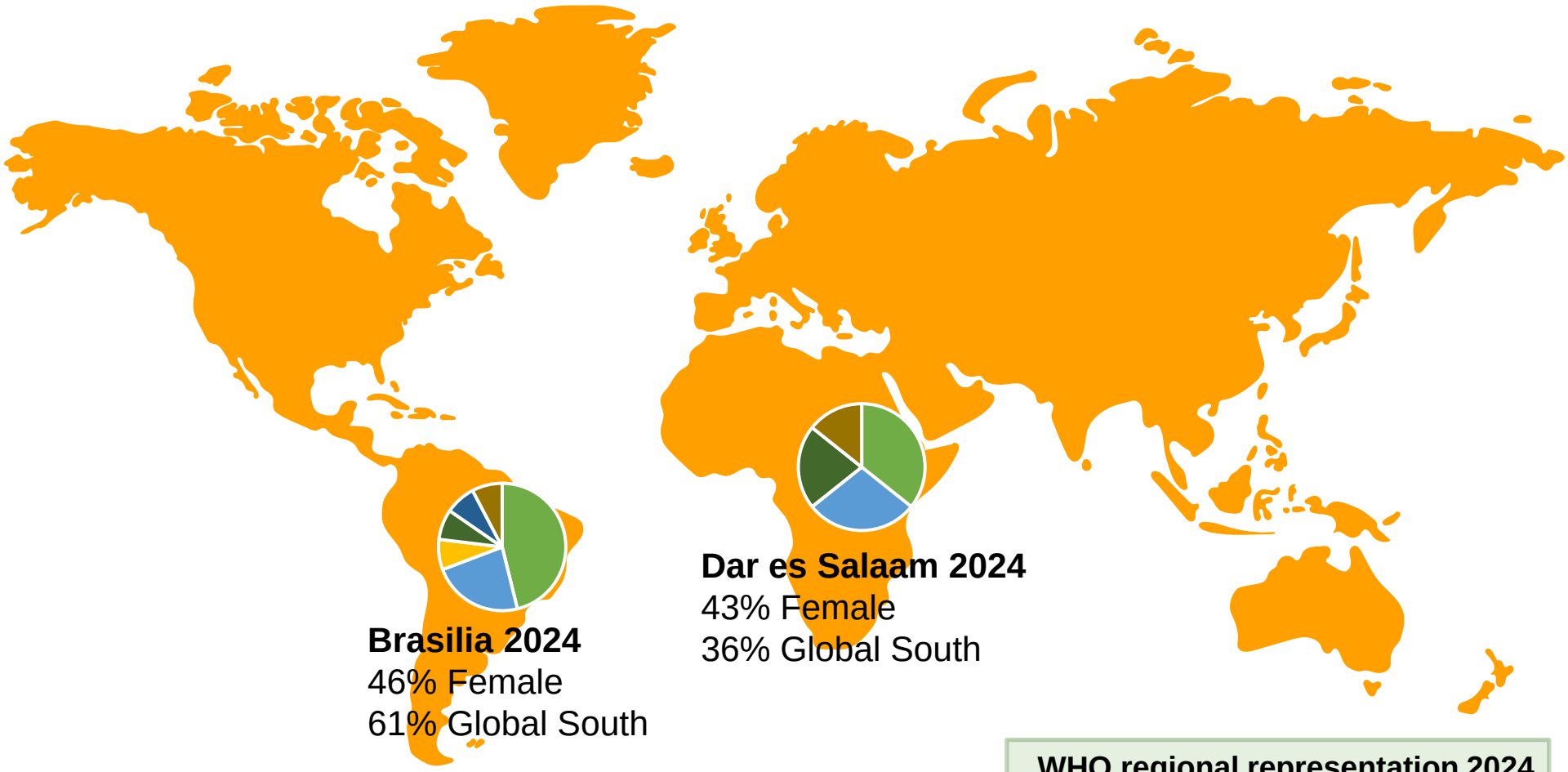
ePQS portal

- We expect the submission portal to be live to all applicants 01-January. Please review your company's contact information, manufacturing sites, and general information in the system and submit any changes via a PPQC.
- All individual portal users will need to submit a new User Form (available on the WHO ePQS Portal landing page
  - https://who.my.site.com/ePQS/s/login/

- Login and submission support is available
- Learning materials will be provided by 01-January and presented on during the 15-January Wednesday webinar

Thank-you

Questions, comments, dialogue



Brasilia 2024
46% Female
61% Global South

Dar es Salaam 2024
43% Female
36% Global South

WHO regional representation 2024

- AFRO
- AMRO
- EMRO
- EURO
- SEARO
- WPRO

Image by Freeimages.com