

Overview of the WHO Pesticide Evaluation Scheme (WHOPES)

1. Background and objectives

The WHO Pesticide Evaluation Scheme (WHOPES) was set up in 1960, to promote and coordinate the testing and evaluation of pesticides for public health. The global objectives of WHOPES are to:

- Facilitate the search for alternative pesticides and application methodologies that are less hazardous and effective; and
- Develop and promote policies, strategies and guidelines for the selective and judicious application of pesticides for public health use, and assist and monitor their implementation by Member States.

WHOPES functions through the participation of representatives of governments, manufacturers of pesticides and pesticide application equipment, WHO Collaborating Centres and research institutions, as well as other WHO programmes, notably Chemical Safety and the Global Malaria Programme. It is not a pre-qualification program.

2. WHOPES activities

WHOPES is responsible for two main activities within WHO:

- Evaluation and specification of public health pesticides (PHPs)
- Promotion and guidelines development for public health pesticide management

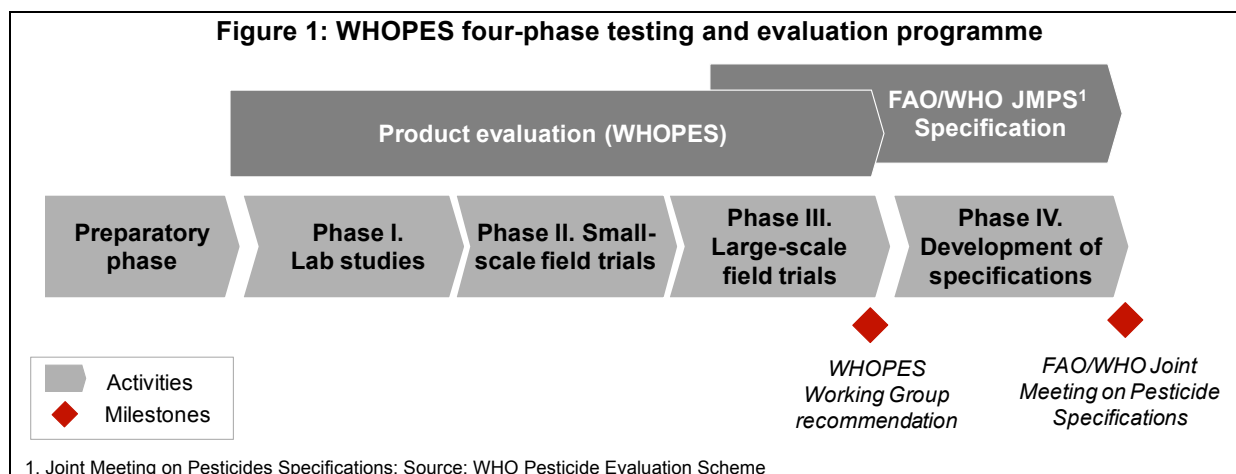
These activities play complementary roles in providing technical support to WHO Member States and other stakeholders for procuring and utilizing public health pesticides.

2.1 Evaluation and specification of public health pesticides (PHPs)

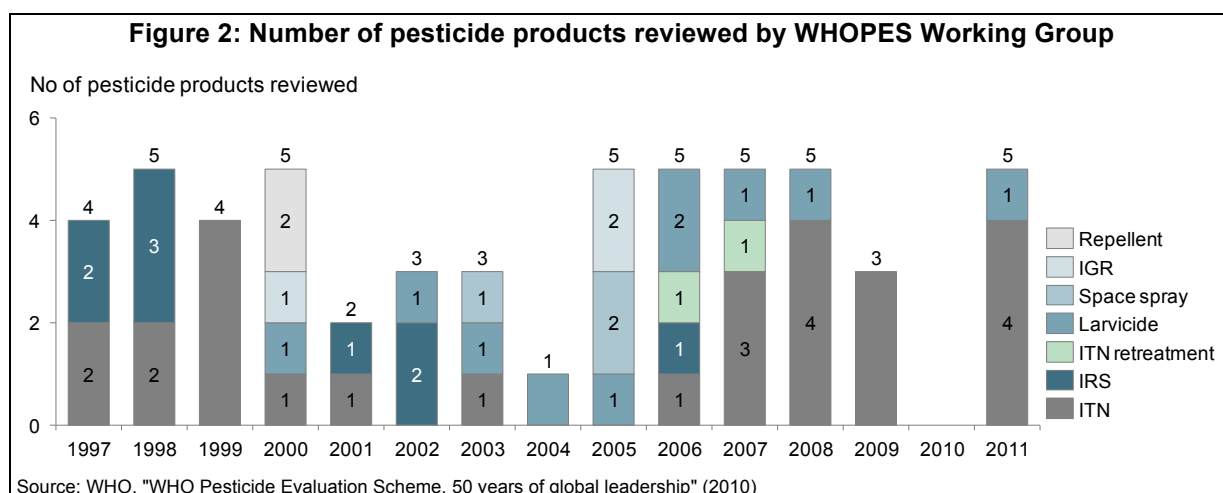
In its present form, WHOPES comprises a four-phase testing and evaluation programme, evaluating the safety, efficacy and operational acceptability of public health pesticides, and developing specifications for quality control and international trade. As a complementary activity, it also develops guidelines for testing, evaluation and specification of the main categories of pesticide products. The product recommendations issued by WHOPES facilitate the registration of pesticides by Member States, whereas the product specifications provide a point of reference for product quality control and commercial trade of pesticide products.

The testing and evaluation programme can be described by the following activities (*see Figure 1*):

- **Preparatory phase:** The dossier of evidence submitted by the manufacturer is reviewed by the WHOPES secretariat to assess if any additional data is required, based on the established testing guidelines for the product. The secretariat informs the manufacturer of any complementary trials required, and defines trial protocols and time plans together with its collaborating research centers and the manufacturer.
- **Phase 1:** The properties of the product are evaluated in a laboratory setting. In particular, the biological efficacy and the residual effect of the product are evaluated. This phase also includes a risk assessment of the product for the intended use.
- **Phase 2:** The product properties are evaluated in small-scale field trials. In this phase, the biological efficacy and impact on vector behavior is evaluated in field settings, and the perceived adverse effects on users are investigated.
- **Phase 3:** The product is evaluated in large-scale field trials. The biological efficacy and residual activity of a product as well as operational acceptability is assessed.
- **Phase 4:** Upon satisfactory completion of WHOPES phase 1, 2 and 3, WHO specifications of the product are developed and published.



Upon completion of the Phase 2 and 3 trials, a scientific committee, the WHOPES Working Group, assists WHOPES in reviewing the existing information as well as the reports of WHOPES-supervised trials. The group assesses the safety, efficacy and operational acceptability of the submitted product, and makes recommendations on its suitability for public health use. All products except long-lasting insecticidal nets (LNs) are reviewed after completing Phase 3, whereas LNs, because of the extensive Phase 3 study required, may receive an interim recommendation after satisfactory completion of Phase 2. The reports of the WHOPES Working Group are issued as WHO documents and are widely distributed¹. Since 1997, a total of 55 products, on average four products yearly, have been reviewed by WHOPES (see Figure 2).



The requirements and timelines for WHOPES evaluation of a particular pesticide product are established and agreed upon by the manufacturer, following the critical assessment of the data package and the extent of information available at the time of submission of the product. In the absence of any efficacy data, normally 2 to 3 years of research is required before WHO recommendations on use can be developed.

WHO specifications for public health pesticides are part of the International code of conduct on the distribution and use of pesticides². Under the new procedure, established in 2002, WHO specifications are restricted to the data package and product evaluated by WHOPES and are developed by the FAO³/WHO Joint Meeting on Pesticide Specifications. Determination of "equivalence" for "me too"

¹ <http://www.who.int/whopes/recommendations/wgm/en/>

² <http://www.fao.org/waicent/faoinfo/agricult/agp/agpp/pesticid/>.

³ Food and Agriculture Organization of the United Nations

products is based on procedures and requirements outlined in the Manual on development and use of FAO and WHO specifications for pesticides⁴.

2.2. Promotion and guidelines development for public health pesticide management

The International code of conduct on the distribution and use of pesticides constitutes the framework for WHOPES in promoting the sound management of public health pesticides throughout their life-cycle. This activity is carried out in close collaboration with the Food and Agriculture Organization of the United Nations to ensure complementary, harmonized and coordinated guidance to responsible bodies at national level and to all stakeholders. It includes the promotion of safe handling and use, efficacy, cost-effective application and quality control of pesticide products for public health use.

In addition, technical support to the Member States in capacity strengthening for pesticide management constitutes a major activity of WHOPES. This includes optimizing and harmonizing pesticide registration requirements and procedures, as well as capacity strengthening for post-registration monitoring and evaluation of public health pesticides and reducing trade in substandard pesticide products.

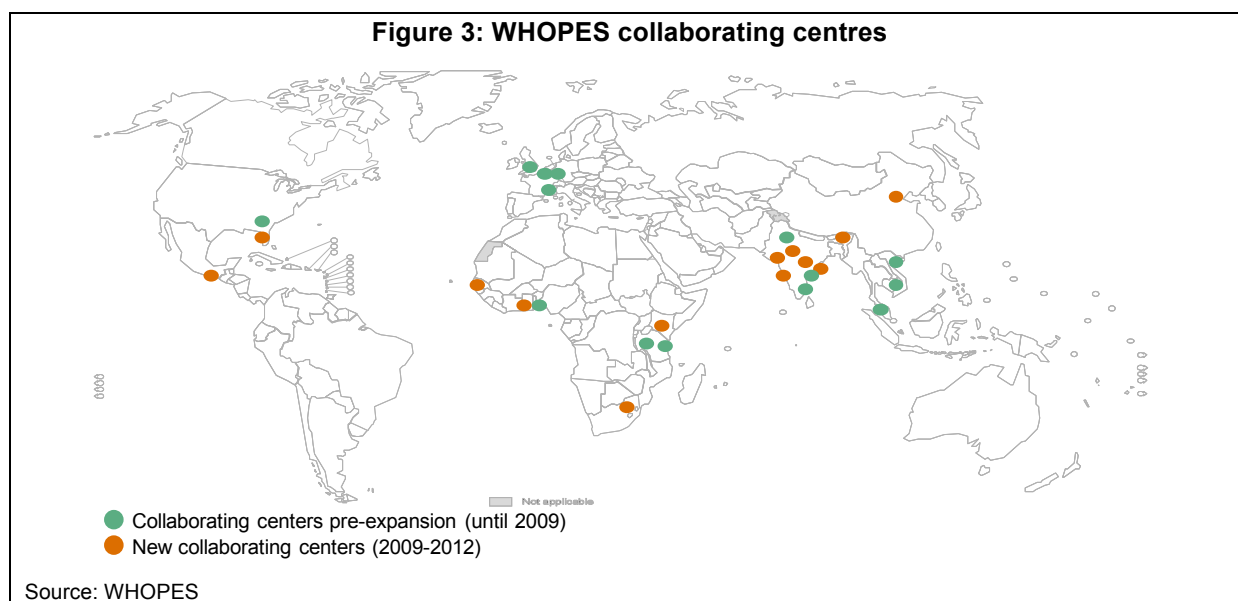
The global monitoring of use of insecticides for vector-borne disease control⁵ by WHOPES serves as an international reference for monitoring trends in use of public health pesticides.

2.3. Organizational capacity and stakeholder interaction

WHOPES' activities are coordinated by the WHOPES secretariat, currently consisting of two technical staff (including the coordinator) supported by one secretary. WHOPES also dispose of a network of collaborating centres, which conduct all WHOPES-supervised trials and in some cases also perform quality control of products. WHOPES has significantly expanded the network in recent years, almost doubling the number of sites during the period 2009-2012 (See Figure 3),

The work of WHOPES is also sustained by external scientists and scientific institutions, who contribute with their expert knowledge and human resources, in most cases at their own cost.

The Global Collaboration for Development of Pesticides for Public Health (GCDPP)⁶ was established by WHOPES in 1997 as a unique public-private partnership. This mechanism has been used as a vehicle for information exchange with industry and other stakeholders on the public health pesticide needs and product development, as well as promoting their safe and effective use in public health.



⁴ <http://www.who.int/whopes/quality/en/>

⁵ http://whqlibdoc.who.int/publications/2011/9789241502153_eng.pdf

⁶ <http://www.who.int/whopes/gcdpp/en/>

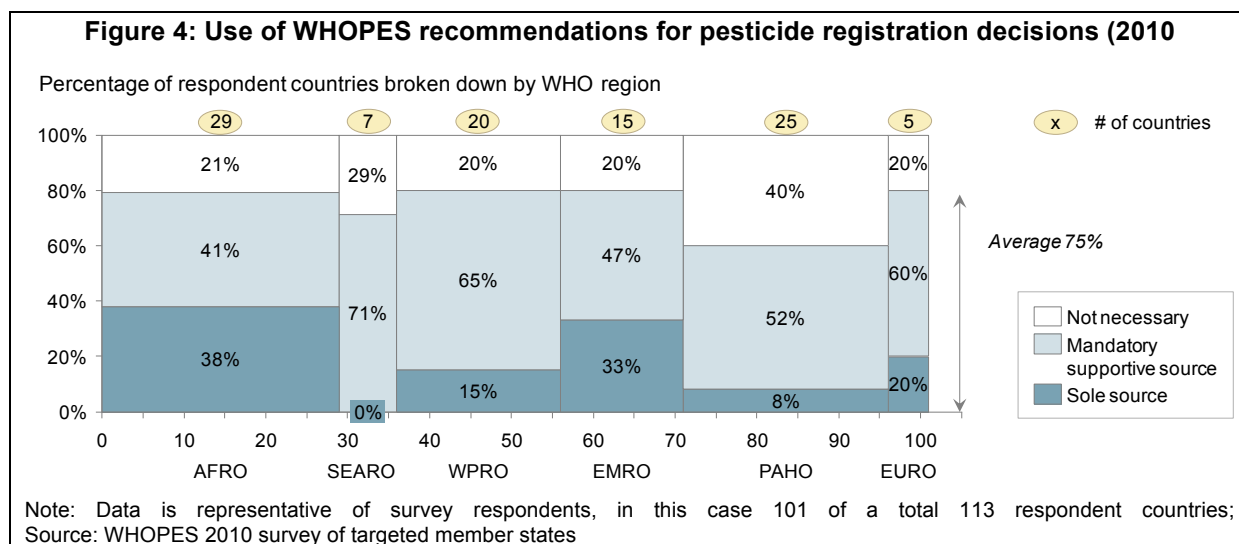
3. Optimizing public health outcomes: Attributable benefit of WHOPES

Vector-borne diseases account for about 16% of the estimated global burden of communicable diseases. In most cases, vector control is the main intervention for reducing and interrupting transmission; in some cases it is the only available intervention for this purpose.

Vector control has undergone a major expansion in recent years: for example, international funding for malaria control is estimated to have reached US \$ 2 billion in 2011, of which about 50 to 60% was for vector control. A particular feature of the recent scaling up of vector control programmes has been the acceleration in the introduction of new products, as well as increased investment in research and product/technology development for this purpose.

While vector control is being scaled up in disease endemic countries, a large share of countries is characterized by very limited capacity in vector control and in regulation of public health pesticides. In many cases the in-country regulatory process lacks the capacity to perform a full evaluation of products, and the management of pesticides post-registration is also limited.

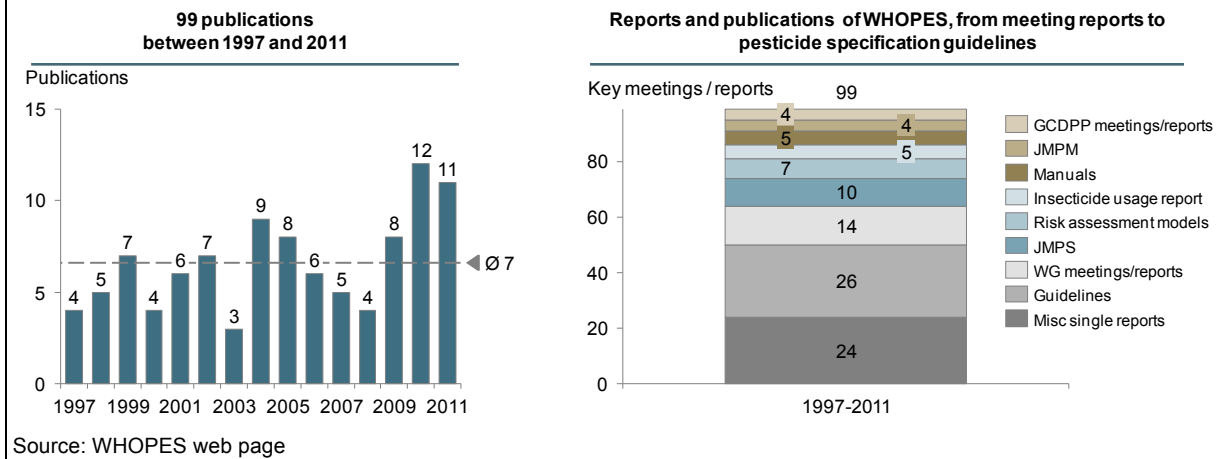
In this context, WHOPES plays an essential role in evaluating and recommending pesticide products, as well as building in-country capacity for pesticide testing, evaluation and management. In fact, a recent survey shows that ~75% of WHO Member States rely, partly or solely, on WHOPES product recommendations for their pesticide registration decisions (see Figure 4).⁷



Furthermore, WHOPES has over the last decade developed technical guidance covering a range of topics, and supported their implementation through regional and local workshops.. Figure 5 provides an overview of WHOPES publications and reports since 1997. During the same 1997-2011 period, the WHOPES secretariat included on average one technical staff.

⁷ http://whqlibdoc.who.int/publications/2011/9789241501217_eng.pdf

Figure 5: Overview of WHOPES reports and publications



In summary, WHOPES benefit to vector-borne disease control by:

- Ensuring Member States have access to relevant information and technical advice to enable them to register and use safe, efficacious and operationally acceptable products
- Enabling product quality control and facilitating commercial trade of pesticide products through internationally accepted product specifications
- Developing Member State's capacity for evaluation, registration and management of pesticide products
- Harmonizing regulatory systems to ensure faster, more efficient regulatory processes and better allocation of resources

**Pesticide products under
WHOPES laboratory and
or field testing and
evaluation**

Application

Mosquito larviciding

Indoor residual spraying

Long-lasting insecticidal nets

*DawaPlus 2.0 LN**

*LifeNet LN**

Mapomol SafeNet LN

MiraNet LN

*Olyset Plus LN**

Olyset Duo LN

Panda Net 2.0 LN

*PermaNet 3.0 LN**

***Kit for long-lasting treatment of
mosquito nets***

Product

VectoMax FG

Alphacypermethrin WG

Akanet LN

Veeralin LN

Yahe LN

*ICON MAXX**

Manufacturer

Valent BioScier

Tagros Chemic

Kuselace Co., c

Tana Netting, UAE

Bayer CropScience, France

Mainpol GmbH, Germany

A to Z Textile Mills Ltd, Tanzania

Sumitomo Chemical, Japan

Sumitomo Chemical, Japan

Life Ideas Textiles, China

Vestergaard Frandsen, Switzerland

Vector Control I

Fujian Yamei, C

Syngenta, Swit: