REPORT OF THE SIXTH MEETING OF THE GLOBAL COLLABORATION FOR DEVELOPMENT OF PESTICIDES FOR PUBLIC HEALTH

WHO/HQ, GENEVA
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World Health Organization
DEPARTMENT OF CONTROL OF NEGLECTED TROPICAL DISEASES
WHO PESTICIDE EVALUATION SCHEME (WHOPES)
REPORT OF THE SIXTH MEETING OF THE GLOBAL COLLABORATION FOR DEVELOPMENT OF PESTICIDES FOR PUBLIC HEALTH (GCDPP)

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1. INTRODUCTION

The sixth meeting of the Global Collaboration for Development of Pesticides for Public Health (GCDPP) was held at the headquarters (HQ) of the World Health Organization (WHO) in Geneva, Switzerland on 24–25 April 2008.

Dr Lorenzo Savioli, Director, Department of Control of Neglected Tropical Diseases (NTD), opened the meeting on behalf of Dr Hiroki Nakatani, Assistant Director-General of WHO HIV/AIDS, TB, Malaria and Neglected Tropical Diseases, noting the role of GCDPP as an advisory group to the WHO Pesticide Evaluation Scheme (WHOPES). GCDPP gives advice, inter alia, on matters related to the development of insecticides and their safe, judicious and effective use in the field of public health. Participants were reminded the GCDPP meets every other year to discuss a main theme; this year the theme was pesticide registration, which required inter- and intra-sectoral collaboration. The wide representation at the meeting of different institutions, especially different associations of pesticide manufacturers, as well as the Food and Agriculture Organization of the United Nations (FAO) and the United Nations Environment Programme (UNEP) was welcomed. The meeting was informed of the signing with FAO in March 2007 of a Memorandum of Understanding (MoU) on a joint programme on sound management of pesticides. The subject of the sixth GCDPP meeting was one of the tangible products of such collaboration.

Dr Savioli thanked the Bill & Melinda Gates Foundation (BMG) for its award to WHOPES to support capacity strengthening on sound management of public health pesticides, which has become a priority, particularly with the increased use of pesticides for vector-borne disease control in developing countries.

Dr Savioli invited the meeting to discuss the draft FAO/WHO guidelines on registration of pesticides and to advise WHO on the refinement of the guidelines so that they are pragmatic and useful for the main target groups (governments of Member
countries, particularly developing countries, and countries with economies in transition).

The meeting was convened in plenary sessions (Annex 1) and attended by 20 representatives of industry, 6 representatives of national and government-supported agencies, 1 representative from BMG; 5 representatives of regional and international organizations, 7 representatives of universities and research institutions and 7 temporary advisers as well as members of the WHO Secretariat (Annex 2). Mr Soo Hian Tan was appointed as Chairman and Ms Sandhya Kulshrestha and Mr Kevin Sweeney as rapporteurs.

2. SECRETARIAT REPORT ON DEVELOPMENTS SINCE THE PREVIOUS GCDPP MEETING

Dr Morteza Zaim, Scientist in charge of WHOPES and Secretary of GCDPP, provided a brief report on activities carried out by the programme since the previous GCDPP meeting in September 2006 in as far as they relate to the two main objectives of the scheme, which are: (i) to facilitate the search for alternative pesticides and application technologies that are safe and cost-effective; and (ii) to develop and promote policies, standards and guidelines for safe and judicious application of pesticides and to assist and monitor their implementation by Member States.

Since the previous GCDPP meeting, WHOPES has tested and evaluated 10 pesticide products: three formulations of spinosad for mosquito larvicide; a product for indoor residual spraying (IRS); two products for long-lasting treatment of mosquito nets and for long-lasting insecticidal nets (LNs). The reports of WHOPES Working Group meetings provide critical reviews of existing literature as well as of studies organized and supervised by WHOPES. These reports are widely distributed among national control programmes, registration authorities and other stakeholders and are intended to facilitate the registration and use of such products by Member States.
Dr Zaim thanked the collaborating institutions, some of which were represented at the meeting, for their valuable support to the work of WHOPES in testing and evaluating public health pesticides in the past two years.

There are currently seven LNs under WHOPES testing and evaluation, four of which are new or improved formulations of existing products; the other three are undergoing large-scale testing and evaluation for the development of full WHO recommendations on their use. The list also includes a microencapsulated formulation of fenitrothion for IRS and a mosquito treatment kit undergoing large-scale testing and evaluation for full recommendations. In general, most insecticide products submitted to WHOPES for testing and evaluation in recent years have been for treatment of mosquito nets or factory treated nets. There has been a decline in the development of other insecticide products, especially for IRS. Use of DDT is increasing, and investment in development of alternative chemicals to replace this compound in IRS activities has been rather limited.

Development of quality standards for public health pesticides has constituted a major activity of WHO since 1953, when the first WHO specification for pesticides was published. Since the previous GCDPP meeting, 16 manufacturers have submitted data packaging and information on 21 products for development of WHO or joint FAO/WHO specifications. The submissions from generic manufacturers have been almost equal to those of the leading companies of CropLife International during the past seven years and since the establishment of the new procedure in WHO for development of pesticide specifications.

Thanks to GCDPP members of manufacturers of pesticide application equipment, WHOPES published in late 2006 the specification guidelines for major equipment used in vector control, after conducting several consultations on the subject, coordinated by IPARC, the WHOPES collaborating centre on pesticide application equipment. Although resources in this important area of activity have diminished significantly,
WHOPES intends to keep the subject high on the agenda of pesticide management.

The very positive and encouraging assessment of stakeholders on generic risk assessment guidelines and the detailed efficacy guidelines published by WHOPES in recent years have enabled investment in the development of three generic risk assessment models for application of insecticides in IRS, space spraying and mosquito larviciding, as well as three efficacy guidelines for mosquito skin repellents, ground-applied space spray products and household insecticide products. All six guidelines are expected to be peer reviewed and published by mid-2009.

In collaboration with FAO, WHOPES is also in the process of developing joint guidelines on different aspects of pesticide management. Guidelines on management of empty pesticide containers are almost final and are expected to be published shortly; the guidelines on pesticide registration, which are the subject of discussion at the current meeting, are due to be finalized by the end of 2008. Other guidelines, listed below, are at different stages of development.

WHOPES, in collaboration with FAO, is developing a training manual on the development of pesticide specifications. This tool provides a step-by-step approach to acquiring the knowledge and skills for basic decision-making on the development of pesticide specifications, including the determination of equivalence. An FAO/WHO Consultation planned for May 2008 in WHO/HQ will review and finalize the training manual.

In addition to the development of learning tools, WHOPES has been working with colleagues in the vector ecology and management unit to support Member States in incorporating the principles of integrated vector management (IVM) and sound management of pesticides into their national policies. Development of a WHO-wide definition for IVM has been part of this activity, which is defined as a rational decision-making process for the optimal use of resources for vector control.
WHOPES has also been supporting the activities of UNEP and other WHO programmes in assisting Member States in the development of alternatives to DDT. A good example is supporting the development of the GEF Project proposal on Demonstration of sustainable alternatives to DDT and strengthening the national vector control capacities in Middle East and North Africa in collaboration with the WHO Regional Office for the Eastern Mediterranean (EMRO).

It is understood that pesticide management requires an inter- and intra-sectoral approach as well as close collaboration with the health and agriculture sectors in particular. In March 2007, FAO and WHO signed an MoU on development of a joint programme on pesticide management to enhance the provision of unified, coordinated and consistent advice and support to Member States and other stakeholders on sound management of pesticides. This further builds on the excellent collaboration between the two organizations on development of pesticide specifications through the FAO/WHO Joint Meeting on Pesticide Specifications. The Code of Conduct on the Distribution and Use of Pesticides will be used as the framework and guiding document for the sound management of pesticides. The first joint meeting of the two organizations on pesticide management was held in FAO/HQ in October 2007. The second meeting is scheduled to take place at WHO/HQ in Geneva on 6–10 October 2008.

WHOPES established a database in 1997 and regularly publishes data/information on global use of insecticides for vector control. There have been initiatives in recent months to support institutionalization of reporting on insecticide use in Member States, and collaboration with FAO has been initiated to collect and publish data on use of pesticides in major crops that may influence the development of resistance in vectors and pests of public health importance, i.e. cotton and rice.

Activities to support countries have been reinforced through a four-year project award by BMF on reduction of health risks through sound management of pesticides. Part of the award goes towards supporting normative functions, but a significant
amount is also directed in supporting 12 countries, with priority in Africa, to build their capacity on sound management of pesticides following a careful situation analysis and needs assessment. These are: African Region (AFRO) – Cameroon, Kenya, Madagascar, Mozambique, Senegal, United Republic of Tanzania; Region of the Americas (AMRO) – Ecuador, Guatemala; Eastern Mediterranean Region (EMRO) – Morocco, Sudan; South-East Asia Region (SEARO) – Thailand; and Western Pacific Region (WPRO) – Cambodia.

Dr Zaim thanked BMG and especially Dr Kate Aultman for their recognition of the importance of investment in sound management of pesticides and capacity strengthening, and hoped that this marked a turning point in bringing additional funds and resources to vector-borne endemic countries for building their capacity in this very important area.

Collaboration with BMG is expanding in different areas of work; one example is a joint meeting that is planned in collaboration with the Institute of Tropical Medicine in Antwerp Belgium on 10–11 July 2008 on Development of quality standards for long-lasting insecticidal mosquito nets (LNs): information gap and the way forward. The objectives of the meeting are: (i) to inform industry, research partners and other stakeholders of the experience gained in testing and evaluating LNs and the information gap in development of quality standards for such products and (ii) to call for their support in generating the data/information required to meet the identified needs.

Dr Zaim concluded his report by thanking the individuals and institutions represented at the meeting for their continued support of WHOPES activities and their contribution in making GCDPP a unique public–private partnership in WHO.

3. OBJECTIVES OF THE MEETING

The objectives the sixth GCDPP meeting were: (i) to discuss the draft FAO/WHO guidelines on registration of pesticides and (ii) to advise WHO on the refinement of the guidelines so that
they are pragmatic and useful to the main target groups, i.e. the governments of Member countries, particularly developing countries, and countries with economies in transition.

The document is intended to serve as an umbrella document for registration of agriculture and public health pesticides, with more detailed guidance on technical elements of the registration process to be provided in separate guidelines. The draft guidelines will ultimately be reviewed and finalized by the Second FAO/WHO Joint Meeting on Pesticide Management, which is schedule to take place at WHO/HQ in Geneva on 6–10 October 2008. A revised version of the draft based on the input of the sixth GCDPP meeting and that of WHO regional offices and selected Member States will be circulated among FAO/WHO Panel Members and the observers of the meeting, i.e. associations of pesticide manufacturers and nongovernmental organizations, by late June 2008.

Given that pesticide registration is a major step in pesticide regulation and management in a country, the meeting was invited to critically review the draft guidelines and forward constructive comments and suggestions. Participants were also reminded that these were joint FAO/WHO guidelines for the registration of pesticides. Other institutions whose staff were not GCDPP members had also been invited to contribute in order to ensure that this key document addressed the needs of both sectors.

4. PRESENTATION AND DISCUSSION OF THE DRAFT GUIDELINES ON REGISTRATION OF PESTICIDES

The meeting discussed the draft guidelines on registration of pesticides that had been circulated electronically to participants ahead of the meeting. The guidelines are intended to provide general advice on principles and process as well as requirements for registration of pesticides, including institutional and administrative organization. They highlight the vital role of inter- and intra-sectoral collaboration in registration of pesticides, especially the important collaborative role of the
health, environment and agriculture sectors in this effort. The guidelines are not intended to give in-depth technical guidance on most of the registration requirements; separate guidelines have been developed or are under development by FAO\(^1\) and/or WHO.\(^2\)

The meeting noted that the guidelines also constitute an important contribution towards the Strategic Approach to International Chemicals Management (SAICM). SAICM, a multi-sector and multi-stakeholder approach adopted at the International Conference on Chemicals Management (ICCM) in 2006 and subsequently endorsed by a number of international organizations, including, FAO, UNEP and [noted by] WHO, has as its overall objective to achieve the sound management of chemicals throughout their life-cycle so that, by 2020, chemicals are used and produced in ways that lead to the minimization of significant adverse effects on human health and the environment. SAICM recognizes that the sound management of chemicals is essential to achieve sustainable development and identifies, inter alia, that the need to take concerted action is accentuated by a wide range of chemical safety concerns at the international level, including a lack of capacity for managing chemicals in developing countries and countries with economies in transition, dependency on pesticides in agriculture, exposure of workers to harmful chemicals and concern about the long-term effects of chemicals on both human health and the environment.\(^3\)

Registration of pesticides is the process whereby the responsible national government or regional authority approves the sale and use of a pesticide following the evaluation of comprehensive scientific data demonstrating that the product is effective for its intended purposes and does not pose an unacceptable risk to human or animal health or the environment. Registration is an important step in management of pesticides, enabling authorities to exercise control over quality, use levels, claims, labelling, packaging and advertising of pesticides, thus

\(^{1}\) http://www.fao.org/waicent/faoinfo/agricult/agp/agpp/pesticid/

\(^{2}\) http://www.who.int/whopes/en/

\(^{3}\) http://www.chem.unep.ch/saicm/
ensuring that the interests of end-users as well as the environment are well protected.

The guidelines are intended to cover registration of all types of pesticides used in the different sectors, including agriculture and public health. The following definitions were proposed for inclusion in the guidelines as defined in the International Code of Conduct on the Distribution and Use of Pesticides\(^1\) (Code of Conduct):

**Pesticide** means any substance or mixture of substances intended for preventing, destroying or controlling any pest, including vectors of human or animal disease, unwanted species of plants or animals causing harm during or otherwise interfering with the production, processing, storage, transport or marketing of food, agricultural commodities, wood and wood products or animal feedstuffs, or substances which may be administered to animals for the control of insects, arachnids or other pests in or on their bodies. The term includes substances intended for use as a plant growth regulator, defoliant or agent for thinning fruit or preventing the premature fall of fruit, and substances applied to crops either before or after harvest to protect the commodity from deterioration during storage and transportation.

**Pesticide board** means the officially or legally appointed body that takes the final decision on the request for registration.

**Responsible authority** means the government agency or agencies responsible for regulating the manufacture, distribution or use of pesticides and more generally for implementing pesticide legislation.

The Code of Conduct describes the shared responsibility of many segments of society, including governments, industry, trade and international institutions. Originally adopted in 1985 by the FAO Conference and revised in 2002, the Code of Conduct promotes sound pesticide management practices that

minimize potential health and environmental risks. The revised Code includes the life-cycle approach to pesticide management and calls upon all private and public entities to support its implementation. The Code of Conduct provides a framework for management of all pesticides, including those intended for use in agriculture and in public health.

It was emphasized that governments should introduce the necessary legislation for the regulation of pesticides and make provisions for its effective monitoring and enforcement, including the establishment of appropriate education, advisory, extension, pesticide analytical and health-care services. In so doing, they should take full account of local needs, social and economic conditions, levels of literacy, climatic conditions and availability of appropriate and affordable pesticide application and protective equipment. Governments should strive to establish pesticide registration schemes and infrastructure under which products can be registered before their local availability and use. The legislation should allow for inclusion of all types of pesticides, as defined in the registration scheme, and also allow for phased introduction or a regional approach if needed.

The increasing complexity of evaluation and assessment of pesticides and their management requires substantial resources and adequate national infrastructure, including well-trained personnel in the various fields of pesticide management. The guidelines therefore promote the establishment of a single national authority for registration of all pesticides to optimize the use of limited resources available in most countries.

The guidelines promote transparency, information exchange and mutual acceptance of data in pesticide registration process in order to, among other things, prevent duplication of efforts by other regulatory authorities as well as to inform all stakeholders of pesticide risks. Further, the guidelines promote the advantages of the establishment of harmonized (by region or subregion) pesticide registration requirements, procedures and evaluation criteria.
Mr Sweeney made a presentation on the "Global joint pesticide reviews: the US EPA experience with visions for public health pesticides". The joint review is a formal process with a targeted time line whereby a pesticide registration application is submitted to participating countries, the workload is split between countries, the reviews of data are exchanged and peer reviewed, and national risk assessments are undertaken with the goal of a harmonized and simultaneous registration decision. In a global approach to the regulation of pesticides:

- work-sharing arrangements between regulatory authorities in Member countries take place as a matter of routine, such that data submissions prepared by industry in the standardized format are accepted in all Member countries and made available and used globally;
- there is generation of a single monograph for each active substance, serving the needs of the regulatory authorities in all Member countries;
- Member countries ensure that the benefits derived from work-sharing and the experiences gained through a Pesticides Working Group are taken into other relevant international fora, thereby helping countries to efficiently manage their pesticide regulatory systems for the benefit of public health.

Mr Sweeney recommended that the meeting consider the importance and inclusion of Global Joint Reviews in the Public Health Pesticide Approval Process to encourage public health pesticide development and to include the above in the FAO/WHO Guidelines on pesticide registration. He also asked the meeting to support US EPA efforts to organize a 2009 International Public Health Pesticide Workshop.

Dr Zaim thanked Mr Sweeney for his presentation and welcomed the proposal from US EPA to look for further opportunities for collaboration and cooperation and exchange of information on public health pesticides. He noted the ongoing close collaboration of WHO with US EPA as it relates to hazard
assessment of pesticides. He proposed for a meeting with US EPA to discuss and further clarify the proposal.

He pointed out, however, that WHOPES is not a regulatory authority. The regulatory approval of pesticides is the sole prerogative responsibility of national authorities. WHOPES is an independent Scheme that coordinates the testing and evaluation of pesticides for public health use, and its recommendations are intended to facilitate pesticide registration and use by WHO Member States.

Dr Zaim added that the US EPA proposal supports the same principles that WHO promotes and is included as one of the key principles in the guidelines for registration of pesticides, i.e. coordination and collaboration between national registration authorities, exchange of information, and harmonization of registration requirements and procedures. The guidelines can include only principles and practices that are well established and, as such, the inclusion of the proposal for establishment of a global joint review is premature at this stage. The establishment of the proposed joint review is the responsibility of governments, and WHOPES would be happy to facilitate such collaboration. It should also be noted that while hazard assessments are of global use, risk assessments should be carried out based on the local scenarios and situations. Any joint review process should be mindful of such requirements. Furthermore, registration of public health pesticides should include the evaluation of efficacy data against the local vector or public health pest and under prevailing eco-epidemiological conditions where the product is intended for use. Any joint review process should therefore also be mindful of such requirements.

The meeting also discussed principles of pesticide registration and noted that Responsible Authorities, in managing their national or regional registration schemes, should follow a number of important principles that are practised internationally. The acceptance and use of these principles would ensure greater efficiency, transparency and optimal use of resources in the registration process. They include the following:
• science-based decisions;
• transparency and exchange of information;
• comprehensive, harmonized and clear registration requirements and criteria;
• use of all available information and mutual acceptance of data;
• risk assessment and mitigation based on the local situation;
• risk–benefit analysis;
• post-registration monitoring and evaluation;
• re-registration or periodic review procedures.

The meeting reiterated that the evaluation of the data submitted in the registration dossier should follow internationally accepted and agreed evaluation standards and procedures in as much as these are available. These procedures need to be regularly updated to ascertain that they are in line with current scientific developments. It is essential that all steps in the registration process are transparent, based on sound and published criteria, with full information given to the applicant on the outcomes of the various steps in the registration procedure.

To avoid duplication of efforts in the evaluation of data for registration, some countries have agreed that data evaluated by another country would be accepted in their process for registration if the testing of pesticides follows the agreed test guidelines or protocols and complies with the principles of Good Laboratory Practice (GLP) and the evaluation is done based on the agreed criteria.

Intellectual property rights, data ownership, data compensation, data citation and data confidentiality were extensively discussed at the meeting. Certain data should never be considered confidential, irrespective of patent or data protection periods. These are data that are needed for the protection of human health and the environment. However, information including the analytical impurity profile of the technical grade active ingredient, the composition of the pesticide formulation, and the manufacturing process of the active ingredient and the
formulation, which is Confidential Business Information, should never be disclosed to a third party. The WTO TRIPS agreement gives indications on data property rights and their uses by different parties.\(^1\)

The meeting also discussed some specific issues related to the registration of pesticides. These include pesticide mixtures, formulants, equivalence determination, minor use and microbial pest control agents. Of great interest is the issue of minor uses, which applies to pesticides used on a small scale, which may not provide sufficient economic incentive for a registrant to support initial or continuing their registrations. The meeting noted that it is a problem in many countries and recommended that governments should develop criteria and procedures for registration of such products that will on the one hand allow for an acceptable efficacy and risk assessment while on the other reduce the data requirements for applicants. Procedures for the registration of minor use products are generally based on extrapolation of efficacy and residue data from one country to another, or between pests and/or crops. Mutual acceptance of data is an important principle that Responsible Authorities should adopt to allow for effective minor use registrations.

If the active ingredient or product has already been registered in the country on another crop or against another pest, a label extension, with the agreement of the registrant, may be considered an appropriate way to register a minor use product.

Member States should design procedures suited to their own specific needs and not necessarily adopt all the elements of a regulatory scheme as may be in operation in another country, particularly in countries with much resources. However, all countries in which pesticides are used should have an effective pesticide registration scheme in operation. Such a scheme can assist in ensuring that pesticide use does not result in unreasonable risk to man, livestock and the environment.

\(^1\) http://www.wto.org/english/tratop_e/trips_e/trips_e.htm
The meeting recognized the need for the establishment of a "Pesticide Board" as an officially or legally appointed body that takes the final decision on the application for registration of a pesticide. It should consist of highly qualified independent experts who together cover all the relevant fields of pesticide evaluation and management. Members could be drawn from government, academia or may be independent experts, and should cover at least the sectors of agriculture, health and environment. In some legal systems, the Pesticide Board will take the final decision to register a pesticide, i.e. it "signs the registration". In others, the accountable Responsible Authority may need to administratively formalize the registration decision. The Responsible Authority serves as the secretariat to the Pesticide Board. It deals with all matters related to the implementation of the pesticide registration scheme, such as receipt of applications, evaluation of registration dossiers, preparation of summaries and draft decisions for the Pesticide Board, correspondence with applicants, and archiving and maintenance of the Register. The Responsible Authority may rely entirely on its own staff to execute these tasks, or it may call upon external expertise for part of it. The latter will be most likely to be needed for the evaluation of registration dossiers, when external experts such as chemists, entomologists, plant pathologists, weed scientists, toxicologists and environmental scientists may need to be assigned from other government agencies or academia, or contracted. All those who have access to the pesticide registration dossiers should sign a confidentiality declaration in which they are obliged not to disclose any confidential proprietary pesticide data.

The meeting made editorial and other specific comments and recommendations for consideration and inclusion in the guidelines.

Dr Zaim informed the meeting that principles of comparative risk assessment and substitution principles have not appeared in the current draft and will be included in the revised version of the guidelines. No other issues on registration of pesticides were proposed by the meeting for inclusion in the guidelines.
5. CONCLUSIONS AND RECOMMENDATIONS

The meeting noted that there had been sufficient discussion on the guidelines and that specific recommendations made to different sections of the draft guidelines adequately covered the objectives of the document. WHOPES was requested to make the necessary amendments to the draft based on the discussions and recommendations of the meeting and to submit the revised document for review by the FAO/WHO Joint Meeting on Pesticide Management, to be held at WHO/HQ in Geneva on 6–10 October 2008.

The meeting noted the importance of harmonization of registration requirements and procedures and requested international organizations, such as WHO and FAO, to facilitate the establishment of regional and or subregional registration schemes.

It reiterated the need for an intersectoral approach to pesticide management and recommended the close collaboration of health, agriculture and environment sectors.

The meeting was informed of plans for the formation of the world mosquito control association. It reiterated the need for close collaboration with such scientific associations in building the capacity of Member States in vector control.
ANNEX 1 AGENDA

1. Welcome address and opening remarks
2. Introduction of participants
3. Appointment of Chairman and Rapporteurs
4. Secretariat report – Developments since the last GCDPP meeting
5. Objectives of the meeting
6. Presentation and discussion of the draft guidelines on registration of pesticides
7. Conclusions and recommendations
8. Closure of the meeting
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