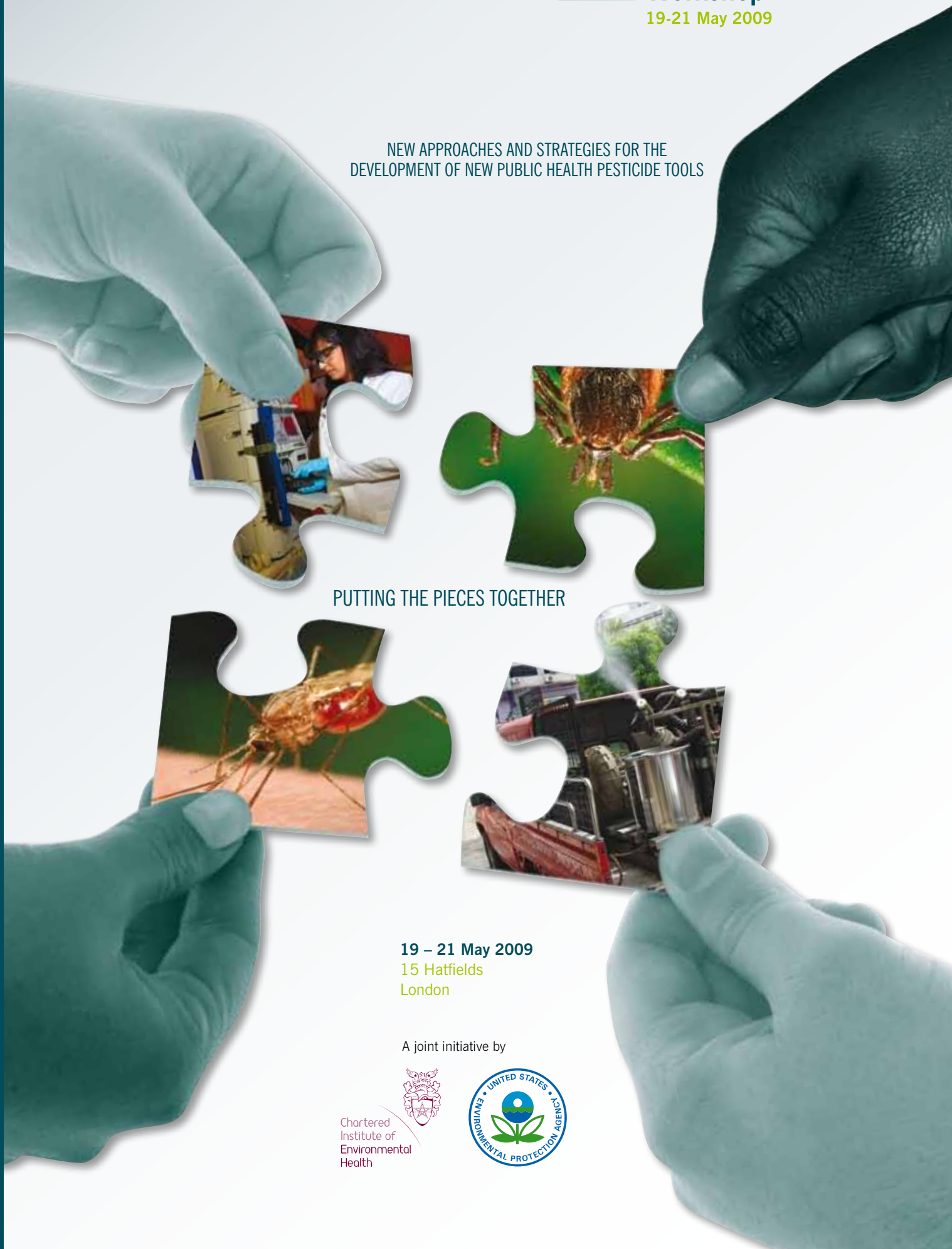
Report of the International Public Health Pesticides Workshop

19-21 May 2009

NEW APPROACHES AND STRATEGIES FOR THE DEVELOPMENT OF NEW PUBLIC HEALTH PESTICIDE TOOLS



PUTTING THE PIECES TOGETHER

19 – 21 May 2009
15 Hatfields
London

A joint initiative by

Chartered Institute of Environmental Health

United States Environmental Protection Agency

Organized by the US Environmental Protection Agency (EPA) and the Chartered Institute of Environmental Health (CIEH)

with the support of:
UK Health and Safety Executive (HSE)
Interregional-4 Project (IR-4 Project)
CropLife International

and together with:
The Bill and Melinda Gates Foundation
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Keywords

(for internet/literature searches)

Public health pesticides; Pesticide registration; Pesticide regulation; Pesticide management; Malaria; Mosquitoes; Pests; International workshop

Executive Summary

The first International Public Health Pesticides Workshop was held 19-21 May 2009 in London, UK at the Chartered Institute of Environmental Health (CIEH).

It was organized by the US Environmental Protection Agency (EPA) and the Chartered Institute of Environmental Health (CIEH) with the support of the UK Health and Safety Executive, the US Agency for International Development, the Interregional Research Project 4 (IR-4) and CropLife International; together with Bill and Melinda Gates Foundation, US Department of Agriculture, Agricultural Research Service, the US Armed Forces Pest Management Board, and the US Centers for Disease Control and Prevention.

The purpose of the workshop was to identify new approaches, processes and implementation strategies for the development and approval of public health pest control tools, leading to improved availability of safe, efficient, and cost-effective insecticides to control insects that transmit disease.

Representatives from government and non-government agencies, other organisations and the public health and vector pest control industries agreed to work towards a better framework for conducting global joint reviews of new public health pesticide products.

The 100 participants from 22 countries, representing regulatory and other government agencies, public health authorities, the World Health Organization (WHO), the World Bank, the pest control industry and other technical experts, considered current pest control topics including:

- availability of tools for use in public health programmes
- possibilities and prospects for development of new tools
- the regulatory processes currently in use around the globe
- the WHO Pesticide Evaluation Scheme (WHOPES)
- the possibilities of global cooperation to review public health pesticides and other mechanisms to encourage development and facilitate approval of these pesticide uses.

The Workshop confirmed the need for harmonization of regulatory review processes and data requirements for public health pest control tools among the different schemes operating internationally. This would facilitate the development and approval of these tools.

Participants identified the following next steps to advance the important work of increasing the availability of appropriate pesticides to improve public health around the world by:

- communicating the content and findings of this Workshop to a broader audience, initially by convening a meeting of regulators from developing countries
- conducting a test case for global review of new public health pesticide products
- initiating discussions with world regulatory authorities and WHO on regulatory review processes and data requirements specific to public health pesticides

Table of contents

Background and scope

Increasing pressures from pests that vector or cause diseases demand effective vector control measures that meet the needs of the public health community and ensure public and environmental safety.

The organizers jointly initiated the International Public Health Pesticides Workshop in consultation with stakeholders to improve the availability of products to control public health pests in industrialized and developing countries.

From a global perspective, public health programs are faced with a depleting arsenal of safe, efficient and cost-effective insecticides. This is mainly due to the resistance of major vectors to many common agricultural insecticides.

In addition, the withdrawal or abandonment of certain pesticides for reasons of safety or high cost of registration and evaluation has further reduced the available options. Obstacles, such as disincentives for pesticide development and registration, financial and technical constraints for data generation and discrepancies in regulatory standards among countries limit access to newer and less hazardous pest control methods for vector control officials.

If a global approach to public health pesticide registration can be developed, the continued supply of new pesticides for public health may be ensured. While various countries and international organizations have worked to develop registration strategies for pesticides to control pests that impact the public's health, different standards and control measures prevent public health officials from fully utilizing these strategies.

The regulatory approaches of different authorities should be brought together in a framework for registration and dossier preparation that is coupled with a strategy that promotes public health pesticide development. This framework could include a strategy for expedited shared dossier reviews, creating a regulatory environment that promotes development of new public health pesticide uses by industry and cooperating agencies.

Purpose

The purpose of the meeting was to identify new approaches, processes, and implementation strategies that will lead to development and approval of new public health pest control tools. The meeting outputs complement on-going global public health efforts and lay the groundwork for establishing a process for conducting global reviews of new public health pesticide products.

Introduction

The first International Public Health Pesticides Workshop was held 19-21 May 2009 in London, UK (www.iphpw.org). It was organized by the US Environmental Protection Agency (EPA) and the Chartered Institute of Environmental Health (CIEH) with the support of the UK Health and Safety Executive, the US Agency for International Development, the Interregional Research Project 4 (IR-4) and CropLife International; together with Bill and Melinda Gates Foundation, US Department of Agriculture, Agricultural Research Service, the US Armed Forces Pest Management Board, and the US Centers for Disease Control and Prevention.

The three-day workshop was attended by a wide array of representatives including those from the WHO Pesticide Evaluation Scheme (WHOPES), the Stockholm Convention, developed and developing countries, industry, and other interested parties.

The aim of the meeting was to bring countries together to address challenges facing the development and use of public pesticides. More than 100 delegates attended from more than 22 countries, all focused on communicating global themes and aims within the public health pesticides world.

This sustainable event planted 200 trees to offset carbon emissions caused by the workshop.

Day one

Plenary session

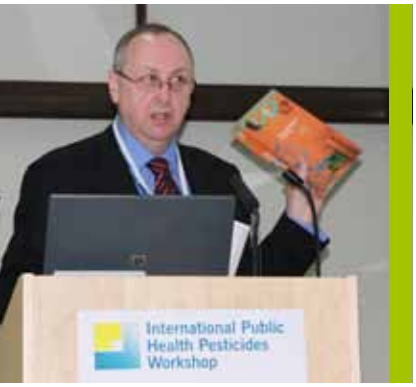
Lois Rossi, Director Registration Division, US Environmental Protection Agency, in welcoming the more than 100 participants acknowledged their commitment to this timely workshop.

She introduced other EPA staff (Ms. Kathy Monk, Mr. Kevin Sweeney, Mr. Marion Johnson, and Ms. Susan Jennings) and the workshop facilitator Mr. Jeff Blair. She proceeded with an overview about regulatory obstacles limiting access to new methods for vector control while pointing to the need to develop a strategy to address these obstacles in the context of on-going international efforts. The overriding theme of her presentation was that of harmonization:

"Regulatory authorities face similar problems everywhere," said Ms. Rossi, "We need to work together to take advantage of harmonisation efforts that have taken place over the last decade. We hope to foster open communication, promote dialogue with all stakeholders and identify concrete steps."

In charging the attendees to conduct the IPHPW productively, Lois Rossi specified its pre-agreed goals, procedures and objectives:

- Provide an overview of the scope of global public health pesticide registration, approval, and regulation; national legislative frameworks; and related legal processes
- Discuss requirements for data generation that are acceptable nationally and globally
- Identify preliminary approaches to a harmonized data generation program and suggest ways to share data both nationally and internationally
- Identify and recommend the types of information, strategies and actions needed to develop new public health pesticide tools in order to address both near-term and long-term burdens of vector-borne diseases
- Explore approaches to share the regulatory review work for public health pesticides in order to streamline the approval process and provide incentives for development; and, develop a pilot project as a first step to implementation



Graham Jukes, Chief Executive of the Chartered Institute of Environmental Health introduced the "three days of intensive discussion."

He talked about the recent WHO book "Public Health Significance of Urban Pests" and paid tribute to one of the authors, Xavier Bonnefoy, who died in 2007. Mr. Jukes said, "This book encapsulated CIEH's involvement in a whole range of issues around the public health significance of urban pests." He emphasised the importance and need to ensure public health practitioners and their agencies have the appropriate policies, tools and management systems in place to combat present and future disease threats.

SESSION 1 - Past, present and future outlooks for controlling vector-borne disease and public health pests. The objective of this session was to summarize initiatives to control vectors/vector-borne diseases and other public health pests; report on successes/failures of currently used public health pesticides, and describe tools needed for the future.

Joseph Conlon, American Mosquito Control Association (AMCA) described the association's mission, which is "to promote control of and research on mosquitoes and related subjects in the broadest sense and to disseminate information on the bionomics of mosquitoes and related subjects worldwide."

He gave an overview of the mosquito control situation in the USA where Integrated Pest Management (IPM) is well-established. Ultra-low volume (ULV) pesticide applications from truck mounted sprayers and aircraft are used extensively to control adult mosquitoes. Larval mosquito control practices are widely used and often combined with breeding area modification when needed.
In terms of personal protective measures, window screens are used effectively and, while repellant availability is good, even in zones with active cases of West Nile Virus personal use of insect repellents is low (about 50% or less). Challenges facing mosquito control professionals in the USA include the implementation of the Clean Water Act (no pollutants in any navigable waterway) and the Endangered Species Act.

Pyrethroid insecticides are used extensively in mosquito control programs. Etofenprox was recently registered as an adulticide and very recently there was a new repellant registered with catnip as the active ingredient.

AMCA members need highly specific mosquito control insecticides, products with new modes of action to prevent mosquito resistance to currently used pesticides, and those that will have few non-target environmental effects.

The US public is looking for natural products, said Mr. Conlon, and this is something the industry is constantly seeking out. He also emphasized that he feared that the application of the "Precautionary Principle" could lead to problems for vector-control program implementation and pesticide use in the USA and elsewhere.

Rajandar Sharma, Joint Director (Entomology) National Vector-Borne Disease Control Program, India talked of national health policy goals for VBDs (vector-borne diseases).

Kala Azar is endemic in four states and 52 districts, he reported, and Japanese encephalitis and dengue fever and Chikungunya have widespread viral activity with frequent outbreaks. He said that India hoped to reduce mortality from malaria, dengue and Japanese encephalitis by 50% by 2010. He also said they aimed to eliminate visceral leishmaniasis by 2010 and lymphatic filariasis by 2015. He explained that there are around 1-2m cases of malaria annually in India and lymphatic filariasis is endemic in 250 districts affecting a population of up to 525m.people.

Dr. Sharma provided an overview of integrated vector management (IVM) in India, which involves the use of five pesticide use patterns:

- indoor residual spraying (IRS);
- long lasting insecticide treated nets (LLNs);
- use of larvivorous fish;
- larval source reduction and larviciding in urban areas; and
- environmental modifications to reduce mosquito breeding.

India has an extensive insecticide resistance monitoring program that has detected DDT and/or malathion resistance in malaria vectors.

He described the steps in the process for introduction and registration of new pesticides in India. This process usually requires two-three years of efficacy field trials (in three phases), making application for registration to the Central Insecticide Board (CIB) (one-two years), monitoring by an expert group (6-12 months), and an annual review by a technical advisory committee.

Currently, a 25% WP formulation of diflubenzuron and a 0.5% granular formulation of pyriproxyfen are under review for consideration as new public health larvicides in 2009. Dr Sharma also provided an exhaustive list of public health pesticides approved for use in India that can be found in his presentation.

Issues facing the industry, said Dr. Sharma, include ongoing problems with formulations of the biolarvicide, *Bacillus thuringiensis var israelensis* (Bti), which are registered with the CIB. The storage temperature mentioned in the CIB registration was 150C to 250C but during trials by the National Institute of Malaria Research, the storage temperature was reported up to 450C. A legal case was filed and procurement was stopped. Because of, no anti-larval measures can be undertaken in urban settings with these products.

Qiyong Liu, Director of the Department of Vector Biology and Control at the National Institute for Communicable Disease Control and Prevention, China explained that the main approach for vector control in China is pesticide application.

He described this as follows: “China has a long history of public health and pest control,” he said, “and by 2005, there were about 87 active ingredients registered for pesticides.” Pyrethroids make up 53% of this number, with the remainder consisting of organophosphorous, carbamate, inorganic, microbial and organochlorine pesticides. There are, he said, more than 2,000 products registered in 66 formulations. Target vectors include mosquitoes, rodents, house flies, cockroaches and fleas.

The Institute for the Control of Agrochemicals, Ministry of Agriculture (ICAMA) is the national authority responsible for pesticide registration and supervision. Established in 1963, it’s affiliated to the Ministry of Agriculture and is responsible for pesticide registration, quality control, bioassay, residue monitoring, law enforcement, information exchange and co-operation.

In 1997 the State Council promulgated “Regulations on the Management of Pesticides”, which includes the registration pesticides, the production license, business license and standardization. The Ministry also has rules that cover the regulation of pesticide advertising, production practices, and pesticide management in China. He also mentioned that China was addressing the requirements of the Stockholm Convention.

After an overview of the development of pesticides in China, Dr. Liu talked about the current registration situation in the country.

In the last ten years, the Chinese Pest Control Operation Services have grown and pest management professionals have quickly organized themselves to establish professional rules, standards, training guidelines and protocols for professional practices.

The Department of Vector Biology and Control (DVBC), affiliated to the National Institute for Communicable Disease Control Prevention of China CDC is a professional organisation to provide technical supports to the central government for the control of disease vectors and public health pests.

The DVBC runs the National Vector Surveillance Networks. A total of 37 labs are accredited to evaluate the qualification of public health pesticides and 21 labs belong to the CDC. Insecticide surveillance networks are present in 18 Chinese provinces.

Dr. Liu promoted the Third International Forum for Sustainable Management of Disease Vectors which takes place in 2010 in Zhejiang. Topics to be covered include emerging vector-borne diseases under climate change, risk-assessment and alert on vector and vector-borne diseases, rapid and accurate identification of disease vectors, sustainable development and application of pesticides, vector surveillance and control in emergency response, vector surveillance and management in big events.

Dr. Steven Schofield, Senior Advisor, Pest Management/ Entomology, Department of National Defence, Canada gave a presentation on pubic health pesticides, perspectives from a (relatively) small military

He mentioned two dualities; that of protecting the health of individuals and the health of the mission, i.e., public health. Canada has a risk-based pesticide regulation system, he explained, going on to point out that in the Canadian Pest Control Products Act 2002, the words “health” and “risk” account for 1% of the text and never does it mention the benefit of protecting public health (from vector-borne diseases).

In Afghanistan, where Canada has its largest military contingent, infrastructure and sanitation and engineering solutions (for vector control) are satisfactory but as he explained, “In a battlefield, the risk is the same as what you would expect to see for indigenous populations.”

He followed with a discussion that summarized personal protection insect bite precautions (IBPs) in terms of their scope of use and “combat” friendliness. The current IBP construct includes:

- topical repellents with no real alternatives to DEET;
- bednets – none of which are considered long lasting insecticide treated nets by the Canadian military;
- permethrin treated uniforms;
- spatial repellents.

As an example, in Kabul in Afghanistan, only 11% of the troops use DEET and only 21% sleep under a bed net. Seventy-seven percent wear permethrin treated uniforms but only 4% of the troops use all three tools in combination for personal protection.

In terms of protecting the mission, vector-abatement tools remain very limited and intervention is quite difficult in battle conditions. Dr. Schofield concluded by saying that any future developments need to be culturally sensitive because despite the availability of tools. As he explained, "if nobody uses products, what's the point?"

SESSION 1 DISCUSSION: Ensuing discussion raised several additional matters not mentioned by panelists.

Mr. Karl Malamud-Roam (AMCA) was concerned about offsetting the influences of anti-pesticide activists whose case was often based on extreme examples, such as the Bhopal incident.

Dr. R.S. Sharma (India) emphasized that anti-malaria practices such as indoor residual spraying (IRS) were usually welcomed by the affected communities in India.

Dr. S. Schofield (Canada) felt that skepticism about PH pesticide exposure was essentially a western phenomenon; he mentioned that CropLife has successfully challenged a particular court decision in Ontario.

Dr. Joe Lines (WHO Global Malaria Program) asserted that pesticide safety perceptions depend on needs, exposure, and experience.

Various comments on the implications of current scaling-up of coverage with insecticide treated bed nets (ITNs), being distributed to hundreds of millions of people for protection against malaria, led Dr. Kate Aultman (B & M Gates Foundation) to ask "How difficult is it getting disparate groups working together?"

Dr Sharma remarked that regulators may trump public health authorities, whereas Joe Conlon opined that AMCA finds EPA very easy to work with.

Referring to Dr. Quiyong Liu's presentation, Mr. Paul Whylie (Stockholm Convention Secretariat) questioned whether China had phased out DDT production and/or usage since 1983; in response Dr. Liu explained that China keeps a DDT stockpile for emergency PH applications.

When asked about DDT continued usage for vector control in India, Dr. Sharma replied that it is only used where the vectors are not resistant. He added that, for the past 25 years, effective alternative insecticides such as malathion have been used for malaria control in areas with DDT-resistant vectors.

SESSION 2: Vision for New Tools covered new tools that may be developed for public health pest control in the future. The scope of this discussion included: new chemicals; new vector/pest targets and modes of action; and new approaches to vector control.

Dr. Kathryn Aultman, Senior Program Officer, Global Health Programs, Bill and Melinda Gates Foundation, presented her vision for new tools for public health pest control.

"A series of self-evident statements," Dr. Aultman said, "set out the broad characteristics for vector control. They have to reduce transmission of pathogens by vectors but this is not the same as reducing the abundance of vectors. We need to prevent them from transmitting (whether this is biting or being infected or being infectious to others). This is not synonymous with killing."

New tools should reduce transmission by vectors and be:

- Globally accessible
- Profitable for manufacturers
- Safe, efficacious
- Acceptable to users
- Fit for the market

She also said that her concern was being able to reach the poorest quintile of the population. "Any tool must be at an affordable price for the world's poorest. We need to reach the farthest recesses," she said.

Profits in vector control, she said, are razor-thin compared to its counterparts in drugs. Specific actions such as articulating an analytical framework for prioritizing tools; establishing target product profiles (TPPs), supporting product field testing and reviewing evidence, all need to be undertaken.

"What we need to do as a community is develop the means for a consensus view," she added. She likened the process to a football match. "A football player has to pass the ball downfield to the striker. Teamwork allows him to know where to send the ball to set up a goal. It's a quintessential moving target, a dynamic system with many moving parts."

The pesticide regulatory framework should include the following elements:

- Stable and predictable regulatory environment
- Cooperation between regulators and industry
- Swift and transparent regulatory approval process for pharmaceutical products
- Harmonization of regulatory requirements globally
- Adjustment of regulatory requirements to advances in science and technology

Dr. Aultman emphasized that we must develop an initial vision of public health need by;

- conducting field studies for proof of principle
- precisely defining the target product profile
- consider public health strategy and policy development while organizing marketing elements such as procurement and delivery, financing, infrastructure development and prequalification

Dr. Aultman said it was vital to consider different behaviours and ecologies of vectors around the world; find the big gaps; and develop tools accordingly. “We are overdue a revolution in vector control,” she said, “but innovation is biologically possible and within economic reach.”

Tom McLean, Executive Director Innovative Vector Control Consortium (IVVC), UK, presented on the new public health pesticides pipeline.

“As you well know, the range of appropriate insecticides is very small,” he said. “Effective Disease control and eventually elimination requires new and better insecticides to overcome resistance and information about mosquito populations and disease epidemiology.”

He described the “Insecticide Resistance Time Bomb” and asked “Are we mapping vector resistance to insecticides or simply the presence of entomologists?”

Dr. McLean described the synergy of key objectives, which includes

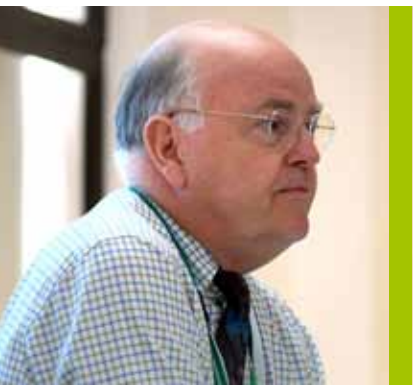
- novel sustainable public health products
- developing new paradigms for vector control
- repurposing existing insecticides and developing new formulations to manage insecticide resistance
- the issue of residuality
- improving vector control systems and best practices by making use of information systems for decision support

He talked of exciting and new opportunities in the pipeline for indoor residual spraying and long lasting insecticide treated nets. He emphasized that new formulations and products coming into the public health insecticide development pipeline will “stretch” existing registration systems.

"Current registration systems are designed to fit known conventional patterns of action and may reject innovative products," he said, "We need systems that will recognise alternative killing mechanisms, anti-feedants and growth regulators and we need mechanisms to assess resistance breaking."

Dr. McLean mentioned a terrific response from the agrochemical industry to step up to the plate in bringing through active ingredients: "We are seeing a range of products working their way through that are specifically public health-related active ingredients that won't come through a regulatory process.

Nobody has ever created a public health insecticide that didn't come through the agricultural process and how are we going to deal with that?" He suggested that one way to speed introduction of new products is to develop a "prequalification process" as has been used with success for antimalarial drugs.



Graham White, US Department of Agriculture (USDA) gave an overview of the US Deployed War-Fighter Protection Program.

The program's objective is to "screen, develop, and evaluate new and existing public health insecticides and improve application methods to provide protection to deployed warfighters from arthropod vectors of disease."

He talked about the development of new pesticides and application methods to protect military personnel from biting arthropods. The $5m per year funding, he explained, was divided into $3m to the USDA Agricultural Research Service, $1.6m per year for other competitive proposals and grants of up to $250,000 per year.

The emphasis, said Dr. White, is on development of new insecticides, chemistries and better formulations, personal protection measures and system spray technologies.

He also talked through some of the achievements of the USDA, including the use of DDT in the Pacific War and the 60% mortality-rate reduction of children in the Gambia in 1991 by using the pyrethroid net technology developed by the USDA and Department of Defence.

The USDA has more than 100 entomologists on committees around the USA, he explained, and there is a swathe of patent applications. But, he says, "The EPA's (Environmental Protection Agency) approval is inherent in what we're doing and there is a curious crossover issue. If our programme were to discover something in Iran or Iraq or somewhere useful to other allies in the WHO context, it needs EPA approval even if we never use it in the US." Herein, said Dr. White "lies a way in which we might negotiate a label."

Paul Whylie, Programme Officer, Stockholm Convention spoke about the Global Alliance to develop and deploy alternatives to DDT.

The alliance's objectives, he said, are to bring together key organisations and stakeholders to facilitate the identification of gaps in existing programmes and catalyze complementary action. The group is concerned with raising awareness of all stakeholders involved in disease vector control and to monitor and share the progress towards the development and deployment of alternatives to DDT.

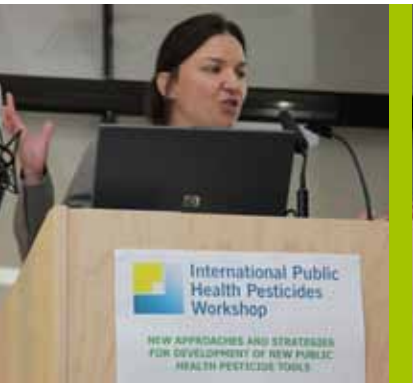
The goals of the alliance are to:

- strengthen the base of knowledge available to inform policy formulation and decision making
- overcome the complexity and cost of deploying alternatives to DDT
- make available new alternative vector control chemicals.

The challenges associated with implementing these goals, he said, were obvious and to do with cost and commercialisation processes. The alliance assembly, said Whylie, will meet every two years (the next one in 2011), to approve the work plan of the steering committee (to be formed this year), which comprises 15 members (10 parties and one from each sector).

Further to this, thematic groups will be created to address the gaps raised by the steering committee and to mobilise operational resources. The next conference of the convention will be held in 2011. "We have DDT and we have the mosquito and in between we have indoor residue spray," said Mr. Whylie, "the solutions we see are new cost-effective products or the use of new existing products which will eliminate the need for DDT and IRS. We are looking for a win-win situation."

The ultimate goal of the alliance is to eliminate the use of DDT while helping to facilitate solutions that will negate the transmission of the malaria parasite.



Session 3: The next session saw **Serena Guarnaschelli, Susanne Frick, Sarah Harvey and Soren Peter Andreasen from Dahlberg Consulting** in Switzerland presenting the results of the "Regulatory Landscape for Novel Public Health Pesticide Products Survey", commissioned by the Bill and Melinda Gates Foundation, to be published later this year.

The survey, Ms. Guarnaschelli explained, was borne of the perceived regulatory burden in bringing public health pesticide products (PHPPs) to market. The report examines the impact of the country level registration processes and WHOPES recommendations on PHPPs market access and innovation while identifying some of the 'roadblocks' to development and registration.

She added that the presentation was designed to create a fact base in order to prompt further discussions at the workshop. The survey looked at public health pesticide regulation in Brazil, Nigeria, Senegal, Tanzania and Zambia in depth and China and India at a high level by interviewing key stakeholders including regulatory authorities, WHO Pesticide Evaluation Scheme, ministries of health, environment, and agriculture, and pesticide manufacturers.

Because of the availability of data, the focus of the report is on formulation innovation within existing product categories using existing active ingredients (AI).

Some of the findings weren't surprising. For new formulations with an existing AI, the costs and time taken for registration are significant factors in the process to market. Registration constraints impact manufacturers' market entry strategy and have an impact on decisions for investment in innovation.

The group expects to publish the findings in late 2009.

This was followed by an overview of the **WHOPES** scheme, presented by **Dr. Morteza Zaim and Dr. Rajpal Yadav,** scientists on the scheme.

The international WHOPES scheme was established in 1960 and functions in collaboration with a network of collaborating centres and research institutions as well as a panel of experts to coordinate testing and evaluation of PHPs.

The four-phase scheme facilitates the search for alternative pesticides and application methods as well as developing and promoting policies, strategies and guidelines for PHP applications.

WHOPES' priorities, said Zaim, are to increase collaboration with national programmes and stakeholders (including NGOs and industry), to mobilise resources for strengthening national regulatory capacity and to expand WHOPES testing and evaluation.

Dr. Zaim summarized the application dossier, which includes information about the manufacturer, physical-chemical properties of the pesticide, manufacturing process and specifications, together with human and environmental toxicology. The evaluation process examines safety, efficacy, operational acceptability and adherence to WHO quality standards.

Duration and cost of WHOPES studies are variable depending on what is being tested for and what information is available. "In the international community, expectations on WHOPES are rising," he said, "and WHOPES sees the important role it has to play today but our regular budget is dwindling, so much that our regular budget today for such activities is zero."

The latest guidelines were developed in 1996, said Zaim. "We have realized that some of these need updating. The guidelines were too general for industry and research institutions, so what we have been doing is to develop more detailed guidelines with the aim of harmonising the procedure."

He added that six more guidelines would be published by the end of the summer at www.who.int/whopes/guidelines/en/. WHOPES is also developing risk-assessment models and, in collaboration with the International Programme on Chemical Safety (IPCS), is trying to harmonise these.

Dr. Zaim welcomed criticisms and suggestions to how the WHOPES recommendations could be improved.

Finally, Dr. Zaim ended the morning session by outlining his vision for WHOPES, in which he emphasized that registration was the key to sound management of pesticides.

Registration programs should be characterized by an adequate legal framework with comprehensive data requirements. Internationally accepted and agreed evaluation standards and procedures should be followed and decision makers should make use of all available information. Processes should be transparent and strive for harmonization. However, risk assessment and mitigation should be based on local situation.

The **Pesticide Industry Panel** session opened the afternoon session by discussing the current regulatory landscape, hurdles to registration, product stewardship issues and suggestions for regulatory solutions.

BASF, Bayer Environmental Science, Bestnet, Clarke Mosquito Control, Sumitomo, Syngenta and Vestergaard Frandsen were represented by the newly formed Vector Control Project Team (VCPT) of CropLife International.

The group was formed to ensure the promotion of investment in new solutions, assuring safety and sustainability, sharing responsibilities and compliance, and timely access to technology.

The global plant science industry federation CropLife International (**represented by Vincent Dartigues, Head of Product Development and Regulatory Affairs and International Regulatory Manager Bernhard Johnen**), presented their five key founding principles for improvement of current processes.

- Encourage public/private partnerships for new product development (leveraging resources a la IVCC)
- Establish a harmonized set of public health product registration requirements
- Review new actives and end use products with relevant risk/benefit assessments for human safety, disease control and lives potentially saved
- Establish one universal dossier package assessed by work-share review by relevant experts from global regulatory bodies and stakeholder countries
- Following the work-share data review, registration and re-registration decisions to be fast-tracked in countries to improve speed and consistency of public health product registrations (e.g. OECD or European model)

Mr. Johnen hit home the importance of good science-based risk assessment, saying, “Risk can be negligible, acceptable or significant but it can’t be zero.”

Additionally, the VCPT felt strongly that the pesticide industry can offer excellence in R&D, expertise and knowledge in vector control. Based on this experience and in an attempt to streamline the current public health regulatory landscape, the VCPT submitted a white paper entitled “Improving the Development Time and Speed to Market of New Innovative Vector Control Products” (Appendix B) based on challenges that include limited market size, difficulty to re-purpose agrochemical products, higher regulatory costs, longer and complex registration processes (which can take as long as 5 years) and a lack of incentives to invest in specific new chemistries for public health.

The strengthening of WHOPES should also be encouraged by establishing work-share arrangements with regulatory bodies such as USEPA, EU, etc. by forming an international data review team, which would constitute countries, WHOPES, and regulatory bodies.

The proposal for an improved scheme recommends that all recommendations be based on the following:

- established WHOPES guidelines
- new guidelines
- open dialogue between scientific experts, WHOPES, and the developing company
- develop guidelines to quantify institutions to execute WHOPES-compatible efficacy studies
- data must prove equivalence of me-too products
- WHOPES to provide guidance to countries to establish eco-geographic areas or zones for efficacy trials

In general, VCPT requests a scheme that includes transparency, consistency, speed, and universal acceptance which will enable new tools being brought to market.

Robert Sloss, Innovative Vector Control Consortium (IVCC) UK introduced the IVCC, a not-for-profit company and registered charity to overcome the barriers to innovation in the development of new insecticides for public health vector control.

"The obvious barrier and the reason for the IVCC's existence is the cost of development related to the market size," he said. "If the market were big enough companies would be quite happy to develop new products and new active ingredients. But," he added, "with an insecticide market size of $400m and developmental costs for a new active ingredient of $100-$150m and a timeline of 10-12 years, we are never going to get a financial case unless some of the cost is taken somewhere else."

Another obvious barrier to innovation is genuine marketplace uncertainty, Sloss said. "Funding for vector control within countries has been variable and it has historically been very difficult to predict." Market intelligence is limited and difficult to obtain. There's a diffused market in many different countries and the market intelligence reports are just not available for people to look at and make decisions from."

Dr. Sloss suggested that product quality can be delivered by global performance standards for each product class alongside a risk-based regulatory process. All testing should be carried out by independent GLP-audited labs and there should be a defined process for setting new performance standards for new lasses of products and reviewing and changing standards for current product classes.

Ole Skovmand, Intelligent Insect Nets (IIN), Denmark, presented the advantages to the current WHO procedures as the only truly independent data generated by an independent institution who can guarantee the effects as described by companies.

IIN believes that Private Sector data may not be correlated to field results and proposes a faster method of replicating the WHO tunnel test effect by changing the exposure time to 5 or 10 minutes so evaluation is easier.

Jonathan Peck, Killgerm Group Ltd, UK, stressed the significance of urban pests and the reduction in public health pesticides in the EU.

It's vital, he said, to, "stop classifying pests just by the disease they cause but by the effect on our quality of life." He added, "We should remember that the WHO definition of health is a state of complete physical, mental and social wellbeing, not merely the absence of disease or infirmity."

Mr. Peck mentioned the WHO 2002 Large Analysis and Review of European housing and health Status (LARES) Survey, which looked at pests in eight cities in the European Union (EU) and Osh in Kyrgyzstan. The survey, he explained, covered the housing and health conditions of 2800 households (8400 inhabitants) and focused on allergies, quality of life, sociology and physiology.

The survey found that six dwellings in 10 had been infested (by mice, rats, ants, cockroaches and fleas) in the previous year in the eight cities. It also showed that if you live in a dwelling with mice present you are 2.21 times more likely to suffer from depression and nearly twice as likely to suffer from migraine. "These are significant findings and have a great deal to bear on the quality of life in industrial cities," said Mr Peck.

He also talked about the WHO book, *Public Health Significance of Urban Pests* (see introduction). "One of the conclusions and recommendations of the book," he said, "related to the amateur use of professional products. Everybody recognizes there are some things that amateurs can do but there really needs to be a stricter differentiation between amateur and professional products and this needs to be enforced." He added, "there is no point in new legislation unless there are new resources to enforce it."

Mr Peck raised the problem of cost in getting products approved under the EU's Biocidal Products Directive. "In 1998 there were some 1000 active substances on the European market," he said. "Of these, only 400 went forward to the full the assessment process and it is expected that only 200 will actually be finally supported. So we have lost 80% of active ingredients on the market. We need a better understanding of the role of pest management in protecting public health but also we need not only the products but also the political will of governments and regulators to make it happen."

The National Public Health Authorities and Public Health Pesticides User Panel came together to discuss how regulatory systems affect work and what improvements in registration schemes should be made.

Ima A. Braga, National Dengue Control Program, Ministry of Health, Brazil provided an overview of vector-borne diseases and their control in Brazil.

Six major vector-borne diseases affect the health of the population. In 2008, there were 314,072 cases of malaria, 585,769 cases of dengue, 3,303 of visceral leishmaniasis, 19,542 cutaneous leishmaniasis and 45,381 cases of Schistosomiasis.

Insecticides are widely used in Brazil with more organophosphates being used than pyrethroids.

For *Aedes aegypti* control Bti has been used and the use of insect growth regulators (IGRs) is increasing. Insecticide resistance has been evident in *Ae. aegypti* populations but Brazil has a monitoring program that guides their choice of insecticide for dengue control.

The main problem faced by the program is the loss of pesticide chemistries available for vector control. Dr. Braga explained that insecticides are still an important component of Brazil's vector-control activities and continued to say that the main insecticides were temephos, organophosphates, pyrethroids, and Bti WDG. The use of insect growth regulators (IGR) was started in 2007 in the dengue program.

Pesticide registration and use are regulated by the Ministries of Health, Agriculture and Environment. Within the Health Ministry, the National Agency for Sanitary Surveillance (ANVISA) is responsible for pesticide registration, regulation of their use and monitoring for residues in food.

Aziz Lagnaoui, World Bank described the challenges faced by public health pesticide users including the 'disconnect' between sectors.

These, he explained, included:

- the need for capacity building and pesticide management: mobilizing well trained teams, restricted career paths for entomologists
- local regulations, which are often weak or nonexistent and, where they do exist, there is little enforcement such as an inability to prevent use of some public health pesticides in agriculture
- few countries test the quality of the products they buy, and if they do test them and find out they are substandard they have to return the product, which can lead to implementation delays
- donor policies may involve compliance, which is difficult to adhere to procurement of pesticides is often done on an emergency basis characterized by communication problems between different ministries, procurement of non-registered or inappropriate products that are not used properly, and a general lack of storage facilities
- operational issues, such as small projects which are not well funded while big projects often have complex logistics.

Such complexities often result in country level problems such that the country often cannot deal with logistics without funding in place.

John Milliner, US Agency for International Development, gave an overview of the President's Malaria Initiative PMI with particular attention to the primary vector control tools used, that is IRS and insecticide treated nets (mainly long lasting nets, LLINs).

In 2005 President Bush announced a new five-year, $1.2b initiative to scale up malaria control interventions in high burden countries in Africa. The goal, Mr Milliner explained, is to reduce malaria-related mortality by 50% in 15 selected countries and to achieve 85% coverage of vulnerable groups with four key interventions;

- insecticide-treated bed nets (ITNs)
- indoor residual spraying (IRS)
- intermittent preventive treatment in pregnancy (IPTp)
- and artemisinin-based combination therapy (ACTs).

ITNs and IRS are the two interventions that require insecticides.

IRS faces many challenges because it is so labour intensive. There is a big need to map and target the IRS programme, complete environmental assessments and micro-plan the need for community involvement.

Taking belongings out of the house can be an implementation issue in some places. Pesticide selection and procurement is a very small part of everything else and the real focus is how many structures can be sprayed within a certain time period.
In addition to the logistics of the spray operation, the IRS program has to deal with local politics, ("getting the chief on your side is vital") if you expect to have good village cooperation.

Concerning ITNs, there is a 'disconnect' between the information from the manufacturers on the number of nets delivered and information from the countries on how many nets were distributed. The most consistent and reliable information appears to be from the manufacturers.

Mr Milliner said that 273 million new nets will be needed in Africa by December 31, 2010 in order to meet universal coverage targets. While this is a positive initiative, he said, it creates huge logistical issues. At the country level the biggest issue is the logistical capacity to distribute the nets that have been received. "For example, this will entail 1500 containers at the port of Lagos in Nigeria alone," he explained, and the logistical problems associated with such a quantity means that the concept of what the active ingredient is in the net gets dropped out of conversation."

There may be sustainability problems with net programmes when nets are being given for free and no plans have been made for replacement of nets. Local regulations are an issue as well and all nets from the large donors are purchased in a tendering system that normally takes up to 6 months to complete. Yet the market is growing fast; there is an expectation that the commercial sector will step-up and start to resolve some of these issues on their own.

Richard Tren, Africa Fighting Malaria spoke about the need for advocacy for insecticide spraying and new insecticides.

"Despite growing awareness of malaria and other vector borne diseases, there is little advocacy for insecticide spraying and new insecticides," he said. Mr. Tren continued, "Despite the large upswing in malaria funding, there is limited knowledge about the need for new insecticides for public health. Good vector control products are still needed, even where we have effective solutions, such as vaccines."

Mr. Tren talked of an urgent need for strong science-based public advocacy for insecticides. "There is also substantial opposition to the use of insecticides in public health," he said. The public health insecticide market is small and difficult to engage in and there has been a lot of successful opposition for their use in Public Health. Advocacy for and against public health insecticides was discussed.

A timeline of advocacy against PH insecticides since the 1970s was mentioned, including reasons for the reductions in use of DDT. He claimed that the Pesticide Action Network (PAN) seeks to replace insecticides, even where alternatives do not exist but it is not clear on whose behalf they are acting.

There has been a lot of successful advocacy against insecticides and not much argument from the malaria community. PAN called for the precautionary principle under EU Directive 91/414; ultimately this will lead to decision making from the politicians and wider public and not the scientists, which we should ignore at our peril.

He also said it was important to challenge campaigns to limit man-made chemicals in disease control and compared the situation to HIV/AIDS activists campaigning against the use of ARVs (antiretrovirals).

He went on to say that WHO continues to discuss the problem of resistance but without real ideas for the way forward. Likewise, RBM (Rollback Malaria) has no roadmap for the future.

Alexandra Chaskopoulou, ASNF, State Airport of Macedonia, Greece presented on how regulatory systems affect the work she does in aerial mosquito adulticiding in Thessaloniki, Greece.

There are 50,000 acres of rice-fields and 23,000 acres of natural wetlands in Thessaloniki, she explained, prime location for mosquitoes. Mosquito problems are both nuisance-based and vector-related as there are competent malaria, dengue and Chikungunya vectors in the region.

The only approved mosquito control method in Greece is larviciding, which was previously been done with temephos. The programme is now being challenged and they are running out of control options. At best, she explained, larviciding is 90-95% effective, leaving too many larvae to mature to the adult life stage, “It’s impossible to larvicide every stagnant water source and adult mosquitoes migrate from protected natural areas.”

The programme decided to do adulticiding (aerial spraying method was used) but as this not yet registered method has to be proven safe and effective before it can be approved for wide-area use. Ms. Chaskopoulu explained that aerial spraying can be very effective if it is properly applied, which involves knowledge of the weather conditions for targeting control.

Ms. Chaskopoulou complained that the products her organisation is using under experimental and limited conditions are already reviewed and approved by WHOPES for mosquito adulticiding. She also suggested there is too much concern for use around human populations when human health risk assessments already conducted by WHOPES exist. Exposures from accepted residential uses far exceed that from aerial mosquito adulticiding. She stated that it will "take a minimum of 4 years from concept to registration to get aerial adulticiding approved and the question remains in the meantime, what would happen if a disease outbreak occurred?"

The question and answer session following this panel included a lively discussion:

Robert Wirtz pointed out that there has been a lot of talk about control of adult mosquitoes by aerial spraying, such as in Brazil and Greece, and asked could resources be used in other ways for the control of adults? Ima Braga replied that annual dengue epidemics in Brazil require this intervention to break the transmission cycle.

Ole Skovmund commented that a large area in southern France is being controlled using Bti because they are not allowed to control adults. Alexandra Chaskopoulou responded that if aerial spraying is properly applied it will kill a lot of mosquitoes and not harm the environment but it has to be applied properly.

Egon Weinmueller asked whether you can get a special permit to use temephos in Greece? Alexandra Chaskopoulou replied that they applied for a permit but it was rejected.

Jessica Rockwood commented that selection of insecticides in some countries is not scientifically based so where does insecticide resistance management and monitoring fit in? John Millner replied that IRS was put together by RTI and they will now be doing monitoring but this was not planned originally.

Janet McAllister asked, since the dengue control programme in Brazil based on adulticiding with organophosphates, how do you choose what to use for larviciding? Ima Braga replied that they started by using Bti and are now introducing IGRs. She explained that where they have resistance to pyrethroids, they use malathion.

Paul Whylie commented that PMI appears to be pushing the logistical priorities as opposed to doing the scientific job correctly, which could be a disincentive for progress. John Millner responded that PMI considers resistance monitoring as very important and has now folded all of this activity into RTIs activities.

Paul Whylie asked Richard Tren what he thought about the 2007 intervention of the WHO advocating for DDT use? Richard Tren replied that he was happy that they took that position. Some of the most strident and outspoken advocacy for DDT came out of South Africa but he was not aware that the WHO's statement has had a large effect on the use of DDT. We need to explain the risks properly.

Comment from John Millner: I am a great advocate for DDT but it comes with so much baggage.

In the panel on **National Regulatory Agencies from Disease Endemic Nations,** the presentations and reports outlined country priorities and challenges, with a focus on cost, effectiveness, quality control/assurance, safety and availability of trained/ qualified personnel to assist with the registration process.

Victoria Mupwaya, Environmental Council of Zambia (ECZ), explained that the ECZ was established by the Environmental Protection and Pollution Control Act (EPPCA) and its mandate is to protect the environment and control pollution.

Public Health Pesticides are governed by the Pesticides and Toxic Substances and Hazardous Waste Regulations. The registration process is standard and involves application forms, data sheets, company profiles, approval letters and local trial results. There is also a registration fee of 500USD per product per year.

There is still a need, said Ms Mupwaya, for data sharing, harmonization of labeling, harmonisation of the registration form and the registration process. "Malaria is the number-one killer in my country," she said, "We phased out DDT in the early eighties but reintroduced it again in 2000. We have tripled the usage over the last four years but have moved in the direction of using IVM, with a steady increase in the use of ITNs"

Halimi Mahmud from the Pesticides Board, Department of Agriculture, Malaysia presented on the public health pesticides registration in Malaysia.

Regulated under the Pesticides Act, 1974, registration is the domain of the Pesticides Board.

"One big issue of the registration of pesticides in Malaysia," said Mr. Mahmud, "is inadequacy of the supporting data, local data." He added, "There are cases where there is a need for a company to generate information based on local situations and local data is needed, but in most cases in Malaysia we accept data generated by other countries with similar climates and similar cultural practices."

Harmonised data requirements are an issue, said Mr. Mahmud. "As far as public health pesticides, especially household pesticides such as mosquito coils and mosquito mats, are concerned there seems to be a lack of harmonised data in order to support their registration."

Good quality checks are essential, said Mr. Mahmud: "We have to have good quality-control facilities otherwise whatever we register will cause problems."

Malaysia has agreed to support harmonisation with 10 Asian countries. Said Dr Mahmud, "We are currently in the process of getting funding from the FAO with the aim to assist the Asian countries but at the moment this harmonisation is virtually non-existent."

Geoffrey Onen, Government Chemistry and Analytical Laboratory, Uganda presented through a special tele-conference link on the structure of public health pesticide regulations in Uganda.

Uganda has some of the highest levels of malaria transmission recorded in the world and is estimated to kill 320 people every day. Areas of major interest in vector control are indoor residual spraying and insecticide-treated bednets.

Challenges to regional harmonisation, said Mr. Onen, were posed by the slow pace of the harmonisation process, different registration procedures, limited facilitation, legal barriers (all partner states needing to be present), policy changes due to slow pace and language barriers.

Nolwazi Mkize, Department of Agriculture, South Africa provided an overview, also by special tele-conference link, on the South African pesticide regulatory system and public health pesticide registration.

There were no questions for the panel members or discussion.

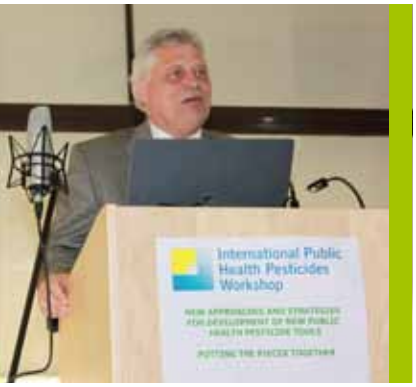
In the **Pesticide Regulator Panel Discussion,** existing registration paradigms were the discussed, along with the importance of developed nations' pesticide registrations/authorizations.

Lois Rossi, US Environmental Protection Agency (EPA), talked about the extensive harmonization efforts among national and regional regulatory authorities and the global joint review process that have been established for agricultural chemicals. She challenged the group to consider how this model might be used for public health pesticides, noting that there are considerable parallels between regulatory issues for public health pesticides and regulatory issues faced for agricultural pesticides, and especially minor uses, 15 years ago.

She suggested that regulatory issues surrounding public health pesticides might benefit by focus from major regulatory authorities. She noted that the U.S., which is also facing a lack of tools for public health uses, intends to focus more attention on this area by having a Public Health Pesticide Officer (Susan Jennings) in the Registration Division; developing a new organizational unit focused on pesticides for public health uses; and becoming more engaged in international issues of public health pesticides.

She presented detailed slides on the history of international harmonization, work-sharing, and joint reviews for agricultural chemicals. These processes are now well established but remain flexible. The available processes of work sharing (use of the work previously done by another national or regional authority) and global joint review (simultaneous evaluation by multiple authorities who receive the application at the same time, divide the work, and then make their own independent regulatory decisions) are being used in different ways at different times and by different countries. She noted how global harmonization efforts had helped Codex to make progress on the many issues that they face in relationship to setting MRLs.

In summary, she suggested the possible advantages of a global process for public health pesticides and possible applications. Possible advantages include: speed; resource savings for regulatory authorities, international standard setting bodies and registrants; harmonization of outcomes (which is a goal not a requirement); and encouraging a regulatory "mind-set" in international standard setting organizations (e.g., use of clear guidance, transparent decision making, established timelines, and communication with stakeholders). Possible applications include: review of new active ingredients or new use for an already registered active ingredient; for data, development of agreed upon data requirements, guidelines for conduct of studies, and review templates; for risk assessment, development of and/or agreement on models and their use; and for capacity building, involvement of countries in the global review process as participants, peer reviewers, or observers.



Keith Dorschner from the Inter-Regional-4 Project (IR-4), USA spoke about how many lives have been saved by the work of the industry.

He explained that IR-4 was founded 45 years ago as a publically funded program that collects pesticide residue data to share with EPA to benefit registration of specialty crops. IR-4 has global initiatives looking at minor use to strive toward global harmonization of pesticide policy for specialty crops. IR-4 has also developed a working group, data portal, capacity building and pilot projects for specialty crops and minor uses.

Dr. Dorschner talked about the Global Minor Use Summit in Rome in 2007, sponsored by IR-4, EPA and FAO. The goal, he explained, was to enhance trade between nations and to ensure growers have access to the most modern and safe pesticides. “We can register all the reduced-risk products we can in the US but if we’re exporting to a country that doesn’t allow residues of that product, it doesn’t do us any good,” he said.

The deliverables of the summit, Dorschner said, included the IR-4 website, a crop-data portal containing information on national data and MRL regulations, involving pesticide registrations worldwide, a CODEX working group and international pilot projects, including a global zoning project.

He reported that the Deployed War Fighters Protection Program and USDA are funding IR-4 to provide regulatory support and data generation capability for registration of new public health pesticide products.

Michel Bouvier d’Yvoire, European Commission Official, DG Joint Research Centre gave an overview of the regulatory framework for biocidal substances and products in the EU.

Public health pesticides, he explained, fall under the definition of biocidal products and are regulated by Directive 98/8/EC. Biocidal products are divided into 23 product types (rodenticides, avicides, repellents, etc). A two step procedure is in place for regulating the placing of biocidal products on the market. The first step is evaluation of the active substance at the EU level up to Annex I inclusion (2 years min). Biocidal products can only enter the market if they are listed in Annex I. The second step is product authorisation at the member state level. There is a mutual recognition procedure in place between member states. A review programme is in place to look at already registered products.

Dr. Bouvier d’Yvoire discussed the review programme, the derogations for essential use (emergency situations) whereby a product can be used for 120 days without full registration and –watchword of the event again – harmonisation issues. He said, “We are lucky that there are 27 member states who can talk to each other so there is a robust process already. In my limited experience,” he added, “decisions are relatively homogeneous and can already be discussed at the appropriate level.” However, Dr. Bouvier d’Yvoire admitted that there is work to do: “We are aware that checking could be more formal and more systematic,” he said, “but this is a general problem worldwide. It’s not enough to do an assessment in an industrialized country and think it will be easily transposed into a disease-endemic country.” He also raised the revision of the Biocide Products Directive, currently in progress and which will be available soon for public comment.

Dr. Bouvier d'Yvoire also identified and discussed evaluation and harmonization issues of importance. These issues included work with other national regulatory agencies and use of WHO/IPCS reviews in the EU Biocidal Review and evaluation process. U.S. EPA and Canada PMRA are now conducting joint reviews with the EU. Areas in need of further work within the EU and between the EU and other national regulatory authorities include risk assessment and risk management. Discussions are also on-going on the revision of the Biocidal Products Directive, especially in reference to transforming the Directive to a Regulation; improving product authorization procedures, and establishing a data sharing scheme for vertebrate tests.

Richard Davis, Director of Approvals of the Health and Safety Executive, UK, gave an overview of the new Chemicals Regulation Directorate (CRD). He described the CRD as a one-stop shop responsible for the regulation of pesticides, biocides and detergents. It's also responsible for monitoring use and impact and research and development. Davis said it was important to look for "opportunities not barriers".

He described the regulation of pesticides and biocides in the UK and the EU. He made specific reference to the Biocidal Products Directive and the evaluation process. First, a registrant submits the dossier and data packages for the active substance. This is followed by identification of Rapporteur Member State (MS), which conducts a completeness check and evaluation. Next, a draft evaluation is made available to the European Commission (EC) for CIRCA consultation. A Technical Meeting (TM) follows. After the TM outputs are made available, a Competent Authorities meeting is held. The Standing Committee on Biocidal (SCBP) votes for inclusion or not and further EU/EC processing leads to an Annex I listing.

Mr. Davis talked of the CRD already "work-sharing" as one member state reviews active substances on behalf of other member states. There is, he said, "A real opportunity for mutual recognition and a real opportunity for products to be registered as one and moved into other member states." Davis added, "It's not a contradiction to say that a regulator can be an innovator." He went on to describe a number of other opportunities for work share with the EU and/or globally including use of lessons learned from the OECD Vision for agricultural pesticides, collaboration within and between review programmes, improving process for active substance evaluation and product authorisations.

There were no questions from the meeting participants.

Day two

Workgroup activities and reports

Morning session: Delegates were divided into three groups comprising national regulatory authorities and WHOPES; registrants, producers and formulators and national health authorities and public health pesticide users.

The work groups' charge was:

- identify the elements, obstacles, and commonalities of the global public health pesticide registration and the associated regulatory landscape
- recommend pesticide development and registration incentives, identifing opportunities for work sharing and joint review activities
- identify the types of new tools needed and recommend how regulators may influence resistance management

Group one: national regulatory authorities and WHOPES
Group Leaders: Ms. Victoria Mupwaya, Environmental Council of Zambia and Ms. Lois Rossi, US Environmental Protection Agency. Rapporteur: Mr. Paul Whylie, Secretariat, Stockholm Convention.

The workgroup identified the following common elements of regulatory processes:

- chemical analysis of product samples by local authorities
- a complete dossier, usually from WHOPES, should be provided
- local data generation, when required, usually consists of efficacy data from field testing done in houses
- requirements may be duplicative for different authorities, which could be an area for efficiency gains; however, cultural, community, and regional aspects must be respected

The extent of information exchange between developed and developing countries must be known in order to assist with the approval and registration of pesticides. The group discussed the need for issues of concern to be addressed in a more "standardized" fashion.

Common sets of data requirements that are more unified (e.g. regional consistencies) can be developed to reduce resource burden and streamline regulatory processes for public health pesticides. Regulatory need to be provided but for manufacturers to develop additional tools but the group could not determine what those incentives would be.

The workgroup identified the following needs:

1. Development of unified core data set (study protocols, efficacy requirements, etc.) that may differ slightly by regional factions.

2. Identification of common/universal data requirements and the identification of local and regional data requirements.

3. Possible development of a comprehensive set of data requirements and information (e.g. prerequisite dossier) that is inclusive of local and individual country needs and addresses those particular concerns.

4. Establishment of additional ways to address data requirements (e.g. data waivers).

5. Pre-market evaluation that would promote the likelihood of public and governmental acceptance by considering what really is desired and amenable to local jurisdictions.

6. Capacity building: Ways to promote self-sufficiency in the individual regulatory authorities.

7. Address the political aspects that effect ultimate "approval" of tools.

8. Do a test case with a new active ingredient/product for public health use to develop a process of concurrent pesticide evaluation/approval among national authorities and WHOPES. This process should consider regional and sub-regional entities that may already exist.

9. Data protection has to be considered.

Group two: registrants/producers/formulators
Mr. Vincent Dartigues, Bayer Environmental Science and Ms. Kathy Monk, US Environmental Protection Agency. Rapporteur: Ms. Susan Jennings, U.S. Environmental Protection Agency.

The group emphasized that regulators should consider both vector control and public health pesticides, in general, recognizing that the risk/benefit analysis may well differ for the two categories and between continents/regions of the world.

The major challenges for public health development and registration were identified:

1. return on investment/probability of success
2. route to market
3. regulatory issues and
4. stewardship

1. Many factors affect a registrant's return on investment and probability of success when developing and marketing a public health pesticide.

Many vector/pest control programmes like to use products that have been successful. Often these programmes are slow to recognize new products, especially those with niche uses. Other challenges arise because procurement officials and recipients of the services prefer simple approaches that they can understand and easily relate to (IRS and bednets). Local capacity is frequently inadequate to support a more integrated or complex approach, even if it has a higher probability of success.

A different paradigm, including a lack of access to new molecules by smaller companies, has prevented new product introductions. Larger companies need to be flexible and license their chemistry because smaller companies are better able to respond more quickly (in a flexible fashion) to market needs but are limited by the resources needed to sell to donor/government markets and for liability coverage.

The capacity and funding of WHOPES is not sufficient to support timely review of new pesticide applications. The industry group generally supports the white paper findings. The WHOPES recommendation process costs too much and takes too long. No fast track system exists for decisions to modify existing products, such as a formulation change

2. A product's route to market can be difficult.

Screening products/new chemistry for agriculture uses may not be appropriate for public health pesticides, since ideal characteristics for both categories differ significantly.

The challenges are complicated due to the fact that customers in the vector control market are rarely the end-user but rather the donor organizations, ministries of health and related government organizations. This can lead to issues with the protection of intellectual property.

Clients in the public health market also include consumers and the professional and consumer markets can be quite different.

3. Regulatory Issues are unique and often conform to the agricultural paradigm.

Given the small market size and marginal returns on investment, a different regulatory paradigm for public health uses is needed.

Regulation is encouraging discovery and development of more specific, less broad-spectrum pesticides that may not be the most effective public health pesticides. Data protection and terms for exclusive use are not long enough.

Data requirements and process under Directives for crops and biocides in the EU are different and cause duplication of work. Harmonization of the data requirements, guidelines and reviews is needed to reduce duplications, hence, speeding up the time to registration. This will enable global acceptance of toxicity, safety, and specifically efficacy and other end-use product-specific data.

Potential solutions are proposed in the CropLife white paper (Appendix B). Communication from government to the public about appropriate use of pesticides and public health issues is necessary.

4. The group recommended that implementation of product stewardship activity in the countries needs support from the government authorities.

It is probable that there is need for new active ingredients for the long-term but development will take time. Implementation of proper product stewardship activity in the countries needs support from governments and agencies.

Group three: national health authorities and public health pesticide users.
Group leaders: Aziz Langnaoui, World Bank and Kevin Sweeney, US Environmental Protection Agency. Rapporteur: David Florin, US Armed Forces Pest Management Board

The workgroup provided their recommendations and vision for each of the prescribed objectives.

1. New Tools.

Only a few classes of insecticides i.e. pyrethroids, organochlorines and organophosphates, are widely used for public health pest control. New tools should have community acceptability, low potential for resistance, be safe and effective; and affordable. Recommendations for public health pesticide tools should be addressed according to use patterns.

Indoor residual sprays (IRS) consist of DDT, malathion and a variety of pyrethroids. New IRS products should be long-lasting (at least a year); cost-effective to apply; formulated for broad applicability; good safety profile; have low potentoial for resistance; and marketed to general consumers in a way that minimizes the cost of applications, i.e. paints with insecticides.
Insecticide treated textiles. Residual pyrethroids are currently the insecticides of choice. New products should retain the above characteristics and be washable/durable, low cost and of low toxicity to children. They must retain insecticidal properties long enough to provide community as well as personal protection. Nets, as individual articles, must also have minimal life cycle impact on the environment and be easy to transport. Regulators and developers should consider the addition of synergists and/or insecticide mixtures in new products.
Space sprays consist primarily of pyrethroids and a few OPs. New products should have no non-target effects, minimal post application persistence, fit into resistance management programmes and have enough activity to not require synergism but be safe enough to establish crop tolerances.
Larvicides must remain target specific, safe for potable water applications, have slow release but persistent characteristics. There is a need for new formulations.
Barrier sprays are needed that are persistent, specific and have high target mortality.
Personal and spatial repellents must be safe, effective, durable and very acceptable to consumers.
Attractants for medically important arthropods are needed that are not only effective but selectively irresistible to the pest, easy to apply, low cost, and consumer friendly.

New pesticide and non-pesticide innovations must be considered and the group identified the following:

- genetically engineered arthropods
- mating disrupters
- sterile male release
- window screening/vector exclusion by building design
- no-pest-strip calendar, expiration indicators, vector specific pathogens and other natural biocontrol agents
- reconfiguring existing tools into innovative uses

- feed-through and systemic (human systemic that produce a repellent effect) pesticides regulating gene expression
- ecological niche management
- insect control naturally incorporated into daily routine giving minimal behavior modification.

Many of these will challenge the regulatory systems currently in place and regulators must consider how to deal with these products in order to be prepared to register them properly.

2. Major regulatory obstacles and recommendations for improvements were discussed.

These included:

- co-ordination between different agencies within nations or regions (e.g. pesticide regulators, fish and wildlife agencies, public health agencies, water quality regulators) is essential. Currently there is an absolute lack of consistent processes to demonstrate product effectiveness. Efficacy should be related to effectiveness to avoid duplicative efforts and use of data elsewhere.
- the benefits of vector/pest control must be known to affected human populations by integrating the risk only-based approaches with the risk-benefit approaches.

Inconsistent approaches exist between nations and international bodies and the workgroup suggested that international standards be funded, developed and adopted. Insufficient capacity exists in many nations to perform assessments of application, efficacy, risk assessment, risk analysis and so there is a need for capacity building on a regional or continental level.

Afternoon Session: Three new work groups were formed. Each group contained representatives of national regulatory authorities and WHOPES, registrants and formulators, national health authorities and public health pesticide users.

In the afternoon session the groups reviewed the stakeholder work group outputs from the morning session and formulated recommendations that should lead to solutions of the problems identified by the stakeholders. These outputs and recommendations were discussed on Day 3.

Day three

Plenary session

The mixed work groups reported their findings and recommendations to the final plenary session. The mixed workgroups outputs are summarized below.

Group One

Reported by Richard Davis from the Health and Safety Executive, UK, group one suggested that data sets need to be examined for similarities, using OECD guidelines.

It was also suggested that WHO/FAO should expedite the completion of guidelines on data requirements for public health pesticide registration.

The group recommended developing simplified requirements tailored to specific uses and needs for products and harmonised evaluation criteria to allow study results to be interpreted in similar ways.

Data sets for PHPs usually differ from those of agricultural use pesticides. It was suggested that this issue should be considered in any future development of data requirements.

The group suggested the use of existing regional structures to facilitate harmonisation efforts, to include the development of regional data portfolios tailored towards capacity.

Also suggested was the mutual acceptance of data evaluation among national authorities, tiered data sets and an increased focus on PHP benefits. This, it was said, will influence product-to-market development and encourage registration.

International networks in the pharmaceutical industry and biological control regulators could be used as potential examples.

The issue of test cases was raised, along with the idea of establishing a working group to deliver a test-case initiative. It was agreed that industry would submit a proposal as soon as possible. The test case would identify obstacles preventing registered tools from entering into markets where most needed. The Global Alliance (Stockholm Convention) offered to serve as a platform for a thematic group.

Next steps include having a regulators meeting to discuss the issues raised and establishing a steering committee to develop the test case.

Group Two
Reported by Janet McAllister (AMCA), the group talked about what elements the ideal registration process would have and how differences between regulatory authorities should be addressed.

It was agreed that for innovative technologies, there is a need to prepare processes and a paradigm that can address these in a speedy and harmonised way. At the moment there are processes that do not depend on WHOPES. The ideal would be one dossier to give to all countries involved for different types of data (safety, efficacy, product-specific).

Other suggestions included a one-stop-shop for information on what's required by all participating governments and a clear, transparent process. This new process should have the confidence from participating countries and donor organizations similar to the trust in the WHOPES process.

Questions were raised about whether exposure models are or should be harmonised. Currently, risk assessments are country-specific but there might be opportunities for sharing results of risk-assessment across regions.

Global participation was discussed, along with how best to document and communicate the results. It was suggested that there is a need for commitment from governments and higher authorities in the countries concerned.

It was noted that previous efforts towards harmonisation may not have succeeded but some countries do accept data generated in other countries, provided elements are similar, follows standard protocol and local elements are added.

An ideal product registration process was mooted as follows:

1. Determine in which countries to sell product (this will likely be greater than in current process)
2. Weight them on the potential sales market in each country
3. Identify core data requirements (which have been harmonised to the extent possible)
4. Identify local-specific data requirements (if any)
5. Generate data and compile into a single core data package
6. Submit core package to lead body
7. Submit local-specific data to local bodies/country
8. Based on data assessment/evaluation of lead body, registration decisions made by individual local bodies/countries (assumes buy-in from local body/country)
9. Looking at speeding up some of the processes:
   a. Conditional registration
   b. Fast-track: formulation amendments, reduced-risk, etc

Group Three

Reported by Bill Jany, group three looked at conclusions for regulators. These included development of a unified core data set, evaluation of a core data set for AIs and formulated products and the development of a non-core data set addressing local safety and efficacy.

Harmonisation of safety and efficacy data requirements was also discussed, along with the idea of standard dossier files and formats. A regulatory requirement matrix to identify duplication and inconsistencies in registration processes was also suggested, along with a test case with a new AI/formulated product.

It was concluded that the pesticide industry should provide additional data protection and longer periods of exclusive use, should promote public-private partnerships and provide incentives to smaller companies dedicated to public health products.

The industry should also develop capacity for delivering products to endemic areas, promote advocacy campaigns to educate public on the registration process as well as establish testing labs and training regulators.

Notes on the discussion in the plenary session can be found in Appendix E.

CONCLUSIONS

The Workshop was designed to improve the availability of safe, efficient, and cost-effective insecticides to control insects that transmit disease and that are used in public health programmes around the world.

The outcomes of the Workshop will complement on-going international public health efforts. Representatives from government and non-government agencies, other organisations and the public health and vector pest control industries agreed to work towards a better framework for conducting global joint reviews of new public health pesticide products.

The Workshop confirmed the need for harmonization of regulatory review processes and data requirements for public health pest control tools among the different schemes operating internationally. This would facilitate the development and approval of these tools. Participants identified the following next steps to advance the important work of increasing the availability of appropriate pesticides to improve public health around the world by:

- communicating the content and findings of this Workshop to a broader audience, initially by convening a meeting of regulators from developing countries
- conducting a test case for global review of new public health pesticide products
- initiating discussions with world regulatory authorities and WHO on regulatory review processes and data requirements specific to public health pesticides.

The organising committee is grateful for the attendance of all the participants and will be taking the issues raised at the Workshop forward.

Full details are available on the website www.iphpw.org

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