

Pesticide Industry Panel Summary

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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 Crop Life 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.

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 based on the challenges which include limited market size, difficulty to re-purpose agrochemical products, higher regulatory costs, longer and complex registration processes (can take as long as 5 years), and a lack of incentives to invest in specific new chemistries for Public Health.

While the VCPT fully supports WHOPES, the following should be streamlined:

- 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)

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.

The IVCC clarified that the major barrier to innovation is the market size as the cost of developing a totally new insecticide active ingredient for Public Health is estimated at \$100-150 million against a market size of \$400 million. The time to development is also another challenge when coupled with a limited number of suitable available insecticide active ingredients not already recommended by WHOPES, but also a limited number of suitable field trial sites.

As identified by VCPT, IVCC also highlights regulatory uncertainties as a major barrier and harder to develop a case, large numbers of countries with different processes, costs, and timelines, long overall regulatory process for products and no process for approving innovative approaches to vector control.

Recommendations include:

- Product quality delivered by Global performance standards for each product class (with targets and clearly defines pass/fail)

- Safety delivered by a risk based regulatory process, which is transparent, published, and standardized
- All testing carried out by independent GLP audited labs and field trial sites
- Clearly defined published and publicized overall regulatory process
- A defined process for setting new standards for new class of products and reviewing and changing standards for current product classes

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

A sound of caution was provided by Killgerm Group Ltd. based on a WHO report entitled "Public Health Significance of Urban Pests" that notes the need to be careful when amateurs utilize pesticides as it leads to medical conditions and problems; this needs to be enforced. The cost of approvals is also a cause for concern based on the 80% loss of active ingredients in Europe in a 1998 review.

It should be noted that no time was given for Question & Answer and therefore cannot be reported.