Advancing Regulatory Harmonisation and Biopesticide Innovation in Africa

04 – 08 March 2024
Cape Town, South Africa

Photo credits: Tanzania Plant Health and Pesticides Authority
BACKGROUND

Biopesticides (and biological control agents) are components of sustainable agriculture and increasingly important tools within Integrated Pest Management (IPM) strategies. Like all other commercial pest control products, biopesticides must be reviewed by regulatory authorities before they can be registered and made available for use by farmers. However, the diverse regulatory landscape for these plant protection products across various African countries continues to significantly and adversely impact biopesticide research, development, and innovation. It is, therefore, necessary to not only tailor regulatory approaches to suit the unique needs of the various countries on the continent but also harmonise relevant aspects across the region to create a cohesive framework that facilitates the effective registration and use of these products. Supporting and promoting innovation in the field is also necessary to ensure a continuous pipeline of effective biopesticide solutions. Once registered, proper product stewardship, including storage and handling, is required to ensure these products remain effective tools in the IPM toolkit.

OBJECTIVES

The workshop brought together regulatory professionals, researchers, industry experts, and policymakers to discuss various aspects of regional and continental harmonisation of registration guidelines for biopesticides in Africa. The workshop was designed to not only provide participants with a comprehensive understanding of the regulatory landscape surrounding biopesticides in Africa but also discuss gaps and challenges that may need to be bridged to promote biopesticide research, development, and innovation in the region. The workshop made a case for regulatory harmonisation, including discussions on various aspects of the harmonisation process, providing insights into their practical implications and applications. Ways of making the registration of biopesticides more effective, such as developing mutual recognition mechanisms, were also explored, as were the latest industry developments, insights from Regional Economic Communities’ experiences, and prospects for the development of continental guidelines. Stewardship practices that should be employed to achieve effectiveness in handling biopesticides, including safety guidelines and how such practices can be incorporated into IPM strategies will also be examined. Additionally, the workshop will cover the latest research findings, regulatory experiences, and innovations within the sector, all aimed at catalysing the development of the biopesticides industry in Africa.

WORKSHOP AGENDA

**DAY 1: REGULATORY LANDSCAPE FOR BIOPESTICIDES AND BIOCONTROL AGENTS:**

This session will provide information on the prevailing regulatory provisions for biopesticides in Africa, including details on key regulatory bodies, their roles, and the legal requirements for registration and approval. Discussions will include recent updates or changes in the regulatory landscape. The session will also offer opportunities for input from various stakeholders on current global regulatory provisions and how these compare with advancements in the region. It is expected that this will illuminate areas of potential improvement in regulatory practices for biopesticides and biological control agents in Africa.

**Session Chair:** Dennis Ndolo, Group Leader, Biopesticides, International Centre for Genetic Engineering and Biotechnology (ICGEB)

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<th>Time</th>
<th>Activity</th>
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<td>08:30 - 09:00</td>
<td>Registration</td>
<td>Nurhaan Larnie, Human Resources Assistant, ICGEB</td>
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<td>09:00 - 09:35</td>
<td>Opening remarks</td>
<td>Dennis Ndolo, Group Leader, ICGEB</td>
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09:35 - 10:00 Workshop format/Housekeeping
  o Dennis Ndolo, Group Leader, Biopesticides, International Centre for Genetic Engineering and Biotechnology (ICGEB)

10:00 - 10:30 The International Centre for Genetic Engineering & Biotechnology: An overview
  o Luiz Zerbini, Acting Director, International Centre for Genetic Engineering and Biotechnology (ICGEB), Cape Town Component

10:30 – 11:00 Keynote: Prospects for biopesticides and biological control agents in Africa
  o Saliou Niassy, Coordinator, African Union Inter-African Phytosanitary Council (AU-IAPSC)

11:00 - 11:30 Coffee Break & Group Photo

11:30 - 12:00 Overview of the IAPSC/CABI biopesticide study
  o Melanie Bateman, Integrated Crop Management Advisor, Centre for Agriculture and Bioscience International (CABI)

12:00 - 12:30 Tracking change in the regulatory terrain for biopesticides and biological control agents in Africa
  o Stella Simiyu, Director, Regulatory Affairs & Stakeholder Relations, CropLife Africa Middle East (CLAME)

12:30 - 13:00 Legal review of the status of biopesticide regulations in selected countries in Southern Africa
  o Dorothy Kyampaire, Assistant Registrar/Legislative Drafter, High Court of Uganda, Uganda

13:00 - 14:00 Lunch

Session Chair: Ramadhan Kilewa, Research Officer, Tanzania Plant Health and Pesticides Authority (TPHPA), Tanzania

14:00 - 15:00 Panel 1: Legal and regulatory considerations for a model framework for regulation of biopesticides and biological control agents in Africa
  Moderator: John Mukuka, Chief Executive Officer, Alliance for Commodity Trade in Eastern and Southern Africa (ACTESA)
  o Dorothy Kyampaire, Assistant Registrar/Legislative Drafter, High Court of Uganda, Uganda
  o Stella Simiyu, Director, Regulatory Affairs & Stakeholder Relations, CropLife Africa Middle East (CLAME)
  o Debbie Muir, Biodiversity Officer: Control & Pesticide Risk Manager, Department of Forestry, Fisheries and the Environment (DFFE), South Africa
  o Ekiejare Adebusola, Regulatory Officer, National Agency for Food and Drug Administration and Control (NAFDAC), Nigeria
15:00 - 15:30  General and country-specific industry perspectives on the regulation of biopesticides and biological control agents in Africa  
Richard Garnet, Consultant, CropLife International

15:30 - 16:30  Panel 2: Challenges in biopesticides and biological control product registration and key considerations for a road map for Africa  
Moderator: Gnonlonfin Benoit, Senior SPS Standards Advisor, Economic Community of West African States (ECOWAS)  
- Paul Ngaruiya, General Manager, Research, Strategy and Planning, Pest Control Products Board (PCPB), Kenya  
- Saliou Ngom, Saliou Ngom, Director of Plant Protection, Ministry of Agriculture and Rural Equipment, Senegal  
- Ivy Saunyama, Agricultural Officer - Pesticide Risk Reduction Officer for Southern and East Africa, Food and Agriculture Organization of the United Nations (FAO)  
- Komivi Akutse, Senior Scientist, International Centre of Insect Physiology and Ecology (ICIPE)

16:30 - 17:00  Coffee & poster session

DAY 2: UNDERSTANDING REGULATORY HARMONISATION:  
This session will focus on some of the key principles of regulatory harmonisation. It will include a keynote presentation focussing on how Global Joint Reviews can be an effective strategy for enhancing the effectiveness of regulatory approvals of biopesticides and biological control agents. To elaborate, GJRs can replace the country-by-country product approval processes with workshares between countries. Critical success factors and the benefits and challenges of regulatory harmonisation will also be discussed.  
Session Chair: Stella Simiyu, Director, Regulatory Affairs & Stakeholder Relations, CropLife Africa Middle East (CLAME)

08:30 - 09:00  Registration and networking

09:00 - 09:30  Keynote: Global joint reviews as a strategy for enhancing regulatory efficiency for biopesticides and biological control agents  
- Imme Gerke, Global Regulatory Strategist, International Development of Regulatory Globalisation (IDRG)

09:30 - 10:00  The essential components for effective regional guidelines  
- Debbie Muir, Biodiversity Officer: Control & Pesticide Risk Manager, Department of Forestry, Fisheries and the Environment (DFFE), South Africa

10:00 - 10:30  Coffee Break

10:30 - 11:30  Panel 3: Making harmonisation work for Africa  
Moderator: Rhoda Mavuka, Head, Crop Production and Molecular Technologies, Tobacco Research Board, Zimbabwe  
- David Wafula, Agricultural Programme Specialist, East African Community (EAC)  
- Gnonlonfin Benoit, Senior SPS Standards Advisor, Economic Community of West African States (ECOWAS)  
- Idrissa Maiga, Acting Coordinator, West African Pesticides Regulation Committee (WAPRC)  
- John Mukuka, Chief Executive Officer, Alliance for Commodity Trade in Eastern and Southern Africa (ACTESA)

11:30 - 12:00  Development of harmonised regional stewardship guidelines and best management practices  
- Evelyn Lusenaka, Director, Stewardship, CropLife Africa Middle East (CLAME)
12:00 - 13:00  General discussion
13:00 - 14:00  Lunch

Session Chair: Kenneth Chipere, Principal Research Officer, Ministry of Lands, Agriculture, Fisheries, Water and Rural Development, Zimbabwe

14:00 - 14:30  Domestication of regional harmonised guidelines for registration of biopesticides and biological control agents: The case of Tanzania
  ○ Ramadhan Kilewa, Research Officer, Tanzania Plant Health and Pesticides Authority (TPHPA), Tanzania

14:30 - 15:00  Practical considerations in the development and domestication of regional harmonised guidelines
  ○ Luis Suguiyama, Independent Regulatory Consultant, USA

15:00 - 16:00  General discussion
16:00 - 16:30  Coffee & poster session
18:00 - 22:00  Social dinner

DAY 3: CASE STUDIES OF REGULATORY HARMONISATION:
The session will share practical experiences from regional regulatory harmonisation programmes on the continent. Efforts that countries have made to domesticate provisions of harmonised guidelines, lessons learned, and challenges encountered will also be discussed. Recognising the role of Good Regulatory Practices (GRPs) in supporting national and regional regulatory efforts aligned with international standards, this session will also introduce a GRP guide developed by the Standards and Trade Development Facility (STDF). It will showcase how the Southern Africa Biopesticides Project has utilised this guide in the process of working with countries in the region in developing draft regional harmonised biopesticides registration guidelines. Potential applications of the GRP guide in other regulatory harmonisation initiatives will also be explored.

Session Chair: Mary Lucy Oronje, Scientist, Sanitary and Phytosanitary Standards, Centre for Agriculture and Bioscience International (CABI)

08:30 - 09:00  Registration and networking
09:00 - 09:30  Keynote: Lessons from the harmonisation of biopesticide regulatory guidelines for biopesticides and biocontrol agents in the East African Community
  ○ David Wafula, Agricultural Programme Specialist, East African Community (EAC)

09:30 - 10:00  The Southern Africa Biopesticides Project
  ○ Dennis Ndolo, Group Leader, Biopesticides, International Centre for Genetic Engineering and Biotechnology (ICGEB)

10:00 - 10:30  Next steps in the development of harmonised guidelines for the registration of biopesticides and biological control agents in Southern Africa
  ○ Loitseng Sebetwane, Registrar of Agrochemicals, Ministry of Agriculture, Botswana

10:30 - 11:00  Coffee Break
11:00 - 11:30  West Africa and the Sahel Harmonised Pesticides Registration Committee
  ○ Gnonlonfin Benoit, Senior SPS Standards Advisor, Economic Community of West African States (ECOWAS)

11:30 - 12:00  SADC guidelines on pesticide management and risk reduction
  ○ Fredrick Otieno, Project Officer, Centre for Environmental Justice and Development, Kenya

12:00 - 13:00  Panel 4: Integration of harmonised guidelines into national regulatory processes – country experiences
DAY 4: PROSPECTS FOR CONTINENTAL GUIDELINES:
The session will share the findings and recommendations in the two AU-IAPSC PPP reports, to get feedback on the reports, and to have a dialogue on how to create synergies across regional harmonisation initiatives to work towards continental harmonisation and further operationalisation of the Africa Continental Free Trade Area (AfCFTA).

Session Chair: Sandrine Loudit Bayendi, InterAfrican Union Phytosanitary Council (AU-IAPSC)

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<th>Time</th>
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<td>08:30 - 09:00</td>
<td>Welcome and introduction to the USDA/IAPSC partnership</td>
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<td>- Rachel Vanderberg, Senior Program Manager, United States Department of Agriculture (USDA)</td>
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<td>09:00-9:10</td>
<td>Setting the stage/Background on continental guidelines</td>
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<td>- Saliou Niassy, Coordinator, African Union Inter-African Phytosanitary Council (AU-IAPSC)</td>
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<td>09:30 - 10:30</td>
<td>Summary IAPSC/CABI PPP reports findings; Summary of the Report on regional initiatives for harmonised registration of plant protection product and potential modalities for an Inter-African Phytosanitary Council (AU-IAPSC) mechanism</td>
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<td>- Melanie Bateman, Integrated Crop Management Advisor, Centre for Agriculture and Bioscience International (CABI)</td>
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<td>10:30 - 11:00</td>
<td>Coffee Break</td>
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<td>11:00 - 12:00</td>
<td>Breakout Groups: Session to collate feedback and recommendations for next steps</td>
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<td>- Moderated by CABI/AU-IAPSC/USDA</td>
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<td>12:00 - 13:00</td>
<td>Presentations from Groups</td>
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<td>13:00 - 14:00</td>
<td>Lunch</td>
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<td>14:00 - 15:00</td>
<td>Summary of the report on areas of overlap, divergence, and opportunities for alignment in the guidelines and laws governing the registration of biopesticides in Africa</td>
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<td>- Sandrine Loudit Bayendi, African Union Inter-African Phytosanitary Council (AU-IAPSC)</td>
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<td>16:00 - 16:10</td>
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<td>16:10 - 16:40</td>
<td>Presentations from Groups</td>
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<td>16:40 - 17:30</td>
<td>Summary, next steps, and SPS forum opportunity</td>
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<td>- Sandrine Loudit Bayendi, African Union Inter-African Phytosanitary Council (AU-IAPSC)</td>
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**DAY 5: BIOPESTICIDE INNOVATION AND STEWARDSHIP:**
The session will focus on stewardship and innovation, examining the challenges faced by innovators in the biopesticide sector. It will provide information on how biopesticides and biological control agents should be used in such a manner as to remain effective, highlighting relevant guidelines and recommended stewardship practices. Discussions will also explore farmers’ perceptions and explore tools for measuring progress and trends in the availability, access, and use of biopesticides in the region.

**Session Chair:** Lawrence Malinga, Research Entomologist, South African Sugarcane Research Institute (SASRI)

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<tr>
<td>08:30 - 08:45</td>
<td><strong>Keynote:</strong> Industry experiences in the biopesticides sector</td>
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<td>○ Samira Amellal, Director General and Chief Executive Officer, CropLife Africa Middle East (CLAME)</td>
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<td>08:45 - 09:15</td>
<td>Challenges faced by growers in the use of biopesticides in Africa</td>
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<td>○ Elrita Venter, Chief Executive Officer, AgriEdge South Africa</td>
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<td>09:15 - 09:30</td>
<td>The South African Bioproducts Organisation</td>
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<td>○ Sheila Storey, Director, Nemlab (Pty) Ltd, South Africa</td>
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<td>09:30 - 10:00</td>
<td>Addressing challenges in innovating biopesticides and biocontrol agents: Constraints faced by industry and innovators in upscaling the use of biologicals in Africa</td>
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<td>○ Sean Moore, Portfolio Manager: IPM, Citrus Research International, South Africa</td>
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<td>10:00 - 10:30</td>
<td>Coffee Break</td>
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<td>10:30 - 11:00</td>
<td>Can farmers produce their own biopesticides: A baculovirus for fall armyworm in Kenya and Zambia</td>
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<td>○ Ivan Rwomushana, Senior Scientist, Invasive Species, Centre for Agriculture and Bioscience, International (CABI)</td>
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<td>11:00 - 12:00</td>
<td>Panel 5: Accelerating adoption of biopesticides, understanding challenges and role of stewardship in localising management of biopesticides in Africa</td>
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<td>Moderator: Evelyn Lusenaka, Director, Stewardship, CropLife Africa Middle East (CLAME)</td>
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<td>○ Eric Kimunguyi, Chief Executive Officer, CropLife Kenya</td>
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<td>○ Rod Bell, Chief Executive Officer, CropLife South Africa</td>
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<td>○ Sean Moore, Portfolio Manager: IPM, Citrus Research International, South Africa</td>
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<td>○ Debbie Muir, Biodiversity Officer: Control &amp; Pesticide Risk Manager, Department of Forestry, Fisheries and the Environment (DFFE), South Africa</td>
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<td>12:00 - 12:30</td>
<td>Regulatory Science – Australia’s perspective: The efficacy considerations of biological agricultural products (biopesticides) IPM Systems</td>
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<td>○ Mizanur Rahman, Senior Risk Evaluator, Australian Pesticides and Veterinary Medicines Authority (APVMA), Australia</td>
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<td>12:30 - 13:00</td>
<td>The CABI BioProtection Portal - Increasing awareness and uptake of bioprotection products globally</td>
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<td>○ Robert Malek, Pesticide Risk Reduction Expert, Centre for Agriculture and Bioscience International (CABI)</td>
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<td>13:00 - 13:15</td>
<td>Workshop evaluation and announcement of poster session winners</td>
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<td>13:15 - 14:00</td>
<td>Closing</td>
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<td>○ Samira Amellal, Director General and Chief Executive Officer, CropLife Africa Middle East (CLAME)</td>
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- Babagana Ahmadu, FAO Representative/Country Director, South Africa, Food and Agriculture Organization of the United Nations (FAO)
- Catalina Pulido, Economic Affairs Officer, Standards and Trade Development Facility (STDF)
- Rachel Vanderberg, Senior Program Manager, United States Department of Agriculture (USDA), Foreign Agricultural Service
- MaryLucy Oronje, Scientist, Sanitary and Phytosanitary Standards, Centre for Agriculture and Bioscience International (CABI)
- Saliou Niassy, Coordinator, African Union Inter-African Phytosanitary Council (AU-IAPSC)
- Dennis Ndolo, Group Leader, Biopesticides, International Centre for Genetic Engineering and Biotechnology (ICGEB)

13:45 - 14:45   Lunch

[Link](#) to all presentations.

For any queries or further information please contact: Kahsay.mawcha@icgeb.org
ABSTRACTS

PROSPECTS FOR BIOPESTICIDES AND BIOLOGICAL CONTROL AGENTS IN AFRICA

Saliou Niassy, Luiza Munya, Sandrine Bayendé, Nana Flaubert Sani
Inter-African Phytosanitary Council of African Union (AU-IAPSC), P.O Box 4170, Yaoundé, Cameroon.

Saliou Niassy, Coordinator, African Union Inter-African Phytosanitary Council (AU-IAPSC)

Insect pests threaten agricultural productivity and food security, inflicting serious economic loss. Chemical control has been the primary strategy for controlling these pests, but overuse or misuse of certain pesticides poses environmental and human health concerns. Moreover, some pests have developed resistance, rendering some chemical pesticides ineffective and expensive. There is therefore a need to expand the range of available pest control options. Biopesticides are seen as a more environmentally friendly complement to synthetic pesticides. Over the past three decades, researchers have developed biopesticides targeting various pests, such as locusts, fruit flies, and armyworms. These biopesticides are made up of viruses, bacteria, and fungi and have been manufactured and commercialised by the private sector. However, despite the significant progress made, the registration process and availability of biopesticides to farmers remain substantial obstacles to their expansion. Biopesticides have a promising future in light of the increasing awareness of environmental and health concerns regarding food production. Nonetheless, more efforts are required to harmonise policies and ensure farmers can access these products. Prospects for biopesticides and biological control agents in Africa are discussed.

OVERVIEW OF THE IAPSC/CABI BIOPESTICIDE STUDY

Melanie Bateman, Integrated Crop Management Advisor, Centre for Agriculture and Bioscience International (CABI)

As part of the USDA-FAS-funded project “Supporting AU-IAPSC Implementation of African Union Plant Health Strategy,” a study was conducted to perform an inventory of guidelines and regulations governing the registration of biopesticides sub-regionally and nationally; to identify areas of overlap, divergence, and opportunities for alignment; and to provide recommendations for next steps for the development of African Continental Guidelines for the registration of biopesticides.

For each regional economic community and country in Africa, the report compiled a list of the guidelines and regulations that address the registration of pesticides in general and biopesticides in particular. Those legal instruments were then examined to determine whether the prerequisites for a biopesticides regulatory framework are in place and to assess whether the main elements for a biopesticides regulatory framework are covered by the identified policy instruments. The analysis included an examination of definitions for key terms and comparisons of the data requirements for the registration of biopesticides in select countries and subregions.

The development of Continental Guidelines for the registration of biopesticides would be timely. The prerequisites for a biopesticide regulatory framework are already in place in most (but not all) countries in Africa. Many countries also have biopesticides regulatory frameworks in place, so there are lessons that can be learned from their experiences in implementing these frameworks. The development of guidelines for the registration of biopesticides by RECs has helped to promote the registration of biopesticides in the countries affiliated with the corresponding initiatives. In the longer term, there is a need for African continental-wide guidelines for biopesticide registration and harmonised policy guidance for conducting the trials and mutual recognition of the results.
Biocides and biological control agents are among the essential components of an integrated Pest Management system that contribute to biotic and abiotic stress management in crop production. They play an important role in increasing crop yield and quality, owing to associated benefits such as safety, biodegradability, reduced carbon footprint, residue, and resistance management. Despite the biologicals market for agriculture being the fastest growing and the accrued benefits widely understood, the growth of the sector in the AME region remains at less than 4% compared to other regions, with Asia leading at 43%, followed by North America at 28%, Europe at 14%, and Latin America at 11%. Accelerating efforts at biopesticide development and commercialisation requires the establishment of an enabling environment comprised of policies, governance structures, regulatory frameworks, research and investment programs, and social, cultural, and economic norms, rules, and practices. Stocktaking of the AME region’s regulatory environment, in terms of the status of development and implementation of respective policies, laws, regulations, guidelines, and/or administrative instruments is necessary. Understanding the stages of development and various approaches for the assessment of products is critical. Additionally, taking stock of the initiatives implemented around the challenges that impact the growth of the sector requires a mechanism for tracking the progress due to the interconnectedness of the factors. Therefore, it is necessary not only to tailor regulatory approaches to suit the unique needs of the various countries but also to harmonise such approaches across the region to create a cohesive framework that facilitates the effective registration and use of these products. Supporting and promoting a holistic system of tracking, assessing, and measuring the progress is also necessary to ensure the suitability of interventions and a continuous pipeline of effective solutions that respond to farmers’ needs to increase productivity and participation in trade.
GENERAL AND COUNTRY-SPECIFIC INDUSTRY PERSPECTIVES ON THE REGULATION OF BIOPESTICIDES AND BIOLOGICAL CONTROL AGENTS IN AFRICA

Richard Garnet, Consultant, CropLife International

Regulatory systems are essential for making safe and effective agricultural tools available. They must protect human and animal health and the environment to deliver economic and social; growth and improve the lives of citizens and businesses. CropLife International developed principles for effective pesticide regulation and the model framework for data requirements to assess the safety and efficacy of biological pesticides. A common understanding of the characteristics of biological-based products and recognising the differences between biological and chemical pesticides facilitate the regulation of biological pesticides. Industry should prepare high quality dossiers and help regulators and assessors efficiently work through the approval process. If the safety characteristics allow, the product may be introduced to the market using a fast-track process. A key topic is the identity and characterisation of the microbe or substance and the specification for the active and the finished product. These differ from those for chemicals because of inherent variability in biological products and because products may be manufactured in an integrated process where there is no “pure” active. The import of microbials for testing is commonly controlled by countries so collaboration between those responsible for biosafety and pesticide registration is helpful. Setting up efficacy requirements to allow testing early in the process and recognising the specificities of biologicals efficacy will significantly reduce the time to market. Biological pesticides contribute to Integrated Pest Management (IPM) programmes and sustainable agriculture, so an efficient approval process is essential to bring them to market.

GLOBAL JOINT REVIEWS AS A STRATEGY FOR ENHANCING REGULATORY EFFICIENCY FOR BIOPESTICIDES AND BIOLOGICAL CONTROL AGENTS

Imme Gerke, Global Regulatory Strategist, International Development of Regulatory Globalisation (IDRG)

The world cooperates along the path that food, feed, and fibre crops travel from the soil to the spoon. We grow crops, transport and store them, process and mix them, and transport them again. At the same time, we have built major barriers to food trade some of which are based either on the lack of pesticides or on the use of the wrong products. If and when food hits such a barrier it is destroyed according to international norms. Ocean dumping requires 15 nautical miles for foods that sink and 25 nautical miles for foods that float. Since 1994, under the leadership of the OECD Working Group on Pesticides, the world cooperates in removing these barriers. Regulators have come together and agreed on data requirements, developed guidelines for how to conduct scientific studies, created standards for Good Laboratory Practice (GLP), made templates available to compile data packages, and developed software to create zip folders for submitting these data packages to the regulators. For risk assessments and regulatory decisions regulators have developed guidelines that on one hand harmonise their approach and on the other hand, allow them to adjust to special regional or national conditions. All these tools are available online free of charge and have been used for 55 chemicals in Global Joint Reviews among up to 16 countries on all continents, except for Africa. In my presentation, I demonstrate how the biopesticide industry can use this path to make their products available worldwide, while regulatory authorities can prevent and remove trade barriers that are based on the use of pest control products.

THE ESSENTIAL COMPONENTS FOR EFFECTIVE REGIONAL GUIDELINES

Debbie Muir, Biodiversity Officer: Control & Pesticide Risk Manager, Department of Forestry, Fisheries and the Environment (DFFE), South Africa

Biopesticides are generally evaluated and registered under the same registration processes as chemical pesticides in most member states. This is cumbersome, costly, and poses an inappropriate regulatory burden on the state. This is because many, if not most of the data requirements and evaluation criteria are not relevant to biopesticides, for example, data requirements for chemical identity are not relevant but appropriate studies on taxonomy for a microorganism are critical. The
level of risk resulting from the use of a biopesticide is lower than a chemical pesticide, thus higher tier testing is unnecessary and can be waived. Countries within a region may have different guidelines for the registration of biopesticides, using various and differing criteria to regulate their registration (OECD, FAO, EU, EPA, etc). This makes the harmonisation for regulatory purposes across a region very difficult to achieve, so the first point for all the member states within the region to agree on is the guiding principles or essential components that all the member states are comfortable with adopting into the regional guidelines, for example following the same set of principles and identifying the acceptable categories that will be harmonised across the region to facilitate and stimulate trade across the region. A set of minimum data requirements for the registration of products and categories are needed, including harmonised data requirements for each category of biopesticide. An agreed framework for the future development of biopesticides, creating a regional blueprint for national regulation and implementation strategies is key for effective regional harmonisation. Harmonisation of registration requirements would make regulation of biopesticides easier, less costly and promote their trade within the region and abroad.

DEVELOPMENT OF HARMONISED REGIONAL STEWARDSHIP GUIDELINES AND BEST MANAGEMENT PRACTICES

Evelyn Lusenaka, Director, Stewardship, CropLife Africa Middle East (CLAME)

Biopesticides are increasingly becoming an important tool within Integrated Pest Management (IPM) strategies, particularly for insect control where most commercially-available biological options exist. As they have very different modes of action from one another and from synthetic chemical pesticides, they, and in particular microbial pesticides, are effective tools within a resistance management programme. Due to their nature, they need to be stored, handled, and used appropriately in order to work effectively and safely. CropLife International has developed guidelines that recommended stewardship practices that should be employed to achieve this with commercially available biological products, including safety guidelines and how they can be usefully included in IPM strategies.

Stewardship is a life cycle approach from the discovery and development of new active ingredients to their use and the final disposal of any waste. Stewardship promotes good agricultural practices and is a key element underpinning the International Code of Conduct on Pesticide Management. When it comes to harmonisation of stewardship practices one size does not fit all, and local adaptation is needed. Overall, a standard platform that allows for adaptation in a way that brings most value to the users of biopesticides is needed. The CropLife network develops harmonised stewardship activities that member companies and other CropLife associations adopt and adapt to suit different situations. Working together we can empower farmers to support sustainable livelihoods whilst safeguarding health and the environment. Harmonisation of stewardship practices among farmers if more consistent or similar could enhance the push of agricultural innovations to move more quickly to farmers, which could result in more safe and nutritious foods and the adoption of more sustainable farming practices that benefit biodiversity and the environment.

To conclude, stewardship provides for sustainability in the use of crop protection products including biopesticides. These important innovations could move to the market in a more predictable and efficient way — as well as be more equally accessible to farmers who best understand their use to maximise their use fully.

DOMESTICATION OF REGIONAL HARMONISED GUIDELINES FOR REGISTRATION OF BIOPESTICIDES AND BIOLOGICAL CONTROL AGENTS: THE CASE OF TANZANIA

Ramadhan Kilewa, Research Officer, Tanzania Plant Health and Pesticides Authority (TPHPA), Tanzania

Harmonised guidelines serve as a regional framework to facilitate the safe, effective, and efficient use of biopesticides and biological control agents across borders. Regional harmonised guidelines for the registration of biopesticides and biological control agents are important for African countries to streamline regulatory processes and promote the responsible use of these environmentally friendly pest management tools. If a consensus process for approving safe uses of biopesticides and biological
control agents for all African countries could be developed, all four interested parties - farmers, consumers and other users, regulators, and the biopesticide industry would benefit. The potential cost relief for new biopesticides and biological control agents' development would be enormous. The four interested parties would benefit if African countries could develop a harmonised framework for the registration of biopesticides and biological control agents and domesticate it at the national levels. Domestication of regional harmonised guidelines for the registration of biopesticides and biological control agents is the process of incorporating the approved guidelines by a high level of authority of the Member States into the extant laws of a country to give it the force of law in that country. The domestication of the harmonised guidelines also requires that the national legal framework be brought into line with the agreed regional instruments. Domestication of regional harmonised guidelines for the registration of biopesticides and biological control agents takes the involvement of multiple stakeholders including consumers, farmers, legal experts, academia, non-government organisations, the biopesticide industry, regulators, research scientists, civil society, and policymakers. Several steps are involved in the domestication of regional harmonised guidelines, including 1) familiarisation of developed guidelines to national stakeholders, 2) development of a roadmap to provide guidance on the domestication of regional harmonised guidelines into national laws/regulations, 3) presentation of a roadmap to other stakeholders, 4) conducting a regulatory impact assessment to comply with legal requirements in the region, 5) drafting/improving existing Regulations to include provisions of regional harmonised guidelines for the registration of biopesticides and biocontrol agents, 6) validation of the developed/improved draft of regulations for Biopesticides and Biocontrol agents, 7) finalisation of the draft of Regulations, and 8) endorsement and publication of the Regulations in the official government gazette. In the case of Tanzania, we have domesticated the regional harmonised guidelines in the Plant Health Regulations of 2023 of Plant Health Act No. 4 of 2020 under the following regulations: In Tanzania, Plant Health Regulations of 2023 of Plant Health Act No. 4 of 2020 covers the issues of Biopesticides and Biocontrol Agents. (Regulation No. 3 (1) (a and b), Regulation No. 10 (7) describe the bioefficacy of biopesticides, and Regulation No. 91 and 92 describe about Application for registration of Biocontrol agents. To conclude, the domestication of regional harmonised guidelines for the registration of biopesticides and biological control agents would enhance the development of the agricultural sector and would strengthen the sale of these products nationally and regionally. It would allow for the application of similar requirements and quality standards. Since many of the countries face similar problems, greater coordination and more information exchange among regulatory authorities would help overcome these challenges.

CONSIDERATIONS IN THE DEVELOPMENT AND DOMESTICATION OF REGIONAL HARMONISED PEST CONTROL GUIDELINES/REGULATIONS

Luis Suguyama, Independent Regulatory Consultant, USA

The regulation of pest control tools is the process where the designated national authority (DNAs) in a country or the regional authority establishes processes for the scientific review and the approval and the sale and use of products that are effective but do not pose an unacceptable risk to human or animal health or the environment. Given the changes in climate, globalization, destination market requirements, consumer demand, need for agricultural sustainability, and others; it is imperative that DNAs and regions take full account of local circumstances and needs, social and economic conditions, levels of literacy, agroeconomic conditions and availability of appropriate and affordable pest control tools and promoting the use of personal protective equipment.

In Africa, there have been many efforts (e.g. albeit successful in the EAC CILSS) to regionally develop and harmonise regulatory standards for pest control tools. This enables regions to benefit from common standards between neighbouring countries, and enhance the ability of farmers to have access to effective and safer pest control tools. Nonetheless, there are challenges and needs to be considered in the development and domestication of regional harmonised pest control regulations.
LESSONS FROM THE HARMONISATION OF BIOPESTICIDE REGULATORY GUIDELINES FOR BIOPESTICIDES AND BIOCONTROL AGENTS IN THE EAST AFRICAN COMMUNITY

David Wafula, Agricultural Programme Specialist, East African Community (EAC)

The East African Community (EAC) is one of the eight Regional Economic Communities (RECs) under the African Union. It comprises of the eight Partner States, Burundi, Democratic Republic of Congo, Kenya, Rwanda, Federal Republic of Somalia, Republic of South Sudan, United Republic of Tanzania and Uganda. Under Article 108 of the Treaty for the establishment of EAC, Partner States have agreed to adopt common mechanism to ensure safety, efficacy and potency of agricultural inputs including chemicals, drugs and vaccines. In addition, provisions of the EAC Protocol on Sanitary and Phytosanitary (SPS) Measures underscores protection of human health from risks arising from biological, chemical and physical substances (including crop protection products).

In line with the aforementioned mandate, the EAC Secretariat with support of a number of development and technical partners coordinated the development and harmonisation of guidelines for testing and registration of conventional pesticides, biopesticides and biocontrol agents. The main focus was harmonisation of requirements for assessing the efficacy, safety, and potency of pest control products in the Partner States. The efforts culminated to the approval of the guidelines in 2019 by the EAC Council of Ministers. The Council further directed Partner States to domesticate the guidelines and pilot their implementation in order to pave way for operationalization of Mutual Recognition. A number of EAC Partner States have conducted efficacy trials leading to registration of some plant pest control products. Insights from the development and implementation of EAC harmonised guidelines will be shared to provide valuable lessons, accomplishments, and challenges. This will offer guidance for similar initiatives being contemplated by other Regional Economic Communities.

THE SOUTHERN AFRICA BIOPESTICIDES PROJECT

Dennis Ndolo, Group Leader, Biopesticides, International Centre for Genetic Engineering and Biotechnology (ICGEB)

Through a grant from the Standards and Trade Facility, as well as in-kind support from the United States Department of Agriculture, ICGEB is leading a regional project covering Botswana, Mozambique, South Africa, Tanzania, Zambia, Zimbabwe, and Kenya aimed at harnessing the potential of biopesticides to mitigate synthetic chemical pesticide residues in agricultural produce and promote trade. The project has four components: i) working with countries in Southern Africa to develop harmonised guidelines for the registration of biopesticides and biological control agents in the Southern Africa region to ensure that more of these products can be registered and available for farmers; ii) conducting field studies to develop strategies for incorporation of non-residue producing biopesticides following conventional pesticides, to help reduce pesticide residue levels in agricultural produce; and hence enhance compliance with residue standards and promote trade; developing materials to promote the use and incorporation of biopesticides in IPM strategies and working with the Centre for Agriculture and Bioscience International (CABI) to populate a portal with information on registered biopesticides. This would provide growers with information on available products and hence enhance their use, and; iv) build the skills, knowledge, attitudes, and behaviours needed to ensure that individuals and organisations can work effectively to achieve the technical outcomes of the project (premised on the recognition that both technical and soft skills are recognised as essential for individuals and organisations to achieve long-term project objectives). Progress achieved so far in the implementation of the project will be presented, highlighting how the Good Regulatory Practices Guide developed by the STDF informed some of the strategies the project adopted in developing the harmonised regional guidelines.
The West Africa Pesticides Registration Committee (WAPRC) was established by ECOWAS Regulation C/Reg.03/05/2008 on harmonisation of the rules governing pesticide registration in the ECOWAS region, in order to implement the Common regulation on behalf of the ECOWAS Commission. Its roles, organization, and functioning are detailed by ECOWAS’ enabling regulation C/Reg.02/06/12. The WAPRC has been adopted and customized, as a regional body in charge of pesticides including biopesticides registration and the coordination of pesticide management for 17 countries in West Africa and the Sahel, following the tripartite agreement in the field of pesticides signed between ECOWAS, UEMOA and CILSS in 2018. WAPRC’s members have been nominated and had their inaugural meeting in March 2022 during which members have adopted harmonised tools and technical procedures for pesticides registration and management in the Sahel and West Africa. This presentation will provide more information on WAPRC’s organization, functioning, and its requirements.

The recently adopted Plant Health Strategy for Africa 2022-2036 (PHSA) has as its vision “a robust and practical management system for healthy plants in Africa”. The PHSA aims to promote the safe and appropriate use of pesticides to protect against human health risks, especially for women, while also protecting crops from pest damage in line. A key action of the PHSA will be enhanced harmonisation of legislation, standards, and procedures, including those for the registration of plant protection products (PPPs), across countries and regions aimed at ensuring the removal of both tariff and non-tariff barriers to realise the full operationalization of the African Continental Free Trade Area (AfCFTA).

On 16 December 2021, the Ministerial Segment of the Fourth Ordinary Session of the Specialized Technical Committee (STC) on Agriculture, Rural Development, Water and Environment (ARDWE) requested the AUC to develop Continental Guidelines for harmonisation of registration of PPPs to improve plant health on the continent. To do this, a continental-level mechanism needs to be established that incorporates and builds on other existing initiatives on the harmonisation of the registration of pesticides at the REC level. This task is being led by the AU-IAPSC.

As part of a project to support the implementation of the PHSA, a study was undertaken to perform an inventory of ongoing efforts at a subregional level for the harmonisation of the registration of PPPs and to propose a mechanism for IAPSC to engage in harmonisation efforts. Information on the harmonisation initiatives was compiled through key informant interviews, a review of policy documents and a literature review. This session provides an overview of the findings of this analysis, summarizing the identified harmonisation initiatives’ geographic coverage, objectives, organizational arrangements, key functions, and processes for guideline development as well as lessons learned. Procedures for the development of guidelines and standards that have been established by some international standard-setting organizations are also described. The analysis of the existing harmonisation mechanisms identified a need for the establishment of a mechanism for supporting continental-level harmonisation. While initiatives are underway in some RECs and other regional organizations to broadly provide a framework for pesticide management, not all AU Member States are affiliated with a harmonisation initiative, and feedback suggests that coordination across initiatives is sometimes disjointed. A continental mechanism for the development of harmonised guidelines could help to support countries outside of the current initiatives and to create synergies across initiatives. A continental harmonisation mechanism would also contribute to the operationalization of the African...
Continental Free Trade Area (AfCFTA). While the continental mechanism under AU-IAPSC would be a new initiative, it would leverage and build on the best components of the mechanisms already in place in subregional initiatives that have preceded it.

**SUMMARY OF THE REPORT ON AREAS OF OVERLAP, DIVERGENCE, AND OPPORTUNITIES FOR ALIGNMENT IN THE GUIDELINES AND LAWS GOVERNING THE REGISTRATION OF BIOPESTICIDES IN AFRICA**

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**Sandrine Bayendi Loudit**, Senior Scientific Officer, African Union Inter-African Phytosanitary Council (AU-IAPSC)

The development of Continental Guidelines for the Registration of Biopesticides would be one step toward harmonisation and would contribute to the sustainable management of pests. This is because biopesticides as a group are generally much less toxic to humans and other mammals than synthetic pesticides and have less impact on wildlife and the environment. Implementation of the Plant Health Strategy for Africa (PHSA) is being undertaken by AU-IAPSC and the AU’s Department of Agriculture, Rural Development, (ARD), with some support from the USDA-FAS-funded project “Supporting AU-IAPSC Implementation of African Union Plant Health Strategy.” Several activities under the project are targeted at promoting regional harmonization, and one activity in particular aims to support the development of Continental Guidelines for the Registration of Biopesticides. As an initial step, a study was conducted to provide an overview of biopesticide regulatory frameworks across the African continent.

The objectives of this report are as follows: Compile an inventory of guidelines and regulations governing the registration of biopesticides sub-regionally and nationally; Identify areas of overlap, divergence, and opportunities for alignment; and Provide recommendations for the next steps for the development of Continental Guidelines for the Registration of Biopesticides.

For each Regional Economic Community (REC) and country in Africa, the report involves the compilation of a list of the identified guidelines and regulations that address the registration of pesticides. The analysis found that, in many countries and subregions, the process for the registration of biopesticides is the same as the process for the registration of conventional pesticides. The development of Continental Guidelines could provide those countries with a blueprint for modifying the approach for the registration of biopesticides to reduce unnecessary regulatory burdens while maintaining a rigorous registration process that safeguards human health and the environment. Some countries and subregions already have biopesticides regulatory frameworks in place, so there are lessons that can be learned from their experiences in implementing these frameworks.

For some of the assessed elements, there were no significant divergences, whereas in some other cases, definitions of different categories used by different countries and subregions overlapped such that the different categories were not mutually exclusive. Alignment of data requirements for the registration of biopesticides would be a major step forward for removing obstacles to the registration of biopesticides and promoting intra-regional trade in biopesticides. This study report is intended to be used as a reference by AU-IAPSC and AU Member States to support development of the Continental Guidelines for the Registration of Biopesticides and to serve as a baseline against which regulatory changes could be tracked following the eventual adoption of these Continental Guidelines.

**INDUSTRY EXPERIENCES IN THE BIOPESTICIDES SECTOR**

Samira Amellal, Director General and Chief Executive Officer, CropLife Africa Middle East (CLAME)

The talk will address the challenges faced by the industry in using biopesticides in Africa, notably highlighting the regulatory and stewardship complexities. The speaker will emphasize the need for
incentivising R&D in biopesticides, increasing awareness, and addressing farmers' perception and use of biopesticides. Despite the challenges, many opportunities exist in accessing new markets, harmonising regulations, and implementing stewardship initiatives. Collaboration between governments, industry, and research institutions is essential for advancing the use of biopesticides and promoting sustainable agriculture in Africa.

CHALLENGES FACED BY GROWERS IN THE USE OF BIOPESTICIDES IN AFRICA

Elrita Venter, Chief Executive Officer, AgriEdge South Africa

The African continent is diverse and complex in the challenges that growers face in the process of safe food production where unique socio-economic, environmental, and cultural aspects play a prominent role. It is furthermore difficult to define and address specific crop protection challenges, due to these aspects, including the numerous variables related to the diverse crop production systems - of which the smallholder farmer is the most prominent. To address these challenges, particularly in the realm of the role of biological control and biopesticides, a fundamental prerequisite emerges - namely, the adoption and assimilation of the Integrated Pest Management (IPM) framework by African farmers. A better comprehension of the purpose and importance of biopesticides will motivate the addressing of challenges associated with the successful implementation of these products. Numerous challenges, depending on the specific crop, biopesticide product, and production area are currently faced by African growers in the form of lack of knowledge and information, limitations of the available biocontrol products, inadequate infrastructure, regulatory constraints, and cultural views. This presentation further elaborates on the nature of these challenges within the outlined headings, providing a summary of the hurdles faced by African farmers in their pursuit of sustainable and effective agricultural practices.

ADDRESSING CHALLENGES IN INNOVATING BIOPESTICIDES AND BIOCONTROL AGENTS: CONSTRAINTS FACED BY INDUSTRY AND INNOVATORS IN UPSCALING THE USE OF BIOLOGICALS IN AFRICA

Sean Moore¹,² and Sean Thackeray³
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Sean Moore, Portfolio Manager: IPM, Citrus Research International, South Africa

Compared to other world regions, the biopesticide industry in Africa is relatively young and relatively small. However, of late, there has been notable growth in the size of the industry, the number of biological products, and uptake of these by end-users. Despite this and numerous impressive success stories, constraints in upscaling the use of biologicals on the continent remain. The main challenges in innovation are the slow rate of discovery of novel species and compounds for the development of biopesticides, and the need for improved formulation to provide better environmental protection and persistence of the product when applied in the field. Additional challenges faced by industry are unreasonable regulatory requirements, inefficiency and disincentivising of innovation. Furthermore, end-user uptake is hampered by product cost, inadequate product efficacy, whether perceived or real, inadequate education, and the lack of compulsion to move away from chemical pesticide usage. Remedies to these challenges are proposed, one of the most important being the arguments in favour of local African development and production of biopesticides. Products will not only be produced more affordably for the end-user but can be tailor-made for local systems – pests, crops, and environmental conditions. Increased bioprospecting for novel compounds and organisms should also be a priority. Cross-disciplinary multiple-entity research initiatives, including industry partners from an early stage, can also improve product quality and efficacy and expedite time to market.
CAN FARMERS PRODUCE THEIR OWN BIOPESTICIDES: A BACULOVIRUS FOR FALL ARMYWORM IN KENYA AND ZAMBIA

Ivan Rwomushana, Senior Scientist, Invasive Species, Centre for Agriculture and Bioscience International (CABI)

In recent years, fall armyworm (FAW), Spodoptera frugiperda, has become one of the most damaging invasive species in Africa. This pest can feed on over 300 different plants including important staple crops such as maize, rice, sorghum, and wheat, as well as forage grasses for livestock. Management of FAW is largely carried out through the use of conventional chemical pesticides. The excessive use of highly hazardous pesticides impacts food quality, the natural environment, and food safety. Therefore, a lower risk control approach is recommended as it provides an environmentally friendly and sustainable strategy to the management of FAW while supporting greater yield, and reducing reliance on pesticides. Biopesticides such as baculoviruses are safe to use and are not hazardous to beneficial insects, mammals, bees or aquatic organisms. The Spodoptera frugiperda multiple nucleopolyhedrovirus (SfMNPV) is specific for the control of the larvae of FAW. The larvae must ingest the virus in order to be infected and getting killed. The viral occlusion bodies infect the larvae only by ingestion through the digestive organs. Depending on the ingested quantity and timing of virus ingestion, the larvae will die within a few days or during the next steps of their development. Consequently, based on the understanding of this mode of action, CABI is developing and testing a model for novel, affordable and sustainable production of baculoviruses at the farm level to combat FAW in Zambia and Kenya. The approach involves starting production with a commercial product and subsequent baculovirus material is produced at the farm level where farmers collect infected larvae and produce their own virus mixture for the rest of the cropping season. The approach ensures that farmers have an effective and locally adaptable solution to manage their FAW problem and increases the longer term understanding of how biopesticides work and the increase in their use on the African continent.

REGULATORY SCIENCE – AUSTRALIA’S PERSPECTIVE: THE EFFICACY CONSIDERATIONS OF BIOLOGICAL AGRICULTURAL PRODUCTS (BIOPESTICIDES) IPM SYSTEMS

Mizanur Rahman, Senior Risk Evaluator, Australian Pesticides and Veterinary Medicines Authority (APVMA), Australia

The farming community has depended heavily on synthetic chemical pesticides to control agricultural pests and prevent yield losses over the past 60 years. Synthetic pesticides, when used appropriately, can give excellent control with minimal adverse effects. However, their use can be associated with some level of risk to human health, the environment, trade, and pest resistance. Consequently, the emergence of biopesticides is generating strong interest in their use in integrated pest management practices. Biopesticides typically exhibit toxicity to a narrow range of target species, are IPM friendly, and degrade to environmentally benign compounds. They are therefore valued with respect to social acceptability and environmental stewardship. However, the limitations challenging greater adoption of biopesticides include the high cost of refined commercial products and certain factors which influence efficacy. By the nature of biological processes which underpin their activity, effectiveness may be limited by the speed and persistence of pesticidal action as well as the significance of timing applications with respect to target pest life cycle and population dynamics. In Australia, the Australian Pesticides and Veterinary Medicines Authority (APVMA) defines a biopesticide as an agricultural chemical product where the active constituent is derived from a living organism (plant, animal, microorganism, etc.). APVMA registration and approval is required for all products prior to use. The legislation sets out requirements, prior to registering any new product, that it must be safe and effective, if used in accordance with the instructions for its use. The APVMA has specific guidelines for biopesticide assessment of efficacy and safety. The APVMA’s Efficacy and Safety team are exploring ways to improve the guidance in view of the principles of acceptable efficacy with a view to regulating the effectiveness and safety of biopesticides, commensurate with risk. Concepts under development include a tiered approach to biopesticide efficacy, a systemic perspective of biopesticide use within integrated crop protection systems, and the need for a quantitative understanding of the
indirect benefits and costs associated with biopesticide use. Regulations, guidance, and policies for
the efficacy of biopesticides vary from country to country although the work of certain global agencies
provides for some flexibility in biopesticide regulation. The international efficacy guidance is
considered in a discussion of how contemporary regulation can acknowledge the broader value of
biopesticides in agricultural pest management systems. The APVMA is working towards such goals
as the Australian delegate for the OECD Expert Group on Biopesticides (EGBP).

THE CABI BIOPROTECTION PORTAL - INCREASING AWARENESS AND UPTAKE OF
BIOPROTECTION PRODUCTS GLOBALLY

Robert Malek, Pesticide Risk Reduction Expert, Centre for Agriculture and Bioscience
International (CABI)

CABI is an international, inter-governmental, not-for-profit organization tackling global issues such as
food security and food safety. We support growers and agricultural service providers to lose less and
grow more through research, international development, and publishing of agricultural information.
The CABI BioProtection Portal is an open-access tool that helps growers and agricultural service
providers to find biocontrol and biopesticide solutions. The Portal lists more than 4,000 bioprotection
products, covering over 900 crops. It includes information on 2,200 pests across over 40 featured
countries. The biocontrol market is growing, but a lack of knowledge is hindering widespread adoption.
The Portal aims to bridge this gap in awareness and empower users to make their own informed
decisions. By providing valuable information the portal fosters the understanding and adoption of
sustainable alternatives to chemical pesticides. This proactive approach safeguards farm workers'
and consumers’ health. It also enhances plant health and preserves biodiversity, for a healthier
environment.
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