

Harmonization of Registration Requirements in *Southeast Asia*



- February 2003 to October 2008:

GTZ Regional Project '*Commercialization of Biopesticides in SE Asia*'

- Overall goal: Introduction of new biocontrol products in markets of the region
- Initiation of harmonization of registration requirements
 - Draft registration guidelines for microbials and semiochemicals submitted to ASEAN until end of 2008
 - Initial intention: no immediate changes in regulatory laws, but creating a basis for discussion on potential future legislation



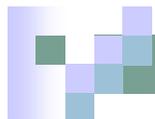
■ Southeast Asia

- Significant problems with pesticide residues and occupational poisoning
- Use of biocontrol technology could have broad impact on agroindustry (export, food safety in domestic markets)
- ASEAN endorses use of environmentally friendly technology
- However, in 2003, local regulatory frameworks oriented/tailored towards chemical pesticides in almost all countries (except Philippines).
 - No inter-country communication and recognition of regulatory issues, in particular biocontrol products



PEACE
STABILITY
COURAGE
DYNAMISM
PROSPERITY

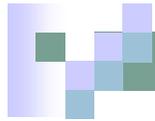




Situation in Partner Countries

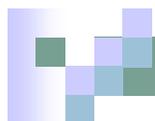
Microbials - Data requirements for registration before cooperation

Data requirements	Thailand	Vietnam	Indonesia
General	Microbials as such recognized, treated according to FAO guidelines	Formally treated like chemical pesticides	Microbials as such recognized, but treated like chemical pesticides
Identity of MPCA	Yes	Yes	Yes
Biological properties and further information	Yes	Yes	Yes
Analytical methods	Yes	Yes	Yes
Toxicology and exposure	Yes (acute and chronic)	Yes	Yes (partially; mouse, fish)
Metabolism and residues	Yes	Yes	Yes (residues)
Environmental fate and behaviour	No	No	No
Ecotoxicology	Yes	Yes (partially)	No
Efficacy (MPCP)	Yes	Yes	Yes



Situation in Partner Countries

- Complicated or inappropriate regulatory procedures for biopesticides (All)
- Products like pheromones impossible to sell, or illegally sold (Thailand, Indonesia, Vietnam)
 - Uncertain markets
 - Reluctance of companies to invest into biocontrol
- Regulatory institutions without proper knowledge and guidelines for products



Discussion on regulatory guidelines with partners



Country	Governmental	Local Industry
Thailand	<ul style="list-style-type: none">- Department of Agriculture (DOA)	<ul style="list-style-type: none">- Uniseeds Co. Ltd.- Ekos Ecosystems Co. Ltd.- Ecovet Co. Ltd.
Indonesia	<ul style="list-style-type: none">- Department of Agriculture- Vocational Education Development Centre for Agriculture (VEDCA)	<ul style="list-style-type: none">- CV Hetts Bio-Lestari- PT Biotama- PT Uni Jaya
Vietnam	<ul style="list-style-type: none">- National Institute for Soils and Fertilizers (NISF)	<ul style="list-style-type: none">- Humix Co. Ltd.- Emi Phot Co. Ltd.
Philippines	<ul style="list-style-type: none">- Dep. Agriculture, Bureau of Plant Industry (BPI)- Dep. Agriculture, PhilRice	
Laos	<ul style="list-style-type: none">- Luang Prabang Municipality- The Heritage House (La Maison du Patrimoine)	<ul style="list-style-type: none">- General Service Laos (GSL)

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- Project Workshop 8-10 April 2006 in Medan, Indonesia, in cooperation with IBMA



Registration guidelines:

- Assessment of current status of regulation and data requirements
- Focus on which products? Microbials, Pheromones
- Comparison of national data requirements with **OECD requirements**

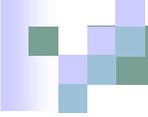




- Cooperation on registration guidelines

OECD guidelines as basis for discussion:

- Guidance for registration requirements for microbial pesticides
 - Version 21 May 2003
- Guidance for registration requirements for pheromones and other semiochemicals used for arthropod pest control
 - Version 26 February 2002

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- Project Workshop 6/7 December 2006 in Bangkok, Thailand, in cooperation with IBMA



Registration issues:

- What are regulatory guidelines good for?
- Safety record of biopesticides
- Should regulation of biocontrol products become easier?
- How can change in regulation be initiated?
- Step by step plenary discussion of OECD guidelines for microbials and pheromones





- Project Workshop on 6 March 2007 in Hanoi, Vietnam
 - **Indonesia announces new legislation for registration of microbials and pheromones**
 - Step by step review and editing of draft guidelines for microbials and pheromones
 - Formulation of questions addressed to meeting with BPSG of OECD
 - Determination of schedule to approach ASEAN

- Meeting with OECD-BPSG on 25 April 2007 in Braunschweig, Germany
 - Participation with representatives of regulatory authorities from Thailand, Indonesia and Vietnam at RECECA meeting
 - Questions were addressed to BPSG that remained unclear during inter-country discussion process; especially regarding pheromones (efficacy tests, registration requirements in general, etc.)



■ Preliminary Results

- **Indonesia** has created a new legislation for registration including a simplified procedure for registration of microbials and pheromones effective in 2007
 - New registration form
 - E.g., data requirements microbials:
 - General information
 - Identity of active agent
 - Biological properties
 - Application
 - Data on efficacy
 - Toxicology
 - Pheromones will need only 'notification', no registration



■ Preliminary Results

- **Thailand** is discussing new registration guidelines and procedures for microbials and pheromones (2007). Expected to become law in 2008.
 - Registration requirements for microbials mainly follow FAO guidelines, with simplifications.
 - Pheromones will need only 'notification' (mode of action, MSDS, Label), no registration



■ Outlook

- December 3-4, 2007, project workshop in Indonesia
 - Initiation of cooperation with ASEAN
 - Further review of draft guidelines