

Session 3: Pesticide Registration

Code of Conduct

Article 2: Definitions

Registration means the process whereby the responsible national government or regional authority **approves the sale and use of a pesticide** following the evaluation of scientific data aimed at demonstrating that the product is effective for its intended purposes and does not pose an unacceptable risk to human or animal health or the environment under the conditions of use in the country or region.

(Mentioned in Articles 1, 5, 6, 10 and 11)

Code of Conduct

Article 6: Regulatory and technical requirements

Governments should...

- introduce policies and legislation to regulate pesticides throughout the life cycle
- establish a pesticide registration scheme and infrastructures under which each pesticide product is registered before it can be made available for use
- harmonize registration requirements

Pesticide industry should...

- provide national regulatory authorities with all data necessary to assess quality and risks

International organizations should...

- give assistance to countries which do not yet have facilities and expertise

Code of Conduct

Article 6: Regulatory and technical requirements

Changes

- Added: reference to **life cycle and policy**
- Added: **legally binding instruments** in addition to guidelines
- Added: introduce legislation to **prevent sale and use of pesticides to/by children** (ILO convention)
- Added: licensing scheme or permits **for pest control operators**
- Added: establish **GAP** for each agricultural use pesticide
- Added: **control counterfeiting** through national and international cooperation

Code of Conduct

Article 6: Regulatory and technical requirements

Continued...

- Deleted: reference to **GAP practices** and resulting residues
- Added: Regulate pesticide residues in accordance to Codex recommendations or national/regional standards
- Added: pesticides should conform with **applicable national standards** in addition to FAO specifications

Code of Conduct

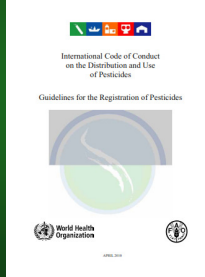
Article 6: Regulatory and technical requirements

6.1.1 introduce the necessary policy and legislation for the regulation of pesticides... **In so doing, governments should take full account of factors such as local needs, social and economic conditions, levels of literacy, climatic conditions, availability and affordability of appropriate pesticide application and personal protective equipment;**

6.1.2 as recommended by the International Partnership for Cooperation on Child Labour in Agriculture, introduce legislation to **prevent the use of pesticides by and sale of pesticides to children**. The use of pesticides by children in a work situation should be included in National Hazardous Work Lists for children under ILO Convention No. 182 on the Worst Forms of Child Labour in countries which have ratified it.

Guidelines

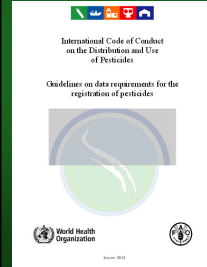
Guidelines for the registration of pesticides (2010)



- Principles of pesticide registration
- Outline of the pesticide registration process
- Data requirements and the registration dossier
- Evaluation of the registration dossier
- Decision making
- Specific issues
- Institutionalization and administrative organization
- Coordination and collaboration
- The pesticide register
- Phased development of a registration scheme
- Funding of pesticide registration

Guidelines

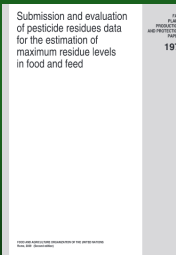
Guidelines on data requirements for the registration of pesticides (2013)



- Scope, objectives and responsibilities
 - Data requirements for registration of pesticides
 - Types of data and information
 - How data may be used
 - Factors that affect data requirements
 - Special considerations
 - Biochemical pesticides
 - Emergency and experimental use
- ANNEXES
- Chemical pesticides
 - Biochemical pesticides

Tools

Manual on the submission and evaluation of pesticide residue data for the estimation of maximum residue limits in food and feed (2009)



- Selection of compounds for evaluation
- Data and information required for JMPR evaluations
- Preparation of data dossiers for the consideration of the FAO Panel of JMPR
- JMPR Practices in evaluation of pesticide residue data
- JMPR practices in estimation of maximum residue levels, and residue levels for calculation of dietary intake of pesticide residues
- Estimating dietary intake of pesticide residues
- Use of JMPR recommendations by regulatory authorities

Regional Harmonization in Southeast Asia

Summary of Regional Status

Registration decision

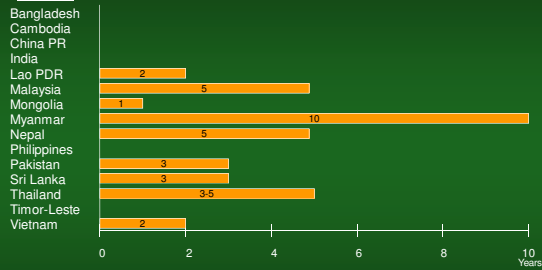
Who makes the final registration decision?

1. Board of independent experts from agriculture, health, environment, etc.?
2. Technical committee of dossier evaluators?
3. Head of the registration unit/Registrar?

- Most countries checked all three options
- Needs further clarification

Registration Validity Period

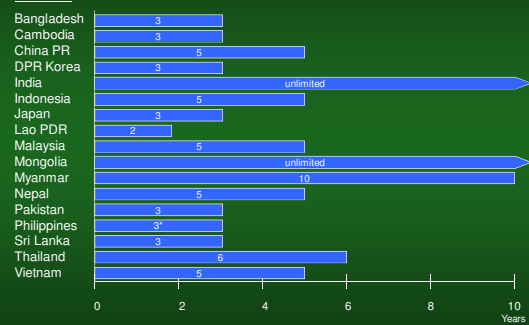
Countries



- Short validity periods indicate dossier evaluation
- Long validity periods do not allow for routine periodic reviews

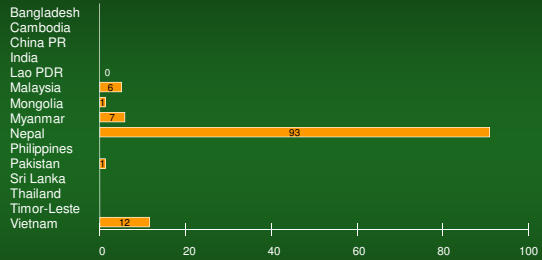
Registration Validity Period

Countries



Restricted Use Pesticides

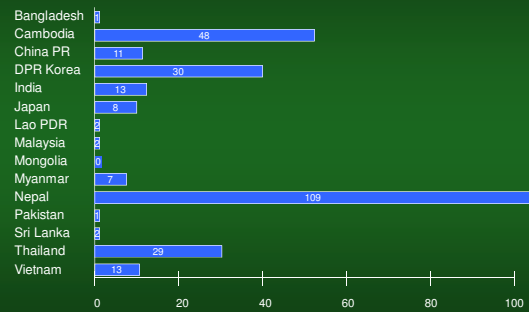
Countries



- Most countries have a few pesticides where the use is restricted

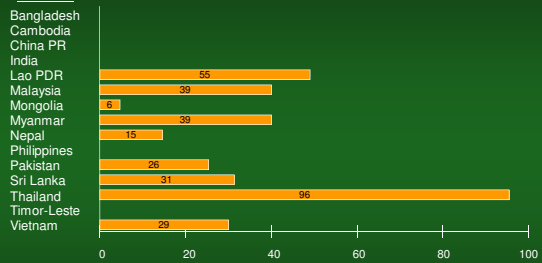
Restricted Registrations

Countries



Banned Active Ingredients

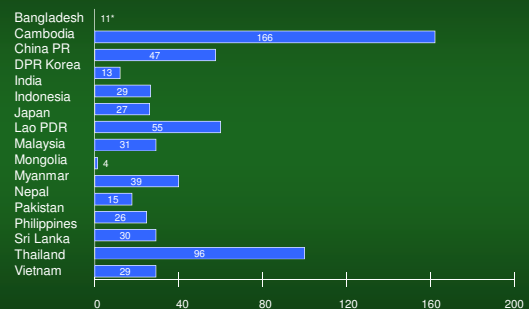
Countries



- The number of banned pesticides varies greatly

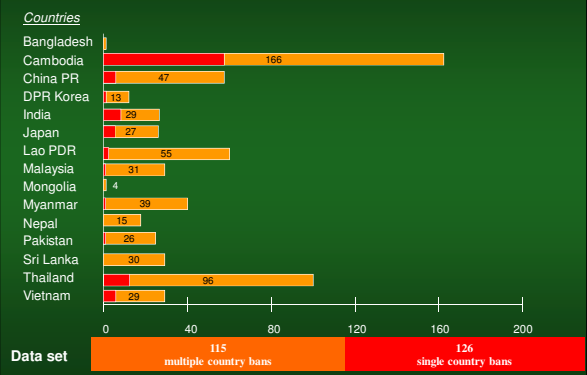
Banned Active Ingredients

Countries



* archive data

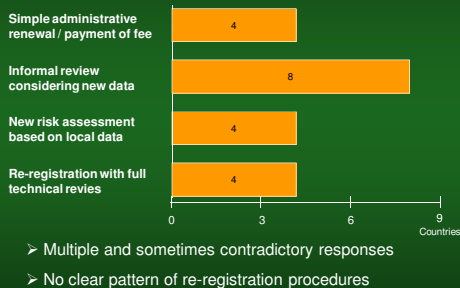
Observation: single country bans



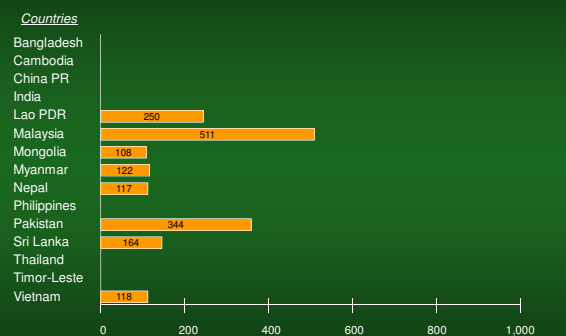
Stockholm Convention (POP) - Banning status



Registration renewal

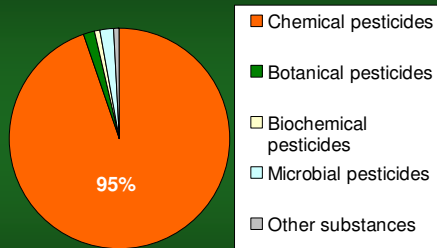


Registered Active Ingredients 2014



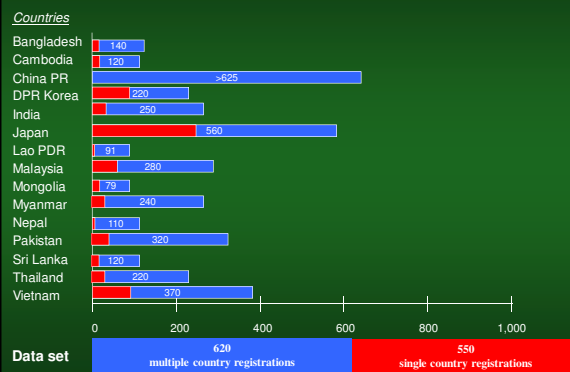
Pesticide registrations

7 countries

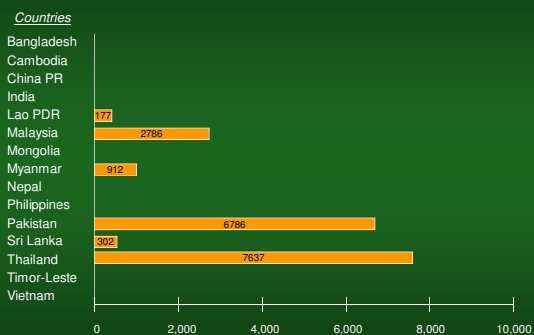


➤ Almost all registered active ingredients are chemical pesticides

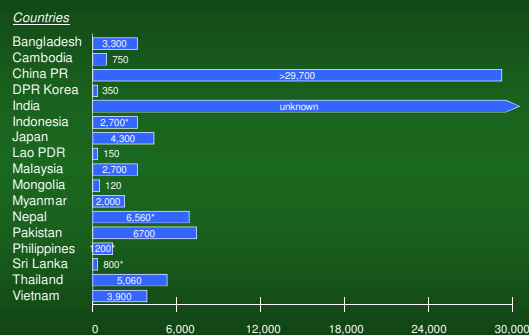
Observation: single country registrations



Registered formulated products 2014

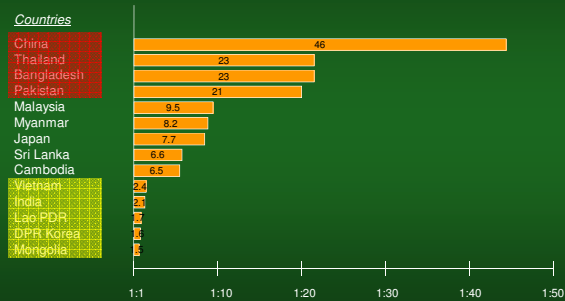


Registered Formulated Products



* archive data

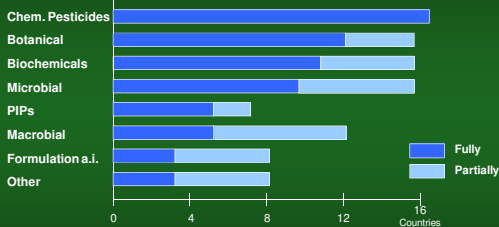
Analysis: Ratio Formulations : a.i.



Registration products

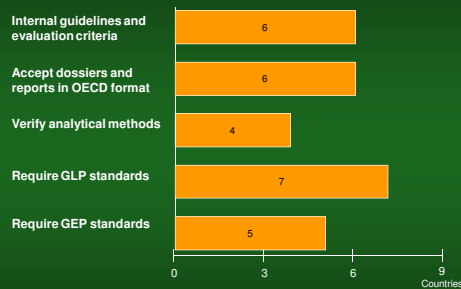
Types of pest control products requiring registration	Lao PDR	Malaysia	Mongolia	Myanmar	Nepal	Pakistan	Sri Lanka	Thailand	Vietnam
•Chemical pesticides	Y	Y	Y	Y	Y	Y	Y	Y	Y
•Botanical pesticides	Y	Y	Y	Y	Y	Y	Y	Y	Y
Biochemical pesticides	Y	N	Y	Y	N	Y	Y	Y	Y
•Microbial pesticides	Y	Y	Y	Y	N	Y	Y	Y	Y
•Plant-Incorporated-Protectants	?	Y	Y	Y	Y	N	Y	Y	Y
•Biocontrol agents	Y	Y	Y	Y	Y	N	Y	Y	Y
•Non-pesticide a.i.	?	N	Y	N	N	N	Y	N	
•Other substances	Y	Y	Y	N	N	Y		Y	Y
•Nutrients, inoculants	Y	Y	-	Y	N	N		Y	Y
•Soil conditioners	Y	N	N	N	N	N		Y	?
•Drugs	Y	Y	Y	N	N	Y	Y	Y	Y
•Plant/Animal extracts	Y	Y	N	Y	Y	N		Y	Y

Regulated Pest Control Products



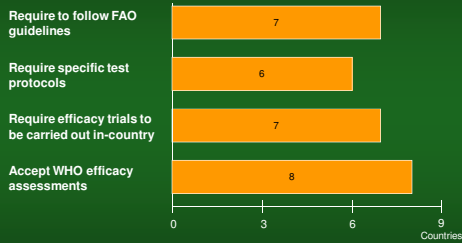
- Chemical pesticides are regulated in all countries
- Other pest control agents are partially regulated

Technical dossier evaluation



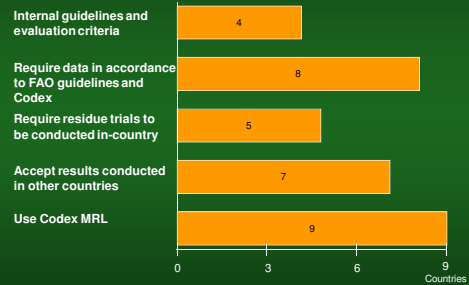
- General procedures are largely harmonized

Bioefficacy assessment



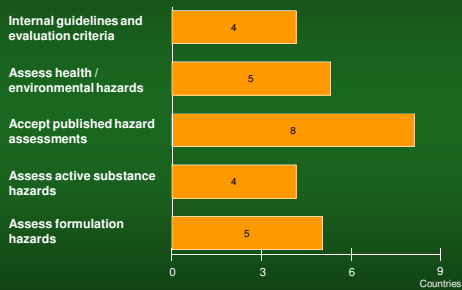
- General assessment procedures are largely harmonized
- Number of test protocols, field trials and growing seasons varies among the countries

Residue assessment



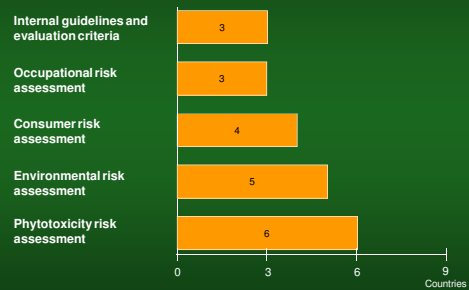
- Residue assessments are more or less harmonized

Hazard assessment



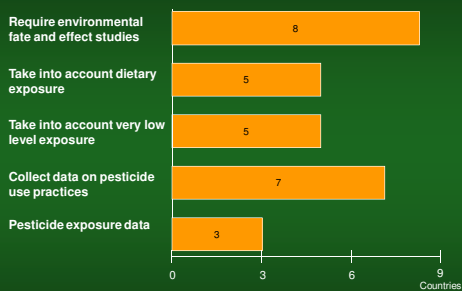
- General procedures are largely harmonized

Risk assessment



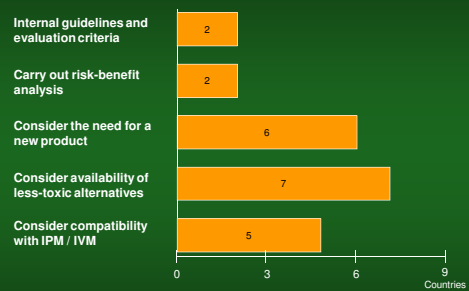
- General procedures are largely harmonized

Risk assessment (continued)



- All countries consider pesticide risk
- Not all countries have the capacity or data to assess risks

Risk-benefit analysis



- Countries consider multiple factors
- Few countries conduct formal risk-benefit analysis

Exchanges Discussion

Exchange

- Review Article 6 and discuss how the changes in the 3rd revision affect regulatory and technical requirements
- Clarify process of registration decision in your country
- Give recommendations for priorities and changes for regulatory and technical requirements