



Food and Agriculture Organization  
of the United Nations

# FAO Pesticide Registration Toolkit **Registration Strategies**

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Workshop on FAO Pesticide Registration Toolkit  
16 - 19 June 2015, Dar es Salaam, Tanzania

# Toolkit menu

## Registration approaches

### Objective of the tool

Explanation of different pesticide registration strategies  
*and*

Guidance to select the most appropriate strategy

Toolkit
Registration strategies
Registration process
Data requirements and testing guidelines
Assessment methods
Decision making
Risk mitigation

# Registration strategy

The **pesticide registration strategy** is the overall strategy that a registration authority applies to evaluate and authorize pesticides.

*Depends on:*

- National legislation
- Human resources (staff number, -training, -expertise)
- Funding
- ...

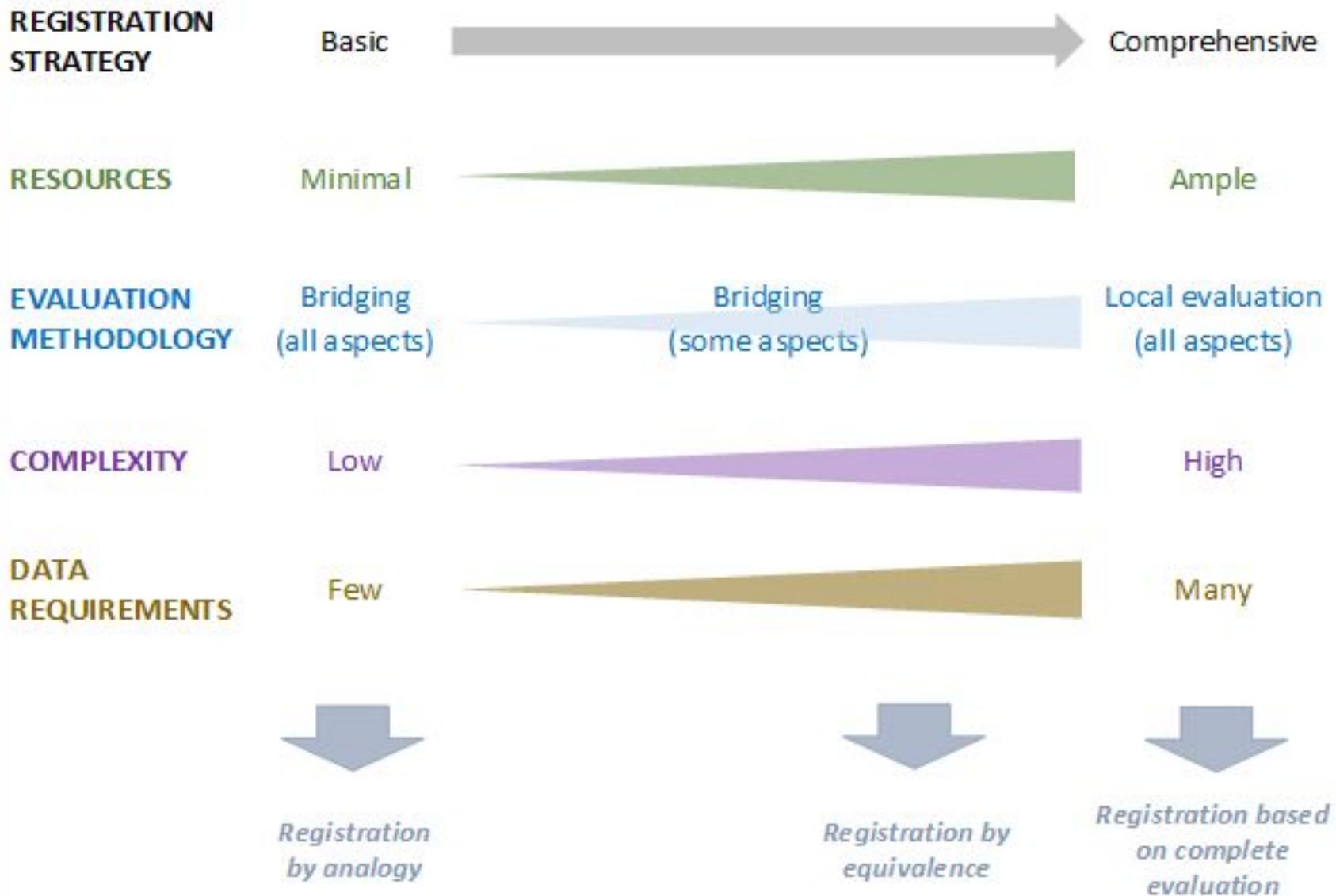
# Registration strategy

A pesticide registration strategy ranges from **basic** to **comprehensive**

Differs in:

- Pesticide evaluation method
- Complexity of the evaluation
- Amount of data needed
- Resources required

Pesticide registration strategies may range from basic to comprehensive, depending on resources available. The strategies will differ in the evaluation methodology that can be applied, the complexity of evaluation of the pesticide and the amount of data required to conduct the evaluation.



# Registration strategy

Two main registration strategies presented in the Toolkit (so far...):

- Registration by **analogy**
- Registration based on **complete evaluation**
  - plus: various ways to rationalize the approach, to optimize the use of resources

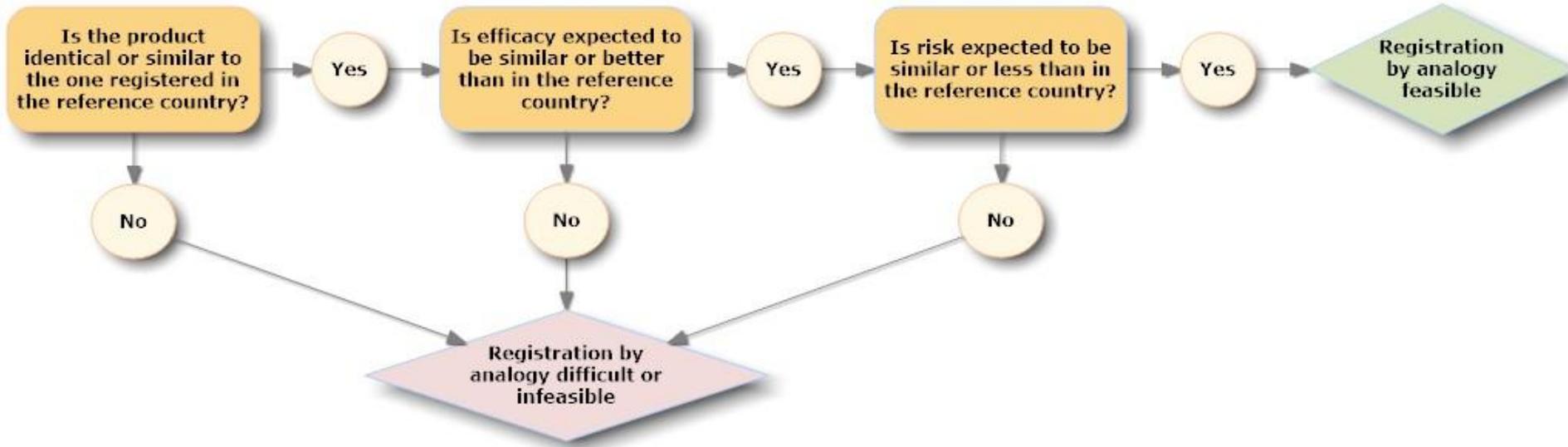
# Registration by analogy

## Basic registration strategy - limited comparison:

1. pesticide product submitted for authorization in a **resource-limited country**, and
2. similar products registered in **one or more reference countries**

Since product registered in reference country:  
**Assumption:** pesticide quality, efficacy and risks evaluated and acceptable in that country

# Registration by analogy



Local application when compared with reference country:

- Product identical or similar?
- Efficacy similar or better?
- Risk similar or less?

# Registration by analogy

Analogy  Complete evaluation

Analogy:

- Much less resources
  - Less complex
- but:
- More uncertainty

➡ Progressively, move from analogy towards more comprehensive evaluation

# Registration by analogy

Registration by analogy is **applied by many registration authorities**, around the world!

But not a very formalized approach.

Toolkit:

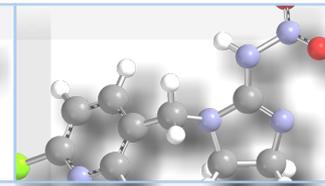
- Structure the approach better:
  - Check-list
  - Guidance

# Registration based on complete evaluation

- **Classic strategy** to pesticide registration
- **Comprehensive evaluation** of all aspects of the pesticide registration dossier
- Requires **broad range of local expertise** as well as **sufficient financial resources**

# Aspects of the pesticide registration evaluation

**Identity, composition and physical & chemical properties**



**Analytical methods**

**Mode of action, handling, safety, application & efficacy**



**Residues**

**Impact on human health**



**Environmental fate & effects**

**Classification, packaging & labelling**



# Registration based on complete evaluation

## Different aspects can be evaluated at different levels of complexity

- Rationalizing complete evaluations, e.g. by:
  - Registration by **equivalence**: for equivalent (generic) pesticides
  - **Bridging**: assessment conducted in one country is used and interpreted for the situation in another country
  - **Extrapolation** of data from other countries: e.g. replacing local residue and efficacy trials
  - **Extrapolation** of data from other crops or pests: e.g. for minor uses
- Assessment Methods Tool provides further guidance

# Phased development of pesticide registration scheme

FAO recommends that registration authorities **work towards increasingly comprehensive** evaluation of a pesticide.



Phased development will, over time, result in more reliable pesticide evaluations and better informed registration decisions.

# Phased development: options

- Registration by **analogy**
- **Bridging** existing efficacy or risk assessments
- **Acceptance** of data from other countries
- **Extrapolation** among crops and/or pests
- **Prioritization** of specific groups of pesticides
- **Prioritization** of specific protection goals
- Setting up **fast-track** registration channels
- Registration by **equivalence**

# Registration Approaches

**Next: Group discussion**

