



Food and Agriculture Organization
of the United Nations

FAO Pesticide Registration Toolkit

Registration Strategies

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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
- ...

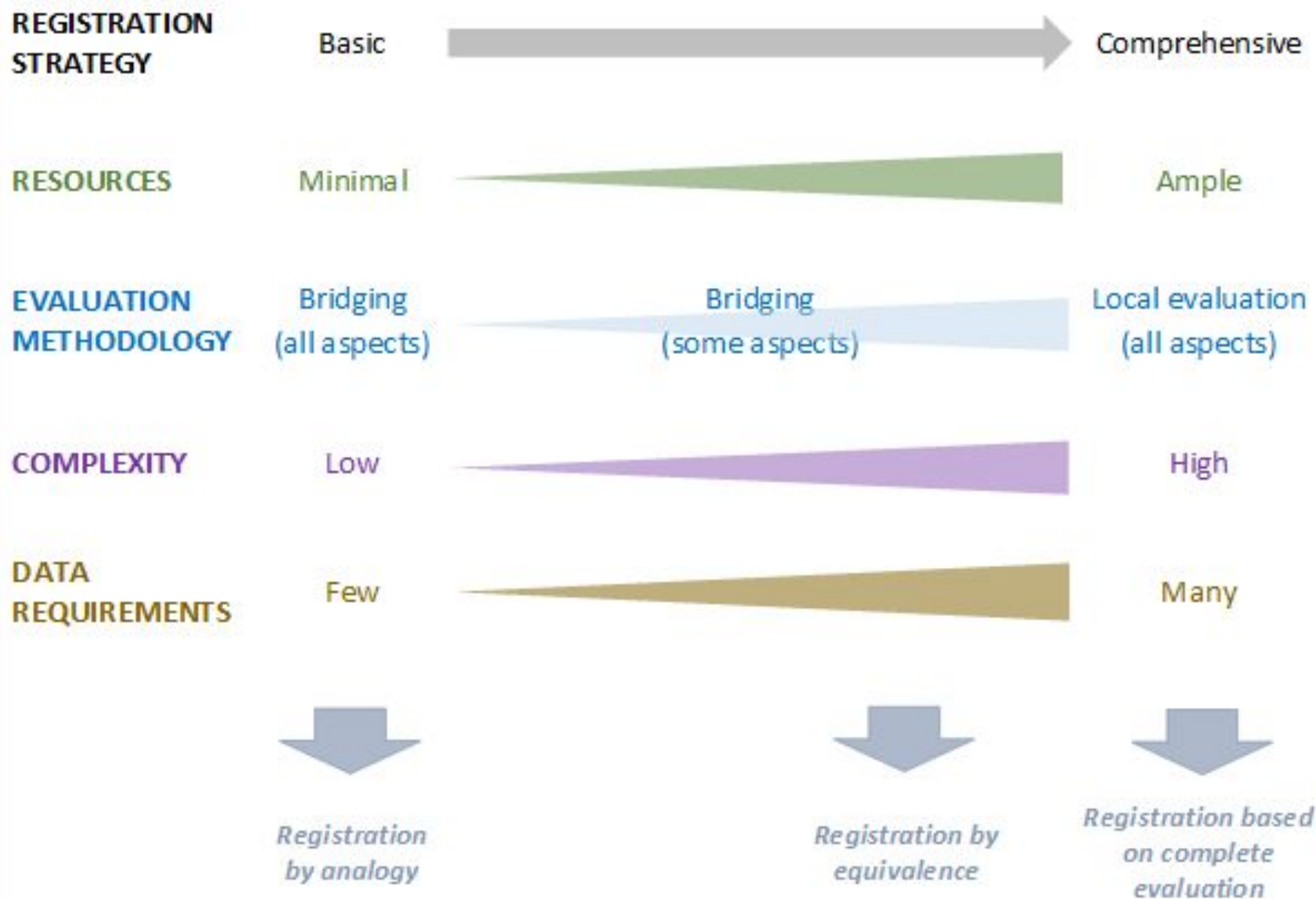
Registration strategy

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

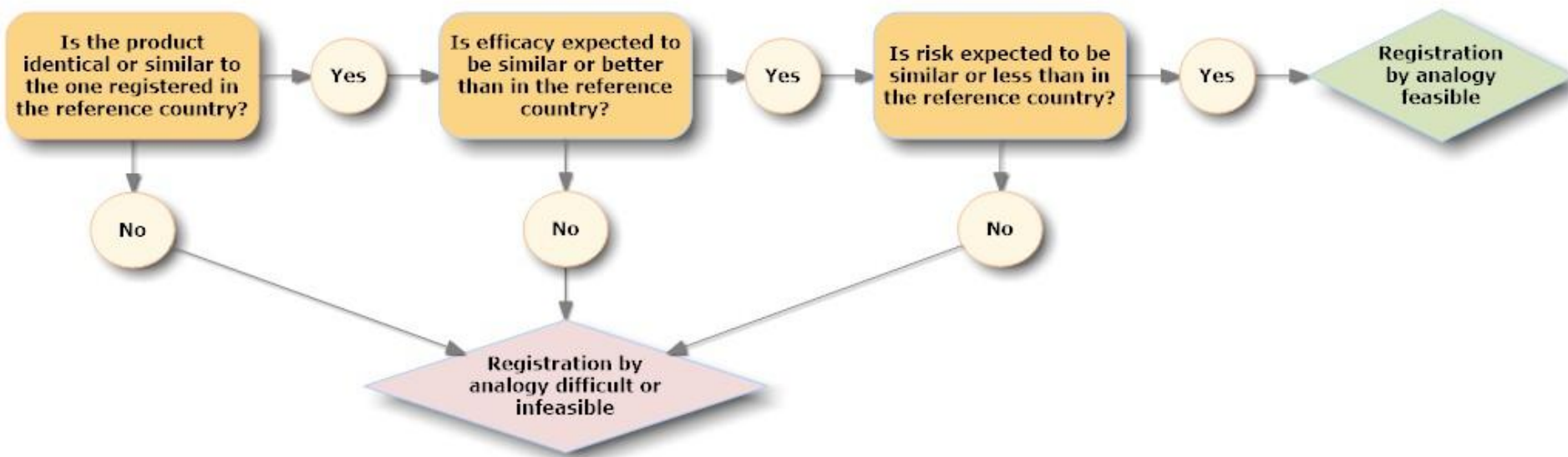
Basic registration strategy - **limited comparison**:

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

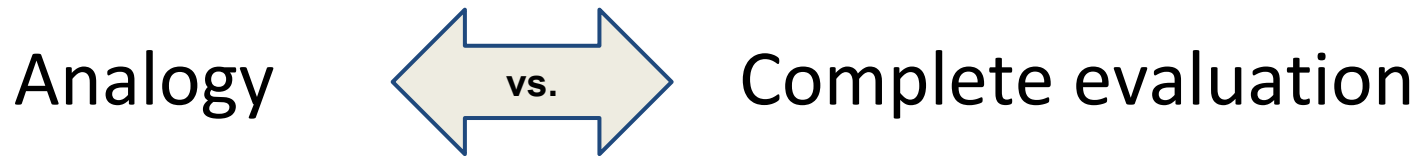
Registration by analogy



Local application when compared with reference country:

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

Registration by analogy



Analogy:

- 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:

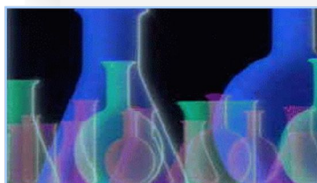
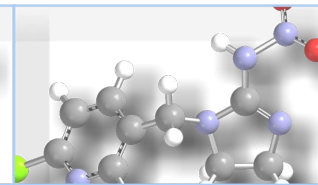
- Structure the approach better:
 - Check-list
 - Guidance

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



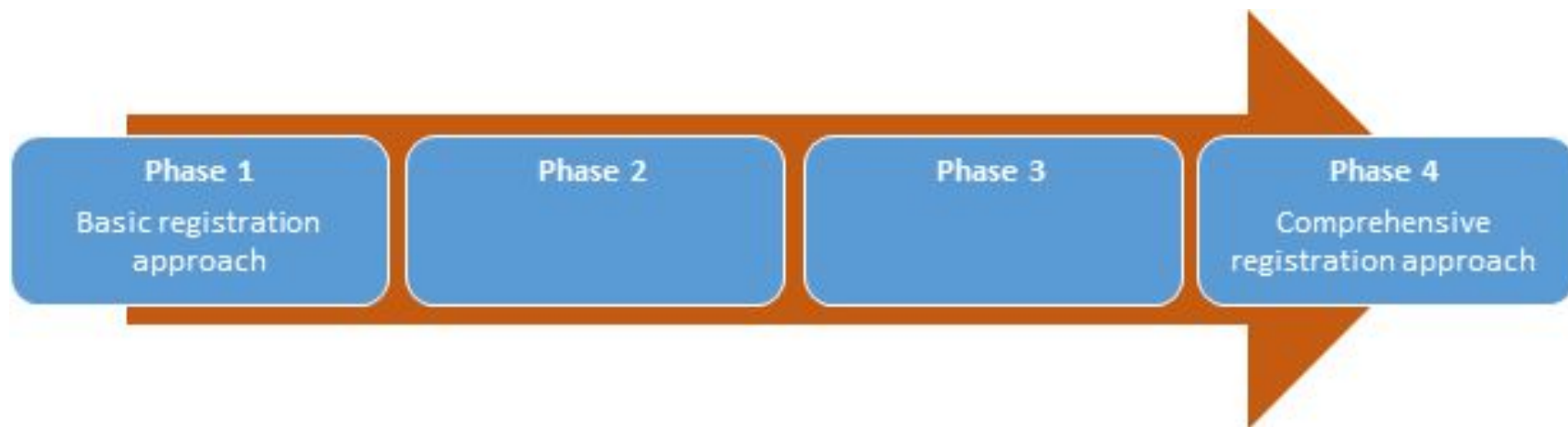
Registration based on complete evaluation

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

