

Pesticides Invention to Market



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What is an agrochemical?

A chemical which can safely be applied to a crop in order to give the farmer:

- Higher yields
- Better quality produce
- Reliability
- Ease of harvest

Agrochemicals include **insecticides**, **fungicides** and **herbicides** which are collectively known as crop protection products.

Crops are in competition with weeds, plant diseases, insects and other organisms.

- About 10,000 insect species are classified as pests
- At least 600 species of plants are classified as weeds
- Some 1,500 different fungi cause plant diseases



Insect control



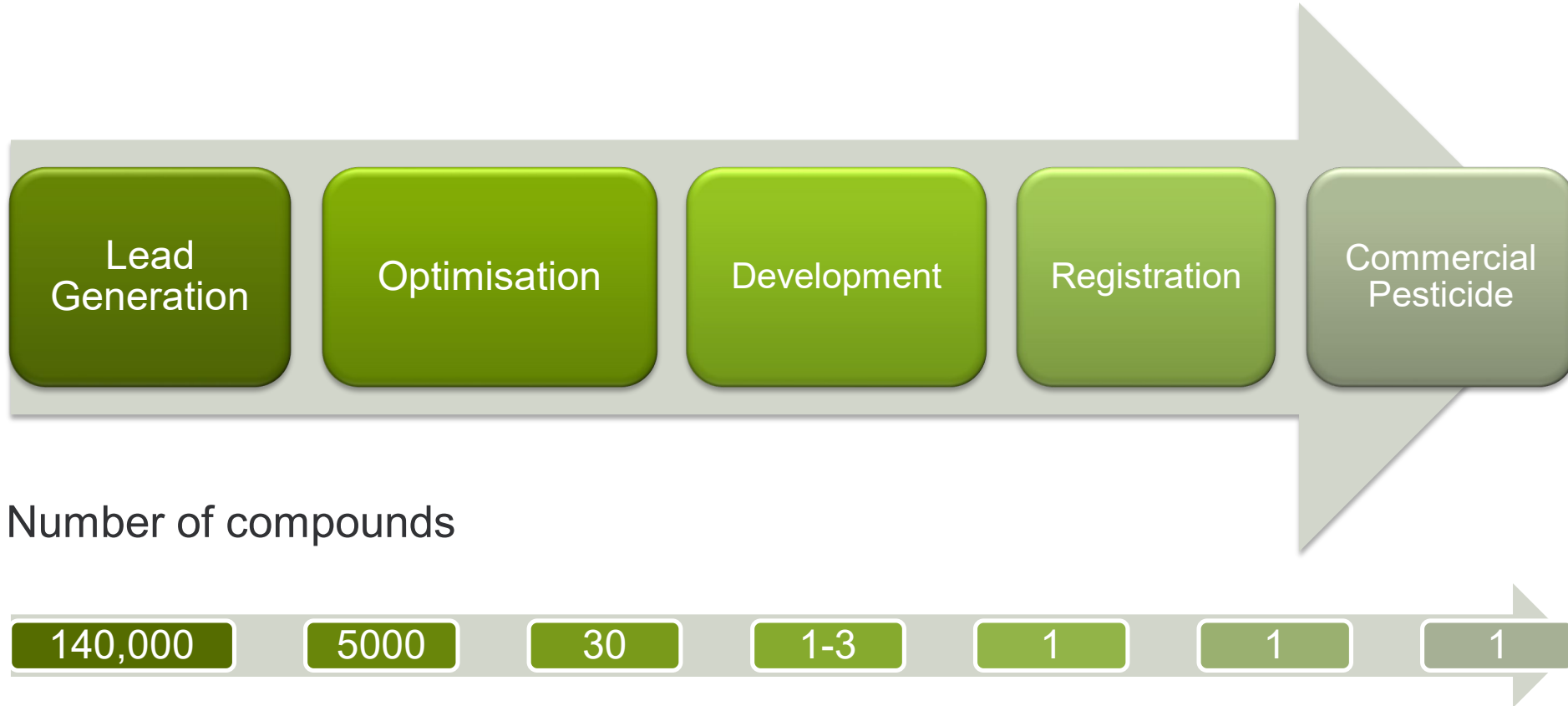
Fungal control



Weed control



The Route to Market



Step 1: Determining the context-of-use



Step 2: Addressing core principles

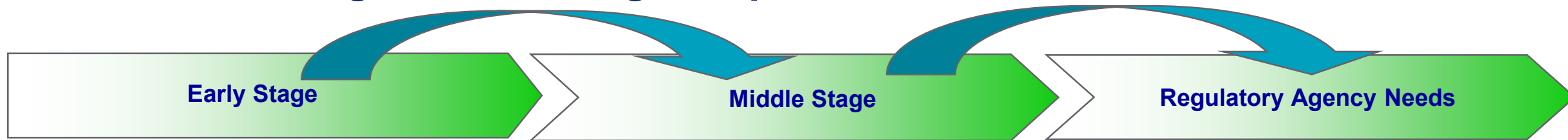


Step 3: Fit-for-purpose criteria

Criteria	Prioritization	Hazard Screening	Risk Assessment
chemical applicability domain	Less Important	Less Important	Less Important
SOP - source and species of cell/tissue	Less Important	Less Important	Less Important
assay description	Less Important	Less Important	Less Important
quality of verification datasets	More Important	Less Important	Less Important
SOP - metabolic competence status	More Important	Less Important	Less Important
FFP test validity (acceptance criteria)	More Important	Less Important	Less Important
Independent peer review	More Important	Less Important	Less Important
Endpoint or pathway for prediction	More Important	More Important	Less Important
explanation of mechanistic basis	More Important	More Important	Less Important
Assay robustness	More Important	More Important	Less Important
Data accessibility	More Important	More Important	Less Important
Biological comparison with in vivo data, animal or human	More Important	More Important	Less Important
Statistical evaluation of model/assay	More Important	More Important	Less Important
Level of certainty in prediction	More Important	More Important	Less Important
biological variability and sub-populations of relevance	More Important	More Important	More Important

Knowledge Needs Differ According to Development Phase

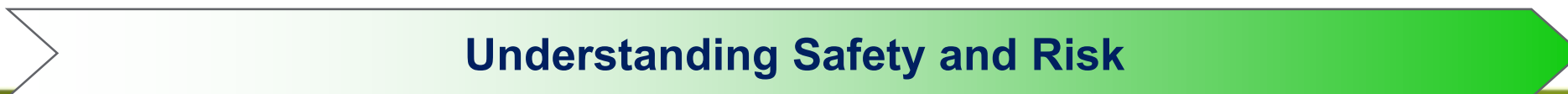
Toxicological Knowledge Required:



Acute Hazard
Genetic Toxicity
Understanding of PK
Low Dose Target Organ & Carcinogenicity Potential
Developmental and Reproduction Toxicity Potential

ADME
Sub Chronic Toxicity
Reproductive Toxicity
Preliminary Risk Assessments

Acute Hazard
Genotoxicity
Carcinogenicity & Chronic Toxicity
Reproductive Toxicity
Developmental Toxicity
Neurotoxicity
Sub Chronic Toxicity (Non-Rodent)
Dermal Absorption
ADME
Metabolite Testing
Manufacturing Intermediates
Formulation Toxicity
Definitive Risk Assessments



Questions?

Bringing plant potential to life