Using problem formulation to construct fit-for-purpose environmental risk assessments of regulated stressors

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Using problem formulation to construct fit-for-purpose risk assessments

Environmental risk assessments (ERAs)

- Performed to evaluate the likelihood of adverse effects in the environment occurring as a result of exposure to biological, physical or chemical stressors.
- ERAs must be “fit-for-purpose”
  - Focus on the key aspects that the assessments must consider
  - Provides relevant information for decision-makers

FACILITATE DECISION MAKING

Using problem formulation to construct fit-for-purpose risk assessments

Fit-for-purpose

"using the right tool to adequately answer the risk managers questions"

VALIDITY	RELIABILITY	TRANSPARENCY
•The assessment measures exactly what we set out to measure	• Consistent • As accurate as possible • As realistic as possible	•Clearly explains the logic of what has been done, how and why it has been done

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- In the EU, ERAs for different stressors are covered by different regulations, e.g.:
  - **Pesticides (EC) No 1107/2009**
    - Well codified risk assessments, tiered approaches with specific data requirements and trigger values that guide the assessment
  - **Genetically modified crops: Directive 2001/18/EC**
    - Case-by-case risk assessments with a set of data requirements expected for all types of products**.**
- Emerging technologies such as: gene drive modified mosquitoes, RNA interference-based genetically modified plants and pesticides, etc raise questions on whether existing ERA tools can be readily applied

How to ensure that the ERAs are fit-for-purpose?

Using problem formulation to construct fit-for-purpose risk assessments

Problem formulation

- Implicitly used by risk assessors.
- Early described more explicitly in the frame of the EPA pesticide risk assessment (USEPA, 1992[1]).
- Identified as a useful tool for organizing and harmonizing ERAs for GM crops.
- Now used explicitly in ERAs for GMOs submitted to EFSA (e.g. EFSA, 2010[2]) and other countries (e.g. India)
- Could be useful for new technologies under development

PF helps ensuring that the assessment will be fit-for-purpose (validity, reliability, transparency)

[1] https://www.epa.gov/sites/production/files/2014-11/documents/framework_eco_assessment.pdf
[2] https://www.efsa.europa.eu/en/efsajournal/pub/1879

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ORIGINAL PAPER

Problem formulation in the environmental risk assessment for genetically modified plants

Jeffrey D. Wolt · Paul Keese · Alan Raybould · Julie W. Fitzpatrick · Moisés Burachik · Alan Gray · Stephen S. Olin · Joachim Schiemann · Mark Sears · Felicia Wu

COMMENTARY
GM Crops and Food: Biotechnology in Agriculture and the Food Chain 4:1, 1-6; January/February/March 2013; © 2013 Landes Bioscience

Putting problem formulation at the forefront of GMO risk analysis

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When applying risk assessment and the broader process of risk analysis to decisions regarding the dissemination of genetically modified organisms (GMOs), the process has a tendency to become remarkably complex. Further, as greater numbers of countries consider unconfined release of specific GMOs. This approach, which we present here, is the result of incremental developments and improvements based upon participant feedback over a series of focused training workshops (see supplemental materials), and therefore has several novel features

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Problem formulation and hypothesis testing for environmental risk assessments of genetically modified crops

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Environmental risk assessments can provide high confidence of minimal risk by testing theories, "risk hypotheses", that predict the likelihood of unacceptable harmful events. The creation of risk hypotheses and a plan to test them is called problem formulation. Effective problem formulation seeks to maximize the possibility of detecting effects that indicate potential risk; if such effects are not detected, minimal risk is indicated with high confidence. Two important implications are that artificial test conditions can increase confidence, whereas prescriptive data requirements can reduce confidence (increase uncertainty) if they constrain problem formulation. Poor problem formulation can increase environmental risk because it leads to the collection of superfluous data that may delay or prevent the introduction of environmentally beneficial products.

Keywords: risk assessment / problem formulation / scientific method / certainty / data requirements

Problem Formulation in Environmental Risk Assessment for Genetically Modified Crops: A Practitioner's Approach

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Abstract

Problem Formulation, a tried and tested aspect of Environmental Risk Assessment (ERA), is increasingly being applied to assess the potential risks associated with the cultivation of genetically modified (GM) crops. The first step in the ERA, problem formulation is a way of focussing on those aspects of the environment which most need protection or are most at risk of harm, framing relevant scenarios in which they may be harmed and devising a plan

Safety Assessment of Food and Feed Derived from GM Crops: Using Problem Formulation to Ensure "Fit for Purpose" Risk Assessments

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Abstract

All genetically modified (GM) crops intended for use in food and feed must be assessed for their safety to humans and animals. The data and methodology used to conduct these assessments has been developed over many years. International organisations like the Food and Agriculture Organization (FAO) of the United Nations, the World Health Organization (WHO) and the Organisation for Economic Cooperation and Development (OECD) have been facilitating the harmonisation of food and feed risk assessment methodologies. The Codex Alimentarius Commission, established by FAO and WHO in 1963, has developed harmonised international food standards, guidelines and codes of practice and promoted coordination of all food standards work undertaken by international governmental and non-

ESTEL

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What is Problem Formulation?

Allows the organization of the risk assessment in a transparent and logical way

- Considers the relevant Protection goals
- Relevant available information is compiled to address key questions
- Facilitates an initial risk characterization to establish:
  - If the risk characterization can be completed with available information
  - If more information is necessary
- If more information is needed, problem formulation allows:
  - The development of a clear analysis plan, or
  - The identification of the information needed to facilitate decision making

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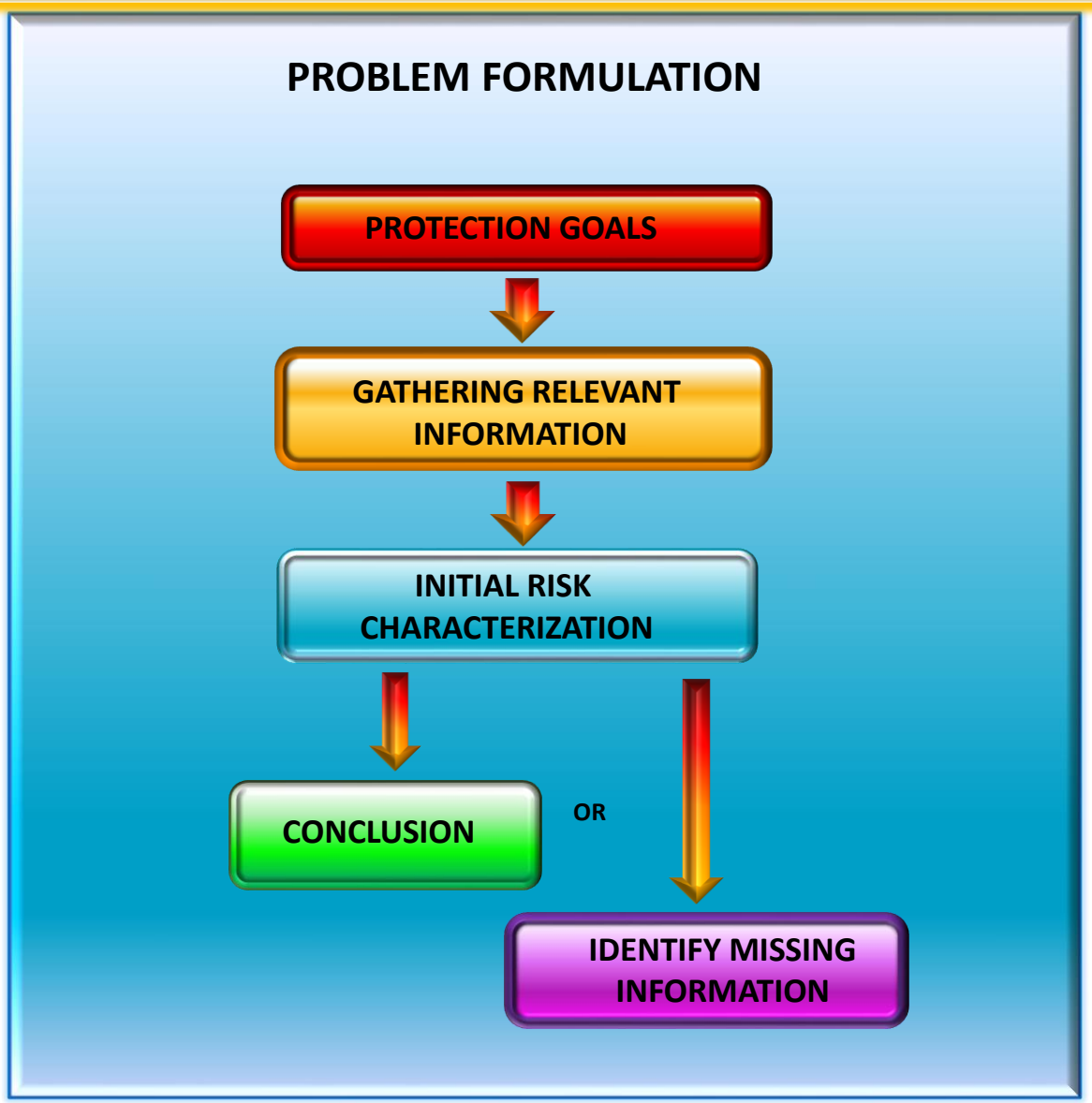

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PROTECTION GOALS:

- Different regulatory frameworks may have different protection goals

A good understanding of the protection goals set in the regulatory framework within which we are operating is essential

- Usually the protection goals set by policy are very broad and not always clear. They need to be translated to more operative protection goals that can then be translated to testable hypothesis

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Evaluating environmental risks of genetically modified crops: ecological harm criteria for regulatory decision-making

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Development of a framework based on an ecosystem services approach for deriving specific protection goals for environmental risk assessment of pesticides

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ABSTRACT

General protection goals for the environmental risk assessment (ERA) of plant protection products are stated in European legislation but specific protection goals (SPGs) are often not precisely defined. These are however crucial for designing appropriate risk assessment schemes. The process followed by the Panel on Plant Protection Products and their Residues (PPR) of the European Food Safety Authority (EFSA) as well as examples of resulting SPGs obtained so far for environmental risk assessment (ERA) of pesticides is presented. The ecosystem services approach was used as an overarching concept for the development of SPGs, which will likely facilitate communication with stakeholders in general and risk managers in particular. It is proposed to develop SPG options for 7 key drivers for ecosystem services (microbes, algae, non target plants (aquatic and terrestrial), aquatic invertebrates, terrestrial non target arthropods including honeybees, terrestrial non-arthropod invertebrates, and vertebrates), covering the ecosystem services that could potentially be affected by the use of pesticides. These SPGs need to be defined in 6 dimensions: biological entity, attribute, magnitude, temporal and geographical scale of the effect, and the degree of certainty that the specified level of effect will not be exceeded. In general, to ensure ecosystem services, taxa representative for the key drivers identified need to be protected at the population level. However, for some vertebrates and species that have a protection status in legislation, protection may be at the individual level. To protect the provisioning and supporting services provided by microbes it may be sufficient to protect them at the functional group level. To protect biodiversity impacts need to be assessed at least at the scale of the watershed/landscape.

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EMBO reports

Optimising environmental risk assessments

Accounting for ecosystem services helps to translate broad policy protection goals into specific operational ones for environmental risk assessments

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Regulated products such as genetically modified organisms (GMOs), plant protection products (PPPs) or feed additives for livestock are subject to an environmental risk assessment before they can be approved for use in agriculture. This assessment aims to evaluate any possible risk that the deployment of such products may pose to the environment. Robust environmental risk assessments require an explicit formulation of potential problems to identify plausible and relevant exposure scenarios and potential adverse effects from predicted exposures. The actual risk is then characterised by testing specific hypotheses about the likelihood and severity of these to support regulatory decision-making. These protection goals can vary between jurisdictions, but their overall aim is to minimise harm to the environment, including biodiversity and ecosystems, caused by human activities.

However, policy protection goals, such as protecting biodiversity, are often too generic and vague to be useful for scientific risk assessment, and need to be translated into specific, operational ones. Because protecting everything, everywhere, forever is not always tenable, operational protection goals, also termed specific protection goals, have to delineate the environmental components that need to be protected, where and over

The Millennium Ecosystem Assessment, which is widely applied, distinguishes four categories of ecosystem services: provisioning services (products such as food/feed, water, fibre or energy); regulating services, such as pollination, pest control, water and air purification; cultural services (recreation, tourism or cultural heritage); and supporting services that are necessary for the other ecosystem services to function, such as nutrient cycling, soil formation, oxygen production or habitat provision. Irrespective of the various classifications for ecosystem services (Box 1), ecosystem services are highly interconnected and interdependent, and involve

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Protection goals in environmental risk assessment: a practical approach

Monica Garcia-Alonso · Alan Raybould

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Abstract Policy protection goals are set up in most countries to minimise harm to the environment, humans and animals caused by human activities. Decisions on whether to approve new agricultural products, like pesticides or genetically modified (GM) crops, take into account these policy protection goals. To support decision-making, applications for approval of commercial uses of GM crops usually comprise an environmental risk assessment (ERA). These risk assessments are analytical tools, based on science, that follow a conceptual model that includes a problem formulation step where policy protection goals are considered. However, in most countries, risk assessors face major problems in that policy protection goals set hypotheses that can be used in ERAs. Examples are provided to show how this approach can be applied to two areas of environmental concern relevant to the ERAs of GM crops.

Keywords Environmental risk assessment · Genetically modified crops · Protection goals · Assessment endpoints · Policy · Regulation

Introduction

Environmental risk assessments (ERAs) are an essential part of regulatory decision-making for genetically

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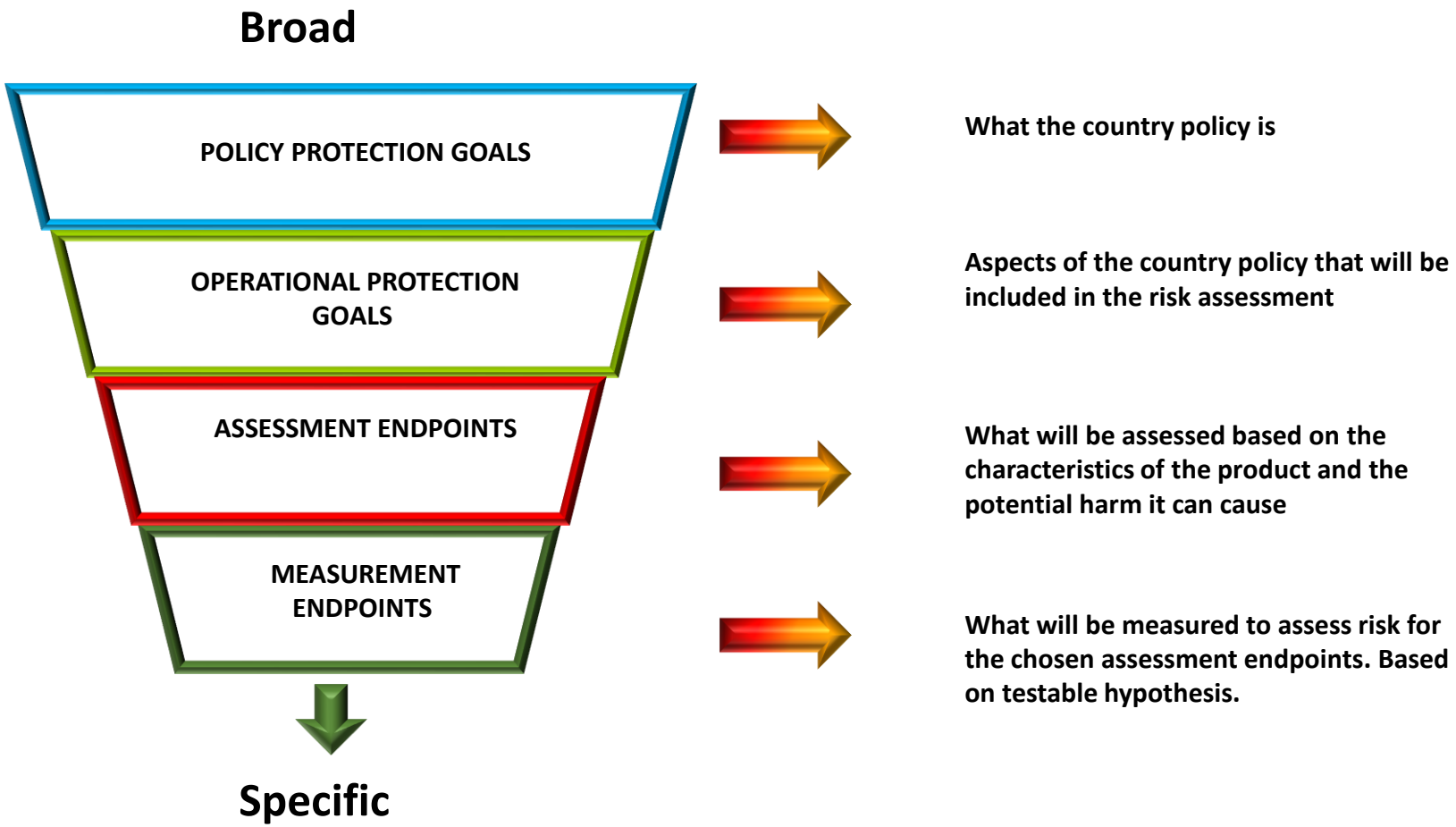

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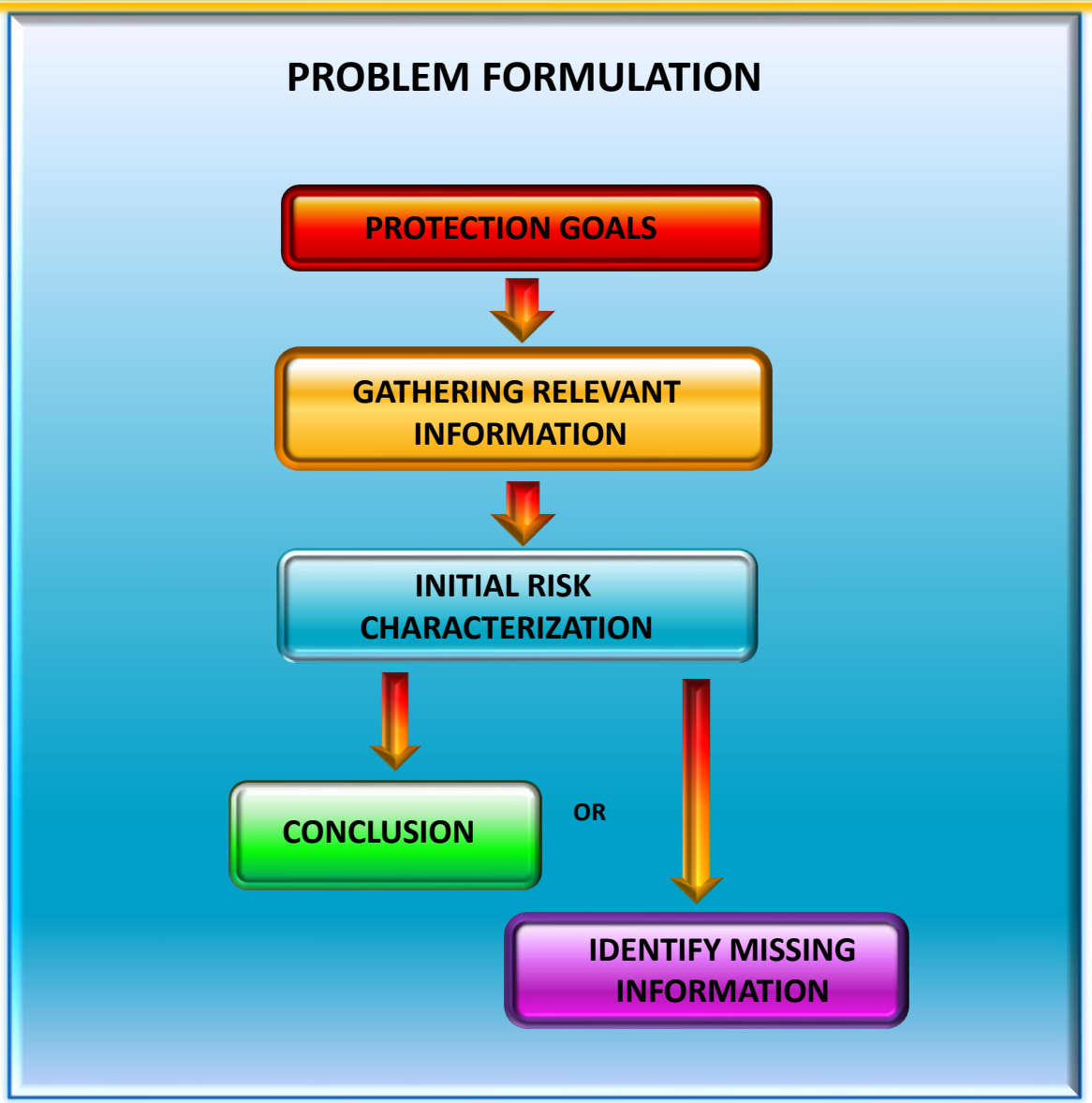

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GATHERING RELEVANT INFORMATION:

- Collection of information relevant to the hypotheses formulated that may help prove or disprove the hypotheses
- There are different sources of these sort of information
  - From studies conducted within the regulatory package
    - e.g. Ecotox studies
  - Relevant peer reviewed publications
    - e.g. information related to the compounds or class of compounds
  - Previous risk assessments
    - e.g. risk assessment conducted in other countries

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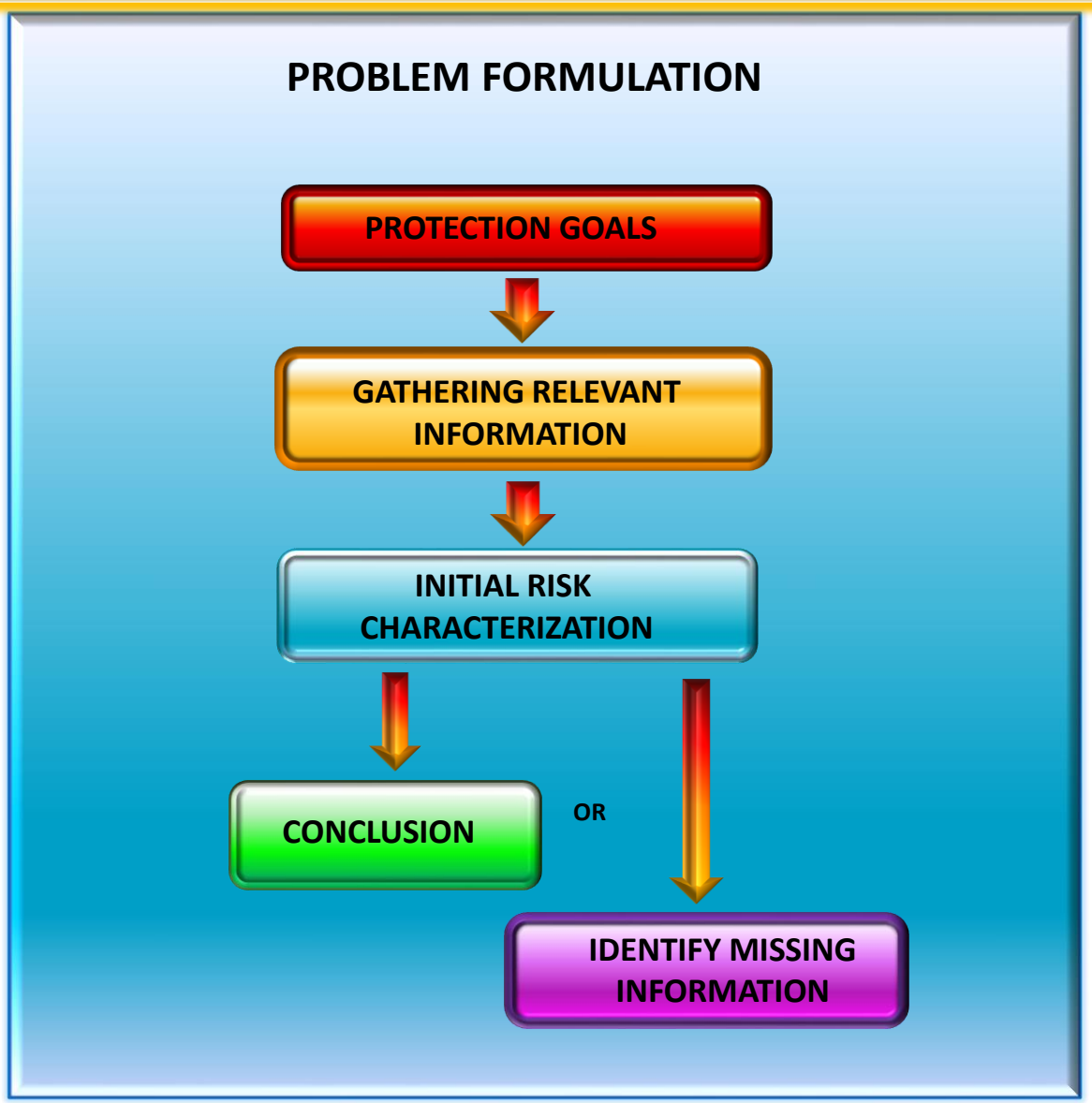

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INITIAL RISK CHARACTERIZATION

Risk = f (Hazard, Exposure)

If there is no exposure or the hazard is very low (no toxicity found), the risk can be considered low

If the exposure levels are not known or the level of hazard is not known

Risk Conclusion: The risk is low

Need more information to make a risk conclusion

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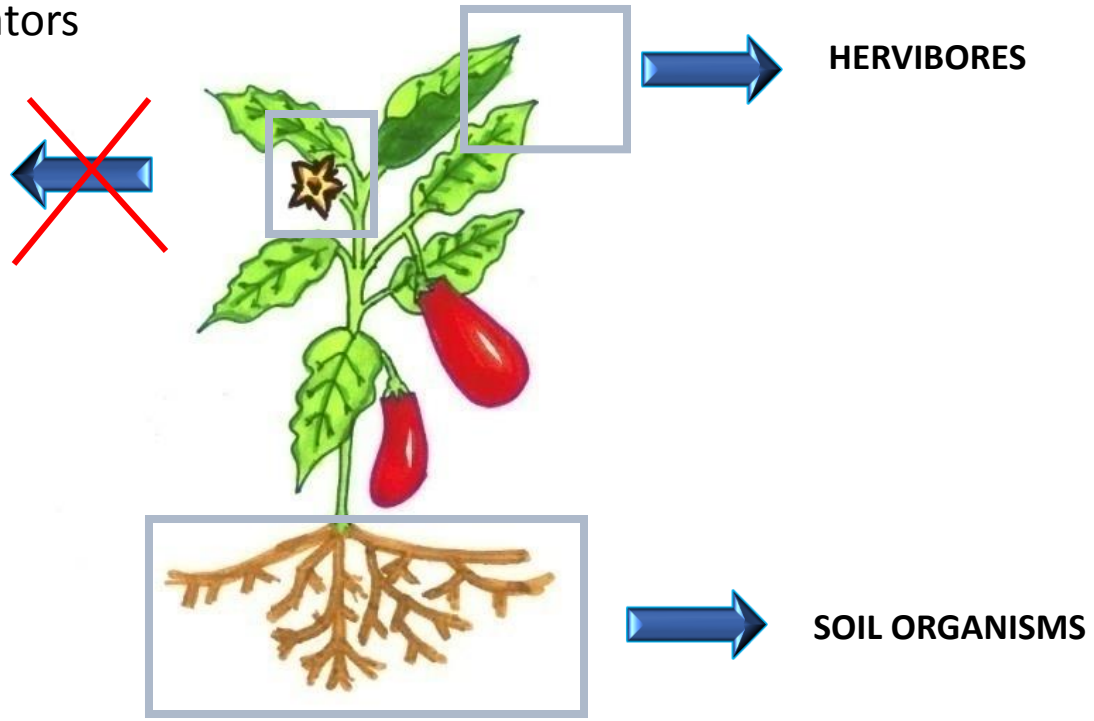
Example:

No protein expressed in pollen,
low risk to pollinators



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QUALITATIVE RISK MEASURES

- When the risk can not be quantified, qualitative measures can be used.

			RISK ESTIMATE			
EXPOSURE	LIKELIHOOD ASSESSMENT	Highly likely	Low	Moderate	High	High
		Likely	Low	Low	Moderate	High
		Unlikely	Negligible	Low	Moderate	Moderate
		Highly unlikely	Negligible	Negligible	Low	Moderate
			Marginal	Minor	Intermediate	Major
			CONSEQUENCE ASSESSMENT			

HAZARD

http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/content/raf-3/$FILE/raffinal4.pdf
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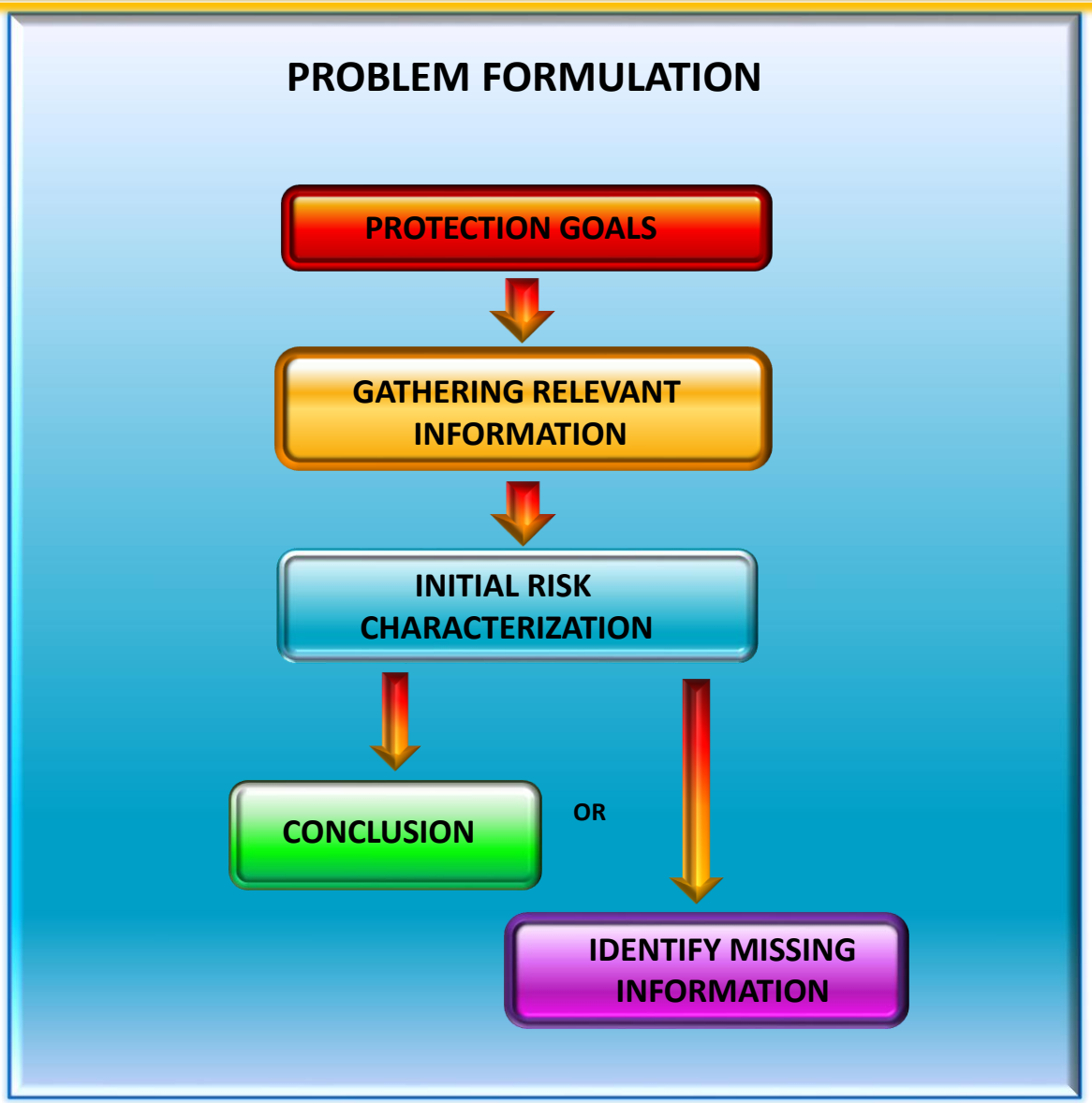

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Identifying missing information

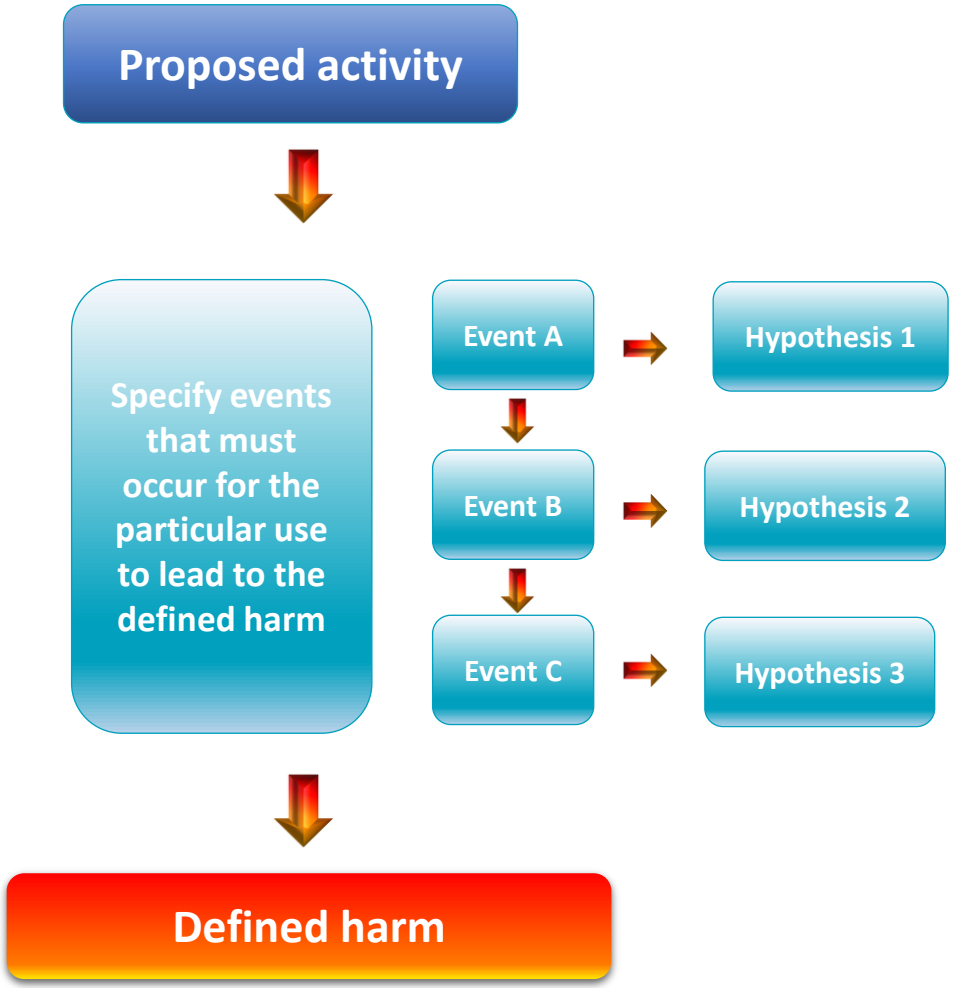
- If the initial risk characterization can not be completed more data may be needed
  - Characterization of hazard
  - Characterization of exposure
- The data must be relevant to the assessment endpoints and risk hypotheses formulated

The purpose always is to collect data that facilitates

decision making

("need to know" versus "nice to know")

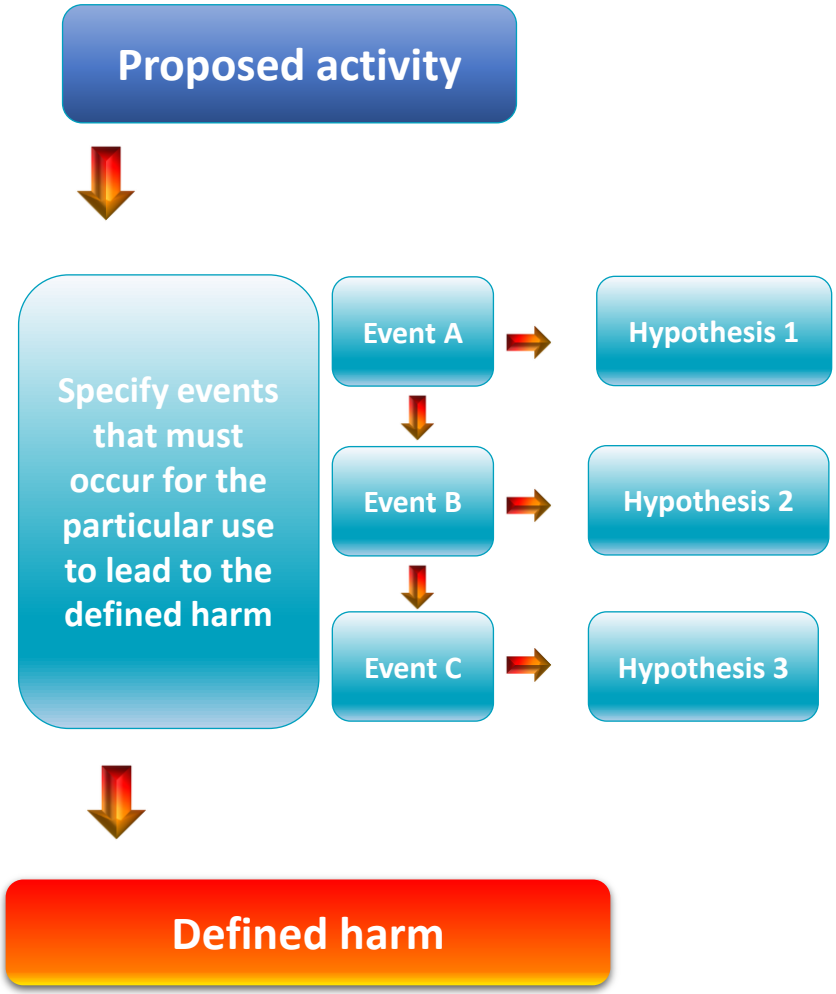
Implementation: Pathways to Harm

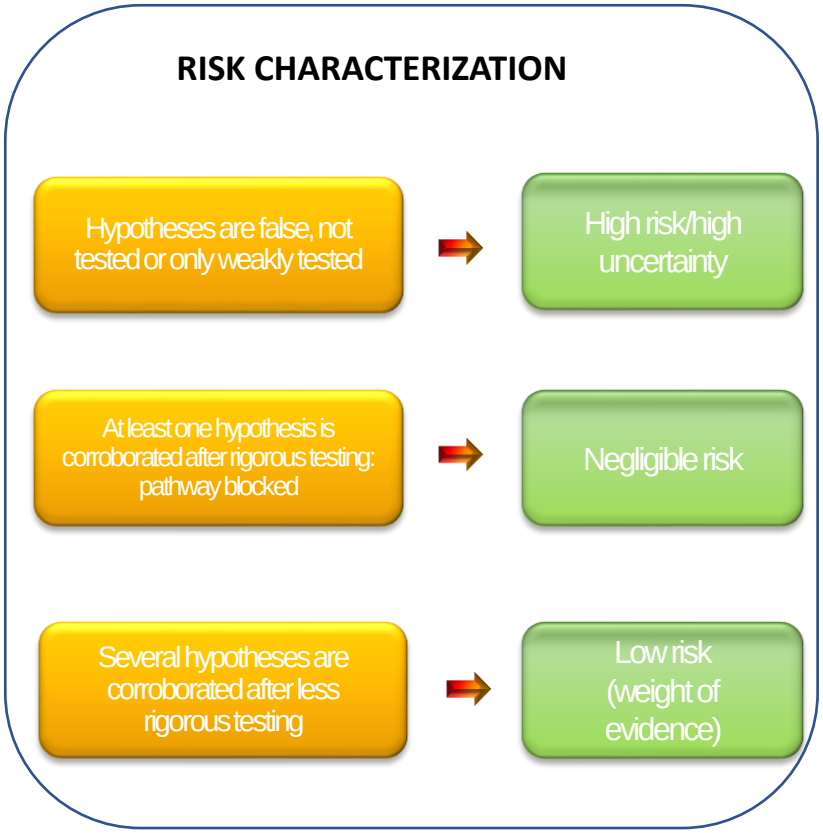


Choice of hypothesis depends on definition of harm & decision-making criteria

Slide based on material provided by Dr. A. Raybould

Implementation: Pathways to Harm

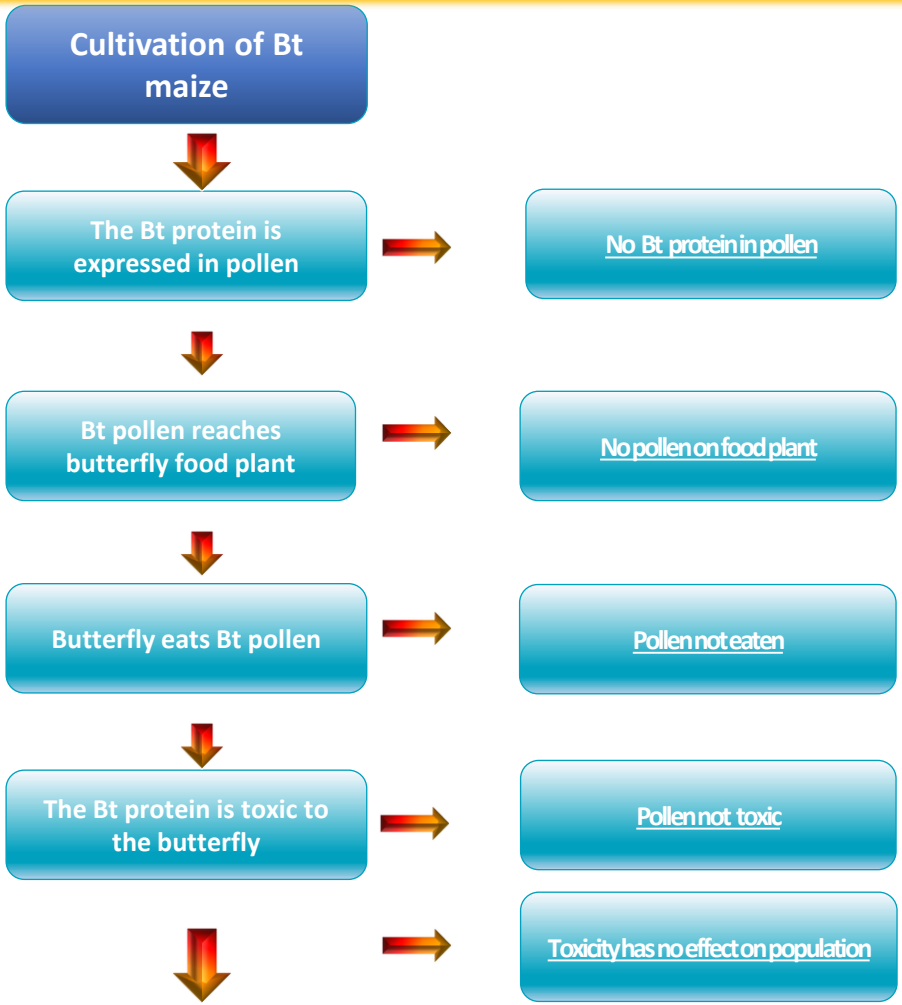




Slide based on material provided by Dr. A. Raybould

Pathways to Harm

Example: assessing the potential population decline of a valued species of butterfly due to the cultivation of Bt maize



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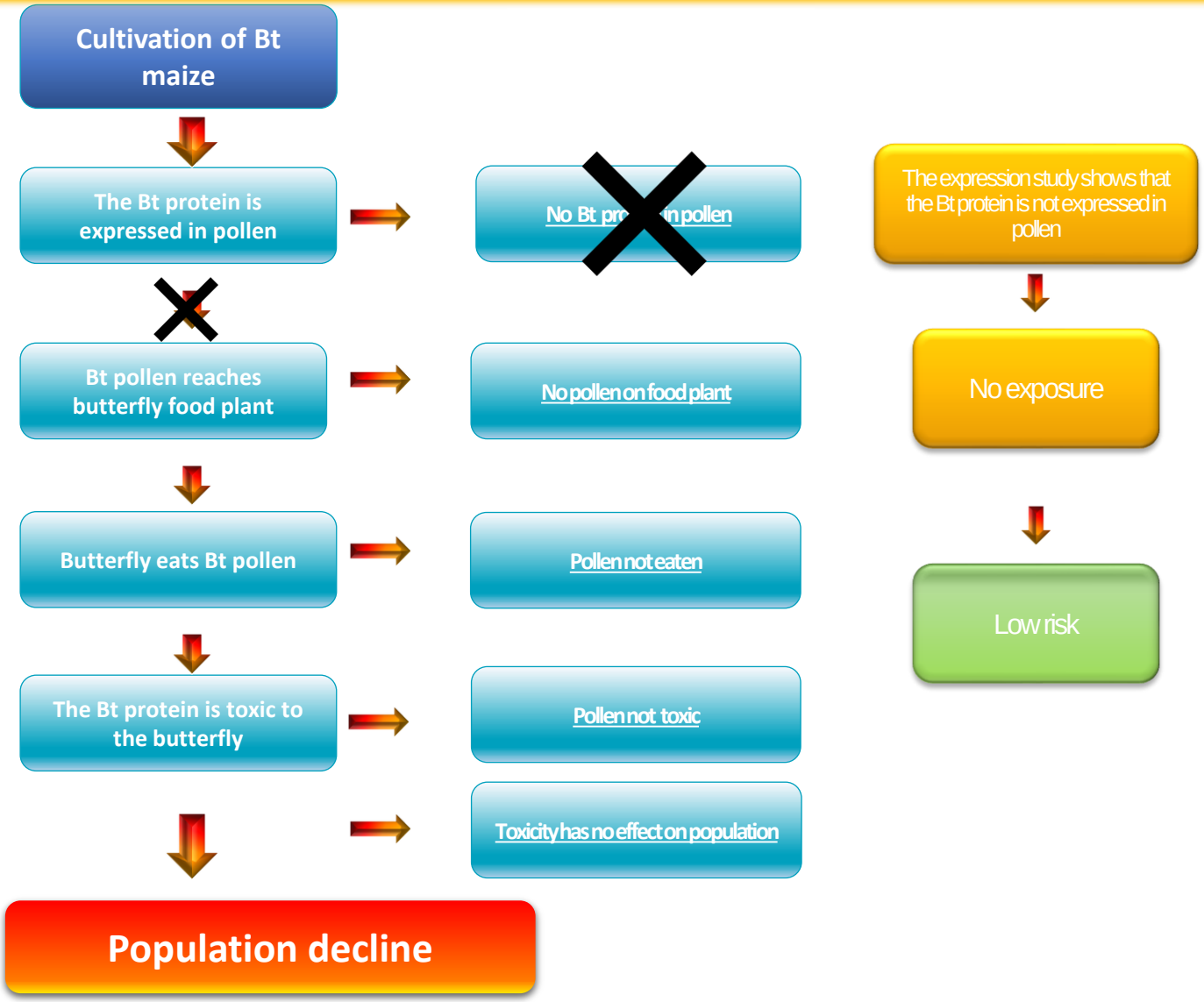

Pathways to Harm

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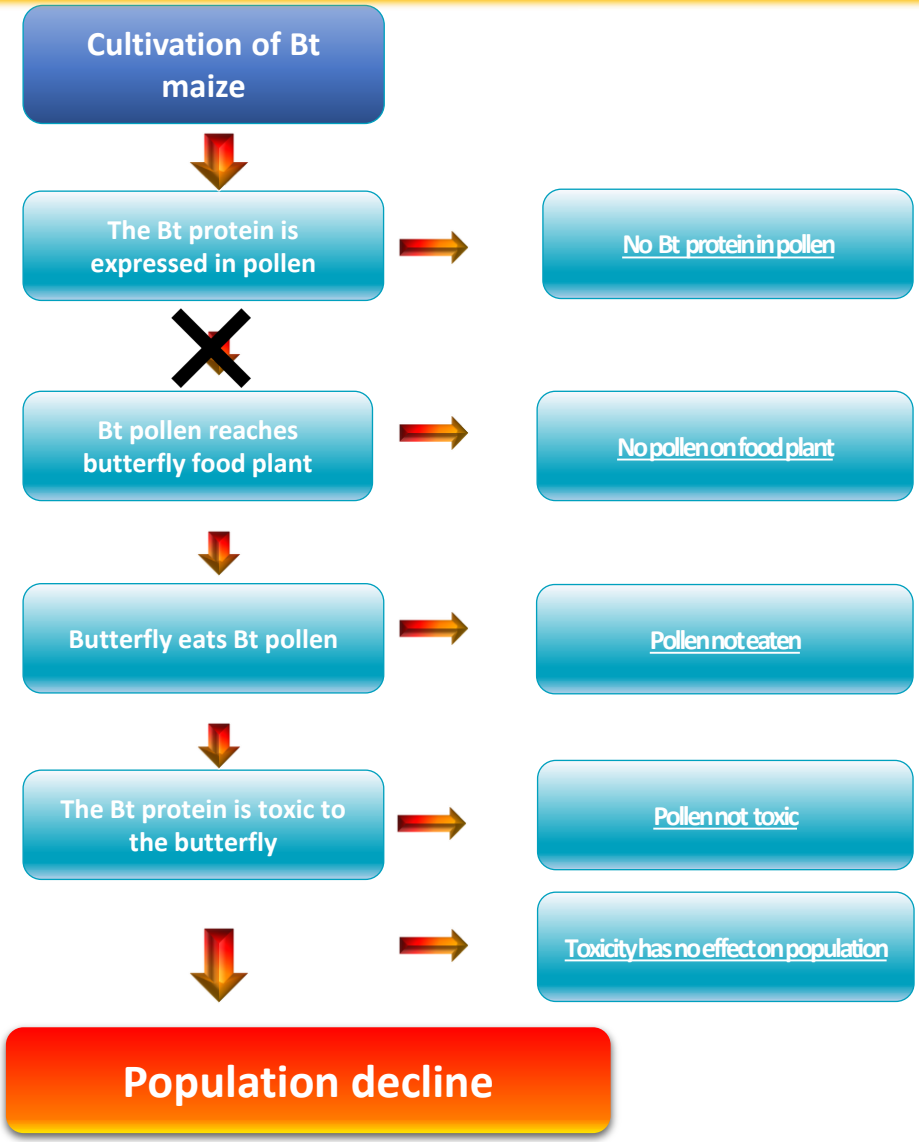
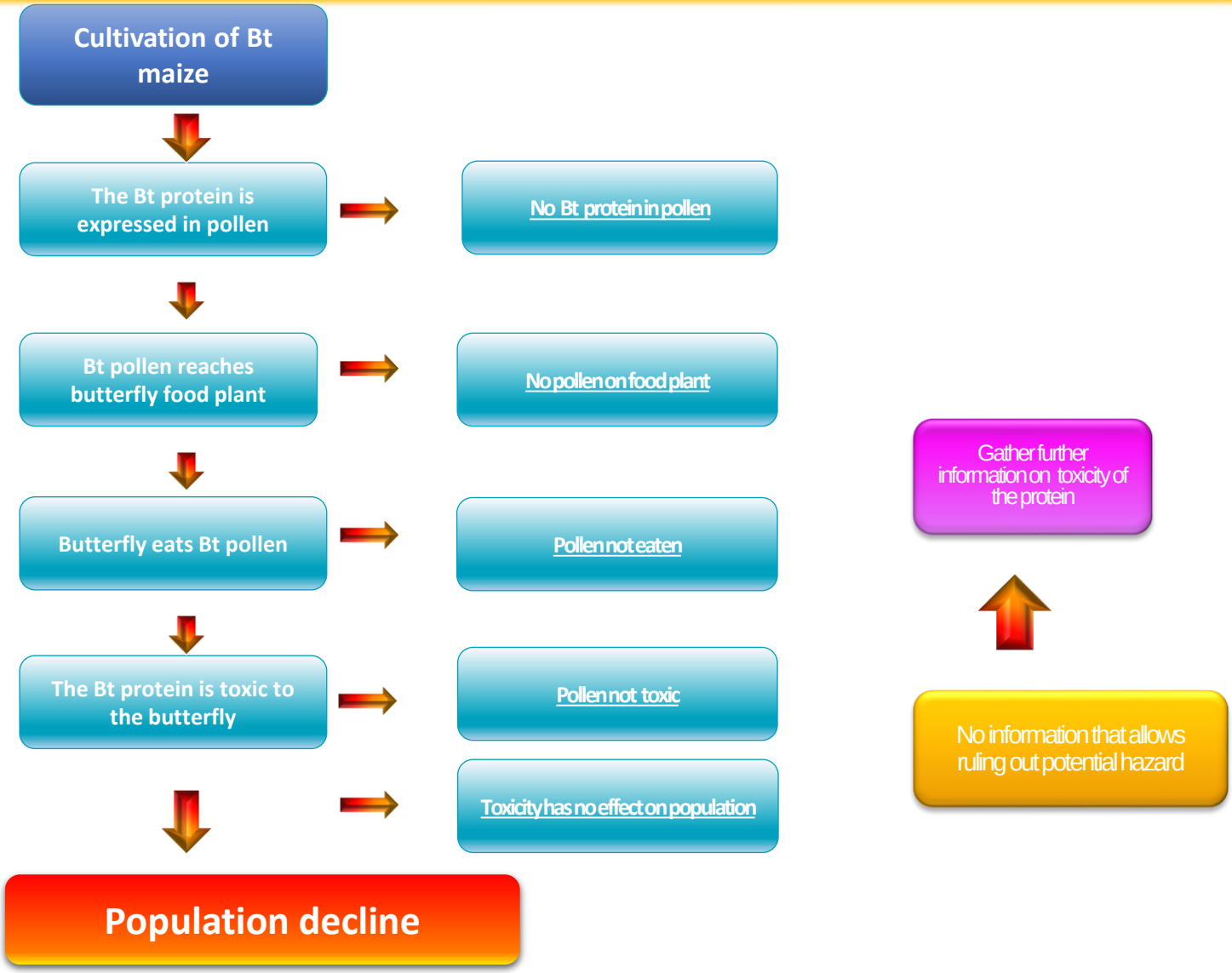


Once the path is blocked a risk conclusion can be made

Testing all the hypothesis is not always useful/necessary

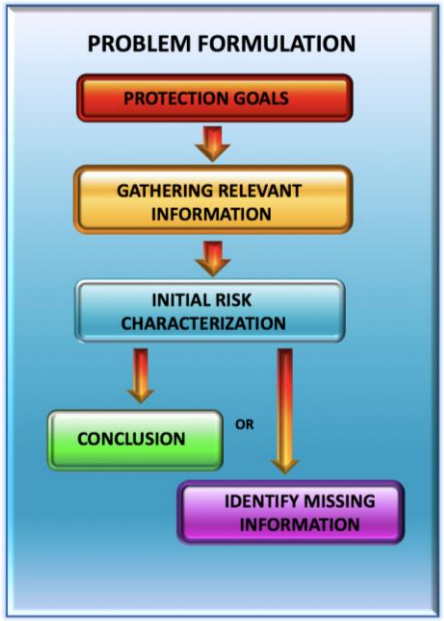
Pathways to Harm

Example: assessing the potential population decline of a valued species of butterfly due to the cultivation of Bt maize



Problem formulation

- **Protection goals:** clear definition of what is being assessed and what is regarded as harmful
- **Gathering relevant data:** data relevant to the assessment endpoints and risk hypotheses
- **Initial risk characterization:** a pathway to harm can be used
- **Conclusion:** can be reached when pathways are clearly blocked
- **Identifying missing information:** when a pathway can not be blocked with existing information, a clear plan for collection of key data can be drawn



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Summary

- ERAs are conducted to **facilitate decision making**, they must be **fit-for-purpose.**
- Problem formulation provides a useful method for ERAs that can be applied to any kind of stressor.
- Problem formulation can be implemented using pathways to harm
  - Taking into account relevant protection goals to define the specific harms
  - Formulating hypotheses to test the events that constitute the pathway
  - Making risk conclusions with existing information, or
  - Identifying information that must be gathered to continue the assessment

Thank you for your attention!