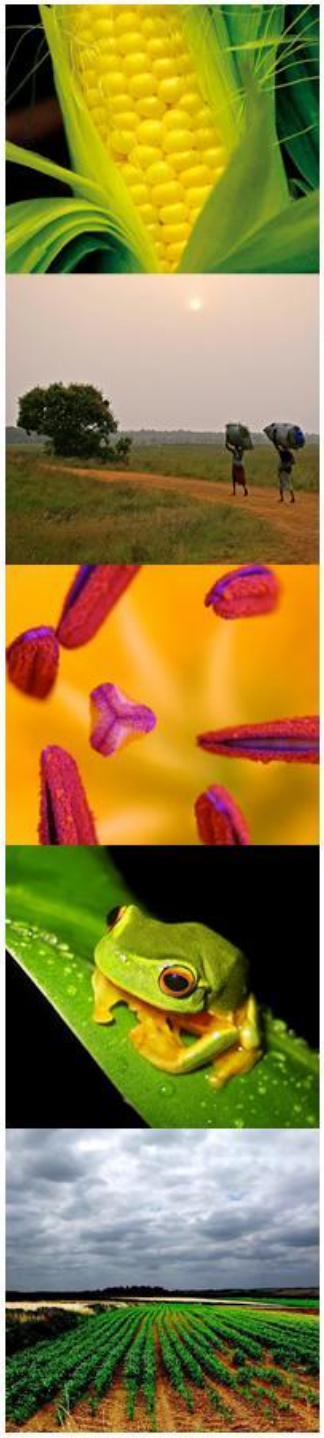

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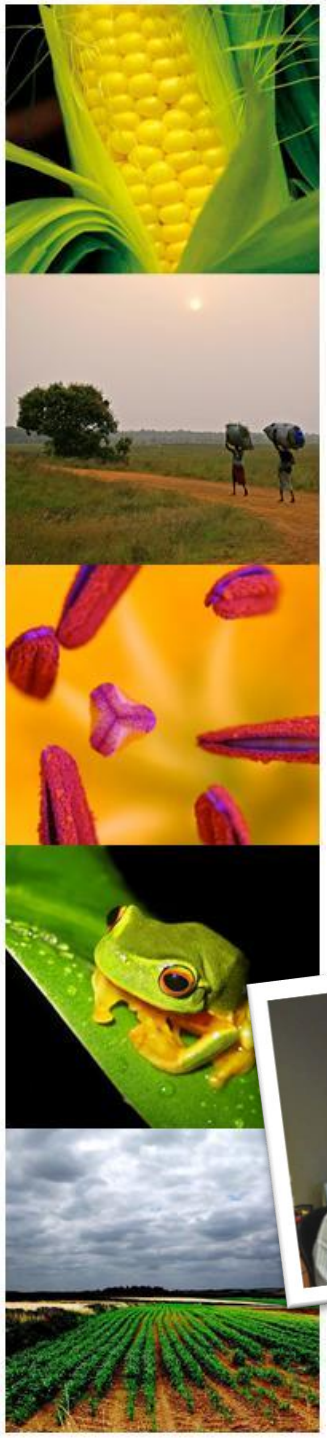
GMO RISK ANALYSIS SHORT COURSE

University of Pretoria, 4 September 2019

science & innovation
Department:
Science and Innovation
REPUBLIC OF SOUTH AFRICA

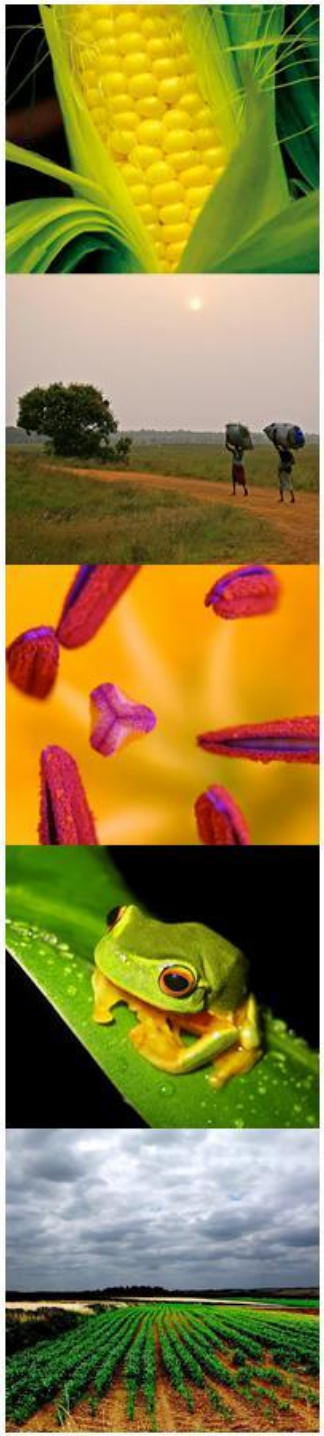
technology innovation AGENCY



Introduction to Environmental Risk Analysis of GMOs

James Rhodes, MSc

Biosafety South Africa, james@biosafety.org.za



OVERVIEW

- Risk Analysis Background
- Risk Analysis Framework
- Decision making
- Conclusions

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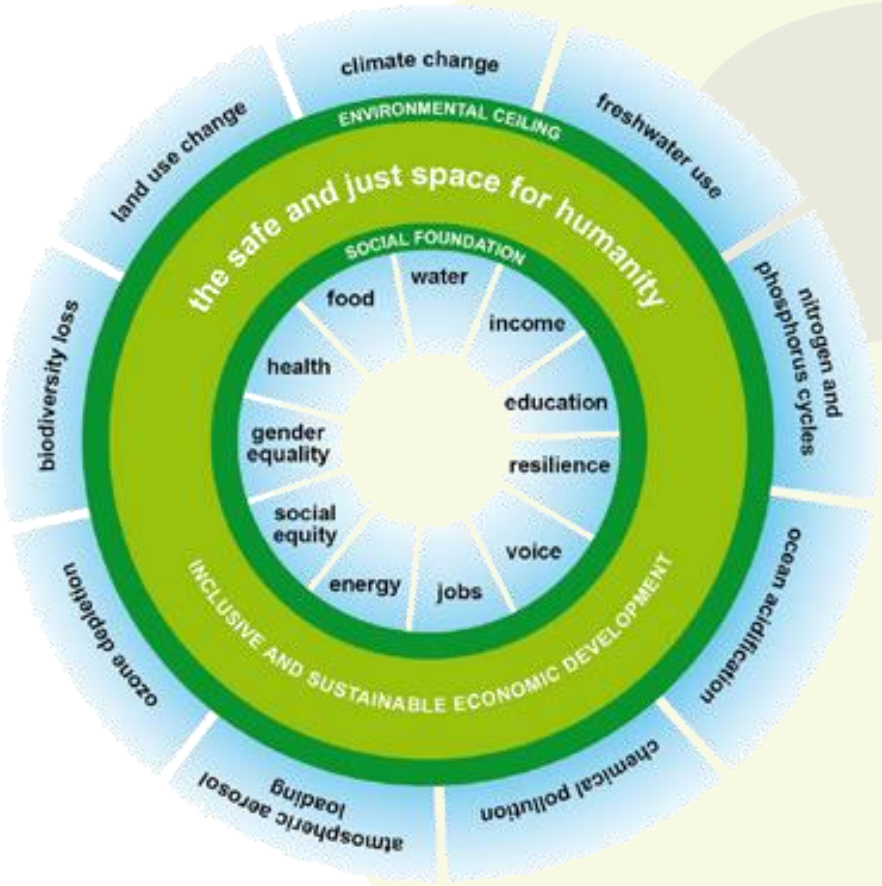
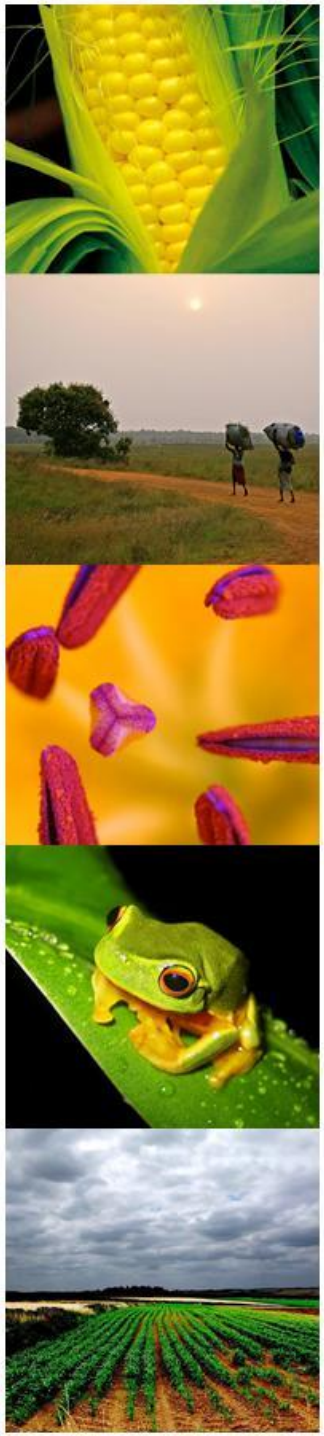
DEFINING SUSTAINABILITY



- The social foundation consists of the eleven top social priorities identified by the world's governments
- Between social and planetary boundaries lies an environmentally safe and socially just space in which humanity can thrive.

Kate Raworth, Oxfam 2012



RISK ANALYSIS OF GMOs- BACKGROUND

Harm - is an adverse outcome or impact.

Hazard - is any potential source of harm (the possibility to cause harm).

Risk - is the probability of a harm occurring under defined circumstances.

Safety - is the condition of not being exposed to or being protected from harm; not likely to be harmed.

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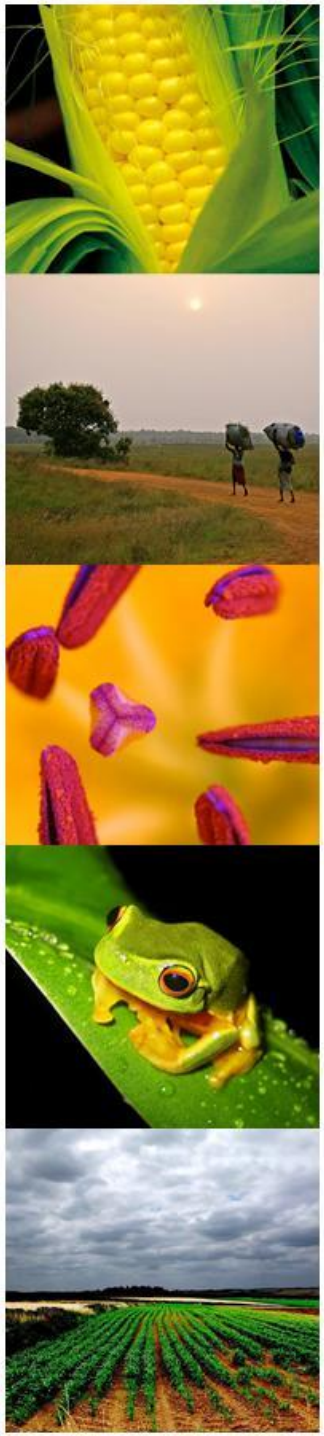

RISK ANALYSIS OF GMOs- BACKGROUND

- Risk analysis frameworks has gone through considerable development from when regulators and scientists first started characterising risks from GMOs

This process is:

- contextualised
- science based performed on a case by case basis
- iterative
- comparative

and take into consideration

- the nature of the introduced sequences (the trait)
- the characteristics of the organism
- the receiving environment

and interactions between these

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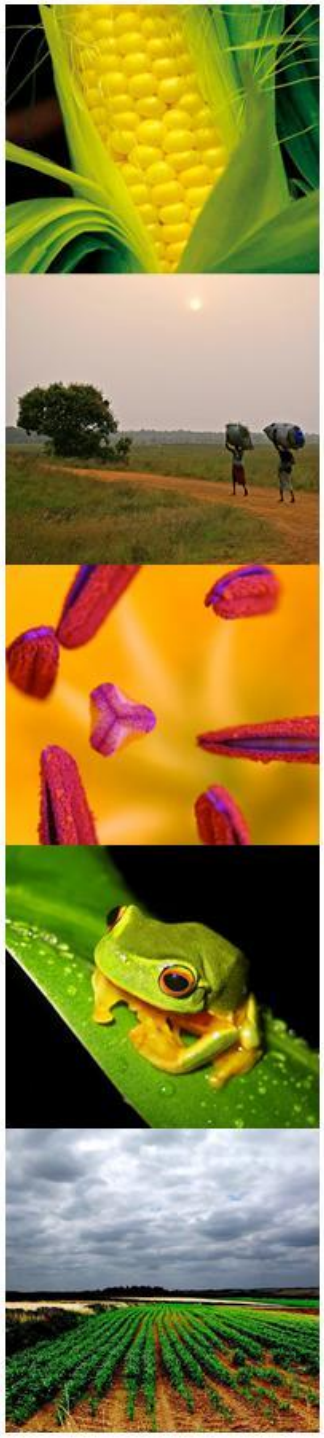

ENSURING SUSTAINABILITY

GOAL

SUSTAINABLE

Environment

Health

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TOOL

RISK ANALYSIS

Setting the context & scope

Risk management

Risk assessment

Risk communication

viability

Socio-political

Economic

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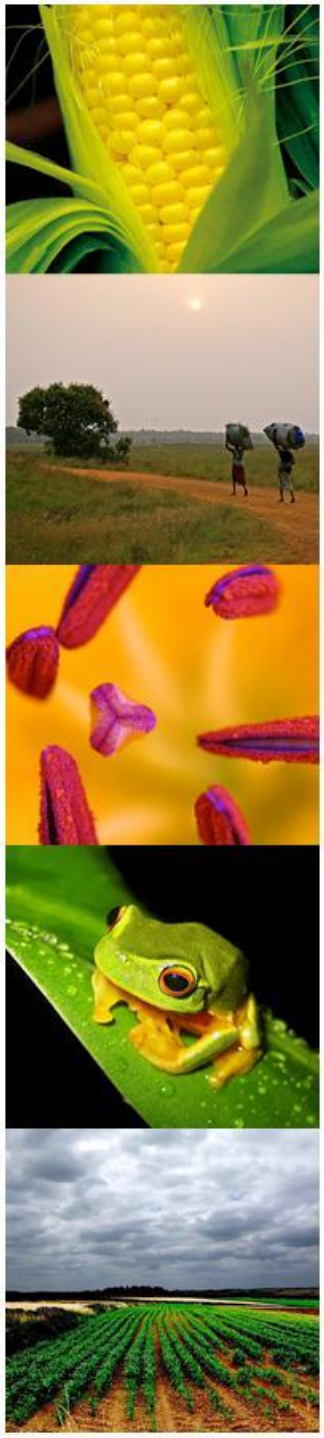
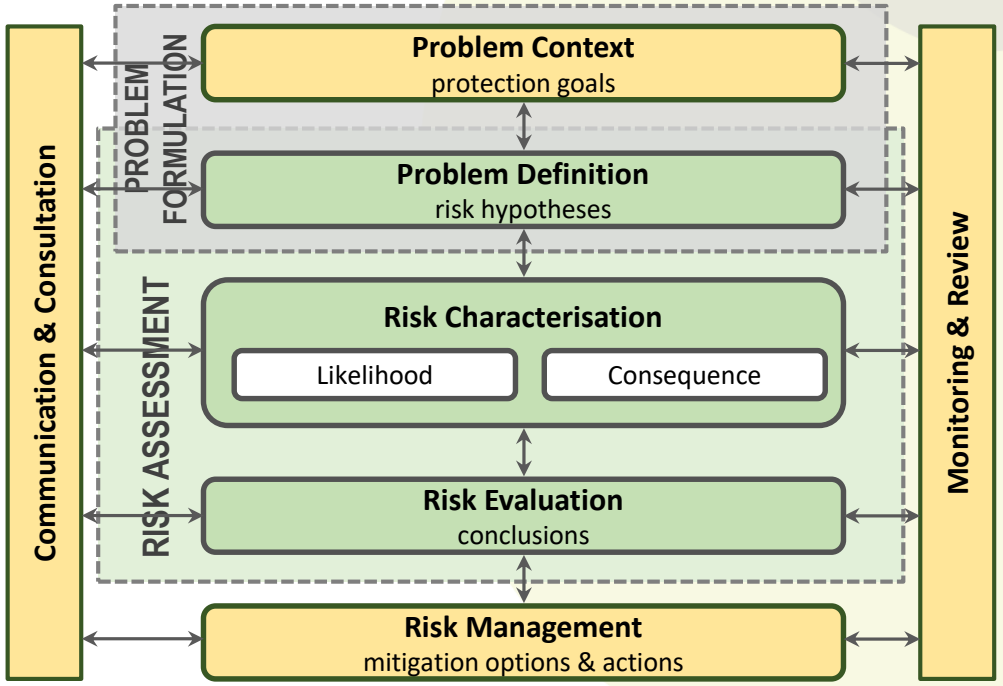


ENSURING SUSTAINABILITY



Society

Science

Adapted from Wolt *et al*. 2010. Transgenic Research 19: 425-436 & *Johnson et al. 2007. Trends in Plant Science 12(1): 1-5.*

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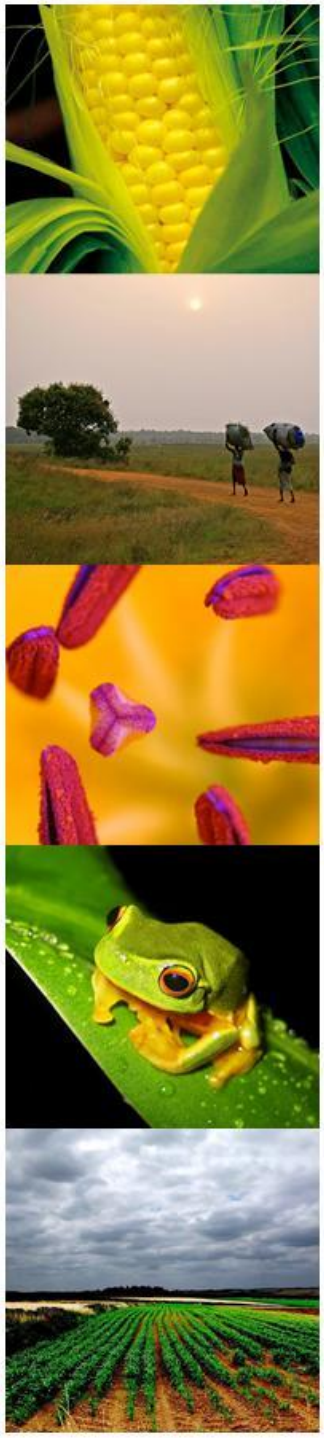
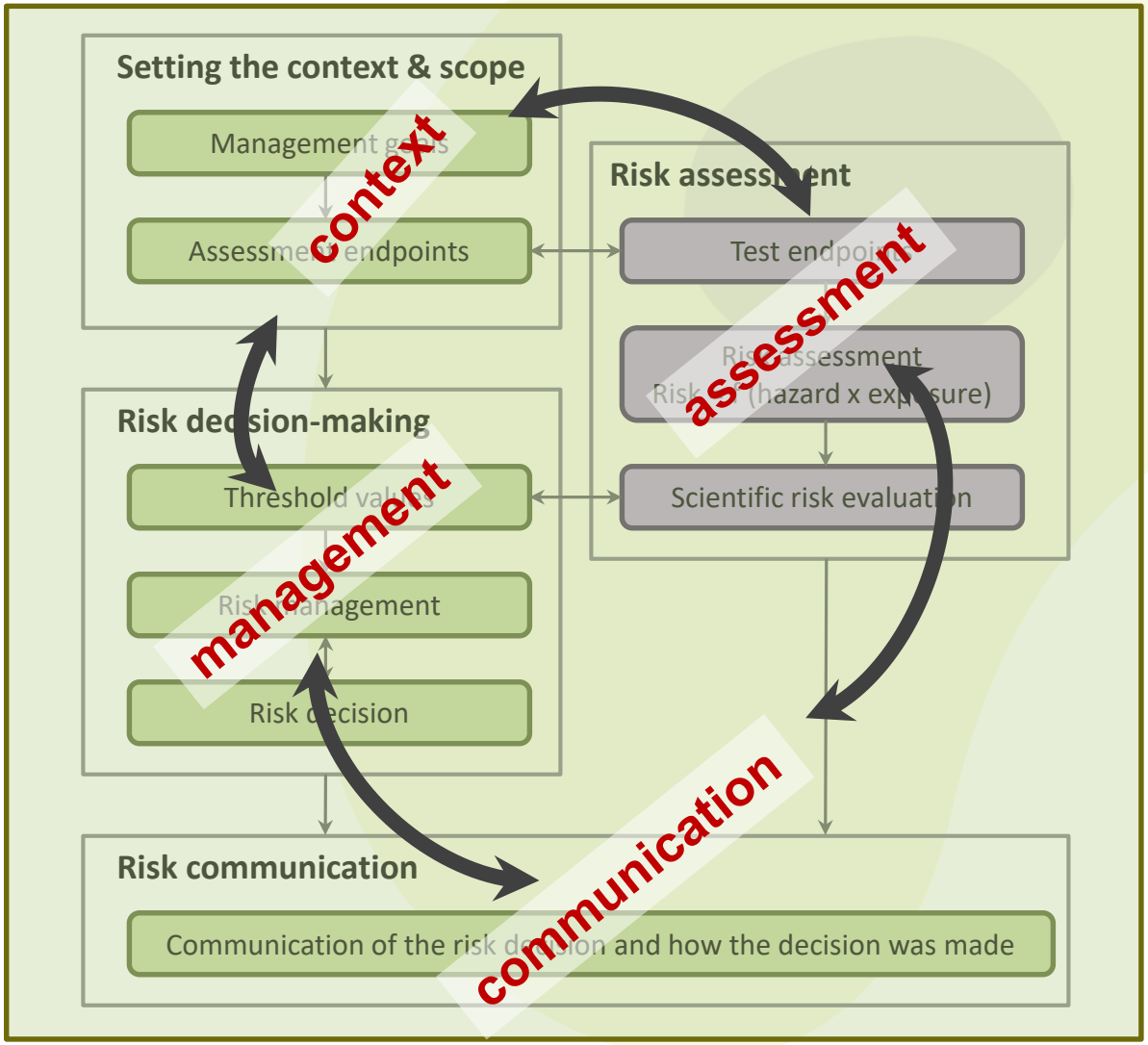


A FRAMEWORK FOR RISK ANALYSIS

Adapted from Johnson et al. 2007. Trends in Plant Science 12(1): 1-5.



Stages of risk analysis:

Key issue identification, **risk assessment**, **risk decision-making** and **risk communication**.

Progression through the system is not linear, but iterative

Green boxes - driven by society

Purple boxes - driven by science

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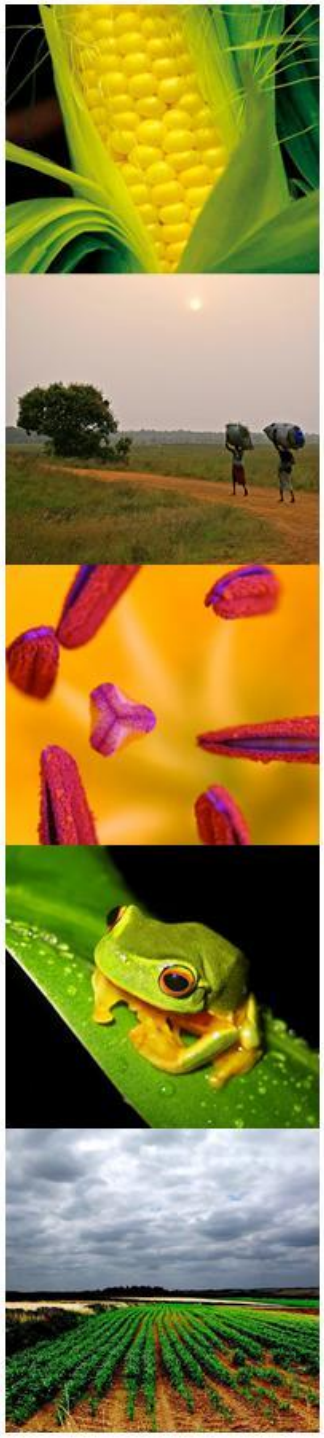

RISK ANALYSIS OF GMOs: SETTING THE CONTEXT

- What needs protecting?
- Harms can then be identified
  - A harm would be detected if there is an adverse change
- Risk assessment then tests whether these harms will occur
  - e.g. will cultivation have an adverse effect on the population size of a chosen species of importance

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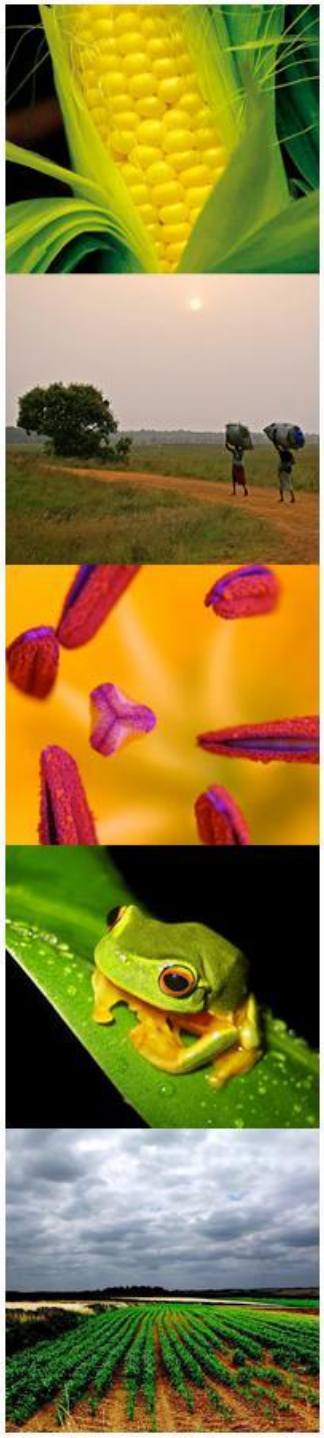

RISK ANALYSIS OF GMOs: SETTING THE CONTEXT

- The comparative approach is used i.e.
  - conventional agriculture is the usual baseline from which to evaluate effects
  - do activities with this GM crop cause greater impact than the unmodified crop
  - can also be compared to other potential practices (push pull systems)

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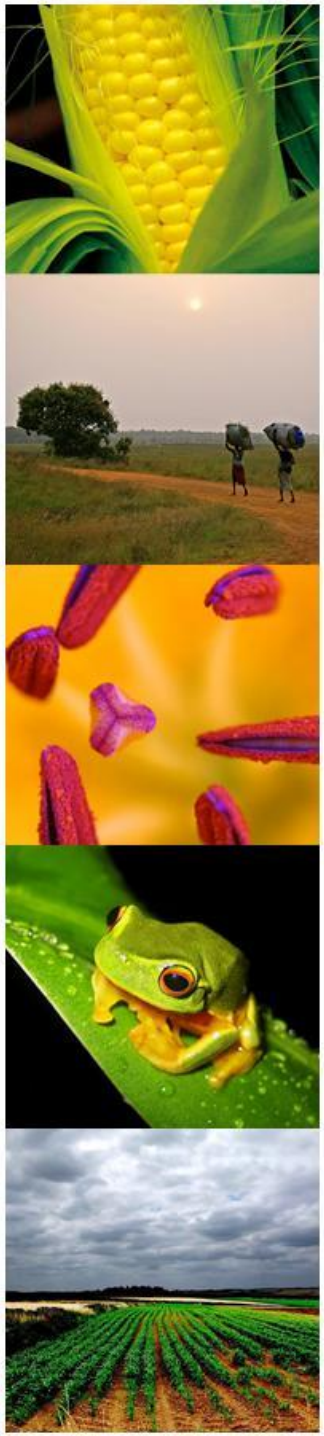

RISK ANALYSIS OF GMOs: RISK ASSESSMENT

- Risk assessment evaluates the likelihood and consequences to human health or the environment following exposure to a source of risk

THE WHAT CAN GO WRONG

Hazard Identification

HOW LIKELY **X** **WOULD IT BE A PROBLEM**

(Likelihood/ Exposure Assessment) **X** **(Consequences/ Hazard Assessment)**

=

WHAT IS THE RISK

Risk Characterisation

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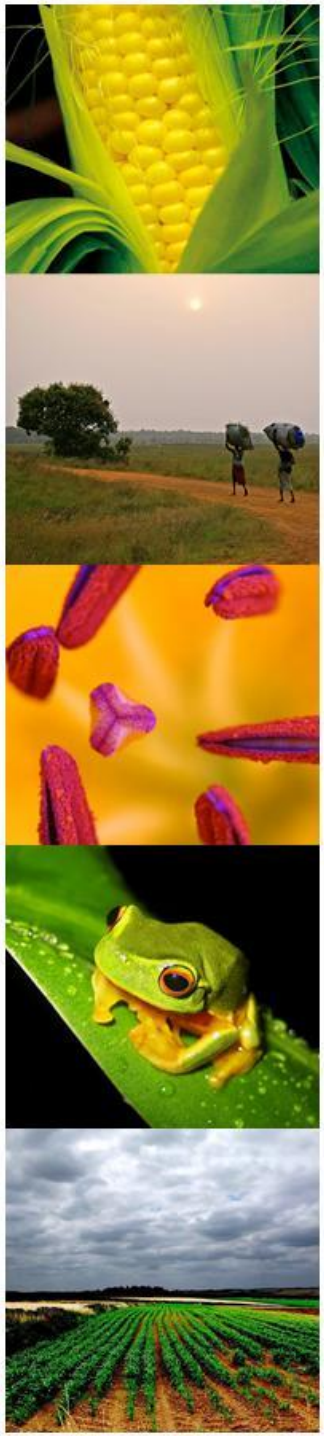

RISK ANALYSIS OF GMOs: RISK ASSESSMENT

- Data is not a substitute for policy and decision making criteria - harms cant be discovered
- Focus on the quantity of data during risk assessment
- Safety data vs. quality and efficacy data
- Much of this data are irrelevant for risk assessment and may obscure risk assessment
- This can delay approvals as it takes longer to review dossiers, this can:
  - delay or prevent the introduction of beneficial products
  - prevent or delay the phase out of harmful products

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RISK ASSESSMENT

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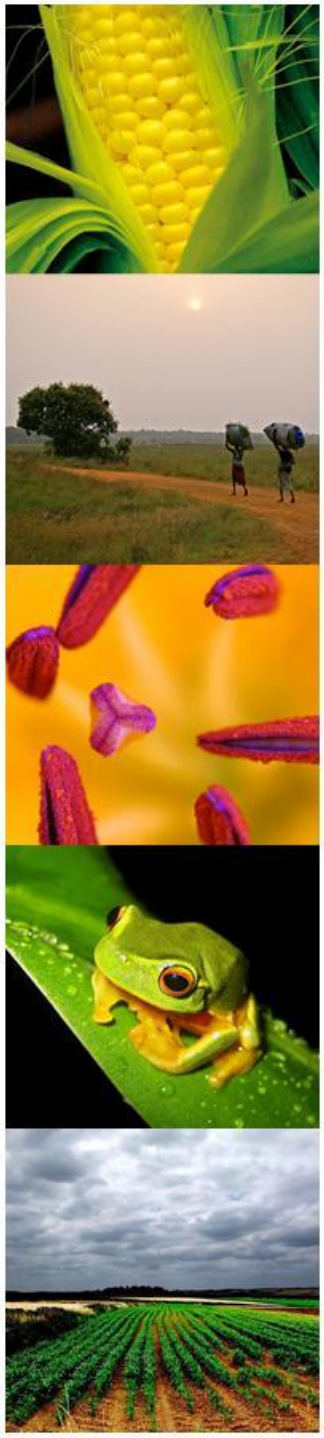

2. RISK ASSESSMENT: SCIENTIFIC RISK EVALUATION

- No such thing as zero risk
  - therefore we accept some level of uncertainty or risk
  - the question is "are the risks acceptable?"

		RISK ESTIMATE			
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			

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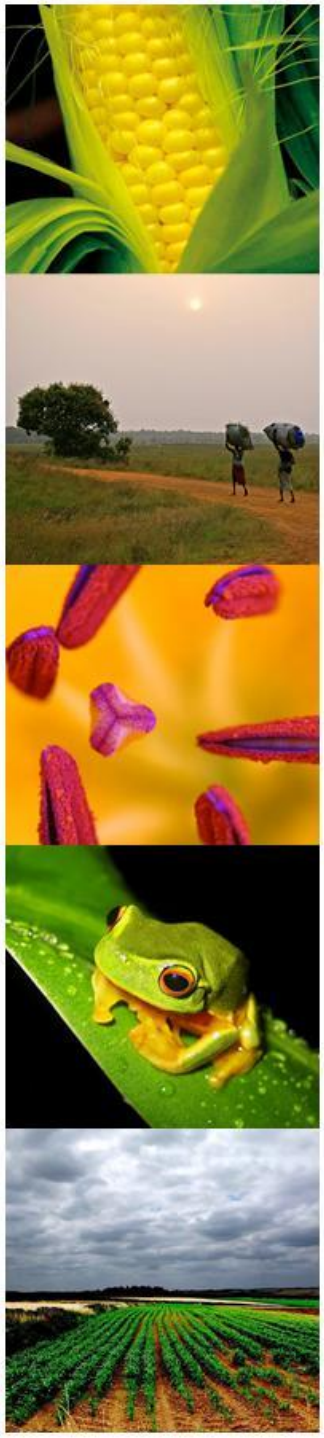

3. RISK DECISION MAKING: RISK MANAGEMENT

- Uncertainty is generally highest during early stage development of a GM crop.
  - the risks may not be fully characterised and are managed by reducing the likelihood of risks occurring
  - enables the generation of relevant biosafety data to reduce uncertainties/ characterise risks
  - this can result in changes in license conditions and feed into evaluations of the same or similar GMOs
- Risk management includes preparation of a risk management plan as well as monitoring and reviewing to provide feedbacks on the risk analysis

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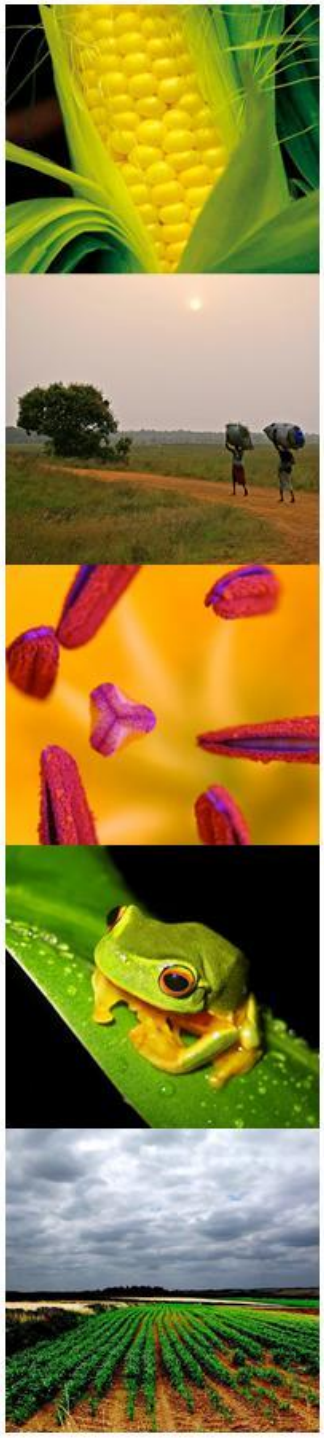

4. RISK COMMUNICATION

- Establishes a dialogue between decision makers and stakeholders to provide open, transparent and consultative risk based regulation of GMOs

- It is an important component of risk analysis

    - may include an explanation of the risk assessment findings and reasoning for any imposed risk management conditions

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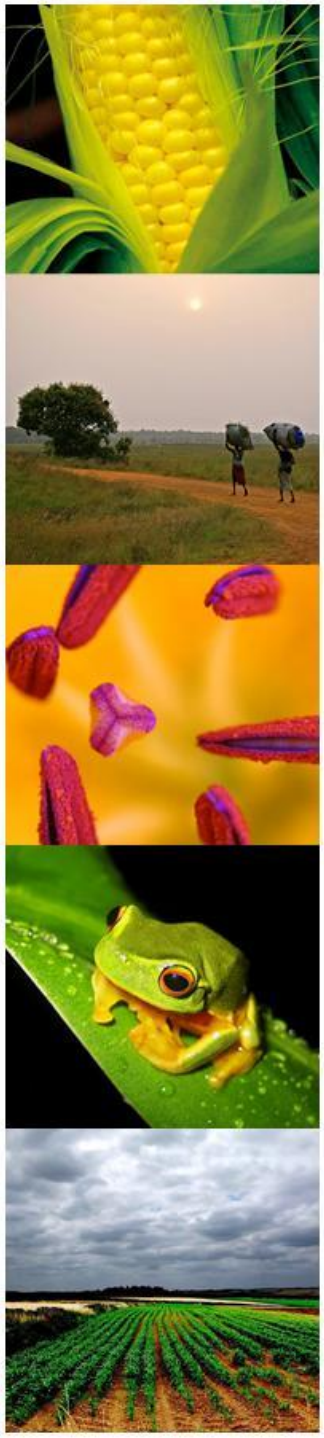

SUMMARY

- Risk analysis is a robust tool with which all decisions with activities associated with GMOs can be based

- Risk assessment and risk management activities are based on the context and scope of the in the first step of the risk analysis.

- Data is not a substitute for policy

  •decision making criteria (clear assessment endpoints must be determined- harms can't be discovered).

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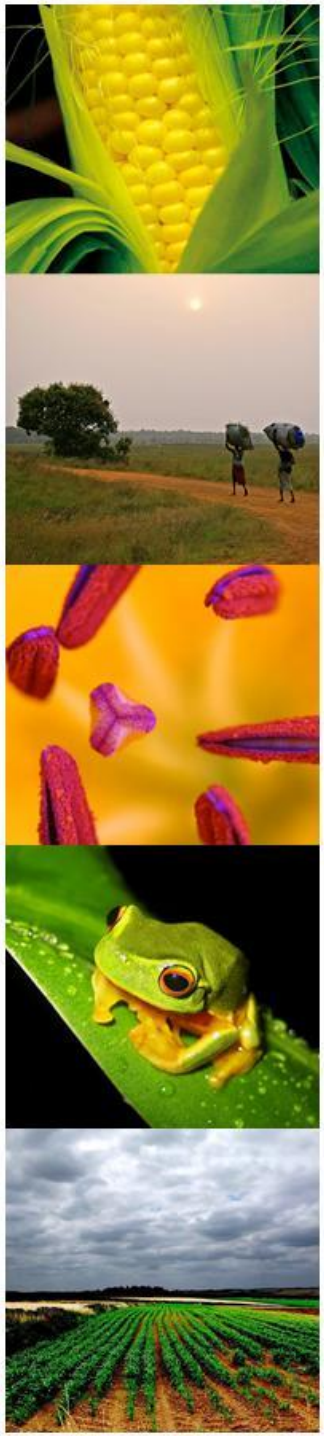

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Questions?

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