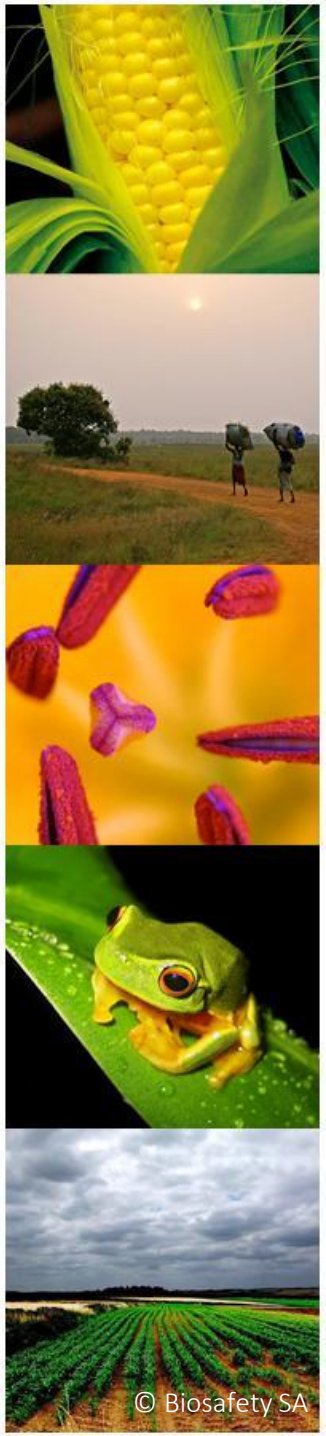


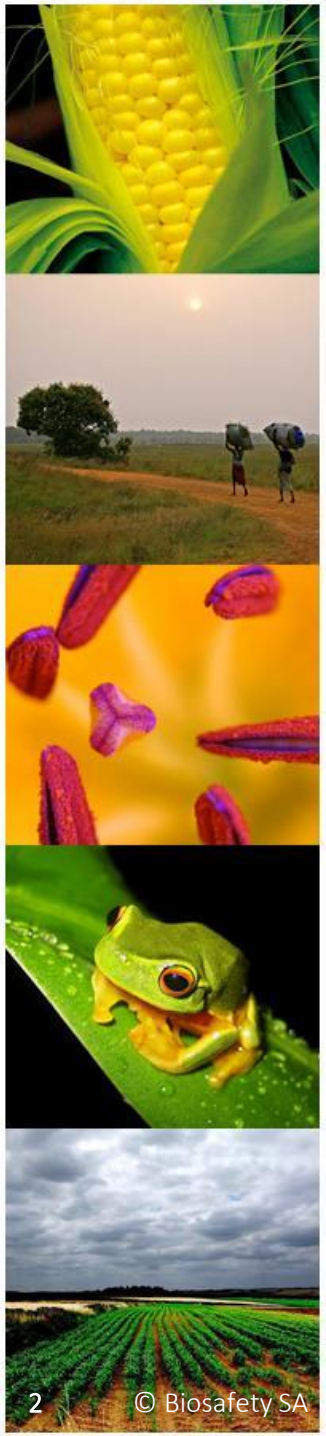
biosafety
SOUTH AFRICA

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 & Context

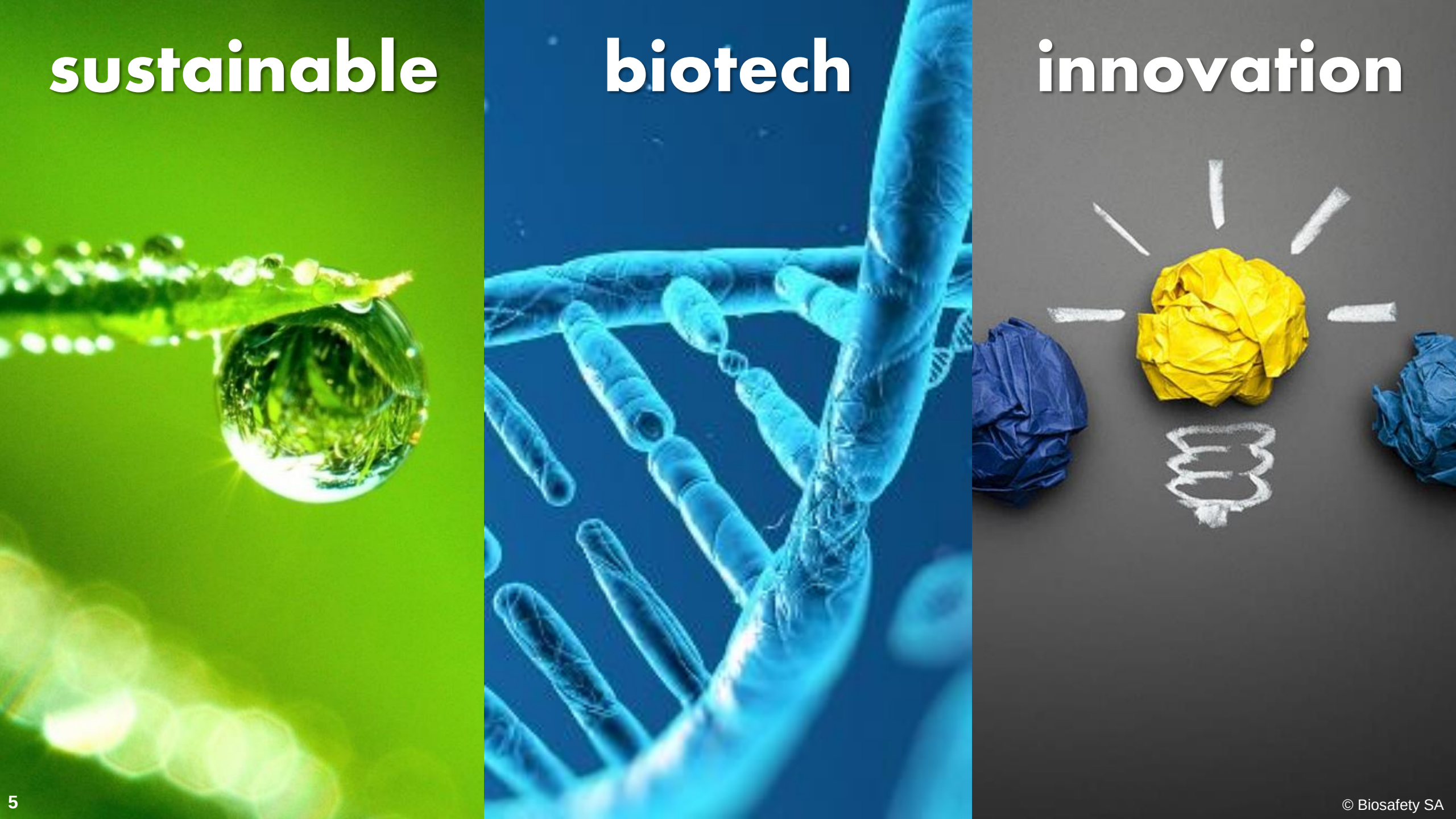
Hennie Groenewald, PhD

Biosafety South Africa, hennie@biosafety.org.za

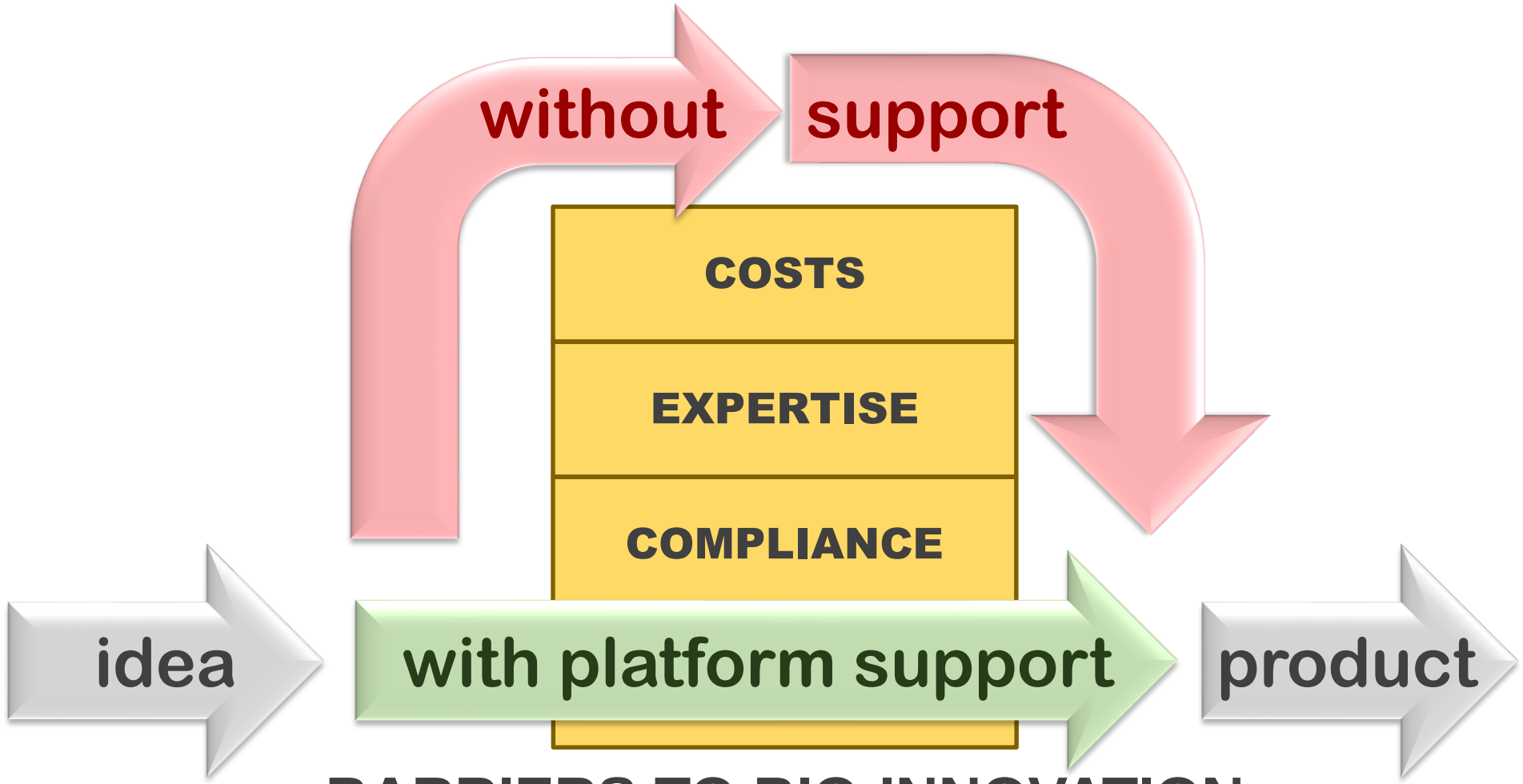
OVERVIEW

- Biosafety South Africa
- The workshop
- GMOs & why they are regulated
- SA's GMO policy & regulatory environment
- Risk analysis for sound decision making
- GMO risk in context
- Sustainable biotech innovation

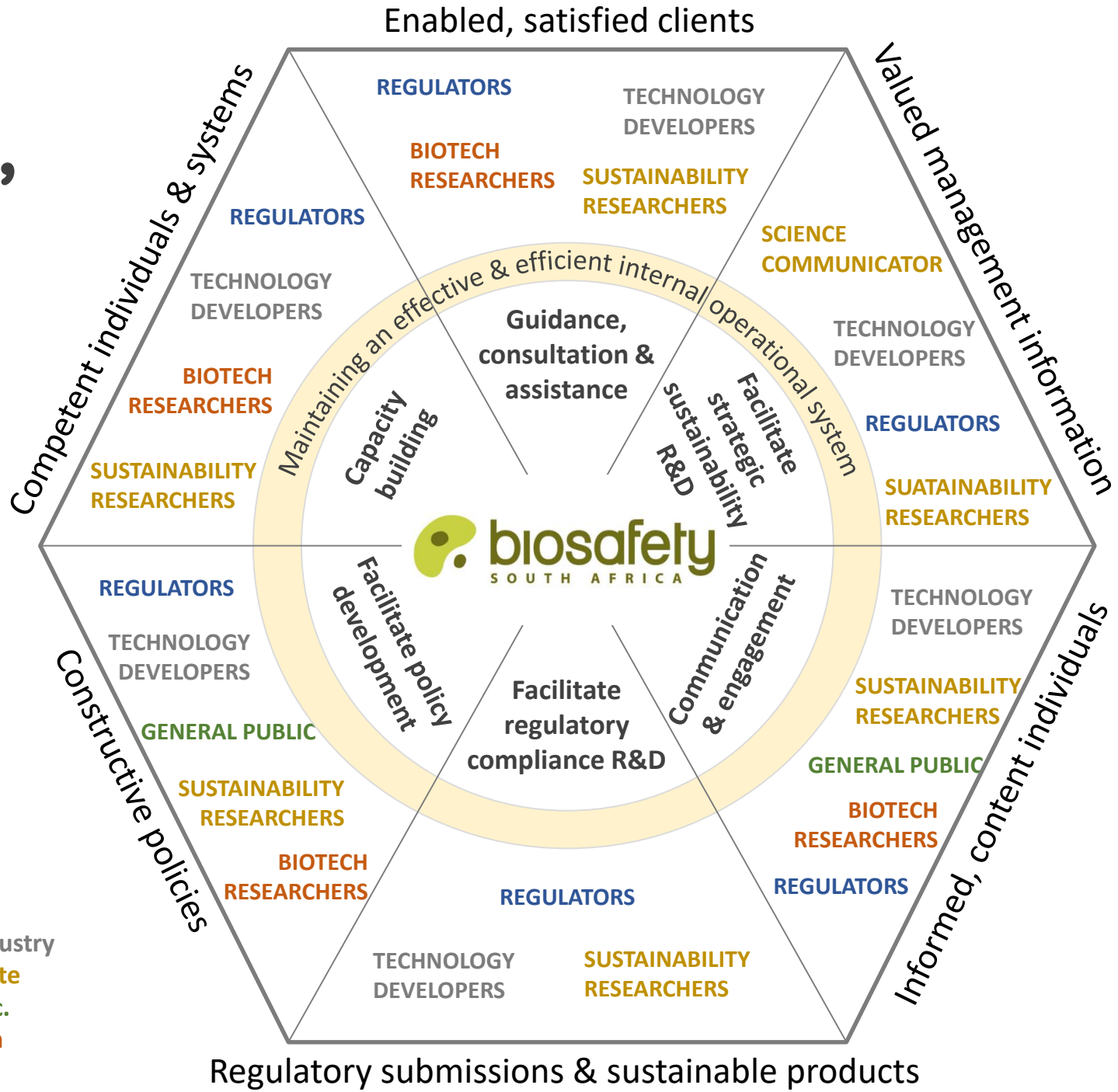
Biosafety South Africa



National platforms reduce barriers to bio-innovation



Biosafety SA service offering, stakeholders & objectives



Government & academia
Universities, science councils & industry
Academia, science councils & private
Target audiences, media, NGOs, etc.
Biotech - agriculture, food & health

biosafety SOUTH AFRICA

ABC the basics | dig deeper | about us | search | contact | MENU

www.biosafety.org.za

Supporting innovation in biotechnology by ensuring the development of safe, sustainable biotech products.

KNOW THE BASICS

This section is aimed at the person who has heard a lot about biosafety, biotechnology and GMOs but doesn't quite understand what all the fuss is about. Here you will find the basics, not only about the science and technology behind these products, but also how they are regulated in South Africa to ensure their safety and sustainability.

read more

ABC

DIG DEEPER

This section covers the more technical aspects of biosa
sustainability research, development, practice and regulation and is
aimed at researchers, technology developers,
other stakeholders directly engaged with bios

TALK TO US

Found what you were looking for?

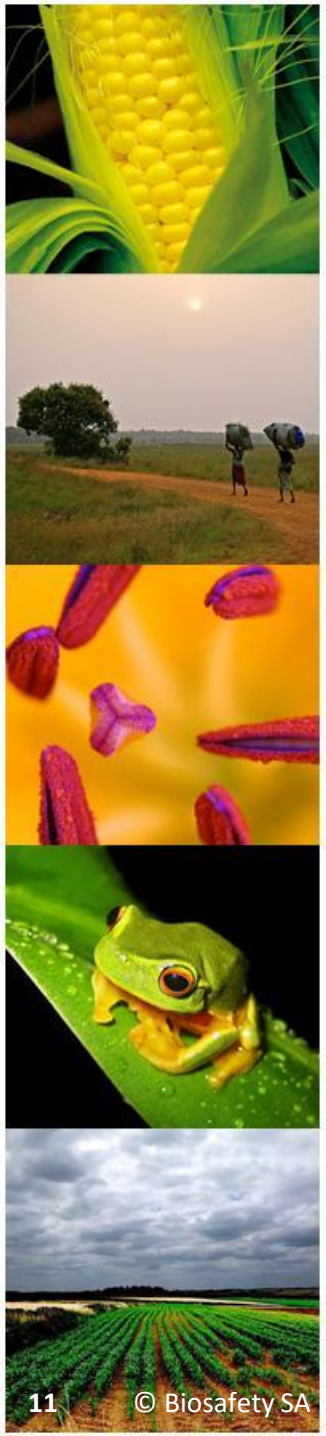
The workshop

WORKSHOP OBJECTIVES

1. Understand risk analysis theory to be able to structure your own thinking and continue skill development after the workshop.

2. Ability to accurately contextualise GM technology, its regulation and the risk analysis of GMOs.

3. To become critical thinkers and confident decision makers who can add value to and improve national biosafety systems.

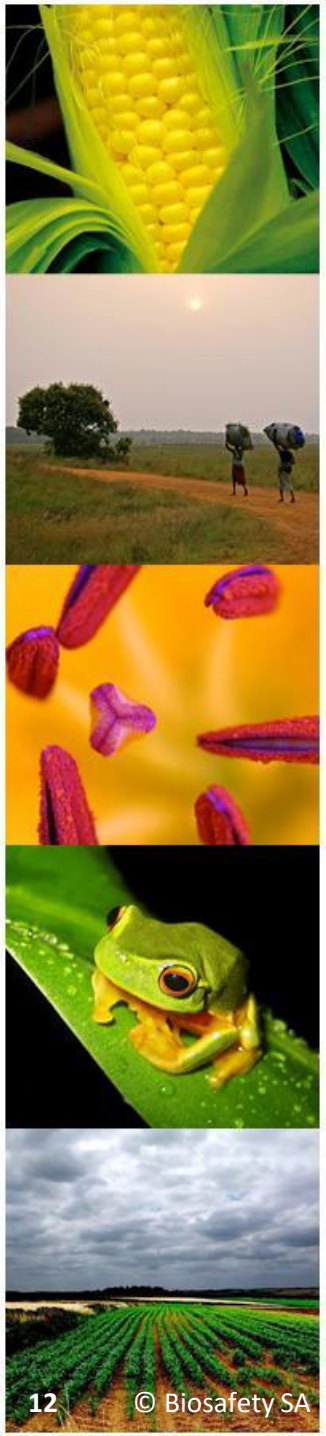


GENERAL PRINCIPLES

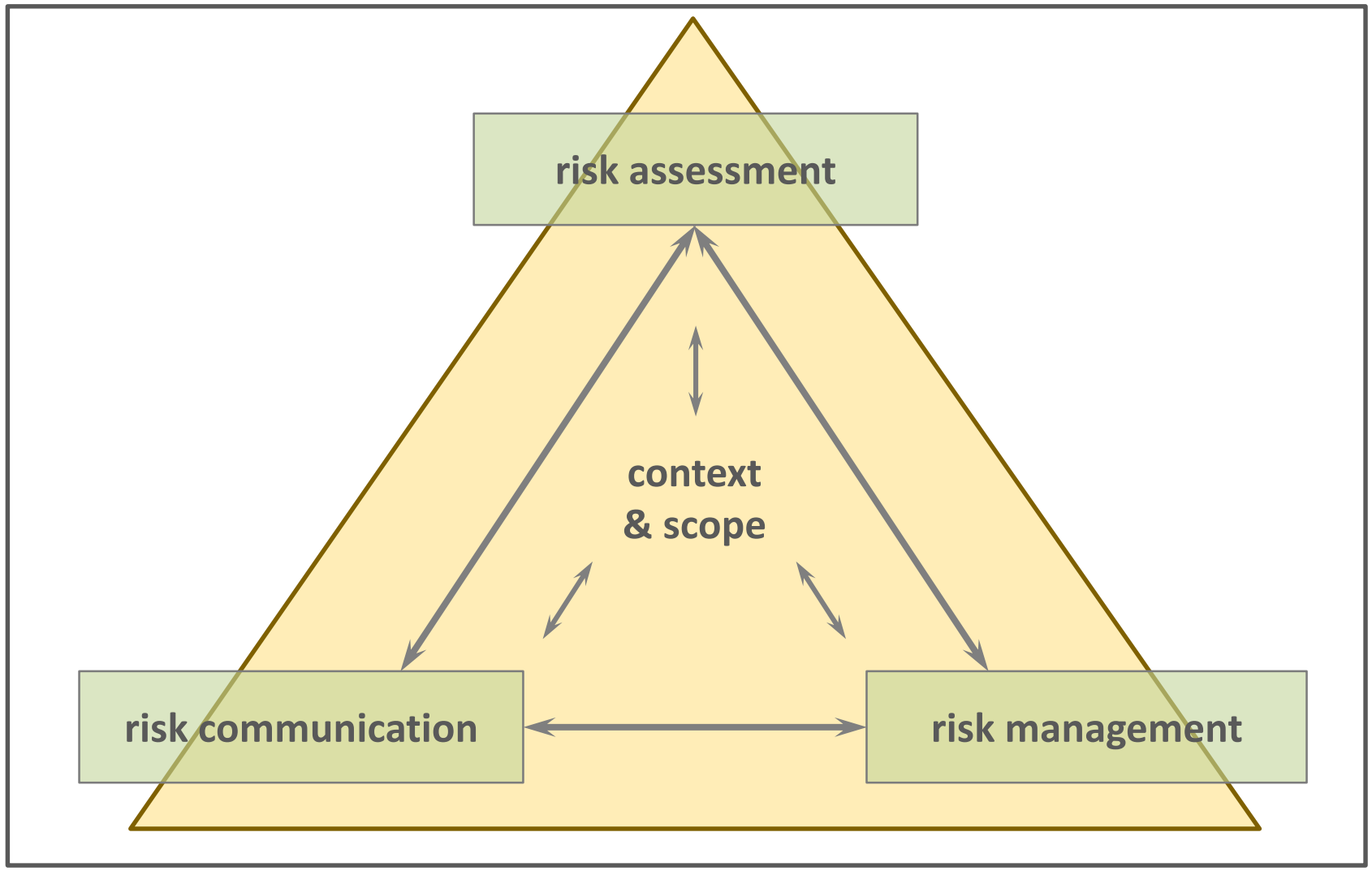
1. The risk analysis framework stands central to all content.

2. Should be highly interactive to ensure participants engage with the content to facilitate knowledge and skills transfer

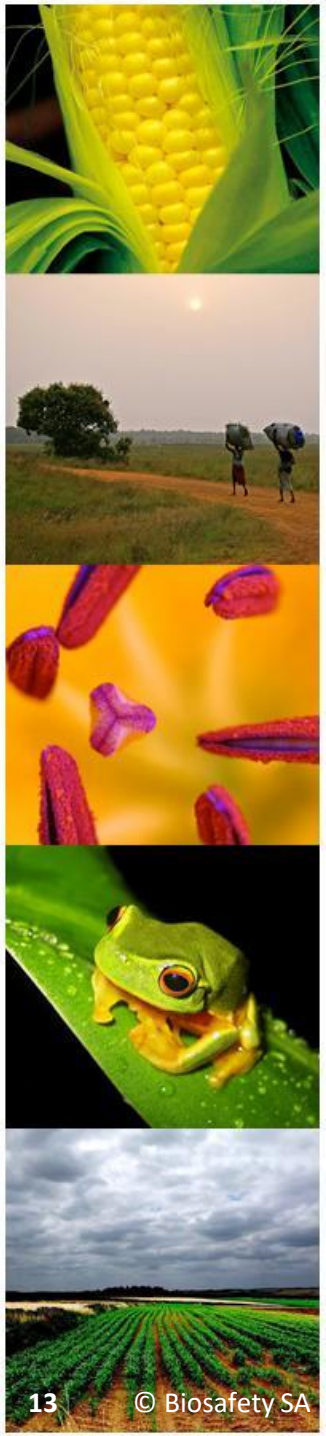
3. Theory translated into practical capability through active engagements.



RISK ANALYSIS



… is the contextualised, iterative integration of risk assessment, risk management and risk communication.



GMO RISK ANALYSIS WORKSHOP OVERVIEW

I. introduction & context — **Hennie**

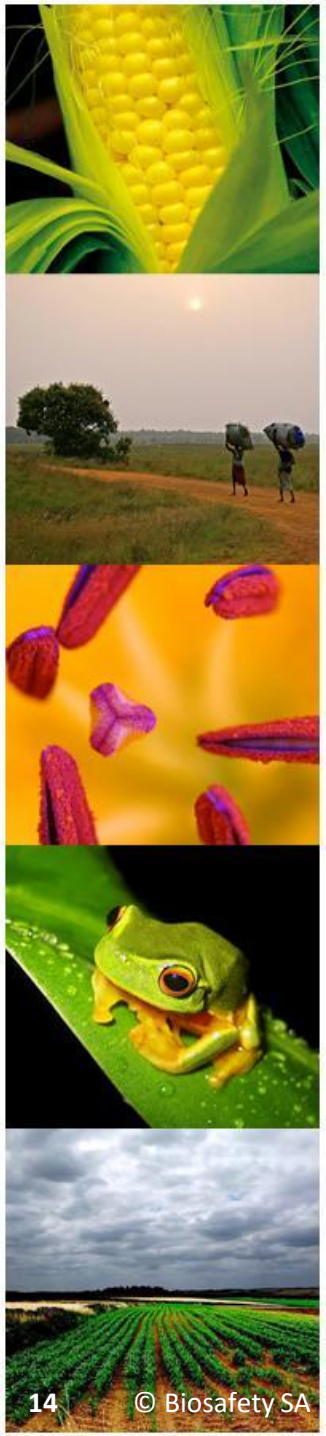
II. environmental risk assessment — **James**

III. food safety assessment — **James**

IV. socio-economic impact assessment — **Hennie**

V. engagement & communication — **Hennie**

VI. integration, contextualisation & conclusion — **James**



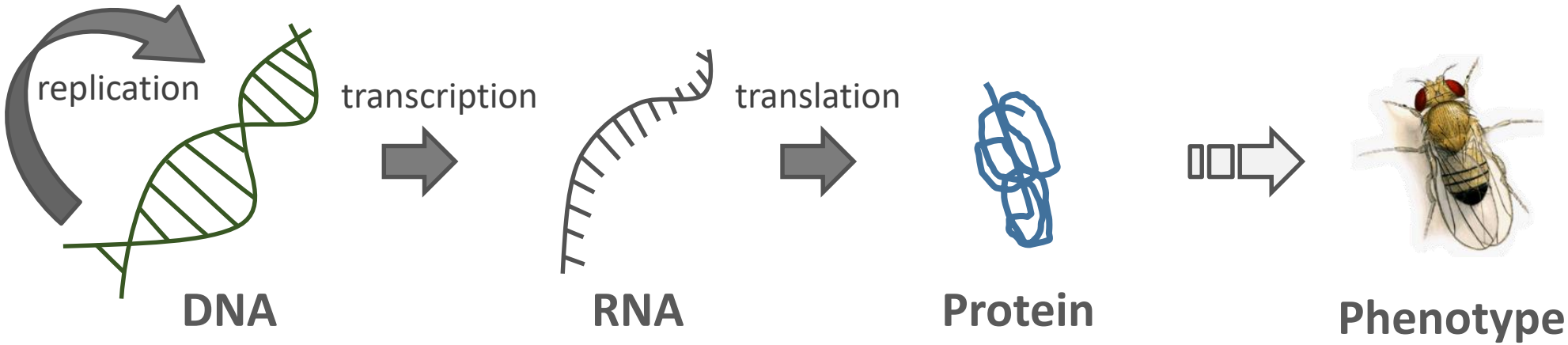
PROGRAM

Time	Activity
09:00	Start
~11:15-11:40	Coffee/Tea break
13:00-14:00	Lunch
16:00	End


Let's take the plunge!

GMOs & why they are regulated

The central dogma of genetics



CONCLUSION:

You can change the phenotypic traits of an organism by introducing genetic variation - by transferring specific DNA/genes or changing the genes itself

(e.g. breeding & selection, mutagenesis, transgenesis or gene editing…)

Genetic variation

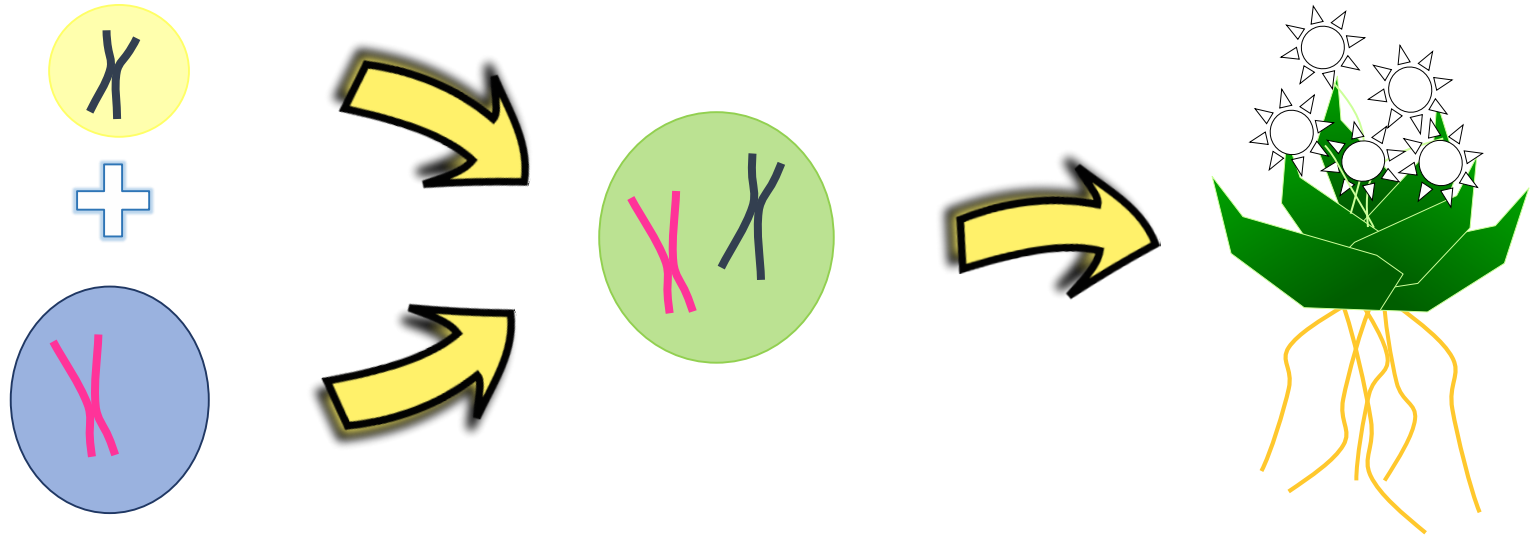
Natural

Selection

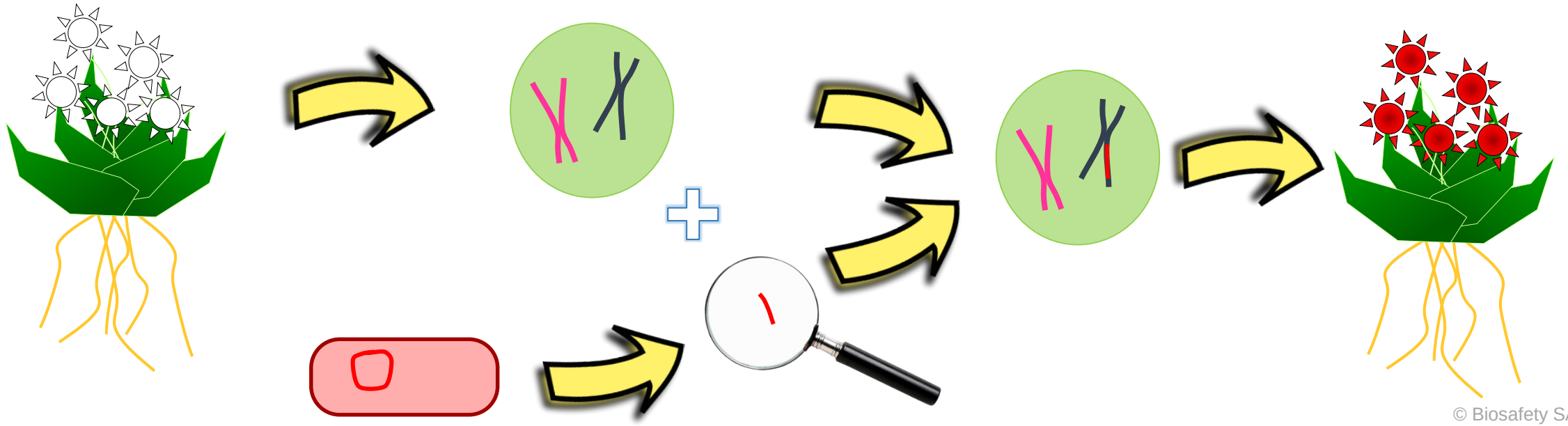
Induced

Genetic modification

Sexual reproduction



Genetic modification



Example: GM tomato plants expressing a bacterial ACC-deaminase

Klee et al, 1991. The Plant Cell, 3: 1187-1 193.

The molecular biology → The physiology → The phenotype

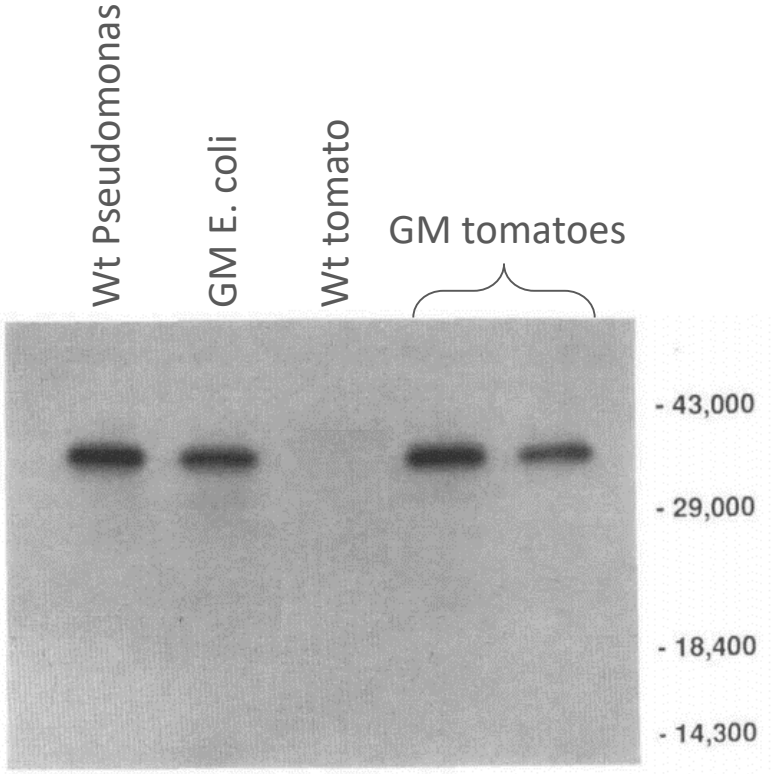


Figure 2. Protein Gel Blot Analysis Showing Expression of ACC Deaminase in Bacteria and Transgenic Tomato Plants.

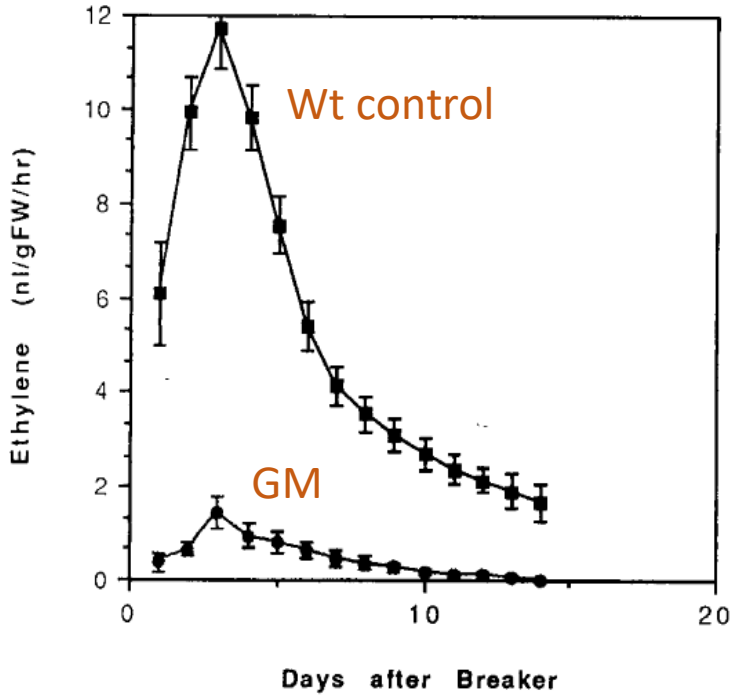


Figure 3. Ethylene Generation by 5673 Transgenic (– ● –) and UC82B Control (– ■ –) Ripening Fruit.

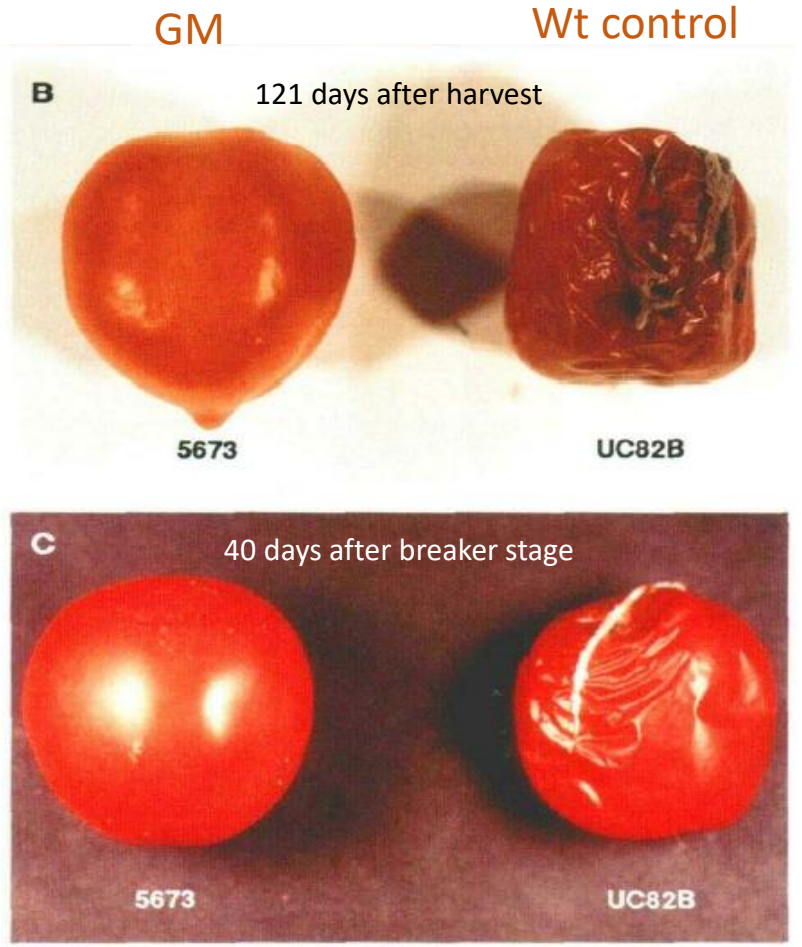


Figure 4. Effect of ACC Deaminase Expression on Ripening Tomatoes.

Commercial GMOs: SA

[GM% 2017]

85%

90%

100%

Commercial GMOs: Internationally










etc. etc.

Other commercial GM products

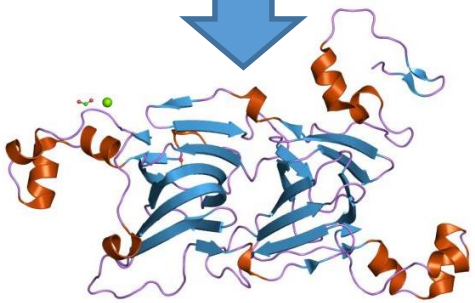
For more information see
http://biosafety.org.za/information/know-the-basics/gmo-science

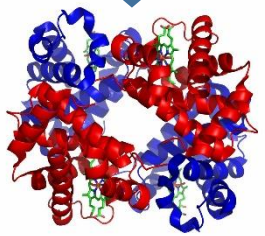
The novel context introduced by GMOs

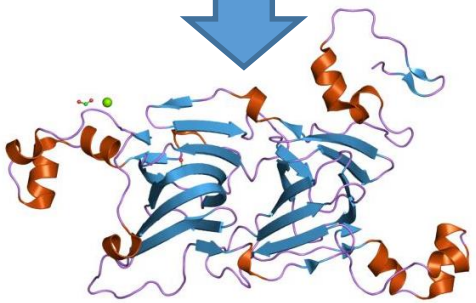
Wild type peanut

Wild type maize

GMO maize







Legally defined

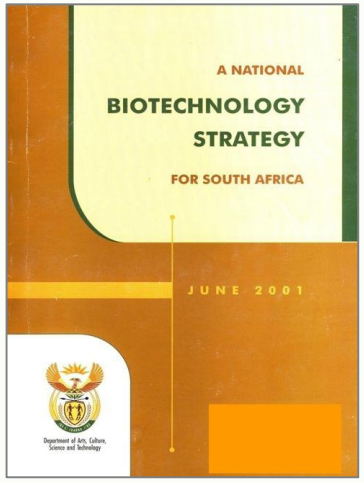
Genetically Modified ORGANISMS Act (SA):

"GMO means an organism the genes or genetic material of which has been modified in a way that does not occur naturally through mating or natural recombination or both".

SA's GMO policy & regulatory environment

EVOLUTION OF SOUTH AFRICA's BIOTECH POLICY

2001
Nat Biotech Strategy



2003 instruments:
NBAC, BRICs, NBN, PUB

2009
Merge into TIA

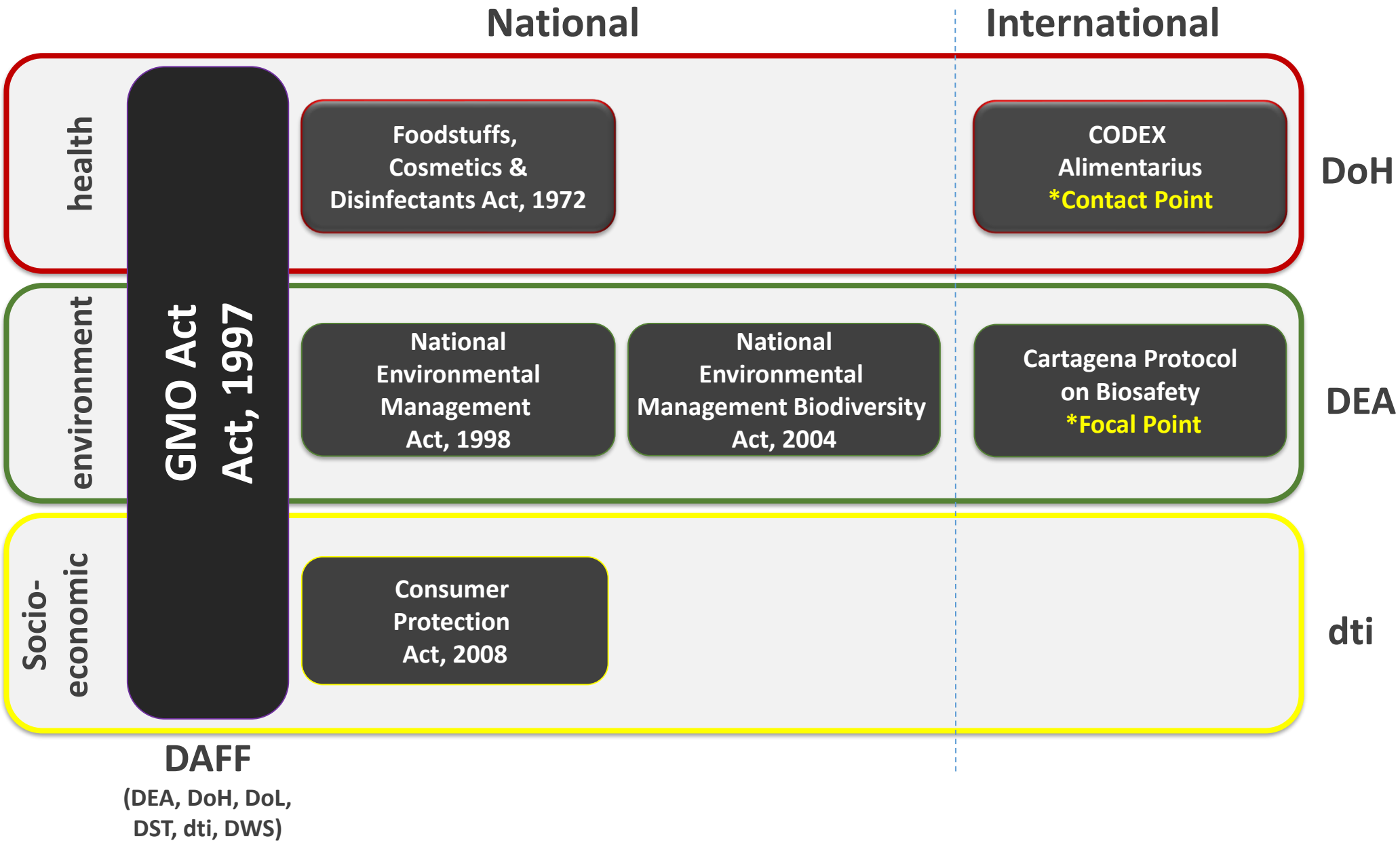
Incorporation
of 'learnings'

2013
Nat Bio-economy Strategy

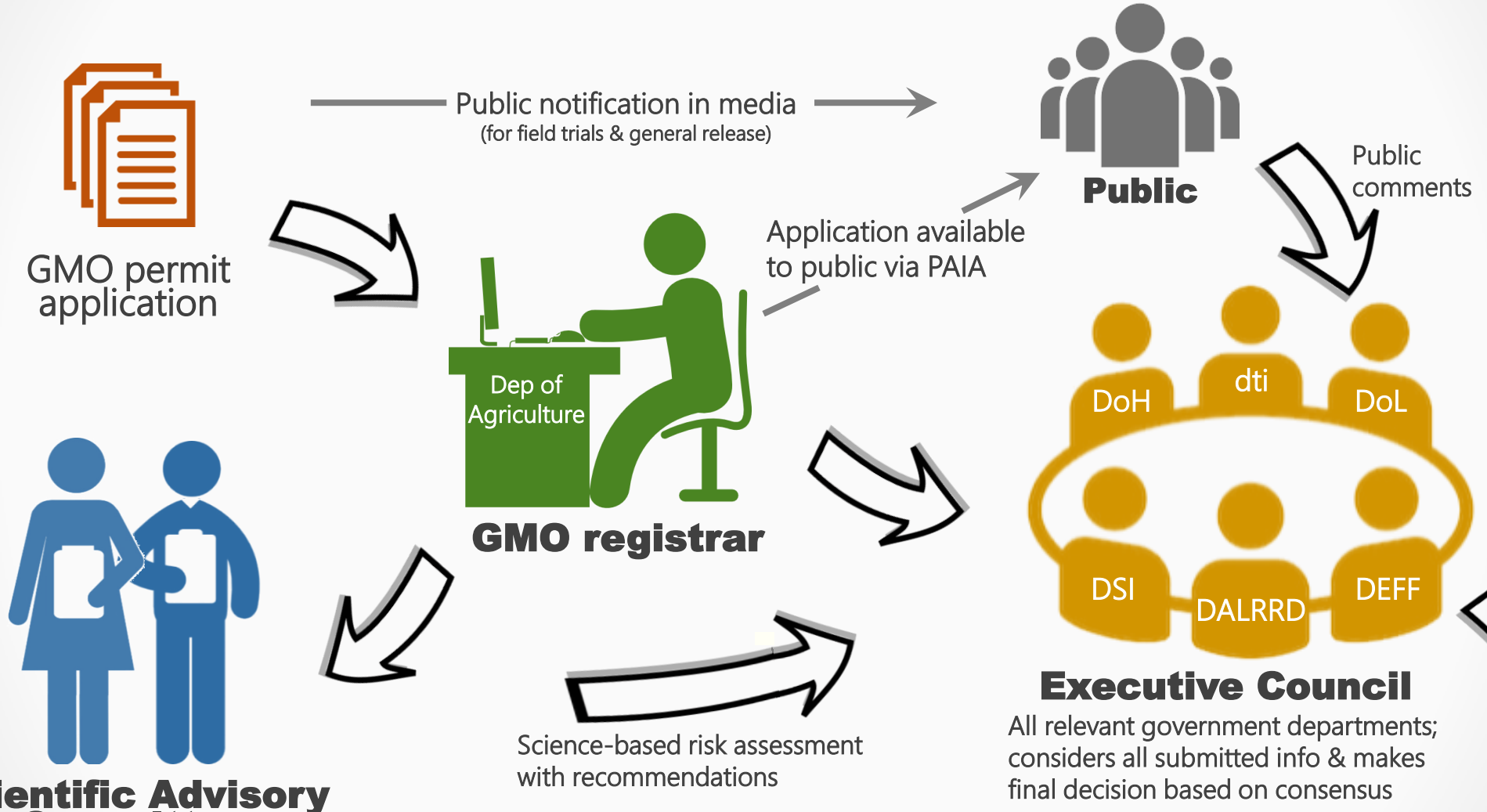
2020
Fully functioning NSI

2050
Bio-economy 5% of GDP

SA's REGULATORY FRAMEWORK FOR GMOs



SOUTH AFRICA'S GMO PERMIT APPLICATION PROCESS



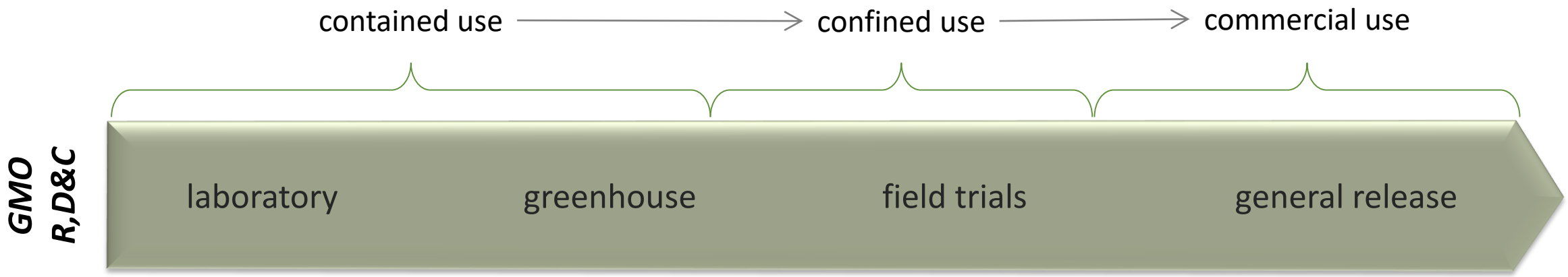
Permits issue for:
- Contained use.
- Field trials.
- Commodity clearance.
- General release.

GMO DEVELOPMENT PROCESS & PERMITS

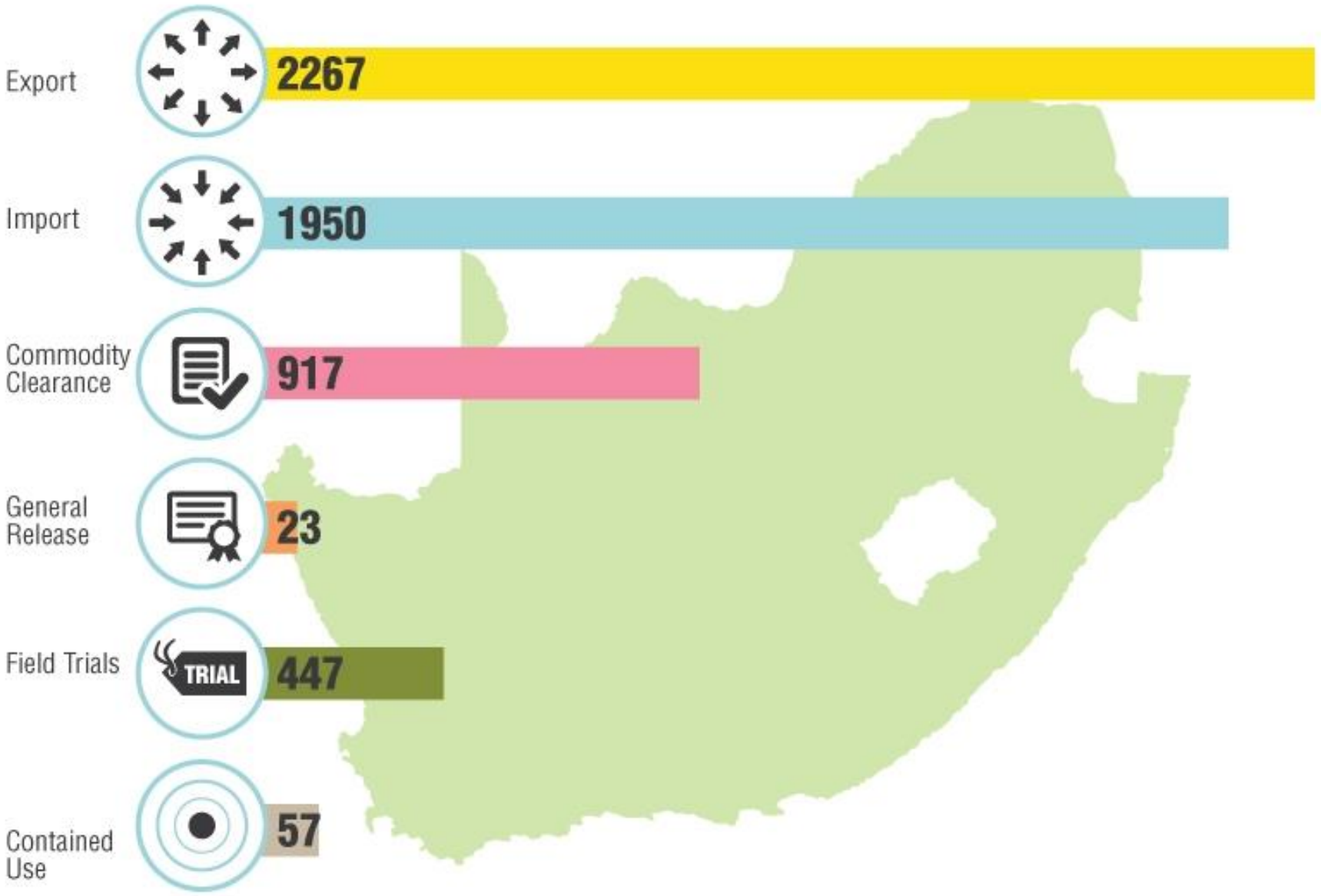
GMO ACT PERMITS		
Registration of GMO facilities	Field trial	General release
Contained use permit*		Commodity clearance
Import for contained use	Import for release into the environment	
Export		
*not applicable to bona fide research organisations		

tiered risk analysis

(increasing risk assessment, management & communication requirements)



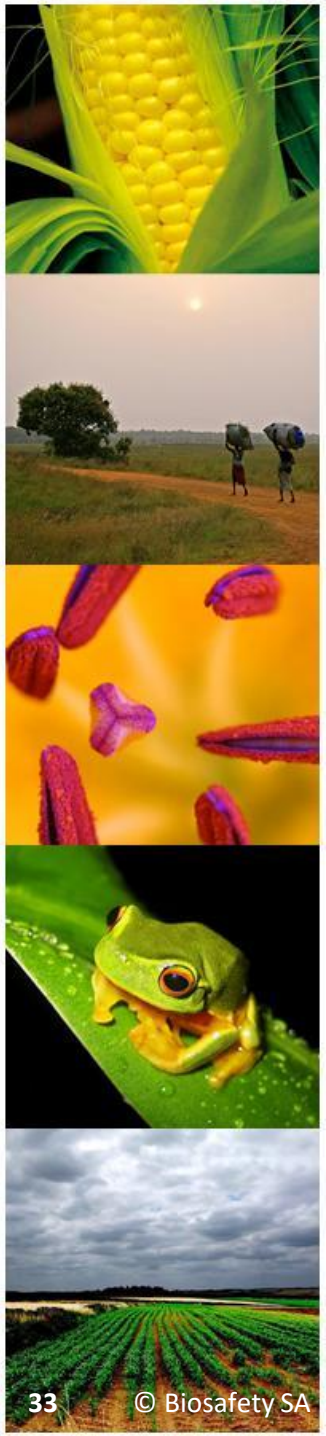
Permits issued 1999-2018



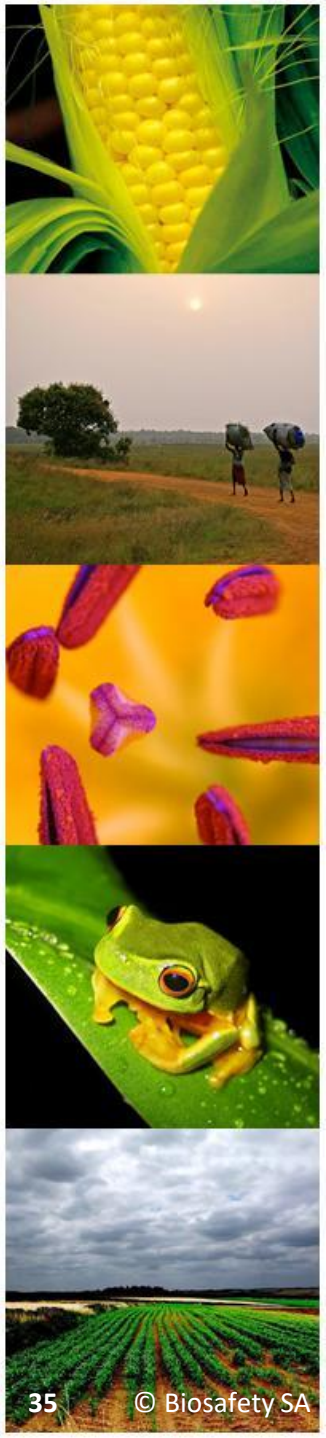
Permits NOT issued 1999-2018

Type	Organism	Trait	Applicant	Reason
General release	Yeast (wine)	Malolactic fermentation	International company	Export wine market
General release	Potato	Insect resistance (Bt)	SA research council	Not market relevant, no industry support
Field trial	Grapevine	Reporter gene	University	? (approved on appeal)
Field trial	Sorghum	Nutritional genes	SA research council	Indigenous crop (level 3 containment)

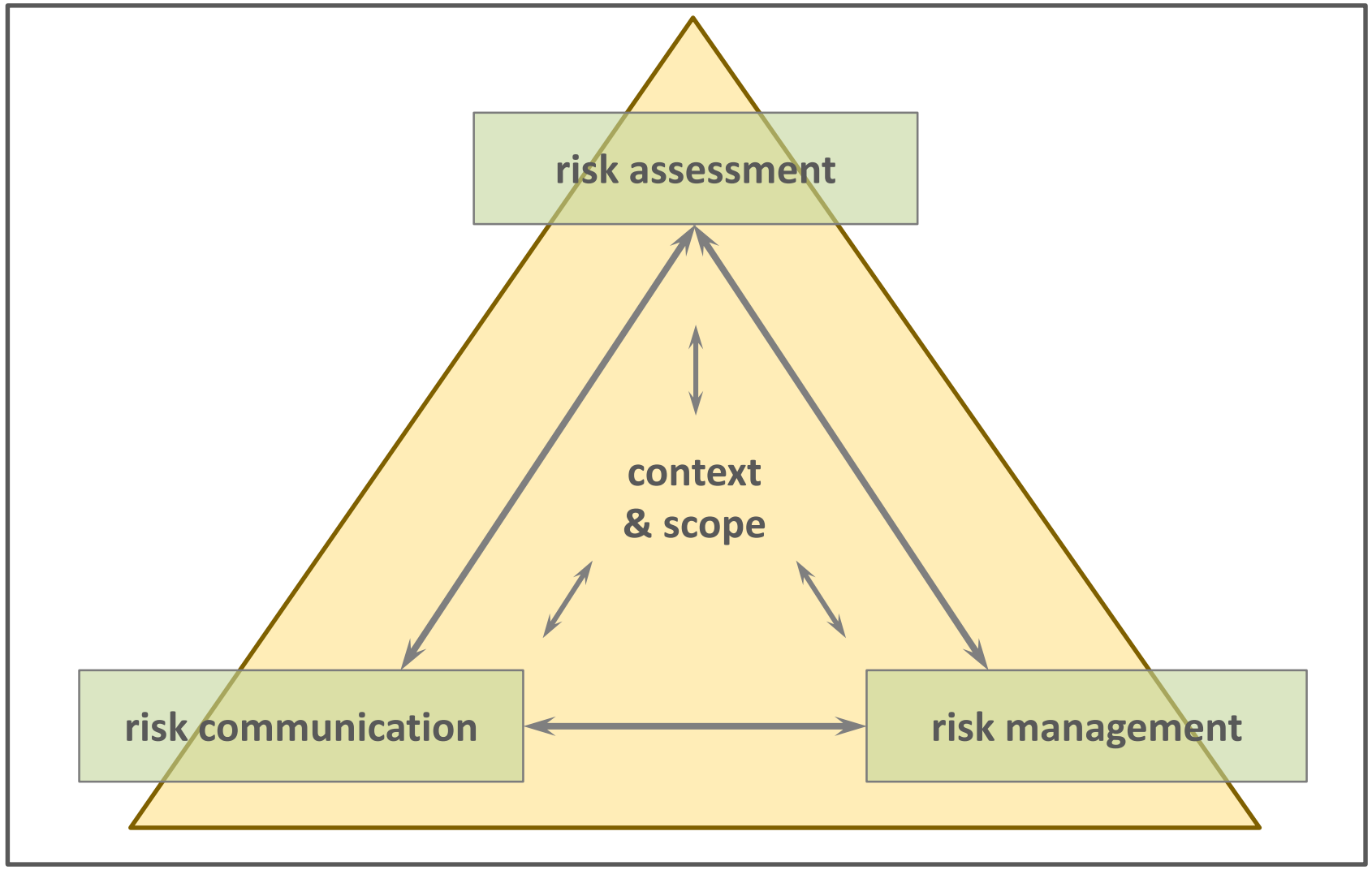
For more information see http://biosafety.org.za/information/know-the-basics/regulation-of-gmos



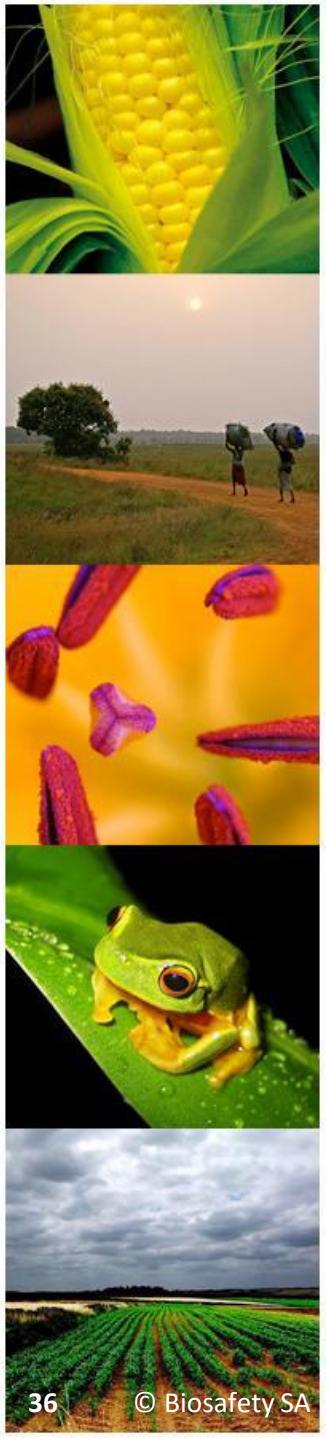
Risk analysis for sound decision making



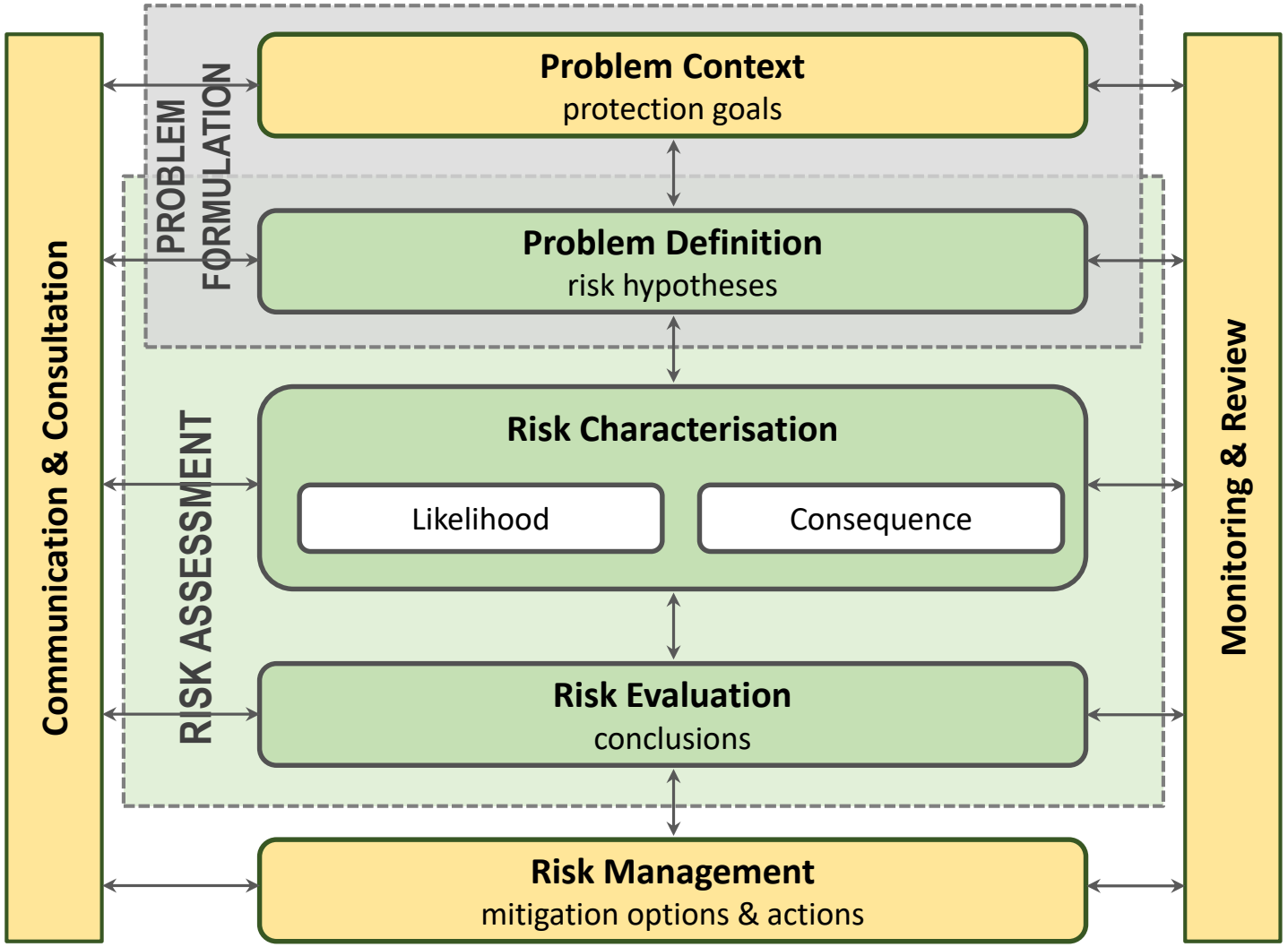
RISK ANALYSIS



… is the contextualised, iterative integration of risk assessment, risk management and risk communication.



RISK ANALYSIS

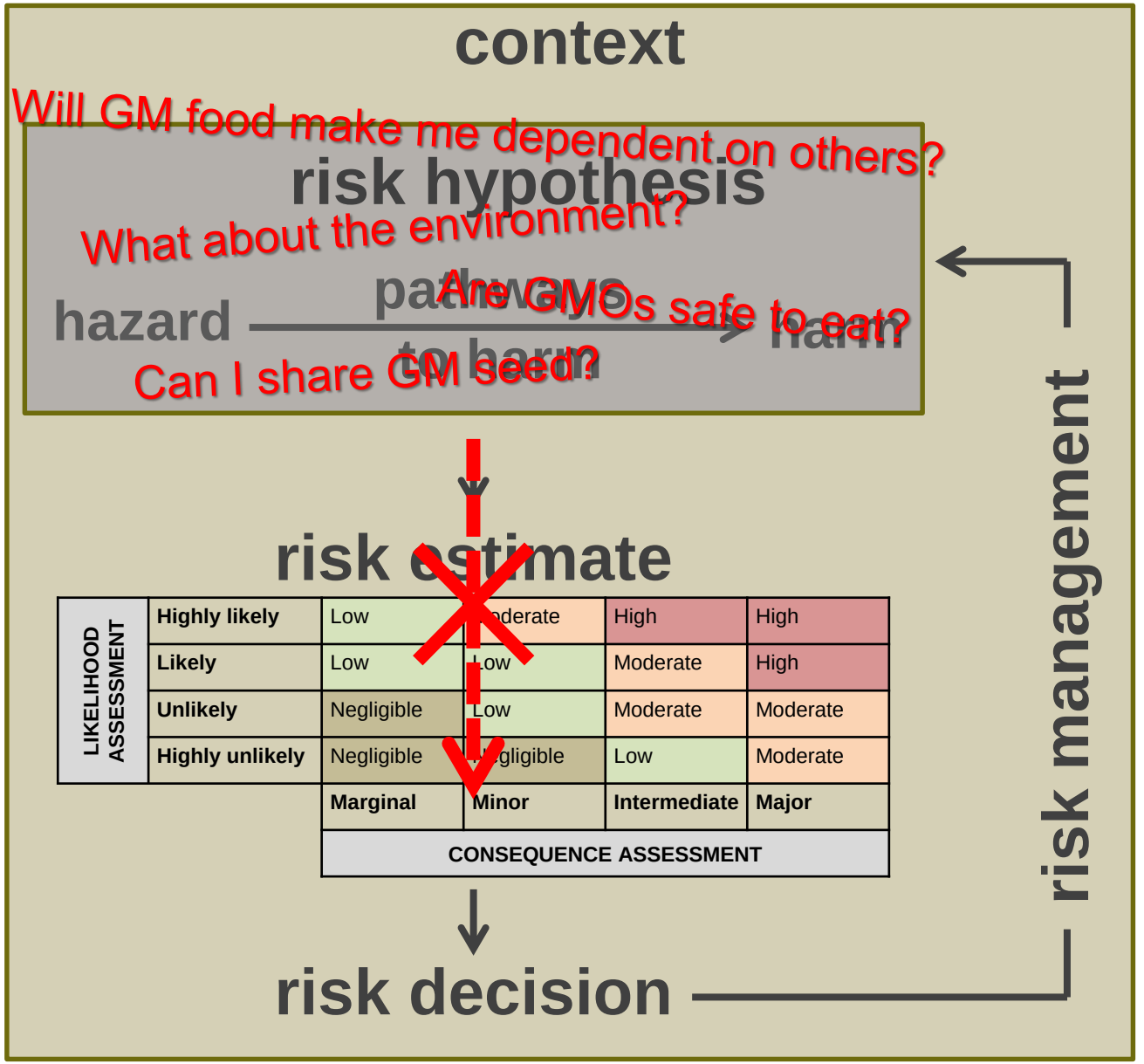


Society

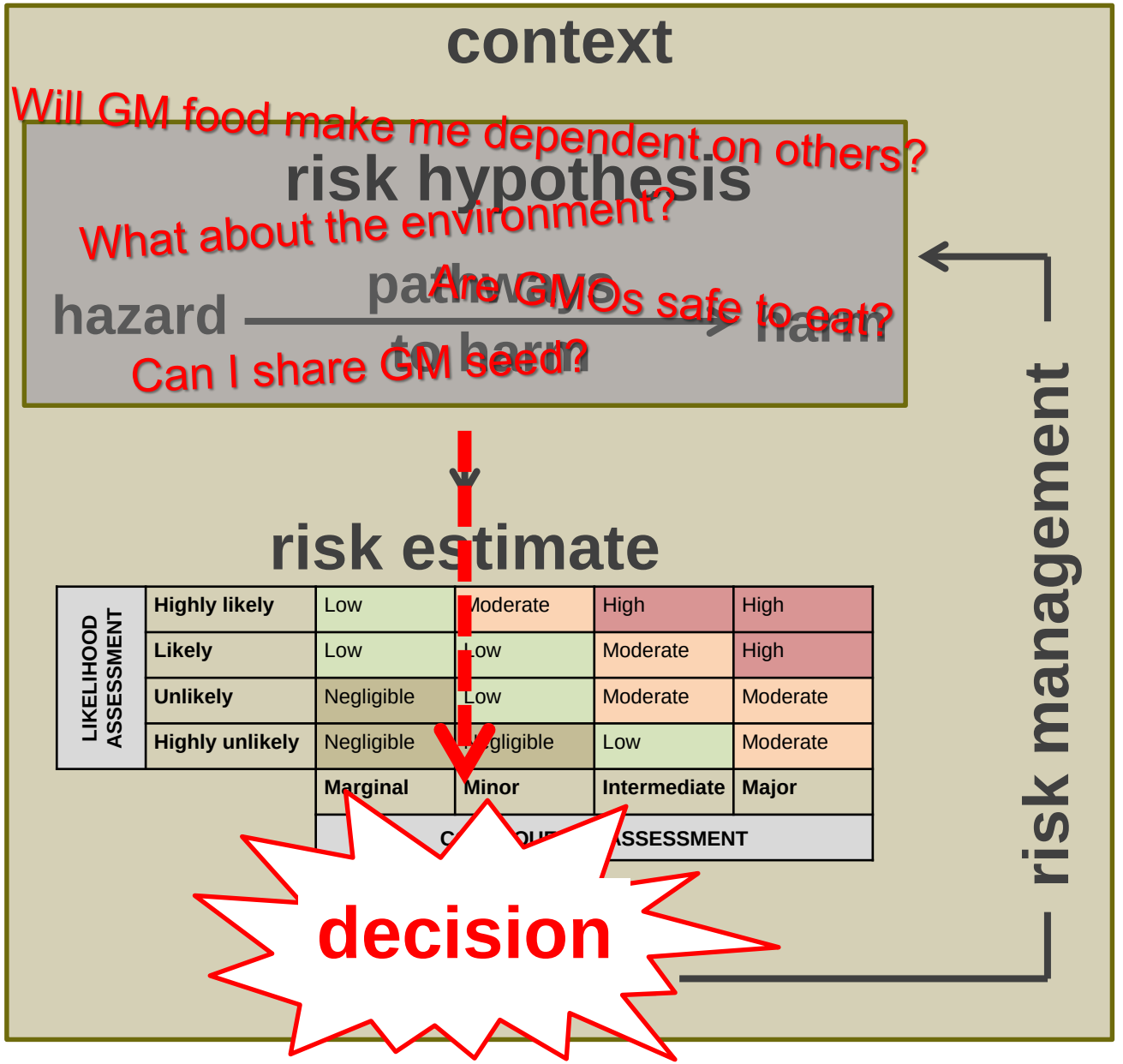
Science

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

RISK ANALYSIS



RISK ANALYSIS



For more information see http://biosafety.org.za/information/dig-deeper/sustainable-gm-product-development

GMO risk in context

RISK DEFINED

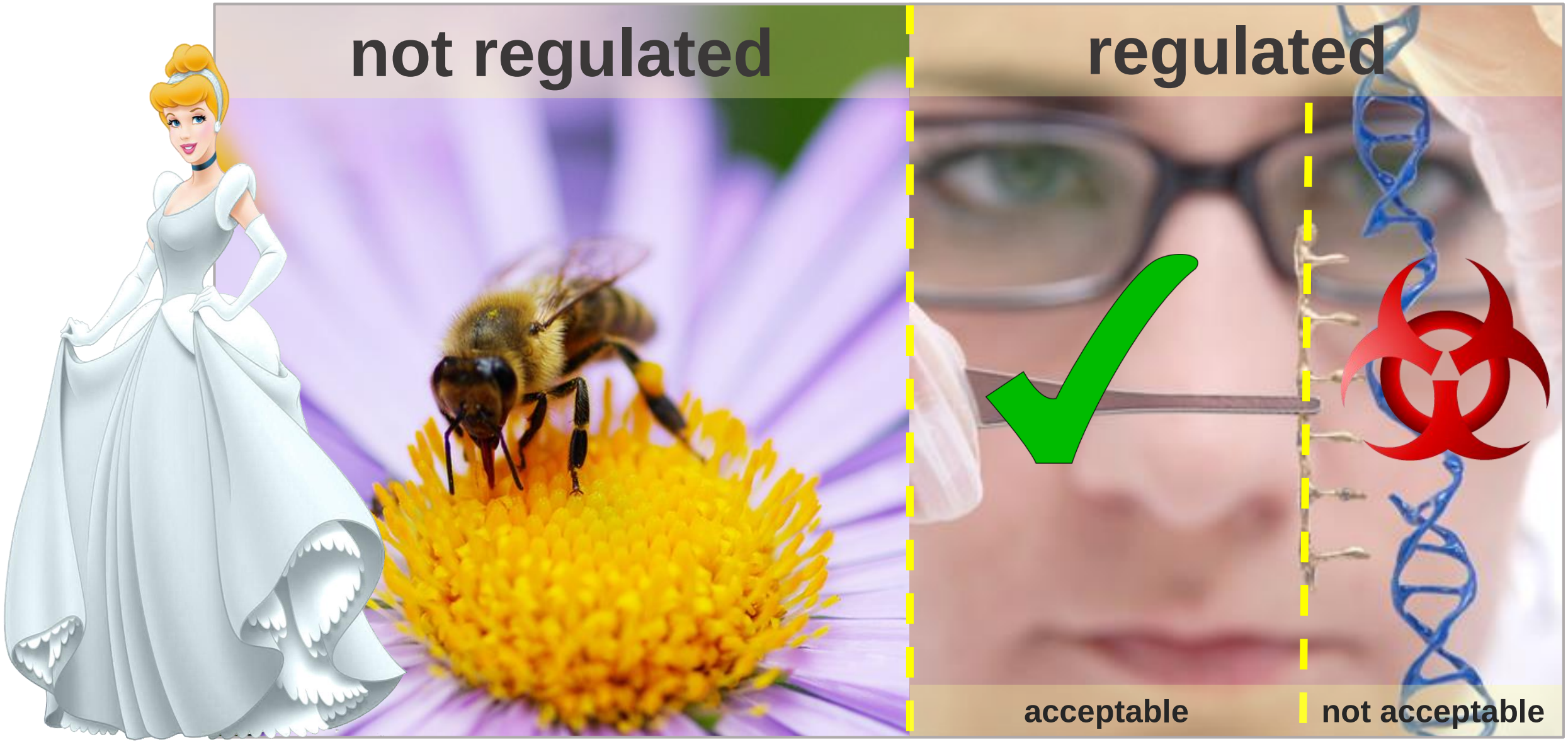
- **Hazard** - is any potential source of harm (the possibility to cause harm).
- **Harm** - is an adverse outcome or impact.
- **Risk** - is the probability of a harm occurring under defined circumstances.

$$hazard \xrightarrow{exposure} harm$$

$$risk = likelihood\ x\ consequence$$

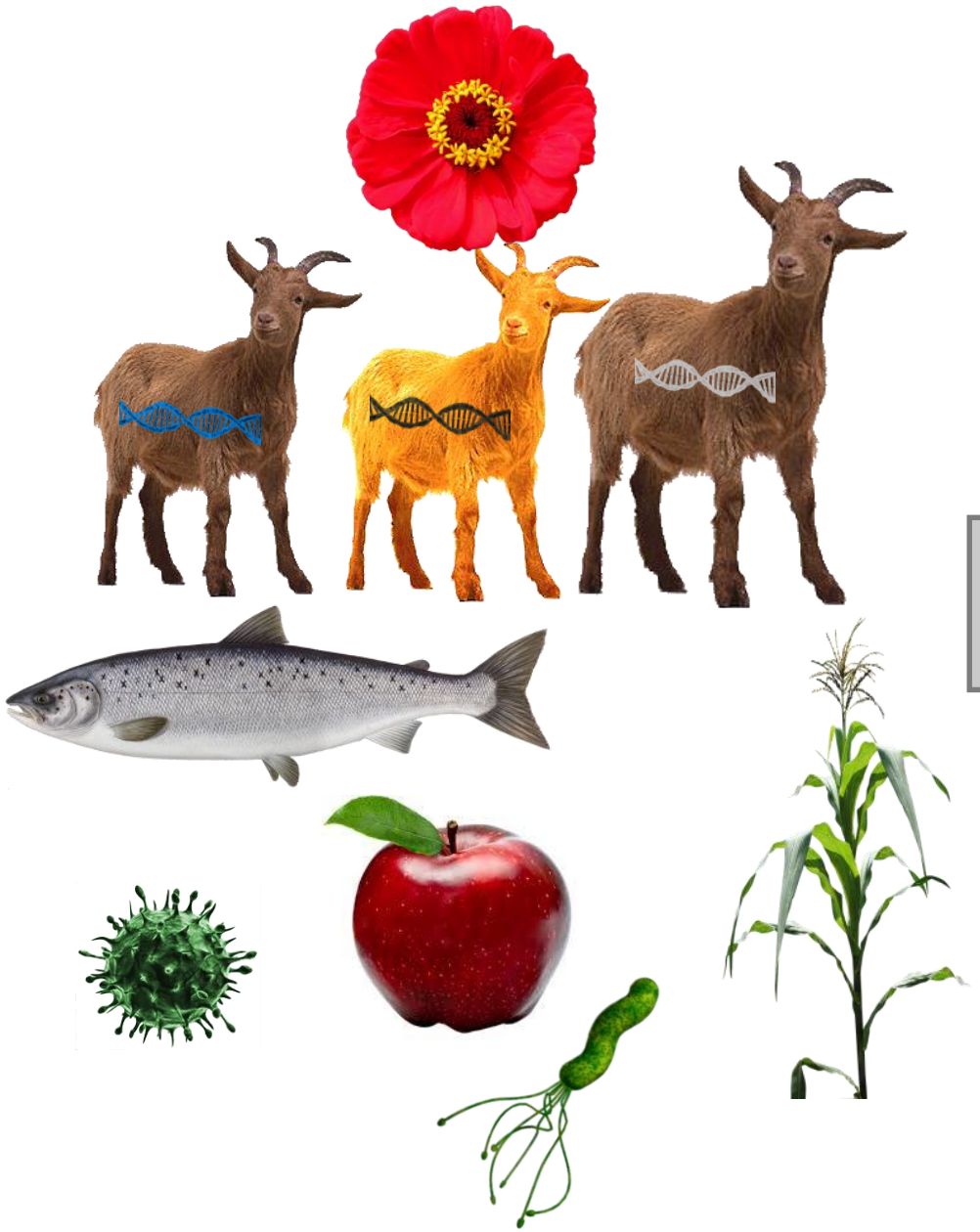
While remembering that -

- There is no such thing as zero risk or absolute safety.
- Risk should be assessed in a relevant context ("GMOs" vs. Bt maize).
- Risks can be managed.
- Potential benefits counterbalance the potentially associated risks.



0 risk

The risk of “GMOs” vs “commercialised Bt maize X123”



specific development regulation
(TIME)

The risk of “outsiders” vs “locals”

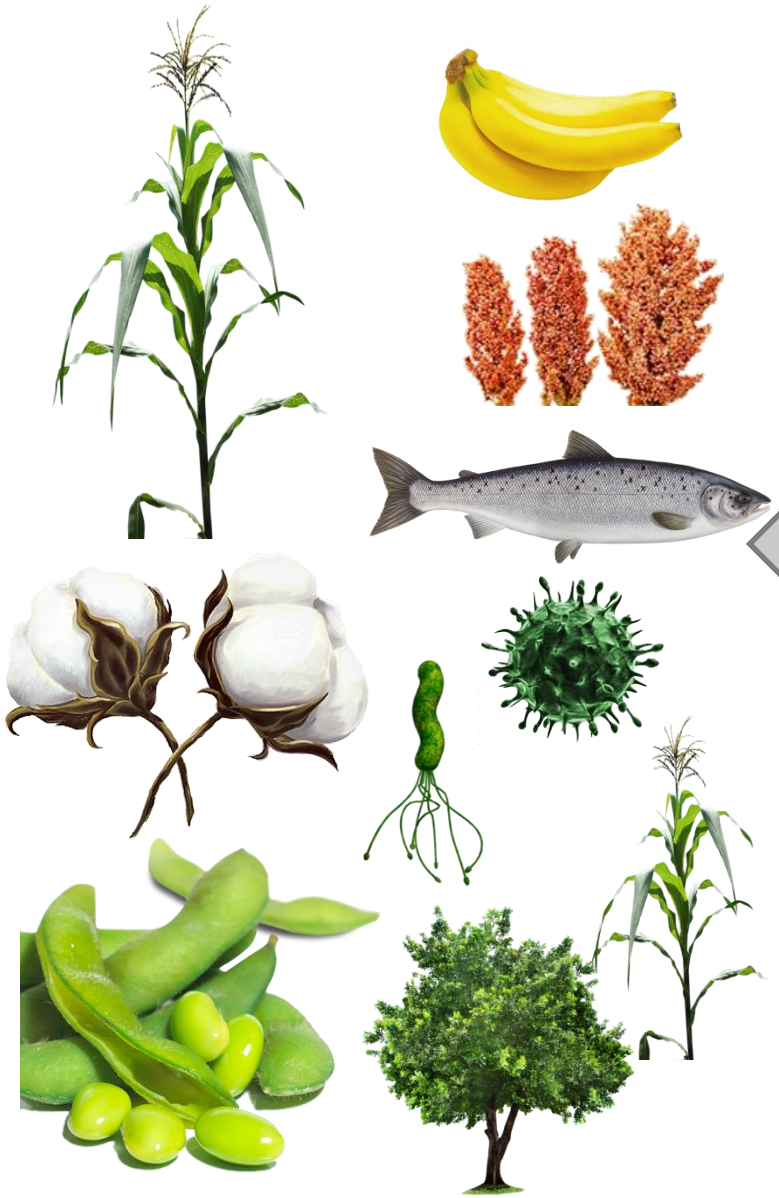
syngenta

CORTEVA™ agriscience

DUPONT

PIONEER

BAYER



SASRI

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

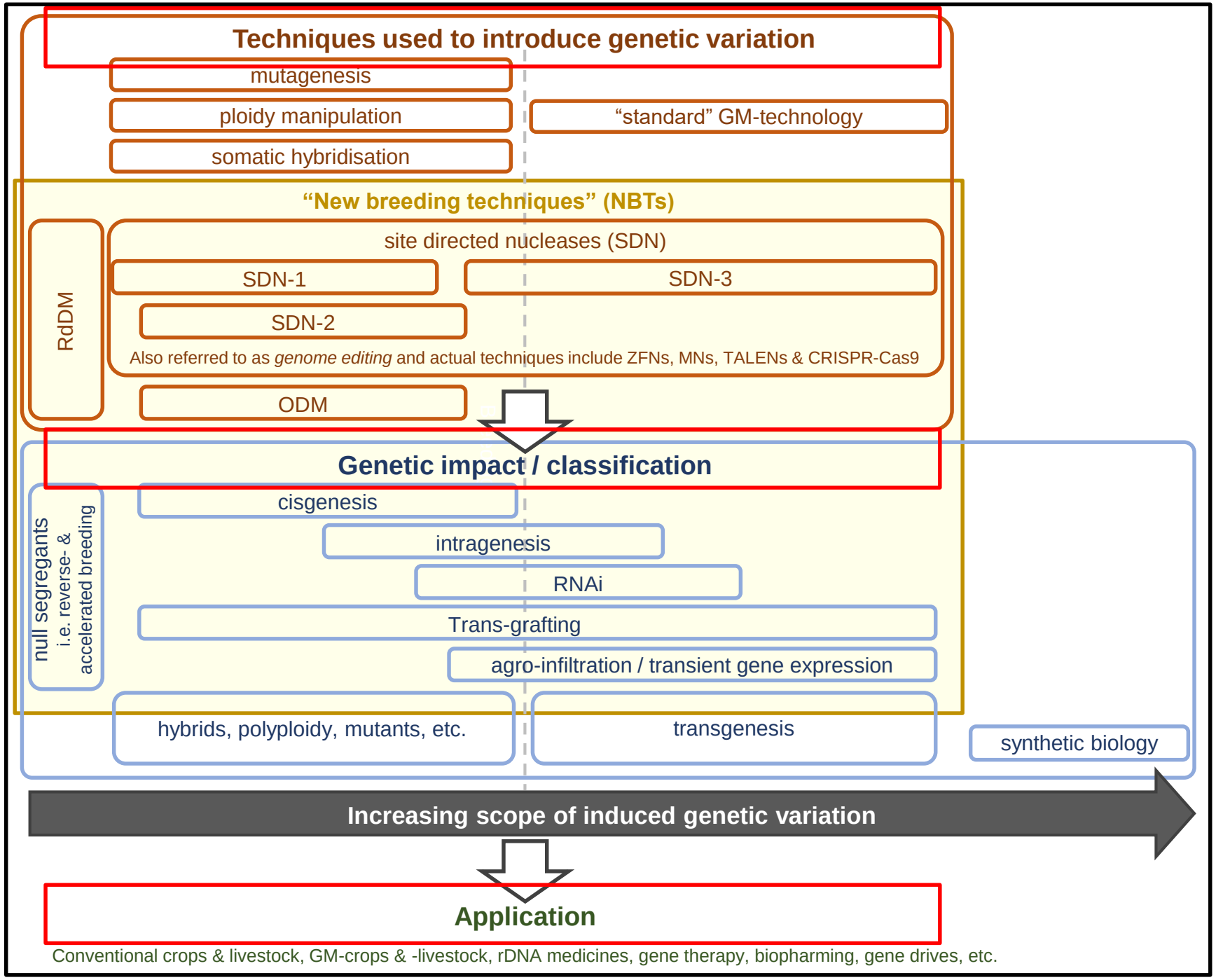
CSIR
our future through science

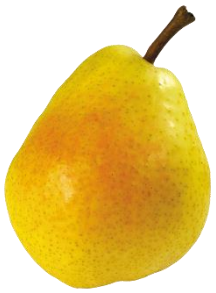
NORTH-WEST UNIVERSITY
YUNIBESITI YA BOKONE-BOPHIRIMA
NOORDWES-UNIVERSITEIT

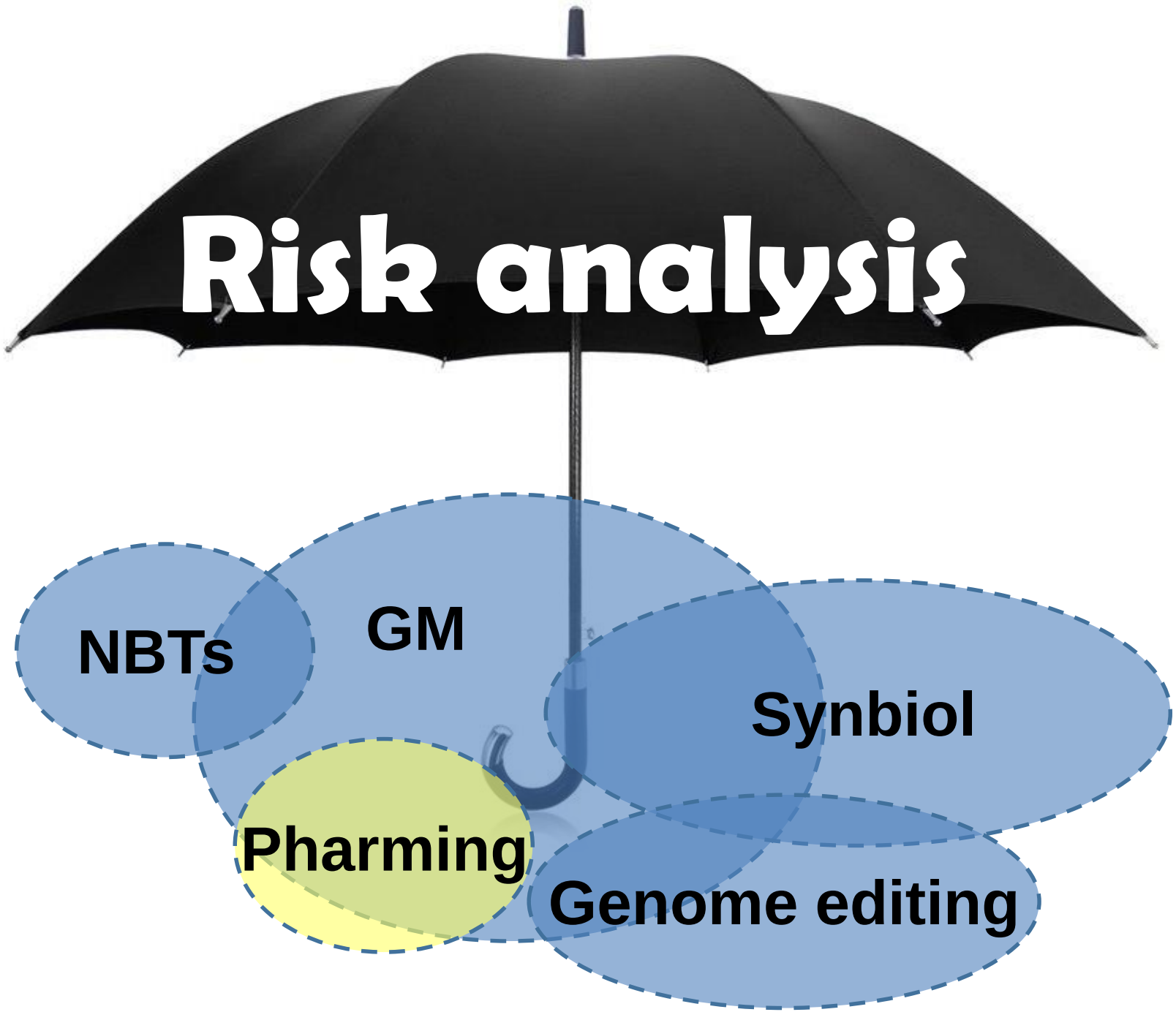
ARC • LNR
Excellence in Research and Development

UNIVERSITEIT STELLENBOSCH UNIVERSITY

Induced genetic variation

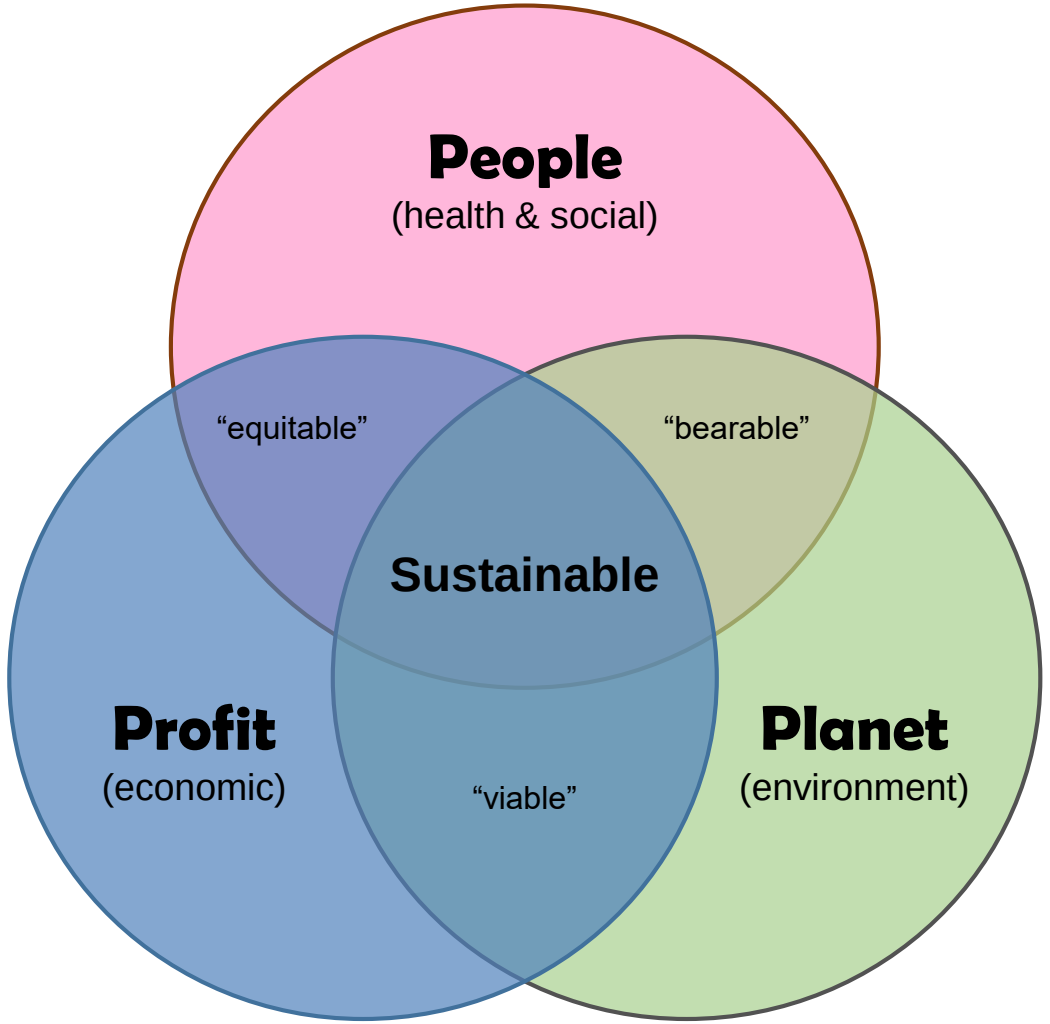






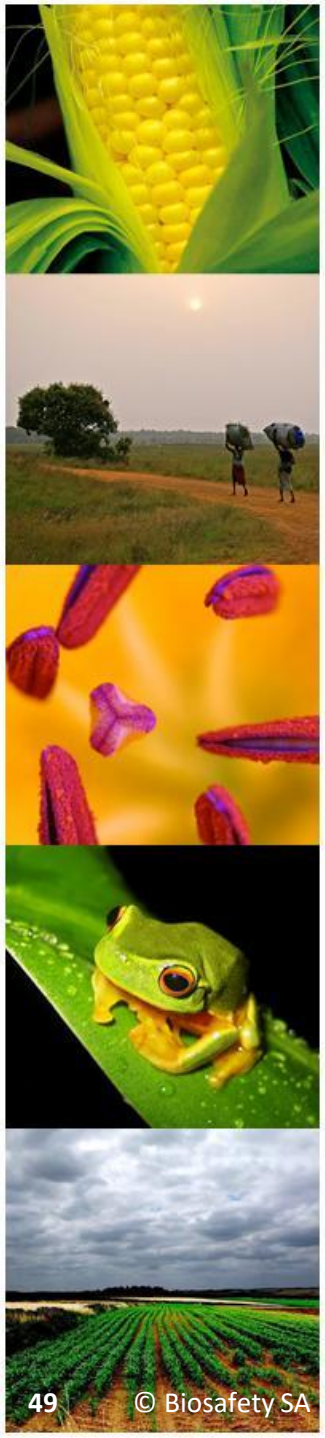
Sustainable biotech innovation

THE “TRIPLE BOTTOM LINE” FOR A SUSTAINABLE PRODUCT

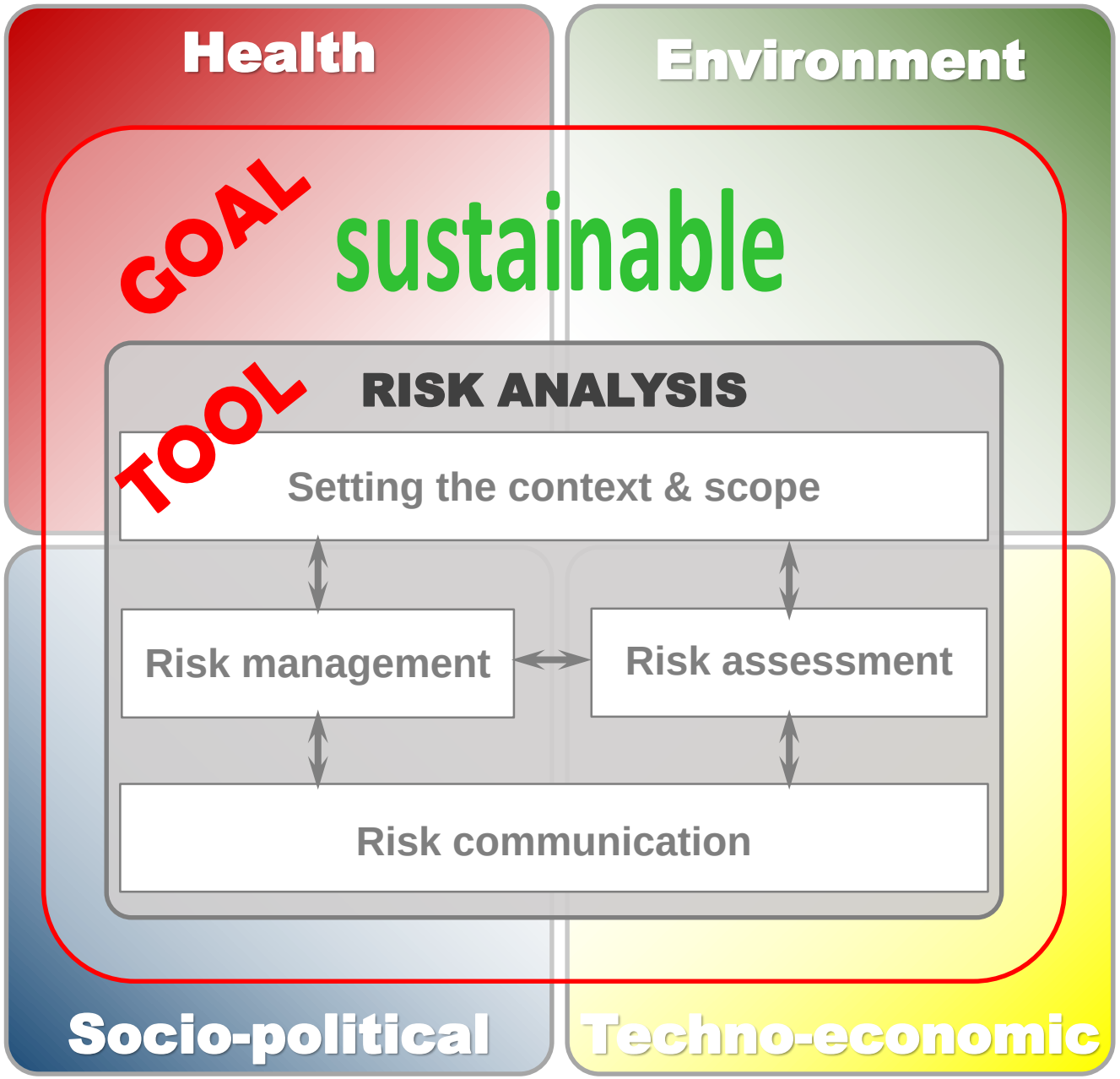


Technology ≠ Product

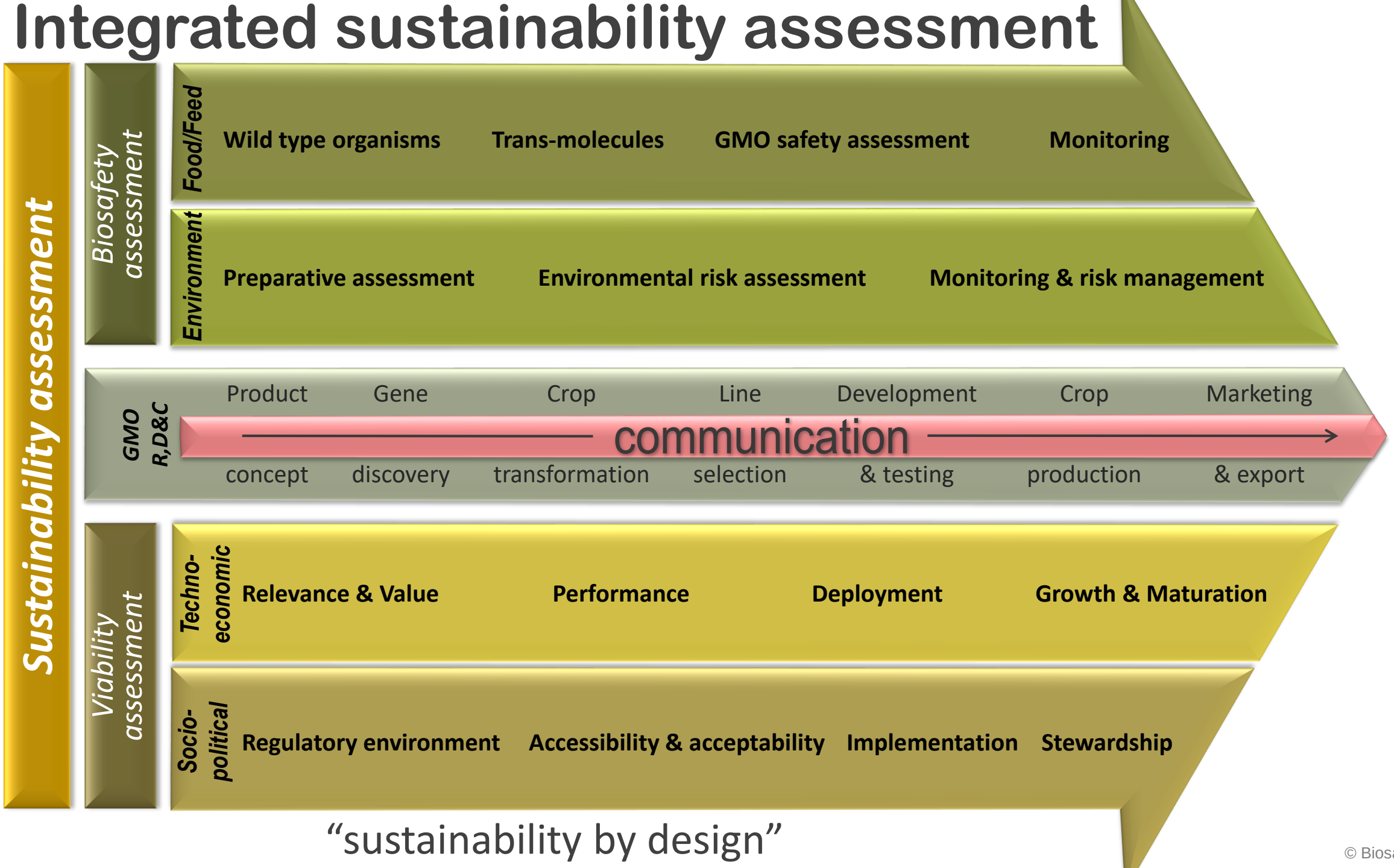
Sustainable biotech products



ENSURING SUSTAINABILITY



Integrated sustainability assessment



"sustainability by design"

Dr Hennie Groenewald | hennie@biosafety.org.za | www.biosafety.org.za |