











# Implementation of the Cartagena Protocol on Biosafety in South Africa

22/11/2018





# **Presentation Overview**

- ☐ Background
- ☐ Status of genetically modified (GM) products in South Africa (SA)
- ☐ Implementation of the Cartagena Protocol on Biosafety in SA
- ☐ Legislative Framework
- □ Regulatory Approach
- ☐ Risk Management Approach for SA
- ☐ Public awareness and Participation

# Background

#### South Africa is the 3rd most biodiverse country in the world



**7%** of the world's reptiles, birds and mammals



10% of the world's plants



2% of the world's land area

15% of the world's coastal marine species









# STATUS OF GM PRODUCTS IN SOUTH AFRICA

OVER THE PAST FIVE YEARS ON AVERAGE

In addition, many GM-derived medicines, including anti cancer agents, vaccines, insulin, cytokines and growth factors are on the South African market.



2.7 million hectares of GM crops were planted in South Africa.



90% of maize is GM (HT and/or IR)



95% of soybean is GM (HT)



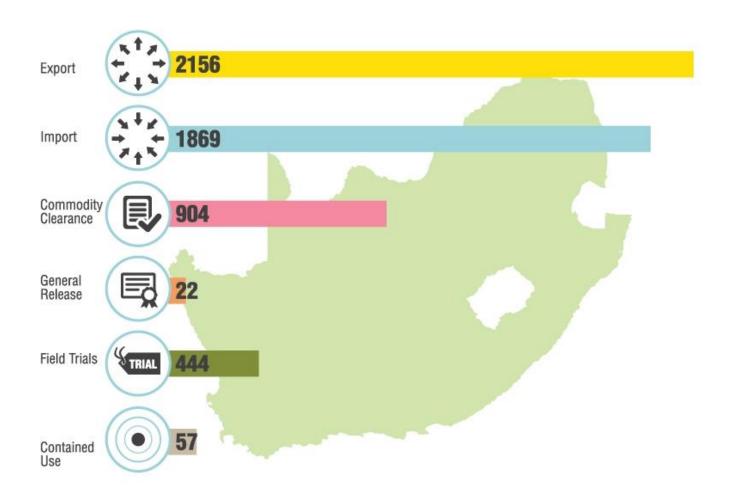
100% of cotton is GM (HT and/or IR)



Since 1999, 393 permits for confined field trials on 10 different crops have been issued.

IR - Insect resistant HT - Herbicide tolerant

# NUMBER OF PERMIT TYPES ISSUED IN SOUTH AFRICA FOR THE PERIOD 1999-2017



### IMPLEMENTATION: BIOSAFETY PROTOCOL IN SOUTH AFRICA

# <u>Progress towards Facilitating the establishment and further development of effective biosafety system</u>

Acceded to the Protocol in 2003

DEA is the NFP

DAFF is the Competent National Authority (CNA)

- 2003, the <u>Public Understanding of Biotechnology (PUB)</u>
   <u>programme</u>, the Department of Science and Technology (DST)
- 2005, Integrated of biosafety activities into the NBSAP-1
- Development of Environmental Risk Assessment (ERA) <u>Framework</u> documents on:
  - Genetically modified crops (2008)
  - Genetically modified fish (2012)
  - Pharmaceutical crops (2015).
- Between 2008-2010, <u>South Africa-Norway Biosafety Cooperation</u>
   <u>Project:</u> a <u>report on Monitoring the Environmental Impacts of GM</u>
   Maize in South Africa
- 2010, <u>Biosafety South Africa</u>
- 2013, the Bio-economy Strategy
- 2015, Revised NBSAP

## **GMO LEGISLATIVE FRAMEWORK IN SA**

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LEGISLATION

**HOW THE LEGISLATION IS APPLIED** 

Human and animal health and safety

Environmental

the responsible Provides for measures **3enetically** 

# Foodstuffs, Cosmetics and Disinfectants Act Occupational Health and Safety Act

Defines labelling requirements for GM containing foods (Regulation 25, 2004). Safeguards the health and safety of the workers,

cleaning personnel and any other person,

involved with activities with GMOs.

National Environmental Management Biodiversity Act Regulates possible impacts of GMOs on biodiversity and introduces minimum monitoring requirements, implemented through SANBI (South African National Biodiversity Institute).

Provides general guidance with regards to the

criteria that may trigger an EIA for GMOs, the

safety Socio-economic

National Environmental **Management Act** 

**Consumer Protection Act** 

objectives of such an EIA and the administrative procedure to follow Introduced mandatory labeling requirements for all GM goods (Regulation 293, 2008).

viability

http://biosafety.org.za

# THE GMO PERMIT APPLICATION PROCESS



#### PERMIT ISSUED FOR:

Contained use –
 Field trials –
 Commercial commodities –
 General release –



ADVISORY COMMITTEE



#### DEPARTMENT OF AGRICULTURE, FORESTRY AND FISHERIES

Applications sent to GMO Registrar



The Executive Council, consisting of several government departments, makes final decision, taking public input into consideration.

SCIENTIFIC EVALUATION BY THE ADVISORY COMMITTEE

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## Risk Management approach for SA

Assessment Endpoints

Environment & Biodiversity Protection

#### MONITORING FRAMEWORK

#### General surveillance monitoring

Makes provision for general observations.

Focuses on indirect,
delayed and/or long term
effects as well as
cumulative effects.
The con
parame
selected

Covers those effects which would have not been anticipated in the ERA.

#### Case by case monitoring

The content and parameters have to be selected on a case-by-case basis.

Identified risks to be monitored could in principle be direct, indirect, immediate, delayed, or long term (cumulative).

Monitoring methods, scope and time frame are determined by the risk (level thereof) to be monitored.

#### **Target monitoring**

Focuses on local populations of specific species that are 'indicators' of change.

Relies on broad scale observational data from surveillance monitoring with the collection of detailed information on changes in target species' population and habitat, in response to specific threatening processes.

#### Meta-analysis monitoring

Systematic review process based on previous research studies to answer a specific research question.

Relies on comprehensive datasets, reports or studies. Monitoring by use of data from existing networks

Depended on secondary data from various organisations and institutions that have systems in place to collect data relevant to that which can be used for the desired monitoring purposes.

Independent monitoring (SANBI)

Integration and alignment of independent and compliance monitoring

Specified monitoring plan/protocol structure informed by research question(s), hypothesis or identified risk

Outline of focus area and monitoring priorities

Outcomes/Outputs based on tangible scientific-based evidence

Compliance monitoring (by the applicant)

#### RENCES

a-Alonso, M., Jacobs, E., Raybould, A., Nickson, T.E., Sowig, P., kens, H., Van Der Kouwe, P., Layton, R., Amijee, F., Fuentes, A.M. and Jalla, F., 2006. A tiered system for assessing the risk of genetically fied plants to non-target organisms. *Environmental biosafety research*, –65.

ade, P.P., Melo, M.A. and Kido, E.A., 2014. Post-release monitoring: the lian system, its aims and requirements for information. *Transgenic arch*, 23: 1043–1047.

Impact – measured by contribution and influence on regulations and policy



Evaluation, Reporting and information (data) management



## **Outreach and cooperation**

#### **School awareness activities**



#### **Capacity building**



#### **Universities**













More info please visit:

http://biosafety.org.za https://www.pub.ac.za

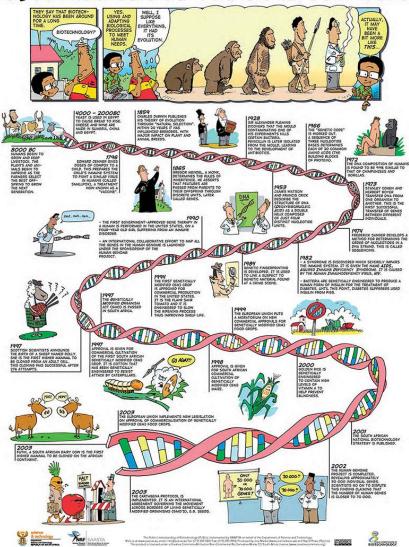
## **Examples of publications**



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## **Examples of publications**

## BIOTECHNOLOGY THROUGH THE AGES

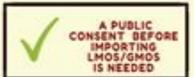


# 15TH ANNIVERSARY CARTAGENA PROTOCOL ON BIOSAFETY



OUR COUNTRY IS PART OF
AN INTERNATIONAL AGREEMENT:
THE CARTAGENA PROTOCOL ON BIOSAFETY
ENSURING THE SAFE HANDLING, TRANSFER AND
USE OF LIVING MODIFIED ORGANISMS (LMOS)
KNOWN AS GENETICALLY MODIFIED ORGANISMS
(GMOS)







STRICT RISK ASSESSMENTS AND
RISK MANAGEMENT OF GMOS/LMOS ARE DONE
AT EVERY STAGE OF GMO IMPORTS
TO EVALUATE AND MONITOR
BEFORE AND AFTER
THESE PRODUCTS ARE AVAILABLE



SIGNIFICANT INFORMATION, EXPERIENCE AND EXPERTISE OF THE REGULATION OF GMOS ENSURES SUSTAINABLE DEVELOPMENT

-Hennie Groenewald

# Case study Public perceptions of Biotechnology in South Africa

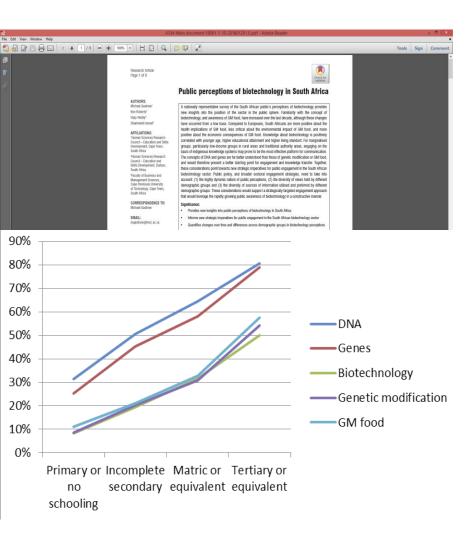


Figure 1, Knowledge of core biotechnology concepts, by education level.

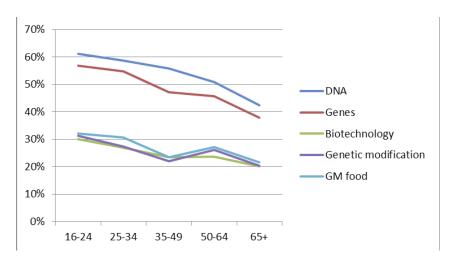
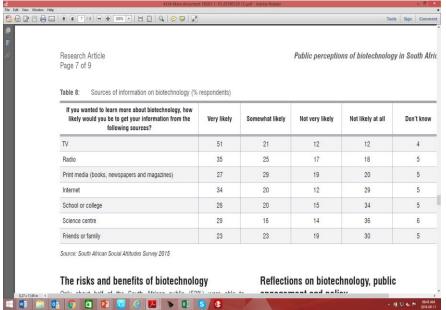


Figure 2, Knowledge of core biotechnology concepts, by age group.





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