



REGULATORY AND SAFETY ASSESSMENT PERSPECTIVES: SOUTH AFRICA

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Food Allergy and Safety Assessment Workshop
Nairobi (Kenya)
11-12 August 2014



OVERVIEW

- Biosafety South Africa
- Regulatory framework
- Risk Assessment
- Safety assessment for foods derived from GM crops
- Labeling of GM crops in South Africa
- Communication surrounding GM crops
- Summary

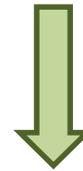


BIOSAFETY SOUTH AFRICA

National biosafety service platform that:

Promotes biosafety and sustainability of biotech products > delivery of value adding services

Investment in strategic biosafety research



Operate under the auspices of

- *Technology Innovation Agency (TIA)*
- *Department of Science and Technology (DST)*



science & technology

Department:
Science and Technology
REPUBLIC OF SOUTH AFRICA

to support innovation in biotechnology



SOUTH AFRICAN REGULATORY FRAMEWORK FOR GMOs

- South Africa has had a fully developed regulatory framework for GMOs since 1997
- Why the need for regulation?

Conventional foods are considered safe > History of safe use

GM crops → novel traits

- The novelty aspect associated with the crop > GM crops undergo formal, rigorous environmental and food safety assessments to ensure their safety
- New risk assessment approach developed



RISK ANALYSIS AS THE BASIS FOR THE REGULATORY SYSTEM

- A comprehensive risk analysis is the basis of all regulatory activities associated with GMOs.
- Although there is some variation in how risk analysis frameworks are presented they always follow the same basic, iterative steps:
 - setting the context (comparative and case-by-case)
 - risk assessment
 - risk management
 - risk communication
- Information to be collected during field trials are based on the outcomes of the risk analysis.



SOUTH AFRICAN REGULATORY FRAMEWORK FOR GMOs

Number of national and international regulations govern the use of GMOs in South Africa.

Aims :

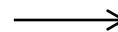
- Ensure that any activities with GMOs are assessed with regards to their potential risks to human health and the environment.
- Ensure that approved activities are conducted in a controlled manner including, if necessary, strategies to mitigate and/or manage any potential risks.

National Regulation



- GMO Act (*Act No.15 of 1997; Act No. 23 of 2006*)
- NEMBA Act (*Act no. 10 of 2004*)
- NEMA Act (*Act no. 107 of 1998; Act no. 8 of 2004*)

International Regulation



- Cartagena Protocol
- Codex Alimentarius





REGULATION OF BIOTECH PRODUCTS IN SOUTH AFRICA

POTENTIAL IMPACT	LEGISLATION	EXAMPLE OF HOW THE LEGISLATION IS APPLIED
Human health and safety	Medicines and Related Substances Control Act	Ensuring the safety, efficacy and quality of human and animal medicines and medical devices, e.g. pharmaceutical products and animal vaccines.
	Foodstuffs, Cosmetics and Disinfectants Act	Regulation of the quality and safety of food, e.g. obligatory quality control, the use of safe additives and colorants and the indication of nutritional information.
	Occupational Health and Safety Act, 1993	Ensuring implications with regard to the health and safety of the workers, cleaning personnel and any other person, involved with activities with GMOs are taken into account.
Environmental safety	Environmental Conservation Act	The regulation of biotechnological activities/products, e.g. cheese or vinegar production where the environment may be impacted by waste production or the activity itself.
	National Environmental Management Act	Regulates products, activities and developments to ensure that they are socially, environmentally and economically sustainable, e.g. renewable resources.
	National Environmental Management Biodiversity Act	Regulates, for example, the sharing of benefits arising from bioprospecting involving indigenous biological resources.
	Agricultural Pests Act	Provides measures by which agricultural pests may be prevented and combated. For example prohibiting the importation of equipment that might be contaminated.
	Animal Diseases Act	Provides measures for the control of animal diseases and parasites, e.g. restricting the importation of controlled animals and the prerequisite for quarantine.
Socio – economic	Patents Act and/or Plant Breeders' Rights Act	Makes provision for the protection of new technologies and/or varieties of plants generated through biotechnological techniques such as marker assisted breeding.
	Consumer Protection Act	Protects consumers by ensuring access to information and honest marketing, e.g. minimum labeling requirements and substantiating claims to health benefits.
	Intellectual Property Rights From Publicly Financed Research Act	Protects intellectual property emanating from publicly financed biotechnology research and development projects and ensures that it is available to South Africans.
	Conservation of Agricultural Resources Act	The regulation of activities that involve alien and weedy species, as used for example in forestry, to prevent the introduction or spread of invasive species.

Genetically Modified Organisms Act
 Regulates all activities with GMOs, including confined research and development, field trials, general release and import/export of any GMO.

SOUTH AFRICAN REGULATORY FRAMEWORK FOR GMOs (National Regulation)

- GMO Act is implemented by the Directorate Biosafety of the Department of Agriculture, Forestry and Fisheries
- Act makes provision for the appoint of members to regulatory bodies (AC, EC) which exercise oversight over the safety assessment and approval of GMO applications.



GM CROPS IN SOUTH AFRICA

- Commercial GM crops in SA: 3 crops (maize, cotton, soybean)
2 traits (herbicide tolerant, insect-resistant)
multi-national companies

GMO ACTIVITIES APPROVED UNDER THE GENETICALLY MODIFIED ORGANISMS ACT, 1997

Type of approval: **General release – conditional**
 Use of the event: Importation/exportation
 Commercial planting
 Food and/or feed

Event	Crop	Trait	Company	Year approved
TC1507	Maize	Insect resistance Herbicide tolerant	Pioneer	2012
BT11xGA21	Maize	Insect resistance Herbicide tolerant	Syngenta	2010
GA21	Maize	Herbicide tolerant	Syngenta	2010
MON89034xNK603	Maize	Insect resistance Herbicide tolerant	Monsanto	2010
MON89034	Maize	Insect resistance	Monsanto	2010
Bollgard IIxRR flex (MON15985x MON88913)	Cotton	Insect resistant Herbicide tolerant	Monsanto	2007
MON88913 (RR flex)	Cotton	Herbicide tolerant	Monsanto	2007
MON810xNK603	Maize	Insect resistant Herbicide tolerant	Monsanto	2007
Bolgard RR	Cotton	Insect resistant Herbicide tolerant	Monsanto	2005
Bollgard II, line 15985	Cotton	Insect resistant	Monsanto	2003
Bt11	Maize	Insect resistant	Syngenta	2003
NK603	Maize	Herbicide tolerant	Monsanto	2002
GTS40-3-2	Soybean	Herbicide tolerant	Monsanto	2001
RR lines 1445 & 1698	Cotton	Herbicide tolerant	Monsanto	2000
Line 531 / Bollgard	Cotton	Insect resistant	Monsanto	1997
MON810 / Yieldgard	Maize	Insect resistant	Monsanto	1997





Safety of foods
derived from
GM crops

Subject of significant
interest between
technology developers,
consumers and policy
makers

Questions



“Are GMOs safe to eat?”
“Can they cause allergic reactions?”
“How are the safety and quality of GM foods ensured?”

GM FOOD SAFETY ASSESSMENT

- GM foods undergo more rigorous safety assessments than conventional foods because of the novelty aspect associated with the crop
- New risk assessment approach developed
- Led to the development of the concept of Substantial Equivalence = comparing the novel food (GM) to its conventional counterpart (non-GM)
- Goal is not to establish absolute safety but rather to consider whether the GM food is **as safe as its conventional counterpart** > significant differences therefore become the focus of the assessment
- The National Department of Health developed a national guideline on the "*Food Safety and Risk Assessment of Genetically Modified Organisms and Products Thereof*" in line with Codex Alimentarius requirements.

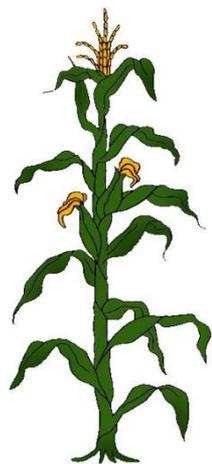


GM FOOD SAFETY ASSESSMENT

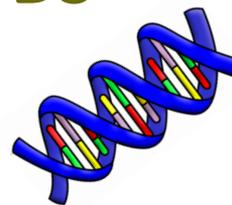
- Applicants must submit all the relevant data required for the food safety assessment including full descriptions of the test procedures, methods, results and conclusions.
- In general, the assessment of the safety of GMOs intended for food or feed is conducted on a case-by-case basis.
- Ultimately, food safety assessments are conducted to provide science-based evidence that foods derived from GM crops are safe for consumption.
- Environmental safety and socio-economic sustainability of a GM crop have to be assessed and approved before the crop can be released for commercial production.



ELEMENTS IN THE SAFETY ASSESSMENT OF GM FOODS



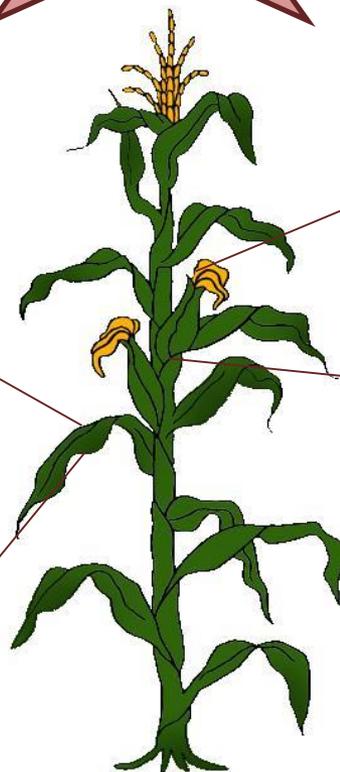
1. Host plant & its use as food (known natural toxins/allergens)



3. Genetic material and modification process used to introduce the GM trait into host plant

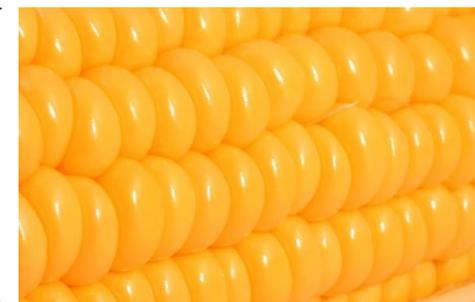


2. Donor organism(s) (known natural toxins/allergens)



4.1. GM molecular characterisation

4. GM plant



4.2. Food safety

- new expressed substances (toxicity & allergenicity);
- compositional analyses;
- evaluation of metabolites;
- food processing;
- nutritional modification



LABELING OF GM FOOD IN SOUTH AFRICA

Consumer Protection Act (DTI, since October 2011)

- Applies to goods approved by the GMO Act's Executive Council
- Food producers, importers, packagers have to choose one of three mandatory labels for GM foods:
 - GM content at least 5% = **“containing GMOs”**
 - Food produced directly from GMO sources = no need for testing, labelled as **“produced using genetic modification”**
 - Argue scientifically impractical and not feasible to test food for GM content = **“may contain GMOs”**
- Voluntary labels:
 - GM content is 0.9% or less = **“does not contain GMOs”**
 - GM content is between 1% and 4.9% = **“GM content is less than 5%”**
 - **“May contain genetically modified ingredients”** if it can't be detected



LABELING OF GM FOOD IN SOUTH AFRICA

OCTOBER 2012 > DTI published draft amendments to the regulations governing the labeling of GM food.

All locally produced and imported food containing **5% or more GM ingredients or components** = must be labelled as "**contains genetically modified ingredients or components**".



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Maize products consumed in Namibia contains GMO

18 Feb 2013

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There are strong indications that some of the maize products consumed in Namibia contains a certain level of the banned growth enhancement substance known as the Genetically Modified Organisms-GMO.

A study conducted by the Namibia Consumer Trust, NCT, on three maize products in Namibia shows that GMO was used either during production or in their processing.

According to the findings, the Ace Instant Porridge contained close to 57 percent, White Star Maize Meal nearly three percent and Top Score Maize Meal just over one percent of the GMO.

The NCT's Chairperson Sandi Tjaronda describes this as a total violation of consumers' rights, adding that Namibia being a signatory to the Cartagena Protocol, Namibia through the Namibian Agronomic Board has to see to it that the Bio-safety Act is implemented.

Kaaronda stresses that the long-term impact of GM food has not yet been established and that is why over 40 countries worldwide, including Kenya in Africa, have decided to totally ban or restrict such products.

He notes that if the Bio-safety Act is enforced, the agronomic industry will not be able to sell GM food without the knowledge of consumers.

Some more maize samples from the maize triangle of Otavi have also been taken to laboratories for further tests.

The NCT held a media conference in Windhoek on Monday.

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SUMMARY

- South Africa has had a fully developed regulatory framework for GMOs since 1997
- A comprehensive risk analysis is the basis of all regulatory activities associated with GMOs
- National and international regulations govern the use of GMOs in South Africa.
- The regulation of GMOs in SA is principally governed by the GMO Act and aims to regulate responsible use of GMOs
- Act makes provision for the AC and EC to oversee the safety assessment and approval of GMO applications.
- Regulation of biotech products takes human health & safety, environmental and socio-economic aspects into consideration



SUMMARY

- GM foods undergo rigorous safety assessments > based on substantial equivalence
- The National Department of Health developed guidelines on the "*Food Safety and Risk Assessment of Genetically Modified Organisms and Products Thereof*" > in line with Codex Alimentarius requirements.
- Food safety assessment of GMOs are conducted on a case-by-case basis to provide science-based evidence that GM foods are safe for consumption.
- Specific labeling requirements exist in South Africa regulated by the Consumer Protection Act.
- Biosafety issues should be communicated with care based purely on science





THANK YOU

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