The South African Regulatory System

Gillian Christian, Registrar, Genetically Modified Organism Act of 1997,
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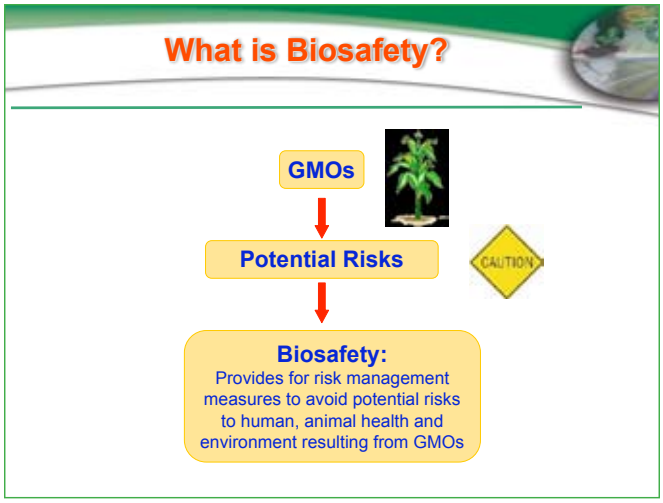
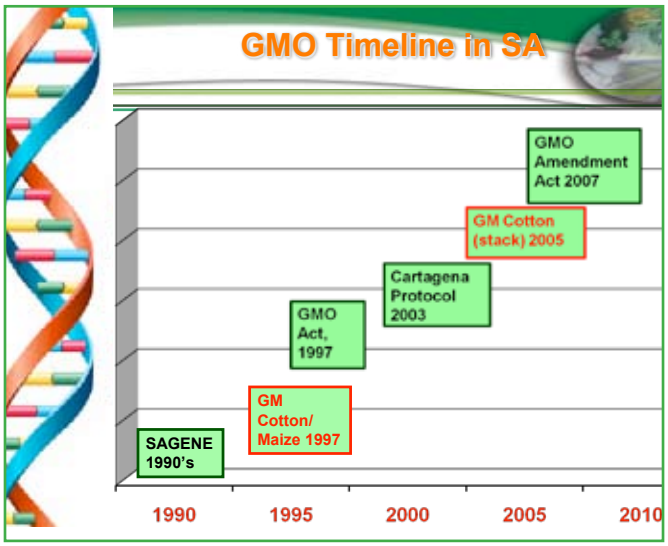
Since the implementation of the Genetically Modified Organisms Act of 1997 (Act 15 of 1997) (GMO Act) in December 1999, all activities with GMOs in South Africa (SA) are conducted according to permits issued in terms of this Act. Due to the growing importance of Biosafety and related issues, the Department decided to elevate the GMO unit, previously housed in the Directorate Genetic Resources, to a fully functioning directorate. The GMO Act is now administered by the Directorate Bio-safety and makes provision for the appointment of a Registrar, two regulatory bodies i.e. the Advisory Committee and the Executive Council and inspectors.



The Registrar, who is appointed by the Minister of the Department of Agriculture, Forestry and Fishery, is responsible for the administration of all activities in terms of the GMO Act. GMO applications are subjected to a multidisciplinary process of scientific evaluation by an expert panel of scientists constituting the Advisory Committee (AC), which acts as the national advisory body on all matters relating to GMOs. The Advisory Committee consists of ten scientists who are appointed by the Minister of Agriculture, Forestry and Fisheries. The Advisory Committee is further supported by subcommittee members representing an extended pool of scientific expertise from various disciplines. The Advisory Committee together with subcommittee members are responsible for the evaluation of risk assessments of all applications as it relates to food, feed and environmental impact, following which a recommendation is submitted to the Executive Council.

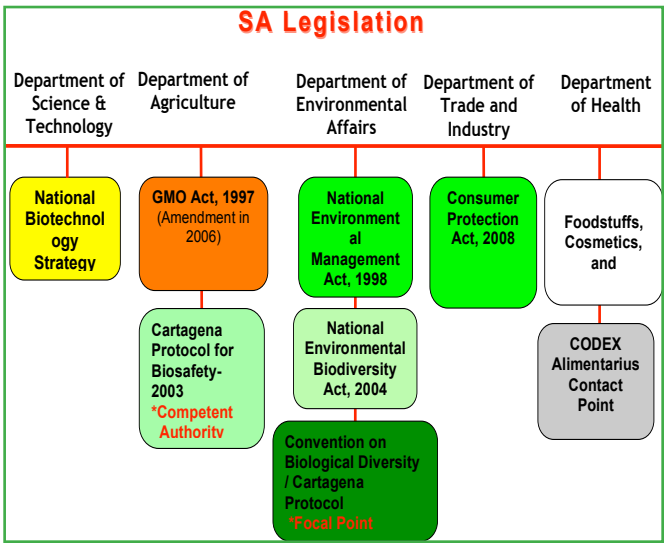
The Executive Council (EC) is the ultimate decision-making body and currently consists of officials from six different government departments (Agriculture, Forestry and Fisheries, Health, Environmental Affairs, Labour, Trade and Industry and Science and Technology) and the chairperson of the Advisory Committee who have all been appointed by the Minister in terms of the GMO Act. With the implementation of the

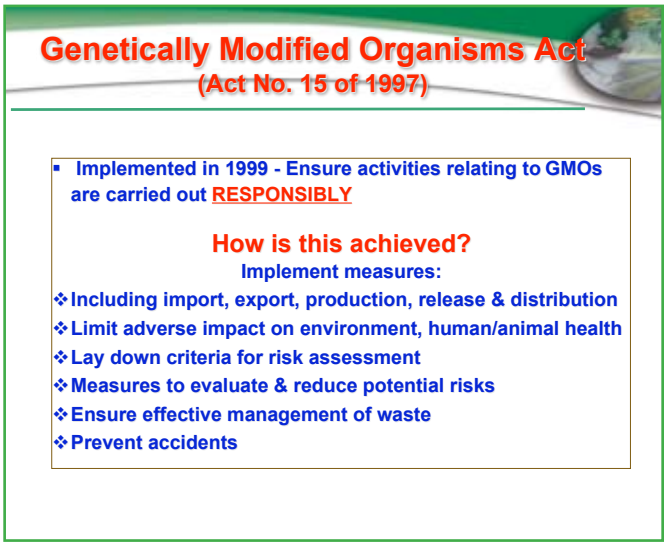


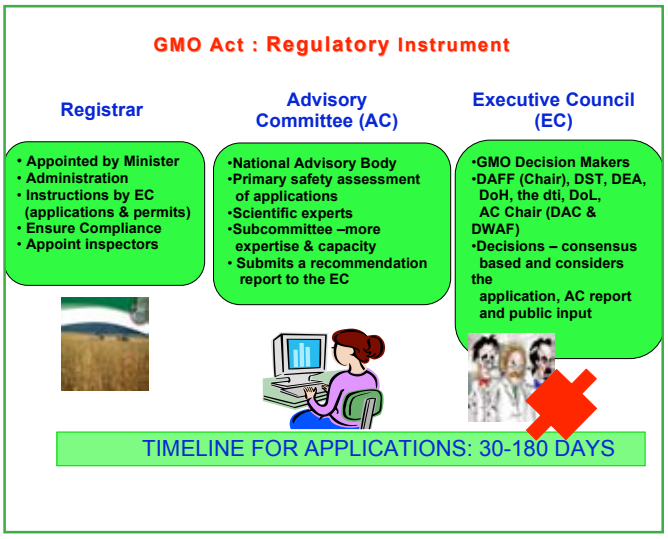
GMO Amendment Act, 2006 in the near future, the Council will additionally include members from the Department of Water Affairs and the Department of Arts and Culture.

The objectives of the Council are to advise the Minister of Agriculture, Forestry and Fisheries on all aspects concerning the development, production, use, application and release of GMOs, and to ensure that all activities with regard to GMOs (importation, exportation, transit, development, production, release, distribution, contained use, storage and application) are performed in accordance with the provisions of the Act. Approved GMO activities are regulated by way of permits issued by the Registrar and accompanying permit conditions are monitored for compliance by inspectors within the Department of Agriculture, Forestry and Fisheries.

The existence and application of the GMO Act in South Africa provides the country with a decision-making tool that enables

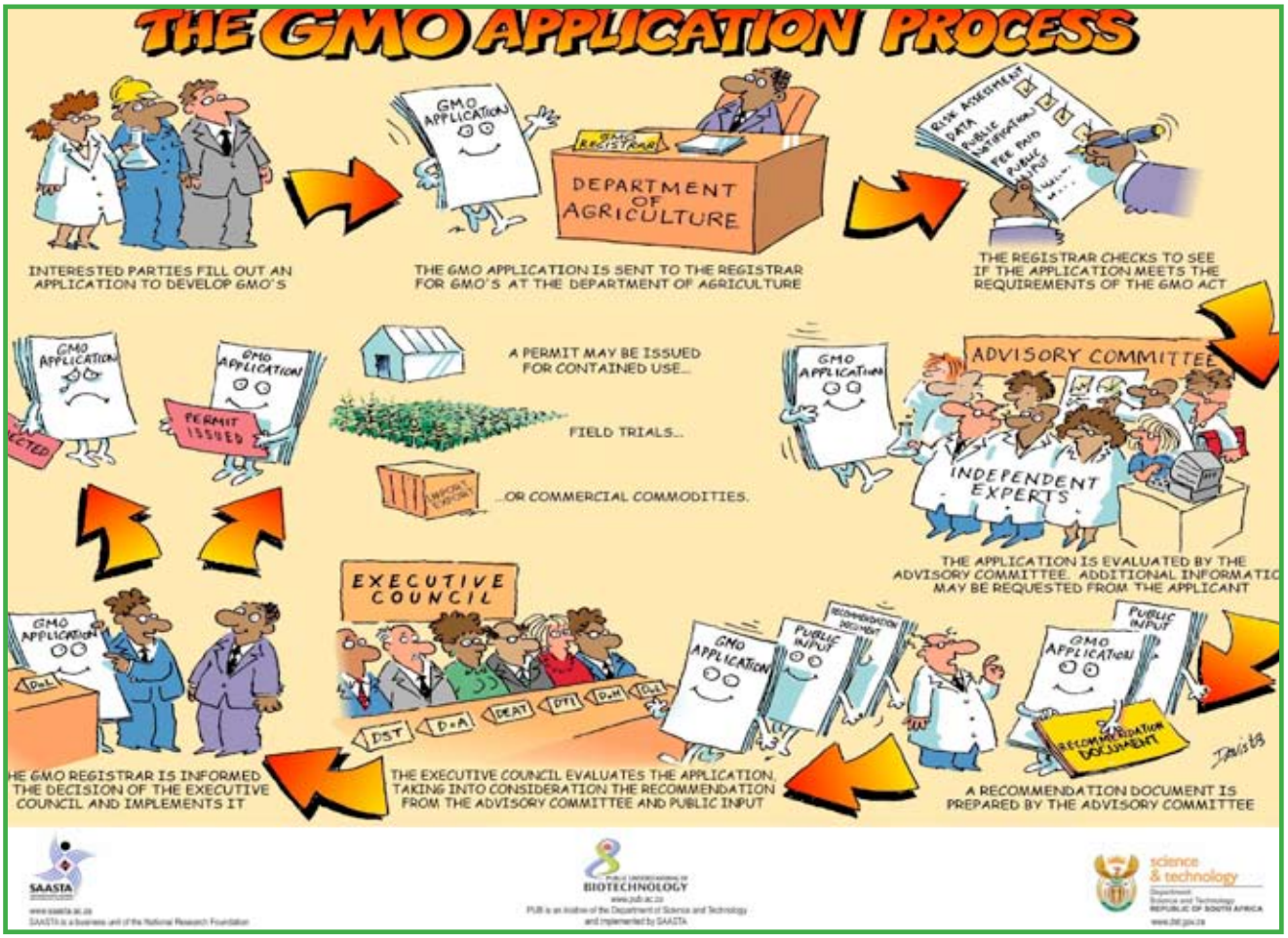






authorities in South Africa to conduct a scientifically-based, case-by-case assessment of the potential risks that may arise from any activity involving a particular genetically modified organism. The Biosafety regulatory framework thus provides an enabling policy environment that facilitates the availability of biotechnology in South Africa by ensuring the safety thereof.

Despite ten years of adoption in South Africa, genetically modified crops have exclusively incorporated traits for insect resistance and/or herbicide tolerance. As biotechnology advances beyond the realm of agronomic traits, the regulatory system will be particularly challenged to respond to these emerging new technologies. The directorate will therefore continue to pursue efforts to strengthen its regulatory framework, exploit capacity building initiatives and participate in regional and international biosafety engagements.



GMO Amendment Act (Act 23 of 2006)

- Process of amending the Act was initiated in 2003
- Amendments included:

❖ Expanding the scope to include the regulation of exports
❖ Alignment of legislation with provisions of Cartagena Protocol on Biosafety
❖ Alignment with related legislation such as National Environmental Management: Biodiversity Act, 2004
❖ Improve and streamline administrative processes into the Act

- The GMO Amendment Act will be implemented once the accompanying amendment regulations have been finalized

Permits

GMO activities are regulated through permits issued by the Registrar. These include permits for:

❖Import
❖Export
❖Contained use
(Activities in laboratories, greenhouse, glasshouse depending on containment levels)
❖Trial release
(Limited environmental release to provide for generation of SA data in different agro-ecological zones)
❖General release (conditional)
(Preceded by field trials, feeding studies, monitoring plan and annual reports etc)

Monitoring for compliance

- Monitoring for compliance to permit conditions are carried out by inspectors within the department.
- Inspection officials are authorized by the Registrar in terms of the GMO Act and perform functions aimed at:

❖Measure effectiveness of risk management measures
❖Detection of possible adverse impacts
❖Ensuring adherence to permit conditions - possible contravention - investigation - warrant

- Findings are reported through the submission of inspection reports

SA Area planted with GM crops 2008

- White maize: 891 000 hectares, 55.7% crop
- Yellow maize: 724 000 hectares, 72% crop
- Soybean: 184 000 hectares, 80% crop
- Cotton: 12 000 hectares, 90% crop *(90% small scale farmers)*

Total Area : 1,811 million hectares

(Source: Clive James, ISAAA 2008)

Public participation and access to information

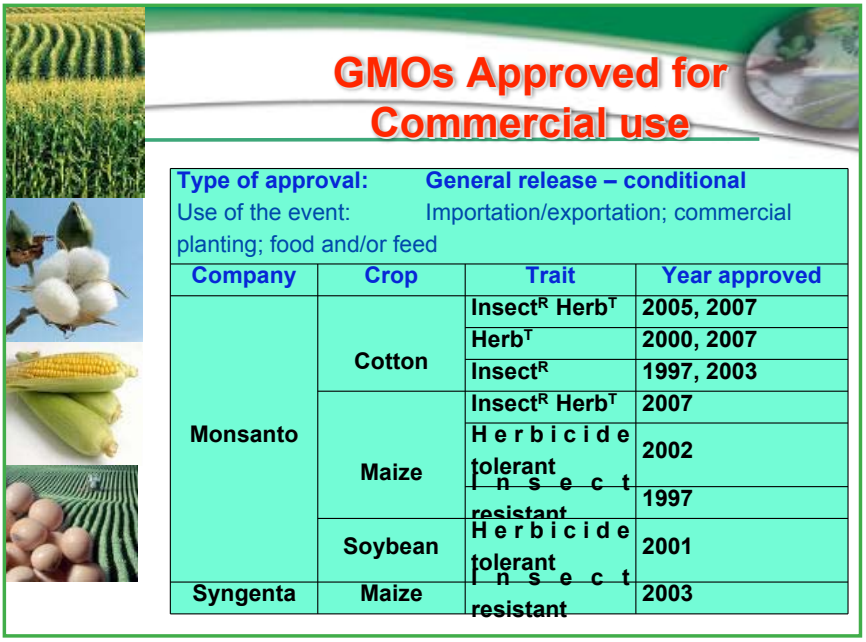
Information on regulated GMO activities can be accessed in various ways:

- Promotion of Access to Information Act
  (Non-confidential Business Information: *Name & Address of applicant, a general description of the GMO, the risk assessment & risk management measures)*
- Newspaper Notifications
  (Public notification by applicants for introduction of GMOs into environment)
- Departmental website (www.daff.gov.za)
  (Permits issued, info on EC decisions, guideline documents etc)
- Agricultural shows, exhibitions
  (Awareness regarding bio-safety regulatory activities)

GM Cotton in SA

Approved events in SA:

- Bollgard (Bt)
  - ❖ naturally occurring soil bacterium
  - ❖ American bollworm
  - ❖ Red bollworm
  - ❖ Spiny bollworm
- Roundup Ready (RR)
  - ❖ tolerant to Roundup Ready herbicide
- Stacked Bt x RR
  - ❖ combined insect resistance and herbicide tolerance



Regulatory Requirements and Technology Diffusion: The Case of Biotech Cotton

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(Presented by Idah Sithole-Niang, Zimbabwe)

The International Cotton Advisory Committee (ICAC) reported that during 2008/09, 48% of the world cotton area was planted to biotech cotton varieties while 54% of all cotton produced globally was from biotech varieties, and that 52% of all cotton traded internationally was biotech cotton. Biotech cotton consisted of the two major traits, insect resistance (IR) herbicide tolerance (HT) used singly, or in combination. The countries that grew this cotton represented both developed and developing economies, including two from Africa, South Africa and Burkina Faso. Growing biotech cotton requires biosafety regulatory oversight, and in Africa, there are only 9 countries with functioning regulatory frameworks, of which only 6 have conducted confined field trials. This paper presents the regulatory requirements and technology diffusion of biotech cotton in a few African countries.

Development of Transgenic Cotton

Transgenic cotton, biotech cotton, is developed by introducing a foreign gene using recombinant DNA and transformation technologies. Expression in the plant is driven by a promoter, and the gene is introduced into the cells of a desirable cotton variety using one of following techniques:

- *Agrobacterium*-mediated
- Particle bombardment using the gene gun
- Pollen tube pathway

The transformed cells carrying a gene of interest are selected using a selectable marker gene, usually coded for an antibiotic or for herbicide resistance. The cells are then regenerated back into a whole plant. Coker 312 is the most common variety that is used for transformation of cotton, as it regenerates with relative ease. Following regeneration, plants with the best agronomic performance and consistent levels of expression of a gene of interest are selected and selfing was done to produce homozygous plants. The progeny is crossed with a preferred variety and back crossed, over several generations, to recover the preferred variety with the gene of interest.

Genes of Interest with Insecticidal Activity

There are four groups of insecticidal genes namely the (a) *Bacillus thuringiensis* (Bt) *crystalline* δ-endotoxins, (b) Bt vegetative insecticidal proteins (Vips), (c) protease inhibitors, and (d) lectins. The Bt crystalline δ-endotoxins are derived from crystalline proteins found in the soil bacterium *Bacillus thuringiensis*. These toxins are activated by proteases in the insect midgut. Following this activation they bind specifically to receptors in the midgut, create pores that eventually lead to lysis and death. The VIPs are also derived from *B. thuringiensis* and bind to separate but specific receptors in the midgut. The protease inhibitors are from plants. They work by inactivating protease enzymes in the gut, thus preventing protein digestion. Lectins are proteins that bind carbohydrate, and in this case bind to carbohydrate moieties on the receptors in the midgut and interfere with gut function and iron metabolism.