GMO-related Activities, Biosafety and Governance Issues in South Africa

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Introduction

- Genetically Modified Organisms (GMOs): any organism, plant or animal which genetic material has been modified not by natural recombination or reproduction.
- Living Modified Organisms (LMOs): any organism, plant or animal which genetic material has been modified not by natural recombination or reproduction, which is **capable of replication**.

Introduction

- Modification of a plant to present certain characteristics (e.g. resistance to herbicide or insect or drought or enhanced nutritional contents or higher yields).
- Livestock or fish can be modified to grow faster, bigger or stronger.
- Featherless chicken, glittering fish or seahorses, malaria-fighting mosquitoes…
- The commercial cultivation of genetically modified (GM) crops is said to have started in 1999 in South Africa (SA). SA is the current leading exporter of genetically modified organisms (GMOs) in Africa with 80% of GM maize, 90% of GM soybean and 100% of GM cotton.

Introduction

- Main traits approved for commercial cultivation are insect resistance and herbicide tolerance.
- Testing of drought-resistant GM maize (Water efficient maize for Africa (WEMA) project (Kenya, Mozambique, SA, Tanzania and Uganda)).
- No official breeding, importing or marketing of GM livestock. No GM animal has been approved for release.
- Use of recombinant bovine somatotropin (rBST), a GM hormone used to stimulate milk production in cows.
- GM vaccine trials are being carried out for some diseases such as measles, HIV-AIDS and tuberculosis.

Outline

1. Overview of the biosafety framework

a. GMO-related Activities in SA

b. Permit and registration of facilities

c. Risk Assessment and Management

d. Labelling

2. Governance issues

a. **Policy** : balance of interests industry/farmers/public, economy/environment/health, apportionment of risks, financial security mechanism, transparency and access to information.

b. **Legal** : User of a GMO-related Activity, potential GMO-related Damage, legal causation, liability.

3. Rethinking the biosafety framework

4. Concluding remarks

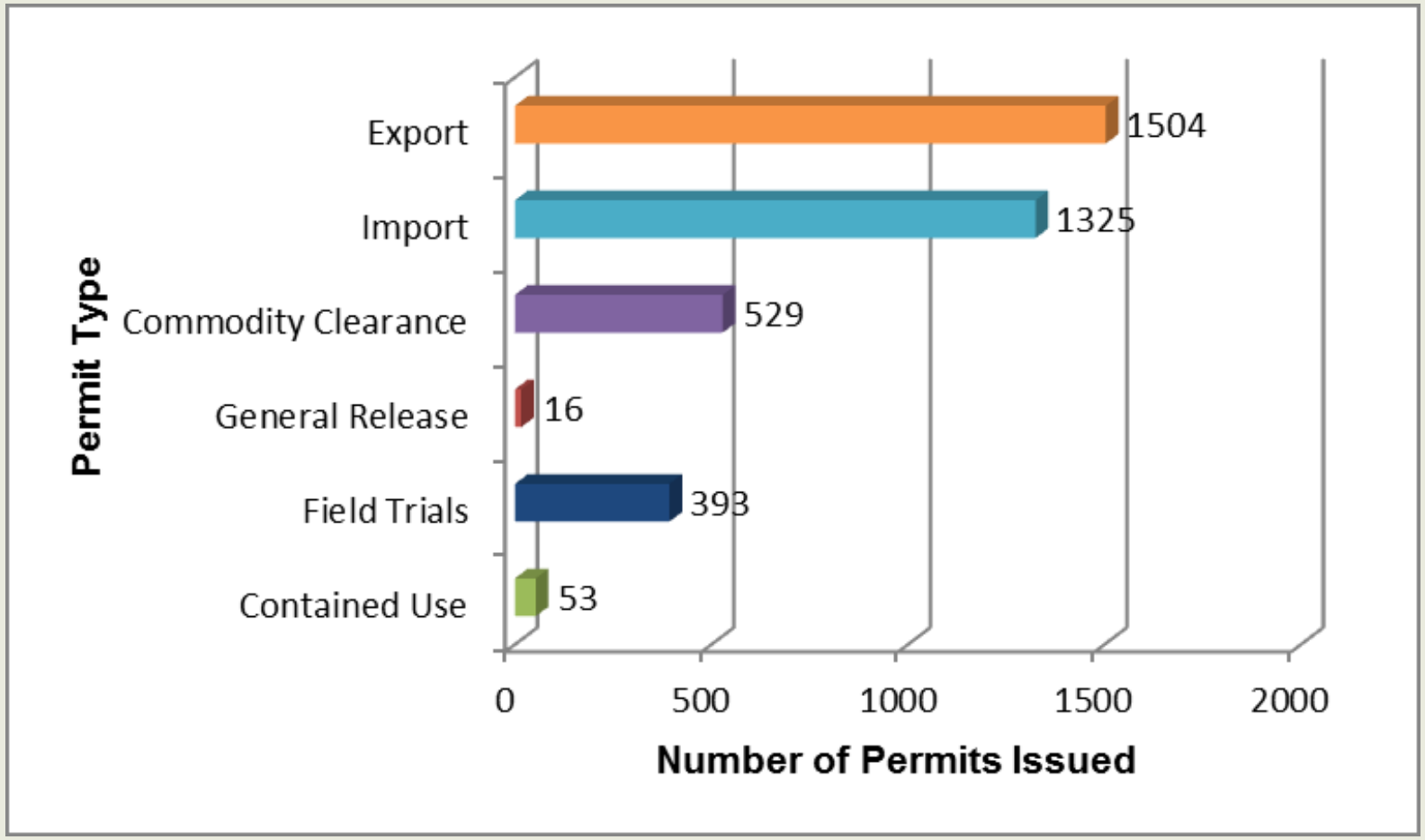
Biosafety Framework: GMO-related Activities

- All activities involving the genetic modification of organisms, the use of GMOs and the use of gene therapy (except human gene therapy). Not limited to the development, application, importation, exportation, production, release and distribution of GMOs (Section 2 of the GMO Act 1997).
- GMO regulations 2010, Regulations on Hazardous biological agents 2001, Guideline documents for environmental risk assessment and food safety regarding GMOs.
- Heavy investments required (520 million rands) for the development of a new GM crop (SA seed industry market value in 2010 = 3630 million rands). Seed regulation: Plant Improvement Act 1976, Plant Breeders' Rights Act 1976. National draft policy on intellectual property.

Biosafety Framework: GMO-related Activities

- Development of GM vaccine (including growing GM plants that can be turned into vaccines).
- Regulation of GM vaccine trials: GMO Act, National Health Act 2003 and Good Clinical Practice guidelines (conduct of clinical trials with human participants), approval of the Medicine Control Council for clinical trials.
- Regulation of pharmaceutical products: Medicines and Related Substances Control Act, Guidelines for Good Manufacturing Practice for Medicines.

Biosafety Framework: Permits (1999-2013)



Biosafety Framework

- Permits required except for organisms used under contained use (containment level 1 and 2).
- Registration of facilities for GMO-related activities for 3 years.
- Duty for users to ensure that appropriate measures are taken to avoid an adverse impact on the environment (Section 17(1) GMO Act).
- The Registrar administers the GMO Act while inspectors are responsible to verify compliance with conditions of the permit. The GMO Act is implemented by the Directorate Biosafety of the Department of Agriculture, Forestry and Fisheries (DAFF).
- The Executive Council (the Council) is the decision-making authority (with members from 7 different State agencies (DAFF, DoH, DST, DEA, DTI, DoL, DAC) after the recommendations of the Advisory Committee which examines all applications for a permit.

Biosafety Framework: Risk Assessment and Risk Management

- Risk assessment and risk management relating to :

*Field trials of transgenic plants and placing on the market of GMOs for cultivation or food or feed purposes.

*Use of pathogens or pathogenic organisms and GMOs in contained facilities.

*Research and development activities for GMO medicinal products and gene therapy.

- Submission of a scientifically-based risk assessment regarding the environment, human and animal safety as well as risk management measures.
- Case-by-case risk assessment which must consider all available scientific information by relevant international organisations. Partly non-transparent risk assessment because of confidentiality of some business information.
- Assessment of socio-economic impacts may include *inter alia* food security, diversity and availability of genetic resources, cultural knowledge and traditions.
- The Advisory Committee (composed of independent scientists with various scientific backgrounds) advises the Council as to the level of risk associated with the activity and permits.

Biosafety Framework: Risk Assessment and Risk Management

- Guidelines for an environmental risk assessment (ERA) regarding GMOs provide minimum requirements
- The South African National Biodiversity Institute (SANBI) is responsible to monitor and report on the environmental impacts of GMOs released into the environment.
- The Council may require an environment impact assessment (EIA) and a socio-economic assessment of a GMO-related activity.
- The Minister may, on the recommendation of the Council, by notice in the Gazette prohibit any activity involving GMOs (Section 14 GMO act).

Biosafety Framework: Risk Assessment and Risk Management

- The Department of Environmental Affairs (DEA) provides general guidance regarding EIAs for GMOs, the criteria that may trigger an EIA and the administrative procedure to follow.
- Regulatory dossier development for a general release: detailed development of GMO, field trial report, food and safety report, environment report, socio-economic issues, risk communication strategy, compliance with mitigation plans, conditions in the GMO permit once a general release is granted.
- To date, an EIA for a GMO has not been required in SA. Since December 2014, EIA regulations require an environmental authorization for the release of GMOs based on a basic assessment report and an environmental management programme.

Biosafety Framework : Labelling

- "**Contains GMOs**" label : goods approved for commercialisation by the Council and all goods containing **at least 5% of GM content** irrespective of whether they are produced in SA or elsewhere **(Regulation 7 (1 April 2011)).**

* "**Produced using genetic modification**" label if the good is produced directly from GM sources and no testing is needed.

* **"May contain GMOs"** label if it can be argued that it is scientifically impractical to test the GM content (Regulation 7(6) of 2011).

* Any **GM ingredient or component containing GMOs** must be labelled (Regulation 7(4) of 2011).

* Products cannot be labelled GM-free unless the percentage of GM is less than 1. (Food with less than 1% pork indicating "pork-free" product?)

- **Voluntary labelling** may be used if the GM content of a product is less than 5% but more than 1% however it is not stated which label is to be used.

Food with GM labels?

- Pioneer's Sasko bread labelled as "soyabean produced using genetic modification"
- Premier's IWISA maize labelled as "contains genetically modified organisms"
- Pioneer (Sasko's) Food's White Star maize meal labelled as "produced using genetic modification"
- Pioneer Food's (Bokomo's) corn flakes labelled as "corn 90% (genetically modified)"
- Certified organic banana Umbhaba only says GM banned under organic standards.
- Woolworths' Ayrshire milk and Parmalat Farmers' Pledge claim no use of recombinant bovine somatotrophin/GM growth hormones (rBGH/rBST).

Governance Issues: Policy

- The National Biodiversity Strategy and Action Plan identified GMOs and invasive species in the list of threats or drivers of negative environmental change.
- Balancing of interests: (1) biotech industry, farmers, public (2) Economy, environment and public health (no unanimity among government departments)
- Apportionment of risks: biotech industry/State/users/public. Financial security mechanism: insurance, financial deposit.
- Risk assessment approach (comparative risk analysis or toxicology risk assessment)? Development of risk mitigating strategies to mitigate the health and environmental risks of GM products.
- Confidentiality of business information issue.
- Scientific uncertainty? Lack of scientific consensus not an absence of risk, level of risk or accepted risk.
- Independent GM vaccine experts to be included in the Advisory Committee.
- Measures to be taken in the case of known controversial uses/products: glyphosate herbicide, antibiotic gene-markers..

Governance Issues: Legal Aspects

- The “user” means a person who conducts an activity with a GMO (Section 1 GMO Act). If a GMO is stolen, is there a presumption of “use”?
- Who is the user of the GMOs during transit ? Implications for LMOs?
- Technical and financial hurdles for a victim to establish causation and prove the extent of the damage.
- Potential negative effects of GMOs may manifest themselves in the long term and be diffuse in nature.

Potential GMO-related Damage

- “Hazard" means an intrinsic biological, chemical or physical characteristic of a GMO which could lead to an adverse impact on the environment (GMO Act Section 1).

An immediate or delayed adverse effect on the conservation and sustainable use of biological diversity, human health and animal health.

-Unintended impacts of insect-resistant GM crops on vulnerable non-target organisms and insects (beetles, butterflies, bees..). SANBI report on MON810.

-Outcrossing of GM plants with wild species, neighbouring fields...

-Use of herbicides on herbicide-resistant GM crops (pollution of land, water, biological resources, super weeds, super-bugs). Glyphosate’s carcinogenic effects on human beings (WHO 2015 report on glyphosate by 17 experts from 11 countries).

Potential GMO-related Damage

-Unintended impacts of field trials on biological diversity (non food-crops such as GM vaccine plants, GM crops for biofuels…) and coexistence issues of GM food crops and non-GM food crops.

-Contamination of non-GM foods: local maize variety in Eastern Cape, unlabelled baby foods containing GM maize, unlabelled GM soya in bread, unlabelled GM products on sale.

Once a single contamination has been identified, testing and monitoring may often result in several other incidents involving the same GM line in one or different countries.

-Contamination by illegal/unauthorised GMOs (Greenpeace/Genewatch UK GM contamination register 1997-2013: 396 contamination incidents across 63 countries (maize = 25% of contamination incidents; soya and rapeseed = 10%). (US Starlink Corn recalls, US illegal GM rice).

-Long-term effects of milk from rBST-treated cows on human beings?

Potential GMO-related Damage

-Mixing of GM and non-GM seeds: Iversen et al paper (detection of transgenes in local maize of small scale farmers due to mixing of GM and non-GM seeds during seed storage in Eastern Cape).

-Personal injury (allergenic reactions, toxicity, use of antibiotic-resistant gene markers, as a result of vaccine trials..).

-Animal health (Seralini's paper on chronic toxicity effects of roundup herbicide and NK603 maize)

-Economic loss (loss of organic status by GM-free/organic farmers and export market).

-Environmental damage (adverse effects on the land and biological resources due to the use of pesticides for herbicide-resistant GM crops, loss of biodiversity).

-Quantum of damages for catastrophic and irreversible damage and how to measure the vulnerability of non-target organisms (beetles, bees..)?

Potential GMO-related Damage

- Biotech industry: patent cases on GM crops, the 2010 Compact (a private compensation mechanism for damage caused by LMOs on biodiversity by leading biotech companies (BASF, Bayer CropSciences, Dow AgroSciences, DuPont, Monsanto and Syngenta)).
- Significant and adverse change to biodiversity measured by comparing the nature and quantum of change of the species or ecosystem from the baseline.
- Mitigation potential damage to biodiversity and response measures (restoration or compensation or combination thereof).
- Remediation of damaged species or ecosystems or alternative restoration (replacing the loss of biodiversity with components of biodiversity for the same or another type of use at the same or another location).

Statutory Liability provisions

-In the case of damage, the user of the GMO concerned is responsible for notifying the Registrar for GMOs and take all necessary measures to eliminate and remedy the effects of the damage (Section 17(1A) GMO Act).

-No specified standard for liability in the case of damage caused by GMO-related activities. Liability is borne by the user concerned (Section 17(2) GMO Act). Liability for damage during vaccine trials?

Rethinking the Biosafety Framework…

- Compulsory EIA for field trials involving non-food and feed GM crops and record of previous trials in other countries.
- Transparency on risk assessments and no confidential business information for competent authorities.
- Longer term assessment of effects of GMOs .
- Need for a pre-market and post-market surveillance for the monitoring of local as well as imported GM foods.

* Lowering of the labelling threshold for GM content to 1% and better enforcement of labelling requirements with an adequate inspection team.

* Stronger control of labels bearing healthier claims such as organic products and baby foods.

Rethinking the Biosafety Framework…

- State support for community seed banks and a national seed bank for local varieties.
- Need for a legal and policy framework for organic products.
- Need for a strict liability standard with the operator as the person liable for GMO-related damage.
- Transparency and better public awareness in the conduct and regulation of GM vaccine trials as well as the marketing and sale of pharmaceutical products including GMOs.

Rethinking the Biosafety Framework…

- Prohibition of the use of antibiotic gene-markers.
- Prohibition (if not mandatory disclosure) of the use of GM growth hormones in cows.
- Legal provisions for disclosure of GM feed and its control (Fertilisers, Farm Feeds, Agricultural and Stock Remedies Act 1947).
- Labelling requirements for animal and dairy products obtained from livestock fed with GM feed.
- Ratification of the Nagoya Kuala Lumpur Supplementary Protocol on rules and procedures pertaining to liability and redress for damage resulting from transboundary movements of LMOs.

Concluding Remarks

- With such a high GM crop acreage in SA is the biosafety discourse still relevant? (GM non-food and feed crops have not yet started, contamination by illegal GMOs/pathogenic GM micro-organisms may affect human health and the economy, concerns for GM vaccines trials).
- Testing for long-term exposure to GMOs deemed not necessary by the biotech industry however reluctance to label GMOs.
- Successful drought-resistant GM crops should preferably not be with stacked genes.
- The GMO debate is a lot about business with profits for GM seed and agrochemical producers and not necessarily in the interests of consumers or the environment.
- We may agree to disagree on the safety of GMOs for now but biosafety measures are necessary for all GMO-related activities and time will tell the rest.

- **Thank you for your attention**