

Liability and Redress Issues with regard to GMO- related activities in South Africa

**Environmental Law Association Conference,
Cape Town (25 August 2012)**

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Introduction

- As from 2007 in South Africa: 62% GM maize crop, 80% GM soybean crop and 90% GM cotton crop.
- Main traits approved for commercial cultivation are insect resistance and herbicide tolerance, but no official breeding, importing or marketing of genetically modified (GM) livestock.
- The potential risks posed by GMO-related activities call for a liability regime stringent enough to cater for GMO-related damages.
- GMOs involving living organisms likely to present more challenges to a liability regime than products derived from GMOs.
- Applicable civil liability and redress rules and possible legal challenges in this area in South Africa ?

Which activities?

- All activities involving the genetic modification of organisms, the use of GMOs and the use of gene therapy.
- These activities are not limited to the development, application, importation, exportation, production, release and distribution of GMOs (Section 2 of the South African Genetically Modified Organisms (SA GMO) Act 1997).

Statutory liability provisions

-In case of damage caused by a release of GMOs or a transboundary movement of GMOs, the user of the GMO 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) of the GMO Act).

-Liability for damage caused by GMO-related activities is borne by the user concerned (Section 17(2) of the GMO Act).



Possible legal challenges

- The interpretation of the term “user”
- The standard of liability
- Legal causation
- Scientific uncertainty issues
- The damage covered
- Limitation period
- Exemption from liability
- Financial guarantees

The Interpretation of the term « user »

- The “user” means a person who conducts an activity with a GMO (Section 1 **SA GMO Act**).
- Does possession have a presumption of “use”?
- Implications for self-replicating living modified organisms?
- Who is the user of the GMOs during field trials, during transit, and in the use of gene therapy ?
- Operator : any person in direct or indirect control of the living modified organism (LMO), including the permit holder, the person who placed the LMO on the market, developer, producer, notifier, exporter, importer, carrier, supplier (Section 2(2)(c) of the Nagoya Kuala Lumpur Supplementary Protocol hereafter the Nagoya Protocol).
- Use of the term “operator” by the European Directive 2004/35/EC on environmental liability, for the one who carries out an occupational activity which might be listed out as a dangerous activity.

Standard of liability

- No standard of liability is specified but a joint and several liability is applicable if more than one person may be liable (Section 17A(4) SA GMO Act).
 - If **a fault-based liability** is applicable, a person conducting a GMO-related activity is liable if there is evidence of a fault or negligence.
- *In case of **an approved activity**: liability of South African competent authorities for negligence?
- *In case of **an unauthorised activity**: the SA State can sue the person who may be liable.
- **Difficulties in measuring intent** to release the GMO (in contained uses, release into the environment or placing on the market).
 - Intent is irrelevant when GM seeds are carried away by birds or the wind.



Standard of liability

- **If a strict liability is applicable**, a person conducting a GMO-related activity is held liable irrespective of any fault or negligence (on the basis of risks caused by these activities?).
- Will it be the GMO permit-holder, the notifier, the exporter, the importer? In the case of an institution?.
- The GMO permit-holder is liable for any damage caused by the GMO introduced on the market (See the Swiss Federal Law relating to Non-Human Gene Technology (Swiss FLRNGT) 2003).
- Capped or uncapped liability? Difficult to assess the level at which the liability should be capped and capping would reduce the application of the « polluter-pays principle ».



Legal Causation

- Potential negative effects of GMOs may manifest themselves in the long term and be diffuse in nature.
- Technical and financial hurdles for a victim to establish causation and prove the extent of the damage.

Legal Causation

- **Establishment of the causal link based :**

- ***On available information :** Confidentiality issues and access to information in the “Biowatch case”.

- ***On the standard of liability :**

- The burden of proof that the damage result from that specific GMO-related activity and that the defendant failed to exercise the care and skill expected of a reasonable practitioner in this field, lies on the person who brings the action if it is a fault-based liability.

- The burden of proof may be shifted to the person held liable by virtue of his or her activities if it is a strict liability.



Scientific uncertainty issues

- Difficulties of accurate assessment of the level of risk posed and the magnitude of potential damage.
- In case of a lack of scientific knowledge or scientific consensus, it shall not be interpreted as indicating :
 - a particular level of risk
 - an acceptable risk or
 - an absence of risk (SA GMO Regulation 4(6) 2010).
- **Need for specification:** for instance, if the proof of the causal link cannot be provided with certainty, the court may be satisfied with overwhelming probability on the basis of the state of scientific and technical knowledge at the time the damage occurred(See Article 33 Swiss FLRNGT).



Damages

- Damage resulting from GMO-related activities:
 - *Personal injury (allergenic reactions, toxicity, use of antibiotic-resistant gene markers..).
 - *Property damage (loss from contamination of land and crops).
 - *Economic loss (loss of organic status by GM-free/organic farmers, loss of 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).

Damages

- “Hazard” means an intrinsic biological, chemical or physical characteristic of a GMO which could lead to an adverse impact on the environment (**SA GMO Act 1997 Section 1**)

Need for precision that the damage caused must be a result of :

*The new properties of the organisms

*The reproduction or modification of the organisms

*The transmission of the modified genetic material of the organisms

(See Article 30(7) of the Swiss FLRNGT)

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

Damages which are measurable or otherwise observable and significant(**Article 2(2)(b) of the Nagoya Protocol**).

Balancing of interests between plants or animals at stake?

How to measure the vulnerability of non-target organisms (beetles, bees..).

Quantum of damages? Possibility of catastrophic and irreversible damage (loss of biodiversity).

To improve the assessment of the level of contamination of non-GM products

- A **lower threshold of tolerance than 5%** of genetic material.
- An **appropriate threshold for the adventitious presence of GMOs** that are contained in non-GMO shipments (Article 13 (2) of the African Model Law on Biosafety : minimum threshold should be less than 0.9%).
- **An official inspection and certification programme for organic food products** and other industries using organic agricultural commodities in their production in South Africa.

Remedial measures

- Duty of care for users to ensure that appropriate measures are taken to avoid an adverse impact on the environment and human and animal health (Section 17(1) SA GMO Act).
- In case a damage has been notified, the Registrar for GMOs and the user will investigate and assess the damage caused (Section 17 (1A) SA GMO Act).

Remedial measures

- **Response measures include but are not limited to the following :**
 - *Cease, modify or control any act, activity or process causing the damage
 - *Minimise, contain or prevent the movement of any GMO causing the damage if the respective activity cannot be avoided or stopped
 - *Eliminate any source of the damage
 - *Remedy the effects of the damage caused by the activity

Remedial measures

- **Need to provide more precision on applicable remedial measures:**

***Restore biological diversity through actions to be undertaken in the following order:**

-Restoration of biological diversity to the condition that existed before the damage occurred or its nearest equivalent and where the competent authority determines this is not possible;

-Restoration by *inter alia*, replacing the loss of biological diversity with other components of biological diversity for the same or for another type of use either at the same or as appropriate at an alternative location.

(Section 2 (2) (d) Nagoya Protocol)

***Where the damage is likely to affect several States?**

***Response measures should be reasoned and a time-limit for response measures be provided.**



Remedial measures

- If a person fails or inadequately implements the measures contemplated in case of damage, the Executive Council for GMOs :
 - *May take any reasonable measure to remedy the situation and recover all costs.
 - *May make proportionate claims from any other person who benefited from these measures.
- **Who bears the costs of what cannot be recovered (the person liable has inadequate funds or no longer exists)?**

Remedial measures

- Only reasonable costs can be claimed by the Executive Council including labour, administrative and overhead costs (Section 17A(3) SA GMO Act).
- In case more than one person is liable, the Council may apportion the liability but such apportionment does not relieve any of them of their joint and several liability for the full amount of the costs. (Section 17A(4) SA GMO Act).
- Any order by the Council to recover all costs has the effect of civil judgment in a magistrate's court (Section 17A (5) SA GMO Act) .

Remedial measures

- **Obligations where there is no damage yet but an imminent threat of damage (Article 5(1) EU Directive 2004)?**
- **In case a damage is not notified or the user cannot be traced what is the applicable procedure?**
- Even if a damage is not notified, procedures need to be clear about who the competent authority will be to :
 - *Identify the user/operator who has caused the damage
 - *Evaluate the damage and
 - *Determine which response measures should be taken and by whom



Exemption from liability

- If the damage occurred when the GMO was in the possession of an inspector, unless such user foresaw or should have foreseen such damage and could or should have prevented the damage but failed to take reasonable action to prevent such damage” (Section 17 (2) of the SA GMO Act).
- Acts of God or force majeure/Acts of war or civil unrest and other exemptions or mitigations provided by domestic laws (Section 6(1) and (2) Nagoya Protocol).
- Proof of an act of God or through gross misconduct of the affected party or of a third party (Article 30(8)of the Swiss FLRNGT).

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Limitation period

- **Specific provisions on the time-limit to claim damages:** 3 years from the time when the injured party becomes aware of the damage and of the person liable but at the latest after 30 years from:
 - *The time that the event that caused the damage occurred in the company or;
 - *The date on which the GMOs were marketed (see Art 32 of the Swiss law).

Financial guarantees

- Identification of the appropriate entities to provide for financial security?
- Modalities of financial security mechanisms?
 - *Availability of insurance for damages resulting from GMO-related activities? A capped liability would help encourage the insurance industry to cover GMO damage.
 - *Compulsory insurance for environmental damage but GMOs may pose a level of potential clean-up cost for which accurate actuarial assessment may be difficult.
 - *Bond retained until such GMO poses no risk?
 - *Setting-up of a collective fund for damage?
Contributors?

Conclusion

- Ratification of the Nagoya-Kuala Lumpur Supplementary Protocol 2010 on rules and procedures pertaining to liability and redress for damages resulting from transboundary movements of LMOs.
- Policy issue for the South African government to decide how risks for these activities will be apportioned among the industry, citizens and the State. Will the State take responsibility for loss suffered that is left uncompensated by the liability regime in cases where damage result from approved GMO-related activities?
- Need for legal provisions for developers/producers of GMOs to ensure safety precautions by the setting-up of financial guarantees on damages resulting from GMO-related activities.



Conclusion

- Transparent and publicly understood provisions for liability for loss.
- Regulation of the organic products' market.
- Compensation for victims and restoration for the environment even if damage is discovered long after it occurred.
- However, there are limitations to a liability regime catering for damages resulting from GMO-related activities due to the unknown level of risk posed by GMOs and the unknown magnitude of potential damage of GMOs.

- **Thank you for your attention**

