KISCH IP



New Genomic Techniques in **South African Agriculture**

Regulation, Intellectual Property & the Emerging Policy Direction

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INTRODUCTION

South African agriculture operates at the intersection of food security, economic competitiveness and increasing environmental pressure. Drought, heat, plant disease, water scarcity, increased input costs and biodiversity concerns are placing growing demands on agricultural production, while farmers and breeders are expected to increase resilience and productivity without proportionately increasing the environmental footprint of farming.

Genetic improvement has always formed part of agriculture, with breeders selecting plants for characteristics such as yield, preferred characteristics, appearance, shelf life, pack out rate, disease resistance, environmental adaptability, nutritional quality and production efficiency. Biotechnology expanded the available breeding toolbox through recombinant DNA technologies and genetically modified organisms ("GMOs"), and more recently through new genomic techniques ("NGTs"), including targeted gene-editing tools such as CRISPR/Cas systems.

NGTs expose a regulatory difficulty that legislation written for an earlier technological era did not necessarily anticipate, raising the question whether South Africa's GMO regulatory regime is sufficiently flexible to deal sensibly with technologies capable of producing very different biological outcomes.

A single targeted nucleotide change with no retained foreign DNA should not automatically be assumed to present the same regulatory problem as a stable transgenic construct merely because both involve techniques that alter genetic material. Equally, a technically small edit does not necessarily mean that the biological effect is insignificant.

A workable regulatory system needs to be able to draw a distinction.

SOUTH AFRICA IS NOT NEW TO *AGRICULTURAL BIOTECHNOLOGY*

Genetically modified maize, soybean and cotton have been cultivated commercially in South Africa for many years. The country's broader bioeconomy literature records substantial adoption of GM crops and agricultural and food-security benefits associated with their use.

The NGT policy debate is therefore not fundamentally concerned with whether biotechnology belongs in agriculture. South Africa already regulates and uses biotechnology at scale. What is changing is the technology itself.

The commercial experience with GM crops also demonstrates another important point for NGTs: the value of a biological innovation is not determined in the laboratory alone.

A plant variety must still move through field development, regulatory assessment, seed multiplication, variety registration, intellectual property and freedom-to-operate review, market acceptance, selection of attractive traits, domestic marketing requirements and, in many cases, export-market rules before the agricultural value can be realised. The costs and complexities of these pathways affect which innovations ultimately reach farmers.

Large multinational developers may be able to absorb substantial regulatory and intellectual property expenditure. Public breeders, smaller seed companies and developers working on crops with relatively small commercial markets may not be able to do so.

This becomes particularly important with NGTs, because one of the potential advantages is the ability of NGTs to shorten or simplify certain breeding tasks through the rapid introduction of preferred traits. That technical advantage can be lost if the downstream regulatory and legal pathway remains disproportionate to the characteristics of the resulting product.

HOW ARE GMOS *REGULATED* IN SOUTH AFRICA?

The principal biosafety statute is the Genetically Modified Organisms Act 15 of 1997, as amended by the Genetically Modified Organisms Amendment Act 23 of 2006. The Act was designed both to enable the responsible development and use of GMOs and to manage potentially harmful consequences to the environment. It establishes the Executive Council, Advisory Committee and Registrar and provides the framework for applications, risk assessment, permits and regulatory control.

Its definition of a GMO is central to the NGT debate. A GMO is defined as an organism the genes or genetic material of which has been modified in a way that does not occur naturally through mating or natural recombination or both.

The GMO Act does not operate in isolation. Environmental legislation, plant-improvement law, plant breeders' rights, patent law, food regulation and other regimes may independently apply to the same product at different and overlapping stages in its development.

The Supreme Court of Appeal underscored this in *African Centre for Biodiversity NPC v Minister of Agriculture, Forestry and Fisheries and Others* in October 2024. The case concerned a GMO general-release approval and the relationship between the GMO regulatory process and environmental-law requirements. The Court set aside the relevant approvals after finding that the statutory decision concerning whether an environmental assessment was required had not properly been dealt with. The case is an important reminder that scientific confidence does not cure a defect in legal process.

Any future NGT framework therefore needs to be scientifically sound and legally and administratively defensible.

BIOSAFETY IS ONLY ONE PART OF THE INNOVATION PATHWAY: *PATENTS AND PLANT BREEDERS' RIGHTS*

Regulatory approval should not be confused with commercial freedom to operate.

A plant may be acceptable from a biosafety perspective while remaining subject to patent rights, plant breeders' rights ("PBRs"), seed-registration requirements or other commercial restrictions.

Patent rights may protect aspects of agricultural biotechnology including, depending on the applicable claims, editing tools, delivery technologies, methods, particular sequences, traits and technical applications. Patent protection is fundamentally exclusionary. A person may therefore be prevented from commercially exploiting protected subject matter notwithstanding that the resulting plant is otherwise lawful from a biosafety perspective.

Plant breeders' rights, by contrast, protect qualifying plant varieties. South Africa's Plant Breeders' Rights Act 12 of 2018, which commenced on 1 June 2025, establishes proprietary protection for qualifying plant varieties. Plant breeding is inherently cumulative. Breeders frequently use existing varieties as starting material for further breeding. PBR systems therefore contain mechanisms intended to accommodate continued breeding while protecting the economic interests of the breeder of the initial variety.

Patent rights and PBRs do not always align neatly.

A breeder may be entitled under PBR law to use a protected variety for further breeding and yet still lack freedom to commercialise the resulting product, because of patent rights directed to the editing technology, sequence or trait concerned.

The breeder's exemption under PBR law therefore does not, by itself, exclude patent infringement questions.

NGTs make this tension between patent rights and PBRs even more visible. Suppose a breeder takes a successful protected variety and introduces a targeted disease-resistance edit. The resulting variety may be distinct and commercially valuable while retaining most of the original genetic material. Several questions may then arise. Is the new variety essentially derived from the initial variety? Does a patent cover the edited trait? Was the editing platform used under licence? Does the breeder's exemption extend far enough to support the intended commercial activity? These questions are regulated under different legal regimes and regulatory approval under the GMO Act, should therefore not be confused with freedom to operate under the patents or PBRs Acts.

WHAT ARE NEW GENOMIC TECHNIQUES?

NGTs are not a single technology or a single biological category. The term is used broadly to describe newer genomic methods capable of producing targeted genetic changes. CRISPR/Cas systems are the most familiar example, but the broader technical landscape includes zinc-finger nucleases, TALENs, base editing, prime editing and related approaches.

Different NGTs can generate substantially different outcomes. A breeder may produce a single nucleotide substitution, a deletion, a small insertion, a gene knockout, an allelic replacement, multiple targeted changes or a more complex genomic alteration. The final plant may contain foreign genetic material, or it may contain none. This is why the regulatory debate becomes distorted when "NGTs" are spoken about as though they all present the same problem.

Technique, genetic change and phenotype are separate enquiries. A small targeted genetic change might be identical to variation that occurs naturally or could arise through conventional breeding or mutagenesis. Conversely, a technically small alteration can have a significant biological effect if it modifies an important regulatory region or biological pathway. A sensible regulatory system needs to accommodate both possibilities.

THE REGULATORY PROBLEM: PROCESS, PRODUCT AND RISK

NGTs expose a longstanding tension between three regulatory approaches.

- *A process-based approach* places substantial weight on the technique used to produce the plant.
- *A product-based approach* focuses more closely on the characteristics of the resulting plant and genetic change.
- *A risk-based approach* calibrates scrutiny according to biological characteristics, trait, exposure, intended use and plausible harm.

These approaches need not be mutually exclusive. Process information may remain relevant where it affects uncertainty, detectability or molecular characterisation. But the mere fact that a modern genomic tool was used does not itself determine every biologically relevant characteristic of the final plant.

Difficulty arises when the targeted change produces a plant materially comparable, at the relevant locus or trait, to one that could have arisen through another breeding route. This is where statutory classification and regulatory proportionality become important.

SOUTH AFRICA'S CURRENT POSITION:
NGTS ENTER THE EXISTING GMO FRAMEWORK

THE 2021 POSITION

In October 2021, the Executive Council published South Africa's regulatory approach to new breeding techniques. The notice concluded that the existing GMO risk-assessment framework applies to NBTs. In practical terms, this means NGT-derived products enter the existing GMO regulatory system rather than a distinct precision-breeding pathway. It is often said that South Africa therefore follows a blanket process-based approach.

The 2021 position is based on the Executive Council's interpretation of the existing GMO definition. The more precise criticism is that the present system does not offer a clearly established route for differentiating between materially different NGT-derived products according to their final characteristics and relevant risks. This becomes particularly difficult where a plant contains no retained foreign recombinant DNA, involves a targeted change and produces an outcome that could plausibly have arisen through another breeding route.

The current South African statutory position leaves no simple product-only route out of the GMO system, but administrative guidance cannot lawfully create an exemption that contradicts the GMO Act.

LEGAL STATUS IS NOT THE SAME AS REGULATORY BURDEN

An organism may fall within the statutory definition of a GMO while nevertheless being subject to differentiated regulatory treatment, provided that such differentiation is authorised by the Act. Conversely, an organism that does not fall within the statutory definition of a GMO presents a fundamentally different legal question. The distinction is important: "Is this organism a GMO?" and "What regulatory burden should this GMO bear?" are separate legal inquiries.

THE MINISTER OF AGRICULTURE SIGNALS A POLICY SHIFT

The political and administrative context changed materially in 2026. At the Grain SA Congress on 11 March 2026, Minister of Agriculture John Steenhuisen stated that advances in plant-breeding technologies, including new breeding techniques and gene editing, offer opportunities to improve crop resilience and yield stability.

More importantly, the Minister stated that the regulatory framework governing genetically modified crops was ***"currently being updated through a tiered risk-assessment system under the GMO Act"*** intended to align regulatory oversight with level of risk while supporting scientific innovation.

Subsequent departmental remarks at the 2026 AFSTA Congress provided additional context. They indicated that discussions had considered simplified processes for certain low-risk applications without compromising safeguards and that the Executive Council was considering the outcomes of those discussions.

The Minister's statement has signalled a policy direction towards more proportionate regulation, but a political statement should not be confused with an enacted regulatory regime.

The practical debate has nevertheless shifted. The key legal issue is now how far differentiated treatment can lawfully proceed under the existing GMO Act, and where further legislative authority is required. That requires distinguishing four routes: statutory interpretation, administrative discretion, regulation-making and legislative amendment.

STATUTORY INTERPRETATION COMES FIRST

The first question is whether a particular plant falls within the statutory definition of a GMO under the GMO Act as it presently stands. That requires interpretation of the statutory definition and its application to the relevant scientific facts.

The Act refers to genetic material modified in a way that does not occur naturally through mating or natural recombination. The interpretive difficulty is whether this focuses primarily on the process used, the resulting genetic change, or both. The issue is particularly acute where the final plant contains no foreign DNA and the same genetic outcome could arise through another breeding route.

Where the statutory definition clearly applies, an administrative body cannot treat a plant as falling outside the GMO Act, merely because it would produce a more convenient policy result. Nor should "could have occurred naturally" be treated as though it were already the statutory test. It may be a useful scientific comparator or future legislative criterion, but it cannot replace the statutory wording.

Where genuine interpretive uncertainty remains, the competent authority may nevertheless make a reasoned determination of the plant's regulatory status.

ADMINISTRATIVE DISCRETION

Even where a plant falls within the GMO Act, the next question is what evidence and procedure are required. This is where administrative discretion becomes important.

The regulator must be able to require the information reasonably necessary to assess the risks contemplated by the statutory framework. It should not automatically follow, however, that every NGT product requires the same evidentiary package developed for a conventional transgenic event. The evidence required should bear a rational relationship to the regulatory decision being made.

A framework developed primarily for stable recombinant transgenic events should therefore not automatically become the evidentiary template for every targeted genomic modification, particularly where particular requirements do not address a material uncertainty in the case before the regulator.

Administrative discretion cannot, however, dispense with requirements imposed by legislation. The proper objective is therefore proportionality within the bounds of legality.

REGULATION-MAKING UNDER SECTION 20

Section 20 of the GMO Act may provide an important statutory basis for differentiated regulatory treatment. It empowers the Minister to make regulations concerning the classification of GMOs and classes of GMOs exempted from control under the Act.

This creates an important distinction between GMO status and regulatory control. A plant may remain a GMO within the statutory definition while falling within a class lawfully exempted from control. The key question is the scope of that exemption power, including whether exemptions may be partial or conditional and whether some regulatory requirements may be retained while others are relaxed.

Section 20 therefore suggests a possible legal middle ground between administrative guidance and amendment of the Act.

PARLIAMENTARY AMENDMENT

If South Africa wishes to provide clearly that a defined category of qualifying NGT-derived plants falls outside the GMO Act, amendment by Parliament would provide the clearest legal basis.

Parliament could define such a category and prescribe criteria for exclusion. These could address retained foreign DNA, categories of targeted genetic change, gene drives, higher-risk applications, record-keeping and future regulatory review.

Such an amendment could provide greater legal certainty for breeders, regulators, investors and trading partners, while preserving greater scrutiny where the characteristics or risks of a particular plant warrant it.

NGT REGULATION AND INTELLECTUAL PROPERTY REMAIN *SEPARATE* LEGAL QUESTIONS

A more proportionate biosafety pathway will not, by itself, resolve the separate intellectual property considerations raised by NGTs. An NGT-derived variety may proceed efficiently through biosafety regulation while still requiring consideration of patent rights, essentially derived variety status and applicable licensing arrangements.

Regulatory reform should therefore be considered alongside the intellectual property framework governing access to protected technologies, traits and plant varieties. Questions of patent scope, licensing structures and the interaction between patent rights and PBRs may influence the practical ability of breeders to develop and commercialise follow-on innovations.

The policy challenge is to maintain effective incentives for innovation while ensuring sufficient legal clarity and workable pathways for subsequent breeding and commercialisation. NGTs make this interaction increasingly significant because they can reduce the time required to introduce a targeted trait into an existing genetic background.

WHAT SHOULD *SOUTH AFRICA* DO NEXT?

A staged approach appears most appropriate.

The existing statutory definition should first be tested against representative NGT scenarios. Regulators can then determine how far current administrative powers permit differentiated and proportionate treatment.

Section 20 should be considered carefully, particularly its classification and exemption powers. Regulations may be used where clearly authorised by the Act, while legislative amendment would provide the clearest basis for any durable exclusion of qualifying NGT-derived plants.

Throughout this process, related legal regimes should remain distinct but coordinated. Biosafety, environmental law, patents, PBRs, seed regulation and trade raise different legal questions, and their respective tests should not be conflated.

CONCLUSION

South Africa's NGT debate increasingly concerns how reform should be structured. The key is to distinguish between statutory interpretation, administrative discretion, regulation-making and legislative amendment.

Biosafety reform should also be considered alongside patents, PBRs, essentially derived variety status and freedom-to-operate considerations, all of which may affect the development and commercialisation of NGT-derived plants.

The objective should be a clear and proportionate framework that reflects South Africa's agricultural priorities, scientific capacity and commercial realities.



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