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Republic of South Africa

PUBLIC NOTICE:
27 October 2021

SOUTH AFRICA'S REGULATORY APPROACH FOR NEW BREEDING TECHNIQUES

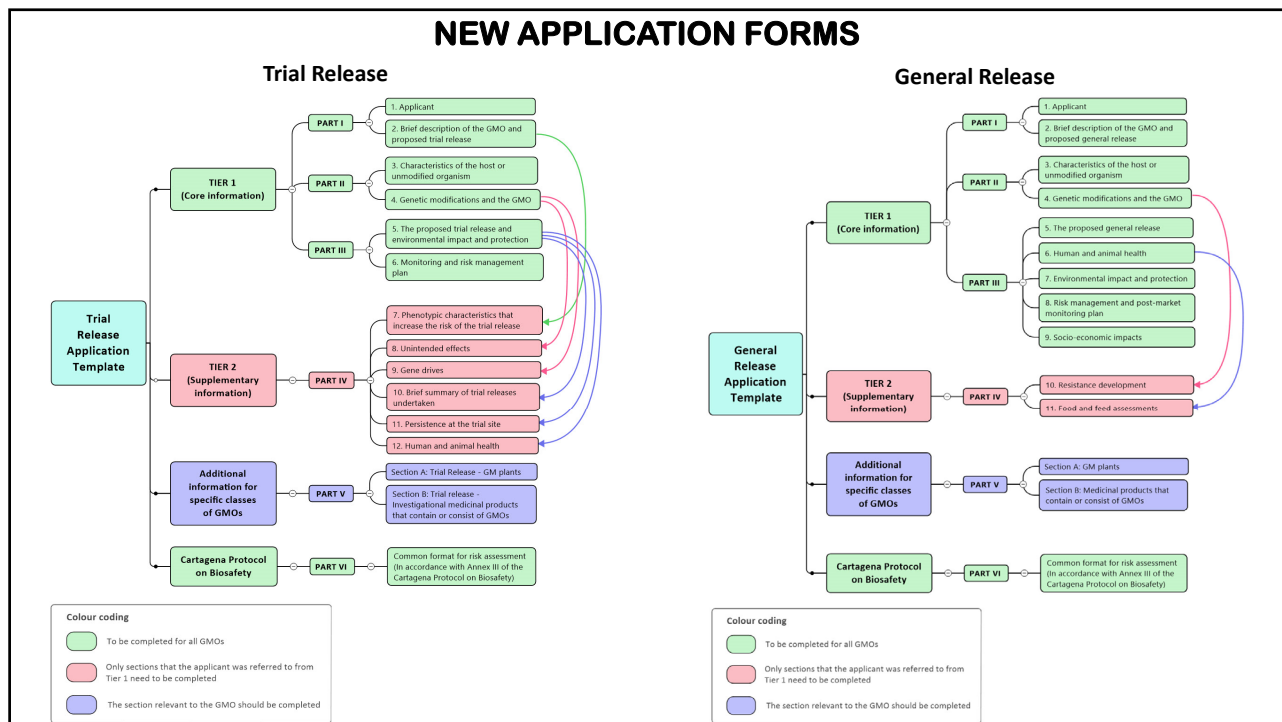
New breeding techniques (NBTs) provide new methods for genetic engineering and enable the production of a range of innovative products. These products are differentiated from those generated using early genetic engineering tools. The nature of NBTs led to discussions whether or not these techniques and their products must be subject to the existing regulatory system for GMOs.

In South Africa the Genetically Modified Organisms Act 1997 (Act No. 15 of 1997), as amended by Genetically Modified Organisms Act, 2006 (Act No. 23 of 2006), regulates the development and use of GMOs. The GMO Act defines a Genetically Modified Organism (GMO) 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. Based on the definition of a GMO under the GMO Act, the Executive Council has concluded that the risk assessment framework that exists for GMOs, would apply to NBTs.

In line with the above, the application templates for contained use, trial release, commodity clearance and general release have been revised and the use of the revised application forms will be effective as of 01 December 2021. The revised application forms will be published on the DALRRD website: [www.dalrrd.gov.za](https://www.dalrrd.gov.za/branches/Agricultural-Production-Health-Food-Safety/Genetic-Resources/Biosafety/Services/PDF-Application-Forms). The revised application forms will also be obtainable upon request from the Office of the Registrar: GMO Act at NompumeleloM@dalrrd.gov.za.

For further information please contact the Chairperson of the Executive Council: GMO Act at the following contact details:
Email: JulianJ@dalrrd.gov.za
Tel: 012 319 6536
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Date: For immediate use on 12 January 2022

JOINT NEWS RELEASE ISSUED BY AGBIZ, SANSOR AND CROPLIFE SA ON THE INDUSTRY APPEAL LOGGED AGAINST SOUTH AFRICA'S REGULATORY APPROACH TO CLASSIFY AND REGULATE ALL NEW BREEDING TECHNIQUES (NBTs) UNDER THE GENETICALLY MODIFIED ORGANISMS ACT 15 OF 1997

In October 2021, the National Department of Agriculture, Land Reform and Rural Development (DALRRD) announced that a diverse and evolving group of products derived from new breeding technologies (NBTs) will be evaluated under the risk assessment framework that exists for Genetically Modified Organisms (GMOs) under the Genetically Modified Organisms Act, 1997 (Act 15 of 1997, GMO Act).

South Africa's decision to regulate all products derived from NBTs as GMOs will have widespread implications not only in South Africa and on South African innovators, but also with regards to international trade of commodities that may contain products derived from NBTs. Asymmetric regulation may cause food insecurity and create significant barriers between South Africa and its trading partners. The current regulatory approach for NBTs will also discourage the development and uptake of the technology by all actors in the South African innovation and research space, including South African-owned seed companies, public and academic sector research organisations and small to medium-sized innovation enterprises.

At the end of November, the agricultural industry lodged an appeal under section 19 of the GMO Act particularly in support of the South African bioeconomy and local innovation and is looking forward to furthering communication regarding the next steps in this process.

In the appeal, under the umbrella of the Agricultural Business Chamber, industry partners suggested that South Africa proactively promote science-based regulation for products derived from NBTs. The broader agricultural value chain is committed to engaging in this process in good faith and to provide more detail to substantiate the points stipulated in the appeal. Agricultural Business Chamber also welcomes joint action with DALRRD and the Executive Council of the GMO Act, to remove any deemed obstacles and to facilitate effective, efficient, and evidence-based regulation of products derived from NBTs.

The South African regulator's interpretation of the GMO definition goes against the widely accepted principle that NBTs should not be regulated differently if they are identical to, or indistinguishable from products that could have been obtained naturally or through conventional breeding methods. This principle is upheld even in countries that use the living modified organisms (LMO) definition of the Cartagena Protocol on Biosafety, that are party to the Protocol, such as South Africa.

Because it would be nearly impossible to ascertain or uniquely identify whether genetic changes have been created by conventional breeding, random mutation, or an approach considered to be an NBT, it would be difficult to classify and test new products. This will create unsurmountable challenges for the reliable enforcement of any possible asynchronous decisions amongst trading partners, as it is not likely that a comprehensive list of products in the global supply chain that has been developed using certain NBTs, will be available.

This decision will risk the ability of South African farmers to access the latest innovative technologies that could further enable them to sustainably produce food with minimal environmental impact, as well as denying consumers access to better end-products.

It is also important to consider that companies who wish to supply products derived from NBTs in South Africa will have to incur additional costs to access the South African market. At worst, international suppliers may bypass South Africa due to time delays and additional regulatory and registration costs. There is also a significant reputational risk for companies if their products are deemed GMOs in South Africa whilst the very same products are not deemed GMOs in the rest of the world. This may result in domestic value chains only having access to outdated technology.

As agricultural challenges continue to grow in the face of climate change, increased pest and disease pressure, and a growing global population, it is imperative that innovative technology such as NBTs be part of the solution to help meet national commitments in terms of food security, climate mitigation and sustainability goals. Our agricultural sector must continue to remain competitive in the international playing field.

While we differ from the decision regarding the regulatory approach for NBTs in South Africa, SANSOR and the broader industry remain committed to engaging with the relevant decision-makers and government departments to create a regulatory environment that promotes innovation and competitiveness, whilst addressing any potential risks in an evidence-based manner. In doing so, the industry will bring these concerns to the attention of decision-makers when the decision on NBT regulation is being reviewed. As an industry collective we view the department and all relevant regulators as critical partners in this process and look forward to working closely to find a mutually acceptable solution.

Enquiries can be directed to

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PUBLIC NOTICE:

11 August 2023

MINISTER'S FINAL DECISION ON THE APPEAL LODGED BY AGRICULTURAL BUSINESS CHAMBER UNDER THE GMO ACT, 1997

The Minister of Agriculture, Land Reform and Rural Development, acting in terms of Section 19(6) of the Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997), has made a final decision on the appeal lodged by Agricultural Business Chamber against the decision taken by the Executive Council regarding South Africa's regulatory approach for New Breeding Techniques (NBTs).

On 26 November 2021, the Agricultural Business Chamber (AgBiz) lodged an appeal against the Executive Council's decision on the regulation of NBTs. The Executive Council decided that NBTs would be subjected to the same risk assessment framework which exists for GMOs, in line with the definition of a GMO under the GMO Act. The grounds for the AgBiz appeal included the following:

- The Executive Council decision was procedurally unfair;
- The definition of a GMO allows for multiple interpretations and could therefore feasibly be interpreted in a manner whereby some products derived from NBTs do not fall under the ambit of the GMO Act; and
- The Minister should give an interpretation to the definition of a GMO which is in line with international best practices.

The matter was referred to the appeal board appointed by the Minister of Agriculture, Land Reform and Rural in terms of Section 19 of the Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997). The Appeal Board deliberated on the matter and upheld the appeal. The reasons for the appeal board decision included the following:

- It appears that the decision was made without affording the persons affected by the decision any opportunity to make comments inputs into the decision-making process;
- The Executive Council's decision is the result of a process-based approach, in terms of which all organisms subjected to NBTs constitute GMOs. However, some NBTs produce non-GMOs and that most jurisdictions that have pronounced regulations on NBT-derived products have taken the alternative interpretation, that is, a product-based perspective; and

- Since the definition of a GMO in the GMO Act permits both a process-based and a product-based interpretation, which results in all NBTs constituting GMOs is in conflict with international best practice and thus unreasonable.

On 31 July 2023 the Minister made the final decision and upheld the Executive Council decision communicated in a public notice dated 27 October 2021. The Executive Council's decision to regulate NBTs under the Genetically Modified Organisms Act, 1997 provides the appropriate framework to manage any potential risks associated with this technology.

For further information please contact the Registrar of the GMO Act at the following contact details:

Email: NompumeleloM@dalrdd.gov.za

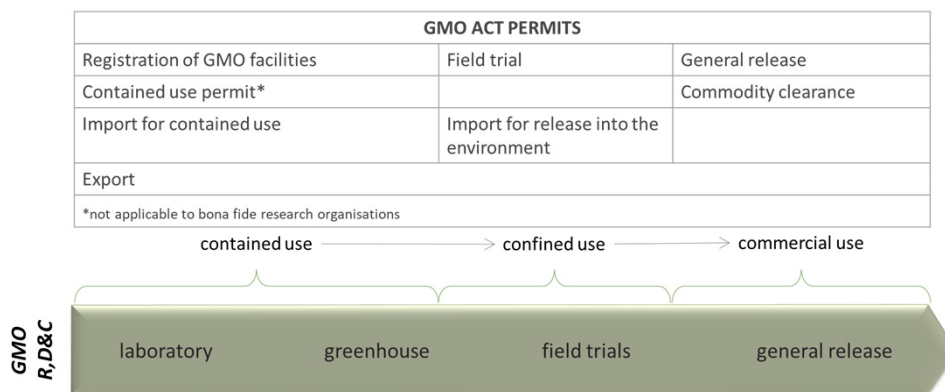
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CONCLUSION

- The products of all "NBTs" - including SDN-1 & 2 genome editing products - are regulated as GMOs in South Africa.
- Meaning...



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