Case for a different approach to new plant breeding techniques

Background

Although South Africa was an early adopter of Genetically Modified (GM) technology and has commercialised and imported multiple GM crops, lines, and medicines over the past three decades, not a single locally developed product has been commercialised - a result of the significant barriers to commercialisation in the GM sector.

Whilst the development of GM technology remains important, a new wave of technological developments has enabled genetics-based innovations that more closely mimic those underlying natural evolution. Products derived from these new plant breeding techniques (NBTs), e.g., genome editing products, are often indistinguishable from natural equivalents.

New NBTs are methods allowing the development of new plant varieties with desired traits, by modifying the DNA of the seeds and plant cells. With NBTs it is possible to breed a wide range of products, it depends on the type of edit made and whether DNA is added to the genome of a different organism or not. In the case where only small deletions or insertions with the same organism DNA is made it is considered to be similar to conventional breeding as the edit could also have happened naturally.

South Africa must be alive to the possibilities that these new innovations offer. NBTs have significantly reduced the technological inefficiencies and risk, and as a result the cost barriers, to induced genetic variation innovation. It has in fact democratised the technology, placing it within reach of public and SMME innovators, particularly those in the developing world.

Initially, there was considerable debate as to how these new products bred with new breeding techniques should be regulated. However, the great majority of countries have now decided that certain products should be exempt from GMO regulation."

The need for new plant varieties

Climate change has now become very real with almost daily reports of heat waves, floods, drought, and extreme storms in the news media. Key cultivating regions in Africa could become unviable in the coming decades under projected climate change scenarios. A recent study¹ done by the University of Bonn projected that if the European Union were to allow the adoption of already existing genetically modified crops, it could result in a reduction equivalent to 7.5% of the total agricultural greenhouse gas emissions of Europe. This is because larger yield increases in more crops would lead to larger greenhouse gas emission reduction. GM and crops bred with NBT hold great potential to assist farmers to adapt to the impacts of climate change. These crops can result in better yields and survive droughts and

¹ Genetically modified crops support climate change mitigation: Emma Kovak, Dan Blaustein Rejto, Matim Quan: https://doi.org/10.1016/j.tplants.2022.01.004

floods, thus helping to ensure sufficient food availability for an increasing global population and at the same time reducing the carbon footprint of agriculture.²

International trends and developments

Current international, best regulatory practice interprets induced genetic variation relative to naturally occurring genetic variation, as this represents a sound, risk-based regulatory threshold for GMO regulation. ³

To date, 19 countries have published their approach to products derived from NBT regulation. Of these, 16 have introduced a "confirmation of regulatory classification" function that enables them to decide on a case-by-case basis if a product should be regulated as a GMO or not.

Whilst most countries still regulate NBT products similar to conventional crops, the majority of them has an initial process where they determine if it should be classified as a GMO or not. All these systems only make the final decision after they reviewed each product. South Africa has, however, decided to follow a blanket approach to classify all products GM and regulate them the same. This approach undermines efforts to attract investment and promote innovation in South Africa, which ultimately undermines the competitiveness of the South African agricultural sector as a whole.

On the 5th of July 2023 the European Commission after many years of deliberations and studies published its proposal for Regulation of plants obtained by certain New Genomic Techniques. The proposal makes a distinction between two categories of New Genomic Techniques (NGT)(similar to NBT) plants

- Category 1: conventional-like NGT plants: This category requires a verification process. In case a plant meets the equivalence criteria, it follows the process for conventional plants.
- Category 2: non-conventional like NGT plants which are considered GMOs. These plants undergo a lighter type of GMO risk assessment.

This means that the EU will in future also differentiate between conventional-like NGT plants and traditional GMOs in terms of regulatory requirements.

Current approach of South African regulator

On the 27th of October 2021, the GMO Council issued a public notice declaring that the risk assessment framework prescribed under the GMO Act will apply to all products of NBT's, in effect classifying all products derived from NBTs as GMOs. The risk assessment process provided for in the GMO Act comes with substantial costs, stigma, trade implications and time delays. The GMO Act was drafted in the mid 1990's, before the development of NBT's.

² The future of eating: how genetically modified food will withstand climate change: Jay Sullivan: https://www.nhm.ac.uk/discover/the-future-of-eating-gm-crops.html

³ Entine et al 2021. Regulatory approaches for genome edited agricultural plants in select countries and jurisdictions around the world. https://doi.org/10.1007/s11248-021-00257-8

The current regulatory approach will greatly inhibit the development of improved crops for South African farmers and consumers, add to the regulatory burden of seed companies and all plant breeders and importers, and place an unnecessary regulatory burden on bioinnovators. Our South African Farmers will be affected the most as they will not have access to these new improved plant varieties that will help them overcome their many challenges such as climate change, an increase in pest and diseases and reducing input costs. This off course will then directly affect the public and consumers as well.

The definition of GMOs in the GMO Act of 1997 can be interpreted as either having a product- or process-basis. The definition reads as follows:

"genetically modified organism" means 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, and "genetic modification" shall have a corresponding meaning."

From a product-perspective "...modified in a way that does not occur naturally" is interpreted as referring to the resulting, modified genetic material itself, i.e., the genotype and by inference the organism or resulting product. Therefore, a GMO will be an organism with a genotype that could not have developed naturally, e.g., a maize plant containing a functional bacterial gene. In contrast, a process-perspective focusses on the act of modification and if this is a "natural" or "artificial" process. From this perspective a GMO will be an organism that results from an "artificial" process/intervention, irrespective of the characteristics of the resulting organism. As highlighted above, some products of NBTs can occur naturally and should not be classified as GMOs. However, such plants could be classified as GMOs if a process-based approach is followed. The South African regulator's current approach represents a process-based interpretation and will result in the bizarre legal construct where a plant will be classified as a GMO in South Africa whilst the very same plant is not regarded as a GMO in jurisdictions that follow a product-based approach. An interpretation that will allow a science-based risk management system to be followed, in line with international best practice will better serve all South Africans.

Recommendations

South Africa cannot afford to be left behind when it comes to developments in plant breeding. It does seem as if we are now out of step with what global and African trends when it comes to new breeding techniques. We need a science-based risk management system. It is possible to interpret the current definition of a GMO in the Act in such way that will allow for a product-based approach. South Africa should pro-actively consider international regulatory alignment and compatibility to promote science-based regulation for products derived from NBTs, to allow their safe and effective use and trade at a global level, particularly in support of locally developed products and the South African bioeconomy.

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