The Hon Thoko Didiza

Minister of Agriculture,

Land Reform and Rural Development

Private Bag X250

Pretoria

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The Hon Blade Nzimande

Minister of Higher Education

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CC: Dr Julian Jaftha, Chair, Executive Council of the GMO Act.

For Correspondence:

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Dear Ms Didiza and Dr Nzimande,

We represent a mix of academic, public and private sector scientists as well as bio-innovators within the agricultural sector. A recent decision by the Executive Council of the Genetically Modified Organisms (**GMO**) Act was made which seeks to regulate all organisms produced using new breeding technologies (**NBTs**; including genome editing) in a similar manner to transgenic organisms.

1. The need for NBTs

The improvement of agricultural organisms relies on the generation of genetic variation that leads to beneficial traits. This has traditionally been introduced by either crossing genetically diverse individuals within a species, or using mutagens. Such approaches alter many genetic loci within a genome and lead to organisms containing both advantageous and detrimental traits. The removal of disadvantageous traits by cross-breeding before the organism can be commercialised is a costly and time-consuming process.

In the 1980's transgenic technologies were developed which rely on new pieces of DNA from other species being randomly integrated into a genome. Although they have been of great use in improving crops for farmers, they are somewhat of a blunt tool. Because this technology involves insertion of novel DNA into the GMO, they are regulated under the GMO Act of 1997, which requires a great deal of information to be provided before commercial licences are granted. This means that only large companies have the capacity to commercialise such organisms, indeed only three multinational

companies (Corteva, Bayer and Syngenta) currently produce GM crops licenced for commercial cultivation within South Africa.

NBTs (including genome editing) have been developed over the past decade and allow precise alteration of DNA. The potential of genome editing is illustrated by award of the Nobel Prize in Chemistry in 2020. Scientists worldwide have embraced the technology and scientific publications in the field of plant NBT are increasing exponentially, having grown 10-fold over the past five years to over 800 per year. They can be used to produce novel genetic variation that is useful, for example in crop improvement for healthier foods, drought tolerance or disease resistance examination of disease. Although some forms of NBT are transgenic in nature (type 1), others are not as they do not lead to insertion of foreign DNA (type 2). This can be because they do not insert transgenes into the genome during the genome editing event, or because the transgenes can be removed afterwards. These forms of NBT are in essence trying to mimic the effect of traditional plant breeding, but in a targeted manner so that only advantageous traits are introduced which decreases the time taken to improve agronomic organisms. From a genetic perspective, it is impossible to differentiate such a genome edited organism from a conventionally bred one and are not expected to possess higher risks for health and the environment. For these reasons 16 countries have already decided to regulate type 2 genome edited plants in the same manner as conventional crops.

2. Impact on academic science and the bio-economy.

We believe that the new regulations will have a detrimental effect on academic research in tertiary education institutes and research councils, industrial R&D as well as on entrepreneurs and SMMEs involved in the bio-economy. According to the 2018/2019 survey on research funding published by the Department of Science and Innovation, approximately 40% of R&D funding comes from industrial sources and the biological and agricultural sciences combined utilise about 12.5% of the countries R&D spend[1]. This demonstrates the standing of sciences using NBTs in the South African research environment, and the importance of private sector investment for their development. Research projects within these areas are of enormous benefit to the South African agriculture and health sectors. We fear that the current regulatory framework will greatly inhibit further development and maturation. This is because the type of regulations envisaged for genome-edited organisms under the GMO Act will put unnecessary regulatory burdens on industry and will disincentivise local investment for both in-house R&D as well as sponsoring projects within the public sector.

Under the current GMO regulations, not one locally developed product has been commercialised, despite South Africa being an early adopter of the technology. Given its excellent science base, South Africa currently has a chance to use NBT to become a significant leader within the region in producing plants and animals for Southern African farmers. This is especially important as global AgBiotech companies normally utilise plant varieties that have been selected for optimal growth by large-scale farmers, but which are not optimised for smallholders[2]. The use of NBT's will decrease the time it takes to develop new varieties for both large- and small-scale farmers that are optimised for conditions within South Africa. Undue regulation will certainly hamper this prospect and will let a small number of current AgBiotech companies continue to dominate this area through the exclusion of smallholder farmers and SMMEs who wish to gain competitive advantages by leveraging NBTs.

Genome editing technologies are currently in a capacity building phase within South Africa, but we know of projects trying to produce virus resistant and drought tolerant plants (Stellenbosch University; University of Cape Town, University of Witwatersrand), tobacco plants for more effective production

of biopharmaceuticals (CSIR), improved sunflowers (Agricultural Research Council), and production of insect pests with reduced virulence and fertility (University of Pretoria). One of the first South African scientific publications using genome editing was from the University of Pretoria, where it is being used for research on the genetics of fungal pathogens of tree crops.

3. A proposed regulatory approach

It appears that the executive council's decision to regulate genome edited organisms under the GMO Act is based on an interpretation of the following passage where 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."

This seems to have been interpreted as meaning that any method of genetic modification, other than by mating or recombination, would produce a GMO. We note that at least one legal opinion has indicated that this interpretation is open to question[3].

Various regulatory authorities around the world have taken either a process or product-based approach to regulating GMO's. A process-based approach examines how the GMO was produced. As we described in the previous paragraph, this is how the executive council have applied the GMO definition to NBTs. In contrast, a product-based approach examines the risks and benefits of the GMO itself on a case-by-case basis.

We believe that a product-based approach makes more sense and, in the case of NBT, two types of regulatory approaches would be necessary. The first type would contain a transgene and should be regulated under the GMO Act. The second type contains no transgene and is indistinguishable from a conventionally bred organism and should, therefore, be regulated like a conventionally produced organism. We believe that this is the most rational and scientific way to regulate these differing technologies. Indeed, most countries have taken this route to regulating NBTs, including Argentina, Japan, USA, Australia, Brazil, Nigeria, and Kenya.

We believe that the decision by the executive council will stifle both academic research within the tertiary education system as well as economic growth in the country by directly curbing development of the bio-economy. As such, we would like to ask your assistance to review and reverse this decision by helping amend the position of the Executive Council and develop a product based approach to regulating NBT's in South Africa

We would appreciate it if you could provide feedback about our concerns at your earliest convenience.