REGULATION OF GENETICALLY MODIFIED ORGANISMS IN SOUTH AFRICA AND INFLUENCE OF THE CARTAGENA PROTOCOL ON BIOSAFETY

By

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A thesis submitted to the Department of Mathematics and Natural Sciences
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Declaration

It is hereby declared that

1. The thesis submitted is my/our own original work while completing degree at Brac University.
2. The thesis does not contain material previously published or written by a third party, except where this is appropriately cited through full and accurate referencing.
3. The thesis does not contain material which has been accepted, or submitted, for any other degree or diploma at a university or other institution.
4. I/We have acknowledged all main sources of help.

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Approval

The thesis/project titled "Regulation of Genetically Modified Organisms in South Africa and influence of the Cartagena Protocol on the biosafety framework of the country" submitted by Kazi Toqi Yasir (17236002) of Fall, 2017 has been accepted as satisfactory in partial fulfillment of the requirement for the degree of Bachelor of Science in Biotechnology on [Date-of-Defense].

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Ethics Statement

The paper's content is based on the author's own research and analysis. All sources used have been appropriately cited with references. No harm was caused to humans, animals, or the environment during the study.

Abstract

Food insecurity has become a global problem that, if left unaddressed, will only worsen due to the adverse effects of climate change and the rapid growth of the world's population. Traditional methods of crop improvement are not effective under these conditions as they require considerable time and effort to implement effectively. Genetically Modified (GM) crops produced with the help of biotechnological tools can be an ideal alternative due to their precision and speedy implementation, with their rapid global adoption and consequent success demonstrating the effectiveness of the technology. South Africa is a prime example of how the application of the technology can assist countries struggling with hunger and food insecurity. Since its approval of GM maize in the late 1990s, the country has seen considerable success with GM crops. The country is now one of the world's leading producers of GM crops and has gained substantial economic benefits from them, unlike many countries in Africa which suffer from food shortages. We assert that this was made possible primarily due to a functional regulatory process being in place. The commencement of South Africa's first legislation took place on 1st December 1999 with the Genetically Modified Organisms Act, 1997. On 14 August 2003, the nation subsequently signed the Cartagena Protocol on Biosafety (CPB), which aims to ensure the safe transfer, handling, and use of GMOs. The CPB had a significant impact on the evolution of the regulatory system of the country and prompted an amendment to be made to the original act. Among other things, the country had put a particular emphasis on the protection of human and animal health and the preservation of biological diversity. The country further published various guidelines to ensure the safe release of GM crops and imposed stricter regulations on the transboundary movement of GMOs. As of 2022, as per the International Service for the Acquisition of Agri-biotech Applications (ISAAA), South Africa approved a total of 72 different events allowing GM crops or their products to be used as food, feed and cultivation. Countries that have not yet implemented a regulatory system can use the CPB and South Africa's regulatory system to develop an effective, functional biosafety framework for the cultivation of GMO crops which will in turn help them to boost agricultural productivity and food security.

Keywords: South Africa; Biosafety; Genetically Modified Crops; Cartagena Protocol on Biosafety; Biosafety Regulation;

Dedication

Dedicated to my parents and my best friend.

Acknowledgement

I'd like to express my sincere appreciation towards my supervisor, Dr. Aparna Islam, Professor at Brac University's Department of Mathematics and Natural Sciences. Without her invaluable oversight and the many hours of direct supervision, this project would not have seen fruition. Dr. A. F. M. Yusuf Haider, Chairperson of the Department of Mathematics and Natural Sciences of Brac University, also deserves my deepest appreciation for fostering a healthy learning environment. I would further like to express my appreciation to Dr. Iftekhar Bin Naser, Associate Professor in the Department of Mathematics and Natural Sciences of Brac University, whose assistance and sound counsel was invaluable throughout.

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List of Acronyms

GMO	Genetically modified organism
LMO	Living Modified Organism
CPB	Cartagena Protocol on Biosafety
GM	Genetically modified
SDG	Sustainable Development Goal
UN	United Nations
ISAAA	International Service for the Acquisition of Agri-biotech Applications
BCH	Biosafety Clearing-House
DALRRD	Department of Agriculture, Land Reform and Rural Development

Chapter 1: Introduction

The second of the 17 Sustainable Development Goals (SDGs) of the United Nations (UN) seeks to "end hunger, ensure food security and better nutrition, and promote sustainable agriculture" by 2030. Unfortunately, as per recent reports, it is safe to assume that the world is far from achieving such targets by this time. According to the "SDG Progress Report" of 2022, a staggering 2.4 billion people lacked a consistent and sufficient food supply in 2020 (United Nations, 2022a). A similar pattern was seen in 2021, when around 2.3 billion people worldwide were either moderately or severely food insecure (FAO et al., 2022). According to "The Sustainable Development Goals Report 2022", the worldwide food crisis began before the COVID-19 pandemic, which exacerbated the situation. Among other factors, unpredictable changes in the climate, as well as its adverse effects and higher food costs, have been held responsible for the crisis (United Nations, 2022b). The fact that the world's population is rapidly increasing will aggravate the issue unless agricultural productivity is significantly enhanced.

The easiest way to increase yield is to cultivate more land, which presents challenges since not all lands are arable and acquiring lands for cultivation may destroy the natural habitats of many organisms, reducing biodiversity. Various other techniques are also being adopted by agriculturists around the world to increase crop output. Chemical pesticides are used to prevent insect infestations, while fertilizers are used to provide plants with an adequate amount of nutrients. Other strategies include preserving the biodiversity of pollinators to ensure effective pollination; avoiding monoculture to prevent exhaustion of soil nutrients; and adding soil microbes to increase soil fertility (Eisenstein, 2020). Although these approaches may increase the yield under ordinary circumstances, none of the methods can help solve the lower agricultural productivity due to effects of climate change, such as, hotter temperatures, droughts, flooding and so on. Along with these abiotic factors, crop yield and quality can be

severely hampered by biotic factors, like insects and pathogens like fungus, bacteria and viruses etc (Yáñez-López et al., 2012). These pests are evolving rapidly and due to climatic changes their habitat is expanding.

Tackling the effects of all these would therefore require enhanced varieties of crops, which can be developed either by conventional breeding techniques or by using modern biotechnology to obtain transgenic or genetically modified organisms (GMOs). In the case of transgenic organisms, DNA materials having desired characteristics are introduced into the organism using genetic engineering tools (Rani & Usha, 2013). In agriculture, the implication of such modifications is to instill beneficial traits into plants, such as resistance to pests and diseases and tolerance against various environmental stresses. Furthermore, plants can also be modified by taking similar approaches so that they mature faster, have higher yields, use fewer natural resources, or are nutritionally enhanced (Phillips, 2008; Rani & Usha, 2013). Although conventional breeding techniques can also help to improve crops and make them more resistant to different stresses, the processes are lengthier and more labor-intensive (Smyth, 2022; Kavhiza et al., 2022). Moreover, it fully depends on availability of desired trait(s) in the sexually compatible gene pool. As a consequence, GM crops can be thought to have the upper hand in improving agricultural plants to boost crop productivity and improve food security.

Due to the various advantages that GM crops have over traditional varieties, the world is seeing an increasing demand for GM crops. According to the International Service for the Acquisition of Agri-biotech Applications (ISAAA) (2019), between 1996 and 2019, the area where biotech crops were planted worldwide increased by over 110 times, reaching a value of 190.4 million hectares. It was also reported that 29 countries grew GM crops in 2019, with an additional 43 countries importing products of GM crops. Furthermore, it was determined that between 1996 and 2018, the use of GM crops and their products generated over 200 billion dollars' worth of economic profits altogether (ISAAA, 2019).

However, it should be highlighted that the use of GMOs comes with certain concerns. Changing the genome of an organism may cause changes in the organism's metabolic pathways, which can affect how it functions and interacts with its environment. There is also the possibility that recombinant genes from GMOs will be transmitted to other species via horizontal gene transfer or directly to their compatible wild-types. For instance, if pesticide or antibiotic resistance genes are transferred in such ways, it can lead to disruption in the ecosystem and may even render the GMO's induced characteristics ineffective. Furthermore, there are risks of impacting non-target organisms as well. In addition, concerns about allergy and the risk of gut microorganisms acquiring antibiotic-resistant genes are also an issue in the case of consumption of foods derived from GMOs (Phillips, 2008; National Institutes of Health, n.d.).

An international regulatory framework that addresses the biosafety concerns about GMOs is the Cartagena Protocol on Biosafety (CPB), which is a supplementary protocol and a product of Article 8(g), 19(3) and 19(4) of the Convention on Biological Diversity. The protocol was adopted on January 29th, 2000 and countries were invited to sign and bind themselves to the treaty. So far, 173 countries have been recognized as parties to the CPB ("Cartagena Protocol on Biosafety," 2022). The protocol seeks to address the potential risks of using "living modified organisms" (LMOs), typically regarded as equivalent to GMOs, while also ensuring that the benefits of biotechnology are fully realised. The protocol deals with the safety of activities involving LMOs that are likely to endanger biodiversity and human health, with an emphasis on the movement of such organisms across international borders. Its key features include the Advanced Informed Agreement (AIA), which requires the exporting country to provide adequate information to the importing country so that they can assess the risks before deciding to import the LMO. The establishment of an online information sharing platform, the Biosafety

Clearing-House, is another important aspect of the CPB ("About the protocol," 2021; Hokanson, 2019; Secretariat of the Convention on Biological Diversity, 2000).

Countries that cultivate or carry out activities involving GM crops or their products address the concerns about GMOs by implementing GMO regulatory frameworks i.e. biosafety frameworks and carrying out relevant assessments according to the biosafety guidelines. Although every government's laws differ, they all share a common goal, which is to protect human health and the environment. The countries that are signatories of the CPB are seen to have a regulatory system influenced by the CPB. In fact, some countries' regulatory systems are a result of the ratification of the CPB (McLean et al., 2012; Hokanson, 2019).

South Africa is one such country whose current regulatory framework includes rules which are directly related to the CPB. South Africa actively grows GM crops and in 2019, 2.68 million hectares of GM crops were grown there, making it one of the top 10 GM crop-growing countries in the world (ISAAA, 2019). South Africa can be considered special with regard to GM crop commercialization as it was the first among the 54 countries on its continent to approve GMOs. The country started approving GMOs as early as 1996, starting with GM maize (Agaba, 2019). The approval took place while the country did not have any formal administrative or written laws regulating GMOs. Following the approval of GM maize in 1996, GM cotton and GM soybeans were approved in 1997 and 2001, respectively. South Africa's decision to start cultivating GM crops was undoubtedly brave, as the second African country to approve a GM crop was Egypt, which gave its first approval of GM Maize in 2008, 12 years after South Africa's first approval. According to ISAAA (2019), South Africa gained a staggering US $2.4 billion of economic gain from 1998 to 2018 from GM crops. In terms of the development and cultivation of biotech crops, the nation has maintained its dominance in

Africa. The success of South Africa and the benefits that it acquired from GM crops can be an exemplary example for countries that are reluctant to grow GM crops.

It must be highlighted that restrictions on food trade have been identified as one of the causes of the global food crisis (The World Bank, 2022). Nations that rely heavily on imports to meet their domestic food demand are at a serious risk of food security. It is predicted that in 2030, over 500 million people will suffer from hunger (The World Bank, 2022). As a result, the need for innovation in the agriculture sector to boost crop productivity and attain self-sufficiency is of utmost importance. Although many African countries experience food shortages, South Africa is in a favourable position (Kavhiza et al., 2022). According to recent reports, it has decreased its grain imports and increased its grain exports. This success can be attributed to the increased cultivation of GM crops, as approximately 80% of South Africa's staple crop, maize and nearly all of its corn and soybeans are derived from GM plants (Lyddon, 2021). Therefore, the adoption and approval of GM crops could be a rapid means of increasing self-sufficiency and food security. However, it should be noted that developing and growing GM crops requires a functional biosafety regulatory system to address the safety concerns of GMOs. Countries, particularly the developing ones, that are falling behind in agricultural productivity and are hesitant to grow GM crops can use South Africa's accomplishments as an example.

In light of this, this study will look at the biosafety laws governing GMOs in South Africa, their evolution, and the extent to which the CPB has influenced them.

Chapter 2: Sources and Method

South Africa is the first country in the continent of Africa to approve GM crop cultivation. The development, usage, and trade of GM crops are regulated primarily by the Genetically Modified Organisms Act, 1997, which is currently under the Department of Agriculture, Land Reform and Rural Development (DALRRD). The act was amended, followed by South Africa's signing of the Cartagena Protocol, which changed many of the aspects of the original act. During the study, the original act and its amendment and the relevant regulations were studied. The Cartagena Protocol on Biosafety was itself studied to determine its possible influence on the amendments. The act, its amendment, and other regulatory documents were downloaded from the country's dedicated website for biosafety, http://biosafety.org.za, and their government website, https://www.gov.za. The websites, in addition to the guidelines, also provided information on other related acts such as the "National Environmental Management Act, 1998" and "Act No. 68 of 2008 (Section 24(6)): Consumer Protection Act, 2008." The CPB was downloaded from the website of the Convention on Biological Diversity, https://www.cbd.int/.

In addition, other relevant documents, research articles, and reports were also studied, which helped to shed more light on existing laws as well as to determine the protocol's influence on the changes in the legislation.

In order to find South Africa's status of GM crop production, the knowledge-sharing platform of the International Service for the Acquisition of Agri-Biotech Applications (ISAAA) was used. The website contains yearly reports of countries that cultivate GM crops and use products of GM crops as food or feed. It also maintains a database containing the list of GM events for all countries.

The website of the Biosafety Clearing-House was another useful platform for obtaining documents such as risk assessment reports, approval documents, and the national reports on the implementation of the CPB. The flowchart below outlines the steps taken during the overall study.

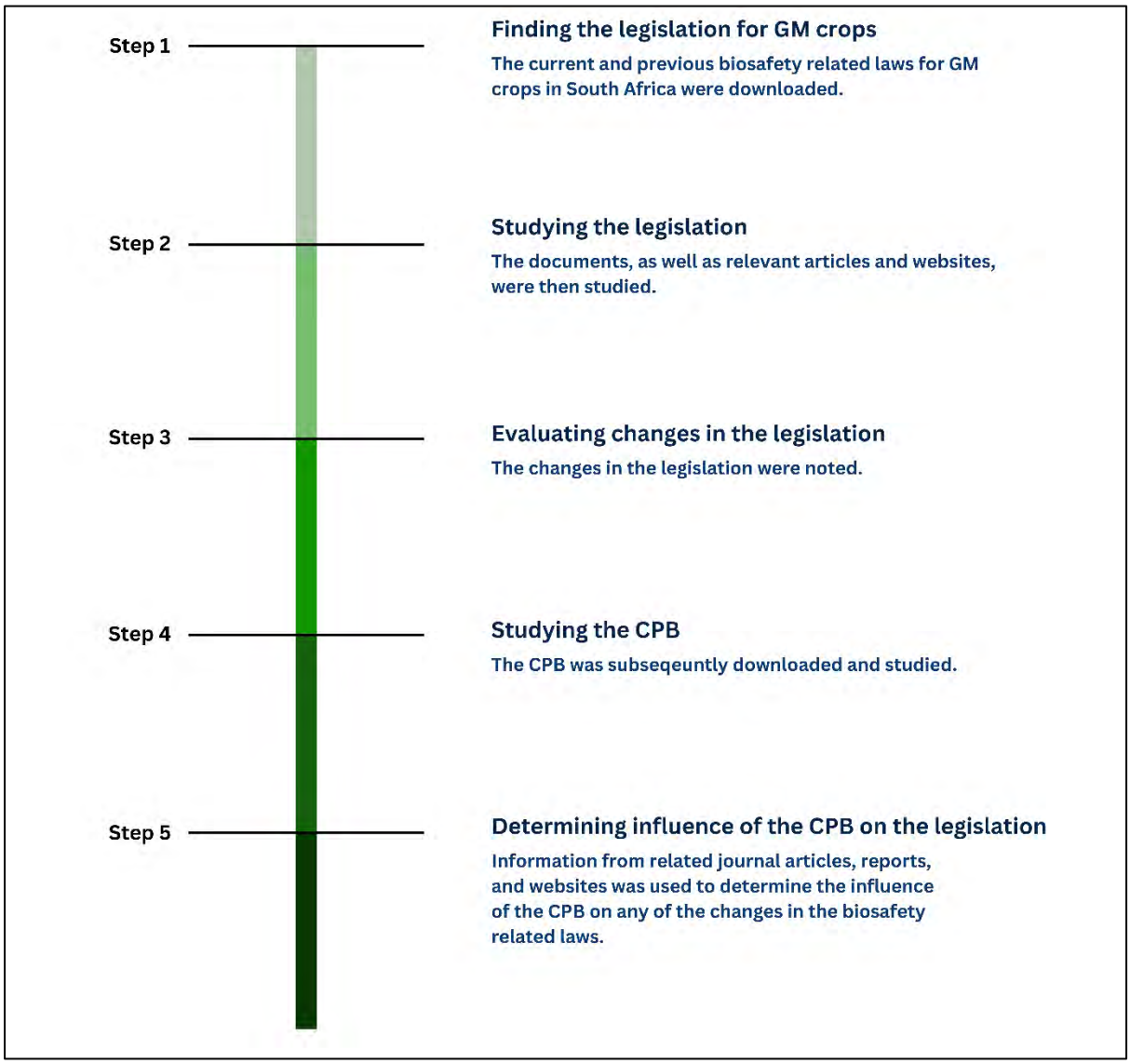

Figure 1: Steps taken during the study

Chapter 3: Results and Discussion

3.1 Principle laws governing the biosafety of South Africa

Several regulatory frameworks and guidelines governs GMO-related (including plants) biosafety in South Africa. Important acts and guidelines that are currently in place are shown in Table 1.

Table 1: GMO-related acts, regulations and guidelines in South Africa.

Competent Authorities	Acts / guidelines	Note
Department of Agriculture, Land Reform and Rural Development (DALRRD)	Act No. 15 of 1997: Genetically Modified Organisms Act, 1997	The laws directly regulate elements of GMOs, including their local development and usage or international trade.
	Act No. 23 of 2006: Genetically Modified Organisms Amendment Act, 2006	
	No. R. 120 of 2010: Regulations in regard to Genetically Modified Organisms Act, 1997	
Department of Health (DoH)	Act No. 54 of 1972: Foodstuffs, Cosmetics and Disinfectants Act, 1972	The laws concern the labelling of GMOs. They also address the safety of GMOs when they are used as food or animal feed.
	No. R. 25 of 2004: Regulations in regard to Foodstuffs, Cosmetics and Disinfectants Act, 1972	
Department of Environmental, Forestry and Fisheries Affairs (DEFF)	Act No. 107 of 1998: National Environmental Management Act, 1998	The laws address the possible impact of GMOs on the environment when they are released and grown commercially. Also included are guidelines for Environment Impact Assessment (EIA), which have information, such as, why an EIA may be required, when to conduct an EIA, and how to conduct an EIA for a GMO.
	List of Activities and Competent Authorities identified in terms of Sections 24 and 24d of the National Environmental Management Act, 1998	
	Act no. 8 of 2004: National Environmental Management Act Amendment Act, 2004	
	Act No. 10 of 2004: National Environmental Management: Biodiversity Act, 2004.	
	No. R.385 of 2006: Regulations in regard to National Environmental Management Act, 1998	
	Environmental Risk Assessment Framework for Genetically Modified Organisms: A Guidance Document.	
	Risk analysis of contained use research and development activities with genetically modified aquatic organisms.	
Department of Trade and Industry and Competition (DITC)	Act No. 68 of 2008 (Section 24 (6)): Consumer Protection Act, 2008.	The laws concerns consumer rights in regard to the use of GMOs, which include the labelling requirements for products derived from GMOs.
	No. R. 293 of 2011 (Section 7): Regulations in regard to Consumer Protection Act, 2008.	

3.2 Changes in the principal laws governing the biosafety of South Africa

The first regulatory body that dealt with GMOs in South Africa was the South African Committee on Genetic Experimentation (SAGENE), established in 1979. The committee was established by the government of South Africa before the country had any GMO-related biosafety legislation. SAGENE was managed by scientists who served as an advisory body for genetic engineering-related development. Initially, the committee was responsible for developing guidelines for GM microorganisms and for conducting experiments. The committee was also responsible for carrying out inspections of laboratories. SAGENE became more influential at the beginning of 1994 and was from then on able to recommend activities related to the import and cultivation of GMOs to any relevant government bodies. It was under SAGENE's presence that the first commercialization of GM cotton, developed by Monsanto, took place in South Africa. SAGENE was replaced by the Executive Council once the Genetically Modified Organisms Act, 1997 commenced on 1st December 1999. Since then, the Genetically Modified Organisms Act, 1997 has been the principal legislation administering GMOs, including transgenic crops, in South Africa (Esterhuizen, 2020).

The Genetically Modified Organisms Act, 1997 had its relevant regulations published on 26th November 1999, which commenced on 1st December 1999. This was followed by South Africa's signing of the Cartagena Protocol on 14th August 2003. The event had a great influence on the regulatory system of South Africa for GMOs and amendments were published on 17th April 2007. The amendments were presented in the "Genetically Modified Organisms Amendment Act 23 of 2006", which took effect on 26th February 2010. The regulations were also changed and published in Gazette no. R. 120 of February 26th 2010, which repealed the earlier published regulations. The flowchart below illustrates how the GMO-related legislation changed in South Africa.

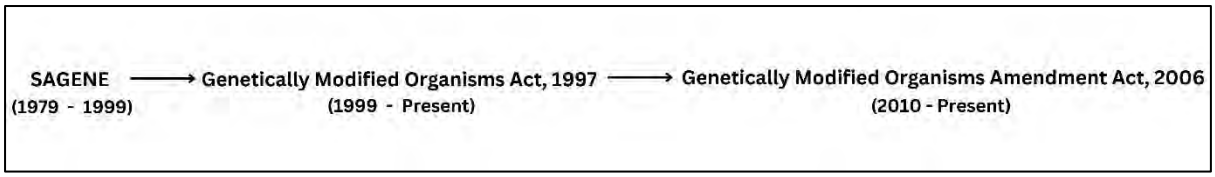

Figure 2: Changes in the GMO-related legislation in South Africa

The changes that were introduced in the amendment and its subsequent regulations show the impacts of the CPB in biosafety policies in South Africa. Upon careful examination, the following changes were identified:

3.2.1 Purpose:

The Genetically Modified Organisms Act, 1997 outlines guidelines so that GMOs are more appropriately used, handled, developed and produced. The guidelines also aim to identify and reduce the chances of any adverse impact that GMOs might have on the environment while they are being used, produced or transported. The act also takes into account the efficient management of waste and aims to reduce the chances of accidents. As per the introduction, the act also establishes the required criteria and conditions for carrying out risk assessments on GMOs. The act also mentions that a "council" will be set up for GMOs. The act would also make sure that GMOs do not pose a threat to the environment, and that steps are taken so that any activities related to GMOs are reported to an authority (*Act No. 15 of 1997: Genetically Modified Organisms Act, 1997*).

In addition to protecting the environment from GMO-related activities, the amendment emphasizes protecting human and animal health, preserving biological diversity, and ensuring its long-term use. The amendment also mentions the establishment of criteria and conditions for conducting scientifically based risk assessments. In addition, criteria would also be laid down for socio-economic considerations, and risk management measures (*Act No. 23 of 2006: Genetically Modified Organisms Amendment Act, 2006*, 2007).

3.2.2 Definitions:

The amendment changes definitions of some of the terms in the Genetically Modified Organisms Act, 1997 and includes definitions for multiple new terms, indicating that new measures are being introduced by the amendment. The definitions that were changed are:

a) “Accident" from

> “Any incident involving an unintended general release of genetically modified organisms which could have an immediate or delayed adverse impact on the environment”

to

> “Any
>
> i) incident involving an unintentional environmental release of genetically modified organisms that is likely to have an immediate or delayed adverse impact on the environment; or on human or animal health within the Republic, or
>
> (ii) unintentional transboundary movement of genetically modified organisms that is likely to have an immediate or a delayed adverse impact on the environment or on human or animal health”

b) “Contained use” from

> “Any activity in which organisms are genetically modified or in which such genetically modified organisms are cultured, stored, used, transported, destroyed or disposed of and for which physical barriers or a combination of physical barriers together with chemical or biological barriers or both are used to limit contact thereof with the environment”

to

"The development, production, cultivation, use, application, storage, movement, destruction or disposal of genetically modified organisms within a facility installation or other physical structure, including a greenhouse that are controlled by specific measures, including physical barriers or a combination of physical barriers together with chemical or biological barriers or both that effectively limit contact of the genetically modified organisms with humans, animals and the external environment and their impact on humans, animals and the external environment"

c) "General release" from

"The introduction of genetically modified organisms into the environment by whatever means, where the organisms are no longer contained by any system of barriers and are no longer under any person's control, so that the organism is likely to survive and be disseminated"

to

"The release of a genetically modified organism into the environment by whatever means, where the organism is no longer contained by any system of barriers"

d) "User" from

"Any natural or legal person or institution responsible for the use of genetically modified organisms and includes an end-user or consumer"

to

"A person who conducts an activity with a genetically modified organism"

In addition, the following new terms were added in the amendment which upon careful observation can be seen to have been either directly taken from the CPB or are related to the articles of the CPB. These includes Activity, Biosafety, Biosafety Clearing-House, Commodity

clearance, Conditional general release, Contained, Convention, Environmental impact assessment, Extension permit, Protocol, Release, Transboundary movement.

3.2.3 People charged with the administration and regulation of the act:

The Genetically Modified Organisms Act, 1997 involved the following people:

a) The Minister of Agriculture (the minister of Agriculture, Land Reform and Rural Development at present).

b) Any officer delegated in writing by the minister to work in the minister's absence.

c) The Minister of Finance (only when finance is involved).

d) An "Executive Council" with a maximum of 8 members appointed by the Minister with at least one officer chosen from each of the following departments:

i) The Department of Agriculture;

ii) The Department of Arts, Culture, Science and Technology;

iii) The Department of Environmental Affairs and Tourism;

iv) The Department of Health;

v) The Department of Labour; and

vi) The Department of Trade and Industry.

The officers are supposed to have knowledge of GMOs and its relationship with their department. The Minister would designate one of the eight members as the chairman and one as the deputy chairman of the council.

e) Any people with relevant knowledge for advising or writing comments that the council or advising committee deems necessary.

f) A Registrar who would be appointed by the minister in consultation with the Council.

g) Officers appointed by Director-General of the Department of Agriculture to assist Registrar.

h) Registrar-appointed inspectors.

i) A panel of independent scientists known as the Advisory Committee consisting of up to 10 members, appointed by the Minister. The committee would have up to eight members with

knowledge related to the development and release of GMOs. Two people would have knowledge of ecological matters and GMOs.

j) An advisory sub-committee if recommended by the advisory committee.

k) Magistrates if warrants are required.

In the amendment, the maximum number of members in the Executive Council has been increased to 10. The amendment also changes the departments from which members of the council are appointed from. For instance, the Department of Arts, Culture, Science and Technology has been split into two distinct departments—"The Department of Arts and Culture" and "The Department of Science and Technology." In addition, a member would also be present from the Department of Water Affairs and Forestry. Unlike the original act, the members of the departments would be nominated by the departments themselves rather than being appointed by the Minister. There is also a provision for the appointment of substitutes of the members by the Minister in the amendment.

The second change involves the Advisory Committee. Among the 10 members, the amendment makes it mandatory to have at least one member from the public sector who is an expert in GMOs and their relation to ecological matters and a second member who is an expert in the relationship between GMOs and human and animal health (*Act No. 15 of 1997: Genetically Modified Organisms Act, 1997*; *Act No. 23 of 2006: Genetically Modified Organisms Amendment Act, 2006*, 2007).

The current administrative structure under the Genetically Modified Organisms Act, 1997 and its amendment has been illustrated in figure 3.

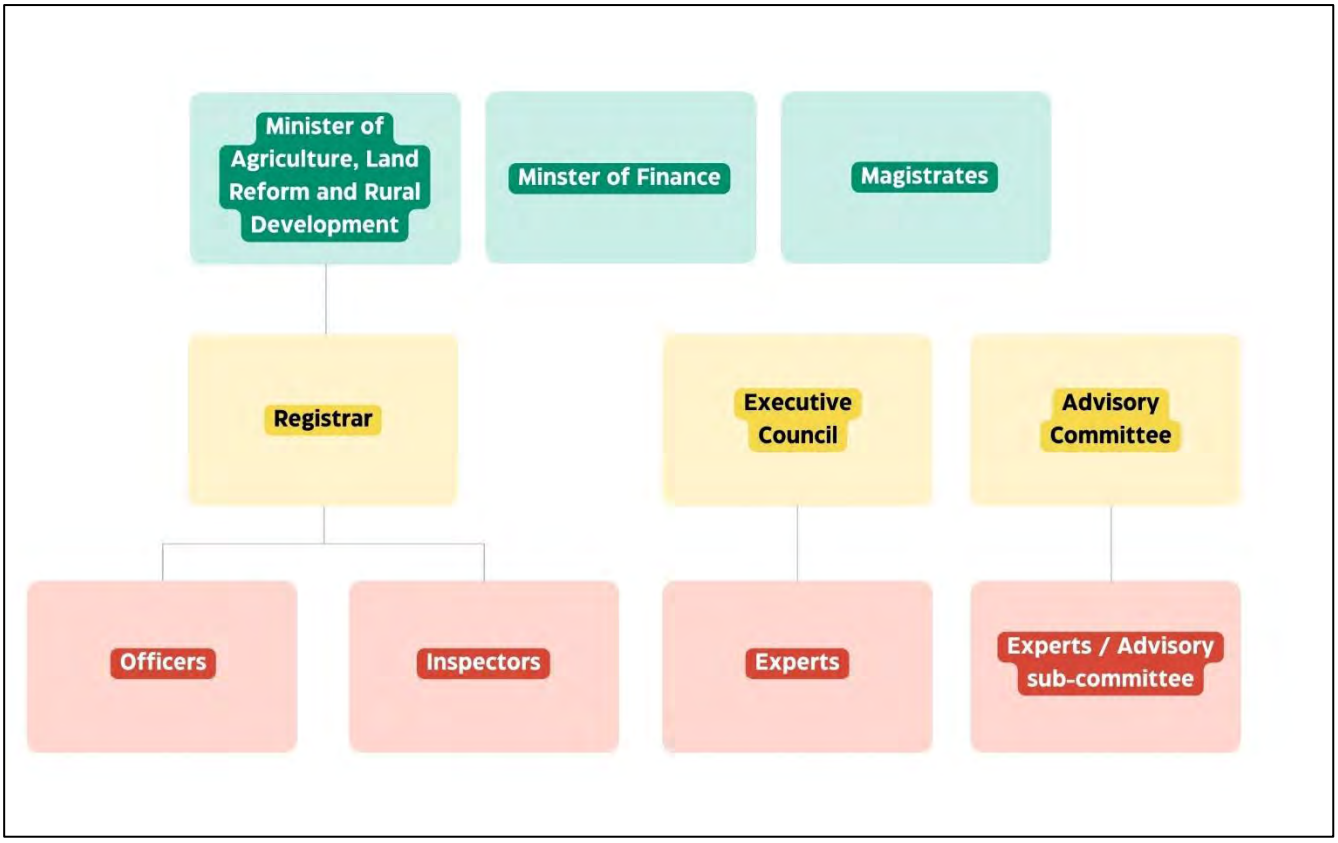

Figure 3: Current administrative structure under the Genetically Modified Organisms Act, 1997 and its amendment.

3.2.4 Role played by the administrators:

The power and duties of the different bodies as per The Genetically Modified Organisms Act, 1997 has been described below.

a) The Minister of Agriculture: The act empowers the Minister of Agriculture (the minister of Agriculture, Land Reform and Rural Development at present) to regulate almost every aspect of the act, including regulating permits for GMO-related activities, procedures for conducting risk assessments and environmental impact assessments, and determining fees for various activities. The Minister may decide to make any regulations which they may deem necessary for the implementation of the act. Furthermore, the Minister is also responsible for appointing various entities under the act. For example, the members of the Executive Council and the Registrar are appointed by the Minister as per the act.

b) Executive Council: According to the original act, the Council has multifaceted functions related to the Minister, the registrar, applicants and foreign countries.

i) *With the Minister:* The Council is responsible for informing and updating the Minister regarding all aspects of GMOs and activities related to GMOs taking place within South Africa. The council is also responsible for making sure that the act is being enforced for every activity, starting from the development or import of GMOs to their commercial release and use afterwards. The Council is also responsible for suggesting to the Minister if any changes or considerations need to be made for any aspect or activities related to GMOs.

ii) *With the applicants*: The Council holds the power to approve or refuse, for any activity related to GMOs including the use of a facility. The Council may also cooperate or get into an agreement with an individual or an institution in this regard. The council, through the register may assess whether an application is in accordance with the act. In addition, the Council may also seek reports of risk assessment and or an environmental impact assessment or any other relevant information before giving an approval to an applicant. When the members of the Council are satisfied, they may issue a permit to the applicant allowing them to carry out their desired activity. If any changes are made in the original, proposed scheme, the applicant may have to ask for a new permit from the Council. The council also monitors any accident related to GMOs including accidental releases of GMOs. In such cases the applicants are required to inform the registrar and provide all details that might be required to mitigate and overcome the effects of the accident. In regard to this, the Council also holds power to carry out an investigation by appointing a board with the registrar's help. The board would then find why the accident took place in the first place so that future accidents can be prevented.

iii) *With the Registrar*: The Council ensures that the registrar maintains records of all GMO related activities, whether it involves 'contained use' or 'trial release'. The record would also have details, including the address of the people associated with the events. In addition, the Council would also make sure that the registrar appoints inspectors to investigate facilities or activities for which permission has been granted to confirm that everything is done as per the criterion in the act.

iv) *With foreign countries*: The Council is responsible for maintaining liaison with other states so that the knowledge related to GMOs can be shared. The Council, in the case of an accident related to GMO, is also responsible for alerting in case there is a possibility of the accident affecting other countries' environment.

c) Registrar: According to the Genetically Modified Organisms Act, 1997, the Registrar is responsible for administering the act and making sure that every related person carries out activities in a proper manner so as to prevent any possible harm to the environment. The Registrar also issues permits to applicants after approval from the Council. The Registrar can also issue notices and or appoint inspectors if the Council advises so against any person or organisation whose activity is suspected to breach the rules of this act. In such circumstances, the GMO or other materials may be asked to be ceased, removed to a safe place or destroyed. The Registrar can also make amendments or take back permits that were given to an applicant. In order to carry out their duty, the Registrar follows the Council's guidance. In addition, as per the regulation (No. 1420), the registrar shall have records of all the facilities that will be used for activities related to GMOs.

d) The Advisory Committee: As the name implies, the Advisory Committee (AC) advises the state on all aspects of GMOs, including their introduction, contained use, import, and export. The AC can also advise on suggested regulations and guidelines. In doing so, the AC has the

power to accept experts' opinions on any point related to GMOs. The advisory committee is also allowed to collaborate with any relevant institutions outside the state with the help of the corresponding national authority.

e) Inspector: Inspectors ensure that the applicants comply with the rules of the act. With the help of a warrant, during an investigation, inspectors have the authority to examine any facility or operations during working hours. They may also take hold of any piece of evidence, documents, or samples in order to prove an activity's noncompliance with the act. Additionally, inspectors can inquire about any activity that they are investigating. During a routine examination, the inspector may carry out similar tasks without a warrant.

In the amendment, there has been no significant change in the roles of the Minister, the Advisory Committee or the inspector. However, the Executive Council and the registrar, in addition to their usual duties, also have to ensure the following.

The Executive Council:

- The Council now has to take stricter measures before approving an application. For instance, in addition to asking for a scientifically based risk assessment, the Council can also ask for an environmental impact assessment, an assessment on socio-economic considerations, and public input while considering an application.
- The council is now required to take into account possible risk management measures put forward by an applicant.
- The Council is now required to consult the Advisory Committee, which includes a pool of scientific experts, before approving an application or for an extension of a permit, and needs to give a written note to the Registrar to issue a permit to an applicant.
- The amendment requires the Council to place emphasis on preserving biological diversity and human and animal health for accidents or possible accidents.
- In the event of a possible unintentional transboundary movement, the Council is required to ensure that the Biosafety Clearing-House aid is also appropriately notified.

• The amendment requires the Council to ensure that satisfactory measures are present before the state is bound into an agreement on activities related to GMOs.

• The council can decide to seize or destroy any materials from any facility if they receive information from the Registrar that the laws of the act are being breached in the said facility or by an individual.

• The council is allowed to consult anyone with relevant scientific expertise if they deem it necessary to carry out any of their functions.

• The council is responsible to ensure that the users follow notification procedures as per article 8 of the Cartagena Protocol on Biosafety where applicable.

The Registrar:

• The registrar must check applications to ensure that they comply with guidelines of the act and forward applications for permits to the Council along with all relevant documents.

• The registrar must make sure that the applicants to whom permits are issued ensure the safety of the environment, humans, and animal health while carrying out any activity related to GMOs.

• The registrar has been given the power to issue permits, make amendments to permits, seize permits or give extension to permits.

• The registrar is required to keep records of all the facilities and sites where there have been activities related to GMOs. The registrar is also required to keep records of the people who are involved in such activities.

• The registrar is responsible for liaising with the Biosafety Clearing-House and providing them with the data listed in regulation no. R120 in the prescribed manner.

At present, permits must be obtained for carrying out almost any activity related to GMO as illustrated by the list below ("List of activities involving GMOs for which the GMO Act requires a permit application," n.d.). Furthermore, figure 4 illustrates the current application

process to obtain permit for an activity related to GMO. List of activities involving GMOs for which the GMO Act requires a permit application:

1. Registration of a facility for activities involving genetic modification (GM)
2. Contained use of GMOs
3. Intentional release into the environment (trial release)
4. General release
5. Commodity clearance
6. Commodity use for food, feed or processing
7. Import for contained use
8. Import for intentional release (trial release) into the environment
9. Import of LMOs that have general release or commodity clearance status
10. Export for (i) contained use or (ii) use as food, feed or processing
11. Export for intentional release into the environment
12. GMO Status certification for export

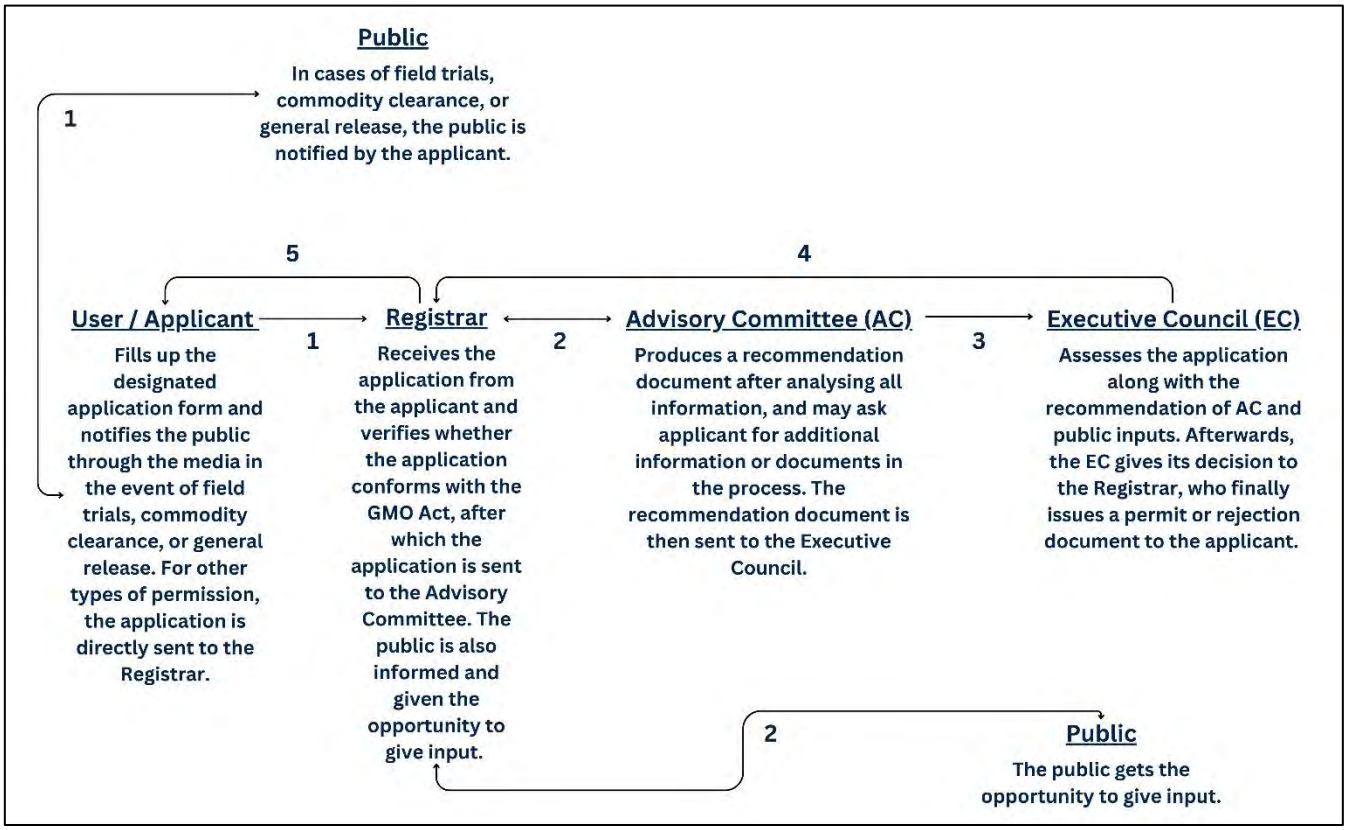

Figure 4: Current application process to obtain permit for an activity related to GMO in South Africa.

3.2.5 Information sharing:

The Genetically Modified Organisms Act, 1997 only allows for limited sharing of information with designated individuals or for legal proceedings although some information may not be kept confidential unless the applicant specifically applies, showing proper reasoning. However, certain information, including an applicant's details, particularly their name and address; basic details of the GMO for which a permit has been obtained; and the location and purpose of the GMO or activity, has been made available for sharing. In fact, the regulation (No. 1420) requires an applicant to notify the public of the aforementioned information through publication in local newspapers that circulate in the proposed area where the facility is to be built or used. Information related to the regulation of GMOs and reports concerning the possible adverse effects of GMOs are also not considered confidential. However, in certain

cases, an applicant showing appropriate reasons may withhold certain information for a certain period of time.

The amendment keeps the provision to make the summary of the scientifically based risk assessment public in addition to the information that was already allowed by the Genetically Modified Organisms Act, 1997. The regulation no. R120 also makes it necessary that an applicant publishes the information mentioned in the earlier paragraph in at least one national newspaper, in addition to publishing it in at least two local newspapers. If the people in the area of the proposed site for a facility do not have access to newspapers, other means must be taken to inform the local community.

3.2.6 Penalties and punishments:

The Genetically Modified Organisms Act, 1997 brought the Council members and the registrar under accountability and gave the Minister of Agriculture (the minister of Agriculture, Land Reform and Rural Development at present) the power to dismiss any member if they are found to have abused their power or neglected their responsibilities. The act also gives power to the related magistrate's court to punish a person found violating any aspect of the act. Punishments include a fee or imprisonment for up to 2 years on a first conviction and a fee or imprisonment for up to 4 years on second and successive convictions. Any applicant or any convicted person may appeal to the minister in the prescribed manner for further investigation. The investigation's findings must be submitted in writing to the minister.

The amendment does not make any significant changes to the terms related to penalties or punishments. It only makes it mandatory that the decision of an appeal should be made available to the registrar and the public, in addition to the minister.

The summary of the changes in the principal laws governing the biosafety of South Africa has been given in Table 2.

Table 2: Summary of changes in the principal laws governing the biosafety of South Africa.

	Summary of changes after the amendment
Purpose of the act	Additionally emphasised on - Human and animal health and the preservation of biodiversity. - Scientifically based risk assessments. - Socio-economic considerations.
Definitions	- Changed definitions of "Accident", "Contained use", "General Release", and "User". - Added definitions for "Activity", "Biosafety", "Biosafety Clearing-House", "Commodity clearance", "Conditional general release", "Contained", "Convention", "Environmental Impact Assessment", "Extension permit", "Protocol", "Release", "Transboundary movement".
People charged with the administration and regulation of the act	Executive Council: - Can have up to 10 members instead of 8. - Shall have a representative from the Department of Water Affairs and Forestry. - Members are nominated by the departments instead of the Agriculture Minister. - Can have substitutes for the members. Advisory Committee: - Must include 1 member from the public sector & an expert in GMOs and their relation to ecological matters. - Must include 1 member who is an expert in GMOs and their relation to human and animal health.
Role played by the administrators	Additional responsibilities of the Executive Council - Can ask applicants for additional assessments and public input. - Required to consult the Advisory Committee. - Has to prioritize biodiversity conservation and human and animal health. - Must ensure proper notifications for transboundary movements. - Can seize materials from violators and seek scientific expertise when necessary. - Has to ensure compliance with Article 8 of the Cartagena Protocol on Biosafety. Additional responsibilities of the Registrar - Must oversee GMO activities, check applications for compliance, and submit them to the Council. - Can issue, amend, or seize permits. - Must maintain records of facilities and personnel. - Must liaise with the Biosafety Clearing House, providing necessary data.
Information sharing	- Summary of scientifically based risk assessment to be made publicly available. - Details of the applicant and GMO activity must be published in at least 1 national newspaper in addition to 2 local newspapers. - If a newspaper is not available in the target area, other means have to be taken to inform the public.
Penalties and punishments	Decisions on appeals are not limited to the minister anymore and are publicly available.

3.3 Influence of the Cartagena Protocol in the biosafety regulatory system

Many of the changes in the Genetically Modified Organisms Act, 1997 brought about by the amendment were a direct result of South Africa's signing of the CPB. In fact, the title of the act has been changed by the amendment to include that one of the purposes of the amendment was to ensure that the biosafety framework in South Africa aligns with the CPB.

The changes brought about by the amendment to some of the definitions highlight the influence of the CPB. For example, the new definition of "accident" talks about adverse impacts on human and animal health, whereas the old definition only mentioned the environment. This new definition also considers cases of transboundary movements. Both of these are in the essence of the CPB, where addressing risks to human health and looking into transboundary movements lie within the scope of the CPB. Similarly, the change in the definition of "contained use" mentions the safety of humans and animals. However, the changes in the definitions for "general release" and "user" do not seem to have been due to the CPB. For instance, the term "user" has been changed in a way that broadens the scope of the definition. Earlier, "user" included people who would use GMOs, whereas the amendment changed it to any person carrying out any GMO-related activity.

The introduction of the terms "Biosafety Clearing-House", "Protocol", "Transboundary movement", "conditional general release" etc. from the clauses of the CPB also indicates South Africa's intention to fulfil the obligation under the CPB. In a similar way, many of the changes brought about by the Genetically Modified Organisms Amendment Act, 2006 and the changes in other relevant acts can be linked to one or more articles of the CPB. For instance, multiple other guidelines were also published, followed by the issuing of the amendment in the subsequent years. These guidelines further helped to improve the functioning of the biosafety framework so that South Africa is able to meet its obligations under the CPB. These documents include the following:

- Environmental Risk Assessment Framework for genetically modified organisms: A guidance document.
- ERA Framework for GM Pharmaceuticals.
- ERA Framework for GM Fish.
- Guidance on compositional analysis and feeding studies data requirements for commodity clearance and general release applications, with emphasis on stacked events.
- Guideline for submission of annual reports for certain activities undertaken in terms of the GMO Act, 1997.
- Guidelines for compiling a public notification.
- Guideline for submission of time extension requests for current permits issued under the GMO Act.
- Standard operating procedures with regard to regulation 4 of the GMO Act.
- Standard operating procedures with regard to regulation 2(2) of the GMO Act.
- Guidelines for working with genetically modified organisms.
- Guidelines for use by the Advisory Committee when considering applications

("Fourth National Report on the Implementation of the Cartagena Protocol on Biosafety," 2019; "Relevant acts, regulations & guidelines," n.d.)

In addition, as per article 2 of the CPB, South Africa made sure that comprehensive biosafety laws, regulations and guidelines are present so that activities related to GMOs are done in a way as to prevent or reduce risks to both the environment and the health of humans and animals. This has been particularly noticeable in the amendment where a stricter process has been enforced for the development, use, or trading of LMOs. For instance, the amendment made submission of a scientifically-based risk assessment mandatory before allowing permission for any GMO-related activity. The applications and the risk assessment reports are scrutinized by both the Advisory Committee and the Executive Council before approval is given. In addition, an environmental impact assessment (which aligns with the demand of article 16 of the CPB) and an assessment on socio-economic considerations (which aligns with the demand of article 26 of the CPB) might also be required if the Council deems it necessary. All these together

would ensure that only applications that satisfy the safe use of GMOs are implemented. This goes very much with the essence of the CPB and would help to ensure highest levels of safety.

Furthermore, the amendment includes a clause which emphasizes that the Executive Council should advise the Minister of Agriculture (the minister of Agriculture, Land Reform and Rural Development at present) in order to prevent future accidents and to mitigate events which can damage biological diversity and human & animal health. The amendment also makes it mandatory for the Registrar to ensure that the activities of the applicants to whom permits are issued are continuously monitored. This would ensure that applicants conform to the guidelines of the act. In this regard, the Registrar can inform the council who has been given the power to decide to seize or destroy any materials from any facility if the laws of the act are being breached. All these align with the recommendation of Article 16, which requires the signatories to take measures to help reduce risk to biological diversity and human & animal health.

In regard to article 15 of the CPB, the regulation of the GMO act, no. R 20, outlines the steps for carrying out a scientifically based risk assessment. Upon careful observation, it can be found that the steps are a reflection of annex III of the CPB (*Regulations of Genetically Modified Organisms Act, 1997*, 2010; Secretariat of the Convention on Biological Diversity, 2000). In addition, an applicant is also required to provide risk management measures whose feasibility and acceptability are assessed by the Council. GMOs which are permitted to be grown commercially are only given a conditional permit and their long-term impact is also monitored as outlined by the National Environmental Management: Biodiversity Act. As well, in 2008, a guideline titled "Environmental Risk Assessment Framework for Genetically Modified Organisms: A guidance document" was published, which contained detailed instructions for carrying out risk assessments. The document is noteworthy as it further helps to achieve the goal of articles 15 and 16 of the CPB. The guidelines particularly outline how

South Africa identifies environmental risks and assesses them. It helps to understand the process of environmental risk assessment and management and is an indication of the country's ability to carry out globally accepted risk assessments for GMOs. For GM plants, the ERA is carried out on a step-by-step tiered process where its development in confined facilities, field trials and finally its general release are closely monitored (*Environmental Risk Assessment Framework for Genetically Modified Organisms: A guidance document*, n.d.).

The influence of article 8 of the CPB has also been seen in the amendment and other regulations. For instance, the Council is given the responsibility of ensuring that notification procedures are followed by all users as per article 8 of the CPB in the event of the importation of a GMO into the Republic (*Act No. 23 of 2006: Genetically Modified Organisms Amendment Act, 2006*, 2007).

In regard to article 12, there is a provision in the amendment which allows the Executive Council to change their decision regarding an activity for which a permit is issued. This was to ensure that a decision can be reverted in the event of finding new scientific evidence indicating that an approved GMO activity may have adverse effects on environment, human or animal health (*Act No. 23 of 2006: Genetically Modified Organisms Amendment Act, 2006*, 2007).

In regard to article 14, the amendment requires the Council to ensure that satisfactory arrangements are present to deal with unintentional transboundary movements before the state is bound to an agreement with another state on activities related to GMOs. It is also required that the arrangements or agreements give protection that is not less than the protection provided by the CPB (*Act No. 23 of 2006: Genetically Modified Organisms Amendment Act, 2006*, 2007). This satisfies the main concern of article 14 of the CPB (Secretariat of the Convention on Biological Diversity, 2000).

In regard to Article 17 of the CPB, the regulation of the GMO act, no. R 20, lists the set of information that is required to be given by a user in the event of an unintentional or the likelihood of an unintentional transboundary movement of a GMO. This again has been found to be similar to the requirements listed in paragraph 3 of article 17 of the CPB. (*Regulations of Genetically Modified Organisms Act, 1997*, 2010; Secretariat of the Convention on Biological Diversity, 2000). Furthermore, the amendment ensures that the Council notifies the Biosafety Clearing-House aid in case of a possible unintentional transboundary movement. The amendment and the subsequent regulation also include new points which would deal with unintentional transboundary movements and the unintentional introduction of GMO within South Africa. In addition to meeting the criteria of article 17, these also help to fulfil the motive of the CPB which is to reduce the risk to biodiversity and human and animal health.

In regard to article 19 of the CPB, the “Department of Agriculture, Land Reform and Rural Development” has been assigned the task of administering GMOs as the Competent National Authority and the " Department of Forestry, Fisheries and the Environment " has been given the role of the National Focal Point. Currently, Ntakadzeni Tshidada from the Department of Forestry, Fisheries and the Environment, is working as the Cartagena Protocol Primary National Focal Point for liaison with the secretariat. These fulfils the requirement of the signatories to have a national focal point for communicating with the secretariat to the CPB and to have one or more national authorities for administering the functions of the CPB (Secretariat of the Convention on Biological Diversity, 2000; "Fourth National Report on the Implementation of The Cartagena Protocol on Biosafety," 2019).

In regard to article 20 of the CPB, the Registrar of the Genetically Modified Act has been given the responsibility for cooperating with the Biosafety Clearing-House and providing them with the data in the prescribed manner and as per the guidelines provided in regulation no. R120. Furthermore, the fact that the amendment makes it necessary to obtain a permit for all activities

related to GMOs including any changes made to an activity for which a permit has already been obtained, makes it possible for the administrators to keep a record of all aspects of GMOs. This further helps in fulfilling the criteria of article 20 (Secretariat of the Convention on Biological Diversity, 2000).

In regard to article 21, the confidentiality of the data of an applicant is maintained by enabling the submission of two sets of documents, one containing confidential business information and one without confidential information. Only the one with non-confidential information is made available to the public. This is further regulated by the Information Act, 2000 (Fourth National Report on the Implementation of the Cartagena Protocol on Biosafety, "2019). Additionally, the amendment has made it mandatory to make certain information publicly available, including the summary of the risk assessment report as per the criteria of article 21 of the CPB.

South Africa has also been keen on fulfilling article 22 of the CPB. The country has a record of conducting multiple workshops, often in collaboration with other organizations or government bodies of other countries, with the aim of assisting other African countries and improving their skills. In addition, South Africa has cooperated in relation to public awareness, education and participation with countries like Kenya, Lesotho, Namibia, Ghana and Zimbabwe (Fourth National Report on the Implementation of the Cartagena Protocol on Biosafety, "2019). The activities essentially conform to paragraph 1 of article 22, which states:

> “The Parties shall cooperate in the development and/or strengthening of human resources and institutional capacities in biosafety, including biotechnology to the extent that it is required for biosafety, for the purpose of the effective implementation of this Protocol, in developing country Parties, in particular the least developed and small island developing States among them, and in Parties with economies in transition, including through existing global, regional, subregional and national institutions and organisations

and, as appropriate, through facilitating private sector involvement (Secretariat of the Convention on Biological Diversity, 2000)”

In regard to article 23, public awareness and participation are promoted by the amendment. Firstly, this is done by keeping a provision for public input before the Executive Committee can approve an application. Furthermore, it is mandatory that applicants use at least one national newspaper and two regional newspapers to inform the public about an activity before it is even submitted to the Executive Council for approval (*Act No. 23 of 2006: Genetically Modified Organisms Amendment Act, 2006*, 2007). South Africa also has a website dedicated to biosafety (http://biosafety.org.za) where the public can access the relevant documents and information. A website for sharing data related to regulatory activities is also made available (www.daff.gov.za/daffweb3/Branches/Agricultural-Production-Health-Food-Safety/Genetic-Resources/Biosafety). Furthermore, certain information is also shared on the DALRRD website. While the amendment's guidelines would ensure public participation, access to information on websites and newspapers would help to raise awareness and improve public understanding of biosafety and GMOs ("Fourth National Report on the implementation of the Cartagena Protocol on Biosafety," 2019).

In regard to article 26 of the CPB, as mentioned earlier, the amendment kept a provision where an applicant can be asked by the Council to provide an assessment of socio-economic considerations of the activity. In addition, the amendments ensure that socioeconomic considerations are given due weight by the Council in the decision-making process (*Act No. 23 of 2006: Genetically Modified Organisms Amendment Act, 2006*, 2007).

Chapter 4: Conclusion

South Africa is continually progressing in the field of biotechnology and with GM crops. As illustrated in figure 5, according to the "GM Approval Database" of ISAAA, from 1997 to 2022, the country gave 152 approvals (72 different events) for food, feed and cultivation. The number of approvals before the amendment took effect (before 2010) was only 55, whereas the number of approvals after the amendment took effect was 100.

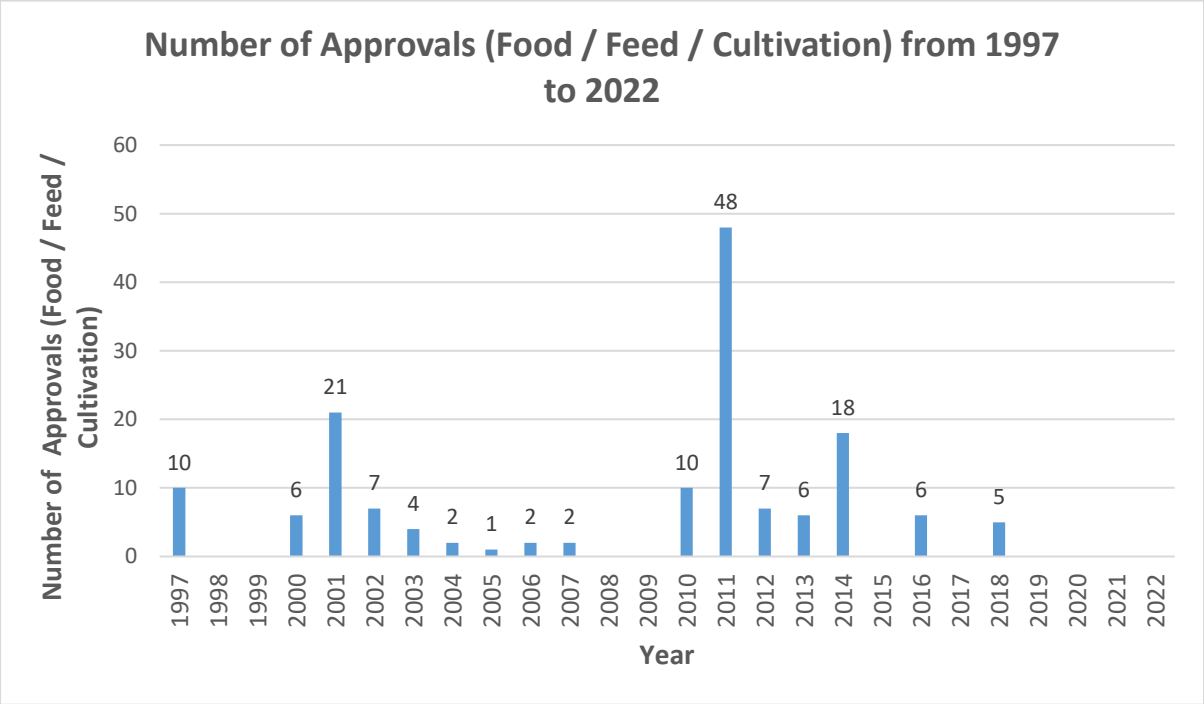

Figure 5: Number of approvals for GM crops and their products (Food / Feed / Cultivation) given from 1997 to 2022.

Furthermore, 340 different GM permits for import, export, commodity clearance and general release were issued in the country in 2021 alone. Around 75% of these permits were related to GM crops, and the remaining were for vaccines ("GM permits issued in South Africa," n.d.). The country has a comprehensive biosafety framework and has systems for handling notifications or requests, monitoring and enforcement, and public information. The government has also established financial allocations for the operation of its biosafety measures and has permanent staff to administer functions related to biosafety. In addition, South Africa

now has state-of-the-art facilities such as the University of Free State testing facility and SciCorp Laboratories, which are equipped to carry out almost any processes related to GMOs ("Fourth National Report on the Implementation of the Cartagena Protocol on Biosafety," 2019). However, credit must be given to the CPB, which certainly had a substantial influence on South Africa's biosafety regulatory system. The country had biosafety laws in place prior to becoming a signatory, but only after signing the CPB did the country begin to introduce new regulations and make significant changes to some of its existing laws. The country's commitment to the CPB becomes evident by examining its BCH portal, where national reports and other relevant documents are regularly submitted as per Article 20 of the Protocol.

South Africa's success with GM crops can therefore be attributed to the establishment of a functional national biosafety framework and the CPB. Countries that are afraid of growing GE crops due to safety concerns about GMOs can take South Africa's success as an example and take action to build a functional regulatory system in their countries. This will enable them to safely harness the benefits of GE crops and contribute to their economy, help reduce hunger, and improve food security.

References

About the protocol. (2021, May 18). The Biosafety Clearing-House (BCH). https://bch.cbd.int/protocol/background/

Agaba, J. (2019, January 15). Why South Africa and Sudan lead the continent in GMO crops. *Alliance for Science*. https://allianceforscience.cornell.edu/blog/2019/01/south-africa-sudan-lead-continent-gmo-crops/

Act No. 15 of 1997: Genetically Modified Organisms Act, 1997 (18029). (1997). https://www.gov.za/sites/default/files/gcis_document/201409/act15of1997.pdf

Act No. 23 of 2006: Genetically Modified Organisms Amendment Act, 2006 (29803). (2007). https://www.gov.za/sites/default/files/gcis_document/201409/a23-060.pdf

The Cartagena protocol on Biosafety. (2022, July 25). The Biosafety Clearing-House (BCH). https://bch.cbd.int/protocol/default.shtml

Eggers, B. (2000). The Cartagena protocol on biosafety. *Journal of International Economic Law*, *3*(3), 525-543. https://doi.org/10.1093/jiel/3.3.525

Eisenstein, M. (2020, December 9). *Natural solutions for agricultural productivity*. Nature. https://www.nature.com/articles/d41586-020-03445-4

Environmental Risk Assessment framework for Genetically Modified Organisms: A guidance document. (n.d.). https://biosafety.org.za/cms/modules/media/scripts/documents/document.handler.php?media_files_id=868

Esterhuizen, D. (2020). *Agricultural Biotechnology Annual* (SF2019-0042). United States Department of Agriculture. https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?fileName=Agricultural%20Biotechnology%20Annual_Pretoria_South%20Africa%20-%20Republic%20of_10-20-2019

FAO, IFAD, UNICEF, WFP, & WHO. (2022). In brief to the state of food security and nutrition in the world 2022. https://doi.org/10.4060/cc0640en

Fourth National Report on the implementation of the Cartagena Protocol On Biosafety. (2019, October 2). Biosafety Clearing-House. https://bch.cbd.int/en/pdf/documents/cpbNationalReport4/BCH-NR4-ZA-248141/1

GM permits issued in South Africa. (n.d.). Biosafety South Africa. biosafety.org.za/cms/modules/media/scripts/documents/document.handler.php?media_files_id=1297

Hokanson, K. E. (2019). When policy meets practice: The dilemma for guidance on risk assessment under the Cartagena protocol on Biosafety. *Frontiers in Bioengineering and Biotechnology*, *7*. https://doi.org/10.3389/fbioe.2019.00082

How are GMOs regulated in South Africa?. (n.d.). Biosafety South Africa. Retrieved February 10, 2022, from https://biosafety.org.za/information/know-the-basics/regulation-of-gmos/how-are-gmos-regulated-in-south-africa

ISAAA. (2019). *ISAAA Brief 55-2019: Executive Summary*. International Service for the Acquisition of Agri-biotech Applications. https://www.isaaa.org/resources/publications/briefs/55/executivesummary/default.asp

Kavhiza, N. J., Zargar, M., Prikhodko, S. I., Pakina, E. N., Murtazova, K. M., & Nakhaev, M. R. (2022). Improving crop productivity and ensuring food security through the adoption of genetically modified crops in sub-Saharan Africa. *Agronomy*, *12*(2), 439. https://doi.org/10.3390/agronomy12020439

List of activities involving GMOs for which the GMO Act requires a permit application. (n.d.). Biosafety South Africa. Retrieved February 10, 2022, from biosafety.org.za/cms/modules/media/scripts/documents/document.handler.php?media_files_id=990

Lyddon, C. (2021, May 24). *Focus on South Africa*. World-Grain.com | World Grain. https://www.world-grain.com/articles/15331-focus-on-south-africa

McLean, M., Foley, M. E., & Pehu, E. (2012). *The Status and Impact of Biosafety Regulation in Developing Economies since Ratification of the Cartagena Protocol*.

National Institutes of Health. (n.d.). *Genetically engineered foods*. MedlinePlus - Health Information from the National Library of Medicine. https://medlineplus.gov/ency/article/002432.htm

Overview of the South African regulatory framework for GMOs. (n.d.). Biosafety South Africa. https://biosafety.org.za/cms/modules/media/scripts/documents/document.handler.php?media_files_id=853

Phillips, T. (2008). *Genetically Modified Organisms (GMOs): Transgenic Crops and Recombinant DNA Technology*. Nature Education. https://www.nature.com/scitable/topicpage/genetically-modified-organisms-gmos-transgenic-crops-and-732/

Rani, S. J., & Usha, R. (2013). Transgenic plants: Types, benefits, public concerns and future. *Journal of Pharmacy Research*, *6*(8), 879-883. https://doi.org/10.1016/j.jopr.2013.08.008

Regulations of Genetically Modified Organisms Act, 1997 (R. 120). (2010). http://biosafety.org.za/cms/modules/media/scripts/documents/document.handler.php?media_files_id=871

Relevant acts, regulations & guidelines. (n.d.). Biosafety South Africa. https://biosafety.org.za/information/dig-deeper/compliance/relevant-acts-regulations--guidelines

Yáñez-López, R., Torres-Pacheco, I., Guevara-González, R. G., Hernández-Zul, M. I., Quijano-Carranza, J. A., & Rico-García, E. (2012). The effect of climate change on plant diseases. African Journal of Biotechnology, 11(10). https://doi.org/10.5897/ajb10.2442

Secretariat of the Convention on Biological Diversity. (2000). *Cartagena protocol on Biosafety to the convention on biological diversity: Text and annexes*. https://www.cbd.int/doc/legal/cartagena-protocol-en.pdf

Servi, H., & Ayaz, F. (2022). Transgenic plants and their impact on the agricultural yield. *Advanced Engineering Days*, *3*, 40-41.

Smyth, S. J. (2022). Contributions of genome editing technologies towards improved nutrition, environmental sustainability and poverty reduction. *Frontiers in Genome Editing*, *4*. https://doi.org/10.3389/fgeed.2022.863193

United Nations. (2022). *Progress towards the Sustainable Development Goals* (E/2022/55). https://unstats.un.org/sdgs/files/report/2022/secretary-general-sdg-report-2022--EN.pdf

United Nations. (2022). *The Sustainable Development Goals Report*. https://unstats.un.org/sdgs/report/2022/The-Sustainable-Development-Goals-Report-2022.pdf

The World Bank. (2022). *Food Security Update*. https://thedocs.worldbank.org/en/doc/4cda3ceaa5a01b7590e7105fd5e6ca4f-0320012022/original/Food-Security-update-LXVI-July-15-2022.pdf