

THE BIOSAFETY (AMENDMENT) BILL, 2017
(BILL NO. OF 2017)

(to be presented by the Minister of Tourism and Environmental Affairs)

MEMORANDUM OF OBJECTS AND REASONS

The object of this Bill is to amend the Biosafety Act No. 7 of 2012 so as to bring it into compliance with the provisions of the Cartagena Protocol on Biosafety and to provide for -

- (a) new biodiversity definitions;
- (b) liability and redress; and
- (c) incidental matters.

S. M. KHUMALO
Acting Attorney-General

A BILL
Entitled

An Act to amend the Biosafety Act No. 7 of 2012 and to provide for incidental matters.

ENACTED by the King and the Parliament of Swaziland.

Short title and commencement

1. (1) This Act may be cited as The Biosafety (Amendment) Act, 2017 and shall be read as one with The Biosafety Act No. 7 of 2012 (hereinafter referred to as the Principal Act).

(2) This Act shall come into force on a date to be appointed by the Minister by notice published in the Gazette.

Amendment of Principal Act

2. The Principal Act is amended by -

- (a) adding the word “modern” before the word “biotechnology” wherever it occurs in the Act.;

Amendment of section 2

3. Section 2 of the Principal Act is amended

- (a) by adding new definitions in alphabetical order as follows -

“adverse effect(s)” means any harmful or detrimental effect on the environment, whether actual or potential that -

- (a) is, or may in future be, more than trivial or insignificant;
- (b) impairs, or may in future impair, human health; or
- (c) results in, or may in future result in, an impairment of the ability of people and communities to provide for their health, safety, and cultural and economic well-being, that is more than trivial or insignificant;

and the risk of a potential adverse effect occurring shall be deemed to be significant if either it is reasonably likely that the adverse effect may occur, or if it is unlikely that the adverse effect will occur but if it did occur it would be serious or irreversible;

“applicant” means a person submitting an application, notification or petition pursuant to the provisions of this Act;

“application” includes notification;

“damage” means adverse effect on the conservation and sustainable use of biological diversity, taking into account risks to human health, that –

- (a) is measurable or otherwise observable taking into account wherever available, scientifically-established baselines recognized by a competent authority that takes into account any other human induced variation and natural variation; and;
- (b) is significant in that the extent of the adverse effects can be determined by the permanence of the damage, quality or quantity of the adverse effect and the extent of the adverse effect on human health and biodiversity.

“export” means the intentional transboundary movement from the area of national jurisdiction of Swaziland to the area of national jurisdiction of another country;

“facility” means any installation or physical structure designated for contained use activities in conformity with this Act;

“import” means the intentional transboundary movement into Swaziland from the area of national jurisdiction of another country;

“modern biotechnology” means the application of -

- (a) in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
- (b) fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;

“product(s)” means processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology;

- (b) by deleting the word “and” and replacing it with the word “or” at the end of paragraph (b) in the definition of the word “genetically modified organism (GMO)”

Amendment of section 3

4. Section 3 of the Principal Act is amended –

- (a) in paragraph (a) by adding the word “or” at the end of that paragraph;
and
- (b) in paragraph (b) by deleting the word “or” at the beginning of that paragraph and inserting the word “of” at the beginning of that paragraph.

Amendment of section 5

5. Section 5 of the Principal Act is amended in sub-section (2) paragraph (a) by deleting the words “Secretariat of the Cartagena Protocol” and replacing them with the words “Secretariat of the Convention on Biological Diversity”.

Amendment of section 7

6. Section 7 of the Principal Act is amended -

(a) in subsection (1) –

- (i) by deleting paragraph (a) and (b) and replacing them with new paragraphs as follows -

“(a) reviewing risk assessments provided in applications or notifications;

(b) conducting risk assessments where necessary”;

- (ii) at the beginning of paragraph (g) and (h) by deleting the word “developing” and replacing it with the words “advise on the development of”;
- (iii) in paragraph (j) by deleting the words “National Authority” and replacing them with the words “Competent Authority”;
- (b) in subsection (4) paragraph (a) by deleting the word “advisers” in the second line and replacing it with the word “advisors”;
- (c) in subsection (6) by deleting the words “scientific” and replacing them with the word “other”.

Amendment of section 8

7. Section 8 of the Principal Act is amended in subsection (2) by adding the words “or a related field” at the end of that subsection.

Amendment of section 9

8. Section 9 of The Principal Act is amended –

- (a) in paragraph (a) by inserting the word “for” between the words “screen” and the word “completeness”;
- (b) in paragraph (c) by inserting the word “as” between the words “permit” and the words “prescribed”;
- (c) in paragraph (e) by deleting the word “applications” and replacing it with the word “activities”;
- (d) in paragraph (f) by inserting the words “subject to section 31, the Registrar shall” at the end of that paragraph;
- (e) adding a new paragraph (i) as follows –

“(i) sit in the National Biosafety Advisory Committee as an ex-officio member”.

Amendment of section 10

9. Section 10 of the Principal Act is amended by inserting the word “the” between the words “with” and “Committee”.

Amendment of section 11

10. Section 11 of the Principal Act is amended by deleting it and replacing it with a new section 11 as follows –

“Authorization procedures for Export of a GMO

(1) A person who intends to export a GMO covered by this Act to another country party to the Cartagena Protocol shall-

- (a) notify the Competent Authority of the country party of import, in writing, prior to the first transboundary movement of the GMO for intentional introduction into the environment of the country party of import by supplying, at a minimum, information specified in the First schedule, in accordance with the Cartagena Protocol and any applicable domestic legislation;
- (b) include a declaration that all information provided in such notification is factually correct;
- (c) prior to shipment, provide the Competent Authority with a copy of the authorisation granted by the importing country where authorisation is required under

the Cartagena Protocol and the applicable laws of that country.

Amendment of section 12

11. Section 12 of the Principal Act is amended by deleting it and replacing it with a new section as follows-

“Application procedures for introduction into the environment

- (1) A person shall not import a GMO for the intentional introduction into the environment for purposes other than placing it on the market and placing it on the market without authorisation under this Act.
- (2) A person who intends to introduce a GMO into the environment or place it on the market shall submit to the Competent Authority an application that complies with the requirements of this section and describe the activities for which authorisation is sought, except as provided under section 19.
- (3) An Applicant shall include in their submissions -
 - (a) the information specified in the first schedule, with the exception of any information the Committee identifies as unnecessary in pre-application consultations;
 - (b) a risk assessment in conformity with the second schedule; and
 - (c) any additional information applicants deem relevant to an assessment of the potential risk and benefits of the requested activity; and

(d) a declaration that the information Contained in their submissions is factually correct.

(4) An applicant may withdraw, without prejudice, the application at any time prior to the issuance of a final decision by the Competent Authority.

Amendment of section 13

12. Section 13 of the Principal Act is amended –

(a) in the heading by deleting it and replacing it with a new heading as follows –

“Requirements for GMO for direct use as food, feed or processing”

(b) in subsection (2) by deleting subsection (7) and replacing it with subsection (6).

Amendment of section 19

13. Section 19 of the Principal Act is amended -

(a) in subsection (3) by deleting the word “my” and replacing it with the word “may”;

(b) in subsection (4) by deleting the word “shall” between the words “and” the word “the”.

Amendment of section 20

14. Section 20 of the Principal Act is amended in subsection (2) (a) and (d) by deleting the word “applicant” and replacing it with the word “petitioner”.

Amendment of section 21

15. Section 21 of the Principal Act is amended in subsection (1) by deleting the words “sections 9, 10” and replacing them with the words “sections 10, 11”

Amendment of section 23

16. Section 23 of the Principal Act is amended –

(a) in sub-section (1) -

(i) by deleting the words “that the operators comply” and replacing them with the word “compliance”;

(ii) by deleting the words “or allowance”;

(b) in sub-section (2) by deleting the words “advise” and replacing them with the words “inform”.

Amendment of section 24

16. Section 24 of the Principal Act is amended in subsection (2) by deleting the word “substantial”.

Amendment of section 25

17. Section 25 of the Principal Act is amended in subsection (2) –

(a) paragraph (a) by deleting the word “proposal” and replacing it with the word “application”;

(b) in paragraph (b) by deleting the words “proposed decisions on” at the beginning of that paragraph.

Amendment of section 27

18. Section 27 of the Principal Act is amended -

- (a) in sub-section (1) paragraph (c) by deleting the words “living” and replacing it with the word “Genetically”;
- (b) in sub-section(2) by deleting the words “in accordance with section 34” and replacing them with the words “prescribed under this Act”.

Amendment of section 28

19. Section 28 of the Principal Act is amended -

- (a) in subsection (1) by deleting the quotation mark after the word “contain” and inserting it after the word “GMOs”
- (b)in sub-section(3) by deleting the words “in accordance with section 34” and replacing them with the words “prescribed under this Act”.

Amendment of section 29

20. Section 29 of the Principal Act is amended in sub-section (2) by deleting the words “in accordance with section 34” and replacing them with the words “prescribed under this Act”.

Amendment of section 31

21. Section 31 of the Principal Act is amended –

- (a) in the heading by deleting the word “*Enforcement*” and replacing the word “*Inspection*”
- (b) in sub-section (i) by inserting the words “or any other officer” between the words “officers” and the word “who”;
- (c) in sub-section (2) -
 - (i) paragraph (a) (i) by deleting the words “has reason to believe it is” and replacing them with the words “determines as”;
 - (ii) paragraph (i) by deleting the words “Competent Authority” and replacing it with the word “Minister”.

Amendment of section 32

21. Section 32 of the Principal Act is amended by deleting it and replacing it with a new section 32 as follows –

Liability and redress

32 (1) The responsible operator shall be liable for damage caused by such GMO and to make compensation therefor.

(2) Where there has been damage, the operator liable to pay compensation under subsection (1), shall also pay the costs of reinstatement, rehabilitation or clean-up measures which are actually being incurred and, where applicable, the costs of preventative measures.

(3) The right to bring an action in respect of the damage caused by a GMO or a product of a GMO shall lapse after three (3) years from the date on which the affected person or the community learned of the damage.

(4) Any person, group of persons or any private or state organisation may bring a claim and seek redress in respect of a breach or threatened breach of any provision of this Act causing or threatening damage to the environment-

- (a) in the interest of that person or group of persons;
- (b) in the interest of, or on behalf of, a person who is, for practical reasons, unable to institute such proceedings;
- (c) in the interest of, or on behalf of, a group or a class of persons whose interests are affected;
- (d) in the public interest; or
- (e) in the interest of protecting the environment or biological diversity,