A BILL
FOR AN ACT TO AMEND THE
NATIONAL BIOSAFETY
MANAGEMENT AGENCY
(AMENDMENT) ACT,
2019
A BILL FOR AN ACT TO AMEND THE NATIONAL BIOSAFETY MANAGEMENT AGENCY (AMENDMENT) ACT, 2019

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In 2015, HOMEF reviewed the National Biosafety Management Agency Act, 2015 through consultations with various stakeholders and experts who critically examined the issues of genetically modified organisms (GMOs) in Nigeria and the Act itself.


Some of the gaps in the Act are in the areas of risk assessments and management; access to information; public consultation and participation; liability and redress; the right to know; decision making and appeals and reviews.

Enormous amounts of discretionary powers (including absolute decision making power without clear oversight or accountability) have been vested on the National Biosafety Management Agency and without enough mandatory duties in the operational provisions to ensure that the Agency will perform a stewardship role to ensure that GMOs do not pose harm to human and animal health, society and the environment.

The composition of the Governing Board of the agency is arbitrary and constitutes conflict of interest. For example, the National Biotechnology Development Agency (NABDA) which is the major promoter of the technology sits on that board, yet there is no sufficient representation of civil society and no representative of farmers and consumers.

In 2019, an amendment of the NBMA Act, 2015 to include evolving aspects of biotechnology such as gene drives, gene editing and synthetic biology was signed into law by the president.

Based on the findings of the previous review and in response to the inclusion of the new definitions on emerging aspects of biotechnology, HOMEF has drafted this bill for an amendment of the NBMA Amendment Act, 2019.

HOMEF believes that enlarging the scope of the NBMA Act to include these emerging technologies is a tremendously dangerous move which would compound the risks already posed by the basic application of the first-generation technology. The amendment proposed highlights the importance of conducting independent risk assessments on these applications and also for the public to be able to access results of such assessments.

Also the amendment seeks to include strict provisions for a precautionary approach to the issues of GMOs and biosafety in Nigeria; clear and mandatory provisions on access to information; public consultation and participation; strict liability and redress; labelling and the right to know; decision-making, appeals and reviews and to resolve conflict of interest and absolute powers of the Agency. Also to prevent threats of irreversible damage and ensure that lack of full scientific evidence should not be used as a reason not to take action to prevent such damage.
About HOMEF

HOMEF is the ecological think tank and an advocacy organization promoting environmental/climate justice and food sovereignty in Nigeria and Africa. Our main thrust is examining the roots of exploitation of resources, peoples and nations. We nurture movements for the recovery of memory, dignity and harmonious living with Mother Earth. HOMEF believes in the rights of Mother Earth, the need to equip communities to push back oppression and the need for justice for the environment, our food systems and natural cycles at every level of policy engagement.

HOMEF believes in contextual solutions over externally generated and imposed ideas and is firmly rooted in the ideals of solidarity and dignity.

Our Core Values: justice & equity in all circumstances, people and the planet in harmony and free from exploitation, dignity (respect), action (solidarity), and knowledge.

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Selected Publications by HOMEF

I. Eco-Instigator (quarterly journal)
II. Threat to Fisheries in the Gulf of Guinea
III. What’s on our Plates?- Report on a Market Shelf Survey for Food Products of Genetically Modified Organisms And Glyphosate-Containing Herbicides in Nigeria-2019
IV. What’s on our Plates?- Report on a Market Shelf Survey for Food Products of Genetically Modified Organisms And Glyphosate-Containing Herbicides in Nigeria-2018
V. Assessing Clean Drinking Water Availability in Juba, South Sudan
VI. Resource Democracy
VII. Living in Fear-Juan Lopez Villar
VIII. Community Dialogue Guide (Oil/Gas)
IX. Community Dialogue Guide (Forest)
X. Community Dialogue Guide (FishNet)
XI. Not on our Plates: Nigeria Does Not Need GM Food
XII. Community Dialogue Guide (Food and Farming Systems)
XIII. Oil Politics: Echoes of Ecological Wars-Nnimmo Bassey
XIV. Community Guide to Environmental Monitoring and Reporting
XV. Oil, Power and a Sign of Hope-Klaus Steiglitz with Sabine Pamperrien
XVI. Nigeria’s Biosafety Management Agency Act 2015: In Whose Interest?
XVII. Resistance to the Military-Corporate Wedlock in Nigeria and Beyond-Nnimmo Bassey (With TNI)
XVIII. To Mint an Illusion: Economic + Poverty Growth in an Extractive Rentier State-Nnimmo Bassey and Patrick Bond
XIX. Beyond Oil: Reimaging Development in the Niger Delta-Ken Henshaw, Ify Malo, Irikefe V. Dafe, Nnimmo Bassey
EXPLANATORY MEMORANDUM

This Act establishes the National Biosafety Management Agency charged with the responsibility for providing regulatory framework, institutional and administrative mechanism for safety measures in the application of modern bio-technology in Nigeria with the view to preventing any adverse effect on human health, animals, plants and environment.

THE NATIONAL BIOSAFETY MANAGEMENT AGENCY (AMENDMENT) ACT, 2020

ARRANGEMENT OF SECTIONS

Sections:
1. Amendment of NBMA Amendment Act 2019
2. Amendment of section 2 (b) & (e)
3. Amendment of section 3 (e)
4. Substitution of section 3 (h)
5. Substitution for section 10(1) (viii)
6. Substitution for section 10(1) (d)
7. Substitution for section 10(1), (e)
8. Insertion of new sections 12(2) (a), (2)(b)
9. Insertion of new sections 13(e), (f) & (g)
10. Amendment of section 18
11. Amendment of section 22
12. Substitution for section 23(1)
13. Amendment of section 23(2)(g)
14. Amendment of section 23(2)(g)(ii)
15. Amendment of section 23(2) (g) (iii)
15. Substitution for section 24(2)
16. Amendment of section 25A
17. Amendment of section (25(1)
18. Amendment of section (25) (2)
19. Amendment of section 26(1)
20. Insertion of a new subsection 26(3)(e)
21. Insertion of new subsection 27(f)
22. Amendment of section 27(a)
23. Insertion of new subsection 28(1) and (2)
24. Amendment of section 28(a)
25. Amendment of section 28(d)
26. Amendment of section 29
27. Amendment of section 30 (1)
28. Amendment of section 30 (2)
29. Amendment of section 31 (1)
30. Amendment of section 34 (b)
31. Amendment of section 34 (c)
32. Insertion of new subsections 34(d to i)
33. Amendment of section 35
34. Amendment of section 36
35. Amendment of section 41(1)(a)
36. Amendment of section 43
37. Amendment of First Schedule: 3
38. Amendment of Part B of the Second Schedule (8)
39. Amendment of the Part B Second Schedule (c)
40. Insertion of new subsection in Part B of the Second Schedule under (h)
41. Insertion of new subsection (12) in Part C of the Second Schedule
42. Insertion of new subsection (4) in Part D of the Second Schedule
THE NATIONAL BIOSAFETY MANAGEMENT AGENCY (AMENDMENT) ACT, 2020

A Bill For An Act to amend The National Biosafety Management Agency Amendment Act, 2019
to make strict provisions for a precautionary approach, clear and mandatory provisions on access to information, public consultation and participation, strict liability and redress, labelling and the right to know, decision-making, appeals and reviews and to resolve conflict of interest and absolute powers of the Agency. Also to prevent threats of irreversible damage and ensure that lack of full scientific evidence may not be used as a reason not to take action to prevent such damage. Additionally, to address policy issues that would help in improving the Act before harm is inflicted on the environment and people.

ENACTED by the National Assembly of the Federal Republic of Nigeria:

PART I – ESTABLISHMENT OF BIOSAFETY MANAGEMENT AGENCY
1. The National Biosafety Management Agency Amendment Act 2019 in this Act referred to as the Principal Act is amended as set out in this Amendment Act.

2. Section 2(b) of the Principal Act is amended by inserting after the words 'human health' in line one with 'animals,' 'plants.' The words 'and parts thereof' are also inserted after the words 'genetically modified organism' in line 2.

PART II FUNCTIONS AND POWERS OF THE AGENCY
3. Section 3(e) of the Principal Act is amended by inserting after the words 'risk assessment' with 'to ensure mechanisms of public participation in decision making'

Section 3(h) of the Principal Act is amended by substituting the word 'contain' in line two with 'consist' and substituting 'organisms' in line two with these phrases 'materials or parts'

PART III – STRUCTURE AND STAFF OF THE AGENCY
4. Section 3(h) of the Principal Act is amended by inserting after the words 'analysis' in line one with 'genetically modified organism.' Substitution of the word 'contain' in line 2 with 'consist.'
PART V - ESTABLISHMENT OF THE GOVERNING BOARD

5. **Section 10(1)** of the Principal Act is amended in subsection (viii) by substituting 'the National Biotechnology Development Agency (NABDA)' with the Federal Competition and Consumer Protection Commission (FCCPC).

6. **Section 10(1)** of the Principal Act is amended in subsection (d) by substituting the words 'conservation' with 'environmental and knowledgeable' and inserting the words 'biosafety issues' in line two after "NGOs". Delete in line two, the words 'and organised private sector'.

7. **Section 10(1)** of the Principal Act is amended in subsection (e) by inserting after the word 'one' in line one with 'established and known.' Also substituting 'Biotechnology Society of Nigeria' with 'small- scale farmers' organisation.'

8. **Section 12** of the of the Principal Act is amended by inserting new subsections in 12(2) (a) and (2) (b) and renumbering of the Principal subsections 2 to subsection 3

   "(2) (a) If a member of the Board is personally or institutionally involved in a specific application, this member cannot participate in the assessment process."

   "(2) (b) "If a member of the Board is personally or institutionally involved in the promotion of GMOs, this member should be excused from the Board."

PART VI - FUNCTIONS AND POWERS OF THE BOARD

9. **Section 13** of the of the Principal Act is amended by inserting new subsections (e), (f), (g)

   "(e) The Board shall endorse key decisions of the Agency before they are implemented"

   "(f) The Minister of Environment shall have oversight of NBMA and the Director General shall report to the Minister."

   "(g) The Minister of Environment shall conduct a periodic assessment of NBMA which can be conducted by way of a survey (use of questionnaires) or meeting with all relevant stakeholders and groups knowledgeable or working on issues of GMOs and Biosafety"

PART VII- FINANCIAL PROVISIONS

10. **Section 18** of the Principal Act is amended by deleting the entire section and subparagraphs "(1)" and "(2)."

PART VIII- REQUEST AND AUTHORISATION

11. **Section 22** of the Principal Act is amended by inserting after the words, 'multi-locational trial' in line three with 'and commercial release of genetically modified organisms'.

12. **Section 23(1)** of the Principal Act is amended by substituting the word 'contained' in line two with 'confined'. Also, by inserting the word 'planned' before 'date' in line four.

13. **Section 23(2)** of the Principal Act is amended in subsection (g) by inserting after the word 'management' in line one with 'and emergency'.

14. **Section 23(2)** of the Principal Act is amended in subsection (g) (ii) by inserting after the words 'confined field' in line two with 'escape from any field trials'
15. **Section 23(2)** of the Principal Act is amended in subsection (g) (iii) by inserting after the word 'environment' in line one with 'human and animal health'.

16. **Section (24) (2)** of the Principal Act is amended by substituting the words 'not substantial' in line two before the word 'is' with 'no' and the substitution of the phrase 'be eaten by humans or animals' with 'pose to the environmental, human and animal health'.

17. **Section 25A** of the Principal Act is amended by adding the new phrase: “The Agency shall carry out separate and independent risk assessments of any gene drive, gene editing and synthetic biology applications received and shall make results of such assessments available to the public.” Also, “the free, prior and informed consent of potentially affected people shall be sought and obtained before products of these technologies are released”.

18. **Section (25) (1)** of the Principal Act is amended by substituting the word 'may' in line four after the word 'Agency' with 'shall'. Also, substitution of the number '21' in line six with '60.' Likewise, the deletion of the phrase 'from time to time' in line four.

19. **Section (25) (2)** of the Principal Act is amended by substituting the word 'may' in line one and line two after the word 'Agency' with 'shall'. Also, the substitution of the words 'or such' after the word 'house' in line two with 'and'. The deletion of the phrase 'from time to time' in line four.

20. **Section (26) (1)** of the Principal Act is amended, by substituting the word 'may' in line one after the word 'Agency' with 'shall'. In addition, insertion of the words 'this information has to be taken into account' at the end of the sentence in line three.

21. **Section 26(3)** of the Principal Act is amended by inserting a new subsection 26(3) (e) “26(3) (e) If a decision is passed such information should be released to the public.”

22. **Section 27** of the Principal Act is amended by inserting a new subsection (f) “27(f) location of the release”

**Decision Making**

23. **Section 28** of the Principal Act is amended by inserting a new subsection 1 and 2 and renumbering appropriately the existing alphabets (a) to (g) to be under the new subsection (2) 28 (1) “Approvals of applications shall be made by the Board, following recommendations made by the National Biosafety Committee and clearance by the Minister of Environment.”

“28(2) With respect to any recommendations and decision taken under section 23 of this Act, and in order to protect the environment, the precautionary approach shall be widely applied by the Agency, where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.”

24. **Section 28 (2) (a)** of the Principal Act is amended by deleting 'relevant' in line one after the word 'the.'

25. **Section 28 (2) (d)** of the Principal Act is amended by substituting the word 'may' with 'shall' in line one.

26. **Section 29 (a)** of the Principal Act is amended by substituting 'section 23' in line two with 'section 28'.

**Appeals**

27. **Section 30 (1)** of the Principal Act is amended by inserting after the word 'Board' in line two with '30 days after the decision'
28. Section 30 (2) of the Principal Act is amended by inserting after the word 'Applicant' with 'and interested and affected parties'.

PART IX - RISK ASSESSMENT AND MANAGEMENT

29. Section 31 (1) of the Principal Act is amended by inserting after the word 'Nigeria' in line four 'The Agency shall also carry out separate and independent risk assessments of any genetically modified organism application and make results of such assessments available to the public'.

30. Section 34 (b) of the Principal Act is amended by substituting the words 'significant' in line three with 'any'. In addition, adding the sentence 'or if there is lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential risks to human health, animal, plant and the environment' after the word 'environment' in line three is inserted.

31. Section 34 (c) of the Principal Act is amended by inserting the words 'risk to' after the word 'any' in line three. In addition, to delete the words 'from time to time' in line three.

32. Section 34 of the Principal Act is amended by inserting new subsections (d) to (i) and renumbering the existing sub sections d and e appropriately. Subsections d and e are now 'k' and 'j' respectively.

"34(d) provide for response measures in the event of damage resulting from living modified organisms, or where there is sufficient likelihood that damage will result if timely response measures are not taken. To that end, the Agency has to:

(e) require that an applicant, in the event of damage, must (i) immediately inform the Agency; (ii) evaluate the damage; and (iii) take appropriate response measures.

(f) require that an applicant take appropriate response measures where there is sufficient likelihood that damage will result if timely response measures are not taken.

(g) make sure that the Agency (i) identifies the applicant which has caused the damage; (ii) evaluates the damage; and (iii) determines which response measures should be taken by the applicant.

(h) require that decisions by the Agency for the applicant to take response measures are reasoned, that remedies are available, including administrative or judicial review of such decisions.

(i) put in place a requirement whereby the Agency itself may implement appropriate response measures, in particular situations where the applicant has failed to do so. Provide the Agency the right to recover from the applicant, costs and expenses incurred in relation to the implementation of the response measures.

(j) undertake any measure, as may be reasonably necessary to avert risk or danger to human health, animal, plant and the environment where the person responsible for such action fails to act and the person so responsible shall bear the cost of any measure taken.

(k) direct any applicant under section 24 of this Act to submit periodic report of the monitoring and evaluation of risk carried out after the approval or permit granted under this Act; and

PART X - OFFENCES, PENALTIES AND ENFORCEMENT

33. Section 35 (1) (a) of the Principal Act is amended by inserting after the words 'contained use' in line one with 'confined and multi-location field trials'.

Section 35 (b) (i) of the Principal Act is amended, by substituting the amount 'N2,500,000.00' in line one with 'N10,000,000.00'

Section 35 (b) (ii) of the Principal Act is amended, by substituting the amount 'N5,000,000' in line one with 'N20,000,000.00' and the amount 'N2,500,000.00' in line three with 'N10,000,000.00'.


Section 35 (2) (i) of the Principal Act is amended, by substituting the amount 'N2,500,000.00' in line one with 'N10,000,000.00'.

Section 35 (2) (ii) of the Principal Act is amended, by substituting the amount 'N5,000,000' in line one with 'N20,000,000.00' and the amount 'N2,500,000.00' in line three with 'N10,000,000.00'.

34. Section 36 (a) of the Principal Act is amended, by substituting the amount 'N5,000,000' in line one with 'N20,000,000.00' and the amount 'N2,500,000.00' in line three with 'N10,000,000.00'.

Section 36 (b) of the Principal Act is amended, by substituting the amount 'N5,000,000' in line one with 'N20,000,000.00'

PART XI- MISCELLANEOUS PROVISIONS
35. Section 41 (1) (a) of the Principal Act is amended by substituting the words 'fault-based' in line one with 'strict'

36. Section 43 of the Principal Act is amended:
Under 'Biosafety' substituting the word 'minimizing' in line two with 'preventing'

Under 'Contained use’ insertion of the sentence 'that effectively prevents their contact with and their impact on the external environment and also 'That effectively limits or prevent the emission of GMOs.' after 'greenhouse,' in line three.

FIRST SCHEDULE: Section 24 (2) (H)
ADDITIONAL INFORMATION REQUIRED IN THE CASE OF NOTIFICATION FOR PLACING IN THE MARKET

37. 3 (c) of the First Schedule Principal Act is amended, by substituting the words 'it is known' in line two with 'there is a likelihood'

Part B- SECOND SCHEDULE Section 24 (3)
INFORMATION RELATING TO GENETICALLY MODIFIED ORGANISMS OR THE PRODUCTS THEREOF

38. (8) of Part B of the Second Schedule Principal Act is amended, by inserting after the word 'used', the sentence 'and has to be done by state-of-the-art molecular genetic methods to verify that the insert has remained stable at the same site in the genome for at least 5 successive generations'

Part B - CHARACTERISTICS OF GENETICALLY MODIFIED ORGANISMS OR PRODUCT THEREOF
39. (c) of Part B of the Second Schedule of the Principal Act is amended under 'Nature of the final genetically modified organisms', under (c) by inserting after the word 'and' with 'molecular genetic' and after the word 'structure,' with the phrases 'to be done by using state-of-the-art molecular genetic methods to verify that the insert has remained stable at the same site in the genome for at least 5 successive generations.'

40. (h) of the Second Schedule of the Principal Act is amended under 'Health considerations' by inserting a new subsection (vi) "(vi) Characterization of new proteins, new nucleic acids and metabolites and their potential for harm"
PART C - INFORMATION RELATING TO THE CONDITION FOR RELEASE AND THE RECEIVING ENVIRONMENT

41. Part C under 'Information on the Release' of the Second Schedule of the Principal Act is amended by inserting a new subsection (12)

“(12) measures to be taken to prevent cross-pollination; and new diseases spreading from GMOs to indigenous and other species”

PART D - INFORMATION RELATING TO THE INTERACTIONS BETWEEN THE GENETICALLY MODIFIED ORGANISMS OR PRODUCTS THEREOF AND THE ENVIRONMENT

42. Part C under 'Characteristics and Factors affecting Survival Multiplication, Gene Expression and Dissemination' of the Second Schedule of the Principal Act is amended by inserting a new sub-section (4) and renumbering of the other subsections appropriately

“(4) measures to be taken to prevent cross-pollination; and new diseases spreading from GMOs to indigenous species”
FACTSHEET ON THE BILL FOR AN ACT TO AMEND THE NATIONAL BIOSAFETY MANAGEMENT AGENCY ACT (NBMA), 2015

This Factsheet contains highlights of the extensive amendments proposed to the 2019 National Biosafety Management Agency Amendment Act by the Health of Mother Earth Foundation (HOMEF). It is expected to be sent to the National Assembly for legislative action. The proposed amendment bill has over 40 clauses, including Miscellaneous Provisions and Schedules.

<table>
<thead>
<tr>
<th>S/N</th>
<th>Section</th>
<th>Current Provision</th>
<th>Amendment</th>
<th>Reason for Amendment</th>
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<tbody>
<tr>
<td>1.</td>
<td>Section 2(b)</td>
<td>safeguard human health, biodiversity and the environment from any potential, adverse effect of genetically modified organism including food safety;</td>
<td>Inserting after the words 'human health,' in line one with 'animals,' and 'plants'. Additionally, insert the words 'and parts thereof' after genetically modified organism in line 2.</td>
<td>This is to make the wording of this section consistent with the protection goals contained in other sections, for example in sections 28 (d), 29 (a), 31 (1), 34 (b) &amp; (c) of the Principal Act.</td>
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<td>Section 2(e)</td>
<td>provide measures for effective public participation. Public awareness and access to information in the use and application of modern biotechnology and genetically modified organisms; and</td>
<td>inserting after the words 'information' in line two with, 'criteria for risk assessment peer review, criteria for decision-making; risk assessment plans and strategies and monitoring protocols '</td>
<td>This is to ensure this important protocols are carried out by the Agency and the active involvement of the Public. Also to know how the Agency intends to monitor human health and the environment to 'determine the effects of GMOs.' (section 2(f)). A lesson from South Africa is that despite growing GMOs commercially for around 17 years, the government has only carried out an assessment of the impact of GMOs on the environment in 2010/2011. This was done more than 10 years after GM crops were grown in that country commercially.</td>
</tr>
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</table>
2. **Section 3(e)**

   **develop measures and requirements for risk assessment;**

   **Insertion of new words after 'risk assessment;' 'to ensure mechanisms of public participation in decision making'**

   This is to ensure all relevant stakeholders and Nigerians are carried along.

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**Section 3(h)**

   **take samples and carry out laboratory analysis of crops, products or materials for purposes of determining if they contain genetically modified organisms and ensure compliance with this Act;**

   **insertion after the words 'analysis' in line one with 'genetically modified organisms.' Substitution of the word 'contain' in line 2 with 'consist.'**

   This revision is essential because the Act is concerned with all GMOs and not just crops. It will also help to clarify the testing of genetically modified materials and products.

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3. **Section (10)(1)(viii)**

   **National Biotechnology Development Agency (NABDA).**

   **Section 10(1) of the Principal Act is amended in subsections (viii) by substituting 'the National Biotechnology Development Agency (NABDA)' with the 'Consumer Protection Council (CPC)'**

   NABDA is one of the promoters of GMOs in Nigeria and cannot be part of the Board. It is their conduct, their technology and products the law is aiming to regulate. Placing them in this Board prepares the grounds for conflict of interest.

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**Section (10)(d)**

   **One representative each of conservation Non-Governmental Organizations (NGOs) and organized private sector;**

   **Substitution of the word 'conservation' with 'environmental and knowledgeable' and insertion of the words 'biosafety issues' in line two after 'NGOs'. Deletion in line two of the words 'and organised private sector'**

   The NGO group, is the only group given a clause and with a proviso. Specifying “conservation NGO” is not good enough. It would serve the interest of the Act better to have a slot for NGOs knowledgeable on biosafety issues or that represent consumers. In addition, the private sector like NABDA should not be represented on the Board, as the private sector is the entity being regulated by the Act for activities relating to GMOs.
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<tr>
<th>Section 10(1)(e)</th>
<th>(e) one representative of the Biotechnology Society of Nigeria.</th>
<th>Insertion after the word 'one' in line one with 'established and known.' Also substituting 'Biotechnology Society of Nigeria' with 'Small-Scale Farmers' organisation.</th>
<th>The exclusion of representatives of farmers in the Governing Board is an oversight. It is critical to ensure participation of well known and established farmers, because they are the prime target.</th>
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<tr>
<td>4. Section 12</td>
<td>The office of a member of the Board shall become vacant if:</td>
<td>Insertion of new subsections in 12(2) (a) and (b) and renumbering of the principal section (2) to (3)</td>
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<td>“(2) (a) If a member of the Board is personally or institutionally involved in a specific application, this member cannot participate at the assessment process.&quot;</td>
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<td>“(2) (b) &quot;If a member of the Board is personally or institutionally involved in the promotion of GMOs, this member should be excused from the Board&quot;</td>
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<td>This amendment guards against conflict of interests and protects the integrity of the Act.</td>
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### Functions and Powers of The Board:

The Board shall

- **Endorse key decisions of the Agency before it is implemented**
- **Minister of Environment shall have oversight of NBMA and the Director General shall report to the Minister.**
- **Conduct a periodic assessment of NBMA which can be conducted by way of a survey (use of questionnaires) or meeting with all relevant stakeholders and groups knowledgeable or working on issues of GMOs and Biosafety**

This Amendment aims to correct the serious deficiencies with the absolute decision making power vested in the Agency. There does not seem to be decision-making powers vested with the Board or the supervising Ministry (Environment). Everything is vested with the Agency. This does not ensure an appropriate balance. The key decisions of the Agency should require an endorsement by the Board/Minister.

The Powers of the Agency needs sufficient checks and balances, that is why these new subsections are built in.

### Section 18(1)

The Agency may, accept gifts of land, money or other property or things from within and outside Nigeria, on such terms and conditions, if any as may be specified by person or organization offering the gift.

Deletion the entire section and subparagraphs "(l)" and "(2)".

Even if the terms and conditions are consistent with the Agency's functions under the Act, there are insidious ways by which such gifts may unduly influence decision-making. Creates a gap for bribery and corruption under the guise of a 'gift'.
### Section 22

As from the commencement of this Act, no person, institution or body shall import, export, transit, carry out the contained use, confined field trial, multi-locational trial without the approval or permit of the Agency.

**Insertion of the word 'and commercial release of genetically modified organisms' after the word 'multi-locational trial'**

This section needs to be reviewed to cover every unauthorised imports, trials or commercial release of GMOs. and the sentence is not complete if it does not refer to GMOs.

### Section 23(1)

Any person, institution or body who wishes to import, export, transit or otherwise carry out a contained field trial, multi-locational trial or commercial release of a genetically modified organism shall apply to the Director General of the Agency not less than 270 days to the date of import, export, transit or the commencement of such activity.

**Substitution of the word "contained" in line two with "confined". Also insertion of the word "planned" before "date" in line four.**

It is essential that the word “planned” be inserted before “date.” The Act should clearly refer to an application for a planned activity, not an already determined activity.

### Section 23(2)(g)

Any application under subsection (1) of this section shall include: (g) a management plan for remediation measures to be undertaken in the event of:

**Insertion after the word 'management' in line one with 'and emergency'**

An emergency response plan is critical because GMOs could also affect human and animal health.
<table>
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<tr>
<th>Section 23(2)(g) (ii)</th>
<th>Substituting the words 'confined field' in line two with 'any confined field trials'</th>
<th>This Amendment is proposed because measures and plans need to be made in case of an unintended release or in the event of escape of GMOs from contained use and confined field trial facilities.</th>
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<td>(ii) the escape or persistence in the environment of a genetically modified organisms from a confined field trial; and</td>
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<td>Section 23(2)(g) (iii)</td>
<td>Insertion after the word 'environment' in line one with 'human and animal health'</td>
<td>In any event, specific references need to be made to a risk assessment indicating the potential risk, the GMOs may pose to human health including food safety, biological diversity, or the environment including the consequence of an unintended release.</td>
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<td>any unintended consequence to the environment from the placing of genetically modified organisms in the market.</td>
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<td>9. Section 24(2)</td>
<td>Substitution of the words 'not substantial' in line two before the word 'is' with 'no' and the substitution of be 'eaten by humans or animals' with 'pose to environmental, human and animal health,'</td>
<td>Section 24(2) of the Principal Act is very subjective, and without clear guidelines on what is a 'substantial risk.' The provisions here convey the notion that risk to human and animal health is acceptable unless the risk is substantial. What is substantial risk in this context? This is at odds with the underpinnings of the precautionary principle, which Nigeria signed to.</td>
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<td>Application under this section may only be granted upon completion of safety risk assessment to determine if there is not substantial risk that the genetically modified organism could be eaten by humans or animals.</td>
<td></td>
<td>Also there is something wrong with the sentence 'Food and feed products are meant to be eaten.' This expression sounds awkward. The avoidance to be eaten is not the outcome of any established risk assessment methodology. The result of a risk assessment is usually characterised as “there is no / no significant / a small/ etc. risk of xxx to the environment / human health,” etc.</td>
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<td>10.</td>
<td>Section 25 A</td>
<td>Application of gene drives, gene editing and synthetic biology.</td>
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<td>Section 25 (1)</td>
<td>(1) The Agency shall upon the receipt of the application and the accompanying information under section 23 of this Act, display copies of such application and relevant information at such places and for such period as the Agency may, from time to time determine to enable the general public and relevant government ministries and agencies study and make comments on the application and relevant information within 21 days.</td>
<td>Substitution of the word 'may' in line three after the word 'Agency' with 'shall'. Also substitution of the number '21' in line five with '60'. Also the deletion of the phrase 'from time to time'</td>
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To enable effective participation, it should be taken into account that the likelihood that larger constituencies have to be consulted, such as farmer associations and organisations.

In addition, the use of “from time to time” is vague and detracts from the promise of openness and transparency and should be substantially reviewed. It seems to indicate that the Agency will decide in respect of which activities concerning GMOs and its products a display will be made and can disclose whatever information it may be inclined to share or can withhold any information. This section does not auger well for transparency and disclosure of information to the public about an issue that is of great importance to their health and wellbeing, culture, way of life and agriculture and food systems, hence the amendment is proposed.
<table>
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<tr>
<th>Section 25 (2)</th>
<th>(2) The Agency may, prior to the display, make announcement in at least 2 national and one local newspapers, the national Biosafety clearing house or such other news media as the Agency may from time to time determine, giving summary of the application and brief information on the place, duration and time for the display.</th>
<th>Substitution of the word 'may' in line one and line two after the word 'Agency' with 'shall'. Also the substitution of the words 'or such' after the word 'house' in line two with 'and'. Similarly, The deletion of the phrase 'from time to time'</th>
<th>Section 25(2) does not provide a saving grace, as the language used is discretionary, saying that the Agency “may” and “may from time to time determine” what information to give out to concerned parties and the public. This double discretion has been created here to give the Agency enough flexibility to determine what information pertaining to which GM activity it will release to the public. No clear rights have been created on the part of the public with regard to accessing information in a timely manner in order to participate in the decision making process. The discretion given to the Agency to decide whether or not public notices will be published in national and local newspapers leaves room for publishing in media that may not bring the notice to a wide audience. There should be clear stipulations of range of publications that would support the basic minimum provisions in the context of public participation. Hence the Amendment is proposed.</th>
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<tr>
<td>11.</td>
<td>Section 26 (1)</td>
<td>The Agency may, in addition to the comment received pursuant to section 23 of this Act, hold public hearings or consultations to obtain further comments and inputs that will assist in the review or processing of the application.</td>
<td>Substitution of the word 'may' in line one after the word 'Agency' with 'shall'. In addition, insertion of the words 'this information has to be taken into account' at the end of the sentence in line three.</td>
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<tr>
<td>Section</td>
<td>Insertion of a new subsection</td>
<td>Comment</td>
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<td>26 (3)(e)</td>
<td>“26(3) (e) If a decision is passed such information should be released to the public.”</td>
<td>Section 26 is too pro-business without due consideration for the people. The public have a right to know the decisions as it affects their environment, crops and health. More so, If a decision is passed such information ought to be released to the public.</td>
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<td>27(f)</td>
<td>“27(f) location of the release” should also been listed as the information that cannot be considered confidential. Other legislation like that of the European Union (EU) requires that it is released.</td>
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<td>28 (1) &amp; (2)</td>
<td>This section has to do with procedure for granting approval.</td>
<td>Generally speaking, section 28 is very weak in terms of decision-making. It does in fact not discuss how decisions are to be made, what should be taken into account and certainly no reference is made to the precautionary principle at all.</td>
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28 (1) “Approvals of applications shall be made by the Board of the agency, following recommendations made by the National Biosafety Committee and clearance by the Minister of Environment.”

“28(2) With respect to any recommendations and decision taken under section 23 of this Act, and in order to protect the environment, the precautionary approach shall be widely applied by the Agency, where there are threats of serious or irreversible damage, lack of full scientific uncertainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.”

It looks like the granting of approval is given to the Agency. This makes it very powerful, and could be compromised. In other countries, there are two layers – an agency or committee that makes recommendations based on the Risk Assessment, and a Board or inter-ministerial body that makes the decision. Hence the need for additional subsections to cover this.
| 14. | Section 28 (a) & (b) | (a) shall take into consideration, the relevant comments, inputs or concerns of the public received under the provisions of this Act; (d) may specify the steps to be taken in the implementation of the risk management plan where there are potential risk to human health, animal, plant and the environment. | Deletion of 'relevant' in line one after the word 'the.' substitution of the word 'may' with 'shall' in line one. An obligation has been created on the part of the Agency by this sub section to take the "relevant comments, inputs or concerns of the public received under the provisions of the Act. "This suggests that where the Agency deems comments, inputs and concerns to be irrelevant, it will then be discharged of its duty to take these into account. All comments need to be considered. Also the Agency must be obligated to take steps to where there is potential risk to human health, animal, plant and the environment. Hence the substitution of 'may' with 'shall' |
| 15. | Section 29 (a) | The Agency may: (a) revoke or suspend the approval or permit or otherwise review any decision taken under section 23 of this Act if it is of the opinion that there is new information to the effect that the genetically modified organisms or its products thereof is capable of having adverse effect on human health, animal, plant or the environment; | substitution 'section 23' in line two with 'section 28'. Also, substitution of the word 'may' with 'shall' after the word 'Agency' in line one. Section 29 deals with revocation of the approval or permit granted and here it refers to a decision taken under section 23. But section 23 does not deal with decision making, section 28 does. Section 23 deals with the application process. |
|   | 16. | Section 30 (1) & (2) | (1) Any applicant who is aggrieved by any decision of the Agency under sections 24 and 25 of this Act may appeal to the Board to reconsider that decision, stating his grounds of appeal, including any additional information.  
(2) Any applicant who is not satisfied with the decision of the Minister may apply to the Federal High Court for a review of the decision. | Insertion after the word 'Board' in line two with '30 days after the decision'  
Insertion after the word 'Applicant' with 'and interested and affected parties' | Section 30(1) of the Principal Act only gives an aggrieved Applicant a clear right to appeal against a decision to the Board. No similar right is given to interested and affected parties who may be adversely affected by a decision. This amendment is necessary in the interests of administrative justice and procedural fairness, to enable interested and affected parties to appeal against approvals.  
Section 30 (2) does not give a time frame. There should be a time frame for appeals here and in 30(2). It appears that an open-ended appeals period could enable applicants to come back to the Authority anytime they feel like. |
| 17. | Section 31 (1) | (1) Every applicant seeking approval for any genetically modified organism under this Act shall, prior to the submission of the application, carry out a mandatory risk assessment of the potential risk the genetically modified organisms poses to human health, animal, plant or the environment in Nigeria. | Inserting after the word 'Nigeria' in line four 'The Agency shall also carry out separate and independent risk assessments of any genetically modified organism application' | Under Section 31(1) the duty falls on the applicant who is applying for permission to carry out risk assessment. This is risky and the results of such assessments could be compromised. Hence the necessity for this amendment. |
| 18. Section 34 (b) | prohibit the import transit, contained use, release or placing on the market of any genetically modified organism if it contains characteristics or specific traits which pose significant risk to human health, animal, plant and the environment | Substitution of the words 'significant' in line three with 'any'. In addition, adding the sentence 'or if there is lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential risks to human health, animal, plant and the environment' after the word environment in line three is inserted. | Section 34(b) sets out the prohibition measures that the Agency may impose. As it stands, section 34(b) can only be operationalised at the discretion of the Agency and only if the specific traits or characteristics pose “significant” risks to human health, animal, plant and the environment. This is very limited and does not take into account the risks that a GMO may pose in relation to the receiving environment and the interaction between the two or to the GMO in its totality. Hence the need for review. |

| 20. Section 34 (c) | require any person, institution or body responsible for any activity relating to genetically modified organisms to take such measures as may be necessary, from time to time, to prevent or limit any human health, animal, plant or the environment; | Insertion of the words 'risk to' after the word 'any' in line three. In addition to delete the words 'from time to time' in line three. | This Amendment is proposed because section 34(c) states that a person, institution or body may also in terms of this section is required by the Agency at the Agency's discretion to take such measures as may be necessary, from time to time, to prevent or limit any [the word risk is missing] human health, animal, plant or the environment. |
Section 34 (d) to (i) The Agency may impose additional measures for management of risks associated with any genetically modified organisms and without prejudice to the generality of the foregoing, may:

Section 34 of the Principal Act is amended by inserting a new subsections (b) to (i) and renumbering the existing sub sections b and e appropriately. subsections d and e are now 'k' and 'j' respectively.

34(d) “provide for response measures in the event of damage resulting from living modified organisms, or where there is sufficient likelihood that damage will result if timely response measures are not taken. To that end, the Agency has to:

(e) require that an applicant, in the event of damage, must (i) immediately inform the Agency; (ii) evaluate the damage; and (iii) take appropriate response measures.

(f) require that an applicant take appropriate response measures where there is sufficient likelihood that damage will result if timely response measures are not taken.

(g) make sure that the Agency (i) identifies the applicant which has caused the damage; (ii) evaluates the damage; and (iii) determines which response measures should be taken by the applicant.

(h) require that decisions by the Agency for the applicant to take response measures are reasoned, that remedies are available, including administrative or judicial review of such decisions.

The issue of liability and redress is squeezed into one provision, in section 34(e). It provides that the Agency may take any measure as it may deem necessary to avert risk or danger to human health, animal, plant or the environment, where the person responsible shall bear the cost of any measure taken. However, no duty of care is created and obligations to first call upon the applicant to take measures to avert the risk or danger.

Thus the need for a review as the provisions of an entire Protocol on Liability and Redress (Nagoya Kuala Lampur Protocol) have been condensed into one subsection.

In addition, monitoring and evaluation are needed under Section 23 of the Act too. Environmental release needs to be monitored.
(l) put in place a requirement whereby the Agency itself may implement appropriate response measures, in particular in situations where the applicant has failed to do so. Provide the Agency the right to recover, from the applicant, costs and expenses incurred in relation to the implementation of the response measures.

(j) undertake any measure, as may be reasonably necessary to avert risk or danger to human health, animal, plant and the environment where the person responsible for such action fails to act and the person so responsible shall bear the cost of any measure taken;

(k) direct any applicant under section 24 of this Act to submit periodic report of the monitoring and evaluation of risk carried out after the approval or permit granted under this Act; and

Section 34(d): Monitoring and evaluation are needed under Section 23 of the Act too. Environmental release needs to be monitored.
<table>
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<tr>
<th>Section 35(1) (a)</th>
<th>1) Any person, institution or body who: (a) imports, export transit or otherwise carries out the activity of contained use or commercial release of any genetically modified organisms without a prior approval or permit of the Agency;</th>
<th>Insertion of the words 'contained use' in line one with 'confined and multi-location field trials'</th>
<th>The Amended is proposed to cover confined and multi-location field trials as they are all part of the process.</th>
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<td>Section 35 (b) (1) (i)</td>
<td>(i) in the case of an individual, to a fine of not less than N2,500,000.00 or imprisonment for a term of not less than 5 years or both such fine and imprisonment; or</td>
<td>Substitution of the amount 'N2,500,000.00' in line one with 'N10,000,000.00'</td>
<td>Section 35: Fines and Penalties prescribed under Part X of this Act are just peanuts for corporations/applicants with multi million or billion dollars' enterprises. The fine/penalty is not sufficient to deter them from committing the offence. Hence the need for a review. The fines should be subject to upward review on a yearly basis.</td>
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<td>Section 35 (1) (b) (ii)</td>
<td>(ii) in the case of a body corporate to a fine of not less than N5,000,000 and, in addition, the directors or officers of the body corporate shall each be liable to a fine of not less than N2,500,000.00 or imprisonment for a term of not less than 5 years or both such fine and imprisonment.</td>
<td>Substitution of the amount 'N5,000,000' in line one with 'N20,000,000.00' and the amount 'N2,500,000.00' in line three with 'N10,000,000.00'.</td>
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<tr>
<td>Section 35 (2) (b)(i)</td>
<td>(i) in the case of an individual, to a fine of not less than N2,500,000.00 or imprisonment for a term of not less than 5 years or both such fine and imprisonment; or</td>
<td>Substitution of the amount 'N2,500,000.00' in line one with 'N10,000,000.00'.</td>
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<tr>
<td>Section 35 (2) (b)(ii)</td>
<td>(ii) in the case of a body corporate to a fine of not less than N5,000,000.00 and in addition, the directors or officers of the body corporate shall each be liable to a fine of not less than N2,500,000.00 or imprisonment for a term of not less than 5 years or both such fine and imprisonment.</td>
<td>Substitution of the amount 'N5,000,000' in line one with 'N20,000,000.00' and the amount 'N2,500,000.00' in line three with 'N10,000,000.00'.</td>
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| 20.     | Any person, institution or body who submits or supplies false information in respect of any activity relating to genetically modified organism under this Act commits an offence and shall be liable on conviction:  
(a) in the case of an individual, to a fine of not less than N2,500,000.00 or imprisonment for a term of not less than 3 years or both such fine and imprisonment; or  
(b) in the case of a body corporate, to a fine of not less than N5,000,000.00. |
|         | Substituting the amount 'N5,000,000' in line one with 'N20,000,000.00' and the amount 'N2,500,000.00' in line three with 'N10,000,000.00'. |
| 21.     | 1) The Board may, on the recommendation of the management of the Agency, make regulations generally for carrying into effect the provisions of this Act:  
(a) handling, transporting, packaging; fault-based liability and redress for damages from the activities of modern biotechnology and genetically modified organisms. Liability and Redress for a damage that occurs as a result of an activity under this ACT is subject to applicable laws; |
|         | Substitution of the words 'fault based' in line one with 'strict' |
|         | Section 41(1): The standard of liability and redress used here is fault-based. Strict Liability, is the standard in the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress and in line with the precautionary approach. Fault-based liability requires a higher burden of proof, and could make it difficult for liability to be established. |
| 22. | Section 43 | “Biosafety” means the application of measures, policies, knowledge, techniques, equipment and procedures for minimizing potential risks that modern biotechnology may pose to the environment and human health; | Under ‘Biosafety’ substitution of the word ‘minimizing’ in line two with ‘preventing’ | Under ‘Biosafety’ replacing the word minimizing with ‘preventing’ would ensure consistency with the title and objectives. |
|      |            | Contained use” means any operation using modern biotechnology undertaken within a facility, installation or other physical structure, such as a building, laboratory or greenhouse; | Under ‘Contained use” insertion of the sentence ‘that effectively prevents their contact with and their impact on the external environment and also ‘That effectively limits or prevent the emission of GMOs.’ after ‘greenhouse;’ in line three. | Under ‘Contained use’ the additional phrase ‘that effectively prevents their contact with, and their impact on, the external environment’ and also ‘That effectively limits or prevent the emission of GMOs.’ Because it is a qualifier of the characteristics of the structure is needed, otherwise any building or structure could qualify for acceptance as contained use. |
| 23. | 3(c) of the First Schedule Principal Act | the words “this product may cause reactions, allergies or other side-effects” where it is known that a particular reaction, allergy or other side effect may be caused by the product; | Substituting of the words ‘it is known’ in line two with ‘there is a likelihood’ | Section 3(c) the Act only allows consumer labelling when the GMO is dangerous; this is not a good concept. Nigeria has always been very strong in the Codex calling for GMO labels and this should be sustained in this Act. The amendment is to enable the authorities to reject GMOs that pose risks to the environment, people and animals. |
| 24 | 8) of Part B of the Second Schedule of the Principal Act | Verification of the genetic stability of the organism and factors affecting it taking into account the relevance of the laboratory experiments undertaken to the authentic ecological conditions under which the organism lives and used; | Insertion after the word 'used' the sentence 'and has to be done by state of the art molecular genetic methods to verify that the insert has remained stable at the same site in the genome for at least 5 successive generations.' | This is necessary to ensure the authenticity of the results.

<p>| 25 | (c) of Part B of the Second Schedule of the Principal Act | Stability of the genetic traits of organisms in them is of both expression and structure; | under Nature of the final genetically modified organisms under (c) by inserting after the word 'and' with 'molecular genetic' and after the word 'structure;' with the phrase 'to be done by state of the art molecular genetic methods to verify that the insert has remained stable at the same site in the genome for at least 5 successive generations.' |</p>
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<th>(h) of the Second Schedule of the Principal Act is amended</th>
<th>(h) Health consideration that has: under Health considerations by inserting a new subsection (vi) Characterization of new proteins, new nucleic acids and metabolites and their potential for harm</th>
<th>Good to know what are the impacts of the new proteins, nucleic acids and metabolites.</th>
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<td>Part C of the Second Schedule of the Principal Act</td>
<td>Part C - Information Relating to the Condition for Release and the Receiving Environment.</td>
<td>Part C under 'Information on the Release' of the Second Schedule of the Principal Act is amended by inserting a new subsection (12) “(12) measures to be taken to prevent cross-pollination; and new diseases spreading from GMOs to indigenous species”</td>
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<td>This is key. Because with GMOs one cannot rule out cross-pollination and contamination.</td>
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| 26 | Part C of the Second Schedule of the Principal Act | Part C under 'Characteristics and Factors affecting survival Multiplication, Gene Expression and Dissemination' | Part C under 'Characteristics and Factors affecting survival Multiplication, Gene Expression and Dissemination' of the Second Schedule of the Principal Act is amended by inserting a new subsection (4) and renumbering of the other subsections appropriately.

“(4) measures to be taken to prevent cross-pollination; and new diseases spreading from GMOs to indigenous species” |