NATIONAL BIOSAFETY (IMPLEMENTATION, ETC.) REGULATIONS, 2017

NATIONAL BIOSAFETY (IMPLEMENTATION, ETC.) REGULATIONS, 2017

ARRANGEMENT OF REGULATIONS

Regulation:

NATIONAL BIOSAFETY MANAGEMENT ACT, 2015

NATIONAL BIOSAFETY REGULATIONS, 2017

In exercise of the powers conferred on it by sections 41 of the National Biosafety Management Agency Act, 2015 ("the Act") and of all other powers enabling it in that behalf, the Governing Board of the National Biosafety Management Agency ("Agency"), makes the following Regulations -

[ ] Commencement

PART I
OBJECTIVE

1. Objective

The objectives of these Regulations include, to-

(a) complement and enhance the provisions of the Act;

(b) provide details of regulatory and supervisory requirements necessary to promote and aid the efficient and profitable implementation of the provisions of the Act ; and

(c) facilitate the attainment of the goals for which the Agency is established in Nigeria.

2. Application and Scope

This Regulation shall apply throughout the Federal Republic of Nigeria subject to the provisions of the Act.

PART II
INSTITUTIONAL BIOSAFETY ARRANGEMENTS AND COMMITTEES

3. National Biosafety Committee

(1) The Director – General shall, from time to time, constitute a National Biosafety Committee (NBC) in accordance with section 31 (3) of the Act.

(2) The NBC shall be an ad-hoc expert advisory committee to address technical issues relating to applications submitted to the Agency under section 23 of the Act.

4. Functions of the NBC

The NBC shall -

(a) review proposals for contained use, confined field trials and commercial release of GMOs;

(b) review risk assessment and propose risk management measures for individual application;

(c) advise the Agency on the issue of permitting GMO activity for individual applications and recommend risk management conditions under which contained use, confined field trials, experimental release or commercial release shall be conducted; and

(d) provide technical advice to the Agency and contribute to the attainment of the functions of the Agency in relation to contained use, confined field trials or commercial release of GMOs.

5. Appointment of Scientific Experts

The Agency may appoint scientific experts with relevant expertise to assist the NBC in the performance of its duties under these Regulations provided that the Agency shall ensure that no person appointed under this regulation has any conflicting interests in the application to be reviewed by the NBC

6. National Biosafety Technical Committee

(1) The Agency may set up a National Biosafety Technical Committee (NTBC) comprising of five or more technical experts appointed under these Regulations to assist in the consideration and review of applications received by the Agency.

(2) In appointing the technical experts to the NBTC, the Agency shall ensure that no member has conflicting interest in the application that the NBTC will be reviewing.

7. Functions of the NTBC

The National Biosafety Technical Committee (NTBC) shall provide technical advice to the Director-General and contribute to the attainment of the functions of the Agency in relation to contained use, confined field trials, experimental release or commercial release of GMOs or its products.

8. **Institutional Biosafety Committee**

(1) An Applicant wishing to carry out contained use activity shall have –
- (a) an established Institutional Biosafety Committee (IBC); or
- (b) access to the use of an existing IBC in another institution.

(2) The Membership of an Institutional Biosafety Committee shall include -
- (a) five members from the respective institution, including the Biosafety Officer in the institution who shall serve as the Chairman of the IBC; and

- (b) two other members not affiliated with the institution, but knowledgeable in modern biotechnology or related fields, and representing such interests as -
  - (i) government's public health or environmental agencies,
  - (ii) persons active in human, plant or animal health concerns,
  - (iii) persons or non – governmental organisations active in environmental or other relevant concerns, and
  - (iv) any Principal Investigator or any other person the IBC may wish to invite to its meetings.

(3) The IBC shall perform the following functions -

- (a) consult with the Agency on procedures and policies relating to biosafety;
- (b) Receive and review applications for contained Research and Confined Field Trials and approve or reject at the Institutional Level,
- (c) Inspect and Monitor Confined Field Trials,

(d) encourage the Principal Investigator to implement the requirements of the Agency;

(e) create and maintain a central library of catalogues, books, articles, newsletters, reference files on available safety equipment, level of biological containment for various host-vector systems and data on the potential bio-hazards associated with certain technologies, and personnel training;

(f) facilitate the exchange of scientific, technical, environmental and legal information and experience relating to GMOs and other products of modern biotechnology;

(g) develop a safety and operation manual and assist Principal Investigators in relevant training for the staff of the Applicant;

(h) ensure the safety of facilities, procedures and practices of the Applicant and that the staff of the Applicant acquire appropriate level of training and expertise;

(i) review and monitor all modern biotechnology research conducted and sponsored by the Applicant institution to ensure compliance with existing laws and Regulations on modern technology and Biosafety;

(j) maintain a list of Principal Investigators and project supervisors, who are competent to perform supervisory duties for particular modern biotechnology projects; and

(k) maintain records and files of each modern biotechnology research project approved by the Institute.

(4) Upon the establishment of an IBC, an Institution shall notify the Agency and forward a list of its membership for approval to the Agency.

(5) The Agency shall upon approval of the IBC, cause the approved list of members referred to in sub-regulation (4) of this regulation to be entered in the IBC Register kept by the Agency and published in the website of the Agency.

9. Notification of accident or violation by an IBC

An IBC shall notify the Agency upon noticing any significant research related accident or violation of these Regulations and the Act; provided that in the case of written notification, it shall be made within 24 hours of becoming aware of the accident or violation.

PART III
GENERAL PROVISIONS APPLICABLE TO APPLICATIONS

10. Acknowledgement of application by the Agency to be in writing

The Agency shall acknowledge in writing any application it received to carry out any of the activities stated in the Act or in these Regulations within twenty-one working days

11. Display copies of application to the general public for comments.

(1) The Agency shall upon receipt of the application and the accompanying information for confined field trial, multi-location trial and commercial release of GMOs, display the copies of such application and relevant accompanying information at relevant location to the general public including relevant government ministries and agencies for comments (if any) within twenty-one working days.

(2) In considering an application for a permit or authorization, the Agency may take into consideration comments, inputs or concerns of the general public and notify the applicant in writing and the public of all information, facts and analysis supporting its decision on the application.

12. Request for additional information by the Agency

Where necessary, the Agency may request for additional information from an applicant upon the receipt of an application for permit for contained use or confined field trial, multi-location trial and commercial release of GMOs.

13. Reference to Information provided in a previous application

(1) Where a person applies for accreditation, certification, permit or the renewal of a permit under these Regulations, the Applicant may make reference to information provided in application previously filed by another Applicant, if –

(a) the information, data or results are not confidential; or,

(b) the applicant had obtained the written consent of the original Applicant for the reference or use of the information.

(2) In applying for accreditation, certification, permit or the renewal of a permit under these Regulations, the Applicant may in addition to the information provided in the application previously filed by another Applicant, under sub-regulation (1) of this regulation, submit additional relevant information.

14. Emergence of new information which identifies actual risks after the grant of permit.

(1) Where new information relevant to an application for confined field trial, multi-location trial and commercial release of GMOs which identifies actual risks to human and animal health or the environment, becomes available to the Applicant after the grant of a permit or authorization, or a renewal of a permit or authorization under these Regulations, the applicant shall –

(a) withdraw the products from the environment, markets and circulation
(b) immediately put necessary measures in place to protect human and animal health and the environment;
(c) notify the Agency as soon as the new information becomes available; and
(d) notify the Agency as soon as possible of any remedial measure taken or proposed to be taken by the Applicant in relation to the identified risks.

(2) The notification by the Applicant to the Agency under sub – regulation (1) of this regulation shall be done in the form prescribed by the Agency and shall be clearly marked “Confidential Information” by the Applicant.

(3) The Agency shall upon the receipt of the notification and in consultation with the Applicant decide whether the information should be kept confidential or not and shall notify the Applicant of its decision.

(4) Where the Applicant withdraws the application, the Agency shall respect the confidentiality of the information provided in the application.

15. Applications to be accompanied by prescribed application fees.

All applications for confined field trial, multi-location trial and commercial release of GMOs or any other activity under the Act or these Regulations shall be accompanied by the fees prescribed by the Agency.

16. Registration of Decisions and Appeals

(1) The Agency shall cause decisions made pursuant to the provisions of the Act and these Regulations to be registered in the National Biosafety Clearing House within 15 days of making the decision.

(2) Any appeal against any decision made pursuant to the provisions of the Act or these Regulations shall be made in writing to the Governing Board not later than 21 working days from the date of publication of the decision by the Agency.

17. Liaison with relevant regulatory Agencies

The Agency may liaise with relevant regulatory agencies to monitor activities with genetically modified organisms to ensure compliance with the requirements of these Regulations.

18. Modification or activities which deviates from terms and conditions of permit

Where an applicant wishes to modify its activities in a way that materially deviates from the terms and conditions of the permit granted under the Act, the applicant shall notify the Agency prior to any such modifications and the Agency shall determine whether the proposed modification requires a new application for its approval.

PART IV
ACCREDITATION OF INSTITUTIONS AND CERTIFICATION OF FACILITIES

19. Application for accreditation by an institution

(1) An institution wishing to be accredited for the purpose of carrying out contained use activities, shall submit an accreditation application to the Agency in the prescribed form.

(2). The Agency shall review every completed accreditation application and inspect the Institution and the Institution's biosafety containment facility.

(3) The Agency shall take its decision on an accreditation application made by an institution within ninety days from the date of receipt of the accreditation application.

20. Conditions for accreditation of an institution

The conditions for the accreditation of an institution includes, the –

(a) competency of the staff of the applicant institution on biosafety matters;
(b) presence of IBC or affiliation with an existing IBC;
(c) existence of physical structures to contain GMO experiments;
(d) existence of appropriate standard and operating procedures; and
(e) any other condition that may be required by the Agency from time to time.

21. Duration of Accreditation of an institution

An initial accreditation decisions shall be valid for three years where the accredited institution provides a satisfactory annual affirmation showing that it has continued to meet the terms and conditions of the accreditation set forth by the Agency.

22. Application for renewal of Accreditation

(1) An institution wishing to renew its accreditation shall apply for the renewal at least ninety days before the expiration of the existing accreditation.

(2) The Agency shall make decision on the application made under this regulation within ninety days from the date of its review of the application and inspection of the facility of the institution.

23. Duration of renewed accreditation

A renewed accreditation shall be valid for five years where the institution provides a satisfactory annual affirmation showing that it has continued to fulfill the accreditation conditions set by the Agency.

24. Certification of Biosafety containment facility

(1) Contained use activities involving GMOs shall be conducted in a certified biosafety containment facility established by an accredited institution to ensure safety and to prevent unintended releases into the environment.

(2) An institution wishing to obtain certification of a biosafety containment facility shall submit to the Agency an application for that purpose in a form prescribed by the Agency.

(3) The Agency shall on receipt of an application for certification under these Regulations –
   (a) review the application; and
   (b) conduct necessary inspections of the biosafety containment facility to determine whether it meets the criteria set out under the Biosafety Containment facility Guidelines issued by the Agency.

(4) The Agency shall make decision on the application for certification of a biosafety containment facility made under this regulation within ninety days of its receipt of the application.

25. Duration of certification of a facility

All certification under this regulation shall be valid for a period of three years where the institution provides a satisfactory annual report showing that the certified facility or other structure has continued to fulfill the conditions for certification set by the Agency in the Biosafety Containment Facility Guidelines issued by the Agency.

26. Renewal of certification of Biosafety containment Facility

(1) An institution shall apply for the renewal of certification of its Biosafety containment facility at least ninety days prior to the expiration of its existing certification.

(2) The Agency shall make decision on the application for the renewal of certification made under this regulation within ninety days of the review of the application and inspection of the facility.

(3) A certificate of renewal under this regulation shall be valid for five years where the accredited Institution provides a satisfactory annual affirmation to the effect that the certified facility or other structure has continued to fulfill the conditions for certification set by the Agency in the Biosafety Containment Facility Guidelines issued by the Agency.

27. Revocation of accreditation or certification.

The Agency may revoke an accreditation or certification granted to an institution under these Regulations where the institution violates any of the terms and conditions stipulated for the grant of accreditation or certification by the Agency.

28. Publication of the names of accredited and certified institutions.

The Agency shall publish on its website the names and addresses of, the –

(a) Institutions accredited under these Regulation; and

(b) biosafety containment facilities certified under these Regulations.

PART V
CONTAINED USE ACTIVITIES

29. Permit from the Agency to conduct a contained use experiment

(1) An applicant wishing to obtain a permit from the Agency to conduct any form of contained use activity including experiment shall submit an application to the Agency stating relevant information in the form prescribed by the Agency.

(2) An applicant wishing to apply to the Agency for a permit under this regulation shall first submit the application to its IBC for review and endorsement and an application shall not be accepted as complete by the Agency unless it contains a written endorsement from an IBC.

(3) The IBC shall either be part of the institution where the applicant intends to carry out the contained use experiment or agree to review the application of an applicant who works at an institution without an IBC.

(4) The Agency shall acknowledge the receipt of an application for a contained use experiment in writing within twenty - one working days of its receipt of the application

(5) The Director- General may, where appropriate, constitute an NBC to review the application for permit and advice the Agency on the issue relating to risk assessment or risk management.

(6) The Agency shall make a decision on whether to approve or reject an application made under this regulation within ninety days of the receipt of the application and where the application is rejected; the Agency shall state the reason in writing and publish same on its website.

(7) When making a decision on an application under this regulation, the Agency shall determine whether the contained use activity or experiment poses significant risks which cannot be addressed through risk management measures and other measures deemed necessary.

PART VI
PERMITS FOR CONFINED FIELD AND MULTI- LOCATION TRIALS

30. Application for permit to conduct confined field and multi-location trials

(1) An applicant wishing to obtain a permit from the Agency to conduct a confined field trial, multi-location trials or to import a GMO for the purpose of conducting confined field trial or multi – location trials shall submit an application to the Agency in the prescribed form.

(2) An applicant wishing to apply to the Agency for permit under sub – regulation (1) of this regulation shall first forward the application to the IBC, for its review and endorsement.

(3) The IBC referred to under sub-regulation (2) of this regulation shall either be part of the institution where the applicant will carry out the confined field trial or agreed to review the application of an applicant who works with an institution without an IBC.

(4) The Agency shall not accept an application as complete unless it contains a written endorsement from an IBC.

31. Applicant to conduct risk assessment and propose risk management measures

The Agency shall require an applicant for a permit to conduct confined field trial and multi-location trials to conduct risk assessment and propose risk management measures for any significant risks identified in the risk assessment process.

32. Acknowledgment of the receipt of application for permit

(1) The Agency –

(a) shall endorse and acknowledge in writing the receipt of an application for permit to either conduct a confined field trial or multi-location trials within twenty - one working days;

(b) may on its receipt of an application for permit to conduct confined field trial or multi-location trials constitute a committee to review the dossier submitted by the Applicant and make recommendations for the consideration of the Agency;

(c) shall make a decision whether to approve and issue a permit or reject the application within two hundred and seventy days from the date of its receipt of the application; and

(d) shall in making a decision on the application, determine whether the confined field trial or multi-location trials pose significant risks that cannot be addressed through risk management measures and other applicable measures deemed necessary.

(2) The Agency shall by a Decision Document -
(a) approve the application stating the terms and conditions; or
(b) reject the application and provide justification for the rejection.

(3) The Agency shall publish on its website any approval or rejection of an application it made.

PART VII
PERMIT FOR COMMERCIAL RELEASE

33. Application for permit to carry out commercial release of a GMO

(1) An applicant wishing to obtain permit for commercial release of a GMO or import of a GMO for such purpose, shall submit an application to the Agency in the form prescribed by the Agency.

(2) Prior to the submission of the application to the Agency, an Applicant shall evaluate the socio-economic impact of commercial release of the GMOs in conformity with the provisions of the Act and Guidelines issued by the Agency.

(3) The Agency may constitute a committee to assist it in the review of the information contained in the application and the committee shall, within thirty days of its composition give its expert opinion and recommendations to the Agency.

(4) The Agency shall endorse and acknowledge the receipt of any application for permit for the commercial release of a GMO or import of a GMO for such purpose in writing within twenty - one working days from the date of receipt of the application.

(5) The Agency shall ensure public awareness and participation in the consideration and grant of permit for commercial release of a GMO or import of a GMO for such purpose in line with the provisions of the Act.

(6) The Agency shall by a Decision Document -
(a) approve the application stating the terms and conditions of the permit; or

(b) reject the application and give its reasons or justification for the rejection of the Application.

34. Contents of a permit for commercial release of a GMO

(1) A permit for commercial release of a GMO shall state the -
(a) objective of the release;
(b) identity of the GMO being released or imported;
(c) period of validity of the permit;
(d) conditions for the release;
(e) monitoring requirements in accordance with Schedule 4 to the Act including the time or periods in the monitoring plan; and
(f) reporting obligations of the Applicant to the Agency.

(2) A permit for commercial release of GMO shall state where appropriate that 5% of the commercial GMO farm up to fifty hectares should be reserved for afforestation by the farm owner.

35. Duration of a permit for commercialisation

A permit for commercialisation shall be for a period not exceeding ten years.

36. Renewal of Permit for commercialisation

(1) Where an applicant wishes to renew a permit for the commercial release of GMO, the applicant shall not later than nine months before the expiration of the permit, submit an application to the Agency and the Agency shall make a decision on the application before the expiration of the permit.

(2) The Agency upon the receipt of the application for renewal of permit, shall -

(a) acknowledge the receipt of the application in writing within twenty-one working days from the date of receipt of the application;

(b) cause the application to be examined for compliance with the Act, Regulations and Guidelines issued under the Act; and

(c) request the applicant in writing for any further information which the Agency considers necessary.

37. Contents of an application for renewal of commercialization permit

(1) The application for renewal of permit for the commercial release of a GMO shall include –

(a) a copy of the expiring permit;

(b) a report on the results of the monitoring of the commercialisation;

(c) a proposal considered appropriate by the applicant for the amendment of or measures additional to the conditions contained in the permit; and

(d) any new information that becomes available with regard to the risks of the product to human health and the environment.

(2) Upon compliance with the provisions of sub-regulation (1) of this regulation, the Agency shall notify the applicant in writing that the application for renewal of permit -
(a) meets the requirements for commercial release and is approved; or
(b) is rejected and state its reasons for the rejection.

38. Duration of a renewed permit for commercial release

(1) The duration of a permit renewed under this Part of these Regulations shall not exceed ten years beginning on the date on which the renewal of the permit is granted.

(2) Where the Agency on specific grounds considers that it is not appropriate to renew a permit for a period of ten years, it may, subject to compliance with these Regulations, renew the permit for such shorter period as it may deem fit, stating in writing, the reasons for the decision.

39. Release of a GMO without further permit with no risk to human and animal health and the environment

Where a GMO has been released for twenty years with a permit from the Agency, and the Agency establishes that monitoring data ha no risk to human, animal health and the environment, the GMO may continue to be released without further permit provided the Agency is notified every five years of its continued release of the GMO

PART VIII
PROCEDURES FOR IMPORT OF GMOS FOR DIRECT USE AS FOOD, FEED OR FOR PROCESSING

40. Permit to import GMOs and GMO products for commercial production

The Agency may issue an applicant with a permit to import GMOs and products for commercial production in accordance with the provisions of these Regulations.

41. Application for permit to import GMOs and GMO products for commercial production

(1) An applicant, who wishes to import a GMO for the first time for direct use as food, feed or for processing which are not already approved for commercial release in Nigeria shall make an application to the Agency in writing with reference to information on the item found in the Biosafety Clearing-House (BCH).

(2) An applicant making an application under sub-regulation (1) of this regulation shall complete an application form prescribed by the Agency.

(3) The Agency on receipt of an application in the prescribed form for GM food, shall –

(a) acknowledge the receipt of the application within ninety days; and

(b) forward information relating to food and feed safety assessment to the National Agency for Food and Drugs Administration (NAFDAC) for review and certification.

(4) NAFDAC shall forward its decision concerning certification to the Agency within ninety days provided that the days during which NAFDAC is waiting for its requested relevant additional information shall not be counted.

(5) Within twenty - one days of receipt of the NAFDAC decision, the Agency shall inform the applicant of its decision.

PART IX
PROCEDURES FOR HANDLING, PACKAGING, TRANSPORT AND LABELING OF GMOS

42. Packaging and Transportation of GMOs

(1) An applicant who wishes to import, export, transit or otherwise carry out a confined field trial or commercial release of GMOs or products derived from the GMO shall ensure that the packaging is –

(a) of good quality, strong enough to withstand the shocks and loadings normally encountered during transport, including trans-shipment between transport units and warehouses as well as any removal from a pallet or over pack for subsequent manual or mechanical handling; and

(b) constructed to prevent any loss of contents that might be caused under normal conditions of transport by vibration or by changes in temperature, humidity or pressure.

(2) An applicant engaging in the transport of GMOs and derived products shall ensure that there is no known risk to humans, animal health and the environment arising from GMOs.

43. Identification and labeling of GMOs

(1) A GMO or derived product shall be clearly identified and labeled in accordance with the Labeling guidelines prescribed by the Agency.

(2) The appropriate identifier unique to each GMO shall be included in the labeling.

(3) The identification referred to in sub-regulation (1) of this regulation shall specify the relevant traits and characteristics of the GMO in sufficient detail for purposes of traceability.

(4) GM content that is below the threshold of four percent shall remain unlabelled where it is due to an unintentional and technically unavoidable mixture.

(5) The organization or person or permit holder that produces or packs the GMO or its product shall be responsible for the identification, classification and labeling.

44. Language on the label of GMOs

(1) The language on the label of GMOs shall be English and where it is labeled in another language, it shall have an English translation written on the label or package insert, where applicable.

(2) A GMO or its product intended for marketing shall be labeled and a GMO that bears no label or whose label is not in conformity with the requirements of labeling as sets out in the these Regulations and terms and conditions of permit shall be banned from import or market.

45. The label of GMO and its products to be easily noticeable

The labels of a GMO and its product shall be easily noticeable, designed and printed simultaneously with the product packaging and commodity label.

46. The labels of GMO or its products shall not to be used until after assessment and approval of the Agency.

(1) The labels of a GMO and its product shall not be used until they have been examined and approved by the Agency.

(2) The Agency shall make a decision after the examination of the label of a GMO and notify the applicant of its decision within sixty days after the receipt of an application from the applicant.

47. Duty on any person that markets GMO and its products

Any organization or person that markets GMOs or its products shall check the label with the goods and ensure that they are in conformity with the provisions of the Act and these Regulations when making their procurements.

PART X
TRANSIT OF GMOS NOT REGISTERED IN NIGERIA

48. Transit shipment of genetically modified organisms

(1) The Agency may approve the application for each transit shipment of a GMO and its products made under these Regulations.

(2) The Agency shall inspect and identify the documents accompanying the trans – shipment of GMO and its products.

(3) The owner or a consignee of a GMO, not registered in Nigeria, but wishing to transport through Nigeria a GMO or its products, shall in advance submit to the Agency, the application for transit permit with the following documents –

(a) completed application form for Transit Permit of GMO;

(b) proof of relevant research done on the GMO issued by relevant authorities of the exporting country or area, or proof of its utilization and marketing permission;

(c) illustration on the utilization of the GMO and intended monitoring measures; and

(d) any relevant documents.

49. Relevant authorities at the port of entry to be notified

(1) The Agency shall sign and issue a transit permit of GMO to an applicant who complies with the requirements of inspection by the Agency and the Agency may inform any other relevant authorities at the port of entry that the applicant has complied with all the requirements.

(2) The Agency may liaise with other relevant regulatory agencies to ensure that the consignment at the port of entry and exit is accompanied by relevant documents.

50. Contents of a Transit Permit

The Transit permit shall include -

(a) suggested method for packaging and handling of GMOs imported through conveyor shipment and shall comply with the relevant international and national laws;

(b) requirement for repackaging and handling of conveyor shipped commodities ;

(c) a requirement that conveyor shipment shall comply with import conditions under these Regulations; and

(d) a copy of the import permit issued by the receiving country indicating the quantities or volumes involved from the country of origin and stating that the consignment may contain genetically modified materials.

51. Packaging and transportation of transiting GMO

(1) The applicant transiting GMO shall ensure that the GMO is appropriately packaged and transported in accordance with these Regulations and other applicable international standards.

(2) After the clearance of the final shipment of a GMO under these Regulations, the period of transit shall not be longer than 48 hours and the applicant shall notify the Agency of the departure or delay of the GMO in transit.

52. Transit of a GMO where no permit has been given.

The Agency, in the event of transit of GMO for which no permit has been given -

(a) shall initiate remedial actions such as refusal of transit, destruction or set conditions for transit; and

(b) may inform and advise the public of such genetically modified organisms.

53. Transit Denial of a GMO

The Agency shall issue a Transit Denial of a GMO to an applicant who does not meet the requirements for transit permit, stating reasons for the denial.

54. GMO involved in an accident while in transit

(1) The person transiting and the person importing a GMO involved in an accident shall –

(a) notify the Agency immediately both verbally and in writing of the accident;

(b) as soon as possible, provide the Agency with information regarding -
(i) the circumstances and scene of the accident,
(ii) the identity and the quantity of GMO released,
(iii) the extent of the accident which is necessary to assess the impact to human, animal health and the environment,
(iv) any emergency measures taken to avoid or mitigate any adverse impact of such accident on the environment, human and animal health, and
(v) action taken to remove the GMO or product from the environment; and

(c) ensure that all appropriate short, medium and long term measures are taken to avoid or mitigate any adverse impact of such accident on environment and human health.

(2) The Agency may inform and advise the public of the accident and in consultation with the relevant regulatory agencies undertake necessary action to minimize risk to human, animal health and environment.

PART XI
DOCUMENTATION AND RECORD KEEPING

55. GMOs imported, exported or transported to be accompanied by appropriate documentations

(1) GMOs that are imported or transported for contained use or confined field trial shall be accompanied by documentation that –

(a) clearly identifies the shipment or package as containing GMOs;

(b) specifies the identity and relevant traits or characteristics of the GMOs;

(c) specifies any requirements for the safe handling, storage, transport and use of the GMOs;

(d) provides a contact point for further information; and

(e) where imported, the name, telephone number and address of the importer and exporter.

(2) GMOs that are exported from Nigeria for direct use as food, feed or for processing in another country shall be accompanied by documentation containing the following information –

(a) in cases where the identity of the GMOs –

(i) is known through means such as identity preservation systems, information that the shipment "contains living modified organisms that are intended for direct use as food, feed or for processing";

(ii) is not known through means such as identity preservation systems, information that the shipment "may contain one or more living modified organisms that are intended for direct use as food or feed, or for processing";

(b) that the GMOs are not intended for intentional introduction into the environment;

(c) the common, scientific and where available, commercial names of the GMOs;

(d) the transformation event code of the GMOs or where available, as a key to accessing information in the Biosafety Clearing-House, its unique identifier code;

(e) the Internet address of the Biosafety Clearing-House for further information; and

(f) any contact point for further information.

56. Establishment of record keeping system and maintenance of information.

The holder of permit of GMOs or its products shall establish a record keeping system and maintain product-related information and documents relevant to the permit for a period of twenty years.

PART XII
SURVEILLANCE AND SAFEGUARDS

57. Notification of the Agency in the event of accident

(1) In the event of an accident, a person granted a permit or authorization shall immediately notify the Agency by any expedient means of communication, provided that a notification in writing shall in addition be made within 24 hours of becoming aware of the accident.

(2) The notification referred to in sub-regulation (1) of this regulation shall include the following information -

(a) the circumstances and location of the accident;

(b) the identity and quantities of the GMOs concerned;

(c) measures taken to remove the GMO or product from the accident environment; and

(d) any information necessary to assess the effects of the accident on the human health and the environment and the measures taken.

58. Modification of conditions, suspension or termination of activities.

Where information subsequently becomes available to the Agency, which could have significant consequences for the risks posed by the contained use, confined field and multi-location trial, the Agency may require the applicant granted a permit under these Regulations to modify the conditions of, or suspend or terminate, the activity.

59. Emergency plan for mitigating against harm

The Agency shall ensure that before any approved activity commences, the -

(a) applicant shall draw up an emergency plan for mitigating against harm, whether immediate or delayed, to humans outside the premises or to the environment as a result of failure of the activity; and

(b) emergency response plans, including the relevant safety measures to be applied shall together with the application for the permit be furnished to the Agency which shall monitor and ensure compliance with the emergency response plans.

60. Management and disposal of GMO materials

An Applicant granted permit that possesses or controls residual GMO material shall manage and dispose of such material to prevent any negative impact on human health, plants, animals and the environment.

PART XIII
LIABILITY AND REDRESS

61. Objective of this Part

The objective of this Part of these regulations is to implement the provisions of the Act in conformity with the Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety.

62. Polluter pays

National Biosafety Management Agency shall endeavour to promote the internalisation of the cost of environmental protection and the use of economic instruments so that the user responsible for pollution bears the remediation cost of the environmental damage caused or likely to be caused.

63. Notification of Damage

(1). Any Operator who becomes aware of Damage resulting from a GMO shall immediately inform the Agency.

(2). Subject to any requirements of the Agency, the Operator shall evaluate the Damage.

(3). Where relevant information, including available scientific information or information available in the Biosafety Clearing-House, indicates that there is a sufficient likelihood that damage will result if timely Response Measures are not taken, the Operator shall be required to take appropriate response measures so as to avoid such Damage

64. Determination of Responsibility

(1). Where the Agency becomes aware of possible Damage, it shall -
(a). evaluate the possible Damage; and, if confirmed; and
(b). identify the Operator that caused the Damage.

(2). A causal link shall be established by Agency between the Damage and the GMO in question in accordance with the provisions of extant laws and regulations.

(3). At a minimum, the Agency shall determine that -

(a) general causation exists and that the change can generally be caused by the GMO in question;

(b) specific causation exists and that the Damage would not have occurred but for the release of the GMO in question, and results directly from the phenotypic or genotypic modification of the GMO in question; and

(c) no superseding event alters the chain of events that otherwise might have connected the release of the GMO in question to the Damage.

(4) The significance of damage shall be determined based on factors such as -

(a) long-term or permanent changes that cannot be naturally reversed within a reasonable time;

(b) scope of qualitative and quantitative changes that adversely affect the components of biological diversity;

(c) reduction in the ability of biodiversity components to provide goods and services; and

(d) scope of any adverse effects on human health in the context of these Regulations.

(5). The Agency shall inform the Operator in writing of its determination of responsibility stating the reasons for the determination and identify the judicial or administrative review mechanisms available to the Operator.

65. Exemptions

(1). An Operator shall not be held responsible upon proof that damage was caused by -

(a) an act of God or *force majeure*;
(b) an act of war or civil unrest;
(c) circumstances relating to national security; or
(d) an act or omission that was the subject of a compulsory order by the government.

(2) An Operator shall not be held responsible where the realization of a risk is specifically assessed in compliance with the provisions of the Act, including those risks for which management measures were proposed in the risk assessment.

(3) An Operator shall not be held responsible where -

(a) the risk assessment and the proposed activity with GMOs were accepted by the Agency;

(b) an authorisation for the GMO in question was granted pursuant to these Regulations or any other regulations;

(a) the risk is posed by an activity specifically authorised or permitted by applicable law or regulations; or

(b) the damage in question is consistent with the type, magnitude and probability of harm presented in the risk assessment.

66. Response Measures

(1). The Agency shall determine the Response Measures to be taken by the Operator not later than 24 hours after notification of risk or damages.

(2). The Agency shall provide the Operator with a written Remediation Plan including, at a minimum -

(a). a detailed and rational overview of the Response Measures to be implemented, including deliverables and timelines; and

(b). the judicial or administrative review mechanisms available to the Operator.

(3). The Agency may implement appropriate Response Measures, where the Operator has failed to do so.

(4). The Agency may recover from the Operator the costs and expenses of, and incidental to, the evaluation of the damage and the implementation of any such appropriate Response Measures.

(5). The Operator shall not be required to bear the costs or expenses of Response Measures in situations where the damage in question is the result of a superseding event or an event defined as an exemption in regulation 66 of these Regulations.

67. Time limitations

The Agency may notify an Operator for a determination of responsibility under regulation 65 of these Regulations and delivery of a Remediation Plan under regulation 67 of these Regulations not later than -

(a). three years from the date on which the Competent Authority knew or should have known of the damage; or

(b). twenty years after the first release in the environment of the GMO in question alleged to have caused the damage; provided, that this twenty year time limitation shall be suspended if the GMO in question has caused Damage to Biological Diversity for which Response Measures have been ordered.

68. Financial limits

Where an Operator is ordered to undertake Response Measures pursuant to a Remediation Plan, the maximum sum shall not be greater than any financial limit established by law for similar regulated activities.

69. Right of recourse

This Regulation shall not limit or restrict any right of recourse or indemnity that an Operator may have against any other person.

70. Rules of channeling liability

(1) The operator shall be primarily liable for any damage, and has the right of recourse against any legal or natural person that he shall claim to have contributed to the occurrence of the damage.

(2) Where there are damages caused by the use of GMOs, the operator shall be held primary responsible for any damage.

(3) Where there is plurality of responsible operators, they shall be held jointly and severally responsible in line with extant laws and regulations.

71. Guarantee of repair

(1) The Agency shall require an operator to establish and maintain a financial guarantee, including a self – insurance for the duration of his responsibilities.

(2) The Agency shall take measures to encourage the development of instruments by the financial guarantee markets to be subscribed to in order to cover the solvency of operators

72. Evaluation of damage

(1) Damages caused by the use of GMOs shall be evaluated according to the following elements of assessment -

(a) the cost of response measures;

(b) the cost of the loss of income due to damages during the restoration period or before the payment of compensation;

(c) costs and expenses related to damage to human health, including medical care and compensations for injury, disability or death; and

(d) costs and expenses related to damage to socio economic values.

(2) In the case of centres of origin or centres of genetic diversity, the uniqueness of their value shall be taken into account in the evaluation of damages, including investment expenses incurred.

PART XIV
MISCELLANEOUS

73. Transparency and Public participation in Biosafety decision making Process

In accordance to Part vii Sections 25(1-2) and 26(1) of the Act the following shall apply to biosafety applications for commercial release of GMOs:

(1). The Agency shall upon the receipt of the application and the accompanying information, 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.

(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

(3). The Agency may, in addition to the comment received, hold public hearings or consultations to obtain further comments and inputs that will assist in the review or processing of the application.

74. Offences and Penalties

(1) Provisions on offences, penalties and enforcement in the Act, shall apply to these Regulations.

(2) Any product that is placed in the market and labeled as GMO products or products derived from GMOs but does not contain GMO shall be confiscated and destroyed by the Agency.

(3) Any expenses reasonably incurred in connection with the destruction or disposal of products referred to under sub-regulation (1) of this regulation, shall be borne by the person who placed the product in the market.

(4) Subject to the provisions of the Constitution of the Federal Republic of Nigeria, 1999 (as amended), the Agency may in collaboration with relevant law enforcement and prosecution Agencies arrest and prosecute offender in line with relevant provision of the Act.

75. Savings and transitional provisions

(1) Subject to the provisions of the Act, approvals, authorisations and permits granted prior to the entry into force of the Act and these Regulations shall remain valid in accordance with terms and conditions stipulated therein.

(2) Any pending applications that were not yet decided prior to the entry into force of the Act and these Regulations shall be deemed to have been submitted for processing in accordance with the provisions of the Act and these Regulations.

76. Interpretation

(1) The terms used in the Act shall apply to these Regulations.

(2) In these Regulations –

"Act" means the National Biosafety Management Agency Act, 2015;

"Agency" means the National Biosafety Management Agency established under section 1 of the Act;

"applicant" means any person, institution, body or their authorised representative in Nigeria who applies for accreditation, a permit or authorization under these Regulations;

"Biological Diversity" means the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; including diversity within species, between species and the ecosystems;

"Biosafety Clearing House" means a pool of information mechanism established under Article 20 of the Cartagena Protocol for exchange of scientific, technical, environmental and legal information on and experience in genetically modified organism (GMO), as part of the clearing house mechanism under Article 8 of the Convention;

"Biosafety" means measures, policies, knowledge, techniques, equipment and procedures applied for the minimizing potential risks that modern biotechnology may pose to the environment and human health;

"Board" means the National Biosafety Management Agency Governing Board established under section 11 (1) of the Act;

"competent authority" means an agency of another country responsible under its national law for the control and regulation of genetically modified organisms or in charge of biosafety matters;

"Committee" means a duly constituted ad-hoc body such as National Biosafety Committee (NBC), National Biosafety Technical Sub-committee (NBTS) and other Committees set up by the Agency to carry out specific duties;

"contained use" means any operation using modern biotechnology undertaken within an enclosed facility, installation or other physical structure, such as a building, laboratory or greenhouse;

"confined field trial" means a small scale experimental release into the environment of a GMO under physical and biological confinement conditions that limit the persistence of the GMO in the environment on completion of the experiment;

"Damage" means an adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health 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;

"day" means a calendar day;

"decision" includes decision adopted by the Agency regarding an application submitted for a GMO or product, following scientific risk assessments and socio-economic evaluations and decision on application for accreditation of Research Institute for modern biotechnology activities or certification of biosafety containment facility;

"Decision Document" means the document setting out the decision adopted by the Agency regarding an application submitted for a GMO or product, following scientific risk assessments and socio-economic evaluations and decision on application for accreditation of Research Institute for modern biotechnology activities or certification of biosafety containment facility;

"Director – General" means the Director – General and Chief Executive Officer of the Agency;

"Ecosystem" means a dynamic complex of plant, animal and micro-organism communities and their non-living environment interacting as a functional unit;

"export" means to take a GMO out of Nigeria;

"facility" includes a scientific laboratory, greenhouse or other enclosed physical structure where contained use activities are carried out;

"food and feed product" means a GMO or its product that is used for food, feed or processing and is primarily intended for consumption by humans or animals or both;

"Genetically Modified Organisms (GMO)" means any organism living or non living that possesses a novel combination of genetic material obtained through the use of modern biotechnology;

"Institutional Biosafety Committee (IBC)" means a committee set up by the Agency to carry out obligations under relevant provisions of these Regulations;

"Institution" means any public or private research institute, a private corporation or other legal entities that wishes to carry out contained use with GMOs in buildings which they own or operate;

"Import" means to bring a GMO into Nigeria;

"Modern Biotechnology" means–

(a) the application of in-vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (rDNA) and direct injection of nucleic acid into cells or organelles, or

(b) fusion of cells beyond the taxonomic family that –

  (i) overcome natural physiological reproductive or recombination barriers, and

(ii) are not techniques used in traditional breeding and selection;

"Multi-Locational Trials (MLT)" means confined field trials conducted in two or more locations simultaneously;

"NAFDAC" means National Agency for Food and Drugs Administration;

"NBMA" means National Biosafety Management Agency;

"National Biosafety Committee (NBC)" means an ad-hoc advisory committee constituted by the Director-General of the Agency when expert or technical advice is needed on the risk assessment or risk management issues regarding an application for GMO activity made under section 31 (3) of the Act;

"NGO" means non – governmental organisation;

"Operator" includes any person in direct or indirect control of a living modified organism, a permit holder, person who placed the living modified organism on the market, developer, producer, notifier, exporter, importer, carrier, supplier or as determined by domestic law;

"PI" means Principal Investigator;

"Response Measures" includes reasonable actions to minimize, contain or mitigate damage, as appropriate to restore Biological Diversity through actions to be taken in the following order --

(a) restoration of Biological Diversity to the condition that existed before the Damage occurred, or its nearest equivalent; and where the Competent Authority determines this is not possible; and

(b) restoration by replacing the loss of Biological Diversity with other components of Biological Diversity for the same, or for another type of use either at the same or, as appropriate, at an alternative location.

"risk assessment" means the four-stage process of identification, characterization, identification of risk elements and evaluation through scientific methods such as tests, analyses and trials of risks and risk sources that GMOs may pose to animal, human and plant health, biological diversity and environment;

"risk management" means the process of assessing, choosing and implementing suitable options to effectively manage risks identified in the risk assessment process;

"significant" means adverse effect is to be determined on the basis of factors, such as the long term or permanent change, to be understood as change that will not be redressed through natural recovery within a reasonable period of time; the extent of the qualitative or quantitative changes that adversely affect the components of biological diversity; the reduction of the ability of components of biological diversity to provide goods and services; and the extent of any adverse effects on human health in the context of the Biosafety Act, 2015; and

"transit" means movement of GMOs through Nigeria to another country.

77. Citation

These Regulations shall be cited as the National Biosafety (Implementation Etc.) Regulations, 2017

MADE at Abuja this 9th Day of March 2017

.....

Ibrahim Usman Jibril
Honourable Minister of State,
Federal Ministry of Environment

EXPLANATORY NOTE

(This note does not form part of these Regulations but is intended to explain its purport)

These Regulations seek to complement and enhance the provisions of the National Biosafety Management Agency Act, provide details of regulatory and supervisory requirements necessary to promote and aid the efficient and profitable implementation of the provisions of the Act, and facilitate the attainment of the goals for which the National Biosafety Management Agency is established in Nigeria.