XXX SESSION OF THE COUNCIL OF MINISTERS

REGULATION C/REG…/…/2020 ON BIOSAFETY IN ECOWAS

(PRELIMINARY DRAFT)

THE COUNCIL OF MINISTERS

MINDFUL of Articles 10, 11 and 12 of the ECOWAS revised Treaty establishing the Council of Ministers and defining its composition and functions;

MINDFUL of the provisions of Article 3, §2. (a) and (b) of said Treaty on "the harmonisation and coordination of national policies and the promotion of programmes, projects and activities, particularly in the sectors of agriculture, natural resources, environmental protection, industry, health, science, technology";

MINDFUL of the provisions of Articles 25, 27, 29, 30 and 31 of the ECOWAS revised Treaty relating respectively to agricultural development and food security; science and technology; the environment; toxic and hazardous waste, and natural resources;

MINDFUL of the provisions of Article 67 of the Revised ECOWAS Treaty on the harmonisation of policies in other areas;

MINDFUL of Decision A.DEC.11/01/05 adopting an ECOWAS Agricultural Policy;

MINDFUL of Supplementary Act A/SA.4/12/08 adopting an ECOWAS Environmental Policy;

MINDFUL of Supplementary Act A/AS.2/06/12 adopting an ECOWAS Policy on Science, Technology and Innovation and its Action Plan;

MINDFUL of Regulation C/REG.5/05/08 on the adoption of an Action Plan for the Development of Biotechnology and Biosafety in the ECOWAS Region;

CONSIDERING that nearly all ECOWAS Member States are signatories to the Convention on Biological Diversity and the Cartagena Protocol on Biosafety to the Convention on Biological Diversity;

CONSIDERING that Article 14 of the Cartagena Protocol provides for the conclusion, by State Parties, of bilateral, multilateral or regional agreements on matters relating to Living Modified Organisms;

CONVINCED that modern biotechnologies open up real and substantial prospects for socio-economic development, human and animal health, and the environment;

AWARE nonetheless, that the adoption of modern biotechnology does present risk factors for human and animal health and the environment, with socio-economic consequences;

RECOGNISING the need for ECOWAS to have a Regulation on biosafety, in order to implement the Convention on Biological Diversity, Cartagena Protocol and Nagoya Kuala-Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety, with a view to ensure adequate protection for the safe use of modified living organisms and derived products resulting from biotechnology;

AWARE ALSO of the need to improve the institutional, legal, scientific and technical capacity of ECOWAS Member States in the implementation of this Regulation, by providing them with the adequate means to prevent, reduce or eliminate the proven and potential risks related to the use of modern biotechnology and its products thereof, taking into account any other form of advanced biosafety-related technology;

DEEPLY AWARE of the need to put in place an institutional, legal, scientific and technical mechanism in the Community, to deal with the nature and scale of proven and potential risks related to living modified organisms (LMO) and their products thereof;

WELCOMING the collaborative effort among the ECOWAS Commission, the UEMOA Commission and the CILSS Executive Secretariat, resulting in the formulation of this Regulation;

ON THE RECOMMENDATION of the meeting of the ECOWAS Ministers who are responsible for Biosafety, held at Abuja, Nigeria on 17 May 2019;

HAVING RECEIVED the opinion of the ECOWAS Parliament, dated …….

ENACTS

SECTION I: GENERAL PROVISIONS

CHAPTER I: DEFINITIONS, SUBJECT, SCOPE OF APPLICATION

Article 1: Definitions

For the purposes of this Regulation:

"Advance Informed Agreement" (AIA) means a procedure that shall apply prior to the first intentional transboundary movement of living modified organisms for intentional introduction into the environment of the Country of import and for which the Country of export shall ensure that there is a legal requirement for the accuracy of information provided by the exporter;

"Competent National Authority (CNA)" means the Authority responsible for the coordination of the implementation of this Regulation at the national level;

"Regional Biosafety Authority (RBA)" means the authority responsible for the coordination of the implementation of this Regulation at the regional level;

"**Biosafety"**means a "Set of measures or actions addressing the safety aspects related to the application of modern biotechnology and to the release into the environment of living modified organisms, that could negatively affect plant genetic resources, plant, animal or human health, or the environment";

"Modern Biotechnology" means the application of:

a) *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles; or

b) fusion of cells beyond the taxonomic family,

that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;

"Regional Biosafety Committee (RBC)" means the Committee comprising representatives from the Member States, set up to assist the Regional Biosafety Authority with the implementation of this Regulation;

"Regional Scientific and Technical Biosafety Committee (RSTBC)" means the Scientific and Technical Committee set up to support the Regional Biosafety Authority and the Regional Biosafety Committee in the implementation of this Regulation;

“Contained use” means any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment;

“General Release” means the intentional release into the environment or placing on the market of an LMO and/or products thereof;

“Unintentional Release” means an involuntary, accidental release, resulting in atmospheric, soil or aquatic dispersion of LMOs and/or their products thereof;

“Controlled Release” means the release of an LMO or product thereof into the environment, under conditions in which preventive and risk management measures are in effect;

“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 form a part; this includes diversity within species and between species, and of ecosystems;

“Damage” means an adverse effect on conservation and sustainable use of biological diversity, taking also into account risks to human and animal health which:

1. Is measurable or otherwise observable, taking into account, wherever available, scientifically-established baselines recognized by a competent authority that takes into account any other human induced variation and natural variations; and
2. Is significant : A “significance” of an adverse effect is determined on the basis of factors, such as :
    a) Long-term or permanent change, to be understood as change that will not be redressed through natural recovery within a reasonable period of time;
    b) The extend of the qualitative and quantitative changes that adversely affect the components of biological diversity;
    c) The reduction of the ability of the components of biological diversity to provide goods and services;
    d) The extent of any adverse effects on human health in the context of the Cartagena Protocol.

“Environment” means the totality of physical, chemical and biological elements, together with the social and economic factors whose interactions affect the surroundings, living organisms, human activities, and condition the well-being of humankind;

“**Labelling”** means the visible and legible logos, brand names, characteristics, and other indicators affixed to a package, to provide information on the LMOs or the products thereof contained therein;

“Risk Assessment” means the measure of potential damage, its scope, and the chances of its occurrence where causative conditions are wholly or partially present;

“Exporter” means any legal or natural person, under the jurisdiction of the exporting Country, who arranges for a living modified organism and/or products thereof to be exported;

“Export” means any intentional transboundary movement from one country to another;

“Risk Management” means the appropriate measures, strategies and mechanisms adopted for risk identification and control purposes;

“Import” means intentional transboundary movement into one country, from another country;

“Importer” means any legal or natural person, under the jurisdiction of the Country of Import, who arranges for the import of a living modified organism and/or products thereof;

“Inspection” means all operations aimed at verifying compliance with the authorisation issued for the use of an LMO and products thereof, in accordance with the standards and procedures in force;

“Genetic Material” means any material of plant, animal, microbial or other origin, containing functional units of heredity;

"Intervention Measures" mean reasonable measures taken to**:**

i. prevent, minimise, contain, mitigate or otherwise avoid the damage, as appropriate;

ii. restore biological diversity by taking action in the following preferred order:

   a. restoration of biological diversity to conditions that existed before the damage occurred or their closest equivalent; and when the competent authority determines that this is not possible;

   b. restoration by, *inter alia,* replacing the loss of biological diversity with other components of biological diversity, whether or not the type of use is identical, at the same location or, as appropriate, at another location.

“Transboundary Movement” means any movement of an LMO and/or products thereof from one country to another;

“Notifier” means the originator of the notification, and exporter of LMOs and/or products thereof;

“Notification” means submission to the competent National Authority, of documents containing the required information, with, where applicable, samples attesting the full responsibility of the successful applicant for the accuracy and comprehensiveness of the information submitted;

“Operator” means any person in direct or indirect control of the living modified organisms, which could, as appropriate and a determined domestic law, include, *inter alia* the permit holder, person who placed the living modified organism on the market, developer, producer, notifier, exporter, importer, carrier or supplier;

“Living Modified Organism (LMO)” means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;

“Product thereof” means any product extracted or manufactured from an LMO, which may be used in human or animal food, and which is transformed or released into the environment;

“Regulated Product” means any product subject to the provisions of this Regulation;

“Technical Regulation” means the document stating the characteristics of a product or of its production procedures and methods, including applicable administrative measures, which are mandatory. It may also, in part or in whole, include terminology, symbols, packaging, marking or labelling instructions for a given product, service, process or production method;

“**Risk”** means the probability of the occurrence of a threat and the exposure of said threat;

"**Transgenic**": refers to an organism that has undergone an artificial gene transfer from one organism to another.

”**User”** means any legal or natural person officially licensed to use an LMO and/or products thereof;

“Use” means the operation or series of operations during which LMOs and products thereof are conceptualised, developed, tested, produced, stocked, marketed, distributed, transported, imported, exported, destroyed or eliminated;

“Contained Use” means any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment;

Article 2: Subject

1. This Regulation establishes the legal and institutional frameworks designed to prevent, reduce or eliminate the potential or proven risks associated with the use of modern biotechnologies and any technology related to biotechnology and products thereof.
2. In that regard, the Regulation:
    a) establishes the guiding principles underpinning its implementation;
    b) institutes the organs and mechanisms for a harmonised approach to the prevention and management of biosafety;
    c) defines the preventive measures and risk assessment and management procedures relating to the use of modern biotechnologies and products thereof;
    d) lays down the rules and principles governing liability and redress for damage resulting from the use of LMOs and products thereof.

Article 3: Scope of Application

1. This Regulation shall apply to all use, including transboundary movement, transit handling and use of living modified organisms and/or products thereof that may have adverse effects on the environment, and in particular, on the conservation and sustainable use of biological diversity, and on human and animal health.
2. This Regulation shall not apply to the transboundary movement of living modified organisms which are pharmaceutical products destined for human and addressed by other relevant international agreements or organisations.

CHAPTER II: GUIDING PRINCIPLES

Article 4: Statement of Principles

This Regulation and the implementation thereof are grounded in the Guiding Principles stated hereafter in Articles 5 to16.

ARTICLE 5: Harmonisation

Subject to Article 49 of the Revised ECOWAS Treaty, and for purposes of achieving its objective of harmonisation, the ECOWAS Commission shall contribute to the coordination of policies and actions relating to biosafety.

Article 6: Recognition of International Standards

The Member States, shall, for purposes of regulating the use and circulation of LMOs and products thereof within the ECOWAS region, and of encouraging international and regional trade therein, under adequate environmental and health conditions:

1. base the health and environmental protection measures adopted, on international standards, directives and other recommendations, with specific reference to those contained in the Cartagena Protocol on Biosafety, the Nagoya-Kuala Lumpur Supplementary Protocol, and other relevant international standards and directives;

2. provide the means necessary to enable the biosafety structures provided for in Articles 17 to 24 of this Regulation, to assess the desirability and scope for the adoption of international standards.

Article 7: Mutual Recognition

1. A Member State may, on the basis of the principle of mutual recognition, accept as equivalent assessment procedures and accreditation systems for living modified organisms and their products from another Member State.
2. The principle referred to in Article 7(1) of this Article
   a. technical regulations, standards and specifications;
   b. conformity and validity of assessment procedures and certificates of conformity of other Member States.
3. The ECOWAS Commission shall develop, in collaboration with Member States, harmonized guidelines for standards and specifications on the conformity of assessment procedures related to the movement of living modified organisms and products thereof within ECOWAS.
4. Notwithstanding Article 7(1) to (3) of this Article, Member States may conclude bilateral agreements with each other.

Article 8: Equivalence and the Principle of National Processing

Each Member State shall accept into its territory, any LMO and product thereof complying with a technical regulation or conformity assessment procedure adopted by another Member State, and deemed equivalent to its own, where the exporting country, in collaboration with the importing country, proves to the latter that said LMO or product thereof was legally manufactured or marketed in its territory, in compliance with the provisions of this Regulation.

Article 9: Free Movement of Products and Equivalence

1. LMOs and products thereof may move freely within the ECOWAS region, provided that they comply with the standards of protection and risk acceptance agreed by the Member States in accordance with the provisions of the relevant provisions of this Regulation.

2. Subject to Article 49 of the Revised ECOWAS Treaty, each Member State shall accept into its territory such LMOs and products thereof as shall conform to the technical and health standards adopted by ECOWAS and socio-economic considerations.

Article 10: Precaution

The absence of any certainties, in view of the current state of biosafety and biotechnological knowledge, must not induce the ECOWAS Commission and the Member States to defer the adoption of measures aimed at averting the risk of severe and irreversible damage to biodiversity and the protection of human and animal health.

Article 11: Prevention

Preventive measures must be taken to avert or reduce effects linked to proven risks of damage to the environment, and particularly, to biological diversity and the protection of human and animal health, through recourse to the best techniques available.

Article 12 : Prior Information and Notification

The notifier shall provide the national competent authority prior notice of any activity related to the use of LMO and/or products thereof, likely to engender damage to human and animal health, and the environment.

Article 13: Liability and Redress

The Party liable for damage shall bear responsibility for redress of any prejudice caused to human and animal health and to the environment.

Article 14: The Polluter Pays

National governments shall endeavour to promote domestication of the costs of environmental protection and the use of economic instruments to ensure that a penalty is imposed on any party responsible for pollution to pay the cost of redress for any damage caused or likely to be caused to the environment.

Article 15: Sustainable Natural Resource Management

Member States shall incorporate matters relating to conservation and the sustainable use of biological resources into the national decision-making process and adopt measures on the use of biological resources aimed at averting or mitigating any adverse effects on biological diversity.

Article 16: Access to Information and Public Participation

The ECOWAS Commission and the Member States shall guarantee and organise public access to information, participation at the appropriate levels of the decision-making process, and access to legal assistance in matters relating to biosafety.

SECTION II: INSTITUTIONAL FRAMEWORK

CHAPTER I: REGIONAL BIOSAFETY ORGANS

Article 17: Regional Biosafety Authority

1. Within the framework of the implementation of this Regulation, the ECOWAS Commission is the Regional Biosafety Authority (RBA).
2. In this capacity, the ECOWAS Commission shall :
   a) working in collaboration with the regional bodies created under the provisions of Article 18 below, coordinate the actions led by the Member States, with a view to decision-making on the overall dissemination of LMOs in the environment, and the handling and use of products thereof;
   b) submit the draft decisions referred to in Article 26.11 of this Regulation, for the consideration of said bodies.
3. In addition, the Regional Biosafety Authority shall :
   a) together with the Member States, establish the criteria for the selection of national reference laboratories;
   b) identify a regional reference laboratory from among the national reference laboratories;
   c) establish guidelines for the use of the regional reference laboratory.
4. The criteria for the identification of national laboratories and the guidelines for the use of the regional reference laboratory shall be fixed by way of an Implementing Regulation.
5. The RBA shall set up and administer an on-line regional Biosafety Clearing House.

Article 18: Biosafety Committees

1. The following are hereby created at the ECOWAS level:
   a) a Regional Biosafety Committee;
   b) a Regional Scientific and Technical Biosafety Committee.

2. The two committees shall work together within the ECOWAS Commission, to effect implementation of the provisions of this Regulation and establish modalities to this end.

3. The ECOWAS Commission shall provide secretarial services to the committees.

Article 19: Missions led by the Regional Biosafety Committee

The Regional Biosafety Committee acts in an advisory capacity to the Regional Biosafety Authority. In this regard, the Committee shall:

a) give opinions and make recommendations to the Regional Authority on projects and decisions :
b) examine draft decisions transmitted by the competent national authorities on issues relating to the use of LMOs or products thereof within the ECOWAS region;
c) issue opinions and formulate recommendations to the Regional Biosafety

Authority based on the findings of the Regional Scientific and Technical Biosafety Committee and of consultations held with stakeholders;

d) propose facility inspection tours to the Regional Biosafety Authority, for purposes of monitoring levels of compliance, with a special focus on laboratories, greenhouses and fields;

e) recommend, where necessary, additional safety measures to be factored into the draft decision submitted for its consideration;

f) recommend issuance of approvals to the Regional Biosafety Committee;

g) check public participation in the decision-making process;

h) encourage public sensitisation, information and education on issues relating to biosafety at the ECOWAS level;

i) contribute to strengthening cooperation between the ECOWAS Member States and ensuring the alignment of their positions during negotiations and in relation to biosafety issues at the international level;

j) validate projects for the harmonisation of joint risk analysis and assessment procedures and regulations, and of regional verification procedures for biosafety products and services, preparatory to their adoption by the Regional Biosafety Authority;

Article 20 : Composition of the Regional Biosafety Committee

1. The Regional Biosafety Committee shall comprise :

   a) the Head of the Competent National Authority responsible for biosafety in every ECOWAS Member State;

   b) a Representative from the ECOWAS Commission;

   c) a Representative from the UEMOA Commission;

   d) a Representative from CILSS;

   e) the Chairperson of the Regional Scientific and Technical Biosafety Committee.

2. The Committee may convene meetings, and call on resource persons, as the need arises.

Article 21: Function of the Regional Scientific and Technical Biosafety Committee

1. The function of the Regional Scientific and Technical Biosafety Committee is to check that the assessment of the potential risks of LMOs and/or products thereof is carried out at the national level prior to release into the environment, in compliance with the Regulation on Biosafety in ECOWAS.

2. The Committee shall act in an advisory scientific and technical capacity to the ECOWAS Commission and the Regional Biosafety Committee.

3. The Regional Scientific and Technical Biosafety Committee has additional responsibility for :

   a) checking the accuracy, quality and reliability of the information received from the Competent National Authorities;

b) proposing to the RBC criteria and modalities for the approval of laboratories, greenhouses, and such facilities as may be used for work presenting risk levels 3 and 4, as identified under the terms of the Regulation on Biosafety in ECOWAS.

Article 22: Membership of the Regional Scientific and Technical Biosafety Committee

Members of the Regional Scientific and Technical Biosafety Committee shall be recruited from the Member States on merit, on a case-by-case basis.

Article 23: Implementation

The organisation, powers and modalities for the functioning of the Regional Biosafety Committee and the Regional Scientific and Technical Biosafety Committee shall be prescribed by way of an Implementing Regulation.

CHAPTER II: NATIONAL BODIES

Article 24: National Biosafety Bodies

1. For purposes of the implementation of this Regulation, the Member States shall appoint or set up national biosafety bodies charged with responsibility for:
   a) the functions of the competent national Authority, with particular regard to decision-making on the use of LMOs and products thereof in the laboratory, in greenhouses, in contained spaces, and in the environment;
   b) scientific assessment and risk management;
   c) the functions of the national biosafety laboratory for detection, identification and quantification of LMOs and products thereof
   d) public information and sensitisation;
   e) public involvement in the decision-making process;
   f) checking the implementation of the LMO post-dissemination plan.
   g) inspecting facilities and certification of laboratories.
2. Member States shall provide necessary support for the smooth functioning of the national biosafety bodies.

SECTION III: NOTIFICATION AND DECISION-MAKING PROCEDURES

CHAPTER I:

AUTHORISATION FOR USE OF LMOS AND/OR PRODUCTS THEREOF

Article 25: Advance Informed Agreement Procedure (AIAP)

1. Advance informed agreement procedure shall apply prior to the first intentional transboundary movement of LMOs and/or products thereof for intentional introduction into the environment of the State of Import or of Transit.
2. The advance informed agreement procedure shall not apply to the intentional transboundary movement of LMOs and/or products thereof identified under the provisions of this Regulation as being unlikely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human and animal health.

CHAPTER II:

NOTIFICATION OF REQUEST AND ACKNOWLEDGEMENT OF RECEIPT

Article 26: Notification and Authorisation for Use of LMOs and/or products thereof

1. Any person intending to undertake the contained use, transit, production, development, import, general dissemination or marketing of LMOs and/or products thereof shall be required to submit a request in writing to that effect, to the competent national Authority of the Member State concerned.
2. The notification shall contain specific information, as prescribed by the Implementing Regulation.
3. The notification shall contain a post-dissemination monitoring plan drawn up in accordance with the specifications of the Implementing Regulation.
4. The competent national Authority of the Member State concerned shall issue a written acknowledgement of receipt within a period of 21 days, indicating :
    a) date of receipt of notification;
    b) whether the notification clearly states the information stipulated above;
    c) whether the proceedings may move forward within the legal national or ECOWAS framework.
5. No decision pertaining to the import, transit, contained use, development, dissemination, production or marketing of an LMO and/or products thereof may be taken by the competent national Authority of a Member State without prior assessment of the risk to the environment, human and animal health, and socio-economic considerations, if applicable.
6. The notifier shall provide the competent national Authority of the Member State concerned with evidence that s/he has adequate means with which to discharge his/her obligations, as stipulated by this Regulation, subject to denial of his/her request.
7. All decisions to grant or deny authorisation must be substantiated.
8. After receiving authorisation, the notifier shall notify the competent Authority of the Member State concerned of all new information on potential or proven risks to human and animal health, biological diversity and/or the socio-economic fabric.
9. The response of the competent national Authority concerned to a notification, may take one of the forms hereunder :
    a) authorisation to import, giving justifications, and stating any conditions arising;
    b) denial of authorisation to import, with justifications;
    c) demand for additional information, with justifications;
    d) extension of timeframe, with justifications.
10. The draft decision of the competent national Authority concerned shall be referred in writing to the Regional Biosafety Authority for an opinion. All

opinions of the competent Regional Authority shall be communicated in writing to the competent national Authority within 90 days.

11. The final decision of the competent national Authority concerned shall be communicated in writing to the notifier and brought to the attention of the general public. The Regional Biosafety Clearing House shall receive a copy of the decision.

12. The authorisation may only be issued if the import, contained use, development, deliberate release or placing on the market of LMOs and/or products thereof is beneficial to at least one ECOWAS Member State and the risks are acceptable and manageable in terms of human and animal health, conservation of biological diversity and protection of the socio-economic fabric and cultural values

Article 27: Simplified Procedure

1. Subject to adequate measures being implemented to ensure the safe, intentional transboundary movement of LMOs and/or products thereof, the competent national Authority may adopt simplified procedures.

2. Prior to the adoption of the simplified procedure, the list of the LMOs and/or products thereof concerned must be submitted to the Biosafety Clearing House.

3. The competent national Authority of the Member State concerned shall draw up a list of all LMOs and/or products thereof exempted from the advance informed agreement procedure, and transmit said list to the regional Authority.

4. The information to be provided in the notification concerning intentional transboundary movements subject to the simplified procedure shall be specified by the Implementing Regulation.

SECTION IV:

PROCEDURES GOVERNING APPLICATIONS FOR AUTHORISATION FOR DIFFERENT USES OF LMOs

CHAPTER I:

PROCEDURES GOVERNING APPLICATIONS FOR AUTHORISATION FOR THE USE OF LMOS IN CONTAINED FACILITIES AND FOR CONTROLLED DISSEMINATION

Article 28: Issuance of Authorisations

Authorisations for the use of LMOs in contained facilities for controlled dissemination is issued by the competent national Authority of the State in which the use is envisaged.

Article 29: Notification and Acknowledgment of Receipt

1. Any legal or natural person desiring to use a regulated product in a contained facility or undertake controlled dissemination of a regulated product shall submit an application for authorisation to the competent national Authority of the State in which the use is envisaged.

2. The content of the application shall be determined by the Implementing Regulation.

3. The competent national Authority shall receive the application and issue a certificate of deposit. The Authority shall screen and send a receipt to the notifier within a maximum of 21 days from the date of issuance of the certificate of deposit.
4. The absence of a written response to the applicant shall not signify approval of the application.

Article 30: *Screening of the Application, Processing Timeline and Notification of Decision*

1. Where an application is deemed receivable, the decision of the competent national Authority to grant or deny the requested authorisation shall be transmitted to the notifier within 180 days from the date of notification of receipt of the application.
2. The competent national Authority may request additional information after initiation of the screening process. In such case, the timeline set for completion of the screening shall be delayed in order to permit the requested information to be provided. In the event of failure on the part of the applicant to provide the required information within the timeframe set by the competent Authority, the processing of the application shall be cancelled.

Article 31: Information of the Regional Biosafety Authority

1. The competent national Authority shall transmit its substantiated decision and any terms and conditions linked to the authorisation granted, to the competent Regional Biosafety Authority within 15 days from the date of decision.
2. The regional Biosafety Authority shall inform the competent national Authorities of the other Member States of the decision, within 15 days from the date of its own receipt of notification.

CHAPTER II:

PROCEDURE FOR THE APPLICATION FOR AUTHORISATION FOR GENERAL RELEASE OF AN LMO INTO THE ENVIRONMENT

Article 32: Grant of Authorisation

All form of release of an LMO or product thereof into the environment, including their placement on the market, shall be conditional upon approval by the Regional Biosafety Authority.

Article 33: Notification and Acknowledgement of Receipt

Any legal or natural person desiring to undertake the release of LMOs into the environment, shall submit an application in that regard to the competent national biosafety Authority. The content of the application shall be determined by the Implementing Regulation.

The competent national Authority shall receive the application and issue a certificate of deposit. The Authority shall screen the application and transmit an acknowledgement of receipt to the notifier within a maximum of 21 days from the date of issuance of the certificate of deposit.

The absence of a written response to the notifier within a period of 45 days from the date of deposit of the application shall not be deemed an acceptance.

The competent national Authority shall inform the Regional Biosafety Authority of the application. The competent Regional Biosafety Authority shall inform the competent national Authorities of the other States of its receipt of the application and of the opinion issued by the country indicated therein.

Article 34: Screening of the Application, Processing Timeline and Notification of Decision

The competent national Authority shall be responsible for the screening of all applications and prepare a draft decision thereon within a period of 180 days.

The competent national Authority may request additional information after initiation of the screening process. In such case, the timeline set for completion of screening shall be delayed in order to permit the requested information to be provided. In the event of failure on the part of the applicant to provide the required information within a period of 180 days, the processing of the application shall be cancelled.

The competent national Authority shall submit a draft decision and the application dossier to the Regional Biosafety Authority for approval.

The Regional Biosafety Authority shall refer to the Regional Biosafety Committee.

The Regional Biosafety Authority shall give its justified opinion within a period of 90 days from the date of receipt of the draft decision.

Article 35: Reconsideration of the Draft Decision by the Regional Biosafety Authority

In the event that the Regional Biosafety Authority issues an unfavourable opinion, the competent national Authority may request a second assessment.

The competent national Authority shall, to this effect, provide additional information to the Regional Biosafety Authority which shall respond to the objections presented, and resubmit the application.

Any notification of non-compliance of the Regional Biosafety Authority must be duly substantiated.

In the event of a second notification of non-compliance, the notifier may appeal.

The modalities for appeal shall be stipulated in the Implementing Regulation.

Under the terms of this Regulation, the competent national Authority must inform the Regional Biosafety Authority and all other competent national Authorities of all information deemed relevant for purposes of the issuance of an authorisation.

CHAPTER III:

PROCEDURE FOR APPLICATION FOR AUTHORISATION FOR LMOS AND PRODUCTS THEREOF FOR DIRECT USE IN HUMAN FOOD OR ANIMAL FEED OR FOR PROCESSING

Article 36: Issuance of Authorisation

Any authorisation for the release of an LMO or products thereof for direct use in human food or animal feed, or for processing, in an ECOWAS Member State shall be issued by the competent national Authority.

Procedure for the granting of authorisation relates to the conditions for general release of LMOs into the environment as provided by Articles 32 to 35 of this Regulation.

However, a simplified screening procedure may be applied to LMOs and products thereof which have already received authorisation for the same use in another Member State. The competent national Authorities shall draw up a list of LMOs and/or products thereof which are exempt from Advance Informed Agreement Procedure. The Authorities shall transmit a copy of said list to the Regional Biosafety Authority, which shall inform the Regional Scientific and Technical Biosafety Committee accordingly.

Article 37: Notification and Acknowledgement of Receipt

The Operator wishing to import an LMO or products thereof, for direct use in human food and animal feed, shall submit an application addressed to the competent national Authority.

The content of the application shall be determined by the Implementing Regulation.

The competent national Authority shall receive the application and issue a certificate of deposit. The Authority shall screen and transmit acknowledgement of receipt to the notifier within a maximum of 21 days from the deposit date. The Authority shall inform the Regional Biosafety Authority accordingly.

The absence of a written response to the applicant within 21 days from the date of deposit of the application, shall not be deemed an acceptance.

The Regional Biosafety Authority shall inform the competent national Authorities of the other Member States of its receipt of the application and the notification of the receivability of the application.

Article 38: Screening of the Application, Processing Timeline and Notification of Decision

The provisions of Articles 36 and 37 above shall be equally applicable to this Article, with the exception of the processing timeline provided for the simplified procedure.

For all applications deemed receivable, the decision of the competent national Authority to grant or deny authorisation for requested use, shall be transmitted to the notifier within 90 days from the date of notification of the receivability of the application. The competent national Authority may request additional information after initiation of the screening process. In such case, the timeline set for completion of the screening shall be delayed in order to permit the requested information to be provided. In the event of failure on the part of the applicant to provide the required information within a period of 90 days, the processing of the application shall be cancelled.

Article 39: Review of the opinion taken by Regional Biosafety Authority

In the event of an unfavourable opinion from the Regional Biosafety Authority, the competent national Authority may request a reappraisal.

The competent national Authority shall, to this end, provide additional information to the Regional Biosafety Authority, which shall respond to the objections made. The competent national Authority shall resubmit the application.

Any outcome be duly substantiated.

In the event of a second negative opinion, the notifier may appeal.

The appeal procedure shall be as laid down in the Implementing Regulation.

Article 40: Basis of Opinions and Decision

1. Without prejudice to the guiding principles contained in Chapter II of these Regulations, the opinions decisions of the Regional and National Biosafety Authorities are based mainly on :
   a) the findings of the risk assessment exercise;
   b) the outcomes of the public participation exercise;
   c) information provided by the notifier;
   d) socio-economic considerations.
2. The competent national Authority, on the advice of the Regional Biosafety Authority, shall issue an authorisation if the evidence points to the fact that the import, contained use, release or marketing of a living modified organism (LMO) and/or product thereof, shall :
   a) benefit the Member State concerned or ECOWAS, without presenting risk of harm to human and animal health, biological diversity, and the environment.
   b) not damage the socio-economic environment of the ECOWAS region.

Article 41: Socio-economic Considerations in the Decision-making Process

The competent national Authority shall, prior to decision-making, ensure that the following elements are factored into the risk management plan drawn up within the broader framework of its risk management measures:

a) the socio-economic incidences of LMOs and/or products thereof on the local communities within the areas concerned;

b) the potential threat of LMOs and/or products thereof to traditional cultures, and cultural and ethical values, as they relate to biological diversity.

CHAPTER IV:

REAPPRAISAL OF DECISIONS

Article 42: Request for a Reappraisal of Decisions on Authorisation for Use

1. Decisions on issuance of authorisations for the use of LMOs may be subject to reappraisal.
2. Reappraisal of a decision may be requested in the light of new scientific information on the adverse effects linked to LMOs or products thereof by :
   a) the Regional Biosafety Authority or the competent national Authority of a Member State;
   b) the notifier/applicant;
   c) any legal or natural person with a stake in acting in the matter.
3. In every case, the request for a reappraisal must be substantiated. The cost of the reappraisal procedure shall be borne by the requester.

Article 43: Purpose of a Reappraisal of Decisions on Authorisation for Use

The purpose of the reappraisal of a decision is to submit the use of the LMO or product thereof concerned to further examination, taking advances in scientific knowledge into account.

Article 44: Suspension or Withdrawal of Authorisation

The competent national Authority may decide to suspend or withdraw previously granted authorisation during the process of a reappraisal of a decision, where an analysis of new information so demands.

In the event of a withdrawal, the competent national Authority shall order the destruction by any appropriate means, of the LMO concerned, and the imposition of specific measures of redress.

The competent national Authority of the State concerned shall inform the Regional Biosafety Authority, which shall in turn inform the competent national Authorities of the other Member States.

The costs of all operations relating to the destruction and rehabilitation exercise shall be borne by the Holder of the authorisation**.**

SECTION V: RISK ASSESSMENT AND MANAGEMENT

CHAPTER I: RISK ASSESSMENT

Article 45: Principles of Assessment

1. The use of an LMO and products thereof shall be subject to preliminary risk assessment, and an assessment of their potential impact on the environment in general and on biodiversity in particular, taking into account the risk to human and animal health, and socio-economic factors. The assessment shall be conducted on a scientific and case-by-case basis.
2. The purpose of the assessment exercise is :
   a) to identify likely dangers and analyse their potential impact on the environment, human and animal health;
   b) to evaluate probability of occurrence and eminence of identified dangers;
   c) to determine modalities for management of identified risks;
   d) to calculate the cost of interventions in the management of identified risks.
3. Assessment procedures must comply with the prescriptions of the Regional Manual on Risk Management and Assessment Procedures governing the introduction of modern biotechnologies and products thereof into the ECOWAS region.
4. Details of procedures and risk assessment modalities shall be as prescribed by the Implementing Regulation.

Article 46: Classification of Risk Levels

1. LMOs and products thereof shall be classified according to risk level, corresponding to the following distinct safety levels :

   - Risk Level 1: LMOs and products thereof recognised as presenting “no risk, in theory”, or “negligible” risk to human, animal health and the environment;

- **Risk Level 2:** LMOs and products thereof known to present “low risk” to human, animal health, and the environment;
- **Risk Level 3:** LMOs and products thereof known to present risks deemed to have a “moderate” impact on human, animal health and the environment;
- **Risk Level 4:** LMOs and products thereof with an impact on the environment proven to present a potentially “grave” risk, or about which nothing is known.

2. The risk levels indicated above, and the safety levels relating thereto, as well as the management procedures and methods adopted in each case shall be prescribed by the Implementing Regulation.

CHAPTER II: RISK MANAGEMENT

Article 47: Purpose of Risk Management Measures

The purpose of risk management measures is to prevent, reduce or contain and eliminate the adverse effects of LMOs on:

a) the environment in general, and biological diversity in particular;

b) human and animal health;

c) human communities.

Article 48: Obligation to Define Appropriate Risk Management Measures

1. Every LMO user is bound, before putting the organism to use, to define measures by which to achieve the following:
    a) adequate risk management, and compliance with all applicable conditions contained in the regulations and requirements in force in the Member State concerned, for the approval of the competent Authorities;
    b) adequate containment and destruction of LMO waste.
2. Every LMO user is bound to adopt the risk management measures approved by the competent Authorities.
3. Ever LMO user has a responsibility to propose additional risk management measures on the basis of any new information available.

Article 49: Containment of LMOs and products thereof

1. Before their initial release, all LMO and/or products thereof shall undergo preliminary containment.
    a) the laboratories, greenhouses and large-scale production facilities shall be classified according to containment level, in ascending order of risk.
    b) there are hereby established 4 containment levels, corresponding to the risk levels defined under the provisions of Article 46 of this Regulation. Each containment level corresponds to specific applicable management and monitoring-assessment measures for LMO use.
2. Modalities for containment according to level; protective measures for laboratories; field trials, large-scale and greenhouse procedures shall be prescribed by the Implementing Regulation.

Article 50: Review of LMO Containment Measures

The user of any LMO is bound to review the containment measures in use, taking into account new scientific discoveries and best available containment techniques.

Article 51: Coexistence Management

1. With regard to management of the coexistence of LMOs approved for release, the competent national Authority of the State concerned shall, on the basis of available best techniques and practices, prescribe safety measures for coexistence between :
   a) transgenic and non-transgenic crops;
   b) transgenic and non-transgenic stocks;
   c) crop systems involving LMOs and natural ecosystems containing related species;
2. The competent national Authorities shall take necessary measures to protect centres of origin, protected and wetland areas.

Article 52: Waste Management

1. Every LMO user is under obligation to adopt appropriate measures for the destruction of LMO waste;
2. Waste management resulting from research, development, handling, production and marketing of LMOs shall comply with the scientific standards for the processing of the different categories of waste identified in the Implementing Regulation.
3. All LMO reproductive material shall be considered waste and must be destroyed.

Article 53: Intervention Strategy and Emergency Plan

1. The user shall put intervention strategies in place before the unconfined release of an LMO, or any activity relating thereto, including transboundary movement. The user shall also submit detailed emergency plans aimed at minimising, confining, circumscribing, mitigating or avoiding potential damage of any description.
2. The intervention strategies and detailed emergency plans referred to above shall be submitted by the user for prior approval by the competent national Authority.
3. In the event of damage or imminent danger resulting from the general or unintentional release of LMOs presenting a threat to human and animal health, biological diversity and the environment, the operator is required to take immediate necessary measures and inform the competent national Authority accordingly.
4. In the event of failure on the part of the operator, the competent national Authority shall take appropriate measures of intervention.
5. The competent national Authority shall have the right to recover from the operator any costs relating to damage assessment and all appropriate measures of intervention taken, as well as the cost of any additional expenditure involved.

SECTION VI: TRANSPORT, TRANSIT, PACKAGING AND LABELLING

CHAPTER I: TRANSPORT AND TRANSIT

Article 54: Transport of LMOs and products thereof

1. Any transboundary movement of an LMO and product thereof shall be subject to prior authorisation of the competent national Authority of the State of Import, in accordance with the provisions of this Regulation.
2. The transport of any LMO and product thereof within the ECOWAS region shall take account of the required containment measures prescribed for the risk level of the LMO. The risk management measures approved by the competent national Authority for the given LMO must include risk management during transport.
3. The specific practical modalities for the transport of LMOs or products thereof shall be prescribed by the Implementing Regulation.

Article 55: Transit of LMOs or products thereof within the ECOWAS Region

1. Any legal or natural person transporting LMOs or products thereof in transit through the ECOWAS region must give advance notice thereof to the competent national Authority of each Member State of transit.
2. The modalities and conditions of transit shall be set out in the Implementing Regulation.

CHAPTER II: LABELLING AND PACKAGING

Article 56: Labelling

When applicable, any LMO or products thereof intended for use in the environment or for placing in the market, shall be labelled in an indelible and tamper-proof manner.

Modalities for labelling shall be prescribed by the Implementing Regulation.

Article 57: Packaging

When applicable, any LMO or product thereof intended for deliberate release into the environment shall be packaged in compliance with the international standards in force, in order to avoid any risk to the environment or human and animal health.

Modalities for packaging shall be prescribed by the Implementing Regulation.

SECTION VII: PUBLIC ENLIGHTENMENT AND PARTICIPATION

Article 58: Public Information Sensitisation

1. Every ECOWAS citizen has the right to access information as to the benefits and risks associated with the use of modern biotechnology and LMOs.
2. ECOWAS Commission and the Member States shall encourage and facilitate public information, sensitisation, education and training, as well as access to information on issues relating to biotechnology and biosafety. In this regard, they shall cooperate with other States and relevant international organisations.
3. Every operator shall ensure that the populations of the areas concerned are informed of the benefits and risks associated with the use of modern biotechnology and LMOs.

Article 59: Public Participation in the Decision-making Process

1. Every citizen has the right to participate in the decision-making process as relates to biosafety management.
2. The ECOWAS Commission and the Member States shall take necessary measures to guarantee public participation in the decision-making process at the regional and national levels and ensure access to justice in matters relating to biosafety, as well as effective implementation of said measures.
3. The Regional Biosafety Authority and the competent national Authorities shall establish the appropriate frameworks and structures necessary to organise public participation in the decision-making process.

Article 60: Confidentiality of Information

1. The competent national and regional authorities shall authorise the notifier to identify information as confidential;
2. The authority shall decide whether or not to consider as confidential the information provided, such as by the notifier;
3. Notwithstanding any requirements in a Member State at the national level, the following information may not, under any circumstance, be deemed confidential :
   a) description of an LMO and its products thereof, the name and address of the notifier, the purpose and destination of import or transit, the location for contained use, release or marketing of the LMO and products thereof;
   b) methods and monitoring plans for the LMOs and/or products thereof, and emergency intervention measures;
   c) assessment of foreseeable effects, particularly effects on human and animal health and on biological diversity.
4. If for any reason, the notifier withdraws a notification before the requested authorisation is granted, the competent national Authority is bound to respect the confidentiality of the information provided.
5. The competent national and regional authority may not divulge to a third-party any confidential information notified as such or forming part of to information exchange.

SECTION VIII: DAMAGE, LIABILITY AND REDRESS

CHAPTER I: Liability Regime

Article 61: Origin of Damage

1. Damage may result from imminent threat or an incident.
   a. Imminent threat of damage is constitutive of a fact or facts which, on the basis of the best scientific, technical and other available information on the matter, is deemed likely to cause damage, if appropriate and timely measures are not taken.
   b. An incident is when a fact or series of facts, originating in the use of an LMO or products thereof, causes damage or creates an imminent and serious threat of damage.
2. The damage can also be caused by:

a. intentional transboundary movements,

b. unintentional transboundary movements;;

c. illegal cross-border movements;

d. handling, transit, packaging of LMOs and/or products derived thereof

3. The damage may also result from living modified organisms and/or products thereof intended to be:

a. directly used for food or feed or to be processed;

b. used in confined environments;

c. intentionally introduced into the environment

Article 62 : Types of Damage

Damage resulting from LMOs and products thereof mainly comprises:

a) damage to the sustainable conservation and use of biological diversity which has not been remedied through an administrative approach;

b) damage to human and animal health, including deaths and bodily injuries;

c) loss of property;

d) loss of income or other economic loss resulting from damage to the conservation or sustainable use of biological diversity;

e) violations of cultural, social and spiritual values, or all other damage to local communities, and the loss or reduction of food security.

Article 63: Damage Assessment

Damage resulting from the use of LMOs is assessed according to the criteria listed below :

a) environmental impact;

b) impact on human and animal health;

c) socio-economic impact;

d) cost of intervention measures.

Article 64: Causality Link

A link of causality shall be established between the damage and the living modified organism, in accordance with the domestic legislation of each Member State.

Article 65: Intervention Measures

1. For purposes of this Regulation, intervention measures shall be defined as appropriate measures taken, in the event of damage or of imminent threat, with a view to :

a) prevent, minimise, contain, circumscribe, mitigate or otherwise avoid said damage or imminent threat of damage;

b) restore biological diversity by taking the following measures according to the order of preference here indicated :

i. restoration of biological diversity to conditions preexisting the damage, or the closest equivalent, where the competent Authority deems complete restoration impossible;

ii. restoration, particularly of lost biological diversity, using various other components of the biological diversity for the same or other purposes, at the same, or other locations, as the situation demands.

2. Where there has been damage, the Member States shall demand, subject to conditions imposed by the competent national Authority, that the approved operator(s) :

   a) immediately inform the competent national Authority;

   b) assess the damage;

   c) take appropriate intervention measures.

3. The competent national Authority shall :

   a) identify the operator responsible for the damage;

   b) undertake an assessment involving all parties, if necessary;

   c) identify the intervention measures to be undertaken by the operator.

4. Where relevant information, including available scientific data, or information available to the Regional Biosafety Clearing House, indicates a high degree of probability of damage if timely response measures are not taken, the operator is bound to take the appropriate response measures in order to avoid the damage.

5. The competent national Authority may take appropriate intervention measures, particularly, where the operator has failed to do so.

6. The competent national Authority is entitled to recover from the operator the cost of the damage assessment and of all appropriate response measures as well as any additional costs and expenses incurred in this connection.

7. Any decision of the competent national Authority requiring that the operator take response measures, must be substantiated. The operator must be notified of such decisions.

8. ECOWAS Commission shall define the modalities for damage assessment in the Implementing Regulation.

CHAPTER II: REDRESS

Article 66: Application of Civil Liability

1. The Member States shall, in their domestic law, enact the specific rules and procedures designed to redress damage.

2. The Member States shall provide, as the occasion demands, for :

   a) the liability standard, including no-fault liability and fault-based liability;

   b) the rules for channeling of liability, where appropriate;

   c) right of recourse.

3. The Member States shall adopt texts identifying offenses and penalties for offenders, in the light of the scope of dangers and damage involved.

SECTION IX: MISCELLANEOUS PROVISIONS

Article 67: Monitoring and Inspection

Monitoring of LMOs shall be carried out at every phase of use.

LMOs shall be subject to inspection throughout their cycle. The necessary control measures shall be carried out by sworn agents of the Member States. Verification exercises shall be carried out to ensure proper authorisation of products and conformity of labelling. The modalities for these controls are laid down in the Implementing Regulation.

Article 68: Dues Payable for Processing of Applications and of Authorisation

Dues shall be payable at the national level for services provided in the process of issuance and renewal of authorisations, as well as all other services provided within this framework.

Article 69: Capacity Building

1. ECOWAS Commission shall provide the Member States the technical and financial support necessary for purposes of human and institutional capacity building in matters relating to biosafety, and for the preparation of this Regulation on Biosafety and Biotechnological Development.
2. ECOWAS Commission and the Member States shall cooperate with the relevant international institutions on the issues of capacity building of the region and biotechnological risk prevention and management.
3. ECOWAS Commission shall provide the Member States with the technical and financial support needed to facilitate protection of intellectual property as pertains to their genetic resources, including the genes they contain.

SECTION X: SPECIAL PROVISIONS

Article 70: Any Other Form of Advanced Biosafety-related technology

The ECOWAS Commission, in collaboration with the Member States, shall take all political, legal and administrative measures necessary to harness aspects of other advanced biosafety-related technologies into proper consideration for socio-economic development.

Article 71: Transitional Provisions

The ECOWAS Commission shall, within a 3-year timeframe with effect from the date of entry into force of this Regulation, ensure the establishment of biosafety institutions and adoption of measures for its implementation.

For the duration of this period, national legislation applicable to the use of LMOs and products thereof, shall remain in force in the Member States.

Similarly, the LMOs and products thereof duly developed or authorised in any Member State, in accordance with the legislation in force in said State, shall continue to be deemed authorised and used.

Article 72: Safeguard Clauses

In implementation of Article 49 of the Revised Treaty, Member States shall reserve the right to edict prohibitions or restrictions on LMOs and/or products thereof, particularly as pertains to their import, export and transit, justifying such edict on

grounds of public morality, order, security; protection of the health or life of persons and animals; conservation of the environment and of biological diversity and, protection of intellectual property regarding genetic resources, including the genes they contain.

The prohibitions and restrictions applied by virtue of the above paragraph, shall not constitute a means of discrimination, or a hidden restriction to trade between the Member States.

The concerned Member State can, after having informed the President of ECOWAS Commission and other Member States, take appropriate safeguard measures pending the decision of the Council of Ministers.

These measures shall not remain in force longer than one (1) year and can only be extended beyond this period by the decision of the Council of Ministers.

As long as the measures are in force, the Council of Ministers shall examine the manner in which they are implemented.

SECTION XI: FINAL PROVISIONS

Article 73: Implementation

The ECOWAS Commission and the Member States shall be responsible, each in its own capacity, for the implementation of this Regulation.

The ECOWAS Commission shall prepare the Implementing Regulation necessary for the implementation of this Regulation.

Article 74: Entry into Force

This Regulation shall enter into force on the date of signature by the Chairman of the Council of Ministers and shall be published in the ECOWAS Official Journal within thirty (30) days.

Done at ……this ……day of …… …… 2020.

CHAIRMAN

FOR COUNCIL