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REGULATION C/REG…/11/09 ESTABLISHING A PROCEDURE FOR THE REVIEW AND AUTHORISATION OF PRODUCTS OF MODERN BIOTECHNOLOGY WITHIN THE ECOWAS

(RELATING TO THE REDUCTION OF RISKS ON MODERN BIOTECHNOLOGY PRODUCTS)?

The Council of Ministers,

MINDFUL of articles 10, 11 and 12 of the ECOWAS Treaty as amended establishing the Council of Ministers and defining its composition and functions;

MINDFUL of Article 3.2.a) on the harmonisation of national policies and the promotion of integration programmes, particularly in the areas of food, agriculture, health, science and technology;

MINDFUL of Article 3.2.b) on the harmonisation and coordination of policies for the protection of the environment;

MINDFUL of Regulation C/REG.5/05/08 on the adoption of the action plan for the development of the biotechnology and the biosafety within the ECOWAS space;

CONSIDERING the obligations of the Member States vis-à-vis the Convention on Biological Diversity and the Cartagena Protocol on Biosafety;

CONVINCED that modern biotechnology offers significant positive potential for socioeconomic development, human well-being, animal health and the environment provided it is developed and used under conditions considered safe for human and animal health and the environment;

AWARE that some countries may require assistance in realising the known and potential benefits of modern biotechnology and to manage the potential risks of products of modern biotechnology;

AWARE ALSO that the safe adoption of modern biotechnology in West Africa will necessitate setting up of a sub-regional biosafety regulatory system to review biotechnology products which would be coming from outside the sub-region or would be produced by the national agricultural research systems (SNRA) within the sub-region;

CONVINCED that a sub-regional biosafety review process will facilitate sharing of reliable information about the environmental impacts and food and seed safety, as they are relevant to modern biotechnology products;

CONVINCED ALSO that a sub-regional approach will reduce investment costs and thereby facilitate deployment of modern biotechnology products within the sub-region;

RECALLING its commitment to prioritise the harmonisation of biotechnology and biosafety policies and procedures in West Africa;

DESIROUS to establish a regional mechanism for ensuring the safe introduction of modern biotechnology, harmonise national biosafety policies, regulations and approaches to risk assessment and risk management under a single framework in order to develop a more uniform and consistent approach to the safe use and application of modern biotechnology, and to minimise obstacles to trade in products of modern biotechnology among Member States;

ENACTS

SECTION 1: GENERAL PROVISIONS

Article 1: Definitions

In this Regulation, unless the context otherwise requires:

”**Accidental release**” means any unintentional release of a regulated article, or material derived thereof, that is not in compliance with the terms and conditions of authorisation;

“**Applicant**” means any natural or legal person, or any public or private institution seeking authorisation under a provision of this regulation;

”**Biosafety**” includes policy, procedures, or techniques adopted with the goal of contributing to the safe application of modern biotechnology in the areas of medicine, agriculture, industry, and the environment, and to the prevention of risks to human and animal health and environmental safety;

"**Competent National Authority**" means a national authority, or authorities, responsible for regulating genetically modified organisms, and/or their derived products, in accordance with national legislation or policy. Where multiple authorities are recognised, references to the Competent National Authority shall include all relevant national authorities. The Competent National Authority(ies) is(are) in charge of carrying out functions stipulated in this regulation;

"**Competent regional authority**" means the West African Biosafety Committee (COAB/WABCo) established by ECOWAS to implement the ECOWAS biotechnology and biosafety action plan as it relates to biosafety;

"**Confined field trial**" / "**Confined release / use**": means dissemination for the purpose of research under conditions that minimise the establishment and spreading in the environment of an organism or its genetic material, and the interaction between the organism or its genetic material and the environment;

"**Derived product**" means any product extracted from or made using an organism with the goal of using it as food or in food or for human or animal health;

"**Dissemination**" means any discharge or release of an organism into the environment;

"**Environment**" includes water, air and land and the interrelationship which exists among and between water, air and land, and human beings, other living creatures, plants, and micro-organisms;

"**Genetically modified organism (GMO)"** means organism, (excluding humans) including microorganisms, whose genetic material was modified by the application of modern biotechnology. Other terms used: transgenic organism, genetically engineered organism (GEO);

"**Inspection/monitoring**" means the set of operations intended to ensure safety and verify the compliance of the activities of projects focusing on GMOs and GMO-derived products in accordance with the standards and procedures in force;

"**Labelling**" means the inserting of logos, brands, details, and indicators of the presence of GMOs and GMO-derived products into packaging content;

"**Modern biotechnology**" means the application of *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or 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. It excludes: *in vitro* fertilisation; natural processes such as conjugation, transduction, transformation; polyploidy induction; and accelerated mutagenesis;

"**Risk**" means the combination of the scale of the consequences of a danger and exposure to this danger, if it occurs, and the probability that consequences will result;

"**Risk assessment**" means measures that aim to estimate the damage that may be caused, the probability that damage will be caused, and the extent of the estimated damage; risk assessment is an estimation of risks and their consequences;

"**Risk management**" means measures applied to ensure that an organism is handled in a healthy manner. The conditions required for risk management change frequently depending on risk assessments. For example, a high-risk experiment may be managed through the application of appropriate confinement measures that aim to reduce risks. The evaluation of even the most minor risks can show in what way risk assessment procedures may be simplified or eliminated;

"**Regulated article**" means any item or product identified as subject to the provisions of this regulation;

"**Unconfined release / use**" means unrestricted dissemination, including commercialisation";

"**User**" means any individual, institution or organisation in charge of the development, marketing and distribution of GMOs;

"**Transboundary movement**" means the movement of genetically modified organisms or GMO-derived products over national borders.

Article 2: Scope

This regulation applies to the development, transboundary movement, handling and use of genetically modified organisms and products derived thereof.

Article 3: Involved Products

(a) Any genetically modified plant, animal, micro-organism, virus or other animate organism or product(s) derived thereof that may have application in agriculture, fisheries (including aquaculture), forestry, or food production;

(b) Any cloned animals that may have application in agriculture, including products derived thereof that may be used as, or in, food, or in food manufacturing; and

(c) Vaccines for use in humans or animals that contain living genetically modified organisms.

SECTION 2: AUTHORISATION PROCESS FOR CONFINED FIELD TRIALS

Article 4: Authorisation

Authorisations for confined release of regulated articles shall be granted by the Competent National Authority of the Member State in which the confined release is intended.

Article 5: Functions of the Competent National Authority

The Competent National Authority shall be responsible for the review of applications in accordance with the guidelines presented in Annex 1 of this regulation.

As appropriate, the Competent National Authority may refer to relevant national and/or international experts or to regional competent authority to provide a scientific opinion on the application.

The Competent National Authority shall also be responsible for enforcing appropriate risk management practices, as identified in Annex 1, through the implementation of effective monitoring and inspection procedures.

Article 6: Applications for Confined Field Trials

1. Submission

An applicant wishing to undertake the confined release (e.g., confined field trial) of a regulated article (e.g., genetically modified plant) shall submit a written application, in the form specified in Annex 1, to the Competent National Authority of the relevant Member State.

2. Completeness check

a. All applications must be screened for completeness by the Competent National Authority and notification of acceptance, or not, of the application as complete is transmitted to the applicant within a period of sixty (60) days of receipt. On acceptance of the completeness of the application, the Competent National Authority should inform the COAB/WABCo simultaneously with the applicant.

b. If the request is not complete in accordance with appendix 2, ANC informs by writing the applicant and asks him to supplement the dossier by indicating the missing parts to him.

3. Processing of application

The Competent National Authority shall review complete applications for confined field trials and provide specific terms for the conduct of approved trials which should include risk management conditions and reporting requirements.

4. Notification

All applications must be processed and authorisation granted or denied within a period of ninety (90) days of acknowledgement of a complete application.

Article 7: General Terms and Conditions of Authorisation

1. In addition to specific risk management terms and conditions that may be required by the Competent National Authority under Article 9, the following requirements apply to all authorisations for confined field trials.

2. Every person who is granted an authorisation for the confined release of a regulated article, or who is in charge of carrying out the confined field trials,

(a) shall prevent the regulated article and any material derived thereof from entering into any feed for livestock, or entering into any food for humans;

(b) shall provide the Competent National Authority on request with copies of, or allow the Competent National Authority to examine,

i. any contracts that the person enters into or has entered into with any persons in relation to the confined release, and

ii. the person's records with respect to the confined release, including records of any trials of the regulated article;

(c) shall be responsible for all costs of the actions required to remedy any situation caused by an accidental release of the regulated article; and

(d) shall be responsible for all costs of collection, storage and disposal of the regulated article and any material derived thereof if the Competent National Authority requires the person to stop the confined release.

Article 8: Notice of Decision

1. The Competent National Authority shall transmit its decision, including supporting rationale, any applicable terms and conditions of authorisation and the dossiers relating thereto, to the applicant within fifteen (15) days of making its decision and simultaneously inform the COAB/WABCo of the decision.

2. The COAB/WABCo shall transmit the decision and supporting documents to the Member States within fifteen (15) days of being notified of a decision.

SECTION 3: AUTHORISATION PROCESS FOR UNCONFINED RELEASE

Article 9: Authorisation

Authorisation for unconfined release, including commercialisation and marketing, of regulated articles, shall be granted by Member States based on the opinion of the Competent National Authority of the Member State and the COAB/WABCo. This opinion will be provided by following the procedure in Article 13.

Article 10: Responsibilities of the Competent National Authority

1. The Competent National Authority of the originating Member State (where the application was submitted) shall be responsible for:

- screening applications for unconfined release for completeness and notification of acceptance for review, or request for additional information,
- forwarding of the application to the COAB/WABCo permanent secretariat,
- participating in the scientific review panel to provide a scientific risk assessment of the application,
- incorporating the opinion of COAB/WABCo into its national decision-making process for unconfined release,
- ensuring compliance with any applicable post-release monitoring and/or product stewardship requirements.

2. The Competent National Authorities of other Member States shall receive opinions from the COAB/WABCo and shall:

- incorporate the opinion into their national decision-making process for unconfined release,

- ensure compliance with any applicable post-release monitoring and/or product stewardship requirements.

Article 11: Responsibilities of the Competent Regional Authority (COAB/WABCo)

The COAB/WABCo shall be responsible for providing opinions on applications for unconfined release submitted by the Competent National Authority. This will include:

- receiving the complete application from the Competent National Authority,

- convening a scientific review panel to provide a scientific risk assessment of the application,

- developing a final opinion on the application based on the scientific risk assessment,

- forwarding the opinion of the COAB/WABCo to the Competent National Authority of the originating Member State,

- informing the Competent National Authorities of the other Member States of the opinion.

Article 12: Applications for Unconfined Release

1. Submission

An applicant wishing to undertake unconfined release, including commercialisation or marketing, of a regulated article shall submit a written application addressing all of the risk assessment criteria and information requirements described in Annex 2 to the Competent National Authority of the relevant Member State.

2. Completeness check

All applications must be screened for completeness by the Competent National Authority of the originating Member State and notification of acceptance of the application as complete, or a request for additional information, should be transmitted to the applicant within sixty (60) days of receipt.

3. Scientific review panel

a. Applications accepted for review will be forwarded by the Competent National Authority to the COAB/WABCo.

b. The COAB/WABCo will convene a scientific review panel to review the application within thirty (30) days of receipt of the application. The scientific review panel shall comprise of individuals with recognised expertise in fields relevant to the review of

applications for unconfined release and shall include at least one representative from the originating Member State and any bordering countries.

c. The Chairperson of the panel shall be designated by the COAB/WABCo and the Secretariat will be provided by the COAB/WABCo.

d. Members of the scientific review panel shall be required to submit a Declaration of Interests affidavit as described in Annex 4 of this regulation.

4. Pre-market scientific risk assessment

a. This scientific review panel shall undertake a pre-market scientific risk assessment consistent with the guidelines contained in Annex 2 of the technical appendices of this Regulation and shall prepare a written scientific risk assessment to be delivered to COAB/WABCo within sixty (60) days of commencement of its work.

b. The scientific review panel can request supplementary information even if the assessment process has commenced. The clock stops until the supplementary information is provided.

c. Failure to provide the supplementary information within one year of the request results in termination of the assessment process.

5. Opinion of the Regional Competent Authority

COAB/WABCo shall prepare an opinion on the application, taking into account the scientific risk assessment, and deliver this opinion to the Competent National Authority of the originating Member State. The opinion will be delivered within thirty (30) days of receipt of the scientific risk assessment.

6. Decision of the Competent National Authority

a. The Competent National Authority of the originating Member State shall make a decision to approve or deny the application for unconfined release, incorporating the opinion of COAB/WABCo.

b. All applications shall be processed and authorisation granted or denied within a period of one hundred and eighty (180) days after acknowledgement of a complete application by the Competent National Authority of the originating Member State.

Article 13: Notice of Decision

1. The Competent National Authority of the originating Member State shall transmit its decision, including supporting rationale, any applicable terms and conditions of authorisation and the dossiers relating thereto, to the COAB/WABCo within fifteen (15) days of making its decision.

2. The COAB/WABCo shall transmit the decision, including any applicable terms and conditions of authorisation, and the opinion of the COAB/WABCo to all of the Member States within fifteen (15) days of being notified of a decision.

3. Member States wishing to take a decision on the unconfined release of the subject regulated article shall incorporate the opinion of COAB/WABCo in their decision-making process.

4. All Member States shall maintain their obligations under the Cartagena Protocol on Biosafety to inform the Biosafety Clearing House of decisions on environmental release of GMOs.

Article 14: Appeal against opinion of COAB/WABCo

Any Member State wishing to challenge the opinion of COAB/WABCo can request a second review conducted by an independent panel. Should a Member State wish to take a decision in conflict with the opinion of COAB/WABCo, liability associated with this decision will lie with the Member State.

SECTION 4: AUTHORISATION PROCESS FOR IMPORTS OF COMMODITIES CONTAINING REGULATED ARTICLES INTENDED FOR DIRECT USE IN FOOD, FEED, OR PROCESSING

Article 15: Commodity Import Authorisation

Authorisation for imports of commodities containing regulated articles intended for direct use in food, feed, or processing, shall be granted by the Competent National Authority of the Member State in which the first importation is intended, subject to Article 16.

Article 16: Functions of the Competent National Authority

1. The Competent National Authority shall be responsible for the review of applications in accordance with the eligibility requirements outlined in Article 18. In cases where all of the eligibility requirements are satisfied, the Competent National Authority may request an opinion from COAB/WABCo based on the information identified in Article 18 and make decisions on whether to authorise the product.

2. For products not meeting the requirements of Article 18, the Competent National Authority shall be responsible for submitting the application to the COAB/WABCo for a pre-market scientific assessment as described in Article 19 and shall incorporate the findings of this review in its decision-making process for commodity import authorisation.

3. The COAB/WABCo reserves the right to review the safety assessment process implemented in the country of origin and to determine if that process ensures an equivalent level of protection to that required within Member States.

Article 17: Eligibility Requirements for Streamlined Review and Authorisation

Products meeting the following requirements may be considered for streamlined review and authorisation by a Member State:

(a) The product shall be approved for cultivation and use in food and/or livestock feed, or processing, in the country of origin. The applicant must provide copies

of letters of authorisation, permits, or other official notifications from the relevant Competent National Authority(ies) attesting to this fact.

(b) The product shall have undergone a safety assessment consistent with the "Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants" published by the CODEX Alimentarius Commission.

(c) The applicant shall provide a risk assessment report or equivalent decision summary published by the relevant Competent National Authority(ies) of the country of origin confirming the nature and extent of the safety assessment performed and any findings relevant to human or animal health.

(d) The applicant shall provide an event-specific detection method for the regulated article that meets the requirements defined in section 2.11 of Annex 3 of the technical appendices of this Regulation.

Article 18: Applications for Commodity Imports of Regulated Articles for Direct use in Food, Feed, or Processing

1. Submission

An applicant wishing to undertake the importation of a regulated article for direct use in food, feed or processing, shall submit a written application addressing all of the eligibility requirements contained in Article 18 to the Competent National Authority of the relevant Member State.

2. Streamlined process

a. Applications shall be screened for accordance with the eligibility requirements outlined in Article 18 by the CNA and notification of acceptance, or not, into the streamlined process be transmitted to the applicant within a period of thirty (30) days of receipt.

b. If accepted into the streamlined process, the application shall be forwarded to COAB/WABCo.

c. COAB/WABCo shall prepare an opinion on the application within sixty (60) days of the acceptance into the streamlined process. This opinion shall be sent to the Competent National Authority of the originating Member State. If COAB/WABCo determines that the product is in-eligible for the streamlined process, it can elect to send the application for a pre-market scientific assessment as detailed in Article 19.5.

d. The Competent National Authority of the originating Member State shall make a decision on the application in accordance with the opinion of COAB/WABCo.

e. All applications accepted into the streamlined process shall be processed and authorisation granted or denied by the Competent National Authority within a period of ninety (90) days of acceptance into the streamlined process.

3. In-eligible applications

In cases where the eligibility requirements under Article 18 cannot be met, the product shall undergo a pre-market scientific assessment and the applicant shall submit an application meeting the information requirements described in Annex 3 .

4. Completeness check

All applications not eligible for the streamlined process shall be screened for completeness by the Competent National Authority of the originating Member State and notification of acceptance, or request for additional information, of the application as complete transmitted to the applicant within sixty (60) days of receipt.

5. Scientific review panel

a. Applications accepted for pre-market scientific assessment shall be forwarded by the Competent National Authority to the COAB/WABCo.

b. The COAB/WABCo shall convene a scientific review panel to review the application with thirty (30) days of receipt of the application. The scientific review panel shall comprise of individuals with recognised expertise in fields relevant to the review of applications for use in food, feed or processing and shall include at least one representative from the originating Member State.

c. The Chairperson of the panel shall be designated by the COAB/WACB and the Secretariat will be provided by the COAB/WABCo.

d. Members of the scientific review panel shall be required to submit a Declaration of Interests affidavit as described in Annex 4 of this regulation.

6. Pre-market scientific risk assessment

a. This scientific review panel shall undertake a pre-market scientific risk assessment consistent with the “Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants” published by the CODEX Alimentarius Commission and shall prepare a written scientific risk assessment and submit this to the COAB/WABCo within sixty (60) days of commencement of its work.

b. The regional scientific review panel can request supplementary information even if the assessment process has commenced. The clock stops until the supplementary information is provided. Failure to provide the supplementary information within a year of the request results in termination of the assessment process.

7. Opinion of the competent regional authority

The COAB/WABCo shall prepare an opinion on the application, taking into account the scientific risk assessment, and deliver this opinion to the Competent National Authority of the originating Member State. The opinion shall be delivered within thirty (30) days of receipt of the scientific risk assessment.

8. Decision of Competent National Authority

a. The Competent National Authority of the originating Member State shall make a decision to approve or deny the application for import for direct use in food, feed or processing, incorporating the opinion of the COAB/WABCo.

b. All applications shall be processed and authorisation granted or denied within a period of one hundred and eighty (180) days of acknowledgement of a complete application by the Competent National Authority of the Member State to which the application was submitted.

Article 19: Notice of Decision

1. The Competent National Authority shall transmit its decision, including supporting rationale, any applicable terms and conditions of authorisation and the dossiers relating thereto, to the COAB/WACB within fifteen (15) days of making its decision.

2. The COAB/WACB shall transmit the decision, supporting documents and, where it exists, the opinion of the scientific review panel, to all of the Member States within fifteen (15) days of being notified of a decision.

3. The authorisation of a regulated article for importation for direct use in food, feed or processing, from a particular country of origin also extends to importations of the same event from any other country of origin and the authorisation shall be binding within every Member State.

4. All Member States shall maintain their obligations under the Cartagena Protocol on Biosafety to inform the Biosafety Clearing House of decisions on importation of commodities for direct use in food, feed or for processing.

Article 20: Appeal against opinion of COAB/WABCo

Any Member State wishing to challenge the opinion of **COAB/WABCo** can request a second review conducted by an independent panel. Should a Member State wish to take a decision in conflict with the opinion of the scientific review, liability for costs associated with this decision will lie with the Member State.

SECTION 5: FINAL PROVISIONS

Article 21: Responsibilities

a. The applicants and users shall be responsible for and shall be in charge of making sure that the appropriate measures are taken to avoid any negative impact on the environment and human/animal health that is likely to result from the use and handling of GMOs under national legislation and regional regulation.

b. The Competent National Authorities shall make sure that the measures are effectively taken.

Article 22: Liability and redress

1. The responsibility for any damage caused by the unauthorized or accidental release of GMOs falls on the implicated applicants and users involved. Remedies under national laws are under the control of Competent National

Authorities. Member States shall formulate regulations on liability and redress for damage or harm caused by GMOs at the national level.

2. In the event of damage caused by a product authorized in accordance with the opinion of COAB/WABCo, this one in connection with ANC concerned shall take measurements for:

a) to identify the causes of this situation;

b) to take suitable measures to repair this damage by the part in fault; and

c) to take all measures to prevent such situations. These measures can be the suspension of the authorization of dissemination, the behaviour of a new scientific review.

Article 23: Accuracy of submitted information

The applicant shall be held legally responsible for the accuracy of the information submitted with an application.

Article 24: Labelling

Labelling of GMOs and products thereof are national responsibilities and Member States shall implement regulations consistent with their national policy.

Article 25: Food aid and emergency relief

A decision to accept commodities containing GMOs shall be at the discretion of the Member State.

Article 26: New scientific Information

1. Where, at any time after receiving authorisation pursuant to Sections 2, 3, or 4, a person becomes aware of any new information regarding risk to the environment, including risk to human/animal health, that could result from the release, the person shall immediately provide the new information to the Competent National Authority responsible for the authorisation. ANC after verification shall inform COAB/WABCo of their information.

2. The Competent National Authority COAB/WABCo shall convene a scientific review panel as described in Articles 12 and 13 and send the findings of the panel to the Competent National Authority of the Member States. Where the scientific panel, on the basis of the new information provided, re-evaluates the potential impact on and risk to the environment, including the potential impact on and risk to human health, posed by the release and determines that there is :

(a) a risk that is less than was apparent at the time of the original authorisation, the Competent National Authority may

   i. where the release has already been authorised, maintain the existing conditions respecting the release,

ii. change the conditions respecting the release, or

iii. remove any of the conditions respecting the release;

(b) a risk that is greater than was apparent at the time of the original authorisation, the Competent National Authority may:

i. impose additional conditions respecting the release, or

ii. change the conditions respecting the release; or

(c) an unacceptable risk, the Competent National Authority shall:

i. refuse to authorise the release, or

ii. where the release has already been authorised, cancel the authorisation and require the person to stop the release and to take any appropriate action necessary to eliminate or minimise the risk.

Article 27: Capacity Building

ECOWAS shall be involved in capacity building activities to strengthen the ability of the competent national authorities to fulfil their obligations under this Regulation. The involvement of ECOWAS shall include:

- Human capacity building,
- Information and sensitization,
- Enhancement of Institutional capacity,
- Creation of infrastructure to perform biosafety-related research, monitoring and evaluation.

Article 28: Technical appendices

1. The technical appendices hereby attached are adopted and shall form integral part of this Regulation.
2. They shall be revised if needed by COAB/WABCo after a period of notification by the ACOWAS Commission and review by the Member States.

Article 29: Publication

This Regulation shall be published by the Commission in the Official Journal of the Economic Community of West African States within Thirty (30) days of its signature by the Chairman of the Council of Ministers. It shall also be published by each Member State in its National Gazette within thirty (30) days after notification by the Commission.

Done at Abuja, this ……November 2009

The Chairman

For Council

His Excellency Chief Ojo MADUECKE