PROCLAMATION No. 896/2015
A PROCLAMATION TO AMEND THE BIOSAFETY PROCLAMATION

WHEREAS, it has become necessary to amend the Biosafety Proclamation No. 655/2009;

NOW, THEREFORE, in accordance with Article 55(1) of the Constitution of the Federal Democratic Republic of Ethiopia, it is hereby proclaimed as follows:

1. **Short Title**

   This Proclamation may be cited as the “Biosafety (Amendment) Proclamation No.896/2015”.

2. **Amendment**

   The Biosafety Proclamation No. 655/2009 is hereby amended as follows:

   1/ Sub-articles (1), (4), (6), (9), (12), (17) and (18) of Article 2 are deleted and replaced by the following new sub-articles (1), (4), (6), (9), (12), (17) and (18):

   "1/ ‘modified organism’ means any biological entity which has been artificially synthesized, or in which the genetic material or the expression of any of its traits has been changed by the
introduction of any foreign gene whether taken from another organism, from a fossil organism or artificially synthesized;

4/ 'contained use' means any operation up to field trial in which modified organisms are produced, destroyed or used in some other way including for teaching and research isolated by physical and chemical barriers in space not exceeding the requirement stated in the appropriate directive issued by the Ministry with a view to effectively preventing their contact with, and their unintended impact on, human, animal and the external environment;

6/ 'advance informed agreement' means a written consent granted by the Ministry for the undertaking of any transaction of modified organism destined to release into the environment in the country other than for contained use;

9/ 'risk' means short, medium or long-term danger that may befall on human or animal health, biological diversity, the environment or socio-economic conditions arising from the impact of modified organism on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity, indigenous knowledge systems and local communities;

12/ 'Ministry' or 'Minister' means the Ministry or Minister of Environment and Forest, respectively;
17/ 'applicant' means any person who submits an application to the Ministry seeking an advance informed agreement or a special permit to engage in a transaction; 

18/ 'authorized' person' means a person who has been given an advance informed agreement or a special permit by the Ministry to engage in a transaction;

2/ sub-articles (19), (20), (21) and (22) are added after sub-article (18) of Article 2 of the Proclamation and the existing sub-articles (19) and (20) are re-numbered as sub-articles (23) and (24):

“19/ 'modern biotechnology' means the application of: 

a) In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid and direct injection of nucleic acid into cells or organelles; 

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;

20/ 'special permit' means a written permit granted by the Ministry for importation of a modified organism for contained use in research or teaching but not for release into the environment in accordance with this Proclamation;
2. "foreign exporter" means any person under the jurisdiction of another country who exports a modified organism;”

3. the designation “Authority” appearing anywhere in the Proclamation is deleted and replaced by “Ministry”;

4. Article 4 of the Proclamation is deleted and replaced by the following new Article 4:

“4. Objective of the Proclamation

The objective of the Proclamation shall be to:

1/ protect human and animal health, biological diversity and in general, the environment, local communities and the country at large by preventing or at least managing down the adverse effects of modified organisms to levels of insignificance; and

2/ enhance access to and transfer of technologies, including modern biotechnology, that serve for conservation and sustainable use of biological diversity.”

5. Article 5 of the Proclamation is deleted and replaced by the following new Article 5:

“5. Advance Informed Agreement

1/ Without prejudice to the provision of Article 3 of the Proclamation no person may engage in any transaction destined for release of modified organism to the environment without obtaining an advance informed agreement from the Ministry.
2/ Any person who intends to engage in any transaction destined for release of modified organism to the environment shall submit to the Ministry an application prepared in accordance with this Proclamation and the regulations and directives issued hereunder.

3/ Any applicant intending to obtain an advance informed agreement shall comply with the requirements set in the regulations and directives issued hereunder."

6/ Articles 6 to 20 of the Proclamation are renumbered as Articles 7 to 21, respectively, and the following new Article 6 is added:

"6. Special Permit

1/ No person may engage in any contained use transaction without obtaining a special permit.

2/ Any person who intends to obtain a special permit for contained use transaction shall submit an application to the Ministry in accordance with the regulations and directives issued hereunder.

3/ A person granted a special permit may not release a modified organism into the environment.

4/ Any person who is conducting research in a contained use shall take all necessary measures to completely avoid the risks that may arise from the transaction."
7/ Article 9 of the Proclamation (as renumbered pursuant to sub-article (6) of this Article) is deleted and replaced by the following new Article 9:

"9. Importation of Modified Organisms

1/ Importation of any modified organism without obtaining an advance informed agreement or a special permit is prohibited.

2/ An application for contained use is not subject to an advance informed agreement but to a special permit.

3/ A person who applies to the Ministry for an advance informed agreement shall have a recognition as the law of the exporting country authorizes the exporter to take such responsibility.

4/ An application for a special permit for the importation of a modified organism shall be accompanied by a statement signed by the foreign exporter indicating the identity of the modified organism."

8/ sub-article (4) of Article 15 of the Proclamation (as renumbered pursuant to sub-article (6) of this Article) is renumbered as sub-article (5) and the following new sub-article (4) is added:

"4/ The Ministry shall issue special permit to an applicant if:

a) there are facilities and institutional systems required to conduct the specified research as per the regulations and directives issued pursuant to this Proclamation;
b) the transaction is not destined for release to the environment;

c) the applicant has the required qualification to conduct the research; and

d) if standard operating procedures that prevent or minimize risks to the insignificant level are in place.”

9/ Article 17 of the Proclamation (as renumbered pursuant to sub-article (6) of this Article) is deleted and replaced by the following new Article 17:

“17. Validity Period of Advance Informed Agreement and Special Permit

1/ An advance informed agreement for commercial release of modified organism shall be valid for ten years.

2/ A special permit for contained use shall be valid for five years.

3/ An advance informed agreement for transit of modified organism shall be valid for three months.

4/ The authorized person may request for extension of the validity period of advance informed agreement for a commercial release or a special permit for contained use of modified organism one year before the expiry date of the validity period.

5/ The authorized person may request for extension of the validity period of advance informed agreement for transit of modified organism one month before the expiry date of the validity period.
6/ The Ministry may, upon the receipt of an application pursuant to sub-article (4) of this Article, decide whether to extend the validity period of an advance informed agreement or to order the revision or the doing of the risk assessment.

10/ sub-articles (3) and (4) of Article 21 of the Proclamation (as renumbered pursuant to sub-article (6) of this Article) are deleted and replaced by the following new sub-articles (3) and (4):

“3/ The custom’s officer shall store the modified organism impounded pursuant to sub-article (2) of this Article in an appropriate storage facility in such a manner that potential risks to biodiversity, the environment and human health are minimized.

4/ The Ministry shall, by examining the samples within five working days, verify whether the material impounded pursuant to sub-article (2) of this Article contains any modified organism or not.”

13/ the following new Article 22 and Article 23 are added after Article 21 of the Proclamation (as renumbered pursuant to sub-article (6) of this Article) and the existing Articles 21, 22 and 23 are re-numbered as Articles 24, 25 and 26 respectively:

“22. National BioSafety Advisory Committee

A National Biosafety Advisory Committee, accountable to the Minister shall be established by regulation to be issued by the Council of Ministers.
23. Grievance Handling

1/ Any person aggrieved by the rejection of an application submitted in accordance with this Proclamation for the issuance or extension of the validity period of an advance informed agreement or special permit, or the suspension or revocation of the agreement or the special permit may, within 45 days from the date of such decision, lodge his complaint with the Grievance Hearing Committee established by the Ministry.

2/ Any person who cannot submit his complaint in accordance with sub-article (1) of this Article due to force majeure may submit his application within 10 days after the end of the force majeure.

3/ The grievance handling committee members and their composition shall be determined by the regulations and directives issued pursuant to this Proclamation.

4/ The grievance handling committee shall, up on examining the compliant submitted to it pursuant to sub-article (1) of this Article provide its findings and recommendation to the Minister within five working days.

5/ An applicant aggrieved by the decision of the Minister given under sub-article (4) of this Article may, with respect to error of interpretation of law, appeal to the Federal High Court within 60 days from the date of the decision.
3. Effective Date

This Proclamation shall enter into force on the date of publication in the Federal Negarit Gazette.

Done at Addis Ababa, this 14th day of August, 2015.

MULATU TESHOME (DR.)
PRESIDENT OF THE FEDERAL DEMOCRATIC REPUBLIC OF ETHIOPIA