FDRE ENVIRONMENTAL PROTECTION AUTHORITY

GUIDELINE FOR THE REGULATION OF GENOME EDITED PLANTS IN ETHIOPIA

DEC, 2024

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PREFACE

Ethiopia, as a rapidly growing nation, faces the urgent task of ensuring food security for its expanding population. In response, recently the government has launched strategic initiatives to transform the agricultural sector, focusing on enhancing productivity and sustainability. Biotechnology plays a vital role in these efforts by offering innovative solutions to improve crop yields, reduce losses,and increase resilience to climate change. The adoption of modern biotechnology aligns with national priorities, including key programs such as mass wheat production expansion, cluster farming, and the "Lemat Turufat" initiative championed by H.E. Prime Minister Dr. Abiy Ahmed.

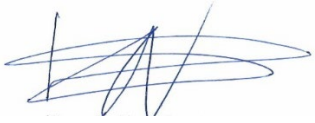
The expansion of mass wheat production, driven by irrigation-based agriculture and cluster farming practices, is a cornerstone of Ethiopia's strategy to achieve self-sufficiency in staple crops. Cluster farming encourages farmers to pool resources and adopt modern technologies, significantly increasing productivity and efficiency. Similarly, the "Lemat Turufat" initiative aims to accelerate agricultural mechanization and innovation, ensuring that Ethiopia's farmers have access to the latest tools and techniques to boost production and improve livelihoods. Modern biotechnology, including the use of genetically modified and genome-edited crops, is a crucial complement to these initiatives, enabling the development of high-yield, drought-tolerant, and pest-resistant crop varieties.

The Environmental Protection Authority (EPA), as the Federal Institution responsible for biosafety regulation and oversee the implementation of the Cartagena Protocol on Biosafety, has played a central role in ensuring that the adoption of biotechnology supports these national efforts while safeguarding public health and the environment. Since the enactment of the Biosafety (Amendment) Proclamation No. 896/2015, the EPA has introduced one Regulation and six Directives to ensure the safe use of biotechnology. By reviewing and approving applications, overseeing environmental releases, and ensuring compliance with biosafety standards, the EPA contributes to Ethiopia's agricultural transformation and food security agenda.

However, with the rapid development of new breeding techniques such as genome editing, there is a growing need to adopt resilient crop varieties that can withstand biotic and abiotic stresses. These advancements are essential to sustaining crop production, enhancing the success of cluster farming models, and ensuring the long-term success of the smart agriculture initiative.

These guidelines are designed to promote transparency, consistency, and predictability in the regulatory process, offering applicants clear guidance on the biosafety permit application requirements. Furthermore, they contribute to Ethiopia's broader efforts, such as wheat self-sufficiency, cluster farming, and the "Lemat Turufat" initiative led by H.E. Prime Minister Dr. Abiy Ahmed, which aim to modernize agriculture, foster innovation, and secure national food security.

I extend my appreciation to all the development partners and stakeholders who have contributed to the development of this strategic guideline, helping bring this vision into reality.



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DEFINITION OF TERMS

Applicant: a person submitting an application to the Authority to determine whether the genome edited products are regulated pursuant to the Biosafety (Amendment) Proclamation 896/2015

Authority: the Environmental Protection Authority of the Federal Democratic Republic of Ethiopia

CRISPR/Cas9 System: adaption of the prokaryotic immune system to introduce directed and intended DNA double-strand breaks in genomes via guide RNA

Early Consultation: the decision process for determining whether the Genome Edited plants or products thereof are regulated under the Proclamation.

Genome Editing: a targeted methods to introduce new traits in organisms using various techniques which induce breaks in the DNA that can be repaired by endogenous mechanisms and lead to a range of changes at a targeted locus within the genome. This may be achieved by deleting, replacing/substitution, duplication of editing organism's own DNA or inserting a DNA sequence in the organism's genetic material;

Gene edited plants: refers to the plant modified using gene editing techniques.

Modified Organism: 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;

Novel Combination of Genetic Material: a combination of DNA sequences which is possible only through modern biotechnology and is not possible to find in nature or obtained through conventional breeding techniques**.**

Oligo-directed Mutagenesis (ODM): an intentional mispairing of an oligonucleotide and genomic target sequence to induce a specific mutation by subsequent repair

Proclamation: the Biosafety (Amendment) Proclamation No 896/2015

Site-Directed Nuclease (SDN): nuclease guided to a specific DNA sequence for cleavage

Transcription Activator-Like Effector Nuclease (TALEN): bacterial transcription factor binding specific DNA bases;

artificially fused to a nuclease protein (e.g., FokI)

Zinc-Finger Nuclease (ZFN): a designed zinc-finger protein recognizing and binding to a specific DNA sequence fused to a nuclease, usually FokI from *Flavobacterium okeanokoites*

1. INTRODUCTION

Genome Editing is the relatively precise targeted modification of the nucleotide sequence of the genome of an organism. Genome Editing (GE) techniques are rapidly developed and deployed to serve agriculture and food production objectives leading to improved crops and other products. The process involves precise deletion, replacement, or the insertion of a single or a limited number of nucleotides. Genome edited organisms may have segments of deoxyribonucleic acid (DNA) from the same or different species.

There are a number of tools described as 'Genome Editing Technology'. Perhaps the most widely used tool is the Clustered Regularly Interspaced Short Palindromic Repeat (CRISPR)Cas (CRISPR-associated protein), but Genome Editing also refers to other methods such as Oligonucleotide Directed Mutagenesis (ODM), Transcription Activator-like Effector Nucleases (TALENs), Zinc-Finger Nucleases (ZFNs) and Meganucleases, as well as variations of these technologies. Whether using conventional breeding methods, recombinant DNA technologies, or Genome Editing Technologies, some genetic changes may be expected. Genome Editing Technologies are not expected to have unique or specifically identifiable environmental or human health concerns relative to other techniques of plant breeding. Genome Editing can be used to achieve genetic outcomes similar to using conventional breeding practices.

Notably, not all products of Genome Editing end up as modified. As such, only those Genome Editing processes or products that result in modified plants shall be subject to regulation under the Biosafety Law (Amendment) Proclamation No. 896/2015 and the directives issued following this Proclamation.

For end-users to benefit fully, products developed using Genome Editing must be subjected to science-based safety regulations. Thus, genome editing developers and other related stakeholders need to be aware of the Biosafety Proclamation, directives and this genome editing guideline prior to the commencement of genome editing research activities and/or commercial release.

2. GUIDELINE FOR THE REGULATION OF GENOME EDITED PLANTS IN ETHIOPIA

2.1 Objective

To provide technical guidance to applicants and the Authority on which genome editing plant products are regulated under the Biosafety Law (Amendment) Proclamation No. 896/2015.

2.2 Scope

a) This guideline provides procedures in determining which genome edited plants and/or derived plant products should be regulated under the Biosafety Law (Amendment) Proclamation No. 896/2015 and which products/process would be exempted and managed as conventional varieties.

b) This guideline shall apply to genome edited plants.

3. OBLIGATIONS OF AN APPLICANT

a) An applicant shall submit an early consultation application as per the form under Annex 1 of this guideline to the Authority providing data on the experimental processes and end product to determine whether it should be regulated under the Proclamation or not.

b) The applicant shall develop a strategy for educating the public about the proposed gene editing project/product.

c) Monitoring the gene edited plant for unpredicted and unintended events and report to the Authority

d) Shall open experimental sites for monitoring by regulatory authority at any required time

e) Shall provide documentation related to any existing or pending intellectual property rights, including patents, associated with the gene editing techniques or edited plant products.

4. OBLIGATIONS OF THE AUTHORITY

a) The Authority shall communicate its decision on early consultation to the applicant within 60 working days.

b) The Authority shall alter/review its decision if new and relevant scientific information previously unknown becomes available.

c) The Authority shall monitor experimental sites and post release monitoring.

5. CATEGORIES OF SCENARIOS REGULATED UNDER THE PROCLAMATION NO.896/2015

The following **genome editing techniques** and derived products shall be regulated under the Proclamation No.896/2015:-

a) All genome editing projects without the required data.
b) All cases of insertions (for foreign gene (s) and/or regulatory elements) from a sexually non-compatible species.
c) All instances where markers used (selectable and reporter genes) for selection are present in the end-product in subsequent generations.
d) In cases where research and developmental phase starts with a modified organism the authority shall regulate genome edited organisms up to the stage where the modified organism component is removed.

6. CATEGORIES OF SCENARIOS NOT REGULATED UNDER THE PROCLAMATION NO.896/2015

The following genome editing techniques and derived products shall not be regulated under the Proclamation No.896/2015: -

a) All modifications by inserting genes from sexually compatible species and where regulatory elements (promoters and terminators) are also from the same species.
b) All deletions/knock outs provided that there is no insertion of foreign genetic material in the end-product.
c) Processed products that do not contain inserted foreign genetic material.

7. REVIEW AND UPDATE OF THE GUIDELINE

This Guideline shall be subject to review based on new and relevant available scientific information.

APPENDICES:

Appendix I**:** Application for Early Consultation on Genome Editing Technology

SECTION I: APPLICANT INFORMATION
1.1 Name of Applicant, Address, Email, Telephone
1.2. Affiliated Institution, Address Email, Telephone, Website
SECTION II: ORGANISM INFORMATION 2.1. Taxonomic description of the plant: Genus, Species (Variety/ Line – where applicable)
2.2. Rationale for genome editing
Purpose of genome editing: Intended use: Research ☐, Import ☐, Environmental release ☐, Placing in the market ☐, etc (Tick as appropriate) **Economic and Social Benefit of the genome editing project:** essential information related to anticipated socio-economic impacts such as on sustainable agriculture, employment, market opportunities and, in general conserving and/or enhancing means of livelihood of the communities likely to be affected shall be considered.
SECTION III: MOLECULAR TECHNIQUES/ CHARACTERIZATION OF EDITS
3.1. Give a summary of the molecular techniques used/to be used 3.2. State the gene or DNA sequence(s) modified: 3.3. Describe the type of genome editing done / to be done (deletion, insertion, substitution, duplication, replacement) withsupporting data*; 3.4. Molecular description of the target organism's nucleotide target sequences, before and after

genome editing with supporting data*; 3.5. Molecular description of the gene edited organisms, their functions and the affected pathways (where applicable) before and after genome editing*;
3.6. Provide the names of vectors to be used/used and show their genetic map (if not applicable, go to 3.7.)

3.6.1 Is the vector naturally Pathogenic?	3.6.2 Is the vector disarmed? Explain its disarmed status.	3.6.3 If yes, how was the vector disarmed?
Yes No	Yes No	

3.7. Describe delivery methods used for genome editing
SECTION IV: GENOME EDITED PRODUCT
4.1. Is the inserted foreign DNA sequence(s) present in the final product?
Yes No If No; Describe the techniques used to remove the inserted genetic sequences and evidence for the same*; Describe detection protocols used to confirm absence of inserted genetic sequences in the genome edited end products and provide data to support this assertion*;
4.2. Has the genome edited product been exempted from respective relevant modified organism legislation anywhere in the World? If Yes, why, where and for what purpose?

Appendix II: Flow chart for the early consultation on Genome Editing Regulation in Ethiopia