NATIONAL BIOSAFETY AUTHORITY
CONTROLLED DOCUMENT
COPY 1 OF 1

NATIONAL BIOSAFETY AUTHORITY

Title: Exemption from GMO Risk Assessment SOP		REF No: NBA/TEC/SOP-018 Revision No.:00 Effective date: 22/04/2025
Department	Biosafety Assessment, Awareness and Collaborations	
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1. INTRODUCTION/ PURPOSE

1.1. The purpose of this standard operating procedure is to provide guidance on the criteria to be undertaken for the non-risk assessment consideration for GMO applications where the Authority determines that there is sufficient experience or information that the GMOs do not pose a significant risk.

2. SCOPE

2.1. This procedure describes all the requirements and the steps to be followed for the determination of exemption from risk assessment for contained use activity, introduction into the environment and importation of GMOs as per Section 28 of the Biosafety Act. This shall apply to both initial applications and incorporation of approved event(s) into new experimental host organisms (including varieties and variations of initial species)

3. ABBREVIATION AND TERMS

3.1. Abbreviations

3.1.1. BSO : Biosafety Officer
3.1.2. CEO : Chief Executive Officer of the National Biosafety Authority
3.1.3. CAN : Competent National Authority
3.1.4. DTS : Director, Technical Services
3.1.5. ERA : Environmental Risk Assessment
3.1.6. GMOs : Genetically Modified Organisms
3.1.7. ITC : Internal Technical Committee
3.1.8. NBA : National Biosafety Authority
3.1.9. QMR : Quality Management Representative
3.1.10. QMS : Quality Management Systems
3.1.11. SOP : Standard Operating Procedure
3.1.12. POE : Point of Entry/Exit

3.2. Definitions of Terms

3.2.1. Applicant refers to a person making an application for consideration to the National Biosafety Authority.

3.2.2. Biosafety Officer refers to an officer of the National Biosafety Authority working in the Technical Services Directorates and can be a Director, Deputy Director, Principal Biosafety Officer, Senior Biosafety Officer, or a Biosafety Officer.

3.2.3. Chief Executive Officer refers to an officer appointed by the NBA Board to oversee the day-to-day management of the National Biosafety Authority.

3.2.4. Competent National Authority refers to the Government Agency mandated to make decisions on applications involving genetically modified organisms.

3.2.5. Genetically Modified Organism refers to an organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology techniques. Modern biotechnology includes the application of:

- In-vitro nucleic acid techniques including the use of 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 and recombinant barriers and which are not techniques used in traditional breeding and selection.

3.2.6. Internal Technical Committee refers to the NBA employees appointed by the CEO to review applications of GMOs and their derived products and makes recommendations to the CEO before the final decision is made.

3.2.7. Product refers to a genetically modified organism intended for direct use as food or feed, or for processing.

3.2.8. Single Window System refers to an online trade facilitation platform that promotes seamless cargo clearance at the POEs.

3.2.9. Sufficient Experience refers to history of safe use or prior approval of similar events by the Authority as determined by the Internal Technical Committee

3.2.10. Sufficient Information/data Refers the rationale for the exemption, including evidence of safety, precedent or international standards and regulatory framework as determined by the Internal Technical Committee

4. RESPONSIBILITY

4.1. The Directorate Responsible for Technical Services is responsible for implementing this procedure.

5. Process Inputs

5.1. Where the Applicant Requests for Exemption

5.1.1. Application Form for Exemption

5.1.2. Risk Assessment Report from the Competent Authority from where it has been approved.

5.1.3. Details of previous approvals or exemptions granted by other competent authorities (where applicable)

5.1.4. Any scientific studies, data or references that support the exemption claim.

5.1.5. Proof of Payment

5.2. Where the Authority Decides to Exempt

5.2.1. Scientific and Regulatory basis: Sufficient experience or information that the GMO or the contained use activity does not pose a significant risk.

5.2.2. Scope of use: The exemption might be limited to certain uses or specific conditions

5.2.3. Approval document/letter from CNA from the country of Origin (where applicable)

5.2.4. Approval document/letter from CNA of destination country (for export and transit consignments) where applicable.

6. PROCEDURE/ METHOD

6.1. Procedure for Exemption of Risk Assessment for GMOs Imports

6.1.1. Any person applying for consideration of non-risk assessment for importation, must apply to the NBA in the prescribed format as per the Third Schedule of the Biosafety (Import, Export and Transit) Regulation, 2011.

6.1.2. All applications must be accompanied by a formal written request and applicable fees.

6.1.3. The designated Biosafety Officer shall screen the application for completeness by confirming that:

- the application form is duly filled in;
- Safety data for GMO import.
- History of safe use (where applicable);
- The applications include evidence of approval of the product for Food/Feed/Processing from the Competent National Authority (CNA) issued by the country of origin; and
- The application includes evidence of payment of the applicable fee.

6.1.4. On satisfaction of the completeness of the application, the Biosafety Officer shall capture the application in the GMO Applications Register. If the applications are deemed incomplete by the Biosafety Officer, written notification shall be provided in this regard to the applicant (s).

6.1.5. The designated Biosafety Officer(s) shall review the available documentation and compile a report of non-assessment of risk for consideration by the Internal Technical Committee (ITC).

6.1.6. The ITC shall review the compiled report of non-assessment of risk on the applications and make recommendations to the CEO for decision making If the application falls under Section 28 of the Biosafety Act.

6.1.7. Once a decision has been made by the CEO, the CEO shall issue a decision document and notify the applicant accordingly.

- If approved for importation, the CEO shall issue an approval document as provided for in the Second Schedule of the Biosafety (Import, Export and Transit) Regulations. The approval will be specific to that consignment and will be valid for only one year and will specify the conditions of approval.

- If an application (s) is rejected or deferred, the Authority shall issue a notification to the applicant, which shall provide reasons for the rejection, where possible.

6.1.8. Once the applicant receives the approval document the import procedures apply.

6.2. Procedure for Exemption from Assessment of Risk for Contained Use Applications

Any person applying for consideration of non-risk assessment for contained use activity must apply to the NBA in the prescribed format as per the Third Schedule of the Biosafety (Contained use) Regulations, 2011. This shall apply to both initial applications and incorporation of approved event(s) into new experimental host organisms (including varieties and variations of initial species).

6.2.1. All applications must be accompanied by a formal written request and applicable fees.

6.2.2. The designated Biosafety Officer shall screen the application for completeness by confirming that:

- The application forms are duly filled in;
- Safety data.
- History of safe use (where applicable); and
- The application includes evidence of payment of the applicable fee.

6.2.3. On satisfaction of the completeness of the application, the Biosafety Officer shall capture the application in the GMO Applications Register. If the application is deemed incomplete by the Biosafety Officer, written notification shall be provided in this regard to the applicant (s).

6.2.4. The designated Biosafety Officer(s) shall review the available documentation and compile a report of non-assessment of risk for consideration by the Internal Technical Committee (ITC).

6.2.5. The ITC shall review the report of non-assessment of risk on the applications, and make recommendations to the CEO for decision making If the application falls under Section 28 of Biosafety Act.

6.2.6. Once a decision has been made by the CEO, the authority shall issue a decision document and notify the applicant accordingly.

- If approved for contained use, the CEO shall issue an approval document as provided for in the Fourth Schedule of the Biosafety (Contained Use) Regulations.

- will be valid for five years and will specify the conditions of approval.

- If an application (s) is rejected or deferred, the Authority shall issue a notification to the applicant, which shall provide reasons for the rejection, where possible.

6.3. Procedure for Exemption from Risk Assessment of Environmental Release

6.3.1. Any person applying for consideration of non-risk assessment for environmental release, must apply to the NBA in the prescribed format as per the First Schedule of the Biosafety (Environmental Release) Regulation, 2011. This shall apply to both initial applications and incorporation of

approved event(s) into new experimental host organisms (including varieties and variations of initial species).

6.3.2. All applications must be accompanied by a formal written request and applicable fees.

6.3.3. The designated Biosafety Officer shall screen the applications for completeness by confirming that:

- The application forms are duly filled in;
- Safety data.
- History of safe use (where applicable);
- The applications include evidence of approval of the product from the Competent National Authority issued by the country of origin; and
- The application includes evidence of payment of the applicable fee.

6.3.4. On satisfaction of the completeness of the application, the Biosafety Officer shall capture the applications in the GMO Applications Register. If the applications are deemed incomplete by the Biosafety Officer, written notification shall be provided to the applicant (s).

6.3.5. The designated Biosafety Officer(s) shall review the available documentation and compile a report of non-assessment of risk for consideration by the Internal Technical Committee (ITC).

6.3.6. The ITC shall review the report for non-assessment of risk on the applications and make recommendations to the CEO for decision making If the application falls under Section 28 of Biosafety Act, a decision will be made within 30 days, otherwise a full risk assessment will be conducted, and a decision will be made within 90-150 days.

6.3.7. Once a decision has been made by the CEO, the CEO shall issue a decision document and notify the applicant accordingly.

- If approved, the CEO shall issue an approval document as provided for in the Second Schedule of the Biosafety (Environmental Release) Regulations.

- The approval will be specific to that application, valid for ten years and will specify the conditions of approval.

- If an application (s) is rejected or deferred, the Authority shall issue a notification to the applicant, which shall provide reasons for the rejection, where possible.

7. PROCESS OUTPUTS

7.1. Report of Non-Assessment of Risk
7.2. Decision Document (Approval, Rejection, or Deferment Letter)
7.3. ITC Minutes

8. Appendices

8.1. Contained Use Exemption Application Form

9. References

9.1. ISO 9001:2015 QMS – Requirements
9.2. Biosafety Act of 2009
9.3. Biosafety (Import/Export and Transit) Regulations, 2011
9.4. Biosafety (Labelling), 2012
9.5. KEBS Standards on Labelling, DKS 2225:2012
9.6. National Biotechnology Development Policy, 2006
9.7. Cartagena Protocol on Biosafety
9.8. NBA Strategic Plan
9.9. Authority service charter

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Document change history

Supersedes Revision / Effective date	Revisions/Reason for Change/Rationale	Current revision / Effective date	Reviewer's name
N/A	N/A	00	

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00	N/A

11.0 Annex 1: Exemption Application Form

Part A of this schedule shall be filled with general information by an applicant making an application for exemption from risk assessment of genetically modified organism(s) in accordance with Biosafety Act Section 28.
Part B of this schedule shall be filled with justification for exemption from risk assessment.

APPLICATION FORM FOR EXEMPTION FROM RISK ASSESSMENT OF GENETICALLY MODIFIED ORGANISM(S) **PART A**	
1.0 General information	
1.1 Name of applicant	**1.2 Physical Address**
1.3 Telephone	**1.4 Email**
1.5 Title of the Application	**1.6 Application Type of**
	☐ New ☐ Renewal
1.7 Type of Application ☐ Contained Use ☐ Environmental Release/ Placing on the Market	
2.0 Information on the Genetically Modified Organism	

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2.1 Name and identity of the genetically modified organism (*Differences between the biological characteristics of the genetically modified organism and those of the recipient organism or parental organisms*)	**2.2 Transformation event (s)**
2.3 Intellectual property ownership of the novel trait, if any	**2.4 Unique identifier for the genetically modified organism (if assigned)**

2.5 Introduced or modified trait (choose the trait from the following list)

2.5.1 Abiotic environmental tolerance	**2.5.2 Altered growth, development and product quality**
☐ Altered photoperiod sensitivity ☐ Cold or heat tolerance ☐ Drought or water tolerance ☐ Other (specify)	☐ Altered ripening or flowering ☐ Coloration ☐ Fertility restoration ☐ Growth rate or yield ☐ Male sterility ☐ Nutritional composition (including allergenicity) ☐ Selectable marker genes and reporter genes ☐ Uptake or degradation of environmental pollutants ☐ Other (specify growth, development and product quality

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2.5.3 Chemical tolerance	**2.5.4 Medical products**
☐ Herbicide tolerance ☐ Other chemical tolerance	☐ Animal vaccines ☐ Development of transplant organs ☐ Production of pharmaceuticals ☐ Other medical products
2.5.5 Pest resistance	**2.5.6 Other — specify**
☐ Bacterial resistance ☐ Fungus resistance ☐ Insect resistance ☐ Nematode resistance ☐ Virus resistance ☐ Other pest resistance	

2.6 Technique used for modification. (Please select techniques used for the transformation)

☐ Plasmid carried by *Agrobacterium tumefaciens*

☐ Electric shock polarization

☐ Biolistic methods

☐ Osmotic shock

☐ Other-specify

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2.7 Description of gene modification		
2.8 Summary of contained use and confined field trial data *(provide information on key results of trials at both contained level and confined field trials whether conducted in Kenya or outside Kenya)*		
3.0. Characteristics of genetic modification		
3.1 Vector characteristics		
3.1.1 Vector(s) identity	**3.1.2 Source(s) or origin**	**3.1.3 Host range**
3.2 Insert or inserts *(Genetic characteristics of the inserted nucleic acid and the function it specifies, and/or characteristics of the modification introduced)*		
3.3 Description of phenotypic characteristics (in particular any new traits and characteristics which may be expressed or no longer expressed)		
3.4 Rate and level of expression of the new genetic material. Method and sensitivity of measurement		
3.5 Activity of the expressed protein (s)		

3.6 Description of identification and detection techniques of the inserted sequence and vector	
4.0 Recipient organism or parental organisms	
4.1. Taxonomic name/status of recipient organism or parental organisms	**4.2. Common name of recipient organism or parental organisms**
4.3 Point of collection or acquisition of parental organisms	**4.4 Center(s) of origin of the recipient organism or parental organisms** *(Describe the exact location and give geographical coordinates)*
4.5 Center(s) of genetic diversity, if known, of Recipient organism or Parental organisms (Describe the exact location and give geographical coordinates)	
4.6 Habitats where the Recipient organism or Parental organism may persist or proliferate	
4.7 Description of the habitat where the genetically modified organism may persist or proliferate	
5.0 Donor organism (s)	
5.1 Taxonomic name/status of the donor organism or parental organisms	**5.2 Common name of donor organism**
5.3 Point of collection or acquisition of donor organism	**5.4 Biological characteristics of donor organisms**

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(Describe the exact location and geographical coordinates)	
6.0 Intended use and receiving environment	
6.1 Description of the proposed use, including the purpose (s) and foreseen products	
6.2 Foreseen dates of the use	**6.3 Quantities of genetically modified organisms for use**
6.4 Suggested method(s) for safe handling, transport and storage	
6.5. History and results of previous use, as well as uses of the genetically modified organism - *(country, region, dates of contained use, release, any adverse effects on the health of human, animal and plant, and environment)*	
6.6 Intended use of the genetically modified organism (Information relating to the intended use of the genetically modified organism, including new or changed use compared to the recipient organism or parental organisms)	
6.7 Receiving environment *(Information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centres of origin of the likely potential receiving environment)*	
7.0 Risk assessment summary (Cite references)	
7.1 Detection/Identification method of the genetically modified organisms (*Suggested detection and identification methods and their specificity, sensitivity and reliability)*	

7.2 Evaluation of the likelihood of adverse effects (*An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential to the health of human, plant and animal, and the receiving environment to the genetically modified organism)*
7.3 Evaluation of the consequences *(An evaluation of the consequences should these adverse effects be realized)*
7.4 Overall risk *(An estimation of the overall risk posed by the genetically modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized)*
7.5 Recommendation *(A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks)*
7.6 Information on monitoring and emergency response plans (describe monitoring methods, recall procedures)
8.0 Additional information
8.1 Availability of detailed risk assessment information (*Please indicate whether more details on the risk assessment are available and how they can be accessed)*
8.2 Any other relevant information

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8.3 Additional notes
PART B
Justification for Exemption from Risk Assessment
1.0 **Rationale** (*Provide a detailed rationale for requesting an exemption)*
2.0 Previous Approvals *(List all Cases of previous approvals of the GMO Event(s)*
3.0 Compliance Statement (Confirm Compliance with all relevant regulations, guidelines permit conditions)

Name ..... **Signature** ..... **Date** .....

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