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ICS 07.080

TANZANIA STANDARD

Biotechnology - genetically modified organisms and derived products – Requirements for handling, transportation and use.

TANZANIA BUREAU OF STANDARDS

0 Foreword

Tanzania embraces science and technology and recognizes the potential benefits of modern biotechnology. On the other hand, the country is also aware of the potential harms to humans, animals and the environment that could results from inappropriate handling and use of genetically modified organisms (GMOs). Thus, this Tanzania standard aims at ensuring that all GMOs and derived products are handled in accordance with relevant national regulations.

This Tanzania standard provides guidance for compliance, and a checklist for monitoring and inspection of genetically modified organisms and derived products to ensure that the handling, transportation and use of GMOs do not cause harm to the environment, and human, plant and animal health.

This Tanzania standard provides the information and records that are required at different stages of handling; transporting, importing, exporting processing, using (direct use as food or feed, contained or confined), and storing of GMOs. It is meant to guide stakeholders, including the public at large, to properly and in a standardized manner handle or use GMOs in the country.

During the development of the standard, reference was made to the following documents:

- Cartagena Protocol on Biosafety to the Convention of Biological Diversity
- The Environmental Management (Biosafety) Regulations, 2009
- The National Biosafety Guidelines for Tanzania of 2004
- DKS 2182 (2012): Code of practice for handling, transfer and use of genetically modified organisms and derived products published by Kenya Bureau of Standards (KEBS).

1 Scope

This Tanzania standard prescribes requirements for safe handling, transfer and use of genetically modified organisms (GMOs) and derived products. It is applicable to genetically modified organisms and derived products intended for contained and confined use, introduction into the environment, placing on the market, importation, , transit and export, direct use as food, feed or for processing. This Tanzania standard is not applicable to genetically modified organisms and derived products which are pharmaceuticals.

2 Normative References

The following referenced documents are indispensable in the application of this Tanzania standard. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies:

TZS 2070, Principles for the risk analysis of foods derived from modern biotechnology- Code of practice

TZS 2071, Biotechnology - Guideline for the conduct of food safety assessment of food derived from Recombinant DNA plants - Code of practices

TZS 2072, Biotechnology - Guideline for the conduct of food safety assessment of foods produced using recombinant-DNA micro-organisms - code of practice

TZS 2073, Biotechnology-Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA Animals-Code of practice

3 Terms and definitions

For the purposes of this Tanzania standard, the following terms and definitions should apply:

3.1 contained use

means any activity undertaken within a facility, installation, or other physical structure which involves genetically modified organisms and/or derived products that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment

3.2 Confinement

Restriction of an organism and its genetic traits to a specific and defined area of the environment, herein called the confined field trial site‟ or the trial site‟.

3.3 confined use/ confined field trial (CFT)

is a restricted environmental release of a genetically modified organisms, for research purposes, under terms and conditions intended to mitigate the establishment and spread, in the environment, of genetic material from organisms and the interaction genetic material with the environment. A single confined field trial may comprise one, or more, transgenic events of a single species that are subject to the same terms and conditions of confinement. These terms and conditions include, but are not limited to, reproductive isolation, site monitoring, and post-harvest land use restrictions.

3.4 Compliance Document Binder (CDB)

Is a file prepared to keep all records used to document all steps of a contained use and/or confined use such as transport, storage, inspection, harvest and disposition, and post-harvest monitoring of genetically modified organisms and derived products.

3.5 Transit

means transportation, by whatever means, of a genetically modified organism to Tanzania from any other jurisdiction for the purposes of conveying such genetically modified organism to any third jurisdiction;

3.6 environment

means physical factors of the surroundings, human beings, including land, water, atmosphere, soil, vegetation, climate, sound, odour, aesthetics, fish and wildlife

3.7 genetically modified organism

means any organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology

3.8 intentional introduction into the environment

means any deliberate release of genetically modified organisms other than contained use.

3.9 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 recombinant barriers and that are not techniques used in traditional breeding and selection.

3.10 National Biosafety Focal Point

means the competent authority designated by the government to coordinate, evaluate, authorize and approve applications for contained use, introduction into the environment, importation, placing on the market, transit and export of genetically modified organisms and derived products (GMO)

3.11 organism

means any entity able to replicate its own genetic material

3.12 placing on the market

means making genetically modified organisms and derived products available for sale

3.13 permit

means a written authority issued by a regulatory agency for the handling, transfer and use of genetically modified organisms and derived products

3.14 derived product

means anything made of or derived from a genetically modified organism, living or dead

3.11 regulatory authority

means any institution mandated by the laws of Tanzania with the responsibility of enforcing laws related to human, plant, animal, and environmental health and safety.

3.15 unintentional release

means a release that takes place without authorization under the laws of Tanzania and takes place as a result of adventitious presence of GMOs with non-GMO shipments imported for direct use as food, feed or for processing but excludes an accident;

3.16 person

includes both natural and legal entities and local communities.

4 General requirements

4.1 Genetically modified organisms and/or derived products should be handled in a safe manner to prevent adverse effects to the environment and human, animal and plant health

4.2 All GMOs and derived products related activities and facilities should be approved in accordance with the relevant laws of Tanzania and requirements of relevant regulatory authorities.

4.3 A person intending to undertake any activity involving the use of genetically modified organisms and/or derived products should:

a) Apply for approval by the National Biosafety Focal Point for the intended activity.

b) Provide risk assessment information necessary for evaluation of potential risks and/or benefits of the particular genetically modified organisms and derived products. The information should include but not limited to:

i) Identity and relevant characteristics;

ii) Quantity and volumes involved;

iii) Novel traits introduced;

iv) Donor of novel traits

v) Methods of production;

vi) The intended use;

vii) Receiving environment;

viii) Methods for safe handling storage and disposal

ix) Related risk assessment and risk management.

x) Means of detections

xi) Biosafety group and level

4.4 Risk assessment should be evaluated on a case by case basis taking into account any known risk posed by potential exposure to the genetically modified organism and /or derived products in accordance with TZS 2073, TZS 2071, TZS 2072, TZS 2070 and relevant laws in Tanzania.

NOTE: The information required for risk assessment may vary with characteristics of the organism and use, frequency, and scale of the intended use. Where the information required relates to a product, a requirement to submit full studies dossier to demonstrate safety to human and the environment is necessary.

4.5 Appropriate measures should be maintained to manage risks identified during the risk assessment process as described in biosafety regulation in Tanzania. The measures should include but not limited to the following:

a) Appropriate information and/or training provided for those involved in handling the organisms;

b) Monitoring procedures applied in such a way that appropriate measures can be taken to manage identified and unexpected effects during and after release;

4.6 Any person undertaking contained or confined use an activity involving genetically modified organisms should keep and maintain the following records in compliance document binder;

a) Name of person responsible for supervision and safety of the activity;

b) Qualifications and training of the personnel involved;

c) A map clearly indicating where the activity is being undertaken;

d) Experimental design and timeline.

e) Risk assessments and risk management;

f) Waste management;

g) Contingency measures in case of unintentional release

h) Approval to undertake the activity;

i) Training of staff involved in the activity

4.7 all records including compliance document binder should be made available to inspectors of the National Biosafety Focal Point and relevant regulatory authorities.

4.8 A written approval from National Biosafety Focal Point; stipulating appropriate conditions for movement should be issued for any genetically modified material whether for import, export, transit, environmental release or for placing on the market. Such material should be:

a) Packaged in accordance with prevailing national regulation and guidelines, applicable international agreements, standards and conventions.

b) Labelled in accordance with the relevant laws in Tanzania and accompanied by the following information:

i) Nature, identity and quantity of contents;

ii) Country or locality where collected, developed, manufactured, reared or cultivated;

iii) Description of any potential risk

iv)Name, address and telephone number of supplier, owner, importer, shipper, forwarding agent;

v) Name, address and telephone of individual and institution of consignee;

vi)Name of transporter(s);

vii) Approval number authorizing movement;

viii) Intended use;

ix) Date of movement;

x) Regulatory status in country of origin;

xi) Declaration that the information provided is factual

4.9 There shall be no authorization for the import or export of GMOs or their products that are banned by the laws of the exporting or as the case may be, importing country.

4.10 a person intending to introduce GMOs and/or derived products into the environment should obtain permit from National Biosafety Focal Point.

Note: a person should bear in mind that, at any time, in light of new scientific information on potential adverse effects to human health and the environment, NBFP may review and change a decision regarding any activity involving genetically modified organisms and derived products.

5 Specific requirements

In addition to general requirements the following requirements should apply.

5.1 Contained use

5.1.1 A person intending to conduct a contained use activity should on application, provide information necessary for risk assessment of potential risks and/or benefits of the particular genetically modified organism and derived products. The information should be as may be prescribed by the National Biosafety Focal Point including but not limited to the following:

a) Name and contact address of applicant;

b) Location where contained use activities should be undertaken;

c) Nature and identity of genetically modified organism;

d) The nature and purpose of activities;

e) Scale of operation and quantity of organisms to be used

f) Description of proposed containment measures and verification of their functioning;

g) Description of any potential risk;

h) A description of remedial measures to be undertaken in the event of any accident and unexpected events;

i) Training and supervision of personnel carrying out the activity;

j) Plans for waste management;

k) Plans for safety and health of personnel;

l) Relevant information from previous uses.

5.1.2 Appropriate risk management measures for contained use should be based on the type of organism whereby a person should adhere to biosafety level requirements.

5.1.3 A person intending to undertake contained use activities should ensure that:

a) Institutional biosafety committee is in place.

b) All facilities adhere to principles of good operational practices, and good occupational safety and hygiene.

c) The level of containment is in accordance with the requirements of the relevant regulatory institutions

5.1.4 Records and reports on activities involving genetically modified material should be maintained within the facility. These should include but not limited to plans and procedures for:

a) Safe handling;

b) Harvesting;

c) Storage;

d) Transportation;

e) Use;

f) Packaging and labelling;

g) Disposal;

h) Contingency procedures.

5.1.5 Genetically modified materials intended for transportation for contained use should be packaged in three levels consisting of:

a) Primary package;

b) Secondary package; and

c) Tertiary containers.

5.1.6 In addition to the information required in 4.8 (b), genetically modified organisms intended for contained use should be labelled to provide:

a) Specific identity, traits and/or characteristics;

b) Biosafety level

c) Methods and conditions for safe handling, storage, transport, use and disposal.

5.2 Confined use/field trial

5.2.1 Appropriate risk management measures for confined use/field trial should be based on the type of organism. The appropriate measures should include but not limited to the following:

a) Plant

i) Applying reproductive isolation,

ii) Controlling persistence or dispersal of reproductive structures such as propagules or seeds,

iii) Destroying volunteer plants after harvest.

b) Animal

i) Confining by appropriate means e.g. fences, filters, islands, ponds.

ii) Applying reproductive isolation by using sterile animals.

iii) Isolation from feral animals of the same species.

iv) Controlling persistence or dispersal of reproductive structures such as larvae and eggs.

c) Micro-organism

i) Using organisms with impaired ability to grow or persist in the environment;

ii) Minimizing gene transfer;

5.2.2 In addition to the information in 5.1, a person intending to undertake a confined use/field trial activity, should on application for confined field trial provide information as may be prescribed by the National Biosafety Focal Point including but not limited to the following:

a) Description of genetically modified organism including the name of the donor organism, recipient organism(s), inserted genes, marker genes, and traits;

b) Purpose and scale of trial/use;

c) Geographical description and location of release;

d) Proximity to human residence and activity;

e) Method and frequency of trials/uses;

f) Time and duration of trial/use;

g) Expected environmental conditions during trial/use;

h) Likelihood of trans-boundary movement;

i) Proposed risk management measures including verification of their functioning;

j) Subsequent treatment of site;

k) Potential impact on the environment;

l) Methods and plans for monitoring the genetically modified organism and derived product;

5.2.2 The safety of the genetically modified organism and/or derived products should be evaluated in accordance with the relevant Tanzania standards and national regulations on risk assessment as may be prescribed by the National Biosafety Focal Point and/or relevant regulatory institutions.

5.3 Import

5.3.1 A person intending to import any genetically modified organisms and/or derived products should on application for approval, provide information as may be prescribed by the National Biosafety Focal Point including, but not limited to the following:

a) Name address and contact details of the importer and exporter

b) Origin, name and taxonomic status of recipient organism

c) Unique identifiers; describing traits introduced or modified and characteristics of the organism

d) Intended dates of transboundary movement

e) Port of entry,

f) Intended use of genetically modified organisms or derived product in Tanzania,

g) Authorized use of genetically modified organisms and/or derived products in the country of export,

h) Quantity or volume to be imported,

i) Risk assessment report in accordance with Tanzania standard and existing laws and regulations in Tanzania

j) Methods and plans for safe handling, storage, transport, use, and disposal

k) Previous approval status regarding the genetically modified organism and/or derived products.

5.3.2 The import consignment should be labelled to clearly identify the nature of modification and intended use.

5.3.3 The import consignment should also be accompanied by documentation as may be prescribed by the National Biosafety Focal Point. This should include but not limited to:

a) A written approval from National Biosafety Focal Point; stipulating appropriate condition(s) for importation

b) Permit of importation from the relevant regulatory agency.

c) Permits from exporting country e.g. phytosanitary certificate.

5.4 Environmental release

5.4.1 Any genetically modified organisms and/or derived products intended for environmental release or placing on the market should comply with specific product requirements for food safety, human health, animal health, plant health, environmental safety, variety release, efficacy, registration, certification and quality, as may be appropriate and in accordance with national requirements and the existing laws, regulations and standards in Tanzania.

5.4.2 A person intending to place on the market any genetically modified organisms and/or derived products should on application for approval for environmental release or placing on the market, provide information as may be prescribed by the National Biosafety Focal Point including but not limited to the following:

a) Name of product, nature and/or traits of the genetically modified organism contained therein

b) Name and contact details of product applicant

c) Name and contact details of manufacturer or distributor in Tanzania

d) Country, scope and date of authorization

e) Regulatory status within the country of export in case of imports (e.g. prohibited, restricted, approved for release) and if banned, the reasons for the ban

f) Unique identifier

g) Intended use

h) Links to information on the genetically modified organism and derived products

i) A risk assessment and management consistent with international and national requirements,

j) Environmental impact assessment

k) Monitoring plan and strategies.

l) Protocol for detection of GMO event after general release.

m) Measures to take in case of unintended use.

n) Instructions and conditions of use, storage, handling and disposal

o) Proposed packaging and labeling

5.4.3 Any genetically modified organisms and/or derived products intended for environmental; release or placing on the market as food or feed should be evaluated for food safety in accordance with the following Tanzania standards:

a) TZS 2070
b) TZS 2071
c) TZS 2072
d) TZS 2073

5.4.4 Genetically modified organisms and/or derived products intended for environmental release or placing on the market should be labelled in accordance with AFDC 11 (6527) P1

5.4.5 Manufacturer(s), importer(s) or distributor(s) of genetically modified organism and derived products should in their premises maintain records of permits for placing on the market of the specific genetically modified organism and/or derived products being handled.

5.5 Transit

5.5.1 A person intending to transport through Tanzania genetically modified organisms and derived products, which are not destined for use in Tanzania should apply for a written approval for such transit from the National Biosafety Focal Point.

On application for transit, the following information should be provided including but not limited to:

a) Name, address and contact details of the exporter;

b) Name, address and contact details of the importer; and/or agent within receiving country;

c) Name and identity of genetically modified organisms contained therein

d) Intended date(s) of proposed entry and exit from Tanzania;

e) Intended use of organism and/or derived product in receiving country;

f) Quantity or volume of consignment;

g) Manner in which consignment will be transferred from the port of entry to port of exit;

h) Methods for safe handling, storage, transport, and use including packaging, labelling, documentation, disposal and contingency procedures;

i) Approval status in the exporting country

5.5.2 All transit consignments containing genetically modified organisms and/or derived products should be accompanied by the following documentation and a declaration from the exporting country regarding the safety of the consignment to human health and environment:

a) A letter of consent from the relevant National Authority of the receiving country, addressed to the National Biosafety Focal Point in Tanzania.

b) A copy of the import permit issued by the receiving country indicating the quantities or volume of the consignment from exporting country and that may contain genetically modified material.

c) Methods for packaging and handling of genetically modified organisms and/or derived products imported through conveyor shipment should comply with the relevant international and national requirements for repackaging and handling of conveyor shipped commodities.

5.5.3 Transportation of GMO within the country shall be in accordance with National biosafety regulations.

5.6 Export

A person intending to export genetically modified organism and derived products from Tanzania should submit to NBFP a written consent granted by a relevant Authority of the country to which the genetically modified organism and derived products are destined, to the effect that the relevant authority has no objection to the intended exportation.

A person who export genetically modified organism and derived products should obtain written approval from NBFP and keep record of documents relating to export and may submit to relevant regulatory authorities if needed for trade facilitation.

Note 1: The presentation of the advance informed agreement by an exporter shall in no way absolve the exporter from complying with any other laws governing foreign trade.

Note 2: The submission of the advance informed agreement shall not preclude the country of the exporter from taking into account other considerations before approving the export.

5.7 direct use as food or feed or food processing

5.7.1 In addition to the information given (transit, import, release) the following should apply to GMO and their derived products to be used as food, feed or food processing.

a) Declaration that products are direct use as food or feed or food processing.
b) Approved use of the GMO,
c) Genetically modified food and feed assistance introduced into the United Republic shall comply national regulations.
d) Food and feed consignment involving grain that contain GMOs shall be milled prior to distribution to the beneficiaries.

e) Food and feed in transit that contain GMO should be clearly identified and labelled in accordance with AFDC 11.

5.7.2 A person intending to use GMO and their derived products as food, feed or food processing in Tanzania should obtain a written consent granted by NBFP.