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THE STANDARDS ACT,
(CAP. 130)

REGULATIONS

(Made under section 36(3)(f))

THE STANDARDS (RECALL, SEIZURE AND DISPOSAL OF PRODUCT) REGULATIONS,
2021

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2021

PART I
PRELIMINARY PROVISIONS

- Citation 1. These Regulations may be cited as the Standards (Recall, Seizure and Disposal of Products) Regulations, 2021.
- Interpretation 2. In these Regulations, unless the context otherwise requires-
- Cap. 130 “Act” means the Standards Act;
“Bureau” means the Tanzania Bureau of Standards established by section 3 of the Act;
“disposal” means the process of rendering the unfit products for the duration of such that it is harmless;
- Cap. 191 “environmental inspector” means an inspector appointed or designated under section 82 of the Environmental Management Act;
“inspector” means an inspector appointed under section 23 of the Act;
“importer” means person or institutions importing commodities or products;
“Minister” means the Minister responsible for industries and trade;
“product” means goods and services designed to be released or launched in a market;
“recall” means the removal of specific batch or batches of a commodity or product from the market for reasons relating to deficiencies in the quality,

safety or efficacy;

“seizure” means the action of capturing suspected or unsafe or unfit product or commodity for further action;

“supplier” means a person who releases or launches commodity or product in the market; and

“unfit product” means a commodity or product violating any provision of the Act and these Regulations.

PART II

RECALL OF COMMODITY OR PRODUCT

Notification of
unfit product

3.-(1) A supplier or manufacturer who suspects on reasonable grounds that a product or commodity is defective or presents a risk of injury to human health or endanger environment or does not meet the requirements of the Act shall, immediately, report the matter to the Bureau and carry out an investigation.

(2) Subject to subregulation (1), where the investigation establishes that the product or commodity is defective or presents a risk of injury to human health or endanger environment or does not meet the requirements of the Act, the supplier or manufacturer shall immediately notify the Bureau and take action to mitigate the risk.

(3) On or before undertaking an investigation referred to in subregulation (1), the supplier or manufacturer shall provide the Bureau with the following:

- (a) proprietary name and generic name, batch or lot number, or unique identification information, pack size, the name and address of the manufacturer, manufacturing date and expiry date;
- (b) the nature of the defectiveness or possible defectiveness, the date on and circumstances under which the defects or possible defects were discovered;

- (c) the total quantity of the defective products or commodity originally in possession of the supplier or manufacturer;
- (d) the date on which distribution of the product or commodity began;
- (e) the total quantity of the defective products or commodity that had been distributed up to the time of the reporting the matter to the Bureau;
- (f) area of distribution of the defective products or commodity;
- (g) list of customers and their respective contact information and quantity of the product or commodity to whom the product or commodity was distributed; and
- (h) the quantity of the recalled products or commodity still in his possession.

(4) Notwithstanding the provisions of subregulation (1), the supplier or manufacturer may voluntarily initiate a recall of any product or commodity after receiving complaints from users or upon proof after investigation that such product has caused or is about to cause injury to the health or safety of users or endangers environment or defectiveness or substandard or unfit.

(5) The supplier or manufacturer who voluntarily initiate a recall under subregulation (4), shall be required to comply with the requirements stipulated under subregulation (1) of this regulation and section 25 of the Act.

(6) On or before undertaking a recall referred to in subregulation (1), the supplier or manufacturer of product and commodity shall provide the Bureau with the following:

- (a) proprietary name and generic name, batch or lot number or unique identification

- information, pack size, the name and address of the manufacturer, manufacturing date and expiry date;
- (b) the reason for the recall, the nature of the defectiveness or possible defectiveness or substandard or unfit, the date on and circumstances under which the defects or possible defects were discovered;
 - (c) the total quantity of the product being recalled originally in possession of the supplier or manufacturer;
 - (d) the date on which distribution of the product began;
 - (e) the total quantity of the product being recalled that had been distributed up to the time of the recall;
 - (f) area of distribution of the product;
 - (g) list of customers and their respective contact information and quantity of the product or commodity to whom product was distributed; and
 - (h) the quantity of the recalled product or commodity still in possession of the supplier or manufacturer.

Investigation by
Bureau and
notification to
Minister

4.-(1) The Bureau shall, upon receiving information or in any way becoming aware that a product or commodity is defective or substandard or unfit or presents a risk of injury to human health or endanger environment or does not meet the requirements of the Act, conduct an investigation into the matter.

(2) Subject to subregulation (1), the Bureau shall, upon investigation, notify the Minister for approval to recall the product or commodity as a mitigating measure.

(3) Upon issuance of a recall order, the supplier or manufacturer shall, on its own costs-

- (a) immediately comply with the requirements or

directives in the order;

- (b) implement the recall procedure as per these Regulations; and
- (c) prepare and submit to the Bureau a weekly progress report or as may be specified by the Bureau on the implementation of the recall order, and the final report of the implementation of the recall order within the period specified therein or under these Regulations which shall also include-
 - (i) reconciliation between delivered and recovered quantities of the product or commodity;
 - (ii) detailed causes of the defect; and
 - (iii) corrective and preventive actions undertaken.

Responsibility
of supplier and
manufacturer

5. A supplier or manufacturer shall prepare, keep and maintain documents that set out procedure for receiving, investigating and responding to complaints that are received in relation to its product or commodity.

Recall
procedure

6. A supplier or manufacturer shall prepare, keep and maintain a document that set out a recall procedure that enables the effective recall of a product or commodity, the name of a contact person who is responsible for the procedure and the name of a contact person who is responsible for conducting recalls.

Prohibition to
sell products
subjected to
recall

7. A person shall not sell, offer or expose for sale or supply any product or commodity subjected to recall.

Health risk
evaluation

8. Where the recall concerns a product or commodity that poses a health risk, the Bureau shall conduct evaluation and take appropriate measures.

PART III

SEIZURE, DISPOSAL AND HANDLING OF UNFIT PRODUCTS OR COMMODITIES

Seizure of
unsafe or
substandard
product or
commodities

9.-(1) Any product or commodity which is proved or suspected to be unsafe or substandard shall be seized by an inspector in a manner prescribed under these Regulations.

(2) An Inspector shall, upon seizure of the product pursuant to subregulation (1), mark it and removes or leave it under the care of the owner or agent, and he shall fill seizure form as prescribed in the First Schedule to these Regulations.

(3) A seized product or commodity shall be kept until an order for its disposal or destruction is issued by the Bureau.

(4) In effecting the seizure of any product or commodity under this regulation, an inspector may, in writing, notify a nearby police station to provide security during seizure.

(5) All accrued costs on seized products or commodities shall be borne by the owner or his agent.

(6) The owner of the products or commodity which has been seized may, within fourteen days from the date of service of the notice of seizure, apply in writing to the Director General for reconsideration.

(7) Subject to subregulation (6), where the Bureau is satisfied that no application has been made within fourteen days, the products or commodities seized shall be forfeited and disposed off at the cost of the owner or his agent.

Restriction of
disposal of unfit
product or
commodity

10. A person shall not dispose off any product or commodity declared by the Bureau to be unsafe or substandard unless he has requested the Bureau and secured a written approval to proceed with disposal under supervision of the Bureau.

Request for
voluntary
disposal of
unsafe or
substandard
products or
commodities

11.-(1) Request to dispose the products or commodities voluntarily recalled shall be made to the Bureau in writing.

(2) A request shall be accompanied by a list and respective quantity of products or commodities to be disposed.

(3) Subject to subregulation (2), the Bureau shall inform the applicant to liaise with relevant authorities responsible for disposal.

(4) The applicant shall submit to the Bureau disposal approval from relevant authorities.

Handling of
unsafe or
substandard
products

12.-(1) A person shall not sell or supply or offer or expose for sale or supply or have in his possession for the purpose of sale or supply unsafe or substandard products.

(2) Owner or agent of products or commodities shall adhere to the following requirements:

(a) keep separately unsafe or substandard products and commodities;

(b) demarcate an area for keeping unsafe or substandard products which shall be labeled conspicuously in red ink with words in English “Unfit for intended use” or in Kiswahili “Hazifai kwa matumizi yaliyokusudiwa”; and

(c) maintain safe custody of unsafe or substandard products in registered premises until they are disposed.

Transportation
and disposal of
unsafe or
substandard
products

13.-(1) Subject to any provisions of these Regulations, an inspector or any other public officer authorised by the Bureau shall supervise the transportation of consignment from the premises to the disposal site for destruction.

(2) The destruction shall be supervised by an inspector, or any other public officer authorised by the Bureau and upon completion of the exercise a disposal form set out in the Second Schedule to these Regulations, shall be duly filled in and signed by the supervisor, the

owner of the consignment or his representative and other authorities who witnessed the destruction.

(3) Upon submission of disposal form to the Bureau, the certificate of disposal set out under Third Schedule to these Regulations shall be issued to the owner of the disposed commodities or product.

PART IV GENERAL PROVISIONS

Offence and
penalty

14. Any person who contravenes or fails to comply with any provision of these Regulations commits an offence and upon conviction shall be liable to the penalty provided for in the Act.

FIRST SCHEDULE

(Made under regulation 9(2))

NOTICE OF SEIZURE

To:

.....

.....

The following goods stored in situated at
..... are seized as goods proved/suspected to be substandard/unsafe
under the provisions of the Standard Act, Cap. 130; that is to say (nature of the goods and
problems):

SN	Description of product(s)	Quantity	Unit	Value

REMARKS

.....

.....

.....

.....

Any claim against the seizure shall be submitted to the Director General within fourteen days of the seizure. In the event of your failure to file a claim within the time stipulated herein Tanzania Bureau of Standards (TBS) may pose dispose of the above goods as may deem fit under the law.

.....			
TBS Inspector (s)	Designation	Signature	Date
.....			
The owner/representative of the seized products	Designation	Signature	Date

SECOND SCHEDULE

(Made under regulation 13(2))

DISPOSAL FORM

Description of the product(s)

.....

Owned by M/S.....

Quantity.....Custom/Total value.....

Fail to comply with requirements for TFS.....

According to the standards (recall, seizure and disposal of product) regulations, 2020, the named product(s) is not allowed to enter into the Tanzania Market.

The destruction exercise was conducted at (location, site).....

on this date by the following methods (state clearly):

1.
2.
3.

Name and Signature of the Owner/in charge/representative of the organization:

(Name): (Signature).....

Names, Title and Signature of TBS Inspector(s)/officer(s), other supervisor(s) and witness of the disposal exercise:-

Name	Title	Organization	Signature

FOR OFFICIAL USE ONLY

Submitted by:

Signature:.....

(Inspector)

Date:.....

Reviewed by:

Signature:.....

(HPCERT/Assigned Officer)

Date.....

Approved by:

Signature:.....

(HCERT/HZone)

Date.....

THIRD SCHEDULE

(Made under regulation 13(3))

CERTIFICATE OF DISPOSAL

This certificate of Disposal is issued to:

Registered Address:

For the disposal of at

..... facility

product was/were under Bill of lading/identification mark

This is to certify that the above product was/were found to be substandard/expired and has/have been destructed by Tanzania Bureau of Standards (TBS) by using method.

QUANTITY:

Date:

.....
For: DIRECTOR GENERAL

Dodoma,
1st September, 2021

KITILA A. MKUMBO
Minister for Industries and Trade