Kenya Bureau of Standards

PRODUCT REGISTRATION GUIDELINES

1. Introduction

Pursuant to the amendments of legal Notice 78 of 28th through Legal Notice 212 of 18th December, 2020, the heads of sections in Quality inspection department were tasked to come up with administrative structures to implement he provisions of the regulations. Consequently, an implementation framework has been established.

Importers are responsible for ensuring that their products and shipments, meet Kenya Standards, Approved Specifications and other Applicable Regulations. Further, importers of products are required to notify the Bureau before importing any product into Kenya and provide proof that the imported product meet Kenya standards, approved specifications and other applicable regulations as Provided for under Legal Notice No. 78 of 28th April 2020 clause 5(2). It is against this background that a framework for Registration of Products is Developed.

Under the Framework, Goods are Registered before shipment based on a Technical Criteria to ensure compliance with Applicable requirements. Registered products still require a Local Certificate of Conformity in order to be permitted into the country. However, the certification process is faster due to Registration.

Product registration fulfils requirements of Article 5 of the world Trade Organization (WTO) Technical Barriers to trade TBT). It is expected to complement the PVOC Programme and address delays experienced by traders due to backlog in the inspection of goods by PVOC Partners at the Ports of Exit.

2. Scope

The Product Registration Process applies to all Regulated Products. However, Mandatory Route A products (High Risk Goods) are not eligible for Registration.

3. References

3.1. The Standards Act Cap 496, Laws of Kenya

3.2. Legal Notice Number 78 of 28th April 2020

3.3. Legal Notice Number 212 of 18th December 2020

3.4. CPR 173: Inspection Process Document

3.5. PVOC Programme Manual

3.6. ISO/IEC 17020 Conformity assessment – Requirements for the operation of various types of bodies performing inspection

3.7. ISO/IEC 17000 Conformity assessment - Vocabulary and general principles

3.8. ISO 9001- Quality Management Systems-requirements

3.9. ISO 9000 - Quality management systems -- Fundamentals and vocabulary

4. Abbreviations

4.1. PRF-Product Registration Application Form
4.2. KENTRADE - Kenya Trade Network Agency
4.3. KESWS - Kenya Electronic Single Window System
4.4. CD - Consignment Document
4.5. PVOC – Pre –Export Verification of Conformity
4.6. MD - Managing Director, KEBS
4.7. DI Destination Inspection
4.8. UCR Unique Consignment Reference
4.9. IDF Import Declaration Form
4.10. KRA Kenya Revenue Authority
4.11. CIF - Cost Insurance and Freight (Customs Value).
4.12. FOB- Freight on Board
4.13. IEC - International Electrotechnical Commission
4.14. IECEE-IEC system of Conformity Assessment Schemes for Electrotecchnical Equipment and componets
4.15. CBTLs-Certification Body Testing Labolatories

5. Definitions

5.1. **Product Registration**

Product Registration is a verification Process involving the technical evaluation of the products to the applicable Standards and Regulatory requirements in order to establish the conformity of the products to specified requirements.

5.2. **Destination inspection** – Destination Inspection under the Product Registration Scheme involves verification of import documents, Physical Inspection of goods and /or testing.

5.3. **Risk profiling** – The Method in which KEBS puts Risk Assessment in to Practise.It replaces 100%and Random Examination of Documents and Goods with a planned and targeted working Method that use the Profiles as a basis.

5.4. **Registered Importer:** An Importer Registered under the Product Registration Guidelines.

5.5. **Registered Exporter**: An Exporter Registered under the Product Registration Guidelines and shall nominate a registered agent (Importer) located in Kenya.

5.6. **Nominated Importer**: An importer nominated by a Registered Exporter and assumes full Responsibility of Registered Products.

5.7. **Manufacturer**

The legal person with responsibility for the design, manufacture, packaging and labelling of a device or product before it is placed on the market under its own name.

5.8. **Technical documentation**

Any certification, design data, drawings, calculations, test certificates and/or test reports which individually or collectively demonstrate that the product meets the basic requirements as outlined in the applicable standard/regulation

5.9. **Recognized Laboratory**

- A laboratory with testing facilities duly accredited to ISO/IEC 17025
- IECEE CBTLs.
- Government owned laboratories.

5.10. **Product Recall**

Any measure aimed at achieving removal from the market of non-complying product after discovery of safety issues or product defects that might endanger the consumer.

6. Framework for Product Registration

6.1. Eligibility for Registration

6.1.1. The following Applicants are eligible to apply for Registration

- Exporters (Brand owners, authorized distributor, Manufacturers)
- Importers (Pin No's., Tax Compliance Certificate, Business Registration Certificate)

6.1.2. Products

All products are eligible for Registration except High risk products covered under Route A of the PVOC Program(Clause 5.3.1of the PVOC manual).

6.2. Documents to be submitted by Applicants

i. Filled Product Registration Form (Appendix B).
ii. Test Certificates for IECEE Scheme.
iii. Test Report(s) issued against applicable Kenya or equivalent International standard by a recognized laboratory.
iv. Valid Manufacturer's QMS certificates (Optional).
v. Colored Product photographs to demonstrate compliance with the labelling requirements.
vi. Material Safety Datasheets for chemical products.
vii. Operation/Instruction Manual for appliances and machines,where applicable.
viii. Distributorship/Dealership agreements if applicant is not the brand owner
ix. Manufacturer's warranty, where applicable
x. Product type approval, where applicable
xi. Regulatory permits, where applicable
xii. Other product certification, where applicable
xiii. Declaration of responsibility for conformity of the product to the applicable Kenya standards, approved specifications and other applicable regulations.
xiv. Business registration certificate and KRA pin certificate.

6.3. **Preliminary Evaluation**

The following criteria shall be applied during preliminary evaluation:

i. Eligibility of the product for registration
ii. Verification of submitted documents
iii. Test reports and test certificate shall be validated as per Appendix F

6.4. **Technical Evaluation**

The following criteria shall be applied during technical evaluation:

i. Test Reports and photographs shall be evaluated for conformity of the product to the relevant standard.
ii. Compliance to other applicable regulatory requirements
iii. Evaluation of type approvals and external product certifications for adequacy in meeting applicable requirements
iv. Review the Quality Management system documentation submitted to establish the exporter's ability to consistently supply quality goods.

6.5. **Registration Fees**

An applicant whose product(s) meet the criteria for registration as outlined in 6.4 above shall be required to pay the registration fee at the rate of **USD 75 for 1 up to 20 products and USD 10 for any additional product.**

6.6. **Certificate of Registration**

A certificate of registration shall be issued in respect of all applications that meet the technical evaluation criteria and payment requirements. The Certificate shall contain:

i. A schedule of products for which the registration is applicable
ii. Terms and conditions for use of the registration
iii. The validity period of the certificate, subject to compliance with the set terms and conditions

7. Clearance of Registered Goods

7.1. Notification of importation - An importer of a registered product shall notify KEBS by submitting a KEBS CD and attach the registration certificate through the Kenya National Electronic Single Window System, before arrival of the registered products.

7.2. The importer of the registered goods shall pay destination inspection fee at a rate of **0.6%** of the approved customs value subject to a minimum of **USD 265** and a maximum of **USD 2,700**

7.3. Issuance of Local CoC for clearance of registered products shall be based on a valid registration status and destination inspection surveillance plan.

8. Monitoring of Registered Products

8.1. KEBS shall establish a surveillance plan and risk profiling criteria for registered products which shall be implemented at the port of entry and in the market

8.2. Monitoring shall involve physical inspection and/or testing

8.3. Monitoring shall also include checking validity of documents submitted during registration.

8.4. The results of monitoring shall be communicated to the registration holder and shall be used to determine future status of the registration.

9. Renewal of Registration

9.1. Applications for renewal should be received at least two (2) months before expiry of registration.

9.2. KEBS shall not be responsible for any consequences of submitting the application late.

9.3. Renewal of application will be based on results of monitoring.

9.4. Notification of renewal is done through email, indicating the Registration Number and submitting updated documents where applicable.

9.5. Payment of registration fee.

10. Responsibilities of the Registration Holder Under these Guidelines

10.1. **Importers responsibility for conformity of registered products**

- The registered importer shall have full responsibility for quality of registered products.
- The importer of the registered products shall provide guidance to the supplies chain downstream on handling requirements for registered products to ensure preservation of quality.
- The importer shall maintain records of (first customer) sales records for registered products with clear mechanism of batch/lot identification and the same shall be provided for verification to KEBS inspectors on demand
- The importer of the registered products shall have a documented procedure for removal from market of non-compliant registered products.

10.2. **Withdrawal of non-compliant registered products from the market**

- Where a registered product in the market has been established to be non-compliant with standard requirements, the importer shall ensure that immediate actions are undertaken to isolate the product to prevent exposure to consumers.
- Institute withdrawal of the non-compliant products for corrective action or destruction as may be required in view of health, safety and environmental consideration.
- All recalls and market withdrawals shall be notified to KEBS in a format prescribed in Appendix 2- Product Recall Notification Form.
- This provision does not prevent KEBS from undertaking any legal measures it deems necessary to protect the consumers or the public from harmful products.

10.3. **Consumer Complaints Register**

Registered importers shall maintain a register of complaints received related to the Registered Product (Appendix 3). Complaints shall be investigated and where valid, addressed and resolved.

11. Suspension of Registrations

11.1. Registered products can be suspended due to minor discrepancies observed during surveillance (Testing, Inspection, Audit).

11.2. KEBS shall include a remark in the Registration document stating that particular product model/line item has been suspended and reissue the Registration

11.3. The Registered Importer/ Nominated Importer shall be immediately informed about the suspension.

11.4. The suspended Registration can be reinstated only if the Applicant provides satisfactory evidence(s) of corrective action(s) donewithin the agreed period between KEBS and Applicant.

11.5. No charges shall be applied for suspension and reinstating suspended registered products.

12. Cancellation/Termination of registrations

Registration can be terminated due to the following reasons

12.1.1. Upon Inspection, testing or compliance review, the registered products are found not to comply and the Applicant declines to take corrective actions.

12.1.2. The Applicant misuses or makes any unauthorized changes in the Registration document so as to receive the benefits of Registration.

12.1.3. The Applicant does not cooperate During Surveillance.

12.1.4. Registered/Licensed products have been subjected to recalls from the market.

12.2. If the Registrant is found to have violated any one of the above clauses, KEBS shall initiate the termination

12.3. The Applicant shall be immediately informed about the termination of the Registration.

12.4. If the Registered importer/exporter satisfactorily completes the required corrective action and would like to register the product(s) again then in such cases the Applicant should submit a new Registration application.

13. Withdrawal of Registration License

13.1. Registration can be withdrawn by the Applicant for various reasons but not limited to the following:

13.1.1. No shipments to the country.

13.1.2. Applicant shutting down their business

13.1.3. If the ownership of the company is taken over by another entity

13.2. Upon receipt of such requests, KEBS shall proceed with the withdrawal of the Applicant's Registration

13.3. If the Applicant intends to reinstate their withdrawn Registration, then KEBS shall consider it as a new application.

14. **Complaints and Appeals**

-Complaints shall be handled as per KEBS QMP-08.

- Any importer /Exporter aggrieved by a decision on Registration, may appeal in writing to the MD KEBS within 14 days.

APPENDIXES

Appendix A**:** Products ineligible for registration

Appendix B: Product Registration Application form

Appendix B: Product Recall Register.

Appendix C: Product Complaints Register

Appendix E: Certificate of Registration

Appendix F :Validation of Test Reports and Test Certificates

Appendix A: Products ineligible for registration

i. Animal and Fishery products (fresh and frozen - not further processed)
ii. Bulk Petroleum products and base oils
iii. Bulk shipments of cereals and pulses such as rice, wheat, Barley, beans, maize etc.
iv. Edible cooking oils
v. Fertilizer
vi. Fresh dairy products
vii. Fresh horticultural produce
viii. Liquid Petroleum Gas (LPG)
ix. Motorcycle helmets
x. Steel e.g. flat bars, Angle bars, Channels, Round bars, Deformed bars, RHS and SHS
xi. Sugar
xii. Tyres
xiii. Used or secondhand goods

APPENDIX B: Product Registration Application Form (REQUEST FOR PRODUCT REGISTRATION)

IMPORTANT: The quality and completeness of the documentation submitted by the Applicant directly influences the time and cost of processing the Registration/License request. Incomplete applications will not be processed.

PURPOSE OF APPLICATION REGISTRATION LICENSE PRODUCT CERTIFICATE TECHNICAL EVALUATION OTHER (SPECIFY)

APPLICATION TYPE	TICK WHERE APPLICABLE
New	
Renewal	
Revision	

APPLICANT'S DETAILS

Contact person		Telephone No.	
Company name		Company Registration Certificate NO.	
Company address		KRA PIN No.	
E-Mail Address			

APPLICANT TYPE

- ☐ Authorized dealer
- ☐ Authorized Distributor
- ☐ Importer
- ☐ Manufacturer
- ☐ Third-party logistics
- ☐ Other(please specify)

PAYMENT DETAILS

Contact Person	
Company Name	Company Address
E-Mail address	Telephone No
Payment type ☐Mpesa ☐ Bank Deposit Demand Note No Invoice Currency to be used	Addresses of invoices to be sent

DECLARATION

By submitting this Application:

- ☐ I/We hereby confirm that the information provided herein for the purpose of obtaining the Product Registration Certificate isaccurate and complete in all respects to the best of my/our knowledge.
- ☐ I/We have read and fully comprehend KEBS's Terms and Conditions for product registration Services which is available at www.kebs.org and hereby confirm my/our acceptance of these Terms and Conditions for obtaining the Product Registration Certificate

Name	Position
Signature	Date

DOCUMENTS ATTACHED TO THIS APPLICATION

- ☐ Factory Audit Report (mandatory)
- ☐ Declaration of Conformity (mandatory)
- ☐ Product Identity Declaration(Mandatory)
- ☐ Test Report orTest Certificate (Mandatory)
- ☐ Regulatory Permit (Where Applicable)
- ☐ Other product certification (Where Applicable
- ☐ Business Registration Certificate (mandatory)
- ☐ KRA PIN Certificate(mandatory)
- ☐ Other (please specify)
- ☐ QMS Certificates (Where Applicable)
- ☐ Product Data Sheet/Technical Data Sheet (mandatory for chemical products)
- ☐ ISO/IEC 17025 Accreditation Certificate (where Applicable)
- ☐ Colored Photographs of Products (Mandatory)
- ☐ Manufacturer's Warranty (Mandatory for new motor vehicle spare parts)
- ☐ Distributorship/Dealership Agreements if the applicant is not the brand owner
- ☐ Product type approval

PRODUCT DETAILS

Please click the appropriate excel template for the data entry of the product details applicable for the certification of your shipment.

- Request for Product Registration Certificate – General Product Details

Note: KEBS may perform technology based remote inspection/audits while promoting public health protocols.

Thank you for taking the time to fill out this form. We appreciate your business.

- Please visit our website www.kebs.org for more information.

Appendix C: PRODUCT RECALL NOTIFICATION FORM

SN	Date of Recall	Products Recalled	Reasons for Recall	Quantity/ Batch Nos	Location/ Premi	Remarks

Appendix D: Certificate of Registration

This document is not and does not substitute in any respect a Certificate of Conformity required for Customs Declaration	**SoR No.** **Issuance date:**

Beneficiary Name:

Phone:

E-mail :

Item No.	Product Description	Country of Importation	Standard Reference
1			
2			
3			
4			
5			
6			
7			

Remarks:

Date of assessment:

Signed:

Authorized Office:

Terms and Conditions:

Appendix E: PRODUCT COMPLAINTS REGISTER

S/ No	Date of receipt	Source of complaint (Name and address of complainant)	Nature of complaint	Source of product	Date assigned IO/SO	Date acknowledged	File re	Investigation officer	Date visit	Remarks/ action taken	Date of resolution	Status & signature

Appendix F

Validation of Test Reports and Test Certificates

(a) IECEE Test Reports and Certificates
These shall be validated through IECEE portal.

(b) Codex Test Reports
(c) ISO test reports
(d) Test Reports from a laboratory with testing facilities duly accredited to ISO/IEC 17025
(e) Test Reports from Government owned laboratories.