



GUIDELINES FOR INSPECTION AND CERTIFICATION OF PRODUCTS REGULATED BY PARTNER GOVERNMENT AGENCIES



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RECORD OF CHANGES

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DISTRIBUTION OF CONTROLLED COPIES

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1.0 PURPOSE

The purpose of this procedure is to provide a framework for inspection and certification of products regulated by partner government agencies in line with Government circular reference OP/CAB 9/83A dated 4th June, 2019.

2.0 SCOPE

- 2.1 This procedure shall apply to products regulated by the following government agencies:
- i. Communications Authority
 - ii. Directorate of Veterinary Services
 - iii. Fisheries Department
 - iv. Kenya Civil Aviation Authority
 - v. Kenya Maritime Authority
 - vi. Kenya Plant Health Inspectorate Services
 - vii. Mines and Geological Department
 - viii. Pest Control Products Board
 - ix. Pharmacy and Poisons Board
 - x. Radiation Protection Board
 - xi. Veterinary Medicines Directorate
- 2.2 The specific products are as listed below in clause 6.2 of this procedure
- 2.3 This procedure does not cover products exempted in line with Legal Notice 127 of 19th June, 2018 and listed in Annex 2 of the PVoC Manual, Version 9.0 dated 1st July, 2019

3.0 TERMINOLOGY

- 3.1 **Definition of terms used**
For the purpose of this procedure the following terms shall apply.
- 3.2 **Inspection:**
Is examination of a product design, product, service, process or plant, and determination of their conformity with specific requirements or, on the basis of professional judgment, with general requirements.
- 3.3 **Verification**
Confirmation by examination and provision of evidence that specified requirements have been met.
- 3.4 **Approved Specification**
A specification in respect of which a standardization mark has been specified under Section 10(1)(b) of the Standards Act Cap 496 Laws of Kenya.

4.0 ABBREVIATIONS AND ACRONYMS

- **CAK** - Communications Authority of Kenya
- **CIF** – Cost, Insurance and Freight (value of goods)
- **COC** – Certificate of Conformity
- **COR** - Certificate of Roadworthiness for Motor Vehicles
- **DVS** - Department of Veterinary Services
- **IDF** - Import Declaration Form
- **KCAA** - Kenya Civil Aviation Authority
- **KMA** – Kenya Maritime Authority
- **KEBS** - Kenya Bureau of Standards
- **KEPHIS** - Kenya Plant Health Inspectorate Service
- **KRA** – Kenya Revenue Authority
- **NCR** - Non Conformity Report
- **PCPB** - Pest Control Products Board
- **PGA** – Partner Government Agency
- **PPB** - Pharmacy and Poisons Board
- **PVOC** – Pre-Export Verification of Conformity to Standards
- **PVOC Partners** – KEBS Appointed Inspection and Certification Companies.
- **QMS** - Quality Management System
- **RFC** - Request for Certification
- **RPB** – Radiation Protection Board
- **VMD** – Veterinary Medicines Directorate
- **WHO** – World Health Organization

5.0 REFERENCES

This procedure makes reference to the following documents, which form part of the QMS documentation:

- 5.1 ISO 9001:2015, Quality Management Systems-requirements
- 5.2 ISO/IEC 17020:2012 Conformity assessment – Requirements for the operation of various types of bodies performing inspection
- 5.3 ISO/IEC 17000:2004 Conformity assessment - Vocabulary and general principles
- 5.4 The Standards Act Cap 496, Laws of Kenya
- 5.5 Legal Notice 127 of 19th June, 2018
- 5.6 PVoC Manual, PVoC Manual, Version 9.0 dated 1st July, 2019
- 5.7 Government Circular Reference OP/CAB 9/83A dated 4th June, 2019

6.0 PROCEDURE DETAILS

6.1 Certification of Products in the Country of Origin

- 6.1.1 To initiate importation of any product under this inspection framework, an importer or exporter shall complete and submit RFC form to the respective PVoC Partner's office together with the following information/documentation:
 - i. Unique Consignment Reference (UCR) Number (mandatory)
 - ii. Proforma / Commercial Invoice (mandatory).
 - iii. Packing List (mandatory).
 - iv. Import Declaration Form (IDF) – (*where applicable*).
 - v. Copy of product technical specification from the manufacturer (*if available*)

- vi. Manual / operating instructions (*where applicable*). The manual/instruction shall include English
- vii. Production data (i.e. Batch size and number, Name of manufacturer, Date of manufacture/expiry, manufacturer's certificates – *where applicable*).
- viii. QMS Certificates (*if available*).
- ix. Distributorship/Dealership agreements- *if available* (only applicable to manufacturer-authorized distributors/ Dealers).
- x. Test reports traceable to the goods being shipped, (*if available*).
- xi. Key documentations relevant to the requirements of the specific government agency. These documentations are listed below in clause 6.2

6.1.2 Review of RFC / Documentation by the PVoC Partner

The PVoC Partner shall review the documentation for completeness and to:

- i. Establish the applicable standard(s), approved specifications and/or regulatory requirements
- ii. Review provided conformity documents (if any) for each line item to define whether they are acceptable or not.
- iii. Prepare inspection and testing (where applicable) instructions with due regard to the requirements of the relevant standard(s) and/or regulatory requirements

6.1.3 KEBS appointed inspection Partner shall undertake inspection in the country of supply as provided for in the PVoC Manual and issue a CoC for products meeting the requirements of the relevant Kenya standard(s), approved specifications and/or regulatory requirements.

6.1.4 Products not meeting the requirements of the relevant Kenya standard(s), approved specifications and/or regulatory requirements shall be issued with a Non- Conformity Report (NCR) and shall not be eligible for exportation to Kenya.

6.1.5 To avoid post issuance amendments of the COC, the PVoC Partner shall send to the owner a copy of the draft certificate for confirmation of its correctness with regard to shipment identification, goods description, quantities and values.

6.1.6 The Inspection Partner shall provide CoC/NCR data to KEBS

6.1.7 KEBS shall make the data available through Kenya National Electronic Single Window System.

6.1.8 Anti-Counterfeiting Measures in the PVOC Process

It should be appreciated that what constitutes counterfeiting or counterfeit goods does not have a standard measure as opposed to the products requirements in the standards. It is therefore not easy to come up with generic or guidelines for checking against counterfeit goods. The following are therefore suggested guidelines that must be checked during inspection:

- 6.1.8.1** Evidence of the existence of the intellectual property rights relating to the finished goods, e.g., valid certificate of registration or legal document confirming subsistence of the right.
- 6.1.8.2** Declaration by the exporters that the intellectual property right does not infringe on a right registered and subsisting in Kenya

- 6.1.8.3 The name, full details and capacity (owner/licensee) of the manufacturer of the goods being exported to Kenya for ease of track and trace purposes
- 6.1.8.4 Detailed actual description of the exported goods to include the type, size, model, brand, make and/or shape, as applicable
- 6.1.8.5 No packaging or labels or similar items like bottle tops for excisable goods to be permitted for export unless so exported by a registered manufacturer of excisable goods
- 6.1.8.6 No packaging or labels or similar items to be permitted for export unless the export is by a manufacturer or assembler domiciled and so registered in Kenya
- 6.1.8.7 No unbranded goods to be permitted for export into Kenya

6.2 Partner Government Agencies' Regulated Products and Required Documentation while submitting RFC to the PVOC Agent

6.2.1 Communications Authority of Kenya (CAK)

6.2.1.1 Products Regulated by CAK

No.	HS Code	Product Description
1.	8526	Radar apparatus, radio navigational aid apparatus, Radio remote control apparatus

6.2.1.2 Documents Required

- i. Type approval issued by CAK

6.2.2 Directorate of Veterinary Services (DVS)

6.2.2.1 Products Regulated by DVS

No.	HS Code	Product Description
1.	0201 - 0210	Fresh/chilled carcasses only
2.	0506	bones and horn-cores
3.	4101 – 4103	Raw hides and skins
4.	0407.11 - 0407.19	Hatching eggs for chicken etc.

6.2.2.2 Documents Required

- ii. Import Permits and Licenses issued by DVS

6.2.3 Fisheries Department

6.2.3.1 Products Regulated by Fisheries Department

No.	HS Code	Product Description
1.	0301 – 0302	Fish, fresh or chilled

No.	HS Code	Product Description
2.	0306	Crustaceans, whether in shell or not, fresh, or chilled
3.	0307	Molluscs, whether in shell or not, fresh or chilled
4.	0308	Other aquatic invertebrates
5.	0511.91.10	Fish eggs

6.2.3.2 Documents Required

- i. Import Permits and Licenses issued by Fisheries Department

6.2.4 Kenya Civil Aviation Authority (KCAA)

6.2.4.1 Products Regulated by KCAA

No.	HS Code	Product Description
1.		Balloons and dirigibles; gliders, hang gliders and other non-powered aircraft and parts thereof
2.		Airplanes

6.2.4.2 Documents Required

- i. Import Permits and Licenses issued by KCAA

6.2.5 Kenya Maritime Authority (KMA)

6.2.5.1 Products Regulated by KMA

No.	HS Code	Product Description
1.		Ships, boats and floating structures
2.		Spares

6.2.5.2 Documents Required

- i. Import Permits and Licenses issued by KMA

6.2.6 Kenya Plant Health Inspectorate Service (KEPHIS)

6.2.6.1 Products Regulated by KEPHIS

No.	HS Code	Product Description
1.	0701 - 0709	Edible vegetables and certain roots and tubers – (Fresh/chilled)
2.	1211, 1213	Oil seeds and oleaginous fruits; miscellaneous grains, seeds; industrial or medicinal plants; straw and fodder
3.		Seeds for sowing under any chapter.

6.2.6.2 Documents Required for Inspection

- i. Import permit issued by KEPHIS

- ii. Phytosanitary certificates from the exporting country

6.2.7 Mines and Geological Department (MGD)

6.2.7.1 Products Regulated by Mines and Geological Department

No.	HS Code	Product Description
1.	3601 – 3604	Explosives and pyrotechnic substances

6.2.7.2 Documents Required

- i. Import Permits and Licenses issued by MGD

6.2.8 Pest Control Products Board (PCPB)

6.2.8.1 Products Regulated by PCPB

No.	HS Code	Product Description
2.	3808	Insecticides, rodenticides, fungicides, herbicides, anti-sprouting products

6.2.8.2 Documents Required for Inspection

- i. Import permit (The permit issued under regulation 2(1) shall be valid for six (6) months from the date of issue)
- ii. Certificate of Analysis for the pesticides being imported
- iii. Valid certificate of registration of the pest control products by PCPB
- iv. Well labelled pesticide packaging material or container shall include; but not limited to; Name and address of the Manufacturer and Formulator, Country origin, Date of manufacturer, Expiry date, Batch number Amount/quantity
- v. Provision of a 'No Objection' letter from the local agent of the product if importing a product not under agencyship
- vi. Evidence of appointed local agent in Kenya

6.2.9 Pharmacy and Poisons Board (PPB)

6.2.9.1 Products Regulated by PPB

No.	HS Code	Product Description
1.	3003, 3004	Medicaments
2.	3006.60.00	Chemical contraceptive preparations based on hormones.

6.2.9.2 Documents Required for Inspection

- i. Importer's Valid License issued by PPB
- ii. Ethical Committee Approval Letter (only for controlled substances intended for scientific purposes such as clinical trials)
- iii. Import Permit Issued by PPB for pharmaceutical products
- iv. Permit for licit Narcotics, Psychotropics and Precursor substances issued by PPB

- v. Certificate(s) of Analysis (CoAs) of the product(s)
- vi. Patient Information Leaflet (PIL) for pharmaceuticals
- vii. Well labelled medicaments shall include; but not limited to; Name and address of the Manufacturer, Country origin, Date of manufacturer, Expiry date, Batch number, Amount/quantity
- viii. Minilab tests (Raman spectroscopy) CoA

Note: Quantities of the products being imported should tally with those allowed in the permit

6.2.9.3 Requirements for Pharmaceutical Inspectors

- i. Be a trained pharmacist who is duly registered in the country of practice
- ii. Should be conversant with international drug control conventions

Note: the PVoC partner should have adequate laboratory infrastructure as spelt out in the WHO Good Practices for Pharmaceutical Quality Control Laboratories, World Health Organization, 2010 Technical Report Series, No. 957, Annex 1.

6.2.10 Radiation Protection Board (RPB)

6.2.10.1 Products Regulated by (RPB)

No.	HS Code	Product Description
1.	2844 - 2845	Radioactive chemical elements and radioactive isotopes

6.2.10.2 Documents Required for Inspection

- i. Import permit issued by RPB

6.2.11 Veterinary Medicines Directorate (VMD)

6.2.11.1 Products Regulated by (VMD)

No.	HS Code	Product Description
1.		Animal Medicaments (excluding goods of heading 30.02, 30.05 or 30.06) consisting of two or more constituents which have been mixed together for therapeutic or prophylactic uses, not put up in measured doses or in forms or packing's for retail sale.

6.2.11.2 Documents Required for Inspection

- i. A market authorization issued by the VMD
- ii. Valid Exporter Market Authorization Dealer License issued by VMD
- iii. Exporter's Valid Import License issued by VMD
- iv. Licensed Local Technical Representative, if the exporter has no physical presence in Kenya



7.0 HANDLING THE GOODS AT THE PORT OF ENTRY

- 7.1 The partner government agencies will still continue to discharge their respective mandates regarding imported goods which they regulate
- 7.2 CoC/NCR data will be shared to the respective agencies through Single Window
- 7.3 KEBS shall **Conditionally Release** consignments regulated by Partner Government Agencies to allow for post-release activities and post-market surveillance control measures in line with the respective PGA's legal and statutory obligations.