



SADC MODEL TECHNICAL REGULATION FOR FROZEN FISH AND FISHERY PRODUCTS AND PRODUCTS DERIVED THEREFROM

SCOPE

1. This technical regulation applies to the handling, manufacture, production, processing, treatment, storing, distribution, transportation and retailing of frozen fish and fishery products and products derived therefrom that are intended for human consumption.

DEFINITION

2. In this regulation, unless the context otherwise requires
 - 2.1. **Accredited facilities:** means a laboratory that has a formal recognition from an accreditation body that, the laboratory is competent and have the necessary infrastructure/ facilities to performed the specified tests and fully comply/ies to the requirements of ISO 17025.
 - 2.2. **Fish and Fishery products:** means any seawater, fresh water organisms or aquatic animals, whether from the wild or farmed:
 - 2.2.1. excluding mammals, reptiles and frogs; and
 - 2.2.2. including mollusc, crustaceans, bivalves, all edible forms, parts and products of such animals

- 2.2.3. including processed, unprocessed or any edible form of fish and includes any products derived from fish intended for human consumption.
- 2.3. **Food business operator:** means a handler, processor, packer, transporter, importer, exporter established within the member state applying for approval of a factory / facility and/or product which is to be processed/exported/imported/ in/to member state.
- 2.4. **Member State Regulatory Authority:** means a regulatory body/competent authority responsible for conducting official inspections and issuing of health certificates for products, appointed/delegated/mandated by government of the member state in the exporting country.
- 2.5. **Production batch number:** means numbers(s), letter(s) or marking(s) or any combination of these in addition to the code representing a particular time on the date of canning, which may indicate a line of production or a particular catch or harvest or delivery of the raw material
- 2.6. **Consignment:** means a quantity of fish or fish product covered by the same health certificate, conveyed by the same means of transport and coming from the same country.

3. ADMINISTRATIVE REQUIREMENTS

- 3.1. All frozen fish and fishery products and product derived therefrom to be offered for sale, shall comply with the requirements of this technical regulations.
- 3.2. The factory/processing facility for the production for canned fish and fishery products derived therefrom, shall be pre-approved by the Member State Regulatory Authority for conformity of production requirements as prescribed in Annex A - A.1. A certificate of approval for the facility shall be issued by the Member State Regulatory Authority. Such approval shall be reviewed annually, or more frequently as may be determined by the Member State Regulatory Authority. For any other new products that were not part of the initial annual approval of the facility, the facility shall apply immediately to add new product/product ranges to the overall approved list.
- 3.3. The factory / establishment shall not dispatch frozen fish and fishery products and products derived therefrom without a valid Member State Regulatory Authority approvals document for the factory / establishment: Provided that in the case of locally produced products originating from the Member State Regulatory Authority approved facilities, a consignment may be released into the trade without the Member State Regulatory Authority pre-inspection.
- 3.4. An importer shall make an application for official inspection and approval of the product(s) to the Importing Member State Regulatory Authority for every consignment of canned fish and fishery products and product derived therefrom which are to be imported into the Member State, in accordance with the requirements of Annex A - A.2.
- 3.5. Application for approval required for export or any other purposes as required by the applicant, shall be made in accordance with the requirements of Annex A - A.3.

- 3.6. The factory/processing facility shall provide the Member State Regulatory Authority with satisfactory evidence of conformity of production upon request.
- 3.7. The factory/processing facility shall inform the Member State Regulatory Authority in writing of any change in process of production affecting any mandatory requirement of this regulation. In the event of such change/s the Member State Regulatory Authority may, at its discretion, demand the submission of fresh evidence of conformity, or a new application for approval.
- 3.8. The factory/processing facility shall immediately report to the Member State Regulatory Authority in writing of any failure, of whatever nature, to conform to the requirements of this technical regulation.
- 3.9. Approval granted by the Member State Regulatory Authority to a factory/processing facilities in accordance with section 1.2 of this technical regulation, **[may be]** suspended and/or ultimately withdrawn upon detection of non-compliance to the provisions of this technical regulation or if the applicant fails to re-apply as required. Reasons of such suspension or withdrawal will be provided to the applicant in writing and the facility shall not sell the identified products. No new batch (es)/production(s) shall be produced after the suspension of the facility, until new approval is granted by the Member State Regulatory Authority or corrective actions are concluded.
- 3.10. A factory/processing facility whose approval has been suspended, must re-apply to the Member State Regulatory Authority in writing within three (3) months of the date of suspension for a reassessment, otherwise approval for the establishment to operate in terms of this technical regulation will be withdrawn.
- 3.11. A factory/processing facility shall, three (3) months before the effective date, notify the Member State Regulatory Authority in writing when its operation is closing down.

- 3.12. Frozen fish, and fishery products and products derived therefrom by the Regulatory Authority shall be subjected to microbiological and chemical testing, as per the requirement of the technical regulation, using tests methods that are accredited or any other method validated against the reference method, and giving results that are better, or at least equal, to the accuracy of the reference method.
- 3.13. In the case where there are no test facilities available in the Member State that are in compliance with the foregoing, the Member State Regulatory Authority shall arrange for test facilities with appropriate accredited test methods within Member States to confirm compliance of the products.
- 3.14. The testing of frozen fish and fishery products and products derived therefrom against the requirements of this technical regulation shall be done by microbiological and chemical test methods that are accredited. that are accredited to use the referenced test methods or any other accredited method validated against the reference method, and giving results that are better, or at least equal, to the accuracy of the reference method. In the case where there are no test facilities available in the Member State that are in compliance with the foregoing, the Member State Regulatory Authority shall determine which facilities may be used in terms of its Conformity Assessment Policy.
- 3.15. The Member State Regulatory Authority shall issue health certificate for export purposes, where required, in accordance with the requirements of the country of destination as prescribed in Annex B. The Member State Regulatory Authority may for the purposes of inspection and verification of products, sample products according to the regulatory risk based sampling plans.

- 3.16. There will be fees applicable as prescribed in the regulation of the Member State, guided by the relevant legislation.

4. TECHNICAL REQUIREMENTS

- 4.1. The manufacture, production, processing and treatment of frozen fish and fishery products and product derived therefrom shall comply with the technical specifications as laid out in the current National Legislation or latest CODEX Code of Practice/Guideline/Standards and/or latest SADCSTAN Harmonized Texts in terms of (a) personnel, (b) facilities, (c) processing, (d) raw materials, (e) final products, (f) additives, (g) microbiological and chemical limits, (h) packaging, labelling and marking and, and (i) contaminants.¹
- 4.2. Manufacturers shall implement and maintain an acceptable Food Safety & Quality Management system such as the HACCP System as recommended by the Codex Alimentarius Commission.
- 4.3. All local raw molluscan shellfish for processing shall be obtained from a source that has a valid permit from responsible Minister/Ministry of Trade to either harvest, grow, process or supply molluscan shellfish.
- 4.4. In the event of an amendment or revision of the current National Legislation or latest CODEX Code of Practice/Guideline/Standards and/or latest SADCSTAN Harmonized Texts, the factory / processing facility shall be in compliance with the amended or revised requirements within six (6) months of publication of the amended or revised standard, unless otherwise declared by a special notice by the responsible government department/ministry. If evidence of compliance to such amendments or revisions cannot be provided, the approval of the factory / processing facility may be withdrawn.

¹ Member States that does not have technical specifications may adopt CODEX/ SADCSTAN or standards in another member state.

Note: The required World Trade Organization (WTO) transparency provision will also be considered in this period.

ANNEX A

(Normative)

A.1 APPLICATION FOR APPROVAL OF A FACILITY AND PRODUCT IN THE MEMBER STATE

The fish business operator shall apply to the Member State Regulatory Authority for approval of the factory / processing facility. Approval of a factory / processing facility shall be valid for a maximum period of one (1) year. The applicant shall reapply for approval annually.

The application shall be accompanied by the following:

- A.1.1** Details of the factory / processing facility for which approval is sought;
- A.1.2** Documentation and records in support of an effective food safety management system and procedures, based on HACCP principles. For new or remodelled factory/processing facilities, provisional approval may be given for a period of three months, in order to generate the required documentation and records;
- A.1.3** Information required by the Member State Regulatory Authority for the measures taken by the fish business operator to ensure ongoing conformity with the requirements of this Technical Regulation;
- A.1.4** Any reasonable additional information to clarify the application as requested by the Technical Regulation and
- A1.5** The Technical Regulation shall issue an official factory / processing facility number on approval of the factory / processing facility.

A.2 APPLICATION FOR APPROVAL OF IMPORTED PRODUCTS

The importer shall apply to the nearest Member State Regulatory Authority regional office as soon as the consignment is available for sampling and inspection and subsequent approval of the (imported) product (s). The importer shall notify the Member State Regulatory Authority before arrival of the consignment.

A.2.1 Applicants shall supply details of the products per consignment for which inspection and approval is sought, by providing the following:

- a)** The applicable permits as required by Member State (including OIE Directives);
- b)** A health certificate (Annex C) containing evidence that imported products originate from a facility approved for export in the country of origin per consignment, for which approval is sought. The Member State Regulatory Authority may also request that specific testing be performed;
- c)** Details of the imported product, bill of entry number (Customs release), quantity, batch codes and number of product per batch code(s), code list and bill of lading;
- d)** The date and place where it will be available for inspection;
- e)** Name and contact details of a contact person;
- f)** The number(s) of the bill(s) of entry and the date authorized by Customs Officials; and
- g)** The voyage number of the cargo carrier (vessel, aircraft) or registration number of vehicle.

A.2.2 Any reasonable additional information to clarify the application as requested by the Member State Regulatory Authority.

A.2.3 The Member State Regulatory Authority may for the purposes of inspection and verification of products, sample such products according to the regulatory risk based sampling plans.

A.3 APPLICATION FOR APPROVAL OF EXPORT OF PRODUCTS

The exporter/fish business operator shall apply to the nearest Member State Regulatory Authority regional office for approval of the product(s). The application shall be submitted at least 5 working days prior to the date on which it is needed.

For exportation of products whose compliance certificate is valid for a period exceeding six (6) months the application shall be lodged 14 working days prior to the time it is needed.

The application shall be accompanied by the following:

A.3.1 Where exporter/fish business operator require official approval for export or any other purposes, applicants shall supply details of products per consignment for which approval is sought, by providing information with regards to the type of approval required (e.g. certificate of compliance, health certificate to a particular country or other specific certification for official purposes);

A.3.2 The applicable permits as may be required by member state;

A.3.3 Details of the labelling and markings used on the packed product(s), as required in this technical regulation;

A.3.4 Where required by the Member State Regulatory Authority, guarantees that the product(s) complies with the prescribed testing requirements outlined in the technical regulation and referenced standards. The Member State Regulatory Authority may also request that specific testing required by the importing country be performed;

A.3.5 Any reasonable additional information to clarify the application, as requested by the Member State Regulatory Authority; and

A.3.6 The Member State Regulatory Authority may, for the purposes of inspection and verification of products, sample products according to the regulatory risk based sampling plans.

A.4 GRANTING OF APPROVAL

A.4.1 The Member State Regulatory Authority/Competent Authority shall issue an approval certificate, to the exporter/fish business operator when all the requirements of this technical regulation have been met.

A.4.2 The Member State Regulatory Authority shall assign a unique number to each approval certificate.

A.4.3 An approvals certificate shall be the sole proof of approval by the Member State Regulatory Authority.

A.5 WITHDRAWAL OF APPROVAL

A.5.1 Any approval granted in respect of canned fish and fishery products and product derived therefrom to the factory / processing facility pursuant to this technical regulation may be withdrawn if compliance with the requirements of this technical regulation have not been maintained. Re-applications will be treated as new applications.

ANNEX B

(Normative)

B.1 EXPORT HEALTH CERTIFICATE

B.1.1 The Member State Regulatory Authority may provide export health certificate to Authorities in countries to which products are exported at the request of exporters, if products have been handled, prepared, processed, packed, transported, refrigerated, stored, and quality are in accordance with the requirements of this technical regulation and/or the requirements of the country of destination. In terms of requirements, all sections of the handling and processing chain are to be in compliance and, where appropriate, random samples may be taken for inspection and verification purposes.

B.1.2 export health certificate shall only be issued for product from approved factories / establishments requiring such certificate. The application shall be submitted at least 14 working day prior to the date on which it is needed, for products approved within the last 6 months by the Member State Regulatory Authority and at least 10 working days for products approved in excess of 6 months prior.

B.1.3 The Regulatory Authority may sample and test the product(s) for the purposes of monitoring compliance and the issuance of export certificate thereof.

B.1.4 For the issuing of export health certificate, it is required that for every consignment:

- a) The product originates from factories / establishments approved by the Member State Regulatory Authority in terms of the requirements of this Technical Regulation;
- b) All products, product codes and volumes per product code are reflected in the request for export; and
- c) The product covered by such an export health certificate shall be fully traceable to its origin including the requirements as per movement document issued by the Member State's Regulatory Authority where applicable.

B.1.5 No export health certificate will be issued for foreign product landed from vessels without monitoring controls [where the anatomical wholeness has not been changed in a Member State]. [Member States to provide an alternative text. No export health certificate will be issued for product landed from vessels which has not been monitored, harvested in a disease prone area and from unauthorized fishing.]

ANNEX C

**C.1 HEALTH GUARANTEES FOR IMPORTED FISH AND FISHERY PRODUCTS
REGULATED UNDER THE MEMBER STATE'S REGULATORY SERVICES**

(ON AUTHORITY'S OFFICIAL LETTERHEAD)	Reference No: _____
Country of dispatch: _____	
Competent Authority: _____	
Inspection Authority: _____	
I. Identification of products	
True description of product: _____	
-Scientific name: _____	
-Presentation of product and type of treatment: _____	
Batch Identification Marks /Code/s	
Type and Manner of Packaging: _____	
Number of Packages/Units:	
Net weight: _____	Gross weight _____
Temperature: Chilled _____ Frozen _____ Ambient _____	
II. Origin of Products	
Name and address of approved factories/establishments/facilities	

Approval number: _____	
Place of loading/ dispatch: _____	
III. Destination of products: _____	
Country of destination: _____	
Port of entry _____	
Transport details: _____ Sea Freight / Air freight	
/Other	
Container number / Flight details: _____	
Seal number/ air waybill number: _____	
Consignor name and address: _____	
Consignee name and address:	

IV. Health attestation

The official inspector hereby certifies that:

1. The fish and fishery products and products derived therefrom specified above, have been caught, landed or farmed (where applicable), processed, packed and stored in a facility/ies approved by the Competent Authority.
2. The fish and fishery products and products derived therefrom comply/ies with the particular CODEX Standard for the specific product/s or where there is no such Standard, with the Technical Regulations legislated by the Member State in terms of the applicable National legislation/CODEX guidelines.
3. The processing plant and where applicable, aquaculture farms specified above, is/are subject to regular inspection/audit by the Competent Authority in that member state to ensure that production, processing practices and food safety systems are in compliance with requirements of the most updated versions of the general CODEX Principles for Food Hygiene and HACCP (CAC/RCP- 1969) as well as with the CODEX Code of Practice for Fishery Products (CAC/RCP 52-2003) and any animal health requirements to be controlled in terms of OIE Directives.
- 4 All products imported into the Member State in terms of this Technical Regulation shall comply with labelling and marking requirements as prescribed by the relevant National Legislations/CODEX standard for labelling of pre-packaged food.
- 5 The products above shall:
 - 5.1 Comply to microbiological spoilage test to ensure commercial sterility as prescribed by relevant national legislation/CODEX Guidelines;
 - 5.2 shall not contain any other substances in amounts that may present a hazard to human health in accordance with relevant National Legislation/ CODEX Guidelines.

Signed at: _____ **Name and qualifications of official**

Inspector _____

Signature of official Inspector:

OFFICIAL STAMP