DEPARTMENT OF TRADE AND INDUSTRY

NO. 810 **10 AUGUST 2018**

NATIONAL REGULATOR FOR COMPULSORY SPECIFICATIONS ACT (Act No. 5 of 2008), AS AMENDED THROUGH LEGAL METROLOGY ACT (Act No. 9 of 2014)

COMPULSORY SPECIFICATION FOR AQUACULTURED LIVE AND CHILLED RAW BIVALVE MOLLUSCS (VC 9107).

I, Dr. Rob Davies, Minister of Trade and Industry, under Section 13 (1) (a) of the National Regulator for Compulsory Specifications Act (Act 5 of 2008) hereby declare the Compulsory Specification as set out in the attached schedule, with effect six (6) months from the date of publication of this notice.

Dr Rob Davies, MP
Minister of Trade and Industry

SCHEDULE

VC 9107

COMPULSORY SPECIFICATION FOR AQUACULTURED LIVE AND CHILLED RAW BIVALVE MOLLUSCS

1 SCOPE

1.1. This Compulsory Specification applies to live and chilled raw aquacultured bivalves molluscan shellfish either in the round or shucked and/ cleaned for direct consumption or further processing (hereinafter referred to as bivalves).

Note: Fish Shops (over the counter sale shops), Hotels, Boarding Houses, Restaurants or Other Eating Houses, as well as entities where the core business are the transportation of goods, are excluded from the scope of this Compulsory Specification.

2 DEFINITIONS

2.1 For the purposes of this Compulsory Specification the definitions in the latest edition of the *SANS (South African National Standard) live and chilled raw bivalves molluscs: 2879* are applicable.

2.2 In addition, the following definitions shall apply:

2.2.1 applicant: a handler, processor, packer, transporter, importer or exporter applying for approval of the product and/or facility/factory/establishment. The handler, processor, packer, transporter, importer or exporter shall be established within the Republic of South Africa;

2.2.2 approval: confirmation by the NRCS that the product and/or facility/factory/ establishment satisfies the requirements of this Compulsory Specification;

2.2.3 conformity of production: evidence that the handling, preparation, processing, packing, transportation, chilling, freezing, storage and quality of live and chilled raw bivalve molluscs as in the scope, and products derived therefrom produced for sale continues to conform to the requirements of this Compulsory Specification;

2.2.4 DAFF: the Department of Agriculture, Forestry and for Marine Living Resources Act 1998 (Act No 18 of 1998), Meat Safety Act; 2000 (Act No 40 of 2000); Animal Disease Act, 1984 (Act 35 of 1984); National Environmental Management Biodiversity Act, 2004 (Act No 10 of 2004) permits;

2.2.5 facility/factory/establishment: South African based premises or processing fishing vessels where preparation and packing of live and chilled raw aquacultured bivalve molluscs harvested according to the SAMSM&CP and are handled and treated to prepare them for commercial purposes;

2.2.6 HACCP (Hazard Analysis Critical Control Point): a system which identifies, evaluates, and controls hazards that are significant to food safety;

2.2.7 NRCS: the National Regulator for Compulsory Specifications as established by the National Regulator for Compulsory Specifications Act, 2008 (Act No. 5 of 2008);

2.2.8 official facility number/code: a unique identification number or code allocated to a facility, factory or establishment by the NRCS.

2.2.9 official sampling: sampling done by an official inspector as defined in and according to the SAMSM&CP;

2.2.10 product safety management system: a management system implemented by a facility/ factory / establishment based on the principles of HACCP as recommended by the Codex Alimentarius Commission; and

2.2.11 SAMSM&CP: the most recent edition of the South African Molluscan Shellfish Monitoring and Control Programme administered by DAFF.

3 GENERAL ADMINISTRATIVE REQUIREMENTS

3.1 All live and chilled raw aquacultured bivalve molluscs as per the scope of this specification, to be offered for sale, shall comply with the requirements of this Compulsory Specification.

3.2 The facility/factory/establishment for the production of the product in the Republic of South Africa shall be pre-approved by the NRCS for conformity of production requirements as prescribed in Annex A - A.1. Such approval shall be reviewed annually or more frequently as may be determined by the NRCS.

3.3 The facility/factory/establishment as referenced in paragraph 3.2 above shall not dispatch any product covered in the scope of this specification, without a valid NRCS approvals certificate.

3.4 Application for approval of the product(s) shall be made to the NRCS for every consignment of the product covered by this specification which are imported into South Africa 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 facility/factory/establishment shall provide the NRCS with evidence of conformity of production on request.

3.7 The facility/factory/establishment shall inform the NRCS in writing of any change in the process of production affecting any mandatory requirement of this Compulsory Specification. In the event of such change/s the NRCS may, at its discretion, demand the submission of further evidence of conformity or a new application for approval.

3.8 The facility/factory/establishment shall immediately report to the NRCS in writing any failure, of whatever nature, to conform to the requirements of this Compulsory Specification.

3.9 A facility/factory/establishment which is suspended must re-apply to the NRCS in writing within three months of the date of suspension for a reassessment; otherwise approval for the establishment to operate in terms of this Compulsory Specification will be withdrawn.

3.10 A facility/factory/establishment shall notify the NRCS, in writing, when its operation is closing down three (3) months before the effective date.

3.11 The testing of product against the requirements of this Compulsory Specification, shall be done by test facilities that are accredited to use the test methods as referenced in the SAMSM&CP. In the case where there are no test facilities available that are in compliance with the foregoing, the NRCS shall determine which test facilities can be used in terms of its conformity assessment policy.

3.12 The NRCS shall issue health guarantee certificates for export purposes, where required, in accordance with the requirements of the country of destination as prescribed in Annex B.

3.13 The NRCS may for the purposes of inspection and verification of products, sample products according to the regulatory risk based sampling plans.

4 SPECIFIC REQUIREMENTS

4.1 The harvesting, handling, preparation, processing, packing, transportation, storage, chilling, quality of the products covered by this specification, the hygiene requirements for the product, as well as chemical contaminants, microbiological

contaminants, and marine biotoxins requirements of the product and the packing facility employee requirements, shall comply with the requirements of the latest edition of SANS 2879.

4.2 The principles of HACCP, as recommended by the Codex Alimentarius Commission, shall as a minimum be used for the implementation of a product safety management system.

4.3 All local live aquacultured bivalves molluscs for packing and/or processing shall be obtained from a source that has a valid permit from DAFF to harvest or supply live bivalves molluscs.

4.4 Farms shall be evaluated and approved annually by DAFF as per the requirements of the SAMSM&CP and animal health guarantees shall be issued to the NRCS. Packers shall also be issued with permits on an annual basis by the DAFF, after official approval of the facility/factory/establishment by the NRCS.

4.5 Land-based wet storage facilities shall conduct monthly microbiological testing of the live aquacultured bivalves molluscs and water against the requirements of the SAMSM&CP.

4.6 All official sampling of live aquacultured bivalves molluscs and water shall take place according to the requirements of the SAMSM&CP.

4.7 No live aquacultured bivalves molluscs shall be harvested, packed or shipped for the purpose of placing on the market for human consumption, when the live bivalves molluscs does not meet the requirements of the SAMSM&CP or when the farm is closed by DAFF.

4.8 In the event of an amendment or updating of the SANS standard referenced in 4.1 above, the facility/ factory / establishment shall be in compliance with the amended or updated requirements within six months of publication of the amended or updated standard. If evidence of compliance to such amendments or updates cannot be provided, the approval of the facility/ factory / establishment may be withdrawn.

5 MARKINGS

The products covered in this specification shall be marked in accordance with the requirements of the latest edition of SANS 2879 as applicable and as per the labelling requirements promulgated in terms of the Foodstuffs Cosmetics and Disinfectants Act (Act 54 of 1972) as amended or in compliance with the labelling requirements of the country to which it must be exported. In terms of South African produced products the official facility/ factory / establishment number issued by the NRCS in accordance with section A 1.4 of this Compulsory Specification shall be included.

ANNEX A

(Normative)

A.1 APPLICATION FOR APPROVAL OF THE FACILITY AND PRODUCT IN THE REPUBLIC OF SOUTH AFRICA

The applicant shall apply in writing to the NRCS for approval of the facility. Approval of a 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 facility for which approval is sought;

A.1.2 Documentation and records in support of an effective product safety management system. For new 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 NRCS for the measures taken by the applicant to ensure ongoing conformity with the requirements of this Compulsory Specification; and

A1.4 The NRCS shall issue an official facility number/code on approval of the facility.

A.2 APPLICATION FOR APPROVAL OF IMPORTED PRODUCTS

The applicant shall apply to the nearest NRCS regional office for approval of the product(s). The applicant shall notify the NRCS at least 10 working days prior to the date on which approval is needed. The application shall be accompanied by the following:

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

a) The applicable permits as required by DAFF (including OIE Directives);

(b) Importers shall supply a health guarantee 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 NRCS may also request that specific testing be performed;

c) Details of the importer, product, bill of entry, quantity, number of product and batch code(s), code list or 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 custom 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 NRCS.

A.2.3 The NRCS may for the purposes of inspection and verification of products, sample products according to the regulatory risk based sampling plans.

A.3 APPLICATION FOR APPROVAL OF EXPORT OF PRODUCTS

The applicant shall apply to the nearest NRCS regional office for approval of the product(s). The application shall be submitted at least one (1) working day prior to the date on which it is needed. The application shall be accompanied by the following:

A.3.1 Where applicants 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 guarantee to a particular country or other specific certification for official purposes).

A.3.2 The applicable permits as required by DAFF;

A.3.3 Details of the markings as required by clause 5 of this Compulsory Specification used on the packed product(s);

A.3.4 Where required by the NRCS, guarantees that the product(s) complies with the prescribed testing requirements outlined in the Compulsory Specifications and referenced standards. The NRCS 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 NRCS; and

A.3.6 The NRCS 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 NRCS shall issue an approvals document, as is applicable for the facility/ factory / establishment, imported products or products destined for export, to the applicant when all the requirements of this Compulsory Specification have been met.

A.4.2 The NRCS shall assign a unique number to each approvals document.

A.4.3 An approvals document shall be the sole proof of approval by the NRCS.

A.5 WITHDRAWAL OF APPROVAL

A.5.1 Any approval granted in respect of the product or the facility/ factory / establishment pursuant to this Compulsory Specification may be withdrawn, if compliance with the requirements of this Compulsory Specification has not been maintained. Re-application will be treated as new applications.

ANNEX B

(Normative)

B.1 HEALTH GUARANTEES FOR EXPORT

B.1.1 The NRCS may provide health guarantees 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 Compulsory Specification 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 Health guarantees shall only be issued for product from approved facility/ factories / establishments requiring such guarantees.

B.1.3 As required, finally prepared product/s shall be monitored on the basis of random testing and surveillance programmes.

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

a) The product originates from facility/ factories / establishments approved by the NRCS in terms of the requirements of this Compulsory Specification;

b) All products and product codes are reflected in the request for export; and

c) The product covered by such a guarantee is fully traceable to its origin as per the movement document issued by DAFF.

B.1.5 No health guarantees will be issued for foreign product where the anatomical wholeness has not been changed in South Africa.

ANNEX C

C.1 HEALTH GUARANTEES FOR IMPORTED FISH AND FISHERY PRODUCTS AND CANNED MEAT PRODUCTS REGULATED UNDER THE NRCS

(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/facility:

.....

.....

.....

Approval number: .....

Place of loading/ dispatch:.....

III. Destination of products:

County of destination: .....

Port of entry .....

Transport details:.....Sea Freight / Air freight /Other

Container number / Flight details: .....

Seal number/ 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 canned meat products specified above, have been farmed (where applicable), processed, packed and stored in a facility/ies approved by the Competent Authority.
2. The fish and fishery products and canned meat products comply/ies with the particular CODEX Standard for the specific product/s or where there is no such Standard, with the Compulsory Specifications/Technical Regulations legislated by the Republic of South Africa in terms of The National Regulator for Compulsory Specifications Act (Act No.5 of 2008) and contained and referenced in the Compulsory Specification.

3. The processing plant and where applicable, aquaculture farms specified above, is/are subject to regular inspection/audit by the Competent Authority in that country 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 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 Republic of South Africa in terms of this Regulation shall comply with marking requirements as prescribed by the relevant national legislations.
5. The products above:
   5.1. are free from microorganisms or substances originating from microorganisms in amounts as prescribed by relevant national legislation;
   5.2. shall not contain any other substances in amounts that may present a hazard to human health in accordance with relevant national legislation.

Signed at: ..... Name and qualifications of official Inspector:

.....

.....Signature of official Inspector:

.....

Official Stamp with date: