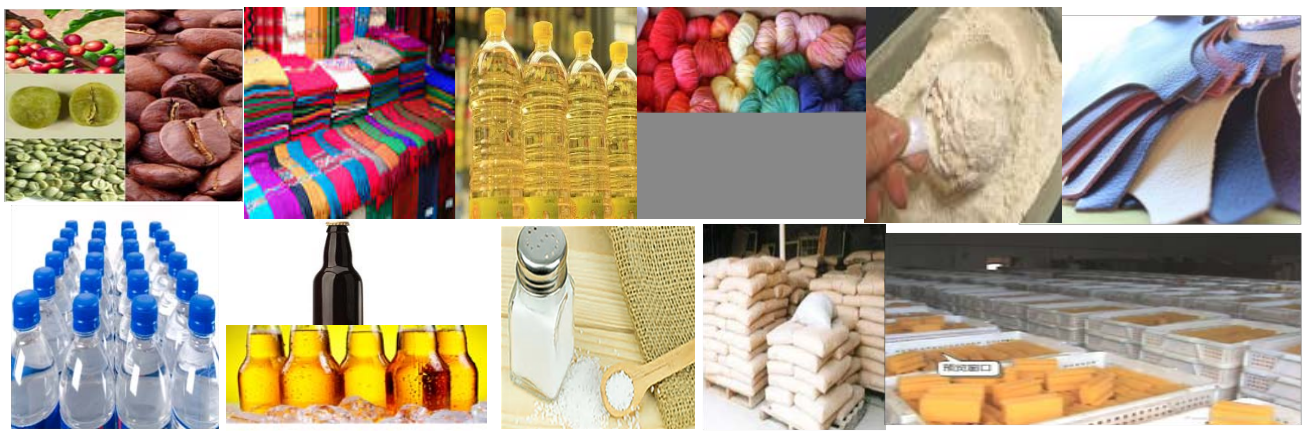
ETHIOPIAN STANDARDS

PRODUCT CERTIFICATION SCHEME FOR IODIZED EDIBLE SALT

In accordance with CES 70- Iodized edible salt -specification



CERTIFICATION SCHEME FOR IODIZED EDIBLE SALT

1 Scope

This conformity evaluation document specifies the specific requirements for the evaluation of conformity of iodized edible salt to its corresponding product standard CES 70.

This document gives technical rules for factory production control by the manufacturer, which includes testing, process control, management system and surveillances.

2 Normative references

This document incorporates by dated or undated reference, provision from other publications. These normative references are cited at the appropriate places in the text and the publications are listed here after. For dated references, subsequent amendments to or revisions of any of these publications apply to this document only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

CES 73, General standard for prepackaged foods--- labeling

ES 299, Edible salt - sampling

ES 308, Edible salt Determination of alkalinity.

ES 309, Edible salt Determination of lead content Spectroptometric method.

ES 310, Edible salt Determination of iron content 1, 10 phenanthroline spectrophotometric method.

ES 312, Edible salt Determination of copper content Zinc dibenzyldithiocarbamate photometric method.

ES 313, Edible salt Determination of iodine.

ES 391, Edible salt Determination of lead content Visual colorimetric methods.

ES 393, Edible salt Determination of arsenic content.

ES ISO 2479, Sodium chloride for industrial use Determination of matter in soluble in water or in acid & preparation of principal solution for other determinations.

ES ISO 2480, Sodium chloride for industrial use Determination of sulphate content Barium sulphate gravimetric method.

ES ISO 2481, Sodium chloride for industrial use Determination of halogens, expressed as chlorine in sodium chloridemercurimetric method.

ES ISO 2482, Sodium chloride for industrial use – Determination of calcium &magenesium content EDTA complexonetric methods.

ES ISO 2483, Sodium chloride for industrial use Determination of the loss of mass at 110 C.

ES ISO 2590, General method for the determination of arsenic Silver diethyldithiocarbamate photometric method Wfp.228072-1

ES 3394, Analysis of sodium chloride for industrial use – Method for determination of cadmum content.

ES 3395, Analysis of sodium chloride for industrial use –Method for determination of mercury content

ES ISO 9001, Quality management system

ES ISO 22000, Food safety management system

ES ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories.

Directive for the ES Mark Licensing

3 Terms, definitions and abbreviations

For the purpose of this standard definition given in CES 70 and the following definition shall apply

3.1
Declaration of conformity document

Document issued by the manufacturer under the rules of this document for the evaluation of conformity indicating that adequate confidence is provided that iodized edible salt is in conformity with CES 70

3.2.1
Declared iodized edible salt
iodized edible salt for which a declaration of conformity has been issued.

4. Requirements for the manufacturer

Requirements of the manufacturer premises , for employees includes those who have a direct involvement with the production processes which produces iodized edible salt shall comply with CES 70.

. 4.1 Requirements for the product

Permissible limit, composition and product quality factors of iodized edible salt shall comply with the requirements specified in clause 4, 5, 6, 7, 8, and 9 of CES 70.

4.2 Requirements for the iodized edible salt production control by the manufacturer.

The manufacturer shall have the permanent internal control of iodized edible salt production exercised by the manufacturer and consists of internal quality control, sampling plan and testing at the Point of receiving raw salt, intermediates and finished product.

4.3 Management system

4.3.1 Quality Manual

The manufacturer documentation shall describe the manufacturing production control and the following:

a) The quality aims;

b) Organization structure;

c) Responsibilities and powers of the management with regard to product quality;

d) The means to monitor the achievement of the required product quality;

e) The effective operation of the factory production control;

f) The manufacturing and quality control techniques, processes and systematic actions that will be used and

g) The examinations and tests that will be carried out before, during and after manufacture and the frequency with which the company will carry out.

NOTE: Manufacturers having a manufacturer production control system which complies with ES ISO 9001, ES ISO 2200 or equivalent management system fulfill the requirements in clause 6 of this document, the system shall document in their operation manual,

The operational manual shall address:

a) Procedures operated to ensure that the manufactured iodized edible salt conforms to CES 70

b) It may be referred to associate documents which provide further details sampling and internal quality control.

4.3.2 Quality policy

The Quality Manual shall include a statement by management defining its policy, objective and commitment to the attainment of product quality.

4.3.3 Management representative

The manufacturer should appoint a management representative, who irrespective of other responsibilities, should have defined authority and responsibly for ensuring that the requirements of this document for the evaluation of conformity are implemented and maintained.

4.3.4 Management review

The manufacturer shall review the factory production control at appropriate intervals as specified in the Quality Manual at least every six month in order to ensure its continuing suitability and effectiveness to meet the requirements of this document for the evaluation of conformity.

4.3.5 Personnel

The Quality Manual documentation shall describe the measures taken to ensure that all the personnel involved in operation that can affect factory production control and production quality have appropriate , qualification, experience, training and all the corresponding records shall be retained..

4.4 System of documentation

4.4.1 Document control

The management representative shall be responsible for the control of all documents and data related to factory production control and to this document for the evaluation of conformity. This control shall ensure that the current issues of appropriate documents are available at essential locations. A master list shall be

established to identify the current revision of documents in order to prevent the use of obsolete documents.

4.4.2 Quality records

The manufacturer shall retain test results, appropriate records and quality records for the period required to comply with its operational manual.

4.5 Internal quality control

4.5.1 Process control

The Quality Manual documentation shall describe:

a) Parameters for production process;

b) Validated procedures for testing other than peer accepted methods (such as methods specified in CES 70);

c) Verification methods;

d) Inspection procedures;

e) Corrective action procedures;

f) The methods/Techniques/ used by the manufacturer to ensure that the iodized edible salt produced conforms CES 70

g) Needs procedure to ensure that non-conforming product is adequately managed,

h) Dispatch with the associate records.

4.6. Measuring and testing

4.6.1 Measuring and testing equipment

The equipment used for measuring and testing shall be regularly checked and calibrated in accordance with the procedures and frequencies laid down in the operation manual. These procedures may include comparison of test results with other laboratories.

4.6.2 Inspection and test status

Procedures for the inspection and test status of the final product and for stages of manufacture shall be detailed in the operation manual.

4.6.3 Handling, storage, packaging and delivery

Handling, storage, packaging and delivery of iodized edible salt shall be in accordance with CES 70.

4.7 Sampling

Sampling of iodized salt is in accordance with ES 299.

4.8 Evaluation of test results

The manufacturer shall check that all individual test results meet the requirements of CES 70.

4.9 preventive and Corrective actions

4.9.1 Preventive action

Preventive actions are steps that are taken to remove the causes of potential nonconformities or potential situations that are undesirable.

The preventive action process is designed to prevent the occurrence of nonconformities or situations that do not yet exist. It tries to prevent occurrence by eliminating causes.

4.9.2 Corrective action

The Quality Manual shall describe procedures for the handling of non-conforming products. The action shall be recorded. In the event of a test result not conforming to the requirements of clause 4, 5, 6, 7, 8 and, 9 of CES 70, the manufacturer shall

a) Immediately determine the affected product quality and stop the production to prevent non-conforming products

b) Take appropriate action to prevent the dispatch of this quality if such iodized edible salt has been released;

c) Conduct product recall

d) Determine the cause (s) of such non-conformity;

e) Take corrective action and

f) Under take a management review of all factory production control procedures.

g) Verify if the preventive and corrective action are effective.

h) All such actions and findings shall be recorded.

4.10 Initial audits of the manufacturer and manufacturing production process control

4.10.1 Application acceptance criteria

The application is made as specified in the relevant CAB's application form

4.10.2 Application reviewing time frame

Application review time shall be as defined in CAB's criteria document /product certification procedure/.

4.10.3 Initial audit

Initial audit shall be carried out as specified in CAB's criteria document /product certification procedure/.

In the case of a new factory (a newly constructed facility or a facility previously not audited) CAB's audit team shall make a relevant audit of the factory and the factory production control in accordance with its product certification procedure.

CAB's audit team shall, among others:

a) Verify that the Quality Manual complies with the requirements of clause 6 of this document.

b) Verify that the equipment used to produce and test the iodized edible salt meets the criteria in operation manual. In the case of a new type of iodized edible salt in an existing factory CAB's audit team shall decide whether a particular audit is necessary.

4.10.4 Initial testing

4.10.4.1 Sampling

a) Sampling shall be carried out in accordance with the method specified in CES 70. The manufacturer shall permit the drawl and collection of samples from their facility for independent evaluation of the product quality by the CAB. No fee shall be levied for the same.
b) Three sets of sample per product per type shall be subjected to testing: the first set will be tested in the factory (or in the outsourcing facility) witnessed by a duly authorized CAB's representative; the second set will be tested in CAB's testing laboratory. The third set will be sealed and signed by both parties and kept by the CAB's manufacturer as reference complaint handling purpose(according to its shelf life).

c) Test sample(s) taken for independent test (CAB's laboratory) shall be packed /sealed and signed in the presence of both parties and shall be submitted to the CAB's Testing Laboratory by the CAB's representative.

d) The auditor/audit team checks the availability of testing facilities required in CES 70 / and or established outsourcing systems in the manufacturing Quality Control for adequacy.

e) The auditor/audit team verifies competence of testing personnel and the testing facility by witnessing testing of the sample in the laboratory of manufacturer.

4.10.4.2 Testing by CAB

a) The tests to be carried out in accordance with the test method specified in CES 70

b) The results of both in plant and in CAB's Testing Laboratory shall comply with the requirements of CES 70

c) If result of the test conducted by the CAB's Testing Laboratory shows non conformance with respect to the specified requirements, the provision for rejection specified in CES 70 shall apply. Retest shall be carried out on the reference sample kept by the CAB on new samples collected by CAB's representative, on which full testing shall be carried out, if necessary.

d) If the retests comply, the initial product certification audit is considered conforming to product specification. If not, the manufacturer will be advised to take corrective action.

e) CAB shall maintain records of all certification activities: application registration, documents provided by applicant, on site evaluation report, including factory test results and test reports of sample.

Note: Where CAB chooses to use test data produced by others (including supplier laboratory under certain conditions), CAB shall insure that the requirements for the suitability and competence of the party conducting the testing as specified in ISO/IEC 17025.

4.11 Reports

After initial audit has been carried out CAB shall prepare a confidential report and send this to the manufacturer in accordance with its criteria document.

4.12 Declaration of conformity

The declaration of conformity of iodized edible salt can be made by the client following the certification of the factory production control by CAB shall be in accordance with the directive for the ES Mark licensing and CES 70.

4.13 Conformity mark

The declaration of conformity entitles the client to use the conformity mark on packaging and documentation ES Mark directive used for the declaration of iodized edible salt (as specified in with the directive for the ES Mark licensing).

4.14 Action to be taken by the manufacturer in the event of non-conformity

The control of non- conforming product and the corrective action to be taken by the client are dealt with clause 6.5 of this document. These are the full responsibility of the client who shall document the procedures in the operation manual.

In the event that the results of the client's testing indicate that the requirements given in clause 4, 5, 6, 7, 8 and, 9 of CES 70 are not met, the client shall double the frequency of testing (see Table 1 and 2 of in This document) which shall be specified in its Quality Manual (including inspection, sampling , test Verification plan) until the problem is resolved.

The client shall declare and report to CAB if it is established that the product no longer complies with the requirements for the declaration of conformity statements that the product conforms to the requirements of CES 70 and the evaluation of conformity described in this document.

4.15 Surveillances

CAB shall conduct manufacturing Surveillance audit and regulatory body conduct market Surveillance audit in accordance with its surveillance audit procedure every quarter and renew the certificate every year.

4.16 Re-certification audits

CAB shall conduct re-certification audit every 3 years. A re-certification audit takes place prior to end of a certification period. The audit shall be planned in due time, in order to avoid expiration of the certificate.

Note:

• A failure to perform the re-certification audit before the expiration of the certificate results in the interruption of the certification cycle. In this case, the wording "certified since" cannot be included on the certificate.

• If a re-certification is conducted after the expiry of a certificate, Initial Audit shall be carried out.

4.17 Sample size and sampling methodology

During the initial and surveillance audit CAB's representative(s) shall take sample as specified in CES 70.

4.18 Classification of non-conformities and recommendations

4.18.1 Major non-conformities

A Major non-conformity exists when the auditor observes a regulatory violation or mandatory requirements of CES 70 failure which requires that the manufacturer:

a. Immediately interrupts production.

b. Holds products in quarantine.

c. Discontinues distribution to customers.

d. Recalls the product.

4.18.2 Minor non-conformities

A minor non-conformity exists when requirements of these evaluation criteria document requirements have been addressed but there is insufficient evidence to demonstrate that it has been properly controlled or implemented.

4.18.3 Opportunity for improvements (recommendations)

In addition to non-conformities, opportunities for improvements may be made by an auditor according to his observations, with a view to help the continuous improvement of the manufacturer's Quality Management System.

The basic requirement to identify and to record improvement opportunities is that the requirements of CES 70 and this conformity evaluation document have been fulfilled but there are still areas for potential improvement of system effectiveness and efficiency.

Opportunity for Improvement will be checked during the following regular audit. If an opportunity for improvement is not resolved and closed by then, the certificate will becomes non-conformity.

4.18.4 Consequences of non-conformities

on-conformity	Initial audit	Surveillance or Re-certification audit
Major	Certification cannot be granted until the non-conformities have been closed.	1. Certification continues 2. The client shall take the actions specified in clause 4.14 as appropriate. 3. The action plan shall be presented to the CAB, at the latest 14 calendar days after the audit date. Evidence that non-conformities have been closed will be checked 60 days after the presentation of the action plan at the latest.CAB shall check the factory within 3 days after the report has been received. If non-conformity is not resolved and closed by then, certificate will be withdrawn.
Minor	Certification cannot be granted until the non-conformities have been closed.	1. Certification continues. 2. An agreement on the action plan shall be reached between the CAB's and the manufacturer. The deadline for this agreement is 60 calendar days after the CAB has received the action plan from themanufacturer. 3. Evidence that non-conformities have been closed will be checked by the auditor, at the latest during the following audit. If

		the non-conformity is not solved and closed by then, it becomes a major non-conformity.

The auditor shall confirm that he/she has reviewed, accepted and verified the effectiveness of corrective actions.

4.19 Certification decision and certificate

4.19.1 The information provided by the auditor/audit team to the CAB, for the product certification decision, shall include, as a minimum:

a) The audit report,

b) Comments on the non-conformities and, where applicable, the corrective actions taken by the client,

c) Recommendation from the auditor on whether or not to grant the certification, together with any conditions or observations.

If sufficient evidence to demonstrate compliance with this conformity evaluation criteria document and other related requirements (such as signing of product certification agreement and service fee settlement), a certificate shall be granted. The decision to issue a certificate remains the CAB's responsibility.

4.19.2 A certificate is valid for a period of 3 years.

4.20 Sample testing frequency

The manufacturer shall determine frequency of sampling and sampling points, and conduct testing as specified in Table 4.20.1 and4.20. 2.

Table 1: Iodized edible salt chemical compositions and quality factors.

Characteristics	Iodized common salt	Iodized table salt		Test method
Sodium chloride (NaCl), % min	97	98		ES ISO 2481
Particle size	Min 93 % pass 4 mm sieve Max 20% pass 1 mm sieve	Min 99% pass 1 mm sieve Max 20 % pass 0.212 mm sieve		
Alkalinity (as Na_2CO_3), % (m/m), max	0.2	0.2		ES 308
Iodine content	**Point of production**	**Point of production**	**Retail level min.**	
as iodine mg/kg salt	20-40	30-40	20-40	ES 313
Iron (as Fe), mg/kg, max	10	10		ES 310
Matter insoluble in water % (m/m), max	0.2	0.05		ES ISO 2479
Sulphate (as SO_4), % (m/m), max	0.5	0.2		ES ISO 2480

++Calcium (water soluble), as Ca , %(m/m), max	0 .5	0.1	ES ISO 2482
++Magnesium (water soluble), as Mg , %(m/m), max	0 .5	0.1	ES ISO 2482
Loss of mass at 110 oc, % (m/m), max	3	0.5	ES ISO 2483
Organoleptic	Normal smell 10g of salt in 100ml water shall give a colorless solution having a neutral reaction	Normal smell 10g of salt in 100ml water shall give a colorless solution having a neutral reaction	Sensory

Table 2: Maximum level of anti-caking in finished product

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S.No	Anti-caking agent	Maximum level
5.2.1	Tricalcium orthophosphate	20 g/kg
5.2.2	Calcium carbonate	20 g/kg
5.2.3	Magnesium carbonate	20 g/kg
5.2.4	Magnesium oxide	20 g/kg
5.2.5	Silicon dioxide, amphorus	20 g/kg
5.2.6	Calcium silicate	20 g/kg
5.2.7	Magnesium silicate	GMP
5.2.8	Sodium aluminosilicate	GMP
5.2.9	Calcium aluminium silicate	GMP
5.2.10	Salts of myristic, palmitic or stearic acids(calcium, potassium, sodium)	GMP
5.2.11	Calcium ferrocyanide	GMP
5.2.12	Potassium ferrocyanide	10 mg/kg, singly or in combinations, as Fe (CN)6
5.2.13	Sodium ferrocyanide 2 } combination, as Fe (CN)6	10 mg/kg, singly or in combination, as Fe (CN)6

Table 3: Maximum level of contaminants

Contaminants	Maximum limits	Test method
Lead, mg/kg expressed as Pb, max	2	ES 309
Copper, mg/kg expressed as Cu, max	2	ES 312
Arsenic, mg/kg expressed as As, max	0.5	ES 393
Cadmium, mg/kg expressed as Cd, max	0.5	ES 3394 (BS 7319-6.)
Mercury, mg/kg expressed as Hg, max	0.1	ES 3395 (**BS 7319-9:1990)**

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Ethiopian Standards Agency

Organization and Objectives

The Ethiopian Standards Agency (ESA) is the national standards body of Ethiopia established in 2010 based on regulation No. 193/2010.ESA is established due to the restructuring of Quality and Standards Authority of Ethiopia (QSAE) which was established in 1998.

ESA's objectives are:-

- ❖ Develop Ethiopian standards and establish a system that enable to check whether goods and services are incompliance with the required standards,
- ❖ Facilitate the country's technology transfer through the use of standards,
- ❖ Develop national standards for local products and services so as to make them competitive in the international market.

Ethiopian Standards

The Ethiopian Standards are developed by national technical committees which are composed of different stakeholders consisting of educational Institutions, research institutes, government or organizations, certification, inspection, and testing organizations, regulatory bodies, consumer association etc. The requirements and/or recommendations contained in Ethiopian Standards are consensus based that reflects the interest of the TC representatives and also of comments received from the public and other sources. Ethiopian Standards are approved by the National Standardization Council and are kept under continuous review after publication and updated regularly to take account of latest scientific and technological changes. Orders for all Ethiopian Standards, International Standard and ASTM standards, including electronic versions, should be addressed to the Documentation and Publication Team at the Head office and Branch (Liaisons) offices. A catalogue of Ethiopian Standards is also available freely and can be accessed in from our website.

International Involvement

ESA, representing Ethiopia, is a member of the International Organization for Standardization (ISO), and Codex Alimentarius Commission (CODEX). It also maintains close working relations with the international Electro-technical Commission (IEC) and American Society for Testing and Materials (ASTM).It is a founding member of the African Regional Organization for standardization (ARSO).

More Information?
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