




ETHIOPIAN STANDARDS



FORTIFIED WHEAT FLOUR PRODUCT CERTIFICATION SCHEME




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Foreword

This product certification scheme has been prepared under the direction of the Technical Committee for Flour and Bread (TC 24) and published by the Ethiopian Standards Agency (ESA).

The scheme has been developed to address observed needs and to support the conformity assessment enterprise local industry and the regulator to ensure that the conformity assessments, producer and regulatory bodies to sustainability conduct selection, determination, review, decision on certification, attestation and surveillance activities that makes sure the product meets the requirements.

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Certification Scheme for fortified wheat flour

1. Scope

This document specifies rules and requirements for certification of fortified wheat flour intended for human consumption in order to verify conformity of the process and product with requirements specified in product standards ES 6132.

This product certification scheme specifies

- Pre-requirements; application, tractability, processing practice, testing or inspection of samples of the product from the production and dispatch centers;
- Assessment of the production processes;
- Inspection of the processing best practice
- tasks of processor, the certification body and regulator,
- Inspection procedures for the certification in accordance with fortified wheat flour standard specification and monitoring guideline for fortified products.

It also provides rules/procedures for actions to be followed in the case of non-conformity, the procedure for the certification of conformity and requirements for dispatching centers.

2. Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ES 6132, fortified wheat flour – Specification

ES ISO /IEC 17067, Conformity assessment — Fundamentals of product certification and guidelines for product certification schemes

ES 665: wheat grain- specification

ES 1052: Wheat flour –specification

ESA/PCSM/001, Product certification scheme policy manual

ES ISO 9001: Quality management system

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

ES ISO 22000, Food safety management system requirements

ES ISO guide 27, Guidelines for corrective actions to be taken by a certification body in the event of misuse of its mark of conformity


Guideline for Internal and External Monitoring of Fortified Edible Fats, Oil, Salt and Wheat Flour Directive for the ES Mark Licensing

3. Terms and definitions

For the purposes of this document, the terms and definitions given in all edible oil standard,

ES ISO 17000 and the following shall apply:-

3.1.

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certification scheme

Certification system as related to specified products, processes or services to which the same particular standards and rules, and the same procedure. apply. [ISO/IEC Guide 2]

3.2.

certification body

Body that conducts certification of conformity. [ISO/IEC Guide 2]

3.3.

characteristic value

Value having a prescribed probability of not being attained in a hypothetical unlimited test series.

3.4.

inspection:

activities such as measuring, examining, testing, gauging one or more characteristics of a product or service and comparing these with specified requirements to determine conformity. [ES ISO 17000]

3.5.

inspection body (for certification)

Body that performs inspection services on behalf of a certification body. [ISO/IEC Guide 2]


3.6.

fortified wheat flour

wheat flour to which nutrients (such as iron, folic acid, zinc and B vitamins) have been added in accordance with the standard.[ES 6132]

4. General requirements

- 4.1. This product certification scheme shall involve activities of Selection, Determination of characteristics, Review, Decision on certification, Attestation and surveillance
- 4.2. The processor and certification body shall full fill the general requirement specified in Policy manual PCM 001-Annex 2.
- 4.3. The products and the raw materials considered in this certification scheme shall fulfill the requirements stated in respective product standards(ES 6132, ES 665 and 1052)
- 4.4. Certification and other conformity assessment bodies conducting product certification for product certification scheme shall fulfill the requirements specified in ES ISO/IEC17065 and product certification scheme procedures ESA/PCP/005.
- 4.5. The processor's scope of certification shall be appropriate to the nature and scale of its activities, products and services and impacts from them.
- 4.6. The processor/producer shall ensure quality, safety and hygiene of processes and products in addition to other legal requirements.
- 4.7. The processors shall full fill the document requirement specified in PCM 001.

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4.8. The processor/producer shall perform an initial review of processes, products and services within the defined scope before application for certification.

4.9. The processor/producer shall maintain

- a) The quality aims (objectives) and the organizational structure, responsibilities and authorities of the management with regard to product quality and the means to monitor the achievement of the required product quality and the effective operation of the internal quality control.
- b) The source and quality of premixes, processing, safety and quality control techniques, and systematic actions that will be used.
- c) The inspections and tests that will be carried out before, during and post production/processing (storage and distribution) and the frequency of inspection and testing activities.

4.10. Internal audits and management review

In order to ensure the continuing suitability and effectiveness of the requirements of this certification scheme, the processor/producer shall perform internal audit and management review at least once a year.

- a) The Internal audit shall cover the scope of this certification scheme.
- b) A management review shall take into account the records of the internal audits.

4.11. Personnel

4.11.1. All the personnel involved in operations that can affect internal quality control and product quality and safety shall have appropriate relevant educational level and field, experience and trainings. Moreover, relevant records with respect to the competency of the experts shall be retained.

4.11.2. The processor/ producer shall provide training to personnel involved in the production process to ensure sustainable quality and safety of the product.

4.12. Documents and records for quality control

4.12.1. The processor shall establish documented procedures/manual and appropriate test methods to ensure that the wheat flour and fortified wheat flour meet the requirements of product specification and establish suitable critical control points to ensure effective and sustainable process control measure.


4.12.2. The processor shall retain certificate of analysis for each premixes used from internationally recognized authorities

4.12.3. The procedure/manual shall describe the methods used by the processor to ensure that the product conforms to the product specification, including appropriate test methods.

4.12.4. The processor shall retain quality and safety records for at least the period equivalent to the shelf life of the products.

4.12.5. The procedure/manual shall describe:

- a)Parameters for production process and premixes source and quality;

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- b) Validated procedures for testing other than test methods specified in the product standards (if any);
- c) Verification methods;
- d) Inspection procedures;
- e) Corrective action procedures;
- f) The process control used by the processor to ensure that the product conforms the product standards
- g) Procedure to ensure that non-conforming product is adequately managed,
- h) Records of dispatch
- i) Compliant handling procedure

5. Identification/Selection

5.1. General

5.1.1. The certification body shall obtain all the necessary information to complete the certification process in accordance with this certification scheme. The application is made as specified in the relevant CB's application form. The application is made on a prescribed form obtainable from the CB on request or can be downloaded from CB's website.

5.1.2. The certification body or conformity assessment body shall follow the requirement of application and application acceptance criteria specified in PCM/001/ Annex 2.

5.1.3. During application the processor/producer/ supplier shall fulfill the requirement specified in PCM/001/ Annex 2.

5.2. Application

5.2.1. CB or scheme owner shall provide the applicant with all information necessary to understand and follow the rules of this certification scheme and ESA/PCM/001.

5.2.2. During application the processor or supplier shall provide certificate of analysis for the premixes used and necessary documents that show legibility of the processor/producer to process the product/s.

5.2.3. For batch production of fortified wheat flour, the processor shall apply for certification two weeks before the commencement of processing/production.

5.3. Application Review


The application shall be reviewed based on the requirements specified on ESA/PCM/001.

5.4. Verification

The conformity assessment body reserves the right to verify the authenticity of any documents of certification submitted by an applicant accordingly.

5.5. Conformance/Compliance

Before making application, and on an ongoing basis, the applicant shall ensure that it meets the requirements of this product certification scheme according to ESA/PCM/001: Annex 2.

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5.6. A signed certification agreement should be concluded before commencing the certification process, covering the product range requiring certification.

5.7. Registration

An organization that intends to be certified on fortified wheat flour shall complete the registration process with the conformity assessment body according to ESA/PCM/001.

6. Determination

6.1. Determination shall be conducted to ensure that the processor has the capability and resources to process/produce fortified wheat flour in accordance with the requirements specified in the respective product standards.

6.2. Determination for this certification scheme shall include

- a) Verification of certificate of analysis for the fortificant(internationally recognized certificate)
- b) Inspection of the process/production condition
- c) Testing of wheat flour and fortified wheat flour


6.3. Inspection

6.3.1. General

- a) The inspection tasks include assessment and acceptance of the factory production control operated by the processor.
- b) Inspection shall include checking that any major change in the production procedure/manual which is relevant to the factory production control of fortified wheat flour has been reported to the certification body by the producer within one month of its implementation.
- c) Inspection of the production conditions shall include the following:
 - i. the competence of the personnel and satisfactory organization of the work;
 - ii. the adequacy of the equipment for production/processing;
 - iii. independence of the department responsible for quality assurance from the production department;
 - iv. the suitability of the test equipment for internal testing;
 - v. The ability of the processor quality and safety system to ensure the quality and safety of the products.
 - vi. Inspection report that shall include an evaluation of the activities from mixing to dispatch of product.

d) Internal inspection by the producer/processor

Continuous internal inspection for continuous production by the processor is intended to ensure that the level of quality remains satisfactory with time and that, in the case of test results which do not conform to the conditions, necessary measures can be taken to improve production. Internal inspection consists of mainly:

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- i. Verification of the wheat grain, wheat flour and fortificant quality
- ii. Verification of the use of the right fortificant Verification of the quality, traceability or origin of certificate of fortificant.
- iii. Assessment of the production process
- iv. Assessment of storage condition.

6.3.2. Initial inspection of the factory

6.3.2.1. Inspection of a new factory/processor

In the case of a new factory/processor; an initial inspection of the factory and the factory production control shall be made. The inspection shall, among other things include:

- a) Production/processing are done according to the production procedure/ manual.
- b) Verify that the production procedure/ manual comply with the requirements of product standard and the certification scheme.
- c) Verify that the equipment used to produce and test the product meets the criteria in this document.
- d) Verification of handling, storage and packaging of the fortified wheat flour based on the product standard

6.3.2.2. Inspection of an existing factory

In case of existing factory, information on any significant changes concerning the factory production control and the equipment shall be considered. Any major change in the production procedure/manual shall be inspected to verify that it meets the relevant criteria of the certification scheme. Inspection shall include


- a) All properties specified in the product standard subjected to internal inspection shall be tested.
- b) The test specimens shall be taken from the point of production and storage area.
- c) Sufficient number of tests shall be done to assure assessment.

6.3.3. Handling, storage and packaging

The production procedure/manual shall describe the precautions taken for the protection of the quality of the fortificant and fortified wheat flour final product and other while under the responsibility of the processor. It shall include:

- a description of the procedures used at the warehouse,
- Guiding label on the packed product that shall allow the safe handling of the products.
- Handling, storage and packaging of the fortified wheat flour final product shall be done in accordance with the requirement in the product standards.

6.3.4. inspection period

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The inspections shall normally be carried out whenever there is production and the processor/producer shall inform in advance before the commencement of production/processing.

6.3.5. Reports

- a) Following each inspection, a confidential report shall be prepared and sent to the processor.
- b) The certification body shall consult, if appropriate; the processor before corrective action is taken.
- c) The certification body and the processor shall have consultation before decision is made by either of them. The certification body shall then make a decision on its final assessment.

Note: consultation should be considered as exchange of information to resolve issues in relation to non conformities observed

6.4. Testing

The purpose of suitability testing is to determine the capacity of the processor/producer to produce fortified wheat flour that complies with the requirements of the respective product standard.

6.4.1. Extent of testing

- a) Testing shall be done for each of the requirement specified in the product standards.
- b) The quality of wheat flour, premixes and fortified wheat flour shall be checked according to the requirement specified in respective product standards.
- c) Verification of compliance of fortified wheat flour, premixes and wheat flour to the respective product standard
- d) The test shall cover the entire range of product type and volumes for which certification is applied
- e) The fortificant/premixes' quality shall be checked based on the document from the source.

6.5. Sampling

6.5.1. The Samples shall be taken under the responsibility of the certification body at the point(s) of release of the wheat flour and fortified wheat flour or warehouses of the factory.

6.5.2. The number of samples taken shall be done according to ES ISO 24333.

6.5.3. Sampling process shall comply with the requirements specified in ESA/PCM/001


6.6. Verification of the long-term quality level

6.6.1. Extent of testing

In order to verify the long-term quality level the producer shall ensure the quality, safety and proper storage of fortificant/premixes and products.

6.6.2. Verification of long term quality

- a) Verification of the quality and safety of fortified wheat flour and fortificant and inspection of storage condition shall be documented.
- b) If satisfactory result is not achieved in one stage all verification stages of quality and safety of

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product shall be repeated if appropriate.

6.6.3. Testing shall apply separately for each batch and each production method.

6.6.4. Approval

Once the test results have been evaluated positively by the certification body, a license is issued to the producer. And the permission of the use of national standard mark shall be provided according to Directive for the ES Mark Licensing.

6.7. Assessment of processes

6.7.1. Criteria for the assessment of laboratories

- a) The laboratory responsible for carrying out internal testing should have at least the equipment needed to carry out tests for the properties listed in the fortified wheat flour standard requirement using the test methods specified in the respective standard.
- b) The laboratories should demonstrate the ability to provide results within a time and in a manner suitable for the processor's factory production control.

Note: the processor/ producer can outsource testing of products


6.7.2. Criteria for the assessment of the production equipment

The inspection shall assess the suitability of the production equipment, transport and storage of premixes in relation to the procedure/manual and in relation to providing the ability to meet the requirements of ES 6132. The following criteria shall be considered:

- a. The use of equipments to protect constituents against contamination described in the ES 6132 within the factory.
- b. All Equipment shall be suitable for continuous mass production.
- c. Measures to be taken to prevent the mixing of different ingredient and premixes.
- d. Each bag of wheat flour shall be stored in one or more separate warehouse, protected to prevent contamination and deterioration. The stores /warehouses/ may include or take the form of fully cleaned and managed. Warehouses or stores /discharge points shall be clearly marked with an indication of the premix and fortified wheat flour batch number and any additional identification required.
- e. Points where the product is released from the factory and/or depot shall allow samples to be taken in accordance with the methods in ES ISO 24333.

6.8. Measuring

The equipment used for measuring and testing shall be regularly checked and calibrated in accordance with the procedures and frequencies laid down in the operational manual. These procedures may include comparison of test results with other laboratories (external quality assurance). The test shall be conducted according to the test method specified in respective fortified wheat flour standard.

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6.9. Review

Review of the inspection and test results shall be done according to ESA/PCM/001.

6.10. Auditing

6.10.1. Initial audit, surveillance audit and Re-certification audit shall be done based on ESA/PCM/001

6.10.2. Re-certification audit shall be conducted at the end of the previous certification period.

Note: the certification period/ duration shall be determined by the certification body based on the nature of production (premixes used, nature of producer, batch)

6.10.3. A re-certification audit takes place prior to end of a certification period for continues production.

The audit shall be planned in due time, in order to avoid expiration of the certificate.

6.10.4. Re-certification audit shall not be applicable to batch production

6.10.5. A failure to perform the re-certification audit for continues production 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.

7. Control of non conforming products

7.1. The procedure/manual shall contain non conforming product handling procedures or any means that shows how to manage non conforming product(s).

7.2. Corrective action

7.2.1. The procedure/manual shall include procedures followed for the review and adjustment of the factory production control in case of non-conformity.

7.2.2. The processor shall take corrections to non-conforming fortified wheat flour and the premixes used.

7.2.3. The processor shall identify the route cause and take corrective actions to control non-conforming fortified wheat flour and the premixes used.

7.2.4. The processor shall document corrective actions taken in accordance of the procedure/manual.


7.2.5. The actions which are taken in the case of non-conformity shall be recorded in a report subject to inspection during the management review.

7.2.6. In the case of test results which show not conforming to the single result limit value conformity criteria specified in respective fortified wheat flour standard product specification, the processor or supplier shall immediately determine the affected quantity, take appropriate action to prevent the dispatch of this quantity and inform the affected customer if such product has been released.

7.2.7. The certification body shall follow the guideline specified in ES ISO Guide 27 to take corrective actions on non conforming product in misuse of mark of conformity.

7.2.8. The certification body shall inform formally the manufacturer on non conformity to take corrective actions

7.2.9. If the manufacturer do not take corrective action with due time, the certification body withdraw or suspend the certificate.

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7.2.10. In case of withdrawal of certification due to non conformity the certification body shall formally inform the regulatory body and the scheme owner within two weeks.

8. Decision on certification


- 8.1.** The certification body shall grant, maintain, extend, reduce, suspend or withdraw certification based on the testing and inspection results.
- 8.2.** If the certification body granted certification for fortified wheat flour, the following information shall be included on certificate of conformity:
- a. Name of the product/scope
 - b. The type of fortificant/premixes used
 - c. The name and address of the processor/producer
 - d. The name and address of the certification body which certifies the factory production control.
 - e. The standard designation of the fortified wheat according to respective standard (Labeling and marking shall be as specified in the product specification).
 - f. Statements 'fortified wheat flour conforms to requirement of respective standard'
 - g. The date of issue and validation of the certificate
 - h. For batch production volume of the product
 - i. The certification number applicable to the processor/producer.
- 8.3.** The certificate shall be valid for the time determined by the certification body.
- 8.4.** Permission of the use of national standard mark / shall be provided according to Directive for the ES Mark Licensing
- 8.5.** The CB shall announce the certified processor/producer and product to the scheme owner and the public through accessible media.
- 8.6.** The processor/producer shall use the certification on the products as a reference based on the ESA/PCM/001 and ES Mark Licensing directive.

9. Surveillance

Surveillance should allow for the choice between periodically taking samples of the product either from the point of production, or from the market, or from both, and subjecting them to determination activities to check that items produced subsequent to the initial attestation fulfill the specified requirements.

9.1. testing or inspection of samples from the open market

- 9.1.1.** the certification body shall take samples of the certified product randomly from the market and test conformance of the product with the requirements of this scheme and respective product standard
- 9.1.2.** If any non-conformity on the product observed during testing the certification body shall take corrective action in due time following clause 7 of this scheme.
- 9.1.3.** The scheme owner shall monitor the implementation of certification scheme and product standard
- 9.1.4.** The scheme owner shall report any non-conformity observed during surveillance of the product to the certification body and the regulator and follow the corrective actions taken

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9.2. testing or inspection of samples from the factory

CB shall conduct factory Surveillance audit in accordance with its surveillance audit procedure and shall be conducted with a time specified by the certification body. The representative samples shall be taken in each surveillance period.

9.3. assessment of the production or the operation of the process

9.3.1. the certification body shall assess and evaluate overall production process, personnel involved, storage and handling of the products based on the certification scheme and product standard

10. Standard mark

The declaration of conformity entitles the processor to use the standard mark on packaging and documentation used for the declared product (where it is required) and the documentation.

11. Compliant handling

- 11.1. The certification body and scheme owner shall handle any compliant in relation to certification based on ESA/PCM/001
- 11.2. Appeals against the decision of the certification body and complaints about the certification body should be addressed to the certification body in the first instance.
- 11.3. Appeals and complaints that have not been, or cannot be, resolved by the certification body can be addressed to the scheme owner.
- 11.4. The processor/producer shall develop complaints handling procedure and record and maintain any complains
- 11.5. The certification body shall evaluate and verify records of complaint and actions taken

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 1970.

ESA's objectives are:-

- ❖ Develop Ethiopian standards and establish a system that enable to check whether goods and services are in compliance 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 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.

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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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