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### **Ethiopia**

# **Food and Agricultural Import Regulations and Standards Report**

### **FAIRS Annual Country Report**

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#### **Report Highlights:**

This report discusses regulatory requirements and standards that must be fulfilled to export food and agricultural products to Ethiopia. Pertinent information on applicable laws, directives, guidelines, procedures, and key regulatory contact details is included. It is recommended that this report be read with the FAIRS Export Certificate Report for a comprehensive understanding of the import regulatory requirements and standards.

#### **Section I: General Food Laws**

The Government of Ethiopia (GOE) is undergoing various reforms and economic liberalizations. Over the past five years, the GOE has been in the process of updating and modernizing the country's food safety, animal and plant health regulatory systems. This ongoing and evolving modernization process is in part attributed to the nation's fast-paced, export-oriented economic growth, which has spurred a rising number of retail and wholesale food outlets, restaurants, and food manufacturers, especially in and around the capital city, Addis Ababa. The GOE has subsequently taken steps to regulate these establishments to ensure the food they produce, distribute or sell comply with food safety and quality requirements.

Another key driver underpinning this modernization effort, is the GOE's interest in boosting agricultural exports, like coffee, sesame, and livestock products, in order to grow the economy and generate much needed foreign exchange. In particular, the GOE recognizes that to export these products abroad that the country needs a reliable food safety system in place to meet the demands of foreign buyers in Europe, Asia and North America. At the same time, the country's economic growth has resulted in increased demand for imported food and agricultural products. The GOE is regulating these imports to ensure their safety and quality.

Despite this modernization, there are still major capacity-related gaps, including a shortage of qualified technical staff and insufficient laboratory capacity, which in turn limits the country's ability to enforce food safety regulations. The GOE is trying to tackle these issues through awareness creation programs, both inside and outside the government, on the importance of food safety.

Broadly speaking, the country's food safety regulatory system is authorized and mandated in Parliamentary Proclamation – Ethiopian Food, Medicine and Healthcare Administration and Control Authority Proclamation No. 661/2009. This legislation provided the legal authorities for the government to consolidate the pre-existing food regulatory system with the aim of better 'protect[ing] the public from health risks emerging out of unsafe and poor quality food.' In particular, the Proclamation authorizes the setting of standards and regulations for locally-produced and imported foods, in areas such as production, promotion, storage, packaging and labeling, distribution, and laboratory testing.

In a subsequent Parliamentary Proclamation – Ethiopian Food, Medicine and Healthcare Administration and Control Authority Regulation No. 189/2010 – the Food, Medicine, Healthcare and Control Authority (FMHACA) was established, under the purview of the Ministry of Health, as the competent authority responsible for setting and enforcing food safety standards and regulations. Under this proclamation, food is defined as "any raw, semi-processed or processed substance for commercial purpose or to be served for the public in any way intended for human consumption that includes water and other drinks, chewing gum, supplementary food and any substance which has been used in the manufacture, preparation or treatment of food."

FMHACA was given further statutory authority to enforce and implement food safety and quality regulations as defined in the <u>Food Medicine and Healthcare Administration and Control Councils of Ministers Regulation No 299/2013</u>. This legislation states that food must be wholesome and produced in accordance with the relevant safety and quality requirements. Imported products failing to meet these standards will be returned to the country of origin or destroyed at the point of entry. For example,

products that are expired or have deteriorated in quality may be seized and returned or destroyed. In a case where the offending product was detected in post-market surveillance, FMHACA has the authority to pull it from stores' shelves and destroy it. This regulation also provides broadly-defined requirements dealing with food storage, handling, and transportation, and prohibits counterfeiting and adulteration.

According to <u>news report</u>, FMHACA will undergo organizational restructuring with a renewed mandate to regulate only products related to food, medicine, tobacco, cosmetics and medical devices. A <u>draft proclamation 2018</u> billing the revised mandate of FMHACA has been sent to the Council of Ministries for deliberation and approval. The new mandate of FMHACA is expected to be similar to the US Food and Drug Administration.

FMHACA has a <u>Directive to Food Exporters</u>, <u>Importers and Wholesalers</u> to remind traders of the requirements that must be met to sell and distribute food and beverage products in the local marketplace.

In October 2018, the GOE revamped mandate of government authorities and ministerial portfolios. As a result of the new restructuring, the Ministry of Livestock and Fisheries, which was autonomous for a short while, is merged into Ministry of Agriculture and Livestock Resources (MoALR). The plant health directorate under MoAR regulates the safety of imported plant product, as authorized in the Plant Quarantine Regulation, Council of Ministers Regulation No. 4/1992. The definition of 'plants' includes living plants, plant products and seeds. Plants and other related articles must be accompanied by an import permit, a phytosanitary certificate from the competent authority from the country of origin, and are subject to quarantine inspection. Shipping containers carrying plants or plant articles must be marked with the following information: contents; origin; address of shipper, supplier, or freight forwarder; name of consignee, and entry point in Ethiopia. In cases where pests are detected in an incoming shipment, MoALR may allow the cargo to undergo treatment to destroy or inactivate the pest.

The Livestock Resources branch of the Ministry of Agriculture is responsible for quarantine and livestock disease issues. Imports of livestock, meat and by-products, and genetics require an import permit along with a health certificate from the country of origin. When applying for an import permit, the importer must identify the type of product, country of origin, means of transport, date of arrival, countries transited, and port of entry. Upon arrival, livestock, meat and by-products, as well as genetic materials will be subject to inspection. The <u>Guidelines for Import and Export of Animal Genetic Material</u> spell out the recommended procedures and requirements in greater detail.



In coordination with FMHACA and MoALR, the Ethiopian Standards Agency (ESA) develops the national food safety standards, some of which are mandatory while others are voluntary. FMHACA and these Ministries enforce the national standards that correspond to their respective jurisdictions. ESA Standards Catalogue contains a list of the voluntary standards, ranging from food microbiology to food labeling and from beans to bananas. It is important to note that health and safety aspects, such as maximum residue limits for pesticides or other contaminants that are found in voluntary standards are, in fact, mandatory and shipments must comply with these requirements. The voluntary aspect of these standards only refers to quality-related issues, such as the grade of the product.

<u>ESA Mandatory Standards</u> 'have the force of law' and are 'enforced by laws and administrative regulations'. Food products subject to specific compulsory requirements are fresh and canned fruits and vegetables, coffee (export), alcoholic and non-alcoholic beverages, edible oil, oilseeds, food additives, as well as pre-packaged foods, including baby foods.

ESA has the goal to make the national standards available online. Presently, if you want a copy of a particular standard, you must go to the ESA library, submit a request, and pay a nominal fee to obtain the copy. Alternatively, importers should be able to provide U.S. suppliers with a copy of both the voluntary and compulsory standards. Post can assist U.S. companies in obtaining copies of standards on a case-by-case basis.

As part of its standards development process, ESA consults with industry and public stakeholders to take their comments and concerns into account. In fact, ESA publishes the draft national standards online along with an open solicitation for public comments. Given this high degree of transparency, the ESA, from Post's perspective, is a model for the broader GOE in the area of open and inclusive rulemaking.

The Ministry of Trade and Industry (MoTI) is responsible for the establishment and enforcement of the legal metrological system. In coordination with FMHACA and MoALR, the ministry has the authority to control the quality of imports and to restrict entry of products that do not comply with Ethiopian standards. MoTI has issued a standing <u>notice</u> to remind importers that incoming products, including certain food items, must comply, where applicable, with ESA Mandatory Standards.



Third-party inspection bodies which have been approved by MoTI can certify the subjected products meet the national standard. Pre-certified products will clear arrival inspection without delay, though MoTI reserves the right to conduct random sampling and testing. Uncertified products will be subject to normal inspection procedures at the point of entry.

Summary of Food Control/Regulatory Bodies, Quality Infrastructure Institutes and their Responsibilities				
	Regulatory			
Gov't	Authority/Agency/			
Ministry	Directorate	Key Responsibilities		

Ministry of Health (MoH)	Food, Medicine and Healthcare Administration and Control Authority (FMHACA)	<ul> <li>FMHACA is responsible to ensure:</li> <li>Food safety and quality</li> <li>Safety, efficacy, quality and proper use of medicines</li> <li>Competence and ethics of health professionals</li> <li>The standards of health institutions and</li> <li>The hygiene and environmental health protection suitability for individuals and community health.</li> </ul>
Ministry of Trade and Industry (MoTI)	Import and Export Goods Quality Control Directorate	<ul> <li>Control quality of export and import goods</li> <li>Regulatory oversight on the importation and exportation of goods that do not comply with the Ethiopian mandatory standards.</li> </ul>
Ministry of Agriculture and Livestock Resources (MoALR)	Plant Health Regulatory Directorate	<ul> <li>Inspection of consignments of plants/other regulated articles including import and export of plants and plant products and provide import and export permits</li> <li>Inspection of required phytosanitary documents &amp; Issuance of phytosanitary certificates.</li> <li>Disinfestations/disinfections of consignments to meet phytosanitary requirements</li> <li>Supervise quarantine treatments including fumigation and weed cleaning processes.</li> <li>Advise and supervise disposal of plant and plant products</li> <li>Crop surveillance for pests- mainly cereals, fruits and vegetables</li> <li>Protection of endangered areas –maintenance and surveillance of pest-free areas/areas with low pest prevalence</li> <li>Inspection, approval and registration of pesticides</li> <li>Food safety risk assessment in different crop products including pests and pesticide application.</li> </ul>
	Animal Health Regulatory Directorate	<ul> <li>Establish a system that ensures access to quality veterinary services to improve the prevention and timely control of animal diseases.</li> <li>Quarantine on import and export of livestock, fish and their byproducts; prevent communicable livestock diseases and the outbreak of migratory parasites.</li> <li>Ensure the proper administration and quality control of veterinary drugs and feeds as well as veterinary services.</li> </ul>

	Veterinary Drug and Feed Administration and Control Authority (VDFACA)	<ul> <li>Responsible for registration and certification of feeds and veterinary drugs that are produced, imported and in use in the country.</li> <li>Setting standards for quality control activities,</li> <li>Marketing surveillance, banning, revoking and suspension of registrations, packaging and labeling, trade and licensing of veterinary drugs and animal feed</li> </ul>
	Ethiopian Standards Agency (ESA)	Establishment of national standards.
Ministry of Innovation	Ethiopian Conformity Assessment Enterprise (ECAE)	Provides certification, inspection and laboratory testing services.
and Technology	Ethiopian National Accreditation Office (ENAO)	Provide accreditation services, by formal third-party recognition, the competence of Conformity Assessment Bodies (CABs) to perform specific activities, such as tests, calibrations, certifications or inspections.
	National Metrology Institute (NMI)	Responsible for the maintenance of Ethiopian National Measurement Standards and Certified Reference Materials (CRM) and also provides calibration, training and consultancy services in the areas of metrology and scientific equipment.
	National Radiation Prevention Authority(NRPA)	Monitor and control of radiation levels in food, water, etc.
Environment, Forest, and Climate Change Commission	Biosafety Regulatory Directorate	Environmental contamination prevention and control

#### **Section II: Food Additive Regulations**

FMHACA regulates the use of additives which must comply with both international and national food safety standards. Individual food and beverage standards, where applicable, reference both permitted and prohibited additives. For example, in the case of wine, tanic acid can be used for clarification purposes, but coloring substances are prohibited with the exception of oenocyanine or caramel. In addition, there is a specific national standard for food additives.

#### **Section III: Pesticide and Other Contaminants**

The Ministry of Agriculture and Livestock Resources (MoALR) regulates and requires all pesticides to be registered prior to use. The registration process requires the applicant to provide efficacy, safety and quality data. Once registered, the pesticide can be used for up to 5 years at which time the registration may be renewed.

In addition to registration, MoALR also is responsible for establishing maximum residue limits (MRLs) and conducting pesticide residue analysis on primary agricultural products. Applicable MRLs, as well as limits for other contaminants, are listed in the individual product standards. For example, in the case of apples, there are 41 different MRLs, as well as limits for heavy metals (e.g. lead) and microbiological contaminants (e.g. coliform). Imported apples, as well as domestically-produced apples, are expected to comply with these requirements. In the event where a national standard does not exist, the GOE will likely defer to the Codex recommendation.

The MoALR's Veterinary Drug and Feed Administration Authority is responsible for setting standards related to veterinary drugs, including maximum residue limits for veterinary drugs and other related compounds. Like pesticides, veterinary drugs must be tested for safety, efficacy and quality and registered prior to use. The registration lasts for five years after which time the registration may be renewed. At present, Ethiopia is using Codex as its basis for veterinary drug MRLs.

There is a general standard for contaminants and toxins in foods. This standard, which draws upon the corresponding Codex standard (193-1995) lays out the 'principles and procedures' to manage and set acceptable tolerances for contaminants and toxins in food and feed. This standard, however, does not identify or list out contaminants and toxins of concern and their corresponding maximum levels. Instead, these are found in standards for individual commodities, where they exist.

#### **Section IV: Packaging and Container Requirements**

In accordance with the Ethiopian Food, Medicine and Healthcare Administration and Control Authority Proclamation No. 661/2009, "packaging material shall be made out of substances, which are safe and suitable for their intended use, and the product shall be packed in container which will safeguard its hygienic, safety, quality and food grade." Further, the Proclamation states that "no...packaging material shall be put into use unless it complies with the international and national safety and quality standards."

Individual product standards may also contain additional guidance and/or requirements as it relates to packaging and container requirements. As an example, the standard for canned peaches indicates packing requirements, including lacquer usage inside the can as well as can thickness.

#### **Section V: Labeling Requirements**

The following information below must be clearly and indelibly marked on the labels of pre-packaged foods in either English or Amharic. (Note: Packaged foods with a surface area less than  $10\text{cm}^2$  may be exempt from having to display some of these labeling elements.) Labels found on U.S. food products are commonly accepted.

Required Labeling Elements for Pre-packaged Foods:

- Name of the food
- Nutrition content
- List of ingredients (except for single ingredient foods) in descending order of weight
- List of minerals or vitamin supplements added to fortify foods (if needed)
- List of ingredients that may cause an allergic reaction
- Net weight or volume of contents
- Name and address of the manufacturer, packer, distributor, importer, exporter or vendor

- Country of origin
- Production and expiration dates (Note: Food products must have at least 50 percent of their shelf life remaining when they arrive at customs. Expired food cannot enter the country not can it be sold in the marketplace. Certain foods are exempt from carrying expiry dates, including fresh fruits and vegetables, wines, beverages with 10 percent alcohol by volume, vinegar and chewing gum.)
- Code identifying producing factory and lot
- Instructions for use (if needed)
- For beverages containing more than 1.2 percent alcohol, the alcohol proof is required on the label.
- GM foods must carry the label with the following statement: 'genetically modified food'.

#### **Required Labeling Elements for Raw Foods:**

- Name
- Ingredient list
- Net content
- Name and address of the producer and/or importer
- Country of origin
- Lot identification
- Expiry date or minimum useful life
- Conditions for product storage

#### **Required Labeling for Animal Genetic Materials**

GOE AAGM Import-Export guideline stipulates that importation of AAGM that includes live animal, semen, embryo, fertile egg, ova, and tissues. Importation of AAGM is allowed for specific purposes such as for commercial breeding and production, research and extension.

For importation of livestock and livestock genetic materials, GOE regulatory authority requires that OIE guidelines be strictly adhered to. This includes from labeling, production and processing, health, manpower, transportation and facility requirements.

#### Required Standards:

- Importations must fulfill the needs of the importer within the national interest
- Must be certified free of GMOs or living modified organisms (LMOs)
- Labeling and contents of transit package/letters.

Ethiopia's labeling requirement for importation of animal genetic materials such as semen, ova and embryo must contain the information below:

- Breed name.
- Donor number,
- Date of production and batch number
- Additionally, transit package and/or letter must include country of origin, species, producer company, volume per package, storage temperature and means of transportation.

## Section VI: Other Specific Standards Food Sanitation Laws/Guidelines

A special permit from FMHACA is required to manufacture, import, export or distribute genetically modified (GM) foods. GM foods must carry the label with the following statement: 'genetically modified food'.

FMHACA has issued guidance for infant formula and food supplements and requires advance product registration. Details are available in the <u>Infant and Follow-up Formula Exporters Importers and Wholesalers Directive (2014)</u> and <u>Food Supplement Directive (2016)</u>.

#### **Section VII: Facility and Product Registration Requirements**

FMHACA requires advance product registration for infant formula and food supplements. Registered facilities can be found here: Food Supplement Suppliers and Infant Formula Suppliers.

#### **Section VIII: Other Certification and Testing Requirements**

The certificates and documents listed below are generally required when shipping food and beverage products to Ethiopia. In addition to Baby formula and food supplements, FMHACA requires registration for milk and milk products, meat and meat products, poultry products, sea foods, processed vegetables, sliced fruits, nuts and their products, therapeutic foods, cereal based complementary foods, confectioneries, fats and oils, processed fruits, packed water, soft drinks, beer, iodized salt and noodles.

- Health certificate
- Certificate of conformity, including laboratory analysis, for products with compulsory standards
- Free sale certificate
- Origin certificate
- Commercial invoice
- Packing list

In addition to the abovementioned documents, shipment of grains, oilseeds, fresh fruits and vegetables require a phyto-sanitary certificate issued by the competent government authority. Similarly, livestock and livestock products require a veterinary certificate.

As noted in Section I, the Ministry of Trade and Industry has issued a standing notice to importers, informing them that all products must comply with national compulsory standards. Third-party certifiers can provide a written attestation that the shipment in question complies with the relevant Ethiopian standard(s), which will allow the cargo to enter into the country without inspection at the point of entry. Un-certified cargoes will be subject to normal inspection procedures.

#### **Section IX: Import Procedures**

The following are the general steps for importing a product into the country. Specific steps for a product that is subject to ESA compulsory standards are found in the earlier-referenced Ministry of Trade and Industry notice.

- An importer must apply for an import permit and obtain a letter of credit from an Ethiopian bank for the total value of the imports before an order can be placed.
- Bank approves letter of credit and authorizes release of foreign exchange. (Note: Because of foreign exchange shortages, it can take several months for an importer to receive the requested L/C.)
- Importer pays foreign supplier for goods.
- Customs clearance and inspection by relevant government authority at Port of Djibouti or dry port in Ethiopia. (Note: Customs clearance and inspection can take several weeks.)

#### Section X: Copyright and/or Trademark Laws

Refer to recent Country Commercial Guide's section on <u>Protection of Property Rights</u> for a complete explanation of the current IPR situation in Ethiopia. Also, Ethiopia's property rights laws, rules, regulations and treaties are available at <u>WIPO</u>.

Summary of Major Proclamations, Regulations, Directives, Guidelines for Food and Agro Products				
Food Control Proclamations and Regulation	Download Link			
Draft Proclamation of Food, Medicine and Healthcare Administration and Control Authority, 2018.	Download			
Regulation No 299/2013 of Council of Ministers: Food, Medicine and Healthcare Administration and Control Authority.	Download			
Ethiopian Food, Medicines and Health care Administration and Control Authority establishment council of Ministers Regulation No. 189/2010.	Download			
Proclamation No. 661/2009: Food, Medicine and Healthcare Administration and Control Authority.	Download			
FMHACA Directives and Guidelines				
Directive for Control of Food Exporters, Wholesalers and Importers, Dec 2017	Download			
Revised Infant Formula (Baby Food) Directive, July 2018	Download			
Infant and Follow up Formula Importers, Wholesalers and Exporters Directive, 2016	Download			
Directive for Food Supplement March 2016.	Download			
Directive for Food Manufacturing Factories Pre-Licensing Directive (Revised), June 2011.	Download			
Directive for Control of Food Advertisement, Dec 2017.	Download			

Directive for Control of Iodized Salt, August 2012.	Download
Directive on Food Retailers Licensing Criteria	<u>Download</u>
FMHACA Service Fees and Charges	<u>Download</u>
Animal Health and Import-Export Related Regulations and Guidelines	
IGAD Regional Animal Health Certification Guidelines (ICPALD)	<u>Download</u>
Regulation No. 341/2015: Regulation to Provide For Live Animals Marketing	Download
Regulation No. 272/2012: Provide for the establishment of Veterinary Drug and Feed Administration Control Authority (VDFACA)	Download
Proclamation No. 267/2002: Animal Diseases Prevention and Control	Download
Plant Health & Related Regulation	
The Plant Quarantine Regulation No. 04/1992	<u>Download</u>
Proclamation 674/2010 for the Administration and Control of Pesticides	Download

#### **APPENDIX I: Government Regulatory Key Agency Contacts**

The Ethiopian Revenue and Customs Authority (ERCA)

Director General Office Head Email: <a href="mailto:nebiyouS@revenue.gov.et">nebiyouS@revenue.gov.et</a>

Tel: 251 116629843 Addis Ababa, Ethiopia

Ministry of Agriculture and Livestock Resources (MoALR)

Plant Health Regulatory Directorate

Director General

Email: hapru.assefa2@gmail.com

Tel: +251-11 646 2311

Livestock Import Export Quarantine Directorate

Email: wondimagegn.dejene@gmail.com

Addis Ababa, Ethiopia

#### Ethiopian Food, Medicine and Healthcare Administration and Control Authority (FMHACA)

Director General

Email: regulatory@fmhaca.gov.et

Tel: +251-11-552-41-20 Addis Ababa, Ethiopia

#### Ethiopian Standards Agency (ESA)

Director General

Email: endalewm@ethiostandards.org; info@ethiostandards.org

Tel: +251 11 -6- 460881 Addis Ababa, Ethiopia

#### Ethiopian Conformity Assessment Enterprise (ECAE)

**Director General** 

Email: teshale.belihu@eca-e.com

Tel: +251-11 646 0569; 251-11 896 2002

Addis Ababa, Ethiopia

#### Ethiopian Intellectual Property Office (EIPO)

Office of the Director General Addis Ababa, Ethiopia E-mail: eipo@ethionet.et Tel: +251 11 558 63 93

Addis Ababa, Ethiopia

#### **APPENDIX II: Other Import Specialist Technical Contacts**

Third party inspection companies for food and agricultural products falling under the list of Mandatory Ethiopian Standards:

#### **SGS** – Ethiopia POC

Bole Sub City, Kebele 03, Gulf Aziz Bld, 4th Floor, Room no 402-403, Addis Ababa 1000, Ethiopia

#### **Intertek** – managed out of Nairobi office:

4F House of Vanguard Chiromo Road Consolata Church Westlands, Kenya Delivery Address Village Market PO Box 696, 00621 Nairobi, Kenya

#### info.nairobi.gs@intertek.com

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