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## **Report Highlights:**

This report presents regulatory requirements and standards that must be fulfilled to export food and agricultural products to Ethiopia. The report contains pertinent information on applicable laws, regulations, directives, guidelines, procedures, and key regulatory contact details. 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.

Fable of Contents     Executive Summary	3
Section I: Food Laws	4
Section II: Labeling Requirements	10
Differences in Nutrient Reference Values	12
Ethiopia utilizes Recommended Dietary Allowance (RDA), which are tailored to the local population's dietary patterns and health needs. These values may differ from the Reference Daily Intakes (RDIs) used the United States. For instance, a U.S. label indicating that a product provides "25 percent Daily Value of Vitamin C" might not align with Ethiopia's RDA for Vitamin C, potentially leading to misinterpretation the product's nutritional adequacy	of of
Implications for Exporters	12
Exporters of U.S. food products should be aware that using U.Sbased RDIs and health claims without adaptation to Ethiopian standards can lead to regulatory issues. To ensure compliance, it's advisable to:	12
Shelf-life / Date Marking Requirements	18
All pre-packaged foods must display a date mark, either as:	18
Country of Origin Labeling Requirements	18
How is an Exception Granted?	20
• Importers must apply to EFDA's Food Registration and Licensing Directorate (part of EFDA's Market Authorization Department).	
Importer Verification Checklist for Labeling:	20
Section III: Packaging and Container Regulations	20
Section IV: Food Additive Regulations	23
Section V: Pesticide and Contaminants	25
Section VI: Other Requirements, Regulations, and Registration Measures	27
Section VII: Other Specific Standards/Laws	35
Section VIII: Geographical Indicators, Trademarks, Brand Names, and Intellectual Property Rights	38
Section IX: Import Procedures	41
Section X: Trade Facilitation	43
APPENDIX I: Government Regulatory Key Agency Contacts	44
APENDIX II: Other Import Specialist Technical Contacts	46

# Disclaimer:

This report was prepared by the USDA/Foreign Agricultural Service, Office of Agricultural Affairs Addis Ababa, for U.S. exporters of food and agricultural commodities. While every possible care has been taken in the preparation of this report, the information provided may not be completely accurate either because policies/regulations/directives have changed since its preparation, or because clear and consistent information was not available. It is highly recommended that U.S. exporters verify the full set of import requirements with their foreign customers, who are normally best equipped to research such matters with local authorities, prior to shipment of goods. FINAL IMPORT APPROVAL OF ANY PRODUCTS IS SUBJECT TO THE IMPORTING COUNTRY'S RULES AND REGULATIONS AS INTERPRETED BY BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY.

# **Executive Summary**

Ethiopian food legislation is designed to ensure food safety, quality, and transparency across the agricultural supply chain. These laws enforce strict regulations on hygiene, labeling, packaging, and contamination control for food products. Businesses involved in food production, import, or distribution must register and comply with the food safety standards, with regular inspections conducted to ensure compliance. The regulations are aimed at protecting consumers from harmful practices.

Several key institutions are involved with regulating food safety, conducting inspections, and setting food standards to protect public health. The Ministry of Health (MoH), Ethiopian Food and Drug Authority (EFDA), Ministry of Agriculture (MoA), Ethiopian Agricultural Authority (EAA), and Ministry of Trade and Regional Integration (MoTRI) are the primary regulatory bodies. EFDA, reporting to MoH, enforces regulations on processed and semi-processed foods, including hygiene, packaging, labeling, and contamination control. The EAA regulates plant, livestock, and related product import and export. While MoTRI oversees mandatory Ethiopian standards for the import and export of agricultural goods. The Institute of Ethiopian Standards (IES) sets national standards and hosts the Ethiopian Codex Contact Point and WTO Inquiry Point. In recent years, these regulatory bodies have undergone restructuring to improve their mandates, capacity, and interagency coordination.

The Government of Ethiopian (GOE) is implementing macro-economic reforms aimed at addressing persistent challenges such as foreign currency shortages, trade deficits, and high inflation. These reforms include ongoing efforts to liberalize trade, reduce import barriers, modernize customs procedures, and attract foreign investment. Ethiopia has adopted a market-based foreign exchange system and removed a two-year import ban on select food and agricultural products. The GOE also has liberalized the export, import, wholesale, and retail trade sectors, which were previously restricted to domestic businesses. The GOE expects these reforms to attract foreign direct investment, enhance trade competitiveness, promote fair trade practices, and support Ethiopia's work towards accession to the WTO.

In August 2024, the Government of Ethiopia introduced the National Food Fortification Program, mandating the fortification of wheat flour, edible oils, and salt, with the requirement applying equally to imported products. To enhance regulatory compliance and trade facilitation, the EAA launched the Integrated Export—Import Certification System (IEICS/e-Phyto), replacing paper-based phytosanitary certificates for agricultural imports. Further strengthening oversight, the Authority's Animal Products and Inputs Quality Testing Center obtained ISO/IEC 17025:2017 accreditation in April 2025, expanding Ethiopia's capacity to test imported animal-source foods, feed, and veterinary drugs. In August 2025, Ethiopia also gazetted its tariff concession schedule under the African Continental Free Trade Area (AfCFTA), providing preferential import tariffs on eligible agricultural products. Overall, the reforms signal Ethiopia's parallel pursuit of trade liberalization and enhanced regulatory controls on food quality, safety, and nutrition.

Notable regulatory updates in the 2025 FAIRS Country Report cover Section II (labeling requirements), Section II (packaging and container regulations), Section IV (food additive regulations), Section V (pesticides and contaminants), and Section VIII (geographical indicators, trademarks, brand names, and other intellectual property rights). The report also provides updated information on import procedures and required documentation.

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

The GOE has been making reforms to modernize the country's food safety and animal and plant health regulatory systems. This modernization process is in part attributed to sustaining Ethiopia's economic growth, which has spurred a rising number of retail and wholesale food outlets, restaurants, and agrofood 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, import, distribute, or sell complies with food safety and quality requirements. A growing middle class is also driving demand for imported products.

Another key driver underpinning this modernization effort is the GOE's interest in boosting agricultural exports, like coffee, oilseeds, horticulture, and livestock products, to grow the economy, ensure food security, and generate much-needed foreign currency. The GOE recognizes that to export these products Ethiopia needs a reliable food safety system in place to meet the demands of foreign buyers mainly in Europe, Asia, and North America.

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

Food, Medicine, Healthcare and Control Authority

Ethiopia's food safety regulatory system was authorized and mandated in 2009 in the Parliamentary Proclamation of the Ethiopian Food, Medicine and Healthcare Administration and Control Authority – Proclamation No. 661/2009. This legislation provides the legal authorities for the GOE to consolidate the pre-existing food regulatory system with the aim of better "protecting the public from health risks emerging from unsafe and poor-quality food." 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 2010, in a subsequent Parliamentary Proclamation – the 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 Food, Medicine and Healthcare Administration and Control Councils of Ministers Regulation No. 299/2013. 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.

In 2019, FMHACA carried out organizational restructuring with a new institutional name and a revised mandate. In February 2019, the GOE Council of Ministries issued <u>Proclamation No.1112/2019</u> authorizing a revised mandate of FMHACA. With the amended structure, FMHACA is renamed as the <u>Ethiopian Food and Drug Authority (EFDA)</u>. The EFDA is mandated to regulate only products related to food, medicine, tobacco, cosmetics, and medical devices. <u>Regulation No. 531/2023</u> also provides the powers and duties of EFDA. The legislative mandate of EFDA has similarities to the U.S. Food and Drug Administration.

## Ethiopian Agricultural Authority

In 2022, the GOE established the Ethiopian Agricultural Authority (EAA) as an autonomous federal government authority by Article 45 Sub-Clause 1 of Proclamation No. 1263/2021 and Council of Ministers Regulation No. 509/2022. EAA is mandated to strengthen the regulatory system by bringing together scattered regulatory bodies and incorporating new regulatory procedures to ensure the efficiency, quality, and safety of agricultural technology, inputs, products, and services. The main mandates of the EAA are to improve the utilization of domestic products by enhancing food safety, to make agricultural products and inputs available for foreign trade in a transparent manner that complies with international standards, to expand market access, and to enhance the country's ability to generate foreign currency from exports. EAA is mandated to lead both Animal and Plant Health Regulatory Directorates and to establish new standards in collaboration with IES. EAA ensures quarantine safety standards are met through field and laboratory testing, and issues an acceptable plant or animal health certificate, pre-entry permits, and post-entry exit permits, prepares a national list of quarantine pests and diseases by studying the distribution of plant and animal pests and diseases.

The Plant Health Regulatory Directorate of EAA regulates the safety of imported plant and plant products, as authorized in the Plant Quarantine 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 and a phytosanitary certificate from the competent authority of the exporting country 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
- Entry point in Ethiopia

In cases where quarantine pests are detected in an incoming shipment, MoA may allow the cargo to undergo treatment to destroy or inactivate the pest.

The Animal Health Regulatory Directorate of the EAA is responsible for animal quarantine and livestock disease issues. Imports of livestock, meat, by-products, and genetics require an import permit along with a health certificate from the exporting country. 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 livestock genetics materials will be subject to inspection. The Guidelines for Import and Export of Animal Genetic Materials spell out the recommended procedures and requirements in detail. For further reference, please see the guidelines attached in Appendix II of this report.

## *Institute of Ethiopian Standards (IES)*

IES is responsible for setting national standards. As part of its standards development process, IES consults with industry and public stakeholders to take their comments and concerns into account. IES publishes the draft national standards online along with an open solicitation for <u>public comments</u>.

MoTRI is responsible for the establishment and enforcement of the legal metrological system. In coordination with EFDA and EAA, MoTRI has the authority to control the quality of imports and to restrict entry of products that do not comply with compulsory Ethiopian standards. MoTRI regulates import and export of goods, including certain food items that must comply, where applicable, with <a href="IES Mandatory Standards">IES Mandatory Standards</a>.

The Ethiopian Radiation Protection Authority (ERPA), under the <u>Radiation and Nuclear Protection</u> <u>Proclamation No. 1025/2017</u>, establishes controls of radioactive materials in food stuffs and non-food items. Through issuance of pre-import permit and import release permit controls, ERPA also establishes regulations regarding the import, use, and authorization of radioactive materials. Though it does not directly address food radiation levels, ERPA underscores Ethiopia's overarching regulatory framework for radiation safety.

Third-party inspection bodies, which have been approved by MoTRI, can certify that subjected products meet the national standard. Pre-certified products will clear arrival inspection without delay, though

MoTRI reserves the right to conduct random sampling and testing. Uncertified products will be subject to normal inspection procedures at the point of entry.

**Table 1: Summary of Key Regulatory Agencies and Responsibilities** 

Government	Regulatory	
Ministry	Authority/Directorate	Key Responsibilities
Ministry of Health (MoH)	Ethiopian Food and Drug Authority (EFDA)	<ul> <li>EFDA is responsible for ensuring:</li> <li>Food safety and quality; regulates processed and semi-processed food products</li> <li>Safety, efficacy, quality, and proper use of medicines</li> <li>Safety, quality, and performance of medical devices.</li> <li>Issues pre-import permit and/or special import permit</li> <li>Issues import release permit</li> <li>Issues Free Sale Certificate</li> <li>Issues health certificate</li> </ul>
Ministry of Agriculture (MoA)	Ethiopian Agricultural Authority (EAA)  Plant Health Regulatory Directorate  Ethiopian Agricultural Authority (EAA)	<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 and issuance of phytosanitary certificates</li> <li>Fumigation of consignments to meet phytosanitary requirements</li> <li>Supervision of 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 area(s) with low pest prevalence</li> <li>Inspection, approval, and registration of pesticides</li> <li>Food safety risk assessment in different crops including pests and pesticide application</li> <li>Issues pre-import permit and import release permit for plant and plant products</li> <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</li> </ul>
	Animal Health Regulatory Directorate	<ul> <li>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> <li>Issues Veterinary Health Certificate</li> </ul>

	Ethiopian Agricultural Authority (EAA)  Veterinary Drug and Animal Feed Administration and Control Directorates	<ul> <li>Responsible for registration and certification of feed and veterinary drugs that are produced, imported and in use in the country</li> <li>Setting standards for quality control activities</li> <li>Market surveillance, banning, revoking and suspension of registrations, packaging and labeling, trade, and licensing of veterinary drugs and animal feed</li> <li>Issues pre-import permits and import release permits</li> </ul>	
Ministry of Trade and Regional Integration	Import and Export Goods Quality Control Directorate	<ul> <li>Quality control of exports and imports</li> <li>Regulatory oversight on the importation and exportation of goods that do not comply with the Ethiopian mandatory standards</li> <li>Work with third party conformity assessment agencies and facilitate pre-shipment inspections</li> </ul>	
(MoTRI)	Institute of Ethiopian Standards (IES)	Sets national standards	
	Ethiopian Conformity Assessment Enterprise (ECAE)	Provides certification, inspection, and laboratory testing services	
	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	
	Ethiopian Radiation Protection Authority (ERPA)	<ul> <li>Oversees radiation safety and controls radioactive materials in food and other goods</li> <li>Establishes radiation limits and may mandate testing or certification for imported food potentially exposed to radiation</li> </ul>	
Ministry of Innovation and Technology	Bio and Emerging Technology Institute (BETin)	Conducts biotechnology research and development in agriculture, environment, manufacturing, and other sectors	
Ministry of Planning and Development (MoPD)	Ethiopian Environmental Protection Authority (EPA) Biosafety Regulatory Directorate	<ul> <li>Prevention and control of environmental contamination</li> <li>Approves import permits for GE seeds and unprocessed GE crops. Note: Reference links for biosafety policy, regulations, and directives are in the summary table below</li> </ul>	

Table 2: Summary of Key Proclamations, Regulations, Directives, and Guidelines

Food Control Proclamations and Regulations	Link
Food and Nutrition Policy	<u>Download</u>
Food, Medicine, and Healthcare Administration and Control Authority, Proclamation No. 1112/2019	Download
Definition of Organization, Powers, and Duties of EFDA	Download

Food, Medicine, and Healthcare Administration and Control Authority, Regulation No. 299/2013 of Council of Ministers	Download
Food, Medicine, and Health care Administration and Control Authority establishment Council of Ministers Regulation No. 189/2010	Download
Food, Medicine, and Healthcare Administration and Control Authority, Proclamation No. 661/2009	Download
Pre-Shipment Inspection Scheme Establishment Proclamation No. 173/1999	Download
Quality and Standard Authority of Ethiopia Establishment Proclamation (No. 102/1998)	Download
Quality and Standard Authority of Ethiopia Establishment (Amendment) Proclamation (No. 413/2004)	Download
Trademark Registration and Protection Proclamation No. 501/2006	Download
Trademark Registration and Protection Regulation No.273/2012	Download
Food Control Directives and Guidelines	
Baby Food Control Directive No. 840/2021	Download
Infant and Follow up Formula Importers, Wholesalers and Exporters Directive No. 335/2020	Download
Food Supplement Directive No. 333/2016	Download
Permitted List of Food Additives, November 2021	Download
Fortified Foods and Fortificants Control Directive - Draft 2023	Download
Administrative Measures and Compliant Handling Directive No. 345/2013	Download
EFDA Service Fees and Charges Regulation No. 370/2015	Download
Animal Health and Import-Export Related Proclamations/Regulations/Directives/ Guidelines	
IGAD Regional Animal Health Certification Guidelines (ICPALD)	Download
Veterinary Drug and Feed Administration and Control Proclamation No. 728/2011	Download
Veterinary Drug and Animal Feed Administration and Control Authority Establishment Council of Ministers Regulation No. 272/2012	Download
Animal Diseases Prevention and Control, Proclamation No. 267/2002	Download
Directive on Risk Assessment Parameters for Modified Organisms No. 05/2018	<u>Download</u>
Directive Issued to Establish Procedures for the Management of Risks from any Transaction Involving Modified Organisms No. 06/2018	Download
Live Animals Marketing, Proclamation No. 819/2014	Download
Live Animals Marketing Council of Ministers Regulation No. 341/2015	Download
Directive for the Registration of Feed Products (No. 995/2024)	Download
Plant Health and Related Proclamations/Regulations	
Seed Proclamation No. 1288/2023	Download
The Plant Quarantine Regulation No. 04/1992	Download

Plant Breeder's Right Proclamation No. 1068/2017	Download
Pesticide Registration and Control, Proclamation No. 674/2010	Download
Biotechnology Policy, Regulations, and Directives	
Biosafety Proclamation (Amendment) No. 896/2015	Download
National Biosafety Advisory Committee Establishment Regulation, No. 411/2017	Download
Directive for Application of Special Permit to Engage in Transaction of GMOs for Research or Teaching, No.04/2018	Download
Directive to Provide Risk Assessment Parameters for Modified Organisms, No. 05/2018	<u>Download</u>
Directive to Establish Procedures for Management of Risks from Any Transaction Involving Modified Organisms, No. 06/2018	Download
Directive to Determine the Requirements for Transport and Storage of Modified Organisms, No. 07 /2018	Download
Directive to Determine the Content of an Application for Undertaking Deliberate Release of Modified Organisms, No. 08/2018	Download

# **Section II: Labeling Requirements**

IES has Compulsory Ethiopian Standards (CES 73 and CES 197) applicable to labeling of prepackaged food products. These are general standards for all prepackaged foods intended for human consumption. CES 73 is the most actively used and referenced general standard for labeling prepackaged food products. While CES 197 is applicable to labeling foods for special dietary uses. The following subsection describes these general standards for labeling prepackaged foods.

IES has a goal to make 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 hard copies. 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.

#### CES 73:2013 - General Standard for Pre-Packaged Foods Labeling

This compulsory Ethiopian standard stipulates general principles of good labeling practice, mandatory components of a label, and exempted products. CES 73 defines prepackaged food as "packaged or made up in advance ready for retail sale in a container." The required elements of a label include names of product and ingredients, ingredient statements including quantitative ingredient declarations where applicable, weight declarations, suppliers contact details, country of origin, storage instructions, date and batch coding, prohibitions on misleading information, allergen declarations, and instructions for use.

# CES 197:2018 - General Standard for Labeling and Claims for Pre-Packaged Foods for Special Dietary Uses

This compulsory Ethiopian standard defines foods for special dietary uses, mandatory components of a label for foods for special dietary uses, and specific prohibition on claims relating to special dietary use if the product concerned does not meet the criteria for these products. The standard has provisions on special requirements relating to appropriate storage conditions and exempted products.

## **Mandatory vs Voluntary Labeling**

## Mandatory Labeling

- Governed primarily by CES 73:2013 Pre-packaged Foods Labelling and enforced by EFDA under Proclamation No. 1112/2019.
- Required information includes: Product name, ingredient list, net content, batch/lot number, shelf-life/date mark, storage instructions, manufacturer/importer name and address, and country of origin.
- Some nutrition information may be mandatory for specific products (e.g., foods for special dietary uses under CES 197:2018, or products that are fortified with vitamins/minerals).

## Voluntary Labeling

- Includes additional information not strictly required, such as nutrition claims, health claims, or marketing statements about nutrient content.
- These are permitted only if they are truthful, not misleading, and consistent with Ethiopian standards. EFDA evaluates such claims on a case-by-case basis.

#### **Mandatory Labeling for Pre-Packaged Foods:**

In accordance with the Compulsory Ethiopian Standard (CES 73), the following information must be clearly and indelibly marked on the labels of prepackaged foods in either English or Amharic. Exporters should note that packaged foods with a surface area less than 10 cm<sup>2</sup> may be exempt from having to display some of these labeling elements. Labels found on U.S. food products are commonly accepted.

- Trade name of the product
- Common name of the product
- Nutritional content
- List of ingredients (except for single ingredient foods) in descending order of weight
- Description of micronutrients used to enrich foods produced with fortification
- Labeling, description, or ads of any food supplement must not represent to be used in disease prevention, treatment, or cure, or in any way characterize as a medicine
- If the product contains any of the following food products or ingredients that may cause allergies, labeling must clearly describe its content:
  - Breakfast cereals containing grain gluten such as wheat, rye, oats, barley, etc.
  - Crustaceans and their products
  - Eggs and by-products
  - Fish and fishery products
  - Peanuts, soybeans, and their products
  - Milk and dairy products, including lactose
  - Nuts and derived products
  - Sulphites are in concentration of 10 milligrams per Kg or higher
- 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, nor 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 alcoholic content by volume, vinegar, sugar, and candies and chewing gums having sugar contents above 35 percent)

- Product identification number/code identifying producing factory and lot
- Instructions for use (if needed)

## **Food Labeling Regulations on Health Claims**

In Ethiopia, health claims on food products are statements suggesting a relationship between a food or nutrient and health benefits or disease risk reduction. These claims are considered voluntary but are strictly regulated. They are governed by CES 73:2013 on pre-packaged food labeling and enforced by EFDA under the Food and Medicine Administration <a href="Proclamation No. 1112/2019">Proclamation No. 1112/2019</a>. Any health claim must be truthful, verifiable, and not misleading to consumers.

Health claims must be supported by credible scientific evidence before they can appear on a label. EFDA reviews such claims on a case-by-case basis, especially for imported foods. Unlike some countries, Ethiopia does not have a list of pre-approved health claims. Only claims that are accurately substantiated and supported by documentation are allowed. Claims that exaggerate benefits, imply disease treatment, or are misleading are prohibited.

Importers must include any health claim in their EFDA registration dossier along with supporting evidence. Labels with unapproved or unsubstantiated claims can be rejected, removed, or lead to product withdrawal. While claims similar to those approved in the United States, such as calcium and bone health or fruits and vegetables and cancer risk, may be allowed, they require EFDA approval based on scientific substantiation for each product.

#### **Differences in Nutrient Reference Values**

Ethiopia utilizes Recommended Dietary Allowance (RDA), which are tailored to the local population's dietary patterns and health needs. These values may differ from the Reference Daily Intakes (RDIs) used in the United States. For instance, a U.S. label indicating that a product provides "25 percent Daily Value of Vitamin C" might not align with Ethiopia's RDA for Vitamin C, potentially leading to misinterpretation of the product's nutritional adequacy.

#### *Implications for Exporters*

Exporters of U.S. food products should be aware that using U.S.-based RDIs and health claims without adaptation to Ethiopian standards can lead to regulatory issues. To ensure compliance, it's advisable to:

- Recalculate nutrient values based on Ethiopian RNIs.
- Obtain EFDA approval for any health claims.
- Ensure all labeling meets the requirements of CES 73:2013.

Failure to adhere to these standards may result in labels being deemed misleading, potentially leading to product recalls or importation issues.

Nutrient Content Claims: Ethiopia distinguishes between absolute descriptors and relative descriptors.

- **Absolute Descriptors:** Refer to specific quantities or amounts of nutrients present in a food product. Examples:
  - "High fiber" → product contains a significant amount of dietary fiber.
  - "Low-fat" → product meets defined thresholds for fat content.

## **Requirements:**

- Must meet CES/EFDA thresholds (the product must truly qualify as "low-fat" or "high-fiber").
- Must be supported by nutrient analysis or credible documentation.
- **Relative Descriptors:** Compares the nutrient content of a food product to a reference value, often expressed as a percentage. Common words include "less," "fewer," "reduced," "light," "more". Examples:
  - "Reduced sugar" → product contains at least 25 percent less sugar than the standard product.
  - "Light sodium" → product has a meaningful reduction in sodium relative to the reference product.

# **Requirements:**

- EFDA requires that relative claims are quantified and verifiable; vague or misleading comparisons are prohibited.
- Implied or Suggestive Claims: Implied claims suggest benefits or qualities without stating them directly, often in marketing language. Any implied claim that could mislead consumers is not permitted.

#### **Other Specific Labeling Requirements:**

## **Labeling Requirements for Alcoholic Beverages**

- For beverages containing more than 1.2 percent alcohol, the alcohol proof is required on the label.
- Alcoholic beverages having less than 10 percent alcoholic content shall state product expiry date on its label.
- Alcoholic beverages are required to contain labels showing alcoholic volume and warning that alcohol consumption may cause health problems.
- The label should also contain a warning that women should not drink alcoholic beverages during pregnancy because of the risks of birth defects.

## Labeling Requirements for Genetically Engineered (GE) Foods

Ethiopia requires mandatory GE labeling ("contains GMO") for GE foods. Imports of GE food are permitted upon authorization under the Biosafety Framework (2009 Proclamation, amended 2015).

• GE foods must be labelled with the following statement: "genetically modified", "genetically modified organism" or other comparable description.

## **Labeling Requirements for Foods Treated with Ionizing Radiation**

• Irradiated foods must contain the phrase "irradiated" or the internationally accepted food irradiation symbol indicating a food product has been irradiated with ionizing radiation may be placed besides the label.

#### **Labeling Requirements for Baby Food Products**

- Labeling requirements for baby food should be in accordance with the national compulsory General Standards for Pre-Packaged Foods Labeling (CES 73).
- Labels should not discourage breastfeeding in any manner and should be designed to provide the necessary information about the appropriate use of the product.

- Any product shall not be described or presented on any label or in any labeling in a manner that is
  false, misleading, or discouraging breastfeeding or is likely to create an erroneous impression
  regarding its character in any respect.
- Neither the container nor the label shall have pictures of the infants or other pictures or texts, which may idealize the use of the product.
- The terms "humanized", "materialized" or other comparable terms may not be used.
- The immediate container of the product should be affixed or written on with a label bearing the following particulars in a clearly legible, conspicuous, and indelible manner at least in Amharic or English.
  - Name of the product and its identification as "infant formula," "complementary food," or "follow-up formula" or its equivalent.
  - The words "IMPORTANT NOTICE" in capital letters and indicated there under, the statement "breastfeeding is the normal and optimal way to feed infants and young children. Breast milk is important for the healthy growth and development of infants and young children. It protects against diarrhea and other illnesses" in characters no less than one-third the size of the characters in the product name, and in no case less than 2 mm in height.
  - A statement of the superiority of breast milk using letters with more than 12 font size.
  - A statement that the product should be used only on the advice of a health professional as to the need for its use and the proper method of use.
  - Precautions and warnings, where necessary.
  - Appropriate instruction for use or preparation.
  - Name and full address of the manufacturer, including country of origin.
  - List of ingredients.
  - Nutritional information declaring in numerical form the amount of nutrients present in the product per portion of the product as recommended for daily consumption or amount per unit for single use.
  - Net content by weight for powdered products or volume for liquid.
  - Date of manufacture and expiry, which shall be indented and indicate at least the month and year in which the product is to be consumed, considering climatic and storage conditions.
  - The storage conditions, and where appropriate, shelf life of the product before and after opening and its reconstitution.
  - Batch or lot number.
  - Required professional advice, if necessary.
- A statement "breast milk is the best food for your baby," or a comparable statement regarding the superiority of breastfeeding or breast milk shall be provided.
- All ingredients on the label of the product need to be listed in accordance with the following subarticles:
  - Source of protein in the product is identified and clearly shown on the label.
  - Except for single ingredient products, a list of ingredients is declared on the label.
  - If the ingredient is from animal or plant, scientific name of the plant and part of animal or plant used is declared.
  - Additives such as fillers, artificial colors, sweeteners, flavors, or binders are listed by their specific names/ "E numbers" and qualified by words.
  - "Natural" or "artificial" in descending order in weight or volume.

## **Labeling Requirements for Baby Food for Infants and Young Children**

- A manufacturer or distributor cannot offer to sell or sell baby food for infants and young children if the labeling includes a photograph, drawing or other graphic representation other than for illustrating methods of preparation.
- A manufacturer or distributor cannot offer for sale or sell baby food for infants and young children, unless the labeling indicates in a clear, conspicuous, and easily readable manner, in Amharic or English, the following particulars:
  - Instructions for appropriate preparation and use in words and easily understood graphics.
  - The age in numeric figures after which the product is recommended.
  - A warning about the health risks of improper use, preparation, or storage and of introducing the product prior to the recommended age; "a minimum font of 3 mm tall letters based on the lower-case letter in bold red color on a white background for packages with less than 200 cm<sup>2</sup> of available label space and large font in proportion to the size of larger packages."
    - No less than one-third the size of the characters in the product name, and in no case less than 3 mm in height in bold red letters on a white background.
  - The list of ingredients and the declaration of nutritional value in accordance with relevant national standards or, in the absence of such standard, with the relevant Codex Standard.
  - The required storage conditions both before and after opening, considering climatic conditions.
  - The product category (whether infant, follow-up, growing up, complimentary food with age group, etc.).
  - Contains the word, "WARNING" and indicated there under, the statement, "before deciding to supplement or replace breastfeeding with this product, seek the advice of a health professional. It is important for your baby's health that you follow all the preparation instructions carefully. If you use a feeding bottle, your baby may refuse to feed from the breast. It is more hygienic to feed from a cup" in characters no less than one-third the size of the characters in the product name, and in no case less than 3 mm in height and in bold red on a white background.
  - Preparation instructions for infant or follow-up formula in powdered form stating that:
    - o Powdered formula is not sterile and may be contaminated with pathogenic microorganisms during the manufacturing process or may become contaminated during preparation.
    - o It is necessary for formulas to be prepared one feeding at a time using water that has been boiled (to 212°F or 100°C) and then added to the powdered infant formula immediately or when the water is at least 158°F or 70°C, before feeding the baby, cooled to body temperature.
    - o Any unused milk must be discarded immediately after every feeding.
  - Includes a feeding chart in the preparation instructions.
  - In the case of follow-up formula, states that the product shall not be used for infants less than six months old or used as the sole source of nutrition for infants in characters "no less than one-third the size of the characters in the product name, and in no case less than 3mm in height."
  - A manufacturer or distributor shall not offer for sale or sell young children formula unless the container or label affixed thereto states that the product shall not be used to feed infants below 12 months or used as the sole source of nutrition for young children" in characters no less than one-third the size of the characters in the product name, and in no case less than 3mm in height.
- A manufacturer or distributor cannot offer to sell or sell baby food for infants and young children:
  - If the labeling contains any health or nutrition claim or any representation that states or suggests that a relationship exists between the product or constitute thereof and health, including the physiological role of a nutrient in growth, development, and normal functions of the body.

## Labeling Requirements for Ready-to-Use Therapeutic and Complementary Foods

- Labeling requirements for ready-to-use therapeutic food and complimentary food products should be in accordance with the national compulsory standard CES 73 General Standards for Prepackaged Foods Labeling.
- A manufacturer or distributor cannot offer to sell or sell ready-to-feed therapeutic food or a complementary food product if the container or label affixed contains:
  - Any text, image or other representation that suggests the suitability of the product for infants under six months including but not limited to references to development milestones clearly reached before six months, the use of pictures of infants appearing to be younger than six months.
  - Any text, image or other representation of the product or is likely to undermine or discourage breast-feeding or create a belief that the product is equivalent or superior to breast milk.
    - Any text, image or representation that undermines or discourages appropriate complementary feeding or that may suggest that the product is inherently superior to home prepared complementary foods.
    - Any recommendation to feed the product in a bottle or otherwise promote the use of bottle feeding.
    - Any endorsement, or anything that may be conveyed or construed as an endorsement by a health professional, an association of health professional or other body; and
    - Any element that allows for cross-promotion of any other baby foods for infants and young children.
- In addition to the above requirements, the label of ready-to-feed therapeutic food or a complementary food product must include:
  - A statement in characters at least one-third the size of the product name, and in no case smaller than 3 mm in height.
  - The importance of exclusive breastfeeding for the first six months and of continued breastfeeding up to two years or beyond.
  - The recommended age of introduction is not less than six months (180 days) and a statement that early introduction of complementary foods negatively affects breastfeeding.
  - Instructions for preparation, storage, handling, and use.
  - A feeding chart showing the appropriate ration/serving size consistent with guiding principles issued by the World Health Organization (WHO).

#### **Prohibitions Related to Labeling of Skimmed or Condensed Milk**

- Labeling requirements for skimmed or condensed milk should be in accordance with the national compulsory standard CES.
- A manufacturer or distributor cannot offer to sell or sell skimmed or condensed milk in powder or liquid form, unless:
  - The container or affixed label contains the words, "this product should not be used to feed infants" in characters no less than one-third the size of the characters in the product name, and in no case less than 3 mm in height.

## Labeling Requirements for Low-Fat and Standard Milk

• Labeling requirements of law-fat and standard milk should be in accordance with the national

compulsory standard CES 73 - General Standards for Pre-packaged Foods Labeling.

- A manufacturer or distributor cannot offer to sell or sell low-fat or standard milk in powder or liquid form, unless:
  - The container or affixed label contains the words, "this product should not be used as an infant's sole source of nourishment" in characters no less than one-third the size of the characters in the product name, and in no case less than 3 mm in height.

## **Labeling Requirements for Plant-Based Meat/Dairy Alternatives**

The Ethiopian standard for plant-based meat or dairy alternatives has the same labeling requirements as any prepackaged foods. In addition to the general labeling requirements for prepackaged foods, the following specific labeling elements are required:

- For plant-based meat products such as texturized soy proteins (TSP) a clear statement "food for human" on the label.
- For dairy alternatives such as soymilk, the label should have clear instructions on disposal of used packages.

## **Required Labeling Elements for Raw Materials for Food Products:**

- Name of the raw material
- 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

## **Labeling Requirements for Fortified Food and Micro-Nutrients:**

- Presentation and description of fortified foods on any label or in any labeling shall not be false, misleading, or deceptive or is likely to create an erroneous impression regarding its character in any respect.
- The label should clearly indicate the pack size within the unit package The label needs to be affixed on all primary packaging of any fortified food and/or micro-nutrient supplement bearing the following information in clearly legible and indelible letters at least in Amharic and/or English:
  - Name of the product
  - Name and full address of the manufacturer, including country of origin
  - List of ingredients
  - The name and amount of micro-nutrients available
  - Net content by weight for solid products or volume for liquids
  - Date of manufacture and shelf-life, which indicates at least the month and year
  - The storage conditions and, where appropriate, the shelf-life of the product before and after opening and reconstitution
  - Batch or lot number
  - Standard mark and logo and registration number
- Appropriate instructions for use or preparation of fortified foods and micro-nutrient products.

## **Labeling Requirements for Animal Feed Products**

The labeling requirements for feed products are specified in the <u>Directive for the Registration of Feed Products No. 995/2024</u>. Feed products must have a clearly written, legible, and irremovable label either in Amharic or English. The label must be written directly on the product's packaging or attached via a non-perishable material sewn to the packaging. Pasted, tied-on, erased, or illegible labels are not acceptable. Labels must avoid misleading words or images.

#### **Label Contents:**

- Name and complete address of the manufacturer
- Trade name of the product
- Brand name
- Date and year of manufacture
- Batch number
- Shelf life of the product
- Nutritional composition of the product
- List of raw materials used, in descending order of quantity
- Net weight of the product
- A clear description of the target animal type, including age group, production type, and grade
- Information on transportation and storage conditions
- Cautionary notices or warnings related to the product's use, if necessary

## **Labeling Requirements for Animal Genetic Materials:**

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

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

## **Shelf-life / Date Marking Requirements**

All pre-packaged foods must display a date mark, either as:

- Best before: for products that can retain their quality beyond a certain date.
- Use by / expiry date: for highly perishable foods where safety cannot be guaranteed beyond the date.
- Format: Dates should be clearly legible and preferably in DD/MM/YYYY or MM YYYY format.
- Placement: On the primary package (the part that directly contacts the food), easily visible to the consumer.
- Special cases: Small packages (≤10 cm²) may have exemptions if space is limited, but the importer may need to provide this info separately (e.g., over-label or leaflet).

## **Country of Origin Labeling Requirements**

- Imported foods must clearly indicate the country of origin on the label.
- Format: Plain, unambiguous text (e.g., "Product of USA" or "Made in the USA").
- Placement: Should be on the main display panel or otherwise clearly visible to the consumer.
- Language: Amharic or English is accepted. Many importers provide both languages for compliance.

**Table 3: Summary of Required Labelling Formats** 

Labeling Information	Requirement	Format	Placement	Language
Shelf-life / Date mark	Mandatory	Best before or Use by; DD/MM/YYYY or MM YYYY	Primary package	Amharic or English
Country of Origin	Mandatory for imports	Product of [Country]/ Made in [Country]	Main display panel	Amharic or English

## Circumstances Under Which Labeling Exceptions May Be Granted

EFDA is the designated competent authority, empowered by the Food and Medicine Administration Proclamation No. 1112/2019 and its subsequent instruments, Proclamation No. 1263/2021 and Regulation No. 531/2023 to issue case-by-case determinations on labeling exemptions. Such exemptions are rarely granted and lie solely within EFDA's discretion. They typically apply only to small packaging formats (under 10 cm²), research or trade samples, emergency or humanitarian imports, transitional grace periods for new requirements, or for language over-labeling. By contrast, all retail products intended for sale to Ethiopian consumers must fully comply with <a href="CES 73:2013">CES 73:2013</a> — General Standard for the Labelling of Pre-Packaged Foods and other applicable Ethiopian standards.

Ethiopian sources (Proclamation 1112/2019, EFDA directives, and CES 73:2013) point to a few exception situations:

- Small packages (≤10 cm² surface area): CES 73 allows omission of certain details (e.g., full nutrition panel) if the pack is too small to carry them, provided information is available through other means.
- Import for research, samples, or emergencies: EFDA may allow food items to be imported without full retail labeling if they are not intended for commercial sale (e.g., clinical trials, laboratory analysis, trade samples, emergency aid shipments). In these cases, EFDA typically requires the importer to submit documentation and may issue a special permit.
- **Grace periods**: When new standards are introduced or labeling rules are updated, EFDA has discretion to give a grace period (sometimes 6–12 months) so existing stock or shipments already in transit can be cleared.
- Language flexibility: By law, labels must be in Amharic or English. In practice, EFDA often accepts English-only labels on imports at entry, provided the importer adds an Amharic sticker or over-label before retail distribution.
- **Foods for Special Dietary Use (FSDU)/Medical Foods:** If EFDA determines that labeling requirements in CES 197 (for FSDU) cannot reasonably be applied (e.g., because of space constraints or international format), it can approve a modified label format, but only through prior authorization.

## How is an Exception Granted?

- Importers must apply to EFDA's Food Registration and Licensing Directorate (part of EFDA's Market Authorization Department).
- EFDA may issue a written authorization or conditional approval stating which labeling elements are exempted and under what conditions (e.g., for research only or not for retail sale).
- EFDA can revoke exemptions if products are found on the retail market without compliant labels.

## **Importer Verification Checklist for Labeling:**

- Product/trade name matches CES/commodity standard
- Ingredients listed in correct order
- Allergens declared
- Net quantity in International System of Units (SI units)
- Manufacturer's name and address present
- Ethiopian importer's name and address included
- Country of Origin stated
- Lot/batch number included
- Expiry/Best-before date clearly printed
- Storage/use instructions (if needed)
- Any special-category marks (dietary, GE, irradiated, alcohol, etc.) applied

# **Section III: Packaging and Container Regulations**

In accordance with the <u>EFDA Proclamation No. 1112/2019</u>, it is generally required that packaging material should be made out of substances, which are safe and suitable for their intended use, and the product shall be packed in a container which will safeguard its hygiene, safety, quality, and food grade. The Proclamation states "no packaging material shall be put into use unless it complies with the international and national safety and quality standards."

Any food product regulated under Proclamation No. 1112/2019 needs to be appropriately packed and its packaging material cannot contaminate the product and must comply with national standards. The EFDA proclamation defines primary packaging as "the covering, wrapper, or container that has direct contact with the product intended for retail sale."

Individual product <u>standards</u> may also contain additional guidance and/or requirements for 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. The packaging of infant and follow up formula must be made from non-plastic material. To obtain approval for packaging materials, a certificate of analysis and specifications are required.

## Special Packaging, Container Size Requirements, or Preferences

Ethiopia does not impose a single universal law on container sizes for imported pre-packed foods. Instead, packaging is governed through product-specific Ethiopian standards and conformity assessment requirements. All imported foods must use safe, food-grade containers that do not contaminate the

product, and those subject to compulsory standards are checked for packaging compliance during preshipment verification by approved bodies. Beyond this, rules focus mainly on technical specifications for particular categories rather than across-the-board restrictions.

For beverages in PET bottles, ES 6792:2021 sets "normal" nominal capacities of 500 ml, 1,000 ml, 3,000 ml, and 5,000 ml, with a mandatory 10 percent extra capacity tolerance, while still allowing other sizes by supplier-buyer agreement. A standard for honey, caps glass jar sizes at 2 kg but permits flexibility for plastic and metal containers. In the case of fresh fruits and vegetables, ES 6689:2021 requires sturdy, clean containers sized and shaped to fit pallet surfaces without overhang, reflecting a focus on logistic efficiency rather than retail pack volumes.

For many other foods, such as edible oils or grocery staples, no strict size regulations exist, but market practice and national quality schemes influence importer choices. Edible oils, for example, are most commonly sold in 0.5 L, 1 L, 3 L, and 5 L packs, with larger containers mainly reserved for institutional buyers. Thus, while Ethiopia's regulations mandate food-safe packaging and set specific size rules in some categories, most container choices for imported pre-packed foods are guided by a mix of product standards, conformity assessments, and prevailing consumer and industry preferences.

## **Packaging Sustainability Measures**

IES embraces international standards related to packaging sustainability measures identical with the International Organization for Standardization (ISO). IES has two optional standards applied to packaging and the environment. These are:

- ES ISO 18606:2015 Packaging and the Environment (Organic Recycling)
- ES ISO 18604:2014 Packaging and the Environment (Material Recycling)

ES ISO 18606:2015: This standard is applicable to organic recycling of used packaging but does not address regulations that exist regarding the recoverability of any residual packaged goods. The standard established the requirements for packaging suitable for organic recycling. The above standard defines organic recycling as the process "through microbial activity, the controlled biological treatment of the bio-degradable components of used packaging, which produces compost, in the case of anaerobic digestion, also methane." In addition, the standard does not consider landfilling and littering as organic recycling.

A package is considered suitable for organic recycling if all the components are suitable for organic recycling. However, individual components of the packaging can be considered recoverable by organic recycling if they meet the requirements of this international standard. The suitability of packing components and packaging material is verified by test methods described in this standard. The standard provides normative descriptions of the maximum concentrations of regulated metals and other substances hazardous to the environment and determination of eco-toxic effects. The standard also contains a recommended assessment checklist for meeting the requirements and provides examples of packaging suitable for organic recycling.

ES ISO 18604:2014: This standard specifies the requirements for packaging to be classified as recoverable in the form of material recycling while accommodating the continuing development of both packaging and recovery technologies. The standard also sets out procedures for assessment of meeting

the requirements. The standard defines material recycling as "reprocessing, by means of a manufacturing process, of a used packaging material into products, a component incorporated into a product, or a secondary (recycled) raw material, excluding energy recovery and the use of the product as a fuel. The standard has established procedures and criteria for recyclable packaging in the product life cycle steps such as design, production, utilization, sorting by the end-user, and collection. For instance, if plastic or PET bottle packaging complies with the standards or specifications, then the packaging is considered 100 percent recyclable.

## **Recycled Content or Design Requirements**

At present, Ethiopia does not mandate specific recycled content percentages in food packaging standards. For instance, ES 6792:2021 for PET bottles defines performance and dimensional requirements but does not include recycled content obligations. However, the National Plastic Waste Management Strategy and Roadmap sets out a pathway to introduce measures such as recycled content targets, deposit-return systems, and circular design standards in the future. The regulatory framework emphasizes recyclability and circularity, even if binding recycled content percentages have not yet been widely applied.

#### **Bans, Restrictions or Limitations on Packaging Materials**

Ethiopia has introduced restrictions on certain single-use plastics through its <u>National Plastic Waste</u> <u>Management Strategy and Roadmap (2024-2034)</u> and subsequent legislation. The long-standing <u>Solid</u> <u>Waste Management Proclamation No. 513/2007</u> established the framework for municipal waste control.

## **Single Use Plastic Restrictions**

On June 2, 2025, the Ethiopian Parliament passed a new law (Solid Waste Management Proclamation No. 1383/2025) to phase out the production and import of designated single-use plastics. The law bans the import, domestic production, and use of single-use plastics, particularly plastic bags thinner than 0.03 millimeters. The law also requires recycling or reuse of disposable items such as bags, bottles, straws, and wrappers, linked to environmental and public health risks. The Environmental Protection Authority (EPA) is granted the power to create implementing regulations and monitor the implementation of these restrictions.

## **Municipal Waste Disposal Laws and Recycling Regulations**

The principal legal basis remains the Solid Waste Management Proclamation which regulates municipal solid waste practices. Building on this, the Solid Waste Management Proclamation No. 1383/2025 and the EPA's plastic waste management strategy have advanced Extended Producer Responsibility (EPR) as a policy tool. The legislation promotes a circular economy by turning waste into new resources and holding producers responsible for their products. Enacted measures introduce obligations for producers to participate in or fund collection and recycling systems, particularly in high-volume sectors such as bottled water and beverages. The policy direction is toward binding producer or importer responsibility for post-consumer packaging waste.

## National Strategies, Goals, or Proposals for Packaging Waste Reduction

Ethiopia has articulated clear national objectives for packaging sustainability through the National Plastic Waste Management Strategy and Roadmap and complementary laws. These strategies call for reductions in single-use plastics, restrictions on difficult-to-recycle materials, expansion of recycling infrastructure, and encouragement of biodegradable or compostable alternatives. The 2025

parliamentary legislation reflects this policy by embedding bans, producer obligations, and waste-reduction targets into enforceable law. Together, these measures form a coordinated national approach to transition away from problematic packaging toward recyclable and sustainable options.

# **Section IV: Food Additive Regulations**

EFDA regulates the use of food additives, which must comply with both international and national food safety standards. Ethiopia has based its national standards on Codex standards. Any food additive to be imported into Ethiopia must follow Codex or Ethiopia's standard concerning its use as an input for food processing.

The revised EFDA Proclamation No.1112/2019 defines food additives as any substance prepared in accordance with applicable requirements and added to food to give flavor, impart color, preserve, or enhance its appearance or other related functional purposes. Article 11 of the proclamation states that the maximum level of food additive use is in accordance with the Ethiopian standard issued by the appropriate body.

According to the revised proclamation, EFDA determines the list of allowable food additives and prohibits the use of some food additives in certain categories. EFDA evaluates the safety of food additives before authorizing the use or new uses for already permitted food additives. Before a new additive can be used or before an additive can be used in a new way from the permitted list, the manufacturer must show that the food additive is safe and get EFDA approval. EFDA created a national list of permitted food additives in November 2021.

Individual food and beverage standards, where applicable, reference both permitted and prohibited additives. Generally, food and beverage products covered under the Ethiopian Standards may contain only permitted additives in accordance with <u>Codex Stan 192</u>, General Standard for Food Additives. For example, in the case of natural wines, the Ethiopian Standard *ES 351: 2001*, which is adopted from the Codex standard, specifies the list of permitted additives that may be added to fresh grapes, musts, and dry grapes during vinification. The standard also provides a list of additives and treatments permitted during vinification and conservation of wines and sweat filtrates. This includes lists of permitted substances and forbidden additives. For instance, tannins can be used for clarification purposes, but coloring substances are prohibited except for oenocyanin or caramel.

Ethiopia uses a positive list system. Only additives included in the EFDA <u>National List</u> (or those permitted in commodity standards) may be used. Certain product standards also explicitly ban additives in specific foods. Permitted additives have defined functional classes, conditions of use, and maximum levels. Some commodities (e.g., flours) prohibit any additives, while EFDA directives require registration and monitoring of additive use.

The <u>National List of Food Additives</u> and related <u>directive</u> are published by EFDA (in English and Amharic) and are accessible on the EFDA website. Commodity-specific rules can be obtained through the Institute of Ethiopian Standards.

EFDA references Codex standards as a scientific basis but requires additives to appear on its national list or relevant ES before use. To add a new additive, industry must submit a technical dossier to EFDA,

which reviews safety data, consults stakeholders, and then publishes an updated list or amended standard.

#### Step-By-Step Process for Industry to Seek Additive Approval

- Preliminary check: Verify whether the additive and the intended use/level are already allowed under the EFDA National List or the relevant ES commodity standard.
- Prepare dossier: Compile a technical dossier with identity (INS number), manufacturing specifications, purity criteria, intended food categories and maximum use levels, toxicological/safety data, and any risk-management proposals (e.g., maximum level).
- Submit to EFDA: If the applicant is an importer, a local agent/representative is normally required. EFDA will conduct a technical evaluation; this may include requests for additional data, lab testing, or review by technical committees.
- Public consultation / stakeholder review: For additions to the national list, EFDA typically issues draft directives and invites stakeholder comments.
- Decision and Publication: If EFDA's assessment supports safety and suitability, the additive/use is incorporated in the National List, or the relevant ES is updated; EFDA then publishes the revised list/directive, and the additive becomes authorized with stated conditions.
- Post-Authorization Controls: Authorized additives are subject to monitoring and enforcement (EFDA may require certificates, testing of imported consignments, or labeling/traceability data as part of market surveillance).

#### Food Additives Control Directive No. 1020/2024

This EFDA <u>directive</u>, issued in August 2024, establishes strict regulations governing the use, import, export, and sale of food additives within Ethiopia. The directive aims to regulate the use of food additives in alignment with Codex Alimentarius standards, ensuring food additives are safe and do not endanger public health.

This directive is applicable to any person who engages in the production, import, export and distribution of an allowable list of food additives permitted by Codex Alimentarius Commission and determined by EFDA that the food additives are not prohibited to be used in food. This guideline does not refer to food additives except when they are used for food preservation or to improve the nutritional content of the food.

- Permitted Food Additives: Only food additives listed by the Codex Alimentarius Commission or
  recognized by Ethiopian standards are permitted for use. The directive specifies the acceptable
  quantities of additives in various foods. It also prohibits additives that conceal food spoilage or lower
  the nutritional value of the food. Additives should be safe, transparent in their usage, and follow
  internationally recognized guidelines.
- **Prohibited Substances**: The directive bans the use of any substances that are not explicitly included in the Codex Alimentarius or EFDA-approved list of food additives. This provision ensures that no unapproved or unsafe substances are introduced into the Ethiopian food market.
- Labeling Requirements: Additives must be clearly labeled, and misleading or deceptive descriptions are prohibited. Labeling of any food additives must meet the Compulsory Ethiopian Standard (CES 73) labeling requirements for pre-packaged foods. The labeling must clearly indicate the additive's name, functional class, and identification number. Misleading or deceptive

descriptions are strictly prohibited. Labels must also contain information about the additive's origin and any necessary usage or storage instructions.

- **Safety Regulations**: Additives must not reduce food quality or nutritional value, nor should they hide any defects in the food. The use of additives is intended to improve the safety and quality of food products, not to cover up poor manufacturing practices. Any additive used must comply with established purity standards.
- Manufacturing, Import, and Export: A pre-licensing requirement is necessary for manufacturers, importers, or wholesalers dealing in food additives. Only additives on the approved list are allowed for manufacturing, importing, or exporting. The directive includes a detailed application process to ensure compliance with these requirements.
- **Notification Requirements**: Any person responsible for placing food additives on the market, whether through manufacturing, import, export, or distribution, must notify EFDA. The notification process requires detailed documentation. The notification application process includes several key requirements:
  - The name, identification number, and functional class of the food additive.
  - The name and address of the manufacturer, including valid contact information (phone number and email).
  - The name and address of the importer, along with a valid contact number and email.
  - Full food additive ingredient list.
  - Labels of the food additive.
  - Original Certificate of Free Sale from the competent authority of the exporting country.
- All submissions for notification must be in Amharic or English.
- The notification must be renewed every two years. The process must start no later than six months before the expiration of the current notification.
- Any changes to the data in the initial application (such as changes in the manufacturer, contact details, or product composition) must be promptly communicated to EFDA.

Hard copies of the Ethiopian standards for food additives are available at IES with payment of nominal administrative fees. Post can assist U.S. companies in obtaining copies of the standards on a case-by-case basis.

#### **Section V: Pesticide and Contaminants**

Ethiopia accepts the Codex General Standard for Pesticides and Contaminants. Food and feed products regulated by Ethiopian standards must comply with the Codex General Standards for Contaminants and Toxins in Food and Feed (Codex Stan 193). The revised EFDA Proclamation No.1112/2019, Article 5 stipulates that any food product cannot have chemical residues including pesticides, fertilizers, veterinary drugs food additives, cleaning chemicals, radioactive substances, and other contaminants above the maximum residue level (MRL) issued or adopted by the appropriate organ.

In 2010, the GOE enacted the <u>Pesticide Registration and Control Proclamation No. 674/2010</u>. The legislation establishes a mandatory registration system for pesticides, tailored to national needs. The registration process involves a risk-based evaluation of comprehensive scientific data demonstrating that the product is effective for its intended purposes and does not pose an unacceptable risk to human or animal health or the environment. The proclamation states, "no person shall import, manufacture or sell a pesticide, which has not been registered under this Act."

Ethiopia's pesticide regulations are governed by the EAA, which oversees the registration, importation, distribution, and use of pesticides. The EAA ensures that pesticides are effective for their intended purposes and do not pose unacceptable risks to human health, animal health, or the environment under the conditions of use in Ethiopia. Ethiopia does not maintain a national MRL list and there is no formalized MRL deferral path, instead it defers to international standards, particularly those established by Codex, when setting MRLs. The EAA references Codex MRLs as guidance, especially where local data is insufficient, aligning domestic requirements with globally recognized standards to ensure food safety and facilitate trade.

The EAA Plant Health Regulatory Directorate is mandated to:

- Regulate pesticide management, relating to importation, distribution, transportation, storage, retailing, and use.
- Adopt regulations.
- Promote the correct use of pesticides and search for alternatives to chemical pesticides.
- Raise awareness and provide technical support when the need arises, etc.

EAA 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 five years at which time the registration may be renewed.

In addition to registration, EAA also is responsible for establishing 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 an event where a national standard does not exist, the GOE will likely defer to the Codex standard.

The EAA regulates pesticides and pesticide residues in foodstuffs by controlling registration, importation, distribution, and authorized use of pesticides. The EAA conducts scientific risk assessments to ensure pesticides are safe for human health, the environment, and agricultural use, and monitors residues in imported and locally produced foods through inspections and testing.

Import tolerance applications are accepted when new pesticides are introduced or when adjustments to existing MRLs are required. Importers must submit supporting scientific data and risk assessments, which the EAA evaluates to determine whether the proposed MRLs are safe and acceptable under national standards.

Imported food products are subject to port inspections, where samples are collected and analyzed for pesticide residues to ensure compliance with established MRLs, often referencing Codex standards when national limits are not available. If residues exceed permissible levels, regulatory authorities can impose sanctions including rejection of the shipment, detention or destruction of the product, fines, and temporary or permanent import restrictions for the responsible importer.

According the recent organizational restructuring and change of mandate as per Proclamation No. 1263/2021, the rights and obligations of Veterinary Drug and Feed Administration and Control Authority are transferred to the EAA. The EAA's Veterinary Drug and Animal Feed Directorate is responsible for setting standards related to animal feed and veterinary drugs, including MRLs 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.

#### **Contaminants**

Ethiopia's regulations on food contaminants are governed by the EFDA, which sets standards for maximum levels (MLs) of contaminants in foodstuffs. These standards aim to protect public health by limiting the presence of harmful substances such as heavy metals, mycotoxins, and other contaminants in food products. EFDA's regulations are informed by international standards, including those established by Codex, to ensure food safety and facilitate international trade.

IES has a general standard for contaminants and toxins in food and feed. 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 contaminants and toxins of concern and their corresponding MLs. Instead, these are found in standards for individual commodities, where they exist. For instance, soymilk must comply with the maximum metal contaminants (lead and cadmium) and pesticide residue limits specified in Codex Stan 193.

Local authorities in Ethiopia establish national MLs for contaminants by referencing international standards, particularly those set by the Codex. In cases where Codex standards are not available, the IES may develop national MLs based on scientific risk assessments and available data. This approach ensures that Ethiopia's food safety standards align with global best practices while considering local conditions and risks.

Exporters wishing to export food products to Ethiopia must comply with the EFDA's regulations, which may include providing documentation such as health certificates and certificates of analysis. These documents should verify that the products meet the required safety standards and do not exceed the established MLs for contaminants. Additionally, exporters may need to submit samples for laboratory testing to confirm compliance with Ethiopian food safety standards.

Port inspection practices in Ethiopia involve the examination of imported food products to ensure they comply with national food safety standards. If contaminants are detected at levels exceeding the established MLs, the EFDA may impose sanctions, including the rejection of the shipment, destruction of the non-compliant products, or penalties to the importer.

## Section VI: Other Requirements, Regulations, and Registration Measures

## **Food Product Registration**

EFDA has a mandatory list of food products that must be registered and approved prior to importation for the first time. Infant formula (milk) and food supplements are strictly prohibited from entering the

market without prior registration and approval. Details are available in the Infant and Follow-up Formula Exporters Importers and Wholesalers Directive No./335/2020 and Food Supplement Directive No. 333/2020. In addition to infant formula and food supplements, EFDA requires registration for milk and milk products, meat and meat products, poultry products, seafood, 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.

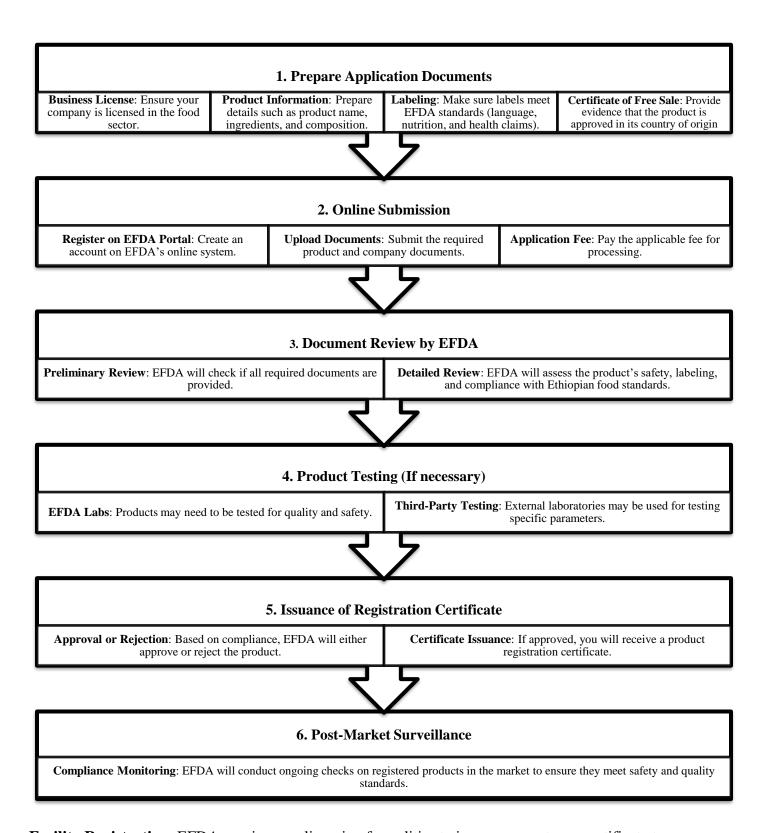
## The required documentation for new registration of imported food products includes:

- Application form for registration.
- Agency agreement between manufacturer/exporter and local importer.
- Certificate of Free Sale (or FDA's Certificate to a Foreign Government for FDA-regulated products).
- Food manufacturing or products registration certificate or approval.
- Authenticated copy of Good Manufacturing Practice (GMP), Hazard Analysis Critical Control Point (HACCP), or ISO 22000.2005 certificates. In appropriate circumstances, internationally accepted certification or certificate of quality management system may be accepted in lieu of GMP and HACCP.
- Certificate of lab analysis of sample product for registration from accredited lab.
- Documents showing the quality and safety of raw materials and food additives used in manufacturing.
- Study evidence for determining shelf life of the product.
- Veterinary certificate attesting it is free of diseases that can be transmitted from animals to human.
- Product sample.
- Technical documents such as:
  - Formulation and manufacturing and packaging procedure.
  - Data on method of analysis and specification of the finished product.
  - Stability study reports and shelf-life assignment.
  - Packaging and labeling requirements for finished products.
  - Quality analysis result.
- Other details of the product:
  - Trade name of the food product.
  - Common name of the food.
  - Nutrition content.
  - List of ingredients (except for single ingredient foods) in descending order of weight.
  - Country of Origin, name, and address of the manufacturer or importer.
  - Production and expiration dates.
  - Product identification number.
  - Net weight or volume of contents.
  - Description of micronutrients used to enrich foods produced with fortification.
  - If the food product contains milk and milk products, fish and shellfish, wheat, barley, peanuts, soybeans, and other food allergens, the label must clearly describe its content.
  - If the food is made with GE ingredients, supporting information must be provided.
  - Irradiated foods must contain clear information showing that the food is irradiated.
  - Instructions for use (if needed).

#### **Food Products Registration Process**

EFDA uses an <u>Electronic Regulatory Information System (eRIS)</u> to oversee the market authorization and import permit approval for food and medical products. Both importers and EFDA use this online system to manage the licensing, registration, and import application process. Figure 1 provides a summary outlining the typical steps for food product registration with EFDA.

**Figure 1: Food Product Registration Process Flow** 



**Facility Registration**: EFDA requires pre-licensing formalities to issue a competency certificate to Ethiopian food manufacturers. According to the revised Food Manufacturing Factories Pre-Licensing Directive, the facility registration requirement applies to local food manufacturers to ensure food safety

and quality. EFDA classifies local food manufacturers into three different entities. This classification is based on the perishability of the product, the manufacturing process of the product, and end users of the product. This does not apply to U.S. facilities exporting to Ethiopia.

## • Special Nutritional Purpose Foods:

- Food supplement/dietary supplement/infant formula
- Follow up formula
- Complimentary foods for infants and young children
- Ready to use supplementary foods (such as Plumpy Nut, Plumpy Sup, F-100 and F-75) for acute and moderate malnourished people
- Special nutritional purpose foods
- Other manufacturers producing foods of similar nature to the above
- **High-Risk Food Products for General Purpose:** Per <u>EFDA's Food Manufacturers Establishment</u> <u>Pre-licensing Directive No. 358/2013</u> (Amharic), the following items are considered high-risk.
  - Processed animal products
  - Processed seafood
  - Processed fruits and vegetables
  - Processed nuts
  - Therapeutic foods
  - Complementary foods (for children three years and older)
  - Fortified foods (iodized salt, edible oil, flour, etc.)

#### Low-Risk Food Products:

- Crackers, snack food, and confectionery products
- Edible oils and fats
- Packed water
- Soft drinks
- Beers
- Extruded products and noodles
- **Notified Food Products**: EFDA categorizes the following food products as *Notified food products*: which require mandatory conformity assessments before being imported, exported, or sold.
  - Hot sauce
  - Legume products
  - Packed rice products
  - Processed seed (corn, wheat, sorghum, barley, oat, etc.) products
  - Packed sugar
  - Bakery raw materials
  - Processed coffee and tea
  - Processed spices
  - Alcohol (more than 10 percent) and liquor products
  - Vinegars
  - Other related food products not mentioned above
  - Imported food aid products donated by governmental or non-governmental organizations
  - Raw materials used for food production

#### **Mandatory Feed Product Registration**

The EEA's <u>Directive for the Registration of Feed Products</u> (No. 995/2024) created a regulatory framework that requires registration for all feed products, including processed fodder, feed ingredients, and raw materials. It applies to both locally produced and imported feed products, mandating that any feed product intended for commercial use must be registered with the EAA. Additionally, the directive includes a focus on quality control and feed product safety, with requirements for market licenses based on these factors.

**Definitions:** The Directive provides specific definitions for various terms used throughout, including "processed feed," which refers to feed made by blending multiple ingredients, and "feed supplement," which includes nutrient preparations for animals. It also defines "feed raw materials" as products or byproducts used in formulating animal feed. The document clarifies the roles of regulatory entities, product registrants, and the concept of product quality assurance systems. It also includes terms related to feed safety and standards, such as "Genetically Modified" (GM) ingredients, certificates of analysis, and product variations (major and minor).

**Registration:** Before any feed product can be imported, marketed or used commercially, it must be registered with the EEA. The product must meet national or international safety and quality standards. The registration process involves submitting various documents, including certificates of competence, product details, and safety reports.

**Application and Re-Registration Process:** The process involves submitting required documents to EAA, such as legal agreements, product safety reports, and product labels. Registrants must comply with requests for additional information within three attempts, or a new application must be submitted. Registered feed products must be re-registering every four years, with any major or minor variations requiring notification and additional documentation.

**Quality and Safety Requirements:** Feed products must adhere to strict <u>quality and safety standards</u>. This involves testing multiple batches of the product and submitting certificates of analysis. Stability studies are required to determine the shelf life of the product in the Ethiopian climate. The packaging must also meet specific standards to ensure it protects the product from contamination and withstands varying weather conditions. U.S. exporters are encouraged to refer the detailed regulations outlined in <u>Veterinary Drug and Feed Administration and Control Proclamation No. 728/2011</u> and Feed <u>Registration Directive No. 995/2024</u>.

## Restrictions on Genetically Modified Feed Materials and Growth Hormones

According to Page 5 (Article 3) of the <u>Feed Registration Directive</u>, genetically modified or feed materials containing growth-stimulating hormones, drugs, or medicinal products cannot be registered for domestic production or importation. Exceptions exist for scientific research and emergency relief feed products, as well as pet food accompanying travelers or diplomatic missions.

## **Required Documents for Feed Product Registration:**

## **Legal Documents:**

- Agency Agreement: For imported products, a legal agency agreement with the foreign manufacturer.
- Manufacturing Agreement: If produced by a third party, an agreement between the producer and manufacturer, as well as between the producer and local importer.
- Manufacturer's Commitment: An agreement stating that the manufacturer and importer are responsible for recovering defective products if necessary.
- Product Recall Procedures: Document showing the manufacturer's procedure for collecting defective products from the market.
- Manufacturing License: Issued by the appropriate authority in the country of origin.
- Good Manufacturing Practice (GMP) Certificate: Or an equivalent certificate of competency issued to the manufacturing company.
- Non-GMO Certification: Evidence that the product is free from genetically modified ingredients.
- Animal Product Health Certification: If using animal by-products, proof that the product is free from diseases like Bovine Spongiform Encephalopathy (BSE).
- Marketing Authorization: A certificate showing that the product is marketed in the exporting country, similar to a Certificate of Free Sale.
- Quality/Safety Management Certificate: As necessary, evidence of the product's compliance with recognized food safety or quality management systems.
- Manufacturer Profile: A general description of the manufacturer.
- Label and Sample: The product's label and a physical sample.

## **Product Description:**

• General Information: Document detailing the product's physical and chemical properties, composition, intended use, usage instructions, precautions, and storage/transportation conditions.

#### **Production Process Documents:**

- Raw Materials List: Detailed list of raw materials and their safety documentation.
- Product Formula: Complete formula of the feed product.
- Manufacturing Flowchart: A flowchart showing the production process.
- Step-by-step Process Description: Detailed explanation of each step in the production process.
- In-process Quality Control: Documentation of quality and safety control activities at each stage of production.
- Batch Record: A batch record of at least one production batch.

## **Quality Control Documents:**

- Product Specifications: Documents outlining the quality and safety specifications of the feed product.
- Certificates of Analysis: Laboratory test certificates from at least three different batches of the product.
- Testing Method Validation: Proof that the product testing methods are valid.
- Stability Study: Stability study report determining the product's shelf life, considering Ethiopian climate conditions.

## **Packaging Documents:**

- Packaging Material Description: Detailed description of the packaging material and its compliance with standards.
- Quality Control of Packaging: Criteria and testing methods for the packaging material to ensure it meets safety standards.

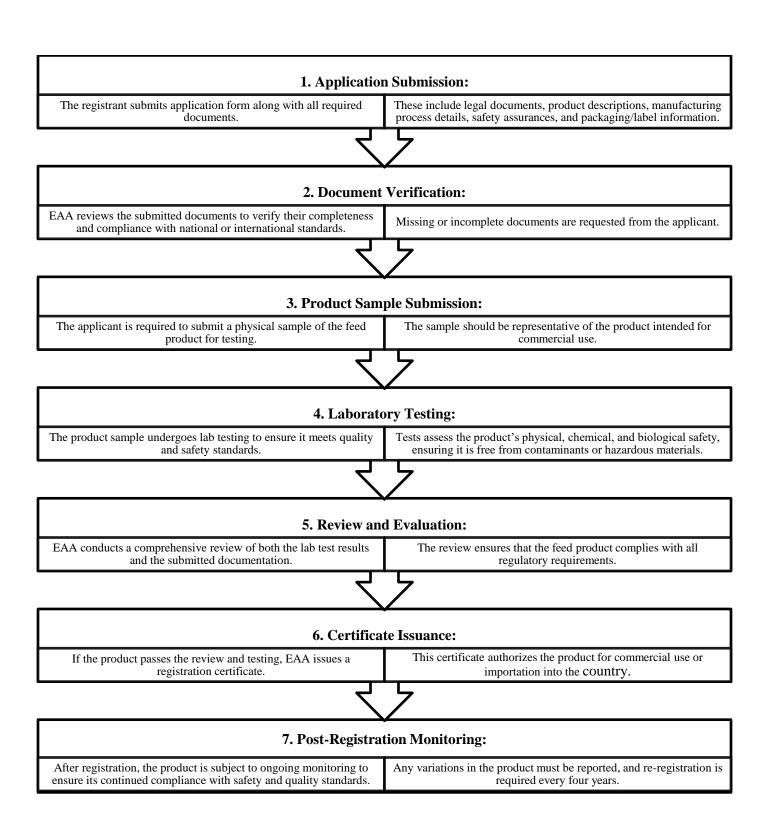
## **Labeling Documents:**

• Label Sample: A sample of the product label, which must include details like manufacturer name, product name, batch number, shelf life, net weight, ingredients, intended use, and any necessary warnings.

## **Product Safety Documents:**

- Safety Assurance: Evidence that the product is free from physical, biological, and chemical hazards.
- Safety Study: A safety study report conducted by the manufacturer or published in a recognized scientific journal.

**Figure 2: Flowchart for Feed Product Registration** 



## Section VII: Other Specific Standards/Laws

**Seed Law** 

In May 2023, Ethiopian parliament enacted a new seed law, marking the third revision in the history of the country's seed regulatory system. The first seed related regulation was in 1997, which was replaced by the seed law 206/2000. That was again revised and replaced by the seed law 782/2013. The new seed law provides a legal framework much-needed to boost seed sector development in Ethiopia. One of the major challenges faced by the Ethiopian seed regulatory system has been the very limited implementation of the laws and regulations. The new <a href="Seed Proclamation No. 1288/2023">Seed Proclamation No. 782/2013</a> and outlines three different systems for registering new crop varieties in the country. One of these systems involves a performance trial conducted by EAA, performance evaluation by a committee of experts, and an approval by a National Variety Release Committee. The second system is designed for varieties that have undergone evaluation in other countries with similar agro-ecological conditions. It allows for a streamlined registration process, recognizing international testing data. The third system permits local farmers and pastoralists to register and use varieties that have been traditionally adapted to their specific environments, facilitating the inclusion of indigenous knowledge and practices.

The new proclamation also outlines seed marketing (including import and export), seed quality standards, testing and certification. The importation of seeds is regulated to ensure the introduction of quality seeds that meet national standards. The proclamation outlines specific requirements and procedures for seed importation:

- Obtain an import permit from EAA prior to bringing seeds into the country.
- Ensure the seed variety is officially registered and approved by the EAA.
- Comply with national seed standards regarding quality, purity, and germination rates, as specified by the EAA.
- Provide a valid phytosanitary certificate from the country of origin confirming the seeds are free from pests and diseases.
- Adhere to labeling requirements, including variety, origin, and germination information.
- Submit seeds for inspection and quarantine by the EAA upon arrival.

#### **Food Fortification**

Ethiopia's Fortified Foods and Fortificants Control Directive is aimed at improving public health by addressing widespread micronutrient deficiencies, particularly in vulnerable groups. The regulation mandates the addition of essential vitamins and minerals, such as iron, iodine, and vitamin A and D, to staple foods like wheat flour, corn flour, salt, and edible oils. The regulatory framework for food fortification outlines specific standards and guidelines for local producers and importers to ensure compliance. For example, salt must be iodized to combat iodine deficiency disorders, which have historically been prevalent in Ethiopia. Wheat and corn flour are required to be fortified with iron and folic acid, addressing issues such as anemia and neural tube defects. Similarly, edible oils must be fortified with vitamin A and D. EFDA oversees the enforcement of these regulations, ensuring that fortified products meet the established standards. EFDA also conducts regular inspections, monitors compliance, and collaborates with stakeholders in the food industry to facilitate the fortification process.

In June 2022, the Ethiopian Standard Council endorsed mandatory fortification of edible oil and wheat flour to address the problem of micronutrient deficiencies in the country. Prior to this decision, IES had a voluntary standard for wheat flour and edible oils. The Compulsory Ethiopian Standards (CES) for fortified edible oils and wheat flour are as follows:

- CES 310: 2022: Fortified Edible Oils: Edible oils must be fortified with Vitamin A and D to address public health concerns related to nutritional deficiencies. The standard specifies the minimum amount of vitamins and nutrients that must be present after fortification to improve the dietary intake of essential nutrients among consumers.
- CES 309: 2022: Fortified Wheat Flour: Wheat flour shall be fortified with Vitamins B1, B2, B6, B12, niacin, folate, and zinc. These micronutrients must conform to the limits set in the national standard.

In October 2023, EFDA drafted a regulation on food fortification as detailed in the "Fortified Foods and Fortificants Control Directive." This draft directive outlines several key regulatory and standards requirements. The directive defines "fortificants" as compounds containing specific micronutrients (vitamins and minerals) intended to be added to a food product. The directive shall be applicable on all fortified foods and fortificants produced locally and imported to the country. Below are the key regulatory requirements and standards based on the directive:

- Mandatory Registration: All fortified foods and fortificants, whether locally produced or imported, must be registered with the EFDA. It is prohibited to manufacture, import, distribute, or sell any fortified products without prior registration.
- Compliance with Standards: Fortified products must meet the national Ethiopian standards or internationally recognized standards in the absence of local standards. The EFDA may require additional information or samples during the product evaluation process.
- Certificates for Market Authorization: Applicants must submit various certificates, including a certificate of competency for local manufacturers or importers, a certificate of Good Manufacturing Practice (GMP), a certificate of analysis, and food-grade packaging certification. For imported products, a certificate of free sale from the country of origin is also required.
- Packaging and Labeling: Fortified products must use food-grade, non-transparent packaging to protect the product's integrity. Labels must clearly list ingredients, net content, production and expiration dates, fortification details, and storage instructions in Amharic or English. Labels must not be misleading or deceptive.
- **Inspection and Testing**: After registration dossier evaluation, the EFDA may conduct onsite inspections to verify compliance with GMP and may test product samples in a laboratory to confirm adherence to standards.
- **Stability and Shelf-Life**: Products must undergo stability testing under conditions that simulate Ethiopia's climate. Applicants are required to submit reports on both accelerated and real-time stability studies, ensuring that products maintain quality throughout their shelf life.
- Major and Minor Variations: Any changes to the product, such as changes in ingredients, packaging, or shelf life, must be reported to EFDA. Major variations that affect the safety or quality of the product require EFDA approval before marketing, while minor variations must still be reported but are subject to less stringent requirements.
- **Re-registration**: Fortified products must be re-registered within 120 days of their registration expiration. Applicants must provide updated certificates, confirm that the manufacturing process remains unchanged, and submit fresh samples for analysis if required.

## **Halal Food Regulations**

Ethiopia has been developing its standards for halal food imports in response to the growing demand, but there are not fully detailed, publicized national halal standards as strict as those found in countries like Saudi Arabia or Malaysia. However, the country follows certain guidelines for halal food imports,

focusing on international standards and religious requirements. Ethiopia also issues halal certifications, particularly for meat exports to the Middle East. The Ethiopian Islamic Affairs Supreme Council (EIASC), Department of Accreditation and Certification, plays a key role in overseeing halal certification and compliance in Ethiopia. The EIASC is responsible for establishing, enforcing, and monitoring guidelines to promote the development of halal services in Ethiopia, as well as issuing certifications for halal products. Prior to granting a halal certificate, EIASC verifies the halal status of raw materials and products through an official site inspection. Also, it may collaborate with foreign halal certifying bodies to ensure imported products meet Islamic dietary laws.

Ethiopia also accepts international halal certifications issued by competent authorities. Ethiopia often relies on international halal standards, such as those set by the World Halal Food Council (WHFC) or International Halal Integrity Alliance (IHI Alliance), to guide its halal food regulations. These international guidelines are commonly adopted by Ethiopian importers and exporters to meet market demands. Importers need to submit halal certification documents issued by these authorities, which prove that the products meet halal standards from slaughter to packaging. With a substantial Muslim population, there is a growing demand for halal food products in Ethiopia. Thus, U.S. exporters catering to this market segment are advised to ensure proper halal certification.

Other Standards: IES' Compulsory Standards Catalogue 2023 contains a list of mandatory 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 MRLs 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. IES' mandatory standards "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.

# Section VIII: Geographical Indicators, Trademarks, Brand Names, and Intellectual Property Rights

Despite being a member of the convention establishing the World Intellectual Property Organization (WIPO), Ethiopia has not yet ratified most international conventions on the protection of Intellectual Property Rights (IPR). Ethiopia is not yet a signatory to the Paris Convention for the Protection of Industrial Property, the WIPO Copyright Treaty, and the Madrid System for the International Registration of Marks, or the Patent Cooperation Treaty.

The Ethiopian Intellectual Property Authority (EIPA) oversees IPR issues including trademarks, brand names, and other intellectual property rights. EIPA facilitates and promotes the legal protection and use of IPR guaranteed by various laws. The authority also administers functions related to trademark registration, invalidation, or cancellation. In addition to its administrative duties, the EIPA is involved in the drafting of intellectual property laws and regulations. In particular, the office has a mandate to study, analyze and advise the government on IPR policies and legislative initiatives. Overall, the IPR system in Ethiopia remains underdeveloped. IPR laws are designed to protect creators, inventors, and businesses

by offering them exclusive rights to their innovations and creations, as well as providing remedies for infringement and unauthorized use.

## **Geographical Indicators (GIs)**

Ethiopia currently lacks explicit legal protection for geographical indications (GIs), though they may receive indirect coverage under the Trademark Registration and Protection Proclamation No. 501/2006 and revised Proclamation No. 273/2012. Legal analysts describe that the existing trademark law does offer limited provisions for the protection of GIs as collective trademarks. In the absence of a distinct legal framework for GIs, both trademarks and GIs are typically protected under the same legal framework. The EIPA has drafted a law on the registration and protection of GIs and conducted industry consultation. The drafted law safeguards the names of products linked to specific geographical areas, ensuring that only products originating from these regions can use the designated GI labels. Local examples include Ethiopian coffee varieties like "Yirgacheffe", "Sidamo", and "Harar", which are protected to preserve their unique qualities tied to geographic origin.

#### **Trademarks**

EIPA oversees trademark protection under the <u>Trademark Registration and Protection Proclamation No. 501/2006</u>, complemented by the <u>Trademark Registration and Protection Regulation No. 273/2012</u>. The law defines a trademark as any visible sign capable of distinguishing goods or services of one person from those of others, encompassing elements such as words, designs, letters, numerals, colors, or the shape of goods or their packaging. This law allows individuals and businesses to register trademarks for goods and services to distinguish their products in the market. The law protects registered trademarks from unauthorized use and provides remedies for infringement. Notably, Ethiopia follows a first-to-file system, meaning trademark rights are granted to the first applicant who registers.

## **Trademark Registration and Application:**

Any individual, association, or legal entity involved in the production and distribution of goods and services can apply for trademark registration if they meet the requirements set forth in the <u>Trademark Registration and Protection Regulation No.273/2012</u>. The registration of a trademark will be valid for seven years from the date of the application. The registration can be renewed for an additional seven-year period. The renewal must be made within three months of the registration expiry, or within six months after by paying a penalty in addition to the regular renewal fee. Failure to renew the trademark within the specified time will result in the trademark being considered waived or canceled.

#### **Key Aspects of Trademark Registration and Protection in Ethiopia:**

- Eligibility for Registration: Natural persons, companies, or other entities can apply to register a trademark. Foreign applicants must appoint a professional representative in Ethiopia.
- Registration Duration and Renewal: Trademark registration is valid for seven years from the filing date and can be renewed indefinitely for consecutive seven-year periods.
- International Filing and Priority: Ethiopia recognizes the right of priority for trademark applications filed abroad, allowing applicants to claim the filing date of an earlier application in a foreign country if filed within six months.
- Distinctiveness Requirement: A trademark must be capable of distinguishing the goods or services of one person from those of others. Marks that are descriptive, generic, or contrary to public order or morality are not eligible for registration.

- Trademark vs. Trade Name: Registering a trade name does not automatically protect the associated trademark. Separate registration is required for trademark protection.
- Nice Classification System: Ethiopia utilizes the Nice Classification (NCL) system for categorizing goods and services into 45 classes, aligning with international standards.
- Use Requirement: If a trademark is not used for three consecutive years after registration, it may be subject to cancellation.

## **Requirements for Foreign Trademark Application:**

- Renewed Business License or Certificate of Registration of a foreign trademark or Certificate of Incorporation.
- Authenticated Power of Attorney, if the application for the registration of a trademark is filed through an agent.
- Sample of trademark: One full-size copy on A-4 paper and eight reduced-size copies on A-4 paper.
- Completed <u>application form</u> in two copies.
- Please refer to this link for information on trademark application fees.
  - Application fee: Application fee of 1,750 birr for one class. If the trademark is subject to a service covering more than one class of goods or services, the fee shall include additional payment of 50% of 1,750 birr).
  - o Certificate Registration fee: 3,000 birr for one class.

# Other Intellectual Property Rights (IPR) Laws

- Patent Law (Proclamation No. 123/1995): This law governs the protection of inventions, minor inventions, and industrial designs. To be patentable, an invention must be novel, involve an inventive step, and be capable of industrial application. Patent protection lasts for 15 years, with a possible five-year extension if the invention is being properly used in Ethiopia.
- Copyright Law (<u>Proclamation No. 410/2004</u>, amended by <u>Proclamation No. 872/2014</u>): Copyright protection is automatic upon the creation of a work, and registration is optional. The protection lasts for the life of the author plus 50 years.
- <u>Industrial Design Regulation</u>: Aesthetic aspects of products, such as shape, color, texture, or ornamentation. Industrial designs are protected for five years, renewable up to 15 years, provided proof of use in Ethiopia is furnished.

Table 4: Summary of Key Intellectual Property Rights Protection in Ethiopia

Type of IPR	<b>Protection Method</b>	Duration of Protection	Registration Authority
Trademark	Registration required	Seven years, renewable indefinitely	EIPA
Geographical Indications	Registration required	Indefinite (if valid criteria met)	EIPA
Copyright	Automatic (registration optional)	Life of author plus 50 years	EIPA
Patent	Registration required	20 years	EIPA
Industrial Design Registration required		Five years, renewable up to 15 years	EIPA

Source: EIPA Proclamations and Regulations

#### **Plant Breeders' Right Protection**

Ethiopia's Plant Breeders' Right Proclamation No. 1068/2017 establishes legal protection for breeders of new plant varieties across all genera and species in Ethiopia. Some species may be exempted through the Ministry of Agriculture directives. To qualify for protection, a variety must satisfy: novelty, distinctness, uniformity, and stability. The protection lasts for 20 years for annual crops and 25 years for trees, vines, and other perennial plants. The breeder has exclusive rights to produce, sell, condition for propagation, import, export, or otherwise commercialize the protected variety. This also covers "essentially derived varieties" and those not clearly distinguishable from the protected variety. The Ministry may impose restrictions (e.g. compulsory licensing) on cases such as inadequate supply, public health, or other public interest concerns. Also, exceptions exist for private use, experimental use, research, or using a variety as an input for further breeding. The application process includes filing with the Ministry of Agriculture, preliminary determinations, sample deposit, use of clear variety denominations, and publication for opposition comments. Determination of protection also requires that genetic resources used in breeding comply with laws on access and benefit sharing when applicable. Infringement provisions cover unauthorized commercial use of protected varieties. Remedies include injunctions, damages, and potentially criminal liability.

Please refer to the <u>2025 Ethiopia Investment Climate Statement</u> on protection of property rights for a complete understanding of IPR situation in Ethiopia. In addition, Ethiopia's property rights laws, rules, regulations, and treaties are available at <u>WIPO</u>.

## **Section IX: Import Procedures**

The following are the general steps for importing a product into the country.

- 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.
- Importer pays foreign suppliers for goods.
- Customs clearance and inspection by relevant government authority at Port of Djibouti or dry ports in Ethiopia. (Note: Customs clearance and inspection can take several weeks.)

# Certificates and documents generally required for importing food and beverage products to Ethiopia:

- Registration certificate
- Agency agreement- legally binding contract in which a company (the *principal*) authorizes another party (the *agent*) to act on its behalf in a foreign market
- Original and copy of health certificates for food items excluding alcoholic drinks:
  - Phytosanitary Certificate if the food item is unprocessed fruit, vegetable, or cereal.
  - Veterinary Certificate if the food is unprocessed animal and animal product.
- Certificate of conformity, including laboratory analysis, for products with compulsory standards
- Certificate of Origin
- Free sale certificate (or FDA's Certificate to a Foreign Government for FDA-regulated products)
- Packing list
- Customs declaration
- Bill of loading, airway bill or track bill

- Commercial invoice
- Certificate of irradiation, evidencing the amount of remaining in it is not harmful to human consumption if the food is irradiated.

Shipment of grains, oilseeds, fresh fruits, and vegetables require a phytosanitary certificate issued by a competent government authority. Livestock and livestock products require a veterinary certificate.

As noted in Section I, imported 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 the country without inspection at the point of entry. A list of third-party certifiers is available in Appendix II. Uncertified cargo will be subject to normal inspection procedures.

# Import of Compound Feed, Feed Ingredients, and Additives

EAA's Veterinary Drug and Animal Feed Administration and Control directorate has a directive to control the import of animal feed and related products. The Feed Processor, Importer, Distributor and Exporter Registration and Certification Directive No. 03/2015 is not available online. The directive requires the following documents to import compound feed, feed ingredients and additives:

- Registration Certificate
- Import Permit
- Sanitary or phytosanitary certificate
- Ingredient composition in order of largest to smallest
- Certificate of Batch Analysis (nutrient profile, contaminants such as mycotoxins, heavy metals, foreign matter, microbiological safety, compliance with declared ingredient composition, etc.)
- Certificate of Good Manufacturing Practice (GMP)
- Certificate indicating that it is free from GMOs
- Certificate of freedom from Protein of Ruminant origin

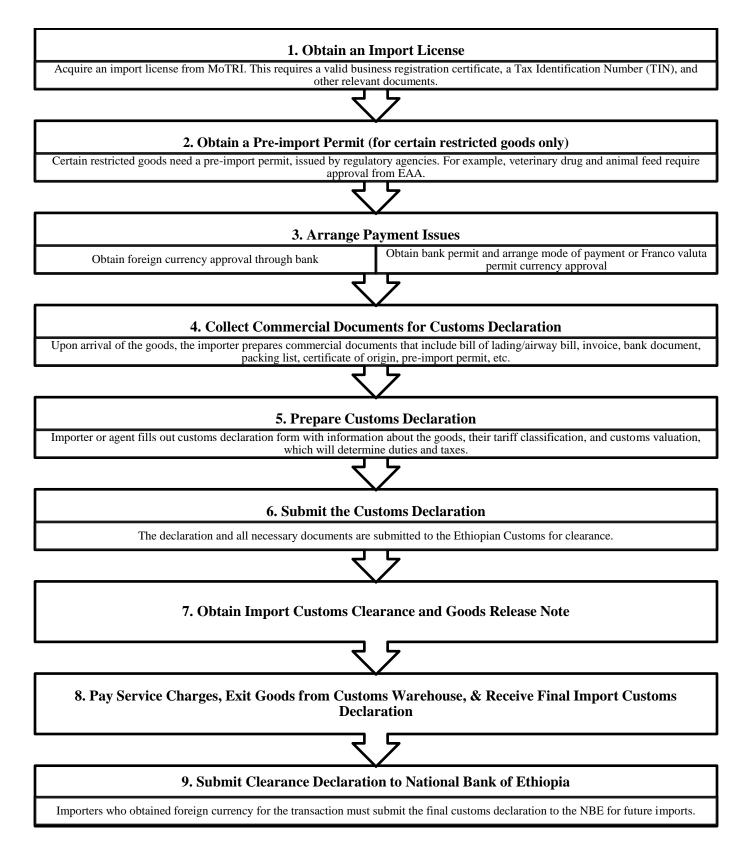
## Import of Animal and Animal Genetics Materials (AAGM)

Importation of AAGM is allowed for specific purposes such as for commercial breeding and production, research, and extension. The following conditions must be met to import AAGM:

- Imports 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.

For importation of AAGMs, GOE regulatory authority requires that the World Organization for Animal Health (WOAH) guidelines to be strictly adhered. This includes from labeling, production and processing, health, manpower, transportation, and facility requirements. The guidelines for import and export of animal and genetic material are enclosed as an attachment.

**Figure 3: Flowchart for Import Procedures** 



Section X: Trade Facilitation

The GOE has an <u>Electronic Single Window (eSW)</u> platform that helps facilitate trade and enhance local capacity. This initiative, launched in January 2020, is part of the government's commitment to improve international trade and ease of doing business in the country. The eSW system automates trade procedures and replaces the need for physical, manual, and duplicative processes. It also plays a key role in enhancing transparency for trade. The single window system connects 16 major cross-border regulatory agencies. It enables traders to submit documentation and receive electronic permits relating to import and export through a single window submission, significantly reducing the time and cost to trade. The automated platform creates a paperless environment and eliminates multiple physical inspections and repetitive document submissions; it has reduced clearance time from 44 days to 13 days with the goal of clearance times eventually reaching only three days.

Before launching the electronic single window service, Ethiopia had been using manual procedures that required frequent face-to-face interaction with regulatory agencies. This resulted in high trading costs and delays due to extensive documentary requirements, high levels of physical inspection of imports, and lack of coordination among border agencies. The electronic single window platform has two major portals:

- *Trader Portal*: The trader submits the trade documents required for customs and border clearance electronically, views the processing procedures and various statistical information, and provides the function to pay the taxes and fees electronically.
- *CBRA Portal*: It provides the function that the person in charge of the authorities to process electronically the verification, inspection and approval of the documents received through the trader portal.

Please visit the <u>Ethiopian Customs Trade Portal</u> for detailed information on taxes, tariffs, and other documentations related to trade facilitation.

## **Required Third Party Inspection**

The Ministry of Trade and Regional Integration (MoTRI) and the Ethiopian Food and Drug Authority (EFDA) require a Certificate of Conformity (COC) for food and agricultural products subject to Compulsory Ethiopian Standards (CES). The COC ensures product quality, food safety, and facilitates faster customs clearance at entry ports. Products falling under CES must be accompanied by a preexport certificate of conformity.

Mandatory standards cover a range of agro-food products, including fresh and canned fruits and vegetables, alcoholic and non-alcoholic beverages, edible oils, oilseeds, food additives, and prepackaged foods. Certificates of conformity can be issued by authorized third-party inspection companies accredited to ISO/IEC 17025. International companies authorized to conduct pre-shipment Verification of Conformity (VoC) programs for Ethiopia include <a href="Cotecna">Cotecna</a> and <a href="Bureau Veritas">Bureau Veritas</a>. U.S. exporters are advised to contact the North America branch offices of these third-party inspection companies to submit inquiries and arrange certification.

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

Ethiopian Food and Drug Authority (EFDA)

Email: contactefda@efda.gov.et

Tel: +251 115 524 118 Addis Ababa, Ethiopia

Ethiopian Agricultural Authority (EAA)

Email: info@eaa.gov.et

Ethiopian Conformity Assessment Enterprise (ECAE)

Email: info-cp@eca-e.com Tel: +251 118 695 041 Addis Ababa, Ethiopia

Ethionia Environmental Protection (Authority)

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

Third-party inspection companies that provide Pre-Export Verification of Conformity for food and agricultural products:

# Cotecna Ethiopia VoC Program Office

Email: info@cotecnakenya.com (coverage from Kenya office)

Tel: +251 116 670 477 Addis Ababa, Ethiopia

## Bureau Veritas Services PLC

Email: contact.ethiopia@bureauveritas.com Tel: +251 118 685 120 or +251 966 685 898

Addis Ababa, Ethiopia

# Control Union Certifications Ethiopia

Email: ethiopia@controlunion.com

Tel: +251 116 298 330 Addis Ababa, Ethiopia

## SGS - Ethiopia

Tel: +251 116 670 778 Addis Ababa, Ethiopia

## Intertek Ethiopia

Tel: +251 929 296 883 Addis Ababa, Ethiopia

Attachments: Guidelines for Import & Export of Animal and Genetic Material (3).pdf