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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.

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Disclaimer:

This report was prepared by the USDA/Foreign Agricultural Service, Office of Agricultural Affairs, for U.S. exporters of food and agricultural commodities. While every possible care has been taken in the preparation of this report, 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

In Calendar Year 2023, the United States exported $269 million in agricultural and related products to Ethiopia. This figure comprises both food assistance and commercial exports. The annual value of commercial export sales is approximately $40 million. Principal U.S. agricultural exports to Ethiopia are wheat, pulses, vegetable oils, and food preparations.

The Ethiopian food legislations are designed to ensure food safety, quality, and transparency across the food 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 these food safety standards, with regular inspections conducted to ensure compliance. The laws also require clear product labeling and are aligned with international standards, such as the Codex Alimentarius, to promote public health and facilitate global trade. The regulations are also aimed at protecting consumers from harmful practices and ensure access to safe, high-quality food products.

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 also implementing macro-economic reforms, including trade liberalization, to address foreign currency shortages, trade deficits, and rising food inflation. As of July 2024, Ethiopia adopted a market-based foreign exchange system and removed a two-year import ban on select food and agricultural products. In March 2024, the GOE liberalized the export, import, wholesale, and retail trade sectors, which were previously limited to domestic businesses. These reforms are expected to attract foreign investment, improve trade competitiveness, fair trade practices, and support Ethiopia's accession to the WTO.

Notable updates in the 2024 FAIRS Country Report include information on food additives, food and feed products registration, food fortifications, halal regulation, and Geographical Indicators (GIs) and Trademarks registration and protection, and labeling requirements for food and feed products. Furthermore, the report provides updated information on import procedures and required documentations.

Section I: Food Laws

Since the past few years, the GOE has been making reforms to modernize the country's food safety, 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 agro-food manufacturers, especially in and around the capital city, Addis Ababa. The GOE has subsequently taken steps to regulate these establishments to ensure the food they produce, import, distribute, or sell comply with food safety and quality requirements.

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

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

Broadly speaking, the country's food safety regulatory system is authorized and mandated in 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 government 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." In particular, the proclamation authorizes the setting of standards and regulations for locally produced and imported foods, in areas such as production, promotion, storage, packaging and labeling, distribution, and laboratory testing.

In 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 Proclamation No.1112/2019 authorizing a revised mandate of FMHACA. With the amended structure, FMHACA is renamed as the Ethiopian Food and Drug Authority (EFDA). The EFDA is mandated to regulate only products related to food, medicine, tobacco, cosmetics, and medical devices. Regulation No. 531/2023 also provide the powers and duties of EFDA. The legislative mandate of EFDA has similarities to the U.S. Food and Drug Administration.

In 2022, the GOE established the Ethiopian Agricultural Authority (EAA) as an autonomous federal government organ having its legal personality 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 existing weak 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. Furthermore, 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 from the country of origin and are subject to quarantine inspection. Shipping containers carrying plants or plant articles must be marked with the following information: contents, origin, address of shipper, supplier, or freight forwarder; name of consignee; and entry point in Ethiopia. In cases where pests are detected in an incoming shipment, 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 quarantine and livestock disease issues. Imports of livestock, meat, by-products, and genetics require an import permit along with a health certificate from the country of origin. When applying for an import permit, the importer must identify the type of product, country of origin, means of transport, date of arrival, countries transited, and port of entry. Upon arrival, livestock, meat, and by-products, as well as 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 on the last page of this report.

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. In fact,

IES publishes the draft national standards online along with an open solicitation for public comments. Given this high degree of transparency, the IES, from Post's perspective, is a model for the broader GOE in open and inclusive rulemaking.

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 IES Mandatory Standards.

Third-party inspection bodies, which have been approved by MoTRI, can certify the 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.

Summary of Key Regulatory Agencies and Responsibilities		
Government Ministry	**Regulatory Authority/Directorate**	**Key Responsibilities**
Ministry of Health (MoH)	Ethiopian Food and Drug Authority (EFDA)	EFDA is responsible to ensure: • Food safety and quality; regulates processed and semi-processed food products. • Safety, efficacy, quality, and proper use of medicines; and • Safety, quality, and performance of medical devices.
Ministry of Agriculture (MoA)	Ethiopian Agricultural Authority (EAA) Plant Health Regulatory Directorate	• Inspection of consignments of plants/other regulated articles including import and export of plants and plant products and provide import and export permits. • Inspection of required phytosanitary documents and issuance of phytosanitary certificates. • Fumigation of consignments to meet phytosanitary requirements. • Supervise quarantine treatments including fumigation and weed cleaning processes. • Advise and supervise disposal of plant and plant products. • Crop surveillance for pests mainly cereals, fruits, and vegetables. • Protection of endangered areas – maintenance and surveillance of pest-free area(s) with low pest prevalence. • Inspection, approval, and registration of pesticides • Food safety risk assessment in different crops including pests and pesticide application.
	Animal Health Regulatory Directorate	• Establish a system that ensures access to quality veterinary services to improve the prevention and timely

		control of animal diseases. • Quarantine on import and export of livestock, fish, and their byproducts; prevent communicable livestock diseases and the outbreak of migratory parasites. • Ensure the proper administration and quality control of veterinary drugs and feeds as well as veterinary services.
	Veterinary Drug and Animal Feed Administration and Control Directorates	• Responsible for registration and certification of feeds and veterinary drugs that are produced, imported and in use in the country. • Setting standards for quality control activities, • Marketing surveillance, banning, revoking and suspension of registrations, packaging and labeling, trade, and licensing of veterinary drugs and animal feed.
Ministry of Trade and Regional Integration (MoTRI)	Import and Export Goods Quality Control Directorate	• Control quality of export and import goods. • Regulatory oversight on the importation and exportation of goods that do not comply with the Ethiopian mandatory standards. • Work with third party conformity assessment agencies and facilitate pre-shipment inspection.
	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.
Ministry of Innovation and Technology	Ethiopian Radiation Protection Authority (ERPA)	• Monitor and control of radiation levels in food, water, etc.
	Bio and Emerging Technology Institute (BETin)	• Conduct 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	• Prevention and control of environmental contamination. • Approval and permit for importation of Genetically Modified (GM) seeds and unprocessed GM crops. Note: Reference links for biosafety policy, regulation, and directives are in the summary table below.

Summary of Key Proclamations, Regulations, Directives, and Guidelines

Food Control Proclamations and Regulations	**Link**
Food and Nutrition Policy	Download
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
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
Guideline to Application for Registration of Plant Protection Products	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 (Amharic and English Texts)	Download
Directive to Provide Risk Assessment Parameters for Modified Organisms, No. 05/2018 (Amharic and English Texts)	Download
Directive to Establish Procedures for Management of Risks from Any Transaction Involving Modified Organisms, No. 06/2018 (Amharic and English Texts)	Download
Directive to Determine the Requirements for Transport and Storage of Modified Organisms, No. 07 /2018 (Amharic and English Texts)	Download
Directive to Determine the Content of an Application for Undertaking Deliberate Release of Modified Organisms, No. 08/2018 (Amharic and English Texts)	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 of prepackaged food products. While CES 197 is applicable to labeling of foods for special dietary uses. The following sub-section describes these general standards for labeling of prepackaged foods.

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.

Required 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^2 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 allergy, labeling must clearly describe its content:
  - Breakfast cereals containing grain gluten such as wheat, rye, oats, barley, etc.
  - Crustacean 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 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).

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

This compulsory Ethiopian standard provides definition of 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. Furthermore, the standard has provisions on special requirements relating to retention of desirable properties by means of appropriate storage conditions, and exempted products.

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 of 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 Modified (GM) Foods

- GM foods must carry the label 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 labeling.

Labeling Requirements for Baby Food Products

- Labeling requirements of baby food shall be in accordance with the national compulsory General Standards for Pre-packaged Foods Labeling (CES 73).
- Labels shall not discourage breast-feeding in any manner and shall 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 breast-feeding 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 use of words such as "humanized," "maternalized," or other similar/analogous expressions for infant food is prohibited.
- The immediate container of the product shall 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 “breast-feeding 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, which the product is to be consumed, considering climatic and storage conditions.
- The storage condition, 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 breast-feeding or breast milk shall be provided.
- All ingredients on the label of the product shall be listed in accordance with the following sub-articles:
  - Source of protein in the product shall be identified and clearly shown on the label.
  - Except for single ingredient products, a list of ingredients shall be declared on the label.
  - If the ingredient is from animal or plant, scientific name of the plant and part of animal or plant used shall be declared.
  - Additives such as fillers, artificial colors, sweeteners, flavors, or binders shall be 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 shall not offer for sale 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 shall not offer for sale or sell a 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 in 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 cm2 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 breast-feeding with this product, seek the advice of a health professional. It is important for your baby's health that you follow all 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:
    - Powdered formula is not sterile and may be contaminated with pathogenic microorganisms

during the manufacturing process or may become contaminated during preparation.
    - It is necessary for formula to be prepared one feed 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 to the baby, cooled to body temperature.
    - Any unused milk must be discarded immediately after every feed.
  - 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 shall not offer for sale or sell a 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 of ready-to-use therapeutic food and complimentary food products should be in accordance with the national compulsory standard CES 73 - General Standards for Pre-packaged Foods Labeling. In addition, the following requirements mentioned in subsequent article should also be respected.
- A manufacturer or distributor shall not offer for sale or sell a ready-to-feed therapeutic food or a complementary food product if the container or label affixed thereto 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 requirements of sub-article (1), the label of a ready-to-feed therapeutic food or a complementary food product shall include:
  - A statement 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."

- The importance of exclusive breast-feeding for the first six months and of continued breast-feeding up to two years or beyond.
- The recommended age of introduction that is not less than six months (180 days) and a statement that early introduction of complementary foods negatively affects breast-feeding.
- 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 feeding should be in accordance with the national compulsory standard CES.
- A manufacturer or distributor shall not offer for sale or sell skimmed or condensed milk in powder or liquid form, unless:
  - The container or label affixed thereto 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 shall not offer for sale or sell low-fat or standard milk in powder or liquid form, unless:
  - The container or label affixed thereto 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 shall have clear "instruction on disposal of used package."

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 food 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.
- Label shall clearly indicate pack size of unit pack.
- Label shall be affixed on every primary packaging of any fortified food and micro-nutrient bearing the following information in clearly legible and indelible letters at least in Amharic and/or English language:
  - Name of the product.
  - Name and full address of the manufacturer, including country of origin.
  - List of ingredients.
  - The name and amount of micro-nutrient available.
  - Net content by weight for solid products or volume for liquid.
  - Date of manufacture and shelf-life, which shall indicate at least the month and year.
  - The storage condition and, where appropriate, shelf-life of the product before and after opening and its reconstitution.
  - Batch or lot number.
  - Standard mark and logo and registration number.
- Appropriate instruction for use or preparation for fortified food and micro-nutrient products.

Labeling Requirements for Animal Feed Products

The labeling requirements for feed products, as specified in the Directive for the Registration of Feed Products No. 995/2024, are as follows:

- **Label Content**:
  - 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 with the packaging.
  - Pasted, tied-on, erased, or illegible labels are not acceptable.
  - Labels must avoid misleading words or images.

- **Mandatory Information on the Label: The feed product label must include:**
  - 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 and Animal Genetic Materials:
Ethiopia's labeling requirement for importation of animal genetic materials such as semen, ova and embryo must contain the information below:

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

Section III: Packaging and Container Regulations

In accordance with the EFDA Proclamation No. 1112/2019, it is generally required that "packaging material shall be made out of substances, which are safe and suitable for their intended use, and the product shall be packed in container which will safeguard its hygienic, safety, quality and food grade." Further, the Proclamation states "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 shall be appropriately packed and its packaging material shall not contaminate the product and comply with national standards. The primary packaging of a processed food shall have a label in Amharic or English language. 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 standards may also contain additional guidance and/or requirements as it relates to packaging and container requirements. As an example, the standard for canned peaches indicates packing requirements, including lacquer usage inside the can as well as can thickness. Packaging of infant and follow up formula must be made from a non-plastic material. In addition, for approval of packaging material, certification of analysis and specification (contact approval) is required.

Packaging Sustainability Measures:

IES embraces international standards related to packaging sustainability measures identical with the International Organization for Standardization (ISO). IES has two specific 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 packaging is considered as 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. Furthermore, 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 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 a plastic or PET bottle packaging complies with the standards or specifications, then the packaging is considered 100 percent recyclable.

Section IV: Food Additive Regulations

EFDA regulates the use of food additives, which must comply with both international and national food safety standards. Any food additive to be imported into Ethiopia shall be permitted by Codex Alimentarius or the country's standard concerning its use as an input for food processing with its due level.

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

According to the revised proclamation, EFDA shall determine the list of allowable food additives and where appropriate prohibit the use of food additives in a certain category of foods. EFDA evaluates the safety of food additives for authorizing the use of new as well as 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 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 *Codex Stan 192*, General Standard for Food Additives. For example, in the case of natural wines, the Ethiopian Standard *ES 351: 2001* specifies list of permitted additives that may be added to fresh grapes, musts, and dry grapes during vinification. The standard also provides list of additives and treatments permitted during vinification and conservation of wines and sweat filtrates. In addition, it contains list of permitted substances and forbidden additives. For instance,

tannin can be used for clarification purposes, but coloring substances are prohibited except for oenocyanin or caramel.

Food Additives Control Directive No. 1020/2024: This EFDA directive, 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 they are safe and do not endanger public health. Key provisions include:

- **Scope:** This directive shall be applicable to any person who engage in the production, import, export and distribution of allowable list of food additives permitted by Codex Alimentarius Commission and determined by EFDA and the food additives that are not prohibited to use in food categories by EFDA. 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 shall 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 the EFDA. The notification process requires detailed documentation. The notification application process includes several key information 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 valid contact number and email.
    - Full food additive ingredient list.
    - Labels of the food additive.
    - Original free sale certificate from competent authority of exporting country.
- **Documentation languages**: All submissions for notification must be in Amharic or English.

- **Renewal**: The notification must be renewed every two years. The process must start no later than six months before the expiration of the current notification.
- **Notification Changes**: 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 the Ethiopian standards shall comply with the Codex General Standard 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 may not have chemical residue including pesticide, fertilizer, animal medicine, food additive chemical, cleaning chemical, a radioactive substance, and other contaminants above the maximum level issued or adopted by the appropriate organ.

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 out contaminants and toxins of concern and their corresponding maximum levels. 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.

In 2010, the Ethiopian government enacted the Pesticide Registration and Control Proclamation No. 674/2010. The legislation establishes a mandatory registration system for pesticides, tailored to national needs. The registration process involves the 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."

The Ethiopian Agricultural Authority (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 maximum residue limits (MRLs) and conducting pesticide residue analysis on primary agricultural products. Applicable MRLs as well as

limits for other contaminants are listed in the individual product standards. For example, in the case of apples, there are 41 different MRLs, as well as limits for heavy metals (e.g., lead) and microbiological contaminants (e.g., coliform). Imported apples, as well as domestically produced apples, are expected to comply with these requirements. In the event where a national standard does not exist, the GOE will likely defer to the Codex recommendation.

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

Section VI: Other Requirements, Regulations, and Registration Measures

Food Products 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, sea foods, processed vegetables, sliced fruits, nuts and their products, therapeutic foods, cereal based complementary foods, confectioneries, fats and oils, processed fruits, packed water, soft drinks, beer, iodized salt, and noodles.

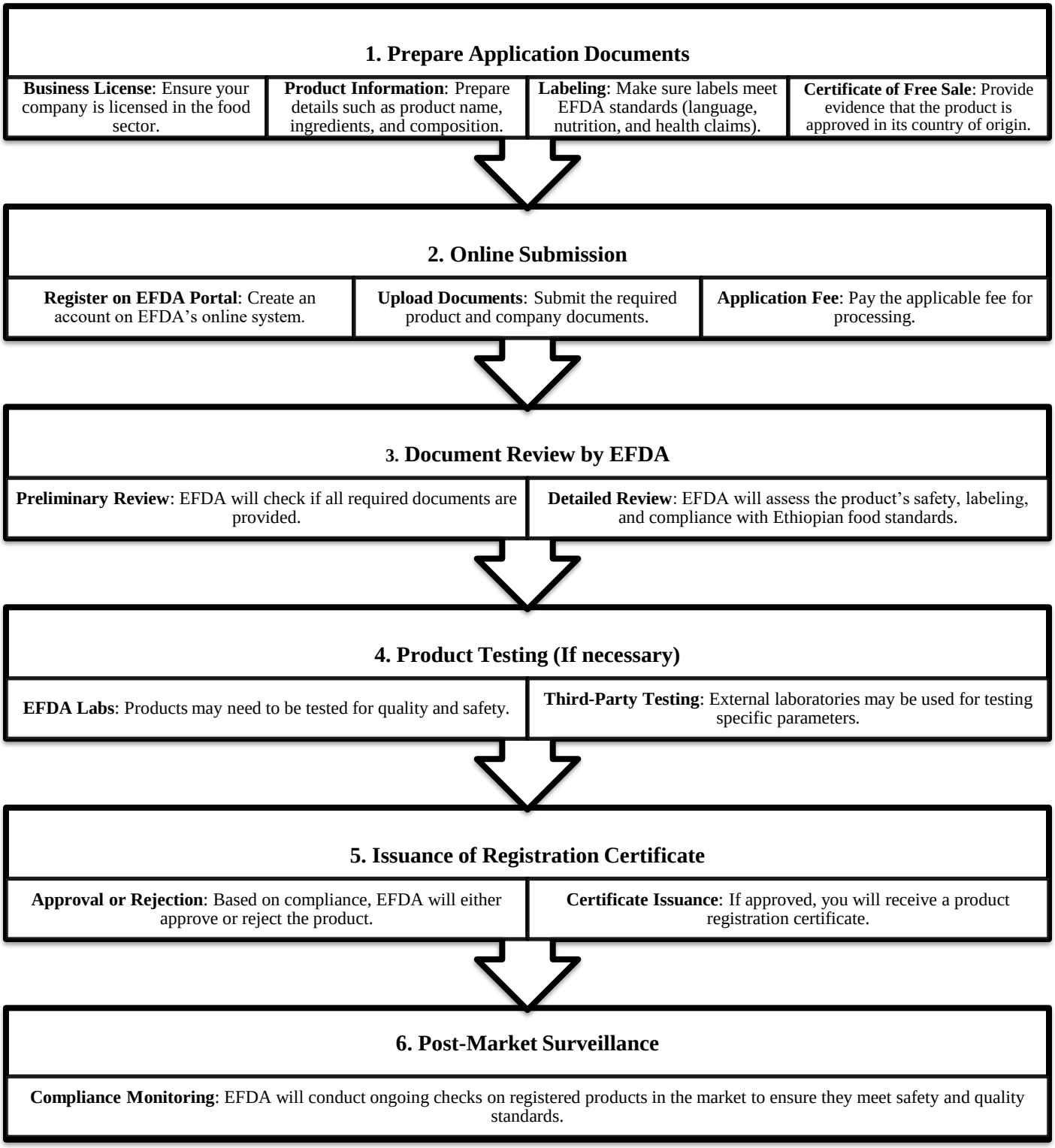
The required documentations for new registration of imported food products include:

- 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 quality and safety of raw materials and food additives used in manufacturing.
- Study evidence for determining shelf life of the product.
- Veterinary certificate attesting 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 product.

    - 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.
    - Made-in country, 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 allergenic, its labeling must clearly describe its content.
    - If the food is made of GM ingredients, a 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 Electronic Regulatory Information System (eRIS) 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 on the next page provides is a summary outlining the typical steps for food products registration with EFDA. The flowchart outlines the steps from application submission to post-market surveillance.

Figure 1: Flowchart for Food Products Registration



Facility Registration: EFDA requires pre-licensing formalities to issue a competency certificate to food manufacturers. According to the revised Food Manufacturing Factories Pre-Licensing Directive, the facility registration requirement applies to local food manufactures to ensure food safety and quality. EFDA classifies local food manufacturers into three different entities. This classification is based on expiry nature of the product, manufacturing process of the product, and end users of the product.

- **Manufacturers of 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 and
  - Other manufacturers producing foods of similar nature as above.

- **Manufacturers of High-Risk Food Products for General Purpose:**
  - Processed animal product
  - Processed sea foods
  - Processed fruit and vegetable
  - Processed nuts
  - Therapeutic foods
  - Complementary foods (for children three years and older)
  - Fortified foods (iodized salt, edible oil, flour, etc.)

- **Manufacturers of 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*:
  - 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%) and liquor products
  - Vinegars
  - Other related food products not mentioned in category I and II above
  - Imported food aid products donated by governmental or non-governmental organizations.
  - Raw materials used for food production.

Feed Products Registration: The Ethiopian Agricultural Authority's (EEA**)** Directive for the Registration of Feed Products (No. 995/2024) provides a comprehensive regulatory system for feed product registration in Ethiopia, ensuring that all products meet national and international safety and quality standards before being marketed or used for animal feed. It establishes a regulatory framework for registering 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 by-products 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 marketed or used commercially, it must be registered with the EAA. 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. Certain products, such as genetically modified feeds and those containing growth-stimulating hormones, cannot be registered. Exceptions exist for scientific research and emergency relief feed products, as well as pet foods accompanying travelers or diplomatic missions.

Application and Re-Registration Process: The process involves submitting required documents, 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-registered every four years, with any major or minor variations requiring notification and additional documentation.

Documentation for Feed Product Registration*:* The directive specifies the documents required for feed product registration. These include legal documents such as manufacturing licenses, agreements, and certificates of good manufacturing practices. Detailed descriptions of the feed product, including its physical and chemical properties, intended use, and packaging, must be provided. Applicants must also submit safety documents proving that the product is free from hazards and meets quality standards, along with labels that clearly display essential product information, such as manufacturing date, shelf life, and storage instructions.

Quality and Safety Requirements: Feed products must adhere to strict quality and safety standards. 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.

List of Required Documents for Feed Product Registration:

The following documents are required to ensure that feed products meet quality and safety standards before entering the market:

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 mad cow disease.
- Marketing Authorization: A certificate showing that the product is marketed in the exporting country.
- 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 for 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:

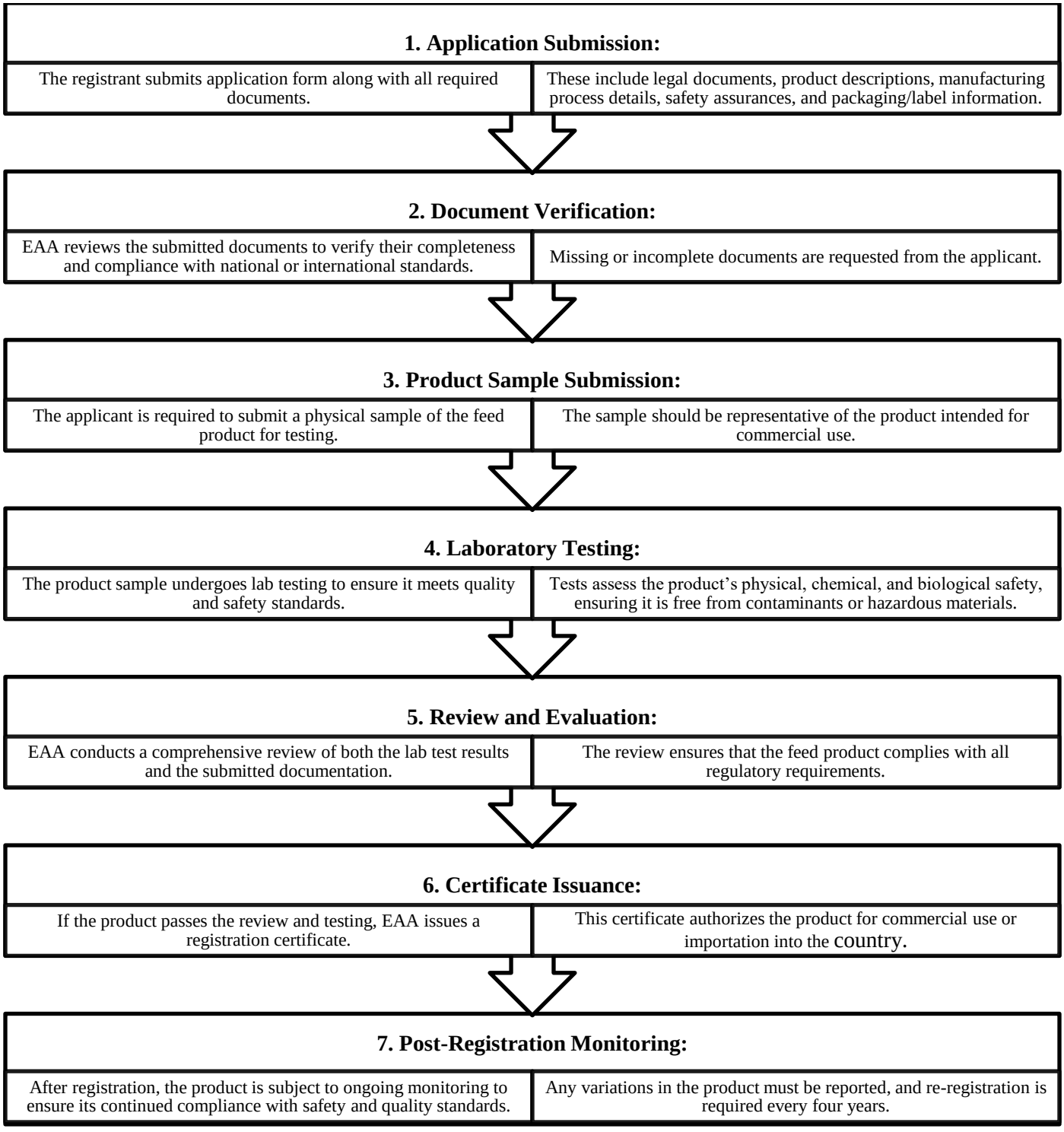
- Label Sample: A sample of the product label, which must include details like manufacturer name, product name, batch number, shelf life, net weight, ingredients, intended use, and any necessary warnings.

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.

Please see figure 2 on the next page that presents a summary of feed products registration and certification process flow.

Figure 2: Flowchart for Feed Products Registration



Section VII: Other Specific Standards/Laws

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 is expected to provide 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 Seed Proclamation No. 1288/2023 repealed the previous Seed Proclamation No. 782/2013 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 new proclamation also outlines seed marketing (including import and export), seed quality standards, testing and certification.

Food Fortification Regulation: Ethiopia's food fortification regulation 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, 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 flour is required to be fortified with iron and folic acid, addressing issues such as anemia and neural tube defects. Similarly, edible oils shall be fortified with vitamin A and D. EFDA oversees the enforcement of these regulations, ensuring that fortified products meet the established standards.

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, 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 free sale certificate 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 the 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 Regulation: 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 countries. 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.

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, safety aspects, such as maximum residue limits for pesticides or other contaminants that are found in voluntary standards are, in fact, mandatory, and shipments must comply with these requirements. The voluntary aspect of these standards only refers to quality-related issues, such as the grade of the product. 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.

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

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 (IPRs). For example, 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 IPRs issues including trademarks, brand names, and other intellectual property rights. EIPA facilitates and promotes the legal protection and use of IPRs 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.

Geographical Indicators (GIs): Currently, in Ethiopia there is little legislation specifically addressing the protection of GIs. 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 requested 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: Before the enactment of Trademark Registration and Protection Proclamation No. 501/2006) currently in force since 2006, Ethiopia did not have any specific legal regimes for the protection of trademarks. The preamble makes it clear that the Trademark Proclamation was needed to safeguard the reputation and goodwill of businesspeople by preventing confusion between similar goods and services. 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 Trademark Registration and Protection Regulation No.273/2012. The registration of a trademark will be valid for seven years from the date of the application. The registration can be renewed for additional seven-year periods. The renewal must be made within three months of the registration expiry, or within six months 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.

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 big size in A-4 paper and eight pieces in A-4 paper.
- Completed application form in two copies.
- 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).
- Certificate Registration fee: 3,000 birr for one class.

Please refer to recent publication of 2024 Country Investment Climate Statement 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 WIPO.

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. (Note: Because of foreign exchange shortages, it can take several months for an importer to receive the requested L/C.)
- Importer pays foreign supplier for goods.
- Customs clearance and inspection by relevant government authority at Port of Djibouti or dry port in Ethiopia. (Note: Customs clearance and inspection can take several weeks.)

Certificates and documents generally required for importing food and beverage products to Ethiopia:
- Registration certificate
- Agency agreement
- Original and copy of health certificates for food items excluding alcoholic drinks:
  - Phytosanitary Certificate if the food item is an unprocessed vegetable, fruit, and 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. Similarly, livestock and livestock products require a veterinary certificate.
As noted in Section I, imported product 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. Uncertified cargoes will be subject to normal inspection procedures. Please refer to recent edition of Country Commercial Guide for further details of Ethiopia's import procedures, regulations, and other relevant information.

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

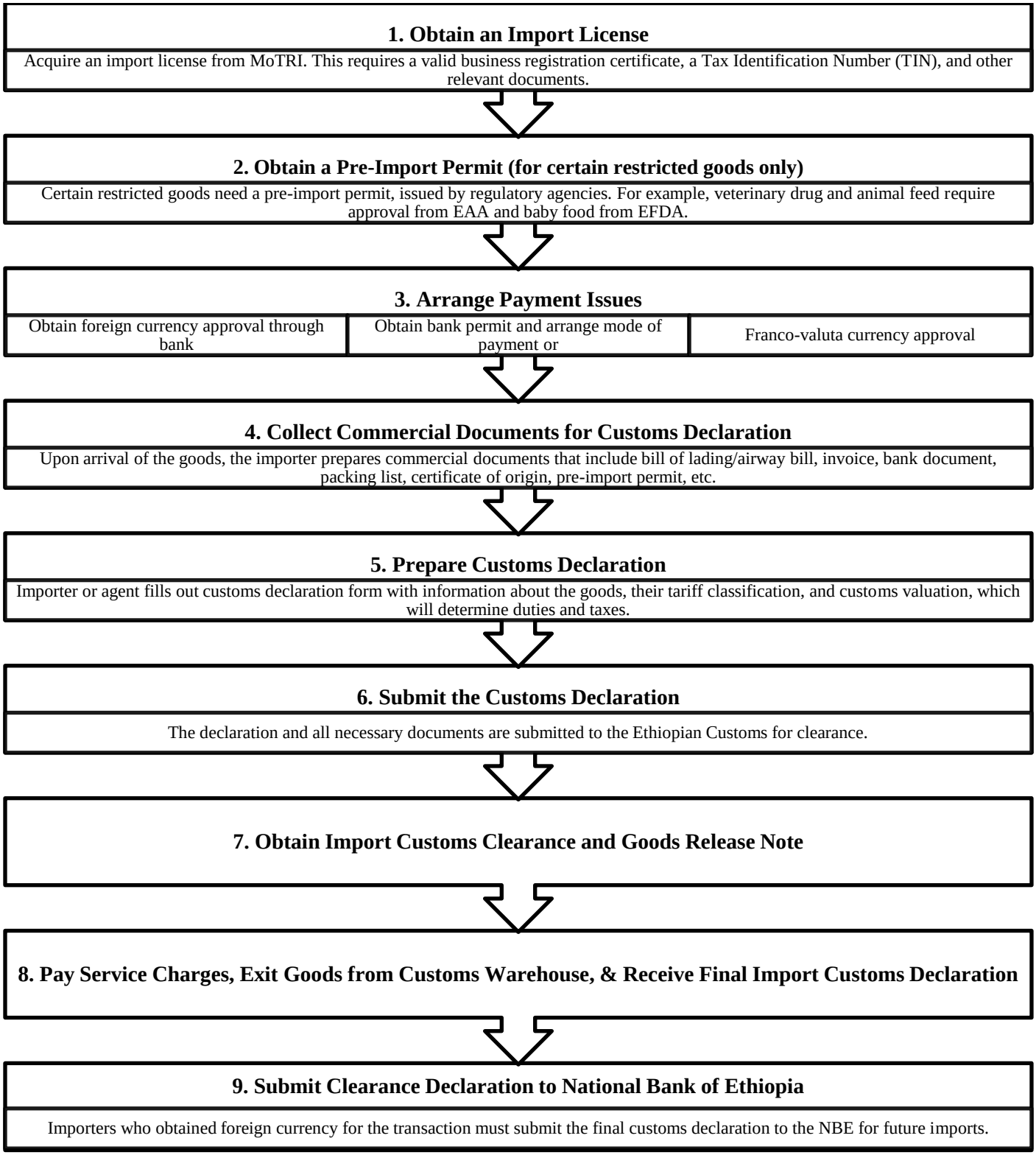
- Registration Certificate
- Import Permit
- Sanitary or phytosanitary certificate
- Ingredient composition in order of largest to smallest
- Certificate of Batch Analysis
- Certificate of Good Manufacturing Practice (GMP)
- Certificate indicating that it is free from GMO
- Certificate of freedom from Protein of Ruminant origin

I**mport of Animal and Animal Genetics Materials (AAGM**): Importation of Animal and Animal Genetics Materials (AAGM) is allowed for specific purposes such as for commercial breeding and production, research, and extension. The following conditions shall be met to import AAGM:

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

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.

Figure 3: Flowchart for Importing Goods and Customs Clearance



Section X: Trade Facilitation

The Government of Ethiopia has an Electronic Single Window (eSW) platform that helps facilitate trade and enhance local capacity. This initiative 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 duplicate 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 will create a paperless environment and eliminate multiple physical inspections and repetitive document submissions, it will reduce clearance time from 44 days to 13 days and eventually to 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 Ethiopian Customs Trade Portal for detailed information on taxes, tariffs, and other documentations related to trade facilitation.

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
Tel: +251 115 534 520

IPPC Official Contact Point
Email: wondale.habtamu@yahoo.com
Tel: +251 115 519 229
Addis Ababa, Ethiopia

Ministry of Trade and Regional Integration (MoTRI)
Tel: +251 115 513 990
Email: info@etrade.gov.et; support@etrade.gov.et
Addis Ababa, Ethiopia

Ministry of Agriculture (MoA)
Tel: +251 116 460 746
Email: info@moa.gov.et
Addis Ababa, Ethiopia

Institute of Ethiopian Standards (IES)
Email: info@ethiostandards.org
Tel: +251 116 460 111
Addis Ababa, Ethiopia

Ethiopia Codex Contact Point
E-mail: codexeth@ethiostandards.org
Tel: +251 116 460 525
Addis Ababa, Ethiopia

Ethiopian Conformity Assessment Enterprise (ECAE)
Email: info-cp@eca-e.com
Tel: +251 118 695 041
Addis Ababa, Ethiopia

Ethiopia Environmental Protection (Authority)
Email: info@epa.gov.et
Tel: +251 111 704 038
Addis Ababa, Ethiopia

Ethiopia Biodiversity Institute (EBI)
Email: info@ebi.gov.et
Tel: +251 116 615 607

Ethiopian Customs Commission (ECC)
Email: hocrecordopr@gmail.com; hocrecordad@gmail.com
Tel: +251 116 675 458
Addis Ababa, Ethiopia

National Bank of Ethiopia (NBE)
Email: compliantoffice@nbe.gov.et
Tel: +251 115 517 430
Addis Ababa, Ethiopia

Ethiopian Intellectual Property Authority (EIPO)
E-mail: info@eipo.gov.et
Tel: +251 115 528 000
Addis Ababa, Ethiopia

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

QITS Inspection Pvt.Ltd.Co
Email: info@qitsinspection.com
Tel: +251 118 332 882
Addis Ababa, Ethiopia

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