Ethiopian Food and Drug Authority

Cosmetics Import, Exportand Wholesale Control Directive

New Edition

March, 2020

Addis Ababa, Ethiopia

Contents

Introduction

WHEREAS, it is necessary to protectthe public health from health risks emerging out of unsafe and poor quality cosmetics;

WHEREAS, it isnecessary to restrict the presence of prohibited ingredients or harmful concentration of restricted ingredients in cosmeticsthat are risky to the public health;

WHEREAS, it is necessary to control and deter illegal cosmetics circulation and sale in Ethiopian market;

WHEREAS, it is necessary to take appropriate administrative measures against violations of this directive and other relevant laws;

NOW, THEREFORE, this directive is issued in accordance with Article 71 (2) of the Food and Medicine Administration Proclamation Nº1112/2019.

PART ONE
GENERAL

1. Short title

This directive may be cited as "Cosmetics, Import, Export andWholesaleControlDirective Nº 48/2020."

2. Definitions

Without prejudice to the definitions provided under Proclamation Nº 1112/2019, in this directive unless the context requiresotherwise:

1) "Adulterated cosmetic" means a cosmetic which bears or contains any poisonous or deleterious substance that may render it injurious to user under the conditions of use prescribed in the labeling; a product consisting in whole or in part of any filthy, putrid, or decomposed substance; a product consisting a substance other than its content or by substituting its content in whole or in part by such other substance; a product whose container is composed, in whole or in part, of any poisonous or deleterious substance; a product prepared, packed, held or stored under insanitary conditions whereby it may have been contaminated or rendered injurious to health;
2) "Application" means the process of officially requesting a regulatory authority to importexport and distributecosmetic;
3) "Applicant" means any person who import, export and/ordistribute cosmetic;
4) "Colorants" means substances which are exclusively or mainly intended to colour the cosmetic, the body as a whole or certain parts thereof, by absorption or reflection of visible light; in addition, precursors of oxidative hair colorants shall be deemed colorants;
5) "Cosmetic'' means any substance or preparation intended to be placed in contact with the various external parts of the human body by means of rubbing, pouring, steaming, sprinkling spraying on or otherwise applied to the human body or any part thereof with a view exclusively or mainly for cleaning, perfuming, changing appearance and/or correcting body odors and/or protecting or keeping them in good condition and article intended for use as component of a cosmetic but such articles exclude laundry soap, articles intended for the diagnosis, treatment, mitigation or prevention of human diseases, and products intended to affect the anatomy or of a physiological process of a human;

6) "Importer" meanslocally incorporated company or legal entity in the field of cosmetics, with permanent address and registered business entity who is responsible for import and/or placing the cosmetic in the market that may or may not be the product owner;
7) "Exporter" means alegally authorized entity which is engaged in exportation of cosmetics abroad;
8) "Importer means" means a legally authorized entity involved in the importation of cosmetics regulated under this directive;
9) "Ingredient" means any substance or mixture of substances intentionally used in the cosmetic during the process of manufacturing. But, it excludes impurities in the raw materials used, and subsidiary technical materials used in the mixture but not present in the final product;
10) "Label" means information written or printed or graphic matter on the immediate or outer packaging and any form of leaflets including user information leaflet and product safety summery;
11) "Misbranded cosmetic" means a regulated product under this directive which is falsely labeled, having misleading labeling or if it does not bear the required labeling information in accordance with this directive and/or other applicable laws;
12) "Notification"means an application submission by an applicant to get a notification note that allows cosmetics to be imported and marketed in Ethiopian market;
13) "preservatives" means substances which are exclusively or mainly intended to inhibit the development of micro-organisms in the cosmetic;
14) "Product recall" means a process of detaining and withdrawal of a cosmetic which is proved to be unsafe or of poor quality, or a product proved to be counterfeited, misbranded, mislabeled or having similar deficiencies from all channels of distribution. But such acts exclude withdrawal or recall of a product by the owner's initiation;
15) "Product variants" means items in a range of cosmetics which are produced by the same manufacturer, similar in composition and are intended for the same use but are available in different colours, fragrances or flavours;
16) "Substance" means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used but excluding any solvent

which may be separated without affecting the stability of the substance or changing its composition;

17) "Wholesaler" means a legally authorized entity involved in distribution of cosmetics in more than one regional state of Ethiopia;
18) "Person" means a natural or juridical person;
19) "Authority" means the Ethiopian Food and DrugAuthority;
20) Any expression in the masculine gender shall also apply to the feminine gender.

3. Scope

This directive shall be applicable onimport, exportandwholesale of cosmetics in Ethiopian market.

PART TWO
CERTIFICATE OF COMPETENCE

4. General

Any person who wants to import, export or wholesalecosmetic in Ethiopian market shall obtain certificate of competence from the authority before commencing cosmetic trading activity.

5. Application to get certificate of competence

1) An applicant for a certificate of competence shall:
   a) complete an application online through ilicense.efda.gov.et;
   b) fulfill the requirements set under Article 6 of this directive; and
   c) Pay the appropriate service fee as per the service fee Regulation.

2) The actual site audit shall be conducted based on satisfactory assessment outcomes of application submitted to the Authority as per the procedures designed in the ilicense.efda.gov.et.
3) The Authority shall evaluate the duly filled self-assessment checklist, inspection report and all other necessary documents submitted by the applicant.
4) The Authority may approve, reject or recommend corrections to the application by providing reason for its decision.

5) Where the requirements have not been met, the applicant shall, as appropriate, be informed through i-license to address the deficiencies or the reason for rejection.
6) Applicants who are required to take corrective action shall carry out remedial measures before re-inspection of the premises. A one-time re-inspection may be carried out by the Authority free of charge whereas inspection request beyond one-time re-inspection shall be subject to additional charge.
7) Notwithstanding sub-Article (6) of this Article, applicants who do not fulfill the requirements set under Article 6 of this directive after the conduct of three round inspections shall make a new application, and a new inspection will be conducted accordingly.
8) Once requirements are met, the Authority shall issue certificate of competence to the applicant.

6. Requirements and issuance of a certificate of competence

1) An importer or wholesaler of cosmetics applying for a certificateof competence under this directive shall fulfill minimum requirements in relation tolocation, building design and construction, materials and manpower.
2) Location of the facility shall:
    a) Atleast be 100 meter away from state owned public toilet and waste disposal or storage sites;
    b) be clean and be reasonably away from flood and swamp prone areas which might compromise safety and quality of the cosmetic;
    c) have basic infrastructures including telephone, electricity, water, and a road suitable for transportation;
    d) be free of conditions which might lead to contamination includingexcessive dust, foul odors, smoke, pest and insect infestations, airborne microbialand chemical contaminants, and other similar conditions.

3) Building design and construction
    a) The warehousesshall provide sufficient space for all activities carried out proportional tothe amount of the products including a storage room and rejected products storage room or area.

b) Notwithstanding sub-article (1) of this article, the warehouse shall have a storage room with minimum size of 25 m^2.
c) The warehouseshall be constructed in such a way that it does not compromise the safetyand quality of the product.
d) Floor of the warehouse shall be made of cement, concrete, ceramic; easily washable, free from cracks, be smooth and not convenient toharbor dirt and water.
e) Wall of the storage room shall be easily washable, free from cracks, and notconvenient to harbor dirt.
f) The roof shall be constructed from materials that do not allow the entry of directsun light and which do not adversely affect the temperature of the room.
g) Rooms shall be constructed in such a way to allow adequate air and lightcirculation.

4) Materials and equipment
    a) Shelves or pallets shall be placed in such a way that they are off the floor, away from the wall and roof and from each other in a manner that allow air flow, men and material movement
    b) Depending on the climatic conditions of the area there shall be ventilator or airconditioner.
    c) Any materials in the warehouse having contact with the regulated product shall notcompromise the safety and quality of products.
    d) An enclosed waste bin, fire extinguisher and first aid kit shall be available.
    e) Shall availnecessary safety materials for workers including glove and working cloths.
    f) For products that need refrigerator for their storage, it shall have refrigerator orcooling equipment.
5) Professional requirements
    a) Any person engaged in import or distribution of cosmetics shall have a store manand technicalpersonnel.
    b) The technical personnel shall at least be ahighshchool graduate.

7. Displaying certificate of competence

Original of the certificate of competence shall be placed in a conspicuous place where itcan be easily seen by clients and regulatory officers.

8. Replacement of certificate of competence

Any person whose certificate of competence is damaged or lost may requestreplacement by submitting online application to the Authority using ilicense efda.gov.et.

9. Change of address, technical personnel and Status

1) No entity shall change location, ownership, technical personnel, working status and change or partition of rooms without prior notification and securing permission of the Authority.
2) Any entity who wants to make a change shall apply using ilicense.efda.gov.et
3) Any importer, exporter or wholesaler of cosmetic who wants to have additional store, in a city or village outside where its first store is located, shall fulfill the requirements set for issuance of a new certificate of competence.

10. Renewal of the certificate of competence

1) Any person shall renew certificate of competence annually. up on the confirmation of regulatory compliance through annual inspection.
2) A certificate of competence shall be renewed before expiry of the service period.
3) Notwithstanding sub-article (1) of this article, in order to renew certificate of competence the authority shall make sure the following requirements are met:
    a) confirmation through annual inspection of fulfillment of good storage practice, good distribution practice, good document practice, professional requirements and design and required products requirements set by the authority; and
    b) Payment of required service fee.
4) If the certificate of competence is not renewed in accordance with sub-article (1-3) of this article, the certificate of competence shall be considered cancelled.

PART THREE
NOTIFICATION

11. General

1) Any importer or person responsible for placing a cosmetic in the market shall notify the authority prior to product importation.Any enquiry on cosmetic notification may be submitted to the authoritythrough https://eris.efda.gov.et.
2) Cosmotics importer or wholesaler shallimport or distribute the cosmetic upon receipt of authorization given in the Notification Note from the responsible directorate of the authority.
3) Cosmotics manufacturer, importer or wholesaler shall report to the Authority of any adverse event or high incidences of adverse event occurred, regardless of the source of the report.

12. Responsibilities of Cosmotics manufacturer or importer

1) A Cosmotics manufacturer or importer shall beresponsible to notify the authority prior toimport or sell of any cosmetics.
2) Cosmotics manufacturer or importer is responsible to ensure that:
    a) All communication with the authority shall be carried out by it'sappointed person(s).
    b) Notified product meets all stipulated regulations and guidelines for cosmetic.
    c) Updated information/document on product quality, safety and claimed benefit shall be available and accessible upon request.
    d) Change(s) to notified product particulars shall be submitted accordingly.
    e) The cosmetic is manufactured in complance with Cosmetic Good Manufacturing Practice (cGMP).
    f) In the incidence of serious adverse event, cosmotics manufacturer or importer shall report to the authority appropriately.
    g) Particulars given for product notification are truthful where all data and information of relevance to the notification has been provided.
    h) Each consignment continues to meet all legal requirements and conforms to standards and specifications declared for the product.

i) Correspondence details such as company's name, address, contact person, telephone number, fax number and email shall be kept updated.

j) Any decision to withdraw the notification of a product shall be informed to the authority. Submission forapplication for withdrawal of the notification shall be done online through https://eris.efda.gov.et/login

13. Submission of cosmetic notification

1) Submissionof application for notification of cosmotics shallbe done online through https://eris.efda.gov.et/login Online application shall be completed for each cosmetic and variant, if any and proceed with the payment of the required service fee in accordance with Service Fee Regulation no. 370/2015 to the authority.
2) Any payment made shall not be refundable once the application has been submitted and payment is confirmed.
3) Any document and material submitted to authority shall be in Amahric or English.
4) The notification note of a cosmeticshall be renewed every 5 years. The renewal process should be done no later than 6 months prior to notificationnote expiry.
5) Any subsequent changes in particulars of the notified cosmeticshall be informed to the authority.

14. Product particularsandrequirements

1) The Notification application shall include, but not limited to the following information
   a) Particulars of product including product name, product type, intended use and product presentation;
   b) Name and address of the manufacturer(s);
   c) Name, address and valid contact number (and e-mail address) of the Cosmotics manufacturer or importer;
   d) Particulars of person representing the company of cosmotics manufacturer or importer including valid contact number;
   e) Name and address of the importer(s), if any;
   f) Full product ingredient list (the content i.e. percentage (%) of the restricted ingredients must be declared);

g) Label(s) of the product
h) Original free sale certificate from competent authority of exporting country

2) A cosmetic placed on the market shall not cause damage to human health when applied under normal or reasonably foreseeable conditions of use. The cosmotics manufacturer or importer shall ensure that safety assessment has been conducted for each product.
3) The following changes shall be considered amendments to the current notification. Changes other than these shall require a new notification.
   a) Product presentation (pack size)
   b) Name and/or address of the manufacturer
   c) Person representing company
   d) Additional importer(s)/ wholesaler(s)
   e) Product Label(s)
4) Cosmetics shall not contain any of the following:
   a) prohibited substanceslisted in Annex II
   b) restricted substances which are not used in accordance with the restrictions laid down in Annex III
   c) colorants
      I. colorants other than those listed in Annex IV and colorants which are listed there but not used in accordance with the conditions laid down in that Annex, except for hair colouring products referred to in sub article 5;
      II. without prejudice to points (b), and (d)(i)substances which are listed in Annex IV but which are not intended to be used as colorants, and which are not used in accordance with the conditions laid down in that Annex;
   d) preservatives
      I. preservatives other than those listed in Annex V and preservatives which are listed there but not used in accordance with the conditions laid down in that Annex V;
      II. without prejudice to points (b), and (c)(i)substances listed in Annex V but which are not intended to be used as preservatives, and which are not used in accordance with the conditions laid down in that Annex;
5) Subject to a decision of the authority to extend the scope of Annex IV to hair colouring products, such products shall not contain colorants intended to colour the hair, other than those listed in Annex IV and colorants intended to colour the hair

which are listed there but not used in accordance with the conditions laid down in that Annex.

6) Regular review and update of the annexes will be conducted by the authority.
7) Product Information File (PIF)
    a. Cosmotics manufacturer or importer shall be responsible for providing all information, certificates/documents and data requested by the authority.
    b. It should be readily available and accessible upon request by the authority.
    c. The PIF shall be in English or for other foreign languages an authorized English translation shall be presented

PART FOUR
PACKAGING AND LABELLING OF COSMETICS

15. General

1) The packaging material shall be made out of substances safe and suitable for its intended use.
2) The cosmetic shall be packed in a container which maintains its quality and safety and quality.
3) The labeling information shall be written in Amharic or English Language.
4) The labelling information on the cosmetic shall not contain medical or therapeutic claims.
5) For the purpose of this article "medical and therapeutic claim" means product claims to diagnose, treat, mitigate or prevent of human diseases, and intend to affect the anatomy or of a physiological process of a human bodies.

16. Immediate container label

1) Cosmetics shall be made available on the market only where the container and packaging of cosmetics bear the following information in indelible, easily legible and visible lettering:
    a) The name of the cosmetic and its function, unless it is clear from the presentation of the product**;**
    b) Name and address of the manufacturer;

c) Instructions on the use of the cosmetic, unless it is clear from the product name or presentation

d) Net content;

e) list of ingredients

I. list of ingredients present in the final product shall be declared in descending order of predominance, intheir concentration by weight

II. ingredients shall be identified by their common name as provided for in the common ingredients nomenclature or, in the absence of nomenclature or of a common name, by its chemical name, its International Non-proprietary name as recommended by the WHO, its IUPAC or CAS Identification reference or its colour index number

III. Botanicals and extract of botanicals should be identified by its genus and species. The genus may be abbreviated.

f) Manufacturer's batch or lot number;

g) Precautions and warnings, where necessary; and

h) Storage condition, as appropriate.

i) If the immediate container label does not bear expiry date, there shall be an indication of Period after opening (PAO) for which the product is safe and can be used without any harm to the consumer. This information shall be indicated, except where the concept of durability after opening is not relevant

2) Where the size, shape or nature of the container or package does not permit all the information provided under this directive to be displayed, leaflets, pamphlets, hangtags, display panel; shrink wrap and the like shall be used. However, these particulars must appear on the container indicating the name of the cosmetic, name of the manufacturer, manufacturer's batch or lot number and manufacturing and expiry date, where appropriate.

3) Where applicable, the manufacturer may use user leaflet that contain relevant labeling information for their cosmetics.

17. Immediate container label of Cosmotics raw materials

1) Cosmetic raw material shall bear the following information in indelible, easily legible and visible lettering in its immediate container label:

a) The name of the cosmetic raw material;

b) Name and address of the manufacturer, including country of origin;

c) Net content;
d) Manufacturer's batch or lot number;
e) Precautions and warnings, where necessary; and
f) Storage condition, as appropriate.

2) Expiry date /Re test date shall be clearly expressed and shall consist of either the month and year or the day, month and year, in that order, where applicable;
3) Where the size, shape or nature of the container or package of the raw material does not permit the display of all the information provided under this article, sticker labling which is not easily removable and bearing the manufacturer logo might be used.

PART FIVE

IMPORT, EXPORT, WHOLESALE AND TRANSPORTATIONOF COSMETIC

18. Import requirements

1) In order to get port clearance, the following documents shall be presented:
   a) Valid notification note
   b) Application letter;
   c) Copy of Certificate of competence;
   d) Certificate of origin;
   e) Invoice;
   f) Packing list;
   g) Airway bill or bill of lading
   h) Manufacturer's declaration of absence of prohibited substances and compliance with the content lists of restricted substances for the cosmetic.
2) Where any original certificate is in language other than English or Amharic, copies shall be presented together with certified translation.
3) Any cosmetic shall only be imported if their label is in accordance with the provisions of this directive.
4) A port clearance shall only be issued for a cosmetic:
   a) Having 60 % and above remaining shelf life if its total shelf life is above 2 years while reaching port of entry; or
   b) Having 50 % and above remaining shelf life if its total shelf life is 2 years and below while reaching port of entry.

5) In order to get port clearance of cosmetics raw material, the following documents shall be presented;
   a) Application letter
   b) Certificate of competence;
   c) Certificate of origin;
   d) Safety data sheet and/or certificate of analysis;
   e) Invoice;
   f) Packing list;
   g) Airway bill or bill of loading.
6) Certificate of origin under this article shall include:
   a) Manufacturers name and specific address;
   b) Way of transportation;
   c) Product description;
   d) The authorized personnel full name and signature; and
   e) Issue date and seal
7) The packing list shall include following information
   a) Product description
   b) Quantity of the product
   c) Batch Number, if applicable;
   d) Expiry date;
   e) Cartoon number where the product is stored

19. Exemptions

1) Cosmetics imported as samples for exibition, research and trial use are exempted from port clearance requirements and shall be accompanied with supporting evidence.
2) Cosmetics imported for personal use shall be expempted from port clearance.
3) Notwithstanding sub-article (2) of this article, the authority may determine through a directive the allowable amount of cosmetic imported for personal use.
4) Where the cosmetic is prepared for use of a specific facility (such as hotels and other hospitality institutions), and the name of the institution is affixed or written on the product, except list of ingridients, labeling and other document requirements stated under Articles (11-13) of this directive may not be applicable.

20. Storage, transport and distribution requirements

1) Any importer or wholesaler of cosmetics shall store, handle and transport the products as per the manufacturer instructions described on the labeling information.

2) Any importer or wholesaler of cosmetics shall store, handle and transport cosmetics as per Good storage practice and good distribution practice requirements.
3) Deteriorated, expired, or damaged products shall be stored separately from other products until disposal.
4) Any cosmetic importer or distributer shall investigate anyidentified adverse event or complaints against storage, handling and transportation practice.
5) Any cosmetic importer or distributer shall make sure products are stored in such a way that it supports the first expired first out (FEFO) and first in first out (FIFO) principles.

21. Export requirement

The Authority may issue the required regulatory document/s up on request.

PART SIX

SAFTEY AND QUALITY OF COSMETICS

22. Cosmetic vigilance

1) Any importer and wholesaler of cosmetics product shall conduct periodic monitering of quality and safety of the cosmeticthey put in the market and shall periodicaly submit safety report to the authority
2) The importer or wholesalershall put in place procedure for handling of cosmetic safety and quality issues.
3) The importer and wholesalerresponsible for placing the cosmetic in the market shall report to the Authority of any serious adverse event or high incidences of adverse eventoccurred regardless of the source of the report.
4) The Authority shall monitor compliance of cosmetics through surveillance in the marketplace and at the premises of the company or person responsible for placing the product in the market.
5) Any importer and wholesaler of cosmetics product shall be responsible jointly and severally for damage caused as a result of qaulity and safety problems associated with the product.
6) For the purpose of this Article “Adverse event” means any untoward medical occurrence that may be present during use, but does not necessarily have causal relationship with this application, that is, an adverse outcome that occurs while the client is applying the cosmetics but is not, or not necessarily, attributed to it.

23. Product Recall

Cosmetic recall shall be conducted as per the requiremnets provided under "Medicine and Medical Device Recall Directive No. 38/2018".

24. Record Keeping

The company or person responsible for placing the cosmetic in the market must keep records of the primary distribution of their products, for the purpose of product recall and traceability up to one year after the opening date.

PART SEVEN

ADMINISTRATIVE MEASURES AND COMPLIANT HANDLING PROCEDURE

25. General

1) Products, entities or individuals who violate requirements of this directive or other applicable laws may be subjected to appropriate administrative measure in accordance with the provisions of proclamation 1112/2019,the Directive on Administrative Measure Taking and Complaint Handling Procedureand other applicable laws.
2) The person against whose product or whom an administrative measure is taken in accordance with sub-article (1) of this article may lodge complaint in accordance with the Directive on Administrative Measure Taking and Complaint Handling Procedure.
3) Complaints may be submitted by the licensee, owner of the business or a duly authorized agent of the owner or licensee. The complaint shall be submitted within 30 days from the time when administrative measure is taken.
4) Without prejudice to sub-article (1) of this article, the following provisions stated under Article 26 and 27 of this Directive may be used as illustrative lists for suspension and revocation:

26. Issuance of warning letter

Without prejudice to grounds of warning provided under the proclamation and other relevant laws, the authority may issue warning letter where the offence committed by the importer, exporter or wholesaler of cosmetic is unintentional anddoesn't cause any harm to human health or body, and where it not punishable with suspension or revocation of certificate of competence.

27. Suspension of certificate of competence

Without prejudice to grounds of suspension provided under the proclamation and other relevant laws, and based on the severity of the violation, the Authority shall suspend certificate of competence of the importer, exporter, or wholesaler of cosmetic from one month to six months, if it:

1) fails to submit, accurately or on time, or falsify information requested by the Authority;
2) imports cosmetic without authorization or notifying to the authority
3) fails to report to the authority occurrence of adverse event or high incidence of adverse event
4) make changes to notified products without reporting to the authority
5) imports or distributes cosmetic containing substances prohibited or restricted as provided under this directive
6) impedes the work of inspectors; and
7) allows a professional who has been suspended by a competent authority from practicing his/her profession to work in the facility;
8) found holding products with the absence of authorized personnel or technical manager;
9) fails to notify the Authority of any change to professionals or premises design and/or place without approval;
10) commits other comparable violations; and
11) is suspended by other government organ (for the same duration of time).

28. Revocation of a License

Without prejudice to grounds of revocation provided under relevant laws, and based on the severity of the violation, the Authority shall revoke certificate of competence of importer, exporter, or wholesaler, up to two years, if it:

1) obtained its certificate of competence through fraudulent acts;
2) intentionally possess or sale a product in any manner from a person having no certificate of competence;
3) add or mix any substance to the product so as to increase its bulk or weight, or make it appear better or for any other similar purpose;
4) import, export or distribute a product other than the product type the certificate of competence issued for;

5) possess or sale any un-notified, adulterated, counterfeited; expired or unlabeled/mislabeled product;
6) Fails to recall or discontinue supplying cosmetic having a quality defect.
7) continue operating its business against the terms and conditions of any suspension measures;
8) is prohibited from doing its business by another appropriate government organ; a
9) engages in any act which constitutes a serious violation in accordance with the directive on Administrative Measure Taking and Complaint Handling and the violation is subject to revocation measure.

29. Public and media disclosure

1) Disclosure of administrative measure shall only be allowed after 30 days of the final decision by the Authority or if the case is under complaint procedure after the final decision on the complaint.
2) Notwithstanding sub-article (1) of this article, the Authority may publicize administrative measures where failure to publicize would result public health risk.
3) Publication in accordance with sub-article (2) of this article shall be approved by the Director General of the Authority.

PART EIGHT

MISCELLANIOUS

30. Duty to Cooperate

The company or person placing the product in the market shall be responsible for providing all information

31. Advertisement and Promotion

1) Any cosmetic owner who wants to advertise their cosmetics shall have certificate of competence.
2) Any advertisementandpromotionof cosmetics shall be accurate, scientifically justifiable and not misleading the end user.
3) The advertisement of the cosmetic shall contain the name of the product.
4) Any advertisement and promotion of cosmetic shall not make medicinal or therapiotic claim.
5) Sample of promotional materials should have appropriate labeling information as indicated under part five of this directive.

32. Service fee

Any person who seeks regulatory service under this directive may be required to pay applicable service fee to the Authority in accordance with Service Fee Regulation of the Authority.

33. Inapplicable laws

1) Cosmetics and Sanitary Item Directive No.24/2014 is here by repealed by this directive.
2) Any working procedure or customary practice which is inconsistent with this directive shall not be applicable with respect to those matters provided for in this directive.

34. Annexes

Annexes which can be accessed from the Authorities website efda.gov.et:

1) Annex I: Illustrative list ofcosmetics by catagories
2) Annex II: List of prohibited substances
3) Annex III: List of substances which cosmetic must not contain except the restrictions laid down
4) Annex IV: List of colorants allowed in cosmetics
5) Annex V: List of preservatives allowed in cosmetics

35. Effective date

This directive shall enter into force on 30/03/2020.

Heran Gerba

Director General

Ethiopian Food and Drug Authority