ETHIOPIAN FOOD AND DRUG AUTHORITY

COSMETIC MANUFACTURING DIRECTIVE

March, 2020

Addis Ababa, Ethiopia

Contents

PREAMBLE

WHEREAS, it is necessary to provide guidance for manufacturers, with regulatory information concerning minimum requirements in manufacturing of cosmetic products;

WHEREAS, it is necessary to protect public health through regulation of cosmetic products to operate in accordance with the required safety and quality requirements;

WHEREAS, it is necessary to lay down regulatory requirements based on the level of the manufacturing and risk of products;

WHEREAS, it is found necessary to take the necessary administrative measures on non-complying cosmetic manufacturers operating against the provision of this directive and other applicable laws;

NOW, THEREFORE, this directive is issued by the Ethiopian Food, and Drug Authority in accordance with article 71(2) of the Food and Medicine Administration Proclamation No. 1112/2019.

PART ONE

GENERAL PROVISION

1. Short title

This directive may be cited as the "Cosmetic Manufacturing Directive No 49/2020.

2. Definitions

Without prejudice to the definition provided under Ethiopian Food and Medicine Administration Proclamation No. 1112/2019:

1) "Manufacturer" means a manufacturer involved in processing or production of trans reginal cosmetic products;
2) **"**Bulk Product" means any processed product which will have to undergo the packaging operation in order to become a finished product;
3) "Date of Manufacture" means date of manufacturing of a batch of product;
4) "Documentation" means all written procedures, instructions and records involved in the manufacture and quality control of products;
5) "Product" means any substance or preparation intended to be used or capable or purported or claimed to be capable of being used, in or for cleansing, improving, altering or beautifying the complexion, skin, hair or teeth;
6) "Finished Product" means a product which has undergone all stages of manufacturing operations;
7) "In-Process control" means checks and tests instituted and carried out in the course of the manufacture of a product including checks and tests done on intermidiate products, environment and equipment in order to ensure that the end product will comply with its specification;
8) "Intermediate Product" means any processed substance or mixture of substances which has to undergo one or more stages of processing to become a bulk product;
9) "Manufacture or Manufacturing" means the complete set of activities to produce a product, comprising of production and quality control, from acquisition of all raw materials through processing and subsequent packaging and release for distribution of the finished product;
10) "Packaging" means the part of production cycle applied to a bulk product to obtain the finished product;
11) "Packaging Material" means any material used in the packaging of a bulk product to

obtain the finished product;

12) "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;
13) "Processing" means the part of production cycle starting from weighing of raw materials to obtaining a bulk product;
14) "Production" means all operations starting from processing to packaging to obtain a finished product;
15) "Quality Control" means all measures taken during manufacturing which are designed to ensure the uniform output of product that will conform to established specifications;
16) "Quarantine" means the status of materials or products set apart physically or by system, while awaiting a decision for their rejection or release for processing, packaging or distribution;
17) "Raw Materials" means any ingredient to be used in the formulation of a cosmetic product;
18) "Rejected" means the status of materials or products which are not permitted to be used for processing, packaging or distribution;
19) "Released" means the status of materials or products which are allowed to be used for processing, packaging or distribution;
20) "Returned" means finished products sent back to the manufacturer;
21) "Sanitation" means hygienic control on manufacturing premises, personnel, equipment and material handling;
22) "Specification of Materials" means a description of a starting material or finished product in terms of its chemical, physical and biological characteristics, if applicable. A specification normally includes descriptive and numerical clauses stating standards and tolerated deviations
23) "Starting Materials" means raw materials and packaging materials used in the production of products;
24) "Authorized or key person" means the person recognized by the Authority as having the esponsibility for ensuring that each batch of finished product has been manufactured, tested and approved for release in compliance with the requirements of marketing authorization;

25) “Calibration” means the demonstration that a particular instrument or device produces results within specified limits by comparison with those produced by a traceable standard over an appropriate range of measurements;
26) “Batch” means a quantity of any cosmetic product produced in a given cycle of manufacture that is uniform in character and quality;
27) “Batch Number” means a designation in numbers and/or letters or combination of both that identifies the complete history of the batch, quality control and distribution
28) “Small scale manufacturer” means those business enterprises with a paid up capital of above Birr 90,000 and not exceeding Birr 1.5000,000;
29) “Medium scale manufacturer” means those business enterprises with a paid up capital of above Birr 1,5000,000 and not exceeding 5,000,000;
30) “Larg scale manufacturer” means those business enterprises with a paid up capital of exceeding Birr 5,000,000;
31) “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;
32) “Person” means a natural or juridical person;
33) “Authority” means Ethiopian Food and Drug Authority;
34) Any expression in masculine gender includes the feminine.

3. Scope

This Directive shall be applicable on all cosmetic manufacturing establishment and operation.

PART TWO
CERTIFICATE OF COMPETENCE

4. General

Any person who wants to engage in cosmetic manufacturing shall obtain certificate of comepetence from the the Authority.

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. depending on the scale of the firm, fulfill the requirements of premises, professionals/personnel and equipments on part four or five provided in respect; and

c. pay the appropriate service fee;

2) The actual conduct of the 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 and, as the case may be, recommend or decide after receiving duly filled application, premises inspection report and all other necessary documents from the inspectors.
4) The Authority may approve, reject or recommend corrections to the application by providing reason for its decision.
5) Where the premises 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.
7) Re-inspection may be carried out once by the Authority free of charge.

6. Pre-approval inspection

1) The Authority shall conduct inspection to ensure compliance of requirements provided under this directive.
2) Once requirements are met, the Authority shall issue certificate of competence to the applicant.

PART THREE
CLASSIFICATIONS

7. The requirements and level of the cosmetic manufacturer

The requirements and regulation of the cosmetic manufacturer shall base on the level of the cosmetic manufacturer.

1) Classification of the cosmetic manufacturer shall be:

a. Small and medium scale cosmetics manufacturer establishment; and

b. Large scale cosmetics manufacturer establishment.

2) The level of the manufacture shall be determined on the basis of financial capability delivered by the banks, or investment offices.

3) The financial statement shall be from any legaly established bank which shows its current financial situation.

4) The financial statement or declaration of financial capability shall be the same with the application delivered to get the trade license or trade office.

PART FOUR
COSMETICS MANUFACTURE AT SMALL AND MEDIUM SCALE

8. General

All small and medium scale cosmetic manufacturers shall be;

1) permitted to manufacture only products produced by small operation, simplified and non advanced technology.
2) Technical Advisory Committee with screening guide will be established to review and categorize the level of sophistication of respective manufacturing process.
3) The requirements for prelicencing are those indicated under article 9, 10 and 11 while the remaining articles except part five of this directive are used for post licensing operation.

9. Premises

1) The Premises walls, floor, and ceiling shall be smooth and have no cracks or holes. They shall be painted and/or made of washable materials.
2) Electrical supply, water supply, lighting, temperature, humidity and ventilation should be appropriate for the intended operation and comfort of personnel.
3) The areas shall be maintained in clean, orderly and sanitary conditions with appropriate and sanitary waste disposal.
4) Premises shall have adequate areas for different activities (Such as weighing area, production area, Storage areas and quality control areas when appropriate).

5) Storage areas shall be adequate enough to store equipment, packaging and raw materials, finished cosmetics, and designed to ensure good storage conditions.
6) Segregated areas shall be provided for the storage of rejected, recalled or returned materials or products.
7) Production areas shall be appropriate both to the products handled, to the operations undertaken within them and to the external environment.

10. Equipments

1) Equipment and utensils used in processing, holding, transferring and fillin shall be appropriate,
2) Material and workmanship shall be constructed in the way to prevent corrosion, buildup of material, or adulteration with lubricants, dirt or sanitizing agent.
3) Utensils, transfer piping and cosmetic contact surfaces of equipment shall be well-maintained and clean and are sanitized at appropriate intervals.
4) Cleaned and sanitized portable equipment and utensils shall be stored and located, and cosmetic contact surfaces of equipment are covered, in a manner that protects them from splash, dust or other contamination.

11. Personnels

1) Authorized personnel who shall be considered as technical personnel in small and medium cosmetics manufacture shall be at least Ethiopian High School Graduate and have the training and/or experience to perform the assigned functions.
2) Personnels performing the manufacture or control of cosmetics shall have the education, training and/or experience to perform the assigned functions.
3) Persons coming into direct contact with cosmetic materials, finished products, bulk or cosmetic contact surfaces, to the extent necessary to prevent adulteration of cosmetic products shall wear appropriate outer garments, gloves, hair restraints etc., and maintain adequate personal cleanliness.

12. Production

1) Written manufacturing instruction and standard operating procedures shall be established.
2) Raw materials and primary packaging materials shall be stored and handled in a manner which prevents their mix-up, contamination with microorganisms or other chemicals, or decomposition from exposure to excessive heat, cold, sunlight or moisture.
3) Containers of materials shall be closed, and bagged or boxed and stored off the floor.
4) Containers of materials shall be labeled with respect to identity and lot/batch identification.
5) The manufacturer shal ensure quality of raw materials, by receiving and documenting their certificate of analysis with acceptance specification from their respective suppliers.
6) Materials not meeting acceptance specifications are properly identified and controlled to prevent their use in cosmetics.

13. Laboratory Controls

1) The manufacturer shall establish quality of its products using its own laboratory or outsourcing the task for competent laboratory with proper contract agreement.
2) Reserve samples of approved lots or batches of raw materials and finished products shall be retained for the specified time period and stored under conditions that protect them from contamination or deterioration and are retested for continued compliance with established acceptance specifications.
3) Appropriate quality of water shall be used and keep records of test results in specified intervals.

PART FIVE

COSMETICS MANUFACTURE AT LARGE SCALE

14. General

All large-scale cosmetic manufacturers shall be;

1) permitted to manufacture products requiring more advanced or complex technology.

2) As stated in article 8 sub article 2 the technical Advisory Committee will screen and categorize the level of sophistication of respective manufacturing process.
3) The requirements for prelicencing are those indicated under article 15 (all sub articles except 9 &10), article 16 (all sub articles) and 17 (all sub articles) while the remaining articles except part four of this directive are used for post licensing operation.

15. Personnels

1) To engage in cosmetics manufacturing the key personnel or head of production shall be pharmacist, chemist, chemical engineer or speciality with cosmetic or related fields.
2) There shall be an adequate number of personnel having knowledge, experience, skill and capabilities relevant to their assigned function.
3) They shall be in good health and capable of handling the duties assigned to them.
4) The organisational structure of the company shall be such that the production and the quality control sections are headed by different persons, neither of whom shall be responsible to the other.
5) The head of production shall be adequately trained and have 2 years of experience in manufacturing practice that have authority and responsibilities to manage production of products covering operations, equipment, production personnel, production areas and records.
6) The head of quality control shall be adequately trained and have 2 years of experience in the field of quality control and shall:
    a. be given full authority and responsibility in all quality control duties such as establishment, verification and implementation of all quality control procedures.
    b. have the authority to designate/ assign when appropriate, personnel, to approve starting materials, intermediates, bulk and finished products that meet the specification or to reject those which do not conform to the relevant specification or which were not manufactured in accordance with approved procedures and under the defined conditions.
7) The responsibilities and authority of key personnel shall be clearly defined.
8) All personnel directly involved in the manufacturing activities should be appropriately trained in manufacturing operations in accordance to GMP principles.

9) Training in GMP shall be conducted on a continuous basis.
10) Records of training shall be maintained, and its effectiveness assessed periodically.

16. Premises

1) The premises for manufacturing shall be suitably located, designed, constructed and maintained.
2) Effective measures shall be taken to avoid any contamination from the surrounding environment and from pests.
3) Painted line, plastic curtain and flexible barrier in the form of rope or tape may be employed to prevent mix-up.
4) Appropriate changing rooms and facilities shall be provided.
5) Toilets shall be separated from the production areas to prevent product contamination/ cross contamination.
6) Defined room shall be provided for, wherever applicable:
    a. Material sampling and dispensing
    b. Raw materials storage
    c. Production, packaging and labeling
    d. Storage of bulk products.
    e. Storage of finished products.
    f. Equipment washing.
7) Wall and ceiling shall be smooth and easy to maintain.
8) The floor in processing areas shall have a surface that is easy to clean and sanitise.
9) Drains shall be of adequate size, cleanable and shall have proper flow.
10) Air intakes and exhausts and associated pipework and ducting shall be installed in such a way as to avoid product contamination.
11) Buildings shall be adequately lit and properly ventilated appropriate to the operations.
12) Pipe work, light fittings, ventilation points and other services in manufacturing areas shall be installed in such a way as to avoid uncleanable recesses and run outside the processing areas.
13) Laboratories shall preferably be physically separated from the production areas.
14) Storage areas shall be of adequate space provided with suitable lighting, arranged and equipped to allow dry, clean and orderly placement of stored materials and

products. Such areas shall be suitable for effective separation of quarantined materials and products.

15) Special and segregated areas shall be available for storage of flammable and explosive substances, highly toxic substances, rejected and recalled materials or returned goods.
16) Where special storage conditions e.g. temperature, humidity and security are required, these shall be provided.
17) Storage arrangements shall permit separation of different labels and other printed materials to avoid mix-up.

17. Equipments

Equipments shall be designed and located to suit the production of the products:

1) Design and Construction
   a. The equipment surfaces coming into contact with any in-process material shall not react with or adsorb the materials being processed.
   b. Equipment shall not adversely affect the product through leaking valves, lubricant drips and through inappropriate modifications or adaptations.
   c. Equipment shall be easily cleaned.
   d. Equipment used for flammable substances shall be explosion proof.
2) Installation and Location
   a. Equipment shall be located to avoid congestion and be properly identified to assure that products do not become admixed or confused with one another.
   b. Support systems such as heating, ventilation, air conditioning, water (such as potable, purified, distilled) steam, compressed air and gases (example nitrogen) shall function as designed and identifiable.
3) Weighing, measuring, testing and recording equipment shall be serviced and calibrated regularly.
4) All records shall be maintained.

18. Sanitation and Hygiene

Sanitation and hygiene shall:

1) be practiced to avoid contamination of the manufacturing of products.
2) Cover personnel, premises, equipment/apparatus and production materials and containers.

19. Production

1) Starting Materials
    a. Appropriate quality of water chemical and microbiological requirements shall be used and keep records of test results in specified intervals.
    b. All deliveries of raw materials and packaging materials shall be checked and verified for their conformity to specifications and be traceable to the product.
    c. Samples of raw materials shall be physically checked for conformity to specifications prior to release for use.
    d. The raw materials shall be clearly labelled.
    e. All goods must be clean and checked for appropriate protective packing to ensure no leakage, perforation or exposure.
2) Batch Numbering System
    a. Every finished product shall bear a production identification number which enables the history of the product to be traced.
    b. The batch number shall be printed on the immediate and/or outer container of the product.
    c. Records of batch number shall be maintained.
3) Weighing and Measurement
    a. Weighing shall be carried out in the defined areas using calibrated equipment.
    b. All weighing and measurement carried out shall be recorded and, where applicable, Counter checked.
4) Procedure and Processing
    a. All starting materials used shall be approved according to specifications.
    b. All manufacturing procedures shall be carried out according to written procedures.
    c. All required in-process controls shall be carried out and recorded.
    d. Bulk products shall be properly labeled until approved by Quality Control, where applicable.

5) Wet Products
    a. Liquids, creams and lotions shall be produced in such a way as to protect the product from microbial and other contamination.
    b. Where pipe-lines are used for delivery of ingredients or bulk products, care shall be taken to ensure that the systems are easy to clean.
6) Labeling and Packaging

a. Packaging line shall be inspected for clearance prior to operation.
b. Equipment shall be clean and functional.
c. Each labeling and packaging line shall be clearly identified to avoid mix-up.
d. Excess labels and packaging materials shall be returned to store and recorded.
e. Any rejected packaging materials shall be disposed off accordingly.

7) Finished Product

All finished products shall be approved by Quality Control prior to release.

20. Water Treatment

1) Water treatment and storage shall be designed, installed, and maintained to ensure the reliable production of water of an appropriate quality.
2) Water shall be produced and stored in a manner that prevents unacceptable microbial, chemical or physical contamination.

21. Quality Control

1) A quality control system shall be established to ensure that products contain the correct materials of specified quality and quantity and are manufactured under proper conditions according to standard operating procedures.
2) Quality control shall involve sampling, inspecting and testing of starting materials, intermediate, bulk, and finished products.
3) Where applicable, environmental monitoring programs, review of batch documentation, sample retention program, stability studies and maintaining shall correct specifications of materials and products.

22. Reprocessing

1) The methods of reprocessing shall be evaluated to ensure that they do not affect the quality of the product.
2) Additional testing of any finished product which has been reprocessed shall be performed.

23. Returned Products

1) Returned products shall be identified and stored separately.
2) All returned products shall be tested if necessary, in addition to physical evaluation before being released for distribution.

3) Returned products which do not comply with the original specification shall be rejected.
4) Rejected products shall be disposed according to appropriate procedures.
5) Records of returned products shall be maintained.

24. Internal Audits

There shall be established system to conduct and record internal audit.

25. Storage

1) Storage areas shall be of sufficient capacity to allow orderly storage of the various categories of materials and products such as starting and packaging materials, intermediates, bulk and finished products, products in quarantine, and released, rejected, returned, or recalled products.
2) Storage areas shall be designed or adapted to ensure good storage conditions.
3) Storage areas shall be clean, dry and well maintained.
4) Where special storage conditions are required (temperature and humidity) these should be provided, checked and monitored.
5) Hazardous materials shall be safely and securely stored.

PART SIX
PACKAGING AND LABELLING OF COSMETICS

26. 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.

27. 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.

28. 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 SEVEN
DOCUMENTATION AND RECORDING

29. Documentation

1) There shall be a system to record all manufacturing, quality control, distribution, recall and return products.
2) Documents shall be dated and authorized.
3) Documents shall be readily available to relevant parties.

30. Specifications

1) All specifications shall be approved by authorized personnel**.**
2) Raw and packaging material specifications shall include at least basic parameters.
3) Bulk and finished product specifications shall include:
   a. Name of product;
   b. Description;

c. Physical properties;
d. Chemical assay and/or microbiological assays and their acceptance limits;
e. storage conditions and safety precautions, if necessary.

31. Documents for Production

Batch Manufacturing Records (BMRs) shall be prepared for each batch of product and each BMR shall include the following:

1) Name of product;
2) Batch formula;
3) Brief manufacturing process;
4) Batch or code number;
5) Date of the start and finish of processing and packaging;
6) Identity of individual major equipment and lines or location used ;
7) Records of cleaning of equipment used for processing as appropriate;
8) In-process control and laboratory results, such as pH and temperature test records;
9) Packaging line clearance inspection records;
10) Any sampling performed during various steps of processing;
11) Any investigation of specific failure or discrepancies;
12) Results of examination results of examinations on packed and labeled products.

32. Documents for Quality Control

Records for each testing, assay result and release or rejection of starting materials, intermediates, bulk and finished product with necessary data shall be maintained.

33. Documentation of contractual agreement

All contractual agreements made between the manufacturer and other parties shall be documented.

PART EIGHT
SAFTEY AND QUALITY OF COSMETICS

34. Quality Management System

1) A quality management system shall be developed, established and implemented as a means by which stated policies and objectives will be achieved.
2) The quality system shall be structured and adapted to the company's activities and to the nature of its products and should take into consideration appropriate elements stated in this directive.
3) The quality system operation shall ensure that if necessary, samples of starting materials, intermediate, and finished products are taken, tested (if necessary) to determine their release or rejection on the basis of test results and other available evidence related to quality.

35. Cosmetic vigilance

1) The manufacturer of cosmetics product shall conduct periodic monitering of quality and safety of the cosmetic they put in the market and shall periodicaly submit safety report to the authority
2) The manufacturer shall put in place procedure for handling of cosmetic safety and quality issues.
3) The manufacturer responsible 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) The manufacturer 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.

36. Product Recall

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

PART NINE
ADMINISTRATION MEASURE AND COMPLIANT HANDLING

37. General

1) Products, the manufacture or individuals who violate requirements of this directive or other applicable laws shall be subjected to appropriate administrative measure in accordance with the Directive on Administrative Measure Taking and Complaint Handling Procedure.
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 may be used as illustrative lists for suspension and revocation:

38. Suspension of a license

1) The Authority may suspend certificate of competence or take such other appropriate administrative measures as it may find necessary, in accordance with the Directive on Administrative Measure Taking and Complaint Handling.
2) Without prejudice to grounds of suspension provided under relevant laws, and based on the severity of the violation, the Authority shall suspend manufacturer's certificate of competence if, but not limited to,:

    a. The manufacturer allows a professional who is not duly licensed or who has been suspended from practicing by a competent authority from practicing his/her profession;
    b. it fails to allow inspection pursuant to applicable laws;

c. the manufacturer is suspended by other government organ;

d. it fails to submit, accurately or on time, or falsify information requested by the Authority;

e. it is found manufacturing products with the absence of authorized personnel or technical manager;

f. it fails to notify the Authority of any change to professionals or premises design and/or place without approval; and

g. any of its permanent professionals is found registered or employed as a permanent staff in any other facility except where dual appointment is permitted by law

h. fails to notify the Authority prior to sell or supply any cosmetic product.

i. Fails to recall its product found defective

j. Inconsistent with requirements of this directive

39. 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 manufacturer's certificate of competence if, but not limited to,:

1) engage 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;
2) engages in manufacturing products other than permitted by the Authority;
3) certificate of competence is not annually renewed within three months from its expiry date.
4) certificate of competence is proved to have been obtained by submitting false information intended to deceive the Authority or it is obtained in other illegal manner.

40. 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 TEN
MISCELLANEOUS

41. Prohibited materials

1) General

All cosmetic manufacturers shall ensure the products are free from Prohibited Cosmetic Ingredients as per the current/updated list provided in the Authorities website efda.gov.et:

2) Cosmetic products shall not contain any of the following:

a. Prohibited substances listed in Annex IV

b. Restricted substances which are not used in accordance with the restrictions laid down in Annex V

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 paragraph 2;

II. without prejudice to points (b), (d)(i) and 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;

II. without prejudice to points (b), (c)(i) and 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;

42. Cosmetic Notification

1) A manufacturer shall notify the Authority prior to manufacture, sell or supply any cosmetic product.

2) A notification process shall be carried out in accordance to Cosmetics Import, export and Wholesale Control Directive No 48/2020

43. Advertisement and Promotion

1) Any cosmetic manufacturer who wants to advertise their cosmetic products shall have certificate of competence.
2) Any advertisementandpromotionof cosmetic products shall be accurate, scientifically justifiable and not misleading the end user.
3) The advertisement of the cosmetic product shall contain the name of the product.
4) Any advertisement and promotion of cosmetic product shall not make medicinal or therapeutic claim.

44. Complaints

1) A person should be designated to handle complaints and decide on measures to be taken

2) There should be written procedures describing the action to be taken, including the need to consider a recall, in the case of a complaint involving a possible product defect.

3) Complaints involving product defects should be recorded with all the original details and investigated.

4) If a product defect is discovered or suspected in a batch, consideration should be given to whether other batches should be checked in order to determine whether they are also affected.

5) Where necessary, appropriate follow-up action, possibly including product recall, should be taken after investigation and evaluation of the complaint.

6) All the decisions and measures taken as a result of a complaint should be recorded and referenced to the corresponding batch records.

7) The authority should be informed if a manufacturer is considering action following possibly faulty manufacture and product deterioration, which may lead to serious safety issue.

45. Waste disposal procedure

All rejected materials shall be clearly identified, recorded and stored separately and announce the Authority before disposal.

46. Service fee

Any person who seeks regulatory service under this directive may be required to pay applicable service fee to the Authority.

47. Inapplicable laws

Any law which is inconsistent with this directive shall not be applicable with respect to those matters provided for in this directive.

48. Annexes

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

1) Annex I: Application form for manufacturing premises licensing;
2) Annex II: Inspection checklist of manufacturing premises;
3) Annex III: Classification of cosmetics;
4) Annex IV: Illiustrative list of cosmetics by catagories;
5) Annex V: List of substances which cosmetics products must not contain except subject to the restriction laid down;
6) Annex VI: List of colorants allowened in cosmetic products;
7) Annex VI: List of preservatives allowed in coametic products.

49. . Effective date

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

Heran Gerba
Director General
Ethiopian Food and Drug Authority