DRAFT

IMPLEMENTING REGULATION ON COSMETIC PRODUCTS

CHAPTER ONE
Objective, Scope, Legal Basis, and Definitions

Objective

Article 1- (1) The objective of this Implementing Regulation is to determine principles and procedures relevant to cosmetic products made available on the market to ensure a high level of protection of human health.

Scope

Article 2 - (1) This Implementing Regulation applies to cosmetic products.

(2) This Implementing Regulation does not apply to a substance or mixture intended to be ingested, inhaled, injected, or implanted into the human body for the purposes set out in point (ö) of Article (4)(1).

Legal basis

Article 3 – (1) This Implementing Regulation has been drawn up based on Article 7 of Law No 5324 on Cosmetic Products dated 24/3/2005 and Article 508 and 796 of Presidential Decree No 4 and Law No 7223 on Product Safety and Technical Regulations dated 05/03/2020.

Definitions

Article 4 – (1) For this Implementing Regulation, the following definitions shall apply:

a) Finished cosmetic product: Cosmetic product or its prototype in the form which is placed on the market or supplied to the end-user,

b) Colorants: substances which are exclusively or mainly intended to colour the cosmetic product, 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;

c) CAS number: the Chemical Abstracts Service number,

ç) Serious undesirable effect: An undesirable effect which results in temporary or permanent functional incapacity, disability, hospitalisation, congenital anomalies or an immediate vital risk or death,

d) Frame formulation: a formulation which that lists the category or function of ingredients and their maximum concentration in the cosmetic product or gives relevant quantitative and qualitative information whenever a cosmetic product is not covered or only partially covered by such a formulation,

e) Distributor: Any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a cosmetic product available on the market,

f) EC number: The number designated by the European Commission according to the structural properties of the substance,

g) Recall: means any measure aimed at achieving the return to economic operator of a cosmetic product that has already been made available to the end-user,

ğ) IUPAC name: The name designated by the International Union of Pure and Applied Chemistry,

h) Economic operator: Manufacturer, responsible person, importer, and distributor,

ı) Manufacturer: Any natural or legal person who manufactures a cosmetic product or has such a product designed or manufactured, and markets that cosmetic product under his own name or trademark,

i) Undesirable effect: An adverse reaction for human health attributable to the normal or reasonably foreseeable use of a cosmetic product,

j) Importer: Any natural or legal person, who places a cosmetic product on the market through import,

k) Good manufacturing practices: All planned and systematized activities which have been standardized to ensure the required quality level for the manufacturing, control, storage, and transportation of cosmetic products,

l) Law: Law No 5324 on Cosmetic Products published in the Official Gazette No 5324 of 24/3/2005,

m) Mixture: a mixture or solution composed of two or more substances,

n) Commission: European Commission,

o) Preservatives: substances which that are exclusively or mainly intended to inhibit the development of micro-organisms in the cosmetic product,

ö) Cosmetic product: means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips, and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odors,

p) Agency: Turkish Medicines and Medical Devices Agency,

r) Substance: 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,

s) Nanomaterial: An insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on a scale from 1 to 100 nm,

ş) End-user: a consumer or professional using the cosmetic product,

t) Making available on the market: any supply of a cosmetic product for distribution, consumption, or use on the market in the course of commercial activity, whether in return for payment or free of charge,

u) Withdrawal: any measure aimed at preventing the making available on the market of a cosmetic product in the supply chain,

ü) Placing on the market: the first making available of a cosmetic product on the market,

v) Prototype: a first model or design that has not been produced in batches, and from which the finished cosmetic product is copied or finally developed,

y) Communique: Communique on Cosmetic Ingredients published in the Official Gazette No … of …

z) National electronic database: Electronic database which is administered by the Agency,

aa) UV-filters: substances which are exclusively or mainly intended to protect the skin against certain UV radiation by absorbing, reflecting, or scattering UV radiation,

bb) Harmonized Standard: A European standard adopted based on a request made by the Commission for the application of Union harmonization legislation,

cc) UZEM: National Poison Control Center, which is responsible for counseling the calls of national poisoning cases and supplying antidote/antitoxins, and delivering them to patients.

CHAPTER TWO
Safety, Responsibility, Free Movement

Safety

Article 5- (1) A cosmetic product made available on the market shall be safe for human health when used under normal or reasonably foreseeable conditions of use, taking account, in particular, of the following:

a) Presentation including conformity with the Article 79 of Law No 6502 on Protection of Consumer published in the Official Gazette No. 28835 of 28/11/2013,

b) Labeling,

c) Instructions for use and disposal,

ç) Any other indication or information provided by the responsible person defined in Article 6.

(2)The provision of warnings shall not exempt persons defined in Articles 4 and 6 from compliance with the other requirements laid down in this Implementing Regulation.

Responsible person

Article 6- (1) Cosmetic products may only be placed on the market if a legal or natural person located in Turkey is designated as responsible person.

(2) For each cosmetic product placed on the market, the responsible person shall ensure compliance with the relevant obligations set out in this Implementing Regulation.

(3) For a cosmetic product manufactured within Turkey:

a) If the manufacturer is located in Turkey, the manufacturer shall be the responsible person. However, the manufacturer may designate, by written mandate, a person located in Turkey as the responsible person who shall accept in writing.

b) If the manufacturer is established outside of Turkey, he shall designate, by written mandate, a person located in Turkey as the responsible person who shall accept in writing.

(4) For an imported cosmetic product, each importer shall be the responsible person for the specific cosmetic product he places on the market. However, the manufacturer may designate, by written mandate, a person located in Turkey as the responsible person who shall accept in writing.

(5) If the responsible person is a natural or legal person appointed by the manufacturer or importer by a written agreement, the responsible person shall be legally responsible on the same basis as the manufacturer or importer within the scope of the Product Safety and Technical Regulations Law No. 7223.

(6) The distributor shall be the responsible person where he places a cosmetic product on the market under his name or trademark or modifies a product already placed on the market in such a way that compliance with the applicable requirements may be affected. And it

becomes legally responsible on the same basis as the manufacturer. The translation of information relating to a cosmetic product already placed on the market shall not be considered as a modification of that product of such a nature that compliance with the applicable requirements of this Implementing Regulation may be affected.

Responsible Technical Personnel

Article 7 – (1) The responsible person shall employ a responsible technical personnel.

(2) The responsible technical personnel is responsible for checking the compliance of the product to be placed on the market with the cosmetic legislation, good manufacturing practices, and other relevant legislation.

(3) Chemists, biochemists, chemical engineers, chemistry teachers, biomedical engineers, biologists, and microbiologists with the condition of completing a training accepted by the Agency or pharmacists may be designated as a responsible technical personnel.

Obligations of the responsible person

Article 8- (1) Responsible persons shall ensure compliance with Articles 5, 11, 13, 14, 15, 16, 17, 18, 19, 20, 21, Article 22 (1), (2), and (5), as well as Article 23, 24, 26 and 27.

(2) Responsible persons who consider or have reason to believe that a cosmetic product which they have placed on the market is not in conformity with this Implementing Regulation shall immediately take the corrective measures necessary to bring that product into conformity, withdraw it or recall it, as appropriate. Furthermore where the cosmetic product presents a risk to human health responsible persons shall immediately inform the Agency, in particular, of the non-compliance and of the corrective measures taken.

(3) Responsible person shall cooperate with the Agency, at the request of the latter, on any action to eliminate the risks posed by cosmetic products which they have made available on the market. In particular responsible persons shall, further to a request from the Agency, provide it with all the information and documentation necessary to demonstrate the conformity of specific aspects of the product, in Turkish or English.

Obligations of distributors

Article 9- (1) In the context of their activities, when making a cosmetic product available on the market, distributors shall act with due care in relation to applicable requirements.

(2) Before making a cosmetic product available on the market distributors shall verify that:

a) The labeling information provided for in Article 22 (1), (a), (d), (f), (g), (ğ), (h) and (ı), and Article 22 (3) and (4) is present,

b) The language requirements provided for in Article 22 (5) are fulfilled,

c) The date of minimum durability specified, where applicable under Article 22 (1), has not passed.

(3) Where distributors:

a) consider or have reason to believe that a cosmetic product is not in conformity with the requirements laid down in this Implementing Regulation, they shall not make the product available on the market until it has been brought into conformity with the applicable requirements.

b) consider or have reason to believe that a cosmetic product which they have made available on the market is not in conformity with this Implementing Regulation, they shall make sure that the corrective measures necessary to bring that product into conformity, withdraw it or recall it, as appropriate, are taken.

Furthermore, where the cosmetic product presents a risk to human health, distributors shall immediately inform the Agency and responsible person, giving details, in particular, of the non-compliance and of the corrective measures taken.

(4) Distributors shall ensure that, while a product is under their responsibility, storage or transport conditions do not jeopardize its compliance with the requirements set out in this Implementing Regulation.

(5) Distributors shall cooperate with the Agency on any action to eliminate the risks posed by products that they have made available on the market. In particular, distributors shall, further to a request from the Agency, provide it with all the information and documentation necessary to demonstrate the conformity of the product with the requirements listed under paragraph 2, especially in Turkish or, where not possible, in English.

Identification within the supply chain

Article 10 – (1) At the request of the Agency, this obligation shall apply for a period of three years following the date on which the batch of the cosmetic product was made available to the distributor.

(a) Responsible persons shall identify the distributors to whom they supply the cosmetic product,

(b) The distributor shall identify the distributor or the responsible person from whom, and the distributors to whom, the cosmetic product was supplied.

Good manufacturing practice

Article 11- (1) The manufacture of cosmetic products shall comply with good manufacturing practice with a view to ensure the objectives of Article 1.

(2) Compliance with good manufacturing practice shall be presumed where the manufacture is in accordance with the standards determined by the Agency under the relevant harmonized standards published in the Official Journal of the European Union.

Free movement

Article 12- (1) Agency shall not, for reasons related to the requirements laid down in this Implementing Regulation, except for the matters not covered by this Implementing Regulation, refuse, prohibit or restrict the making available on the market of cosmetic products which comply with the requirements of this Implementing Regulation.

(2) If a cosmetic product export certificate is requested for a cosmetic product manufactured in Turkey, domestic cosmetic product manufacturers, or the responsible person located in Turkey shall apply via the national electronic database. The work and procedures regarding the application shall be carried out in accordance with the provisions of the relevant guideline which will be published in accordance with this Implementing Regulation.

CHAPTER THREE
Safety Assessment, Product Information File, Notification

Safety assessment

Article 13- (1) In order to demonstrate that a cosmetic product complies with Article 5, the responsible person shall, prior to placing a cosmetic product on the market, ensure that the cosmetic product has undergone a safety assessment on the basis of the relevant information and that a cosmetic product safety report is set up in accordance with Annex I.

(2) The responsible person shall ensure that for all cosmetic products, including those notified under the Cosmetic Regulation published in Official Gazette No 25823 of 23/5/2005:

a) the intended use of the cosmetic product and the anticipated systemic exposure to individual ingredients in a final formulation are taken into account in the safety assessment;

b) an appropriate weight-of-evidence approach is used in the safety assessment for reviewing data from all existing sources;

c) the cosmetic product safety report is kept up to date in view of additional relevant information generated subsequent to placing the product on the market.

(3) Agency, shall adopt appropriate guidelines to enable undertakings to comply with the requirements laid down in Annex I.

(4) The cosmetic product safety assessment, as set out in Annex I shall be carried out by a person in possession of a diploma or other evidence of formal qualifications awarded on completion of a university course of theoretical and practical study in pharmacy, toxicology, medicine or a similar discipline, or a course recognized as equivalent by the Agency.

(5) Non-clinical safety studies referred to in the safety assessment according to paragraph 1 shall be carried out in accordance with the Regulation on Principles of Good Laboratory Practices, Harmonization of Test Units, Supervision of Good Laboratory Practices and Studies published on Official Gazette No. 27516 of 9/3/2010 or with other international standards recognized as being equivalent by the Commission or the ECHA.

Product information file

Article 14 – (1) When a cosmetic product is placed on the market, the responsible person shall be kept a product information file for a period of ten years following the date on which the last batch of the cosmetic product was placed on the market.

(2) The product information file shall contain the following information and data which shall be updated as necessary:

a) a description of the cosmetic product which enables the product information file to be clearly attributed to the cosmetic product;

b) the cosmetic product safety report referred to in Article 13 (1);

c) a description of the method of manufacturing and a statement on compliance with good manufacturing practice referred to in Article 11;

ç) where justified by the nature or the effect of the cosmetic product, proof of the effect claimed for the cosmetic product;

d) Data on any animal testing performed by the manufacturer, his agents, or suppliers, relating to the development or safety assessment of the cosmetic product or its ingredients, including any animal testing performed to meet the legislative or regulatory requirements of countries other than Turkey and EU Member States.

(3) The responsible person shall make the product information file readily accessible in electronic or another format at his address indicated on the label to be presented to the Agency at the request of the Agency.

(4) The information contained in the product information file shall be available in Turkish or English.

(5) The requirements provided in paragraphs (1) to (4) of this Article shall also apply to cosmetic products that have been notified under the repealed Cosmetic Regulation.

Sampling and analysis

Article 15- (1) Sampling and analysis of cosmetic products shall be performed in a reliable and reproducible manner.

(2) Reliability and reproducibility shall be presumed if the method used complies with the guidelines published by the Agency in accordance with the relevant harmonized standards, the references of which have been published in the Official Journal of the European Union.

Notification

Article 16 – (1) Prior to placing the cosmetic product on the market the responsible person shall submit the following information to the Agency via the national electronic database including cosmetic products notified under the repealed Cosmetics Regulation:

a) The barcode and the category of cosmetic product according to Annex 1 of the Communique and its name or names, enabling its specific identification;

b) the name and address of the responsible person where the product information file is made readily accessible;

c) the country of origin in the case of import, and the countries in which the product is placed on the market;

ç) the contact details of a physical person to contact in the case of necessity;

d) the presence of substances in the form of nanomaterials and:

1) their identification including the chemical name (IUPAC) and other descriptors as specified in Article 4 of the Communique;

2) the reasonably foreseeable exposure conditions;

e) the name and the Chemicals Abstracts Service (CAS) or EC number of substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), of category 1A or 1B, under Part 3 of Annex VI to Regulation on Classification, Labeling and Packaging of Chemical Substances and Mixtures published on the repeated Official Gazette No. 28848 of 11/12/2013;

f) Formulation in which volume or quantity ratios, including frame formulation, are specified in intervals to provide rapid and appropriate medical treatment in emergencies.

(2) When the cosmetic product is placed on the market, the responsible person shall notify the Agency via the national electronic database about the original labeling, Turkish label in cases where Turkish information is not included on the original label and the product packaging visual.

(3) Agency shall, without delay, make the information referred to in paragraphs 1, 2 available electronically to UZEM of the Ministry of Health for the purposes of medical treatment.

(4) Where any of the information set out in paragraph 1 changes, the responsible person shall provide an update without delay.

CHAPTER FOUR
Restrictions for Substances

Restrictions for substances listed in the Communique

Article 17 – (1) Without prejudice to Article 5 of this Implementing Regulation, cosmetic product shall not contain any of the following:

a) Prohibited substances: prohibited substances listed in Annex II of the Communique;

b) Restricted substances: restricted substances which are not used in accordance with the restrictions laid down in Annex III of the Communique;

c) Colorants:

1) Colorants other than those listed in Annex IV of the Communique 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

2) without prejudice to point (b), (ç) (1) and (d) (1), substances listed in Annex IV of the Communique 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.

ç) Preservatives:

1) Preservatives other than those listed in Annex V of the Communique and preservatives which are listed there but not used in accordance with the conditions laid down in that Annex;

2) without prejudice to point (b), (c) (1), (d) (1), substances listed in Annex V of the Communique 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.

d) UV-filters:

1) UV-filters other than those listed in Annex VI of the Communique and UV-filters which are listed there but not used in accordance with the conditions laid down in that Annex;

2)without prejudice to point (b), (c) (1), (ç) (1) substances listed in Annex VI of the Communique but which are not intended to be used as UV-filters and which are not used in accordance with the conditions laid down in that Annex.

(2) Cosmetic products shall not contain colorants intended to colour the hair, other than those listed in Annex IV of the Communique, and colorants intended to colour the hair which are listed there but not used in accordance with the conditions laid down in that Annex.

Substances classified as CMR substances

Article 18 – (1) The use in cosmetic products of substances classified as CMR substances, of category 2, under part 3 of Annex VI to Implementing Regulation on the Classification, Labeling and Packaging of Substances and Mixtures shall be prohibited unless the Agency found that substance safe for use in cosmetic products.

(2) The use in cosmetic products of substances classified as CMR substances, of category 1A or 1B under Part 3 of Annex VI to Implementing Regulation on the Classification, Labeling and Packaging of Substances and Mixtures shall be prohibited. However, such substances may be used in cosmetic products by way of exception where, subsequent to their classification as CMR substances of category 1A or 1B under Part 3 of Annex VI to the aforementioned Implementing Regulation, all of the following conditions are fulfilled:

a) They comply with the food safety requirements as defined in Law No 5996 on Veterinary Services, Plant Health, Food and Feed published in the Official Gazette No 27610 of 13/06/2010.

b) There are no suitable alternative substances available, as documented in an analysis of alternatives;

c) The application is made for a particular use of the product category with a known exposure,

ç) They have been evaluated and found safe by the Commission for use in cosmetic products, in particular in view of exposure to these products and taking into consideration the overall exposure from other sources, taking particular account of vulnerable population groups.

(3) Specific labelling in order to avoid misuse of the cosmetic product shall be provided in accordance with Article 5 of this Implementing Regulation, taking into account possible risks linked to the presence of hazardous substances and the routes of exposure

(4) The Agency shall re-evaluate those substances as soon as safety concerns arise, and update the relevant Annexes of the Communique taking into account the decision of the commission.

if necessary.

Nanomaterials

Article 19- (1) For every cosmetic product that contains nanomaterials, a high level of protection of human health shall be ensured.

(2) The provisions of this Article do not apply to nanomaterials used as colorants, UV-filters or preservatives regulated under Article 17 unless expressly specified.

(3) In addition to the notification under Article 16, cosmetic products containing nanomaterials shall be notified to the Agency via national electronic database by the responsible person six months prior to being placed on the market. This notification includes at least the followings:

a) the identification of the nanomaterial including its chemical name (IUPAC) and other descriptors as specified in Article 4 (1) (b), (h) (ğ) and (m) of the Communique,

b) the specification of the nanomaterial including size of particles, physical and chemical properties;

c) an estimate of the quantity of nanomaterial contained in cosmetic products intended to be placed on the market per year;

ç) the toxicological profile of the nanomaterial;

d) the safety data of the nanomaterial relating to the category of cosmetic product, as used in such products;

e) The reasonably foreseeable exposure conditions.

(4) The third paragraph shall not apply to cosmetic products containing nanomaterials that are in conformity with the requirements set out in Annex III of the Communique.

(5) The responsible person may designate another legal or natural person by written mandate for the notification of nanomaterials and shall inform the Agency thereof.

(6) In the event that concerns regarding the safety of a nanomaterial have arisen, the Agency shall evaluate the safety of such nanomaterial for use in the relevant categories of cosmetic products and on the reasonably foreseeable exposure conditions. To this end, the Agency may consult to the Advisory Commission established in accordance with Article 36.

Where the necessary data is lacking, the Agency shall request the responsible person to provide such data. The responsible person shall provide that data within 10 working days. If any tests and analysis require additional time, the Agency shall extend this period only once.

(7) The Agency, may at any time, invoke the procedure in paragraph 6 where it has any safety concerns, for example, due to new information supplied by a third party.

(8) The Agency amends Annex II and III of the Communique, taking into account the decision of the Commission where there is a potential risk to human health.

(9) In cases where safety concerns are justified as a result of the assessment specified in paragraph 6, the Agency shall inform the Commission about its concerns regarding the use of the relevant nanomaterial.

(10) The Agency, taking into account the catalog prepared by the Commission, shall make available a catalogue of all nanomaterials used in cosmetic products placed on the market, including those used as colorants, UV filters and preservatives in a separate section, indicating the categories of cosmetic products and the reasonably foreseeable exposure conditions. The Agency updates this catalog as the catalog prepared by the Commission is updated.

Traces of prohibited substances

Article 20 – (1) The non-intended presence of a small quantity of a prohibited substance, stemming from impurities of natural or synthetic ingredients, the manufacturing process, storage, migration from packaging, which is technically unavoidable in good manufacturing practice, shall be permitted provided that such presence is in conformity with Article 5.

CHAPTER FIVE
Animal Testing

Animal testing

Article 21 – (1) Without prejudice to the general obligations deriving from Article 5, the following shall be prohibited:

a) the placing on the market of cosmetic products where the final formulation, in order to meet the requirements of this Implementing Regulation, has been the subject of animal testing using a method other than an alternative method after such alternative method has been validated with due regard to the development of validation within the OECD and adopted by the Agency,

b) the placing on the market of cosmetic products containing ingredients or combinations of ingredients, which, in order to meet the requirements of this Implementing Regulation, have been the subject of animal testing using a method other than an alternative method after such alternative method has been validated with due regard to the development of validation within the OECD and adopted by the Agency,

c) the performance within Turkey of animal testing of finished cosmetic products in order to meet the requirements of this Implementing Regulation,

ç) the performance of animal testing of ingredients or combinations of ingredients in order to meet the requirements of this Implementing Regulation, after the date on which such tests are required to be replaced by one or more validated alternative methods listed in Regulation on Test Methods to be Applied for Determination of Physico-Chemical,

Toxicological and Ecotoxicological Properties of Substances and Mixtures in the Official Gazette No. 28848 of 11.12.2013 or Annex III of this Implementing Regulation,

(2) In exceptional circumstances, where serious concerns arise as regards the safety of an existing cosmetic product ingredient, if the following conditions are met, the Agency may grant a derogation from the first paragraph by specifying its purpose, duration and scope and notify the Commission through the Ministry of Trade:

a) the ingredient is in wide use and cannot be replaced by another ingredient capable of performing a similar function;

b) the specific human health problem is substantiated and the need to conduct animal tests is justified and is supported by a detailed research protocol proposed as the basis for the evaluation.

CHAPTER SIX
Consumer Information

Labeling

Article 22 - (1) Without prejudice to other provisions in this Article, cosmetic products shall be made available on the market only where the container and packaging of cosmetic products bear the following information in indelible, easily legible and visible lettering.

a) the name or registered name and the address of the responsible person. Such information may be abbreviated in so far as the abbreviation makes it possible to identify that person and his address. If several addresses are indicated, the one where the responsible person makes readily available the product information file shall be highlighted. The country of origin shall be specified for imported cosmetic products,

b) the nominal content at the time of packaging, given by weight or by volume, except in the case of packaging containing less than five grams or five milliliters, free samples and single-application packs; for pre-packages normally sold as a number of items, for which details of weight or volume are not significant, the content need not be given provided the number of items appears on the packaging. This information need not be given if the number of items is easy to see from the outside or if the product is normally only sold individually.

c) the date until which the cosmetic product, stored under appropriate conditions, will continue to fulfill its initial function and, in particular, will remain in conformity with Article 5 (‘date of minimum durability’).

1) The date itself or details of where it appears on the packaging shall be preceded by the symbol shown in point 3 of Annex II or the words: ‘best used before the end of’.

2) The date of minimum durability shall be clearly expressed and shall consist of either the month and year or the day, month and year, in that order. If necessary, this information shall be supplemented by an indication of the conditions which must be satisfied to guarantee the stated durability.

3) Indication of the date of minimum durability shall not be mandatory for cosmetic products with a minimum durability of more than 30 months. For such products, there shall be an indication of the period of time after opening 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, by the symbol shown in point 2 of Annex II followed by the period (in months and/or years),

ç) Particular precautions to be observed in use, and at least those listed in Annexes III to VI of the Communique and any special precautionary information on cosmetic products for professional use,

d) The batch number of manufacture or the reference number assigned by the manufacturer for identifying the cosmetic product. Where this is impossible for practical reasons because the cosmetic products are too small, such information need appear only on the packaging,

e) The function of the cosmetic product unless it is clear from its presentation,

f) A list of ingredients shall be indicated on the container. In addition, it may be indicated on the packaging. The list shall be preceded by the term 'ingredients' or a term with the same meaning in Turkish or English.

For the purpose of this Article, an ingredient means any substance or mixture intentionally used in the cosmetic product during the process of manufacturing. The following shall not, however, be regarded as ingredients:

1) impurities in the raw materials used,

2) subsidiary technical materials used in the mixture but not present in the finished cosmetic product

g) Perfume and aromatic compositions and their raw materials shall be referred to by the terms 'perfume or 'aroma'. Moreover, the presence of substances, the mention of which is required under the column 'Other' in Annex III of the Communique, shall be indicated in the list of ingredients in addition to the terms perfume or aroma.

ğ)The list of ingredients shall be established in descending order of weight of the ingredients at the time they are added to the cosmetic product. Ingredients in concentrations of less than 1 % may be listed in any order after those in concentrations of more than 1 %.

h) All ingredients present in the form of nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word 'nano' in brackets.

ı) Colorants other than colorants intended to colour the hair may be listed in any order after the other cosmetic ingredients. For decorative cosmetic products marketed in several colour shades, all colorants other than colorants intended to colour the hair used in the range may be listed, provided that the words 'may contain' or the symbol '+/-' are added. The CI (Colour Index) nomenclature shall be used, where applicable.

(2)Where it is impossible for practical reasons to label the information mentioned in points (ç), (f), (g), (ğ), (h) and (ı) of paragraph 1 as provided, the following applies:

a) The information shall be mentioned on an enclosed or attached leaflet, label, tape, tag or card,

b) Unless impracticable, this information shall be referred to by abbreviated information or the symbol given in point 1 of Annex II of this Implementing Regulation, which must appear on the container or packaging for the information referred in point (ç) of paragraph 1 and on packaging for the information referred in point (f), (g), (ğ), (h) and (ı) of paragraph 1.

(3) In the case of soap, bath balls and other small products where it is impossible for practical reasons for the information referred to in point (f), (g), (ğ), (h) and (ı) of paragraph 1

to appear on a label, tag, tape or card or in an enclosed leaflet, this information shall appear on a notice in immediate proximity to the container in which the cosmetic product is exposed for sale.

(4) Cosmetic products that are not pre-packaged, are packaged at the point of sale at the purchaser's request or are pre-packaged for immediate sale shall be presented to the end-user in accordance with the requirements of this Implementing Regulation and with an information card containing the information referred to in the first paragraph.

(5) The language of the information mentioned in points (b), (c), (ç) and (e) of paragraph 1 and in paragraphs (2), (3) and (4) shall be in Turkish.

(6) The information mentioned in point (f),(g), (ğ), (h) and (ı)of paragraph 1 shall be expressed by using the common ingredient name set out in the glossary provided for in Article 33. In the absence of a common ingredient name, a term as contained in a generally accepted nomenclature shall be used.

Product claims

Article 23 – (1) In the labeling, making available on the market and advertising of cosmetic products, text, names, trademarks, registered trademarks, pictures and figurative or other signs shall not be used to imply that these products have characteristics or functions which they do not have.

(2) The Agency shall establish a list of common criteria for claims, based on the common criteria published by the Commission, which may be used in respect of cosmetic products, and take appropriate measures to ensure compliance of cosmetic products which are not in conformity with the common criteria.

(3) The responsible person may refer, on the product packaging or in any document, notice, label, ring or collar accompanying or referring to the cosmetic product, to the fact that no animal tests have been carried out only if the manufacturer and his suppliers have not carried out or commissioned any animal tests on the finished cosmetic product, or its prototype, or any of the ingredients contained in it, or used any ingredients that have been tested on animals by others for the purpose of developing new cosmetic products.

Access to information for the public

Article 24 – (1) Without prejudice to the protection, in particular, of commercial secrecy and of intellectual property rights, the responsible person shall ensure that the qualitative and quantitative composition of the cosmetic product and, in the case of perfume and aromatic compositions, the name and code number of the composition and the identity of the supplier, as well as existing data on undesirable effects and serious undesirable effects resulting from use of the cosmetic product are made easily accessible to the public by any appropriate means.

(2) The quantitative information regarding the composition of the cosmetic product required to be made publicly accessible shall be limited to hazardous substances in accordance with Article 5 of Implementing Regulation on Classification, Labelling and Packaging of Chemical Substances and Mixtures published in the repeated Official Gazette No 28848 of 11/12/2013.

CHAPTER SEVEN
Market Surveillance

In-market control

Article 25 – (1) The Agency shall monitor if the cosmetic products made available on the market are in compliance with this Implementing Regulation and do not endanger human and public health and safety via in-market controls of the cosmetic products made available on the market. The Agency shall perform appropriate checks of cosmetic products and checks on the economic operators on an adequate scale, through the product information file and, where appropriate, physical and laboratory checks on the basis of adequate samples.

(2) The Agency shall also monitor compliance with the principles of good manufacturing practices.

(3) The Agency determines production site inspections of cosmetic products, sampling, warning, withdrawal from the market, disposal, rehabilitation and closure of the production site within the scope of market surveillance and inspection.

(4) The Agency periodically reviews its market surveillance activities annually and reports the results to the Commission and EU Member States through the Ministry of Trade. This review is made available to the public electronically and, if necessary, by other means.

Communication of serious undesirable effects

Article 26 – (1) In the event of serious undesirable effects, the responsible person and distributors shall without delay notify the following to the Agency and the manufacturer:

a) all serious undesirable effects which are known to him or which may reasonably be expected to be known to him,

b) the name of the cosmetic product concerned, enabling its specific identification,

c) the corrective measures taken by him, if any.

(2) Where the responsible person reports serious undesirable effects to the Agency, the Agency shall immediately transmit the information referred to in paragraph 1 to the competent authorities of the EU Member States through the Ministry of Trade.

(3) Where distributors, end-users or health professionals report serious undesirable effects to the Agency, the Agency shall immediately transmit the information referred to in paragraph (1) to the responsible person and EU Member States through the Ministry of Trade.

(4) The Agency may use the information referred to in this Article for the purposes of in-market surveillance, market analysis, evaluation and consumer information in the context of Articles 28, 29 and 30.

Information on substances

Article 27 – (1) In the event of serious doubt regarding the safety of any substance contained in cosmetic products, the Agency may request the responsible person to submit a list of all cosmetic products for which he is responsible and which contain this substance. The list shall indicate the concentration of this substance in cosmetic products. The Agency may use the information referred to in this Article for the purposes of in-market surveillance, market analysis, evaluation and consumer information in the context of Articles 28, 29 and 30.

CHAPTER EIGHT
Non-Compliance, Safeguard Clause, Administrative Enforcements

Non-compliance by the responsible person

Article 28 – (1) Without prejudice to paragraph 3 the Agency shall require the responsible person to take all appropriate measures, including corrective actions bringing the cosmetic product into conformity, the withdrawal of the product from the market or its recall, within an expressly mentioned time limit, commensurate with the nature of the risk, where there is non-compliance with any of the following:

a) the good manufacturing practice referred to in Article 11,

b) the safety assessment referred to in Article 13,

c) the requirements for the product information file referred to in Article 14,

ç) the provisions on sampling and analysis referred to in Article 15,

d) the notification requirements referred to in Articles 16 and 19,

e) the restrictions for substances referred to in Articles 17, 18 and 20,

f) the animal testing requirements referred to in Article 21,

g) the labeling requirements referred to in Article 22(1), (2), (5) and (6),

ğ) the requirements related to product claims set out in Article 23,

h) the access to information for the public referred to in Article 24,

ı) the communication of serious undesirable effects referred to in Article 26,

i) the information requirements on substances referred to in Article 27.

(2) The responsible person shall ensure that the measures referred to in paragraph 1 are taken in respect of all the products concerned.

(3)In case of serious risks to human health, where the Agency considers that the non-compliance is not limited to the territory of Turkey, the Agency shall inform the Commission and the EU Member States of the measures which it has required the responsible person to take through the Ministry of Trade.

Non-compliance by distributors

Article 29 – (1) The Agency shall require distributors to take all appropriate measures, including corrective actions bringing the cosmetic product into conformity, the withdrawal of the product from the market or its recall or its disposal, within a given reasonable time limit, commensurate with the nature of the risk, where there is non-compliance with obligations laid down in Article 9.

Safeguard clause

Article 30 – (1) In the case of products meeting the requirements listed in Article 28(1), where the Agency ascertains or has reasonable grounds for concern, that a cosmetic product or products made available on the market present or could present a serious risk to human health, it shall take all appropriate provisional measures in order to ensure that the product or products concerned are withdrawn, recalled or their availability is otherwise restricted.

(2) The Agency shall share with the Commission and the competent authorities of the EU Member States the measures taken and any supporting data through the Ministry of Trade where necessary.

Administrative enforcements

Article 31- (1) Any decision taken by the Agency pursuant to Articles 28 and 30 shall be notified without delay to the responsible person with the exact grounds on which it is based.

(2) Except in the case where immediate action is necessary for reasons of serious risk to human health, the responsible person shall have the opportunity to put forward his viewpoint to Agency before any decision is taken.

(3) Where applicable, the provisions mentioned in paragraphs 1 and 2 shall apply with regard to the distributor for any decisions taken pursuant to Articles 29 and 30.

(4) The Agency shall take all appropriate measures to prohibit or restrict the making available on the market of the cosmetic product or to withdraw the product from the market or to recall it, and when it is impossible to make the products safe, partially or completely dispose of the products commensurate with the nature of the risk, costs to be borne by the economic operator, in the following cases:

a) where an immediate action is necessary in the event of serious risk to human health; or,

b) where the responsible person does not take all appropriate measures within the time limit referred to in Article 28 (1).

(5) The economic operator shall make an announcement regarding the products, with risk in accordance with Article 18 of the Product Safety and Technical Regulations Act by itself or upon the request of the Agency.

Cooperation

Article 32- (1) The Agency participates in the organization of the Commission for the necessary information exchange in order to allow the uniform implementation of this Implementing Regulation and cooperates with the competent authorities of the EU Member States and the Commission in this direction.

(2) Upon a request made by the competent authority of any Member State where the cosmetic product is made available, without undue delay and taking into account the degree of urgency, the Agency shall inform the requesting competent authority whether the product information file satisfies the requirements referred to in Article 14 (2) and whether the information set out therein provides evidence of the safety of the cosmetic product. The requesting competent authority shall provide a motivation for the request.

(3) The Agency may request the same procedure described in paragraph (2) from the competent authority of any Member State in which the responsible person based, for a cosmetic product made available on the market.

Glossary of common ingredient names

Article 33-(1) The Agency shall compile and update a glossary of common ingredient names. To this end, the Agency shall take account of internationally recognized nomenclatures including the International Nomenclature of Cosmetic Ingredients (INCI). That glossary shall not constitute a list of the substances authorized for use in cosmetic products.

National Poison Control Center

Article 34- (1) The Agency notifies the Commission with the contact details of the UZEM.

Penalties for infringement of the provisions of this Implementing Regulation

Article 35- – (1) For those who infringe the provisions of this Implementing Regulation and legislation that put into force to implement this Implementing Regulation, relevant provisions of Cosmetic Law No. 5324 dated 24/3/2005 and Law No: 7223 on Technical Regulations for Products Safety dated 05/3/2020 and Turkish Criminal Code Law No. 5237 shall apply in accordance with the nature of the action.

(2) In the event that the responsible person violates his obligations under this Implementing Regulation, the responsible person shall be legally responsible on the same basis as the manufacturer or importer within the scope of the Product Safety and Technical Regulations Act.

(3) If the responsible person is a legal or natural person designated by a written mandate by the manufacturer or the importer, the provisions in the first paragraph are shall apply to him.

Advisory commissions

Article 36- (1) The Agency may establish temporary or permanent advisory commissions in addition to technical and advisory commissions within its organization, if necessary. The procedures and principles of advisory commissions and their duties, authorizations and responsibilities shall be determined by the Agency.

Compliance with the European Union legislation

Article 37-(1) This Implementing Regulation is prepared according to Regulation (EC) No 1223/2009 of the European Parliament and of the Council as part of compliance with the European Union legislation.

Repealed Regulation

Article 38- Cosmetic Products Regulation published in the Official Gazette No. 25823 of 23/05/2005 has been repealed.

Transitional provisions

Article 39-(1) Cosmetic products which made available on the market before the date this Implementing Regulation enters into force and are compliant with the repealed Cosmetic Products Regulation may be made available on the market for 2 years after this Implementing Regulation enters into force.

(2) Within the time frame specified in the paragraph (1), the notification made according to Article 16 of this Implementing Regulation shall be accepted as compliant with Article 14 of the repealed Cosmetic Products Regulation.

References

Article 40-(1) References to the repealed Cosmetic Products Regulation published in the Official Gazette No 25823 of 23/05/2005 in other regulations shall be understood as references to this Implementing Regulation.

Entry into force and date of application

Article 41- (1) This Implementing Regulation shall enter into force six months after the date of its publication.

(2) Article 16 of this Implementing Regulation shall apply on the date of its publication.

Execution

Article 42-(1) Provisions of this Implementing Regulation shall be executed by the President of the Agency.

ANNEX I
COSMETIC PRODUCT SAFETY REPORT

The cosmetic product safety report shall, as a minimum, contain the following:

PART A – Cosmetic product safety information

1. Quantitative and qualitative composition of the cosmetic product

The qualitative and quantitative composition of the cosmetic product, including the chemical identity of the substances (incl. chemical name, INCI, CAS, EINECS/ELINCS, where possible) and their intended function. In the case of perfume and aromatic compositions, description of the name and code number of the composition and the identity of the supplier.

2. Physical/chemical characteristics and stability of the cosmetic product

The physical and chemical characteristics of the substances or mixtures, as well as the cosmetic product.

The stability of the cosmetics product under reasonably foreseeable storage conditions.

3. Microbiological quality

The microbiological specifications of the substance or mixture and the cosmetic product. Particular attention shall be paid to cosmetics used around the eyes, on mucous membranes in general, on damaged skin, on children under three years of age, on elderly people and persons showing compromised immune responses.

Results of preservation challenge test.

4. Impurities, traces, information about the packaging material

The purity of the substances and mixtures.

In the case of traces of prohibited substances, evidence for their technical unavoidability.

The relevant characteristics of packaging material, in particular purity and stability.

5. Normal and reasonably foreseeable use

The normal and reasonably foreseeable use of the product. The reasoning shall be justified in particular in the light of warnings and other explanations in the product labeling.

6. Exposure to the cosmetic product

Data on the exposure to the cosmetic product taking into consideration the findings under Section 5 in relation to

1) The site(s) of application;

2) The surface area(s) of application;

3) The amount of product applied;

4) The duration and frequency of use;

5) The normal and reasonably foreseeable exposure route(s);

6) The targeted (or exposed) population(s). Potential exposure of a specific population shall also be taken into account.

The calculation of the exposure shall also take into consideration the toxicological effects to be considered (e.g. exposure might need to be calculated per unit area of skin or per unit of body weight). The possibility of secondary exposure by routes other than those resulting

from direct application should also be considered (e.g. non-intended inhalation of sprays, non-intended ingestion of lip products, etc.).

Particular consideration shall be given to any possible impacts on exposure due to particle sizes.

7. Exposure to the substances

Data on the exposure to the substances contained in the cosmetic product for the relevant toxicological endpoints taking into account the information under Section 6.

8. Toxicological profile of the substances

Without prejudice to Article 18, the toxicological profile of substance contained in the cosmetic product for all relevant toxicological endpoints. A particular focus on local toxicity evaluation (skin and eye irritation), skin sensitization, and in the case of UV absorption photo-induced toxicity shall be made.

All significant toxicological routes of absorption shall be considered as well as the systemic effects and margin of safety (MoS) based on a no observed adverse effects level (NOAEL) shall be calculated. The absence of these considerations shall be duly justified.

Particular consideration shall be given to any possible impacts on the toxi-cological profile due to

- particle sizes, including nanomaterials,
- impurities of the substances and raw material used, and
- interaction of substances.

Any read-across shall be duly substantiated and justified.

The source of information shall be clearly identified.

9. Undesirable effects and serious undesirable effects

All available data on the undesirable effects and serious undesirable effects to the cosmetic product or, where relevant, other cosmetic products. This includes statistical data.

10. Information on the cosmetic product

Other relevant information, e.g. existing studies from human volunteers or the duly confirmed and substantiated findings of risk assessments carried out in other relevant areas.

PART B – Cosmetic product safety assessment

1. Assessment conclusion

Statement on the safety of the cosmetic product in relation to Article 3.

2. Labeled warnings and instructions of use

Statement on the need to label any particular warnings and instructions of use in accordance with Article 19(1)(d).

3. Reasoning

Explanation of the scientific reasoning leading to the assessment conclusion set out under Section 1 and the statement set out under Section 2. This explanation shall be based on the descriptions set out under Part A. Where relevant, margins of safety shall be assessed and discussed.

There shall be inter alia a specific assessment for cosmetic products intended for use on children under the age of three and for cosmetic products intended exclusively for use in external intimate hygiene.

Possible interactions of the substances contained in the cosmetic product shall be assessed.

The consideration and non-consideration of the different toxicological profiles shall be duly justified.

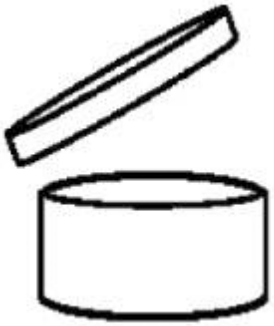
Impacts of the stability on the safety of the cosmetic product shall be duly considered.

4. Assessor's credentials and approval of part B

Name and address of the safety assessor. Proof of qualification of safety assessor. Date and signature of safety assessor.

ANNEX II
SYMBOLS USED ON PACKAGING/CONTAINER

1. Reference to enclosed or attached information.



2. Period-after-opening

3. Date of minimum durability

ANNEX III
LIST OF VALIDATED ALTERNATIVE METHODS TO ANIMAL TESTING

This Annex lists the alternative methods validated by the European Centre on Validation of Alternative Methods (ECVAM) of the Joint Research Centre available to meet the requirements of this Implementing Regulation and which are not listed in Physico-Chemical, Toxicological and Mixtures Of Substances And Mixtures It Will Be Applied In The Determination Of Ecotoxicological Characteristics Regulation On Test Methods Regulation 11/12/2013 dated on official gazette 28848.

As animal testing may not be replaced completely by an alternative method, it should be mentioned in Annex VIII whether the alternative method fully or partially replaces animal testing.

Reference number	Validated alternative methods	Nature of replacement full or partial
A	B	C