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REGULATION

By the Turkish Medicines and Medical Devices Agency:

COSMETIC PRODUCTS REGULATION

CHAPTER ONE
Preliminary Provisions

Objective

ARTICLE 1- (1) The objective of this 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 Regulation applies to cosmetic products.

(2) This 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 subparagraph (ö) of the first paragraph of Article (4).

Legal Basis

ARTICLE 3- (1) This Regulation has been drawn up based on the Product Safety and Technical Regulations Law dated 5/3/2020 and numbered 7223, Article 7 of Law No 5324 on Cosmetic Products dated 24/3/2005 and Articles 508 and 796 of the Presidential Decree No. 4 on the Organization of the Institutions and Organizations Associated, Related and Affiliated to the Ministry and other Institutions and Organizations.

Definitions

ARTICLE 4- (1) For this 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, including the precursors of oxidative hair colorants,

c) CAS number: The number designated by the Chemical Abstracts Service,

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

d) Frame formulation: A formulation which 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: 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 of the substance 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 dated 24/3/2005,

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

n) Commission: European Commission,

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

ö) Cosmetic product: Any substance or mixture intended to be placed in contact with the external parts of the human body; with epidermis, nails, hair system, hair, lips and external genital organs or with the teeth and the mucous membranes of the oral cavity with a purpose exclusively or mainly to clean them, perfume them, change their appearance, protect them, keep them in good condition or correct 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: The first model or design that has not been produced in batches, and from which the finished cosmetic product is copied or finally developed,

y) National Electronic Database: Electronic database, which is administered by the Agency,

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

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

bb) 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) Product presentation including conformity with the Article 79 of Law No. 6502 on the Protection of Consumer dated 7/11/2013.

b) Labelling.

c) Instructions for use and disposal.

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

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

(3) For a cosmetic product manufactured within Turkey:

a) If the manufacturer is located in Turkey, the manufacturer shall be the responsible person.

b) If the manufacturer is established outside of Turkey, he/she 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. However, the importer 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 Law No. 7223.

(6) The distributor shall be the responsible person where he/she places a cosmetic product on the market under his/her 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 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, biomedical engineers, biologists, and microbiologists may be designated as a responsible technical personnel.

(4) If the responsible person fulfills the conditions specified in the third paragraph, he/she may undertake the duty of responsible technical personnel.

Obligations of the responsible person

ARTICLE 8- (1) Responsible persons shall ensure compliance with paragraphs 1, 2 and 5 of Articles 5, 11,13, 21 and 22 and of Articles 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 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 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 reasoned 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 labelling information is available in compliance with subparagraphs (a), (d), (f), (g), (ğ), (h) and (ı) of the first paragraph, and paragraphs 3 and 4 of Article 22,

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

c) The date of minimum durability specified, where applicable under the first paragraph of Article 22 is not exceeded.

(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 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 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.

c) where the cosmetic product presents a risk to human health, distributors shall immediately inform the Agency and responsible person, especially 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 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 reasoned 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 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/lot 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 practices

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

(2) Compliance with good manufacturing practice shall be presumed where the manufacture is in accordance with the relevant harmonized standards, the reference numbers of which have been published in the Official Journal of the European Union.

Free movement

ARTICLE 12- (1) The Agency refrains from implementations that restrict, prohibit and reject the availability of cosmetic products on the market in compliance with this Regulation.

(2) If a certificate of free sale is requested for a cosmetic product manufactured in Turkey, the responsible person 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 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 assessment report is set up in accordance with Annex I/B.

(2) The responsible person shall ensure that for all notified cosmetic products,

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

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

(4) The cosmetic product safety assessment, as set out in Annex I/B 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 assessments according to paragraph 1 conducted to evaluate the safety of a cosmetic product 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 Journal No. 27516 of 9/3/2010 or with other international standards recognized as being equivalent by the Commission or the European Chemicals Agency (ECHA).

Product information file

ARTICLE 14- (1) When a cosmetic product is placed on the market, the responsible person shall be keeping a product information file for a period of ten years following the date on which the last batch/lot of the cosmetic product is 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 the first paragraph of Article 13.

c) a description of the method of manufacturing and a statement on compliance with good manufacturing practices 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.

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:

a) The barcode enabling its specific identification and the category of cosmetic product according to Annex IX and its name or names.

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.

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 their identification including the chemical name (IUPAC) and other descriptors as specified in Article 2 of the Annex I/A, and the reasonably foreseeable exposure conditions.

e) the name and the Chemicals Abstracts Service (CAS) or EC numbers 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, Labelling and Packaging of Chemical Substances and Mixtures published on the Official Journal repeated 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) While making a cosmetic product notification pursuant to the first paragraph, the responsible person shall present the original label of the product in a readable manner to the Agency, in addition the Turkish label and product packaging visual in cases where Turkish information is not included in the original label.

(3) The Agency shall, without delay, make the information referred to in the first and second paragraphs available electronically to UZEM only 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 Certain Substances

Restrictions for substances listed in the Annexes

ARTICLE 17- (1) Without prejudice to the provisions of Article 5, cosmetic product shall not contain any of the following:

a) Prohibited substances listed in Annex II.

b) Substances which are not used in accordance with the restrictions laid down in Annex III.

c) Colorants:

1) 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 coloring products referred to in paragraph 2.

2) Without prejudice to the provisions of subparagraph (1) of paragraphs (b), (ç) and subparagraph (1) of paragraph (d), substances 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.

ç) Preservatives:

1) 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.

2) Without prejudice to the provisions of subparagraph (1) of paragraphs (b), (c) and subparagraph (1) of paragraph (d), 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.

d) UV-filters:

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

2) Without prejudice to the provisions of subparagraph (1) of paragraphs (b), (c) and subparagraph (1) of paragraph (ç), substances listed in Annex VI 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 and hair system 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.

Substances classified as carcinogenic, mutagenic and reproductive toxic substances

ARTICLE 18- (1) The use in cosmetic products of substances classified as CMR substances, of category 2, under part 3 of Annex-6 to Regulation on the Classification, Labelling 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-6 to Regulation on the Classification, Labelling and Packaging of Substances and Mixtures shall be prohibited. However, such substances may be used in cosmetic products by way of exception where 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 dated 11/6/2010.

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, particularly 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, 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 taking into account the decision of the commission.

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 IUPAC name and other descriptors as specified in Article 2 of Annex 1/A.

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.

(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, 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, 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 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 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 the Turkey of animal testing of finished cosmetic products in order to meet the requirements of this Regulation.

ç) the performance of animal testing of ingredients or combinations of ingredients in order to meet the requirements of this 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 Journal No. 28848 of 11/12/2013 or Annex VIII of this 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 authorise 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

Labelling

ARTICLE 22- (1) Cosmetic products shall be made available on the market only where the inner and outer packaging of cosmetic products bear the following information in indelible, easily legible and visible lettering:

a) the name or registered title 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 of minimum durability 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.

1) The date itself or details of where it appears on the packaging shall be preceded by the symbol shown in article 3 of Annex VII or the words: “best used before the end of”.

2) The date shall consist of either “the month and year” or “the day, month and year”, in that order. If necessary, additional 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 article 2 of Annex VII 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 and any special precautionary information on cosmetic products for professional use shall be indicated.

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

e) The function of the cosmetic product unless it is clear from its presentation shall be indicated on the packaging.

f) A list of ingredients shall be indicated on the container. In addition, it may be indicated on the inner 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, 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 and the hair system 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 and the hair system used in the range may be listed, provided that the words ‘may contain’ or the symbol ‘+/-’ are added. The Colour Index (CI) nomenclature shall be used, where applicable.

(2) Where it is impossible for practical reasons to label the information mentioned in subparagraph (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 article 1 of Annex VII, which must appear on the inner or outer packaging for the information referred to in subparagraph (ç) of paragraph 1 and on outer packaging for the information referred in subparagraphs (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 subparagraphs (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 Regulation and with an information card containing the information referred to in the first paragraph.

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

(6) The information mentioned in subparagraphs (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 labelling, 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, tag or card 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 Regulation on Classification, Labelling and Packaging of Substances and Mixtures.

CHAPTER SEVEN
Market Surveillance and Inspection

In-Market Control

ARTICLE 25- (1) The Agency shall monitor if the cosmetic products made available on the market are in compliance with this 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, by carrying out market surveillance and control activities for this purpose, 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 manufacturing 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 and inspection, market analysis, evaluation and consumer information in the context of Articles 28, 29 and 30.

Information on the substances of cosmetic products

ARTICLE 27- (1) In the event of serious doubt regarding the safety of any substance contained in cosmetic products, the Agency may request from 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 and inspection, market analysis, evaluation and consumer information in the context of Articles 28, 29 and 30.

CHAPTER EIGHT
Non-Compliance, Safeguard Clauses, Administrative Enforcements

Non-compliance with the obligations of the responsible person

ARTICLE 28- (1) Without prejudice to the provisions of 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 practices 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 used in cosmetic products referred to in Articles 17, 18 and 20.

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

g) the labelling requirements referred to in paragraphs 1, 2, 5 and 6 of Article 22.

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 contained in cosmetic products 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 with the obligations of 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 paragraph 1 of Article 28, 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 and precaution 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.

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

(5) The economic operator shall make an announcement regarding the products, with risk in accordance with Article 18 of the Law No. 7223 by itself or upon the request of the Agency.

Cooperation

ARTICLE 32- (1) The Agency shall mutually cooperate with the Commission and the competent authorities of the EU Member States for the required information exchange in order to allow the uniform implementation of this Regulation.

(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 kept by the responsible person satisfies the requirements referred to in paragraph 2 of Article 14 and whether the information set out therein provides evidence of the safety of the cosmetic product.

(3) For a cosmetic product made available on the market, the Agency may request the competent authority of the Member State where the responsible person established in the EU is to operate the process specified in the second paragraph.

Glossary of common ingredient names

ARTICLE 33- (1) The Agency shall publish 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 Regulation

ARTICLE 35- (1) For those who infringe the provisions of this Regulation and legislation that put into force to implement this Regulation, the relevant provisions of Law No. 5324, Law No. 7223 and Turkish Penal Code No. 5237 dated 26/9/2004 shall apply in accordance with the nature of the action.

(2) In the event that the responsible person violates his obligations under this Regulation, the responsible person shall be legally responsible on the same basis as the manufacturer or importer within the scope of Law No. 7223.

(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 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 Regulation is prepared according to Regulation (EC) No 1223/2009 of the European Parliament and of the Council dated 30/11/2009 as part of compliance with the European Union legislation.

Repealed Regulation

ARTICLE 38- (1) Cosmetics Regulation published in the Official Gazette No. 25823 of 23/05/2005 has been repealed.

(2) In the legislation, references made to the regulation repealed with the first paragraph shall be deemed to have been made to this Regulation.

Transitional provisions

PROVISIONAL ARTICLE 1- (1) Products which were made available on the market in accordance with the Cosmetics Regulation, which was repealed with Article 38 before the date this Regulation enters into force may be made available on the market for 2 years after this Regulation enters into force.

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

(3) The product safety assessment to be made within the scope of the second paragraph of Article 13 and the product information file to be prepared within the scope of the fifth

paragraph of Article 14 are conducted within six months from the date of entry into force of this Regulation for the products notified within the scope of the Cosmetics Regulation, which was repealed with Article 38 of this Regulation.

Effective Date

ARTICLE 39- (1) This Regulation shall enter into force six months after the date of its publication.

Execution

ARTICLE 40- (1) Provisions of this Regulation shall be executed by the President of the Turkish Medicines and Medical Devices Agency.

Click for Annexes.