REPUBLIC OF TURKEY
MINISTRY OF HEALH

Draft
for
the Regulation on Cosmetics

CHAPTER ONE
Objective, Scope, Legal Basis and Definitions

Objective
Article I
The objective of this Regulation is to lay down the requirements regarding the production, import and sales of cosmetics, under conditions which will ensure that they reach the consumer with accurate, understandable and non misleading information that will present no harm to human health and regarding the principles and procedures related to their in-market inspections.

Scope
Article 2
This Regulation covers the principles relating to the Substances and products considered as cosmetics and to their classification, packaging details, advertisements and inspections and also the precautionary measures on cosmetics.

Legal Basis
Article 3
This Regulation has been drawn up on the basis of Law no. 4703 on "The Preparation and Implementation of Technical Legislation on Products" published in the 11.07.2001 dated Official Journal no.24459 and put into force on 11 January 2002 and Article 4 of the Cosmetics Law no…… dated …./…./……..

Definitions
Article 4
For the purposes of this Regulation, the following terms shall bear the following meanings:

a) The Ministry: The Ministry of Health
b) The Law: Cosmetics Law no…… dated …./…./……..
c) GMP: 'Good Manufacturing Practice'
d) INCI: Abbreviation for 'International Nomenclature Cosmetic Ingredients' referring to the terminology for cosmetic product ingredients
e) CTFA: Abbreviation for "Cosmetic, Toiletries, and Fragrances Association" referring to the dictionary of cosmetic product ingredients compiled by the USA Cosmetic Manufacturers Association
f) Cosmetic product: Any substance or preparation intended to be applied to the various external parts of the human body such as 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 and/or correcting body odors and/or protecting them or keeping them in good condition.

g) Cosmetic product ingredients: Any chemical substance or preparation of synthetic or natural origin, except for perfume and aromatic compositions, used in the composition of cosmetic products.
h) CI: Abbreviation for 'Color Index' referring to Coloring Agent Index number
i) EU: Abbreviation for the 'European Union' referring to the European Union.

Based on this definition, the products listed in Annex I shall be regarded as cosmetics.

CHAPTER TWO
The Technical Features of Cosmetic Products and their Packaging Requirements

The characteristics of Cosmetic Products

Article 5- A cosmetic product placed on the market must not cause damage to human health when applied under normal conditions of use, taking into account, in particular, the product's presentation, its labeling, any instructions for its use and disposal as well as any other indication or information provided by the manufacturer or his authorized agent of by any other person responsible for placing the product on the market.

The provision of such warnings shall not, in any event, exempt any person from compliance with the other requirements laid down in this Regulation.

Substances Cosmetic Products May Not Contain

Article 6- Without prejudice to their general obligations deriving from Article 5, persons or firms that produce, import or place on the market cosmetic products may not market cosmetic products containing the below indicated. The Ministry shall take necessary measures to prevent the production and placing on the market of cosmetic products containing the below indicated.

a) substances listed in Annex II,
b) substances listed in the first part of Annex III, beyond the limits and outside the conditions laid down,
c) coloring agents listed in Annex IV, Part 1, with the exception of cosmetic products containing coloring agents intended solely to color hair,
d) coloring agents listed in Annex IV, Part 1, used outside the conditions laid down, with the exception of cosmetic products containing coloring agents intended solely to color hair,
e) preservatives other than those listed in Annex VI, Part 1,
f) preservatives listed in Annex VI, Part 1, beyond the limits and outside the conditions laid down, unless other concentrations are used for specific purposes apparent from the presentation of the product,
g) UV filters other than those listed in Annex VII, Part 1,
h) UV filters listed in Annex VII, beyond the limits and outside the conditions laid down therein,

In addition, the presence of the traces of the substances listed in Annex II shall be allowed provided that such presence is technically unavoidable in GMP and that it conforms to Article 5.

For the purpose of complying with this Regulation, in cases where cosmetic substance ingredients or combinations of such ingredients used in the manufacturing of cosmetic

products have been subject to animal testing instead of available alternative testing methods approved by the Ministry, such products may neither be sold nor supplied on the market.

Substances Cosmetic Products May Contain

Article 7- Cosmetic Products containing the below indicated may be supplied for sale:

a) the substances listed in Annex III, Part 2, within the limits and under the conditions laid down, up to the dates in column (g) of that Annex,
b) the coloring agents listed in Annex IV, Part 2i, within the limits and under the conditions laid down, until the admission dates given in the same Annex,
c) the preservatives listed in Annex VI, Part 2, within the limits and under the condition laid down until the dates given in column (f) of the same Annex. However, some of these substances may be used in other concentrations for specific purposes apparent from the presentation of the product,
d) the UV filters listed in Annex VII, Part 2, within the limits and under the conditions laid down, until the dates given in column (f) of the same Annex.

At these dates, these substances, coloring agents, preservatives and UV filters shall be:

- definitively allowed, or
- definitively prohibited (Annex II), or
- maintained for a given period specified in Part 2 of Annexes III, IV, VI, and VII, or
- deleted from all the Annexes, on the basis of available scientific information or because they are no longer used.

Updating of Annexes

Article 8- The updating, in light of scientific and technological developments, of this Regulation's Annexes related to cosmetic product ingredients shall be under the authority of the Ministry.

Information Required Present on the Immediate and Outer Packaging

Article 9- Cosmetic products may be marketed only if the immediate and outer packagings bear the following information in indelible, easily legible and visible lettering; the information mentioned in point (g) however, may be indicated on the outer packaging alone:

a) The name or title and the address of the manufacturer or the real or legal persons responsible for marketing the cosmetic product or of their registered office. Such information may be abbreviated in so far as the abbreviation makes it possible to identify the undertaking. It may be required that the country of origin be specified for goods manufactured outside the European Union.
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 form the outside or if each unit contained is normally only sold individually.
c) The date of minimum durability of a cosmetic product shall be the date until which this product, stored under appropriate conditions, continues to fulfill its initial function and, in particular, remains in conformity with Article 5. The date of minimum durability shall be indicated by the words:
   'Best used before the end of…' followed by;

- the date itself,
- details of where the date appears on the packaging.

If necessary, this information shall be supplemented by an indication of the conditions which must be satisfied to guarantee the stated durability.

The date shall be clearly expressed and shall consist of the month and the year in that order. Indication of the date of durability shall not be mandatory for cosmetic products the minimum durability of which exceeds 30 months. For such products, it shall be mandatory however, to indicate, length of period over which the product may be used without posing any harm to the consumer as of the date the packaging is opened. This information on the duration of safe use after opened packaging shall be indicated printed as indicative of the month, subsequent to the symbol provided in Annex VII/2.

d) Particular precautions to be observed in use, especially those listed in the column 'Conditions of use and warnings which must be printed on the label' in Annexes III, IV, VI and VII, which must appear on the label, as well as any special precautionary information on cosmetic products for professional use, in particular in hairdressing. Where this is impossible for practical reasons, an enclosed leaflet, label, tape or card must contain that information to which the consumer is referred either by abbreviated information or the symbol given in Annex VIII, which must appear on both the immediate and the outer packaging,
e) The batch number of manufacture or the reference for identifying the good; where this is impossible for practical reasons because the cosmetic products are too small, such information need appear only on the outer packaging,
f) The function of the product, unless it is clear from the presentation of the product,
g) A list of ingredients in descending order of weight at the time they are added. That list shall be preceded by the word 'ingredients' or its equivalent in meaning in Turkish or in any other foreign language. Where that is impossible for practical reasons, and enclosed leaflet, label, tape or card must contain that information to which the consumer is referred either by abbreviated information or the symbol given in Annex VIII, which must appear on both the immediate and the outer packaging.

   In cases where the manufacturer or his agent or the person to whose order a cosmetic product is manufactured or the real or legal person responsible for placing an imported product on the market does not want to include in the list one or several of the ingredients for reasons of trade secrecy, the procedure to be exercised shall be laid down by a notice to published by the Ministry.

   The following shall not, however, be regarded as ingredients:
- impurities in the raw materials used,
- subsidiary technical material used in the preparation but not present in the final product,
- materials used in strictly necessary quantities as solvents or as carriers for perfume and aromatic compositions.

   Perfume and aromatic compositions and their raw materials shall be referred to by the word 'perfume' or 'flavor/aroma' or 'smell'. Ingredients in concentration of less than 1% may be listed in any order after those in concentrations of more than 1%. Coloring agents may be listed in any order after the other ingredients, in accordance with the CI or denomination adopted in Annex IV.

For decorative cosmetic products marketed in several color shades, all coloring agents used in the range may be listed, provided that the terms ‘may contain’ or the symbol ‘+/-‘ are added.

An ingredient must be identified with priority by the name referred to in INCI, failing that, by one of the names referred to in CTFA, or by one of the other common names.

Where it is impracticable, for reasons of size or shape, for the particulars referred to in points (d) and (g) to appear in an enclosed leaflet, those particulars shall appear on a label, tape or card which is enclosed or attached on the cosmetic product.

In the case of soap, bath balls and other small products where it is impracticable, for reasons of size or shape, for the particulars referred to in point (g) to appear on a label, tag, tape or card or in an enclosed leaflet, those particulars shall appear on a notice in immediate proximity to or on the rack in which the cosmetic product is exposed for sale.

For cosmetic products that are not prepackaged, are packaged at point of sale at the purchaser’s request, or are pre-packaged for immediate sale, particulars listed in Article 9 must be indicated. Principles relating to the filling facilities and filling conditions will be drawn up under a separate heading in the GMP Guide which will be published by the Ministry.

It is required that indications stated in points (b), (d) and (f) of this Article are expressed in Turkish. However, indications stated in point (c) must also be expressed in Turkish in cases where supplementary information indicating the conditions under which product durability is guaranteed is required.

CHAPTER THREE
Advertisement, Inspection and Notification

Advertisement

Article 10- Labels, advertisements and marketing activities may not bear any text, name, commercial brand, drawing or other shapes and figures which explicitly or by implication make misleading reference to the product properties.

The expression ‘not tested on animals’ may be used on the enclosed leaflet, label, tape, card or any other advertising material or in the products’ advertisement campaigns, solely in cases where animal testing has not been done on the finished product and/or its product ingredients and/or during the process of developing the product prototype. The expression ‘not tested on animals’ may not be used other than in the aforesaid cases.

Obligation

Article 11- Persons or firms who manufacture, import or place on the market, cosmetic products are responsible for taking necessary measures in marketing cosmetic products alone, which comply with this Regulation and its Annexes.

Inspection

Article 12- Matters relating to; in-market controls, manufacturing site inspections, sampling, warnings, product recall, annihilation and to the improving or closing down of manufacturing sites will be laid down in a Regulation to be published by the Ministry of Health.

The manufacturer or his agent or the person to whose order a cosmetic product is manufactured or the real or legal person responsible for placing an imported cosmetic product on the market shall for control purposes keep the Product Profile Dossier containing the following information readily accessible to and upon request of the Ministry, at the address specified on the label in accordance with Article 9 point (a):

a) the qualitative and quantitative composition of the product; in case of perfume compositions and perfumes, the name and code number of the composition and the identity of the supplier,
b) the physico-chemical and microbiological specifications of the raw materials and the finished product and the purity and microbiological control criteria of the cosmetic product,
c) the method of manufacture complying with GMP; education/training and job documents of the manufacturer or importer, demonstrating the appropriate level of professional qualification or required experience,
d) assessment of the safety for human health of the finished product. In order to provide this, the manufacturer shall take into consideration the general toxicological profile of the ingredients, its chemical structure and its level of exposure. To that end, the manufacturer shall take into consideration the distinctive features of exposure of the target recipients for whose use the product is supplied or of the parts of the body where the product is to be applied. An exclusive assessment of safety shall be required for products intended for use of children under age three and for personal hygiene products intended for external application on external genital organs. This assessment shall be carried out in compliance with the provisions of the Regulation on Essentials of Good Laboratory Practice and the Certification of Test Laboratories published in the 25/06/2002 dated Official Journal no. 24796.

   Should the same product be manufactured at several places within country territory, the manufacturer may choose a single place of manufacture where the information will be kept available. In such cases, he shall be obliged to indicate the place so chosen to the Ministry of Health upon request for monitoring purposes,
e) the name and address of the qualified person or persons responsible for the assessment referred to in (d); that person must hold a diploma in the field of pharmacy, toxicology, dermatology, medicine or a similar discipline,
f) existing data on undesirable effects on human health resulting from use of the cosmetic product,
g) proof of the effect claimed for the cosmetic product, where justified by the nature of the effect or product.
h) Data related to animal testing done by the manufacturer, his authorized agent or suppliers for reasons of compliance to legislation or other arrangements of countries outside the EU, and for the purpose of further developing the product or of safety assessment of the product or its ingredients,

The information referred to in points (c), (d), (f), and (g) must be available in Turkish.

It must be ensured, with particular respect to trade secrets and protection of intellectual property rights, that the information stated in point (a) and (f) to this Article are made available to public access in any way possible including via electronic facilities. Particulars related to the quantitative composition of the product indicated in point (a) to this Article are limited to only the dangerous substances covered within the scope of Directive no. 67/548/EEC.

For the purpose of complying with this Regulation, finished cosmetic products which, despite the availability of alternative testing methods approved by the Ministry, have been subject to animal testing instead of such methods, may neither be sold nor supplied on the market.

Responsible Technician

Article 13- It is required that the manufacturer or importer has the appropriate level of professional qualification or required experience, or that he employs a responsible technician with such qualification. The technician required available in manufacturing or importing firms has the obligation to have knowledge of the country legislation. Pharmacists or chemists, chemical engineers, biologists or microbiologists who provide necessary documentation for proof of at least 2 years of working experience in the field of cosmetics may be employed as the responsible technician. This person shall also be responsible for ensuring that the GPM laid down in Article 12 point (c) is complied with.

Notification

Article 14- The manufacturer or his agent or the person to whose order a cosmetic product is manufactured or the real or legal person responsible for placing an imported cosmetic product on the market shall submit to the Ministry the Notification Dossier containing the following information and documentation prior to placing the product on the market:

- The name and address of the manufacturer or his agent or the person to whose order a cosmetic product is manufactured or the real or legal person responsible for placing an imported cosmetic product;
- Address of manufacturing location(s);
- The address of place where the Product Profile Dossier is kept;
- The brand and type of the product;
- List of product range;
- The intended function of the product;
- Document evidencing the submission of necessary information on product ingredients to the Poison Center.

CHAPTER FOUR
Analysis Methods, Exclusive Principles on the Use of Substances Other Than Those which have been Permitted for Use in Cosmetics

Analysis Methods

Article 15- The following shall be published by the Ministry, in light of current technical developments:

- the methods of analysis necessary for checking the composition of cosmetic products;
- the criteria of microbiological and chemical purity for cosmetic products and the necessary notification on methods for checking compliance with those criteria.

Exclusive Principles on the Use of Substances Other Than Those which have been Permitted for Use in Cosmetics

Articles 16- Notwithstanding Article 6 and without prejudice to Article 8 (2), it is under the authority of the Ministry authorize, subject to the following conditions, the use within the Republic of Turkey territory, of other substances not contained in the list of substances allowed for cosmetic products:

a) the authorization must be limited to a maximum period of three years;
b) the Ministry must carry out an official check on cosmetic products manufactured from the authorized substance or preparation;
c) cosmetic products thus manufactured must bear a distinctive indication which will be defined by the Ministry

The Ministry shall forward, via the Foreign Trade Undersecretariat, to the European Union Commission, the next of any authorization decision taken pursuant to Article 16 within two months of the date on which it came into effect.

Before expiry of the three-year period provided for in Article 16, the Ministry may submit via the Foreign Trade Undersecretariat, to the European Union Commission, a request for the inclusion in a list of permitted substances of the substance to which it has granted authorization at national level in accordance with Article 16. Notwithstanding Article 16 point (a), the conditional authorization granted by the Ministry shall remain in force until a decision is taken on the request for inclusion in the list.

CHAPTER FIVE
Miscellaneous and Final Provisions

Temporary Ban on the Marketing and Sales of Cosmetic Products

Article 17- If it is noted, on the basis of a substantiated justification, that a cosmetic product, although complying with the requirements of the Regulation, represents a hazard to public health, the Ministry may provisionally prohibit the marketing of that product within country territory or subject it to special conditions. In that event, the Ministry shall immediately inform, via the Foreign Trade Undersecretariat, the European Union Commission thereof, stating the grounds and evidence for its decision. The Ministry shall undertake necessary changes and amendments in line with the conclusions of the discussions to be made.

Remedies for Violations to the Regulation

Article 18- Precise reasons shall be stated, by the Ministry, for any decisions placing a restriction or ban on the marketing of cosmetic products taken pursuant to this Regulation. The measures taken shall be notified to the party concerned together with particulars of the remedies available under the laws in force and of the limits allowed for the exercise of such remedies.

Enforcement

Article 19- This Regulation shall enter into force on the date of is publication.
It is under the authority of the Ministry to grant authorization, for a period of 36 months from notification of this Regulation, within the Republic of Turkey territory, for cosmetic products which do not fully conform to the requirements of this Regulation.

Executive Authority
Article 20- The Ministry of Health shall execute the provisions of the present Regulation.

Transposed European Union Legislation
Article 21- This Regulation has been drawn up for the purpose of harmonizing Directive no. 76/768/EEC and decision no. 96/335/EC of the European Union Cosmetics Legislation.