

The Requests Concerning the Harmonized National Legislation for the Commercialization of Cosmetics in Romania

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Abstract

This paper presents the modern concept of cosmetics in relationship with the quality and biocompatibility requests. We approach aspects concerning the possible toxic effect of cosmetics, the newest laws in this field and the requests for quality assurance in Romania. The security and safety using cosmetics are approached in this paper in relation to permitted substances used to manufacturing cosmetics in accordance with the Romanian laws. We also present the packing and labeling requests with the identification elements used to emphasize the original goods and the commercial communication. The keeping, using and registering conditions for the producer or importer are presented in relationship to the notification imposed by Health Ministry. Finally we draw our conclusions and we make our suggestions.

Key words: *cosmetic good, security and safety of cosmetic goods, packing and labeling of cosmetic goods*

The Modern Concept of Cosmetics Good

The modern cosmetics develop more and more from an empiric activity into a science based on research in this field. It has some subdivisions: preventive cosmetics (goods with protective action), remedied cosmetics (goods with a corrective effect on imperfections) and esthetical cosmetics (goods that create some artistic effects).

Concomitantly with the increase of life expectancy the anti-ageing action has new valences. From this point of view new domains have developed among which: young cosmetics, men cosmetics, children cosmetics, cosmetics for each type of skin, etc. Producers often use more synthesized raw materials for electuaries and adding with conserving effect that ensure a long time guarantee and lower costs.

In the European countries with developed cosmetics there also have appeared the functional cosmetics (ortho-dermic) or dermato-cosmetics. The dermato-cosmetics joint the cosmetics properties with those pharmacological and dermatological to offer care and treatment for all type of skin. The products penetrate the dermo-epithermic barrier the active substances attain the derma and the adipose subcutaneous stratum. They re control some skin problems as wrinkles and deep dehydration just from inside by action on profoundness of tissues. Some

ingredients use for dermato-cosmetics are found in cosmetic products too, but what is different is the concentration and combination.

In Romania, in accordance with the Law of cosmetics the modern concept of these products is defined. So by cosmetics we understand any substance or preparation that become to be in contact with some extern body part as skin, hair, lips, external genitals, tooth or oral mucous. Their exclusive or main purpose is to clean, scent, modify their aspect and/or correct body odors and/or protect and maintain in good condition.

The Impact of Cosmetics on the Human Body

Some cosmetics can cause cutaneous reactions because of substances used for their preparation. At the beginning there appear inflammations that can do eczema, dermatitis, allergies etc. The allergic symptoms can appear on tissues or skin not only if a cosmetics is used inadequate but also if it is used irrational.

Some chemical substances from cosmetics have a degree of noxiousness and can be risk factors. So, at the begining of 2005, The French Association for Customer's Protection analyzed the quality of air fresheners. They have established that these cosmetics spread in air toxic substances with allergic and carcinogenic effects and their commercialization has been delayed.

Recent studies show that the phtalic acids (used as solvent and diluter for the alcohol) have harmful effect on health; they can do spermatic changes and lung affectations. Into perfumes the phtalic acids give a toxic effect. A group of researchers from International Organization Greenpeace has observed that the phtalic acid and the synthetic musk from perfumes have noxiousness effect. They penetrate the skin into the blood and even in maternal milk. Some types of synthetic musk can affect the hormonal system. Due to this reason the nitrate musk has been forbidden in EU since 1995. The synthetic musk gives the persistence of smell and it is used for cremes, soaps, perfumes, air fresheners and detergents.

The North American Contact Dermatitis Group has analyzed 487 undesirable reactions appeared after the use of cosmetics and they offer sure information concerning the risk of secondary effects on cosmetics. These can do possible the cosmetics classification in high, medium and low risk. (see Table 1 and Figure 1).

Table 1. Cosmetics classification after their risk for undesirable local effects

No.	High risk for undesirable effects	Medium risk for undesirable effects	Low risk for undesirable effects
1.	Deodorizers	Shampoos	Tonic lotions
2.	Anti-perspirants	Cosmetics for intimate external hygiene	Solar creams
3.	Hair dye	Make-up	Antiseborrheic creams
4.	Eye-shadows	Lipsticks	Night creams
5.	Make-up remover lotions	Aftershaves	Bubble bath, bath oil
6.	Depilatories	-	Hair lotions
7.	Perfumes	-	-

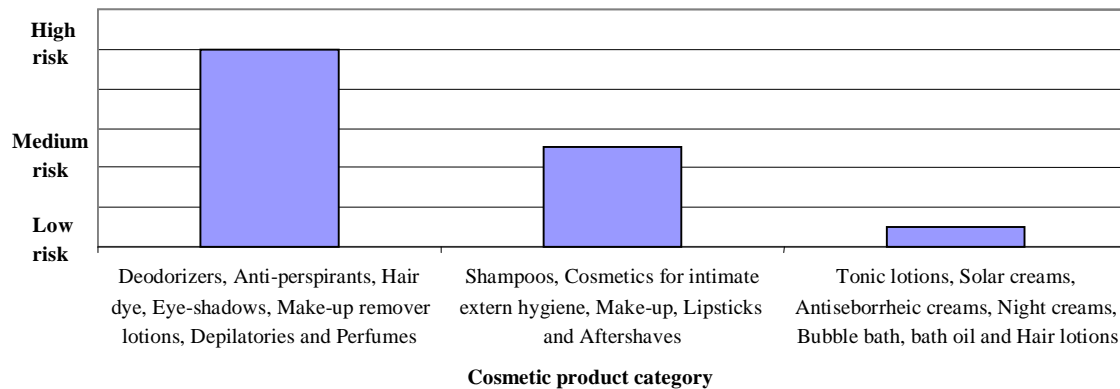


Fig.1. Cosmetics classification after their risk for undesirable local effects

The Harmonization of the National Legislation with the EU Stipulations for Cosmetics Domain

The quality of cosmetics is achieving new dimensions hence the approach of the security and safety in their usage. The legislation observance is essential. The conditions concerning security of customer's cosmetics are a constant preoccupation of EU and they often make changes and completions of these Directives. So, the Directive 2003/15/EEC brings changes and completions to Directive 76/768/EEC concerning the cosmetics.

Romania has transposed in its legislation the settlements from these two Directives in the context of the forthcoming adhesion. The actual legislation for cosmetics domain resides in a general legislation and a specific one.

The general legislation refers to (see Figure 2):

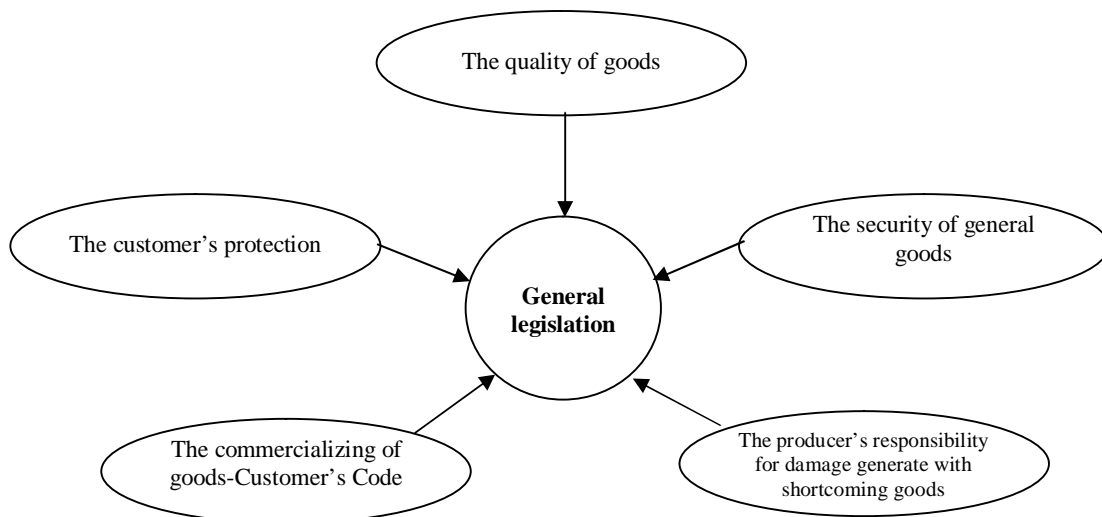


Fig. 2. The components parts of general legislation

- The quality of goods (Law no. 608/2001 and Government Decision no. 71/2002);
- The security of general goods (Law no. 245/2004);
- The producer's responsibility for damage generated with shortcoming goods (Law no. 240/2004);
- The commercializing of goods-Customer's Code (Law no.296/2004);
- The customer's protection and more others.This legislation is valid for all kind of goods commercialized in Romania so it is available for cosmetics, too.

The specific legislation regarding cosmetics (Table 2) settles the main problems concerning the manufacturing, commercialization, goods safety in usage and customer's security.

Despite of this legislation, on the Romanian market we can find yet a lot of unsafe and non-conformed cosmetics (counterfeited cosmetics). Fake cosmetics are made through sophisticated, subtle practices. So, there have been presented cases of original shampoo commercialization by non-authorized people, who put water and soap into the original or fake packing and only preserving at a surface level a fine stratum of perfumed shampoo. These were commercialized at prices similar to the originals.

Among cosmetics, the expensive perfumes hold a high percentage of fake perfumes. They are recognized after the quality and design of the bottle and packing, the sensorial features (smell, color and shape), the quality of the marking, the security elements, the market place and price. The hologram is a recognized element for the marks distribute by the importer 'Prestige'. The other importers have not yet endorsed this system.

Table 2. Romanian legislation regarding cosmetics

No.	Available legislation	
1.	Law. 178/2000	Regarding cosmetics
2.	Order MIR/MSF no. 309/729/2001	Regarding the inventory of ingredients use in cosmetics domain
3.	G.D. no. 560/2001	Regarding some measures to keep the confidentiality of ingredients used in cosmetics
4.	Order MIR/MSF no. 309/729/2001	Regarding the methods of analyze for cosmetics checking
5.	Law no. 508/2002	For changing and completion the Law no. 178/2000 regarding cosmetics
6.	G.D. no.63/2002	Regarding the approval of Good Laboratory Practice and the inspection and checking of these with the occasion of chemicals testing
7.	Law no. 264/2003	For changing and completion the Law no. 178/2000 regarding cosmetics
8.	Law no. 379/2004	For changing and completion the Law no. 178/2000 regarding cosmetics
9.	Order MSF no. 1448/2005	For the approval of Lists contenting the substances permitted in cosmetics composition

The Romanian legislation regarding cosmetics pursues only the commercialization of qualitative sure goods that do not affect the healthfulness and preserve the customer's safety. This responds of The Unique Market and European Commission requests concerning cosmetics.

The most important law is the Law no 178/2000 with its modifications and completions. This is the correspondent of The Directive 76/768/EEC concerning the cosmetics and Directive 2003/15/EEC.

The Security and Safety Requirements for Cosmetics Commercialized in Romania

The most important request concerning the security of cosmetics commercialized on the Romanian market it is that they do not jeopardize the consumer's health when they are use in proper conditions. The Health Minister represents the national authority, which has the competence to establish the legislation regarding the cosmetics commercialization, this notification in the elaboration and administration of data base, the inspection and control on

market and the labeling as information way for the customer. The completions of legislation are made after the recording of side effects on health customers. These completions take into account the specific request regarding the safety of European Commission into chapter I, article 6, 7, and 10-19 that will become operative after the Romanian forthcoming adhesion to EU.

The main requests concerning the cosmetics' security and safety are presented below.

- The usage only of substances approved by The Health Minister for cosmetics production.

For qualitative cosmetics that have preserve the customer' s safety it is forbidden to use dyes, preservatives and UV filters if they are not approve by The Health Minister with one exception referring at those used to hair dying. The Health Minister has admitted for certain substances, cosmetics dyes, preservatives and UV filters to be used in some admissible limits and respecting some conditions.

It is forbidden to use substances considered carcinogenic, mutagen or toxic on reproductive function. These substances are included into the 1st, 2nd or 3rd categories in concordance with the Government Urgency Ordinance no 200/2000 regarding the classification, labeling and packing of chemical substances and preparations that have approved by the Government Decision no 490/2002. This legislation refers also at the alternative ways to prove these substances in stead of using animal tests.

As preparative for the Romanian forthcoming adhesion to EU, the changes and completions of legislation forbid animal tests with any substances or cosmetics. These techniques must be replaced with alternative methods established by the European Commission. The Health Minister must assume these methods in accordance with the following terms; the 11th of March 2009 for testing of ingredients and the 11th of March 2013 for toxicity tests with repetitive doses, the toxicity tests of the reproduction function and the toxicity kinetics.

- The safety evaluation of cosmetics on human health

This will be done in concordance with the 'Good Laboratory Practice' and inspection and verification of these in the case of chemical tests. For the general evaluation of risk on human health, the producer must take into account the toxicological profile of ingredients, the chemical structures and the level of exposure, especially concerning the characteristics of applied regions or customer' s segments that they are meant. For a special evaluation must be done on children goods aged under 3 and for goods destined to the intimate hygiene too.

People who are responsible for these evaluations must have university education and graduated specialization as pharmacy, toxicology, dermatology, medicine or any similar specialization as it is defined in the Law no 200/2004.

- The Romanian legal registration and notification of intention to commercialize cosmetics

This is handed over to the Health Minister by the producer, importer or distributor using a paper or in electronic form. The Health Minister has the responsibility to register the notification, inform the register number of notification and publish the notified list of cosmetics.

- The packing and marking of cosmetics

It has the purpose to increase the security of goods offering minimal information without forbidding their commercialization. The information mentioned of label or pack must present obligatorily identification elements, cosmetics composition, storage warning, validity term, number of fabrication lot, using instruction, special warnings and the notification of the Health Minister. This information must be presented in Romanian or an international language. They must be visible, legible and difficult to be erased. If the dimension or shape of goods can not allow the application of these elements must be used a prospectus, label, folder or attachable cardboard.

- The surveillance of Romanian cosmetics market

Romanian legislation regarding cosmetics establishes the control and surveillance authorities on market and the measures and sanctions that can be applied for the observance of customer's security and safety. The legislation establishes also that the Health Minister is the authority that keeps up the relationship between our country and European Commission and member countries and cooperates with them.

Conclusions

1. Cosmetics are goods dedicated to all types of consumer segments;
2. Some ingredients and the non-observance of hygiene conditions can have an injurious effect on human health;
3. The security and safety in usage for the cosmetics has been ensured by the modifications and completions of the Romanian legislation regarding cosmetics.

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Cerințele legislative naționale armonizate pentru comercializarea produselor cosmetice în România

Rezumat

Acest articol prezintă conceptul modern de produs cosmetic în relație cu calitatea și cu cerințele de biocompatibilitate. De asemenea, tratează aspectele ce privesc efectele negative ale produselor cosmetice, cea mai nouă legislație în domeniu și cerințele de asigurare a calității în România. Securitatea și siguranța folosirii produselor cosmetice sunt descrise în relație cu substanțele permise a fi folosite la obținerea acestora, în concordanță cu legislația românească. Lucrarea prezintă și aspectele legate de cerințele de ambalare și etichetare, elementele de identificare folosite de produsele originale și comunicarea cu consumatorii. Condițiile de deținere, folosire și de înregistrare a producătorilor sau importatorilor sunt conturate în raport cu reglementările emise de Ministerul Sănătății. În cele din urmă se prezintă câteva concluzii și sugestii.