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2008/0035 (COD)

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from :	General Secretariat of the Council/Presidency
to :	Working Party on Technical Harmonisation
No. prev. doc. :	17069/08 MI 540 ENT 314 CONSOM 219 SAN 331 ECO 184 ENV 978 CHIMIE 81 CODEC 1784
No. Cion prop. :	6725/1/08 REV 1 MI 71 ENT 40 CONSOM 25 SAN 37 ECO 27 ENV 109 CHIMIE 7 CODEC 240
Subject :	Proposal for a Regulation of the European Parliament and of the Council on cosmetic products (recast)

Delegations will find attached a Compromise Proposal from the Presidency taking stock of the discussions of the Working Party and COREPER and the amendments of the European Parliament examined by the Working Party.

Delegations are informed that new text compared to the commission's proposal, is indicated in **bold/underlined** and deletions are marked with [~~strikethrough~~]. New text which has already been examined by the Working Party is in **bold** only. It is understood that there is a general reservation from all delegations. DK**,** MT, SI and UK have a parliamentary scrutiny reservation.

ANNEX

2008/0025 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on cosmetic products

(recast)
(Text with EEA relevance)

Ⓔ 76/768/EEC (adapted)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission[1],

Having regard to the opinion of the European Economic and Social Committee[2],

[]

Acting in accordance with the procedure laid down in Article 251 of the Treaty[3],

Whereas:

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1 OJ C […], […], p. […].
2 OJ C […], […], p. […].
3 OJ C […], […], p. […].

new

(1) Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products[4] has been significantly amended on several occasions. Since further amendments are to be made, **in this particular case** it should be recast as one single text in the interests of clarity.

(2) **This Regulation** ~~The recast~~ aims at simplifying procedures and streamlining terminology thereby reducing administrative burden and ambiguities. Moreover, ~~the recast~~ **it** strengthens certain elements of the regulatory framework for cosmetics, such as in-market control, with a view to ensuring a high level of protection of human health.

(3) A ~~recast as a~~ Regulation is the appropriate legal instrument as it imposes clear and detailed rules which do not give room for diverging transposition by Member States. Moreover, a Regulation ensures that legal requirements are implemented at the same time throughout the Community.

↓ 76/768/EEC Recital 1

(4) ~~The provisions laid down by law, regulation or administrative action in force in the Member States define the composition characteristics to which cosmetic products must conform and prescribe rules for their labelling and for their packaging. These provisions differ from one Member State to another.~~

↓ 76/768/EEC Recital 2

(5) ~~The differences between these laws oblige Community cosmetic producers to vary their production according to the Member State for which the products are intended. Consequently, they hinder trade in these products and, as a result, have a direct effect on the establishment and functioning of the common market.~~

[4] OJ L 262, 27.9.1976, p. 169. Directive as last amended by […].

~~𝔼 76/768/EEC Recital 3~~

(6) ~~The main objective of these laws is the safeguarding of public health and, as a result, the pursuit of the same objective must inspire Community legislation in this sector. However, this objective must be attained by means which also take account of economic and technological requirements.~~

~~𝔼 76/768/EEC Recital 4~~

(7) ~~It is necessary to determine at Community level the regulations which must be observed as regards the composition, labelling and packaging of cosmetic products.~~

𝔼 03/15/EC Recital 1 (adapted)

(8) ~~Council Directive 76/768/EEC~~[5] This Regulation ~~has~~ comprehensively ~~harmonised~~ harmonises the ~~national laws~~ rules in the Community in order to achieve an internal market for cosmetic products while ensuring a high level of ~~relating to cosmetic products and has as its main objective the~~ protection of human ~~public~~ health. ~~To this end, it continues to be indispensable to carry out certain toxicological tests to evaluate the safety of cosmetic products.~~

(8a) The environmental concerns that substances used in cosmetic products may raise are considered through the application of Regulation ...[REACH], which enables the assessment of environmental safety in a cross-sectoral manner.

[5] ~~OJ L 262, 27.7.1976. Directive as last amended by Commission Directive 2002/34/EC (OJ L 102, 18.4.2002, p. 19).~~

Ⓔ 76/768/EEC Recital 5 (adapted)

(9) This ~~Directive~~ Regulation relates only to cosmetic products and not to medicinal products, medical devices or biocidal products ~~pharmaceutical specialities and medicinal products~~. ~~For this purpose it is necessary to define the scope of the Directive by delimiting the field of cosmetics from that of pharmaceuticals.~~ The~~is~~ delimitation follows in particular from the detailed definition of cosmetic products, which refers both to their areas of application and to the purposes of their use. ~~This Directive is not applicable to the products that fall under the definition of cosmetic product but are exclusively intended to protect from disease. Moreover, it is advisable to specify that certain products come under this definition, whilst products containing substances or preparations intended to be ingested, inhaled, injected or implanted in the human body do not come under the field of cosmetics.~~

Ⓒ 76/768/EEC Annex I (adapted)
new

(10) The assessment whether a product is a cosmetic product has to be taken on the basis of a case by case assessment, taking into account all characteristics of the product. Typical examples for cosmetic products may include creams, emulsions, lotions, gels and oils for the skin ~~(hands face feet etc.)~~, face masks ~~(with the exception of peeling products)~~, tinted bases (liquids, pastes, powders), make-up powders, after-bath powders, hygienic powders, ~~etc.~~ toilet soaps, deodorant soaps, ~~etc.~~ perfumes, toilet waters and eau de Cologne, bath and shower preparations (salts, foams, oils, gels~~, etc.~~), depilatories, deodorants and anti-perspirants, ~~hair care products,~~ hair ~~tints and bleaches~~ colorants , products for waving, straightening and fixing hair , hair setting products, hair cleansing products (lotions, powders, shampoos), hair conditioning products (lotions, creams, oils), hairdressing products (lotions, lacquers, brilliantines), shaving products (creams, foams, lotions~~, etc.~~), ~~products for making up and removing make-up from the face and the eyes,~~ make-up and products removing make-up , products intended for application to the lips, products for care of the teeth and the mouth, products for nail care and make-up, products for external intimate hygiene, sunbathing products, products for tanning without sun, skin-whitening products and anti-wrinkle products.

Ⓒ 76/768/EEC Recital 6 (new)

(11) **The Commission should define the categories of cosmetic products which are relevant for the application of this Regulation.** ~~In the present state of research, it is advisable to exclude cosmetic products containing one of the substances listed in Annex V from the scope~~

Ⓒ 76/768/EEC Recital 7 (adapted)
new

(12) Cosmetic products should ~~must not~~ be safe ~~harmful~~ under normal or reasonably foreseeable conditions of use. In particular, a risk-benefit reasoning should not justify a risk to human health. ~~it is necessary to take into account the possibility of danger to zones of the body that are contiguous to the area of application.~~

(12a) The presentation of a cosmetic product and in particular its form, odour, colour, appearance, packaging, labelling, volume or size should not endanger health and safety of consumers due to confusion with foodstuffs, in accordance with Council Directive 87/357/EEC of 25 June 1987 on the approximation of the laws of the Member States concerning products which, appearing to be other than they are, endanger the health or safety of consumers.

(13) In order to establish clear responsibilities, each cosmetic product should be linked to a responsible person who is established within the Community. It is in particular necessary to determine who is the responsible person for cosmetic products which are sold directly to the consumer without recurring to an importer.

(13a) Ensuring traceability of a product throughout the whole supply chain helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates market surveillance authorities' task of tracing economic operators.

(13aa) It is necessary to determine under which conditions a distributor is to be considered as responsible person.

(13b) All legal or natural persons in the wholesale trade as well as retailers selling directly to the consumer are covered by reference to the distributor. The obligations of the distributor should therefore be adapted to the respective role and part of the activity of each of these operators.

(13bb) The European cosmetics sector is one of the industrial activities to be affected by counterfeiting, which may increase risks for human health. Member States should pay particular attention to the implementation of horizontal Community legislation and measures regarding counterfeit products in the field of cosmetic products, as for example Council Regulation 2003/1383/EC and European Parliament and Council Directive 2004/48/EC. This Regulation, while aiming at the protection of human health, encompasses provisions that could contribute to the fight against counterfeiting.[6]

[6] A number of delegations expressed a reservation on a last sentence that would be too specific.

(14) To ensure their safety, cosmetic products placed on the market should be produced according to good manufacturing practice.

(15) For the purpose of efficient market surveillance, a product information file should be made readily accessible at one single address within the Community to the competent authority of the Member State where the file is located.

(16) In order to be comparable and of high quality, the results of the non-clinical safety studies carried out for the purposes of assessing the safety of a cosmetic product should comply with the relevant Community legislation.

Ⓒ 93/35/EEC Recital 4 (adapted)
new

(17) ~~Whereas, with regard to the finished cosmetic product,~~ It~~t~~ should be made clear which information is to be made available to the ~~monitoring~~ competent authorities~~,~~ ~~of the place of manufacture or of initial importation into the Community market; whereas~~ T~~t~~hat information should include all the necessary particulars relating to identity, quality, safety for human health and the effects claimed for the cosmetic product~~,~~ ~~;~~ In particular, this product information should include a cosmetic product safety report documenting that a safety assessment has been conducted.

(18) To ensure a uniform application and control of the restrictions for substances, sampling and analysis should be carried out in a reproducible and standardised manner.

(18a) The term mixture as defined in this Regulation should have the same meaning as the term preparation previously used in Community legislation.

𝔼 93/35/EEC Recital 5 (adapted) new

(19) ~~Whereas, however,~~ Ff~~f~~or reasons of ~~monitoring~~ effective market surveillance , the competent authorities should be notified ~~apprised~~ of certain information about the cosmetic product placed on the market. ~~the place of manufacture and of the information needed for rapid and appropriate medical treatment in the event of difficultires~~.

(20) In order to allow for rapid and appropriate medical treatment in the event of difficulties, the necessary information about the product formula should be submitted to poison control centres and assimilated entities if such centres are established by Member States to that effect.

(21) In order to keep administrative burdens to a minimum, both notifications should be submitted centrally for the Community by way of an electronic interface.

(21a) In order to ensure a smooth transition to the new electronic interface, economic operators should be allowed to notify the information required in accordance with this Regulation before its date of application.

𝔼 83/574/EEC Recital 2 (adapted)

(22) ~~Whereas, on the basis of the latest scientific and technical research, a list of substances authorized as ultra-violet filters can be established;~~

(23) The general principle of the responsibility of the manufacturer or importer for the safety of the product should be supported by restrictions of some substances in Annexes II and III. Moreover, substances which are intended to be used as colorants, preservatives and UV-filters have to be listed in the Annexes IV, V and VI respectively in order to be allowed for these uses.

(24) To avoid ambiguities, it should be clarified that the list of allowed colorants contained in Annex IV only includes substances which colour through absorption and reflection and not substances which colour through photoluminescence, interference, or chemical reaction.

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new

(25) To address safety concerns raised, Annex IV, which is currently restricted to skin colorants, should also include hair colorants once the risk assessment of these substances by the Scientific Committee for **Consumer [] Safety (SCCS)** has been finalised. To this end, the Commission should have the possibility to include hair colorants in the scope of this Annex by Comitology procedure.[7]

(25a) The use of nanomaterials in cosmetic products may increase with the further development of technology. In order to ensure a high level of consumer protection, free movement of goods and legal certainty for manufacturers, it is necessary to develop a uniform definition for nanomaterials at international level. The Community should endeavour to reach an agreement on a definition in appropriate international fora. Should such an agreement be reached, the definition of nanomaterials in this Regulation should be adapted accordingly.

(25b) At present, there is inadequate information on the risks associated with nanomaterials [~~regardless of their persistence and solubility~~]. In order to better assess their safety the SCCS should provide guidance in cooperation with relevant bodies on test methodologies which take into account ~~their~~ specific characteristics of nanomaterials.

(25c) The Commission should regularly review the provisions on nanomaterials [~~regardless of their persistence and solubility~~] in the light of scientific progress.

[7] DK, supported by PL, MT, NL, propose adding mention of Commission future action on skin sensitizers.

𝔼 03/15/EC Recital 13 (adapted) new

(26) Given the hazardous properties of ~~special risks that~~ substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR) , [] **category 1A, 1B and 2, pursuant to Regulation (EC) No … of the European Parliament and of the Council of … on Classification, Labelling and Packaging of Substances and Mixtures** [~~category 1, 2 and 3, pursuant to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances~~] ~~Directive 67/548/EEC~~ ~~may entail for human health~~, their use in cosmetic products should be prohibited. ~~A substance classified in category 3 may be used in cosmetics if the substance has been evaluated by the SCCNFP and found acceptable for use in cosmetic products.~~ However, as a hazardous property of a substance does not necessarily always entail a risk, there should be a possibility to allow the use of substances classified as CMR []**2** substances if, in view of exposure and concentration, they have been found safe for use in cosmetic products by the [~~**SCCP]**~~ **SCCS** and are regulated by the Commission in the Annexes to this Regulation. With regard to substances which are classified as CMR 1**A** or **1B [~~2]~~** substances, there should be a possibility, in the exceptional case where these substances are legally used in food and no suitable alternative substances exist, to use such substances in cosmetic products if such use has been found safe by the [~~SCCP]~~ **SCCS**. **This possibility can apply within 15 months at the latest after classification of substances as carcinogenic, mutagenic or toxic for reproduction of category 1A or 1B under Regulation (EC) No …[].** Such substances should be continuously reviewed by the []**SCCS.**

(26a) A safety assessment of substances, particularly those classified as CMR 1A or 1B substances, should consider the ~~global~~ overall exposure to such substances stemming from all sources. At the same time, for those involved in producing safety assessments, it is essential that there be a harmonised approach to the development and use of such ~~global~~ overall exposure estimates. In consequence, the Commission, in close cooperation with the SCCS, the European Chemicals Agency (ECHA), the European Food Safety Authority (EFSA) and other relevant stakeholders, should, as a matter of urgency, carry out a review and develop guidance regarding the production and use of ~~global~~ overall exposure estimates for these substances.

(26b) The assessment of SCCS of the use of substances classified as CMR 1A and 1B in cosmetic products should also take into account the exposure to these substances of vulnerable populations groups, such as children under three years of age, elderly people, pregnant and breast-feeding women and persons showing compromised immune responses.

(26c) The SCCS should give opinion~~s~~ where appropriate on the safety of use of nanomaterials in cosmetic products. These opinions should be based on full information made available by the responsible person.

(26d) Action by the Commission and Member States relating to the protection of human health should be based on the precautionary principle.

Ⓒ 82/368/EEC Recital 11 (adapted)

(27) ~~Whereas the presence of traces of substances which cosmetic products must not contain according to Annex II to Directive 76/768/EEC~~ In order to ensure product safety, prohibited substances should only be acceptable at trace levels if they are ~~is~~ technologically inevitable with correct manufacturing processes and provided that the product is safe. ~~; whereas therefore certain provisions should be made in this connection;~~

Ⓒ 03/15/EC Recital 2 (adapted)

(28) The Protocol on protection and welfare of animals annexed ~~by the Treaty of Amsterdam~~ to the Treaty ~~establishing the European Community~~ provides that the Community and the Member States are to pay full regard to the welfare requirements of animals in the implementation of Community policies, in particular with regard to the internal market.

Ⓒ 03/15/EC Recital 3 (adapted)

(29) Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes[8] has established common rules for the use of animals for experimental purposes within the Community and laid down the conditions under which such experiments must be carried out in the territory of the Member States. In particular, Article 7 of that Directive requires that animal experiments be replaced by alternative methods, when such methods exist and are scientifically satisfactory. ~~In order to facilitate the development and use of alternative methods in the cosmetic sector which do not use live animals, specific provisions have been introduced by Council Directive 93/35/EEC of 14 June 1993 amending for the sixth time Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products[9].~~

[8] OJ L 358, 18.12.1986, p. 1.
[9] ~~OJ L 151, 23.6.1993, p. 32.~~

~~However, these provisions concern only alternative methods which do not use animals and they do not take account of alternative methods developed in order to reduce the number of animals used for experiments or to reduce their suffering. Therefore, in order to afford optimal protection to animals used for testing cosmetic products pending implementation of the prohibition of animal tests for cosmetic products and the marketing of animal-tested cosmetic products in the Community, these provisions should be amended in order to provide for the systematic use of alternative methods, which reduce the number of animals used or reduce the suffering caused, in those cases where full replacement alternatives are not yet available, as provided by Article 7(2) and (3) of Directive 86/609/EEC, when these methods offer consumers a level of protection equivalent to that of the conventional methods which they are intended to replace.~~

ℂ 03/15/EC Recital 5 (adapted)

(30) ~~Currently, only alternative methods which are scientifically validated by the European Centre for the Validation of Alternative Methods (ECVAM) or the Organisation for Economic Cooperation and Development (OECD) and applicable to the whole chemical sector are systematically adopted at Community level. However,~~ The safety of cosmetic products and their ingredients may be ensured through the use of alternative methods which are not necessarily applicable to all uses of chemical ingredients. Therefore, the use of such methods by the whole cosmetic industry should be promoted and their adoption at Community level ensured, when such methods offer an equivalent level of protection to consumers.

Ⓒ 03/15/EC Recital 6 (adapted)
new

(31) The safety of finished cosmetic products can already be ensured on the basis of knowledge of the safety of the ingredients that they contain. Provisions prohibiting animal testing of finished cosmetic products ~~can~~ should therefore be provided. ~~be incorporated into Directive 76/768/EEC. The Commission should establish guidelines in order to facilitate the~~ The application, in particular by small and medium-sized enterprises, of **both test** methods **and assessment procedures for relevant available data, including the use of read-across and weight-of-evidence approaches,** which do not involve the use of animals for assessing the safety of finished cosmetic products could be facilitated by Commission guidelines .

Ⓒ 03/15/EC Recital 7 (adapted)

(32) It will gradually become possible to ensure the safety of ingredients used in cosmetic products by using non-animal alternative methods validated at Community level, or approved as being scientifically validated, by the European Centre for the Validation of Alternative Methods (ECVAM) ~~ECVAM~~ and with due regard to the development of validation within the Organisation for Economic Cooperation and Development (OECD) ~~OECD~~. After consulting the ~~Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers (SCCNFP)~~ []**SCCS** as regards the applicability of the validated alternative methods to the field of cosmetic products, the Commission should immediately publish the validated or approved methods recognised as being applicable to such ingredients. In order to achieve the highest possible degree of animal protection, a deadline ~~must be~~ should be set for the introduction of a definitive prohibition.

Ⓔ 03/15/EC Recital 8 (adapted)

(33) The Commission ~~should establish~~ has established timetables of deadlines for the prohibition of the marketing of cosmetic products, the final formulation, ingredients or combinations of ingredients which have been tested on animals, and for the prohibition of each test currently carried out using animals, up to 11 March 2009 ~~a maximum of six years from the date of entry into force of this Directive~~. In view, however, of ~~the fact that there are no alternatives yet under consideration for~~ tests concerning repeated-dose toxicity, reproductive toxicity and toxicokinetics, it is appropriate for the maximum deadline for the prohibition of the marketing of cosmetic products for which those tests are used to be 11 March 2013 ~~10 years from the date of entry into force of this Directive~~. On the basis of annual reports, the Commission should be authorised to adapt the timetables within the respective abovementioned maximum time limits.

Ⓔ 03/15/EC Recital 9 (adapted)

(34) Better coordination of resources at Community level will contribute to increasing the scientific knowledge indispensable for the development of alternative methods. It is essential, for this purpose, that the Community continue and increase its efforts and take the measures necessary for the promotion of research and the development of new non-animal alternative methods, in particular within its ~~Sixth~~ Framework Programmes for research ~~as set out in Decision No 1513/EC/2002 of the European Parliament and of the Council~~[10].

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10 ~~OJ L 232, 29.8.2002, p. 1.~~

Ⓔ 03/15/EC Recital 10 (adapted)

(35) The recognition by third ~~non-member~~ countries of alternative methods developed in the Community should be encouraged. In order to achieve this objective, the Commission and the Member States should take all appropriate steps to facilitate acceptance of such methods by the OECD. The Commission should also endeavour, within the framework of European Community cooperation agreements, to obtain recognition of the results of safety tests carried out in the Community using alternative methods so as to ensure that the export of cosmetic products for which such methods have been used is not hindered and to prevent or avoid third ~~non-member~~ countries requiring the repetition of such tests using animals.

Ⓔ 93/35/EEC Recital 3 (adapted)

(36) ~~Whereas greater~~ Tt ransparency is needed regarding the ingredients employed in cosmetic~~s~~ products. ~~if the latter are to be placed on the market without any prior procedure, if the necessary information on the finished product is to be available solely at the place of manufacture or of initial importation into the Community and if better information is to be provided to the consumer; whereas~~ S~~s~~uch transparency should be achieved by indication of ~~a product's function and of~~ the ingredients used in a cosmetic product on its packaging.~~;~~ ~~whereas~~ W~~w~~here for practical reasons it is impossible to indicate the ingredients ~~and any warnings regarding use~~ on ~~the container or~~ the packaging, such particulars should be enclosed so that the consumer ~~may~~ can have access to this ~~all necessary~~ information.~~;~~

Ⓔ 93/35/EEC Recital 2 (adapted)

(37) ~~Whereas it has become apparent that it is desirable that data on the ingredients employed in cosmetic products be gathered so that all issues relating to their use and the resulting action at Community level may be assessed with a view, in particular, to the establishment of a common nomenclature of ingredients used in cosmetic products; whereas the gathering of that data can be facilitated if the Commission compiles an inventory of the ingredients concerned;~~ A glossary of common ingredient names should be compiled by the Commission to ensure uniform labelling and to facilitate identification of cosmetics ingredients. ~~whereas that inventory~~ This glossary should not be intended to ~~will be indicative and is not intended to~~ constitute a limitative list of substances used in cosmetic products;

Ⓔ 03/15/EC Recital 14 (adapted)

(38) In order to inform ~~improve the information provided to~~ consumers, cosmetic products should bear ~~more~~ precise and easily understandable indications concerning their durability for use. **Given that consumers should be informed of the date until which the product continues to fulfil its initial function and remains safe, it is important to know the date of minimum durability, i.e. the date by which it is best to use the product. When the date of minimum durability is more than 30 months, the consumer must be informed of the period of time after opening during which the product can be used without any harm to the consumer. However this requirement does not apply when the concept of the durability after opening is not relevant, that is to say for single use products, products not at risk of deterioration or products which do not open.**

Ⓔ 03/15/EC Recital 15 (adapted)
new

(39) A number of substances have been identified by the []**SCCS** as likely to cause allergenic reactions and it will be necessary to restrict their use and/or impose certain conditions concerning them. ~~Certain substances have been identified as an important cause of contact allergy reactions in fragrance-sensitive consumers.~~ In order to ensure that ~~such~~ consumers are adequately informed, ~~it is therefore necessary to amend the provisions of Directive 76/768/EEC to require that~~ the presence of these substances should be mentioned in the list of ingredients **and consumers' attention should be drawn to the presence of these ingredients**. This information should ~~will~~ improve the diagnosis of contact allergies among such consumers and should ~~will~~ enable them to avoid the use of cosmetic products which they do not tolerate**. For substances which are likely to cause allergy to a significant part of the population, other restrictive measures such as ban and restriction of concentration should be considered.**

(39a) In the safety assessment of a cosmetic product it should be possible to take into account results of risk assessments that have been carried out in other relevant areas. The use of such data should be duly substantiated and justified.

(40) The consumer should be protected from misleading claims concerning efficacy and other characteristics of cosmetic products. **[] In particular European Parliament and Council Directive 2005/29/EC concerning unfair business-to-consumer commercial practices in the internal market is applicable. Furthermore, the Commission, in cooperation with Member States, should define common criteria relative to specific claims for cosmetic products [~~, in particular for natural and organic claims~~].**

Ⓔ 03/15/EC Recital 11 (adapted)

(41) It should be possible to claim on a cosmetic product that no animal testing was carried out in relation to its development. The Commission, in consultation with the Member States, has developed ~~should develop~~ guidelines to ensure that common criteria are applied in the use of claims and that an aligned understanding of the claims is reached, and in particular that such claims do not mislead the consumer. In developing such guidelines, the Commission has ~~must~~ also taken ~~take~~ into account the views of the many small and medium-sized enterprises which make up the majority of the "non-animal testing" producers, relevant non-governmental organisations, and the need of consumers to be able to make practical distinctions between products on the basis of animal testing criteria.

(42) In addition to the labelled information, consumers should be given the possibility to request certain product-related information from the responsible person in order to make informed product choices.

Ⓔ 76/768/EEC Recital 8

(43) ~~In particular, the determination of the methods of analysis together with possible modifications or additions which may have to be made to them on the basis of the results of scientific and technical research, are implementing measures of a technical nature. It is advisable to entrust their adoption to the Commission, subject to certain conditions specified in this Directive, for the purpose of simplifying and accelerating the procedure.~~

new

(44) An effective market surveillance is necessary in order to ensure that the provisions of this Regulation are respected. To this end, serious undesirable effects should be notified and competent authorities should have a possibility to request from the responsible person a list of cosmetic products containing substances which have raised serious doubts in terms of safety.

(44a) This Regulation is without prejudice to the possibility for Member States to regulate, within the respect of Community law, the notification by health professionals or consumers of serious undesirable effects to the competent authorities of Member States.

(44b) This Regulation is without prejudice to the possibility for Member States to regulate, within the respect of Community law, establishment of economic operators in the area of cosmetic products.

(45) In case of non-compliance with this Regulation, a clear and efficient procedure for the withdrawal and recall of products may be necessary. This procedure should build, where possible, upon existing Community rules for unsafe goods.

Ⓒ 76/768/EEC Recital 11 (adapted)

(46) In order to address products which, albeit ~~It could happen that although~~ conforming with ~~to~~ the provisions of this Regulation ~~Directive and its Annexes, cosmetic products placed on the market~~ might endanger human ~~public~~ health , a safeguard procedure should be introduced. ~~It is therefore advisable to provide for a procedure intended to remove this danger.~~

(46a) The Commission should provide indications for the uniform interpretation and application of the concept of serious risks in order to facilitate the consistent implementation of this Regulation.

new

(47) In order to comply with principles of good administrative practices, any decision by a competent authority in the framework of market surveillance should be duly substantiated.

(48) In order to ensure an efficient in-market control, a high degree of administrative cooperation amongst the enforcing authorities is necessary. This concerns in particular the mutual assistance in the verification of product informations files located in another Member State.

Ⓒ 76/768/EEC Recital 10

(49) ~~It is necessary, on the basis of scientific and technical research, to draw up proposals for lists of authorized substances which could include antioxidants, hair dyes, preservatives and ultraviolet filters, taking into account in particular the problem of sensitization.~~

Ⓒ 76/768/EEC Recital 9 (adapted)

~~(50) Technical progress necessitates rapid adaptation of the technical provisions defined in this Directive and in subsequent Directives in this field. It is advisable, in order to facilitate implementation of the measures necessary for this purpose, to provide for a procedure establishing close cooperation between the Member States and the Commission within the Committee for adaptation to technical progress of Directives aimed at the removal of technical obstacles to trade in the cosmetic products sector.~~

new

(51) The Commission should be assisted by the []**SCCS,** an independent risk assessment body.

(52) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down procedures for the exercise of implementing powers conferred on the Commission[11].

(53) In particular power should be conferred on the Commission to adapt the Annexes to this Regulation to technical progress. Since those measures are of general scope and are designed to amend non-essential elements of this Regulation they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

(54) Member States should lay down provisions on penalties applicable to infringements of the provisions of this Regulation and ensure that they are implemented. Those penalties should be effective, proportionate and dissuasive.

(55) Economic operators as well as Member States and the Commission need sufficient time to adapt to the changes introduced by this Regulation. [~~Therefore, this Regulation should apply 36 months after its publication.~~] **Therefore it is appropriate to provide for a sufficient transitional period for that adaptation. However, in order to ensure a smooth transition, economic operators should be allowed to place on the market cosmetic products which comply with this Regulation before the expiry of that transitional period.**

[11] OJ L184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L200, 22.7.2006, p.11).

(55a) In order to strengthen the safety of cosmetic products and the market surveillance, cosmetic products placed on the market after the date of application of this Regulation should comply with its obligations regarding safety assessment, product information file and notification, even if similar obligations have already been performed under Directive 76/768/EEC.

(56) Directive 76/768/EEC should be repealed. **However, in order to guarantee an appropriate medical treatment in case of difficulties and to ensure market surveillance, the information received pursuant to Article 7(3) and Article 7a(4) of Directive 76/768/EEC concerning cosmetic products should be kept by the competent authorities during a certain period of time and the information kept by the responsible person should be still available for the same period of time.**

(57) This Regulation should be without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law of the Directives set out in Part B of Annex IX.

(58) Since the objective of this Regulation, namely the achievement of the internal market and a high level of protection of human health through the compliance of cosmetic products, cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale of the action, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity, as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

𝔼 76/768/EEC (adapted)

HAVE ADOPTED THIS ~~DIRECTIVE~~ REGULATION :

𝔼 93/35/EEC (adapted)

Chapter I

Scope, definitions

Article 1

Scope and objective

This Regulation establishes rules to be complied with by any cosmetic product made available on the market, in order to ensure the functioning of the internal market and a high level of protection of human health.

Article ~~1~~ 2

Definitions

1. For the purposes of this Regulation, the following definitions shall apply:

   (a) 'cosmetic product' means ~~A 'cosmetic product' shall mean~~ any substance ~~or preparation~~ or mixture intended to be placed in contact with the ~~various~~ 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, ~~and/or correcting body odours and/or~~ protecting them, ~~or~~ keeping them in good condition or correcting body odours .

𝔼 76/768/EEC (adapted)

~~2. The products to be considered as cosmetic products within the meaning of this definition are listed in Annex I.~~

𝔼 88/667/EEC

~~3. Cosmetic products containing one of the substances listed in Annex V shall be excluded from the scope of this Directive. Member States may take such measures as they deem necessary with regard to those products.~~

new

(aa) 'substance' means 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;

(ab) 'mixture' means a mixture or solution composed of two or more substances.

(b) 'manufacturer' means any natural or legal person who ~~designs or~~ manufactures a cosmetic product or ~~who~~ has such a product designed or manufactured[12], and markets that cosmetic product under his name or trademark;

[12] IE: suggests including "or who modifies the packaging or labelling".

(ba) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer[], who makes a product available on the Community market ; [13]

(bb) 'end user' means either consumers or professionals using the cosmetic product;

(c) 'making available on the market' means any supply [~~by any means , including electronic means,~~] of a product for distribution, consumption or use on the Community market in the course of a commercial activity, whether in return for payment or free of charge;

(d) 'placing on the market' means the first making available of a product on the **Community** market;[14]

(e) 'importer' means any natural or legal person established within the Community, who places a product from a third country on the **Community** market;

(f) 'harmonised standard' means a standard adopted by one of the European standardisation bodies listed in Annex I to Directive 98/34/EC of the European Parliament and of the Council laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on information society services[15] **on the basis of a request made by the Commission** in accordance with Article 6 of that Directive;

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[13] PT proposes adding "and who does not supply the product directly to the consumer". COM reservation, as 'distributor' includes retailer.

[14] DE proposes alignment of 2 c) and d) with Regulation 178/2002.

[15] OJ L 24, 21.7.1998, p. 37. Directive as last amended by […].

(g) 'nanomaterial' means an insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm;

(h) 'preservatives' means substances which are exclusively or mainly intended to inhibit the development of micro-organisms in the cosmetic product;

(i) 'colorants' means 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;

(j) 'UV-filters' means substances which are exclusively or mainly intended to protect the skin against **certain** UV radiation by absorbing, reflecting or scattering UV radiation;

(k) 'undesirable effect' means **an adverse** ~~a harmful~~ reaction for human health attributable to the normal or reasonably foreseeable use of a cosmetic product;

(l) 'serious undesirable effect' means an undesirable effect which results in temporary or permanent functional incapacity, disability, hospitalisation, congenital anomalies or an immediate vital risk or death; [16]

[16] DE call for definition of 'serious risk' to complement Articles 22 and 23; NL, PL highlight perils of definition. SI concerned about divergence of interpretation. See FN 46a.

(m) 'withdrawal' means any measure aimed at preventing the making available on the market of a cosmetic product in the supply chain;

(n) 'recall' means any measure aimed at achieving the return of a cosmetic product that has already been made available to the end user.

(o) 'frame formulation' means 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 formula. The Commission shall provide indications permitting the establishment of the frame formulation and adapt them regularly to technical and scientific progress.

€ 76/768/EEC, recital 5 (adapted)

2. For the purposes of point (a) of paragraph 1, a substance or mixture intended to be ingested, inhaled, injected or implanted into the human body[17] shall not be considered to be a cosmetic product.

3. In view of the various definitions of nanomaterials published by different bodies and the constant technical and scientific developments in the field of nanotechnologies, the Commission shall adjust and adapt point (g) of paragraph 1 to technical and scientific progress and with definitions subsequently agreed at international level. That measure, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 27(3).

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[17] IE supported by MT proposes adding: "or where systemic absorption is intended". COM, PL scrutiny reservation.

℄ 93/35/EEC (adapted)

Chapter II
Safety, responsibility, free movement

Article ~~2~~3
Safety

A cosmetic product made available on the market ~~put on the market within the Community must~~ shall be safe for ~~not cause damage to~~ human health when **used []** under normal or reasonably foreseeable conditions of use, taking account, in particular, of the following :

(a) ~~the product's~~ presentation **including conformity with Directive 87/357**;

(b) ~~its~~ labelling~~,~~;

(c) ~~any~~ instructions for ~~its~~ use and disposal;

(d) ~~as well as~~ any other indication or information provided by ~~the manufacturer or his authorized agent or by any other person responsible for placing the product on the Community market.~~ the **responsible** person defined in Article 4.

The provision of ~~such~~ warnings shall not~~, in any event,~~ exempt ~~any person~~ **persons defined in Articles 2 and 4** from compliance with the other requirements laid down in this ~~Directive~~ Regulation .

new

Article 4

Responsible person[18]

1. For each cosmetic product placed on the market, a legal or natural person shall ensure compliance with the relevant obligations set out in this Regulation (hereinafter 'responsible person'):

2. For a cosmetic product manufactured within the Community, and not subsequently exported and imported back into the Community, the manufacturer established within the Community shall be the responsible person.

   The manufacturer may designate, by written mandate, a person established within the Community as the responsible person **who shall accept in writing**.

3. Where, for a cosmetic product manufactured within the Community, and not subsequently exported and imported back into the Community the manufacturer is established outside the Community, he shall designate, by written mandate, a person established within the Community as the responsible person **who shall accept in writing**.[19]

4. For an imported cosmetic product, each importer shall be the responsible person **for the specific cosmetic product he places on the market**.

   The importer may, by written mandate, designate a person established within the Community as the responsible person **who shall accept in writing**.[20]

18 DE concern about splitting up of responsibilities, highlights smooth running of current regulatory framework enabling effective pinning of responsibility.

19 DE proposes deletion of paragraph 3.

20 DE proposes deletion of the second sentence in paragraphs 2 and 4. Proposes paragraph 4 starts with: "Without prejudice to the provision in paragraph 2,..."

5. For a cosmetic product **[] placed** on the market directly to the **end user** from outside the Community by any means and in the absence of an importer, the person placing the cosmetic product on the market shall designate, by written mandate, a person established within the Community as the responsible person **who shall accept in writing**.[21] [22]

6. The distributor shall be the responsible person when he places a 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.

Translation of information related to a cosmetic product already placed on the market shall not be considered as a modification of this product of such a nature that compliance with the applicable requirements of this Regulation may be affected.

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21 UK propose deletion of paragraph. UK supported by DE express doubts on enforceability and practical application of this provision. IE and PL also concurred with those doubts. UK point out lack of mention and definition of "personal use", and the lack of provision on the figure of "mandatory". DE express concern on clarity of the "written mandate". On the other hand, a number of delegations expressed support for the provision, although they understood the difficulties in implementation.

22 DE proposes alternative wording: ".... in the absence of an importer, a person established within the Community is to be designated and specified by written mandate as the representative of the manufacturer or the importer"

***Article 4 a*[23]**

Obligations of the responsible person

1. The responsible person shall ensure compliance with Articles 3 (safety), 5 (GMP), 7 (safety assessment), 8 (product information file), 9 (sampling and analysis), 10 (notification), 11 (restrictions for substances listed in Annexes), 12 (CMR), [12a (nanomaterials),] 13 (traces), 14 (animal testing), 15 paragraphs (1),(2),(5) and (6) (labelling), 16 (claims), 17 (information to the public), 19 (communication of SUE) and 20 (information on substances)[24].

2. Responsible persons who consider or have reason to believe that[25] a product which they have placed on the market is not in conformity with this regulation shall immediately take the necessary corrective measures to bring that product into conformity or withdraw it from the market and recall it, if appropriate.

Furthermore, where the product presents a risk[26], they shall immediately inform the competent national authorities of the Member States where they made the product available and of the Member State where the product information file is readily accessible to this effect, giving details, in particular, of the non-compliance and of the corrective measures taken.

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23 AT scrutiny reservation.

24 AT and BE stress importance of indication of general responsibility for compliance with Regulation. BE propose inclusion of Articles 2 and 4.

25 AT propose replacing "have reason to believe that" with "have evidence that"; applies also to Article 4b(3) (?).

26 UK, propose mention of 'serious risk', same for preceding paragraphs. Presidency points out current text conforms to New Approach (R 2(8), R 4(7)).

3. Responsible persons shall cooperate with these authorities, at the request of the latter, on any action to eliminate the risks posed by products which they have made available on the market. In particular, responsible persons shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of specific aspects of the product, in a language which can be easily understood by that authority.

Article 4 b

Obligations of the distributors

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

2. Before making a product available on the market distributors shall verify that:

- **the labelling information provided by Article 15 (1)(a), (e) and (g) and Article 15 (3) and (4) is present;**
- **the** language **requirements provided by Article 15(5) are fulfilled;**
- **date of minimum durability specified, when applicable in Article 15(1) is not expired.**

3. Where distributors consider or have reason to believe that:

– a product is not in conformity with the requirements provided by this Regulation, they shall not make the product available on the market until it has been brought into conformity with the applicable requirements;

– a product which they have made available on the market is not in conformity with the Regulation, they shall make sure that the corrective measures necessary to bring that product into conformity, to withdraw it or to recall it are taken.

Furthermore, where the product presents a risk, distributors shall immediately inform the responsible person and the competent national authorities of the Member States where they made the product available to this effect, 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 jeopardise its compliance with the requirements set out in this Regulation.

5. Distributors shall cooperate with competent authorities, at the request of the latter, on any action to eliminate the risks posed by products which they have made available on the market. In particular, distributors shall, further to a reasoned request[27] from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of the product with the requirements listed under paragraph 2, in a language which can be easily understood by that authority.

***Article* 4 c**

***Identification within the supply chain*[28]**

On request of the competent authorities:

– the responsible persons shall be able to identify the distributors to whom they supply the cosmetic product [] ;

– the distributor shall be able to identify the distributor or the responsible person from whom, and the distributors to whom, the cosmetic product was supplied.

This obligation shall be kept during a period of 3 years following the date when the batch of the cosmetic product was made available to the distributor.

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27 PT propose deletion of "further to a reasoned request".

28 PL propose detailed provisions on traceability; submits 3 paragraphs based on Article 17 of the Regulation (EC) No 1935/2004 (MD 30/08).

𝔼 76/768/EEC (adapted)

~~*Article 3*~~

~~Member States shall take all necessary measures to ensure that only cosmetic products which conform to the provisions of this Directive and its Annexes may be put on the market.~~

𝔼 93/35/EEC (adapted)

Article 5
Good manufacturing practice

1. Manufacturing of cosmetic products shall comply with good manufacturing practice[29] with a view to ensure the objectives of Article 1[30].

new

2. Compliance with good manufacturing practice shall be presumed where manufacturing is in accordance with the relevant harmonised standards, the references of which have been published in the *Official Journal of the European Union*.[31]

[29] IT highlights the lack of GMP compliance check procedure.
[30] PT suggests to limit this to a reference to Article 3.
[31] IE suggests deletion of par. 2 and insertion of definition in Art. 2 reading: "In this article 'good manufacturing practice' means the relevant harmonised standards, reference to which has been published in the Official Journal of the European Union.".

76/768/EEC (adapted)

Article 6

Free movement

Member States may not, for reasons related to the requirements laid down in this ~~Directive and the Annexes thereto~~ Regulation , refuse, prohibit or restrict the ~~marketing~~ making available on the market of ~~any~~ cosmetic products which comply with the requirements of this ~~Directive and the Annexes thereto~~ Regulation .

𝔼 93/35/EEC (adapted) new

Chapter III
Safety assessment, product information file, notification

Article ~~7a~~ 7

Safety assessment

1. **In order to ascertain compliance of cosmetic product with Article 3** 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 in accordance with Annex I is set up.

The responsible person shall ensure that:

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

(b) an appropriate weight-of-evidence approach is used in the safety assessment for reviewing [~~relevant~~] data from [~~several~~] all existing sources [~~, including data from in-vitro, in-silico, existing GLP (Good Laboratory Practice) or non-GLP in-vivo and human studies;~~]

(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.

The first subparagraph shall also apply to cosmetic products that have been notified under Directive 76/768/EEC.

The Commission, in close cooperation with all stakeholders, shall adopt appropriate guidelines to enable enterprises, in particular small and medium-sized enterprises, to comply with the requirements laid down in Annex I. The guidelines shall be adopted in accordance with the regulatory procedure referred to in Article 27(2).

2. The cosmetic product safety assessment, as set out in Part B of Annex I shall be carried out by a person in possession of a diploma, ~~certificate~~ or other evidence of formal qualifications awarded on completion of a university course of **study of theoretical and practical study in pharmacy, toxicology, medicine or a similar discipline**, or a course recognised as equivalent by a Member State, [~~extending over a period of at least three years of theoretical and practical study in pharmacy, toxicology, medicine or a similar discipline~~[32]**.**

3. Non-clinical safety studies referred to in the safety assessment according to paragraph 1 and carried out after 30 June 1988 for the purpose of assessing the safety of a cosmetic product shall comply with the Community legislation on the principles of good laboratory practice, as applicable at the time of performance of the study, or with other international standards recognised as being equivalent by the Commission or the European Chemicals Agency.

[33]

[32] UK, IE, MT, PL, COM scrutiny reservation. AT, DE emphasise need for a masters level of qualifications.

[33] SE proposes new paragraph (4): "When agreed test methods applicable for nanomaterials are available, or at the latest 5 years after the entry into force of the Regulation, the Commission shall, where justified, present a legislative proposal on how to amend Annex I of the Regulation to address the assessment of potential risks with the use of nanomaterials in cosmetic and hygienic products." (MD 24/08).

Article 8

Product information file

1. **When a cosmetic product is placed on the market,** the responsible person ~~manufacturer or his agent or the person to whose order a cosmetic product is manufactured or the person responsible for placing an imported cosmetic product on the Community market~~ shall ~~for control purposes~~ keep a product information file for the cosmetic product for which he is the responsible person. ~~the following information readily accessible to the competent authorities of the Member State concerned at the address specified on the label in accordance with Article 6 (1) (a):~~**The product information file shall be kept during a period of … [10 years] following the date when 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 [**~~regularly~~**] updated when necessary**:

(a) a description of the cosmetic product which allows for a clear attribution of the product information file to the cosmetic product;

(b) the cosmetic product safety report referred to in Article 7(1);

(c) a description of the method of manufacturing and a statement on compliance with good manufacturing practice referred to in Article 5;

~~(a) the qualitative and quantitative composition of the product; in the 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 the good manufacturing practice laid down by Community law or, failing that, laid down by the law of the Member State concerned; the person responsible for manufacture or first importation into the Community must possess an appropriate level of professional qualification or experience in accordance with the legislation and practice of the Member State which is the place of manufacture or first importation;~~

ℂ 2003/15/EC Art. 1.6 (adapted)

~~(d) assessment of the safety for human health of the finished product. To that end the manufacturer shall take into consideration the general toxicological profile of the ingredients, their chemical structure and their level of exposure. It shall take particular account of the specific exposure characteristics of the areas on which the product will be applied or of the population for which it is intended. 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.~~

~~Should the same product be manufactured at several places within Community territory, the manufacturer may choose a single place of manufacture where that information will be available. In this connection, and when so requested for monitoring purposes, it shall be obliged to indicate the place so chosen to the monitoring authority or authorities concerned. In this case this information shall be easily accessible;~~

𝔼 93/35/EEC (adapted)

~~(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 as defined in Article 1 of Directive 89/48/EEC 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;~~

(d~~g~~) where justified by the nature or the effect of the cosmetic product, proof of the effect claimed for the cosmetic product~~, where justified by the nature of the effect or product~~;

2003/15/EC Art. 1.7 (new)

(~~c~~h) data on any animal testing performed by the manufacturer, his agents or suppliers, relating to the development or safety ~~evaluation~~ assessment of the cosmetic product or its ingredients, including any animal testing performed to meet the legislative or regulatory requirements of third ~~non-member~~ countries.

~~Without prejudice to the protection, in particular, of commercial secrecy and of intellectual property rights, Member States shall ensure that the information required under (a) and (f) shall be made easily accessible to the public by any appropriate means, including electronic means. The quantitative information required under (a) to be made publicly accessible shall be limited to dangerous substances covered by Directive 67/548/EEC.~~

~~2. The assessment of the safety for human health referred to in paragraph 1 (d) shall be carried out in accordance with the principle of good laboratory practice laid down in Council Directive 87/18/EEC of 18 December 1986 on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their application for tests on chemical substances (34).~~

~~34 OJ No L 15, 17.1.1987, p. 29.~~

3. The responsible person shall make the product information file readily accessible in electronic or other format at his address **indicated on the label** to the competent authority of the Member State where the file is kept.

The information ~~referred to in paragraph 1~~ contained in the product information file ~~must~~ shall be available in [[35]] a language ~~readily~~ **which can be easily** understood by the competent authorities of **the** Member State [~~**as determined by the Member State concerned**~~].

4. The requirements provided in paragraphs 1 to 3 shall also apply to cosmetic products that have been notified under Directive 76/768/EEC.

~~4. The manufacturer or his agent, or the person to whose order a cosmetic product is manufactured, or the person responsible for placing imported cosmetic products on the Community market, shall notify the competent authority of the Member State of the place of manufacture or of the initial importation of the address of the place of manufacture or of initial importation into the Community of the cosmetic products before the latter are placed on the Community market.~~

~~5. Member States shall designate the competent authorities referred to in paragraphs 1 and 4 and shall send details thereof to the Commission, which shall publish that information in the Official Journal of the European Communities.~~

~~The Member States shall ensure that the abovementioned authorities continue to cooperate in areas where such cooperation is necessary to the smooth application of this Directive.~~

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35 DK express doubt on the feasibility of evaluation of PIF if they are available in another MS.

𝔼 82/368/EEC (adapted)

Article 9[36]
Sampling and analysis

1. Sampling and analysis of cosmetic products shall be performed in a reliable and reproducible manner. ~~—new~~

2. In absence of any applicable Community legislation, **reliability and reproducibility []** shall be presumed if the method used is in accordance with the relevant harmonised standards, the references of which have been published in the *Official Journal of the European Union*.

𝔼 76/768/EEC (adapted)

Article ~~7~~10[37]
Notification

𝔼 93/35/EEC

~~2. They may, however, require that the particulars provided for in Article 6 (1) (b), (c), (d) and (f) be expressed at least in their own national or official language or languages; they may also require that the particulars provided for in Article 6 (1) (g) be expressed in a language easily understood by the consumer. To that end, the Commission shall adopt a common ingredients nomenclature in accordance with the Article 10 procedure.~~

[36] DE propose moving this article to Chapter II.
[37] PL proposes specification on period of transition for products already on the market.

~~3. Furthermore, a Member State may, for purposes of prompt and appropriate medical treatment in the event of difficulties, require that appropriate and adequate information on substances used in cosmetic products be made available to the competent authority, which shall ensure that that information is used only for the purposes of such treatment.~~

~~Each Member State shall designate a competent authority and send details thereof to the Commission, which shall publish that information in the *Official Journal of the European Communitites*.~~

new

1. **Prior to placing the cosmetic product on the market t**he responsible person shall submit, **through electronic means**, ~~prior to placing the cosmetic product on the market,~~ the following information to the Commission[38]:

(a) the category of cosmetic product and its [] name **or names, enabling its specific identification**[39];

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

(ba) the country of origin in case of import;

(c) the Member State where the cosmetic product is placed on the market[40];

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

(e) the presence of substances in the form of [] **nanomaterials []in accordance with the provisions of Article 12a (2)**[41];

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38 NL propose indication of information on place of storage when differing from b).

39 PT, supported LT, proposes provision for images of product and copy of labelling. DE, DK reservation; cite problem of presumption of conformity. ES proposes: "(b) the name and address of the responsible person and the address where ... ." COM reservation. COM explains that Article 4 et seq. do enable requests for labelling on an ad hoc basis.

40 BE proposes data on all MS where the product is made available on the market. COM reservation.

41 BE propose adding "and their identification".

(f) the **name and the CAS or EC number** of substances classified as carcinogenic, mutagenic or toxic for reproduction, of category **1A** or **1B**, **under part 3 of Annex VI to Regulation (EC) No …** [];

(g) the frame formulation allowing for prompt and appropriate medical treatment in the event of difficulties;

[42]

[~~2. The frame formulation referred in point (g) of paragraph 1 shall …~~]

The first subparagraph shall also apply to cosmetic products notified under Directive 76/768/EEC.

2. As from the date referred to in Article 34(2), a distributor who makes available in a Member State a cosmetic product already placed on the market in another Member State and translates, on his own initiative, any element of the labelling of that product in order to comply with national law, shall submit, through electronic means, the following information to the Commission:

(a) the category of cosmetic product, its name in the Member State of dispatch and its name in the Member State where it is made available, enabling its specific identification;

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42 PT, supported by LT suggest to add points:
h) The competent authority and languages in which the product information file will be made available;
i) The Member States where the cosmetic product will be made available to the consumer;
j) The address and contact details of the local distributor in each Member State where the cosmetic product is intended to be commercialized;
k) Copy of the labelling for each Member State where the cosmetic product is intended to be commercialised; ". COM reservation. DE highlights costs of adding more information. IE proposes adding detailed dates of last batch on the market, notification, revision and discontinuation.
NL proposes : "The Commission shall investigate the possibility of harmonising the information referred to in Article 10 of this Regulation with the information to be delivered for the CLP regulation as mentioned in Article 45. On the basis of this investigation and following consultation with relevant stakeholders such as the European Association of Poison Centres and Clinical Toxicologists (EAPCCT), the Commission shall adapt when necessary Article 10 and the relevant procedures or formats.".

(b) the Member State where the cosmetic product is made available;

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

(d) his name and address.

3. Where a cosmetic product is not placed on the market as from the date referred to in Article 34(2), the distributor who makes available ~~introduces~~ that product in a Member State shall communicate the following to the responsible person:

(a) the category of cosmetic product, its name in the Member State of dispatch and its name in the Member State where it is made available, enabling its specific identification;

(b) the Member State where the cosmetic product is made available;

(c) his name and address.

On the basis of that communication, the responsible person shall submit, through electronic means, to the Commission the information referred to paragraph 1 of this Article, where notifications according to Article 7(3) and Article 7a (4) of Directive 76/768/EEC have not been carried out in the Member State where the cosmetic product is made available.

4. The Commission shall, **without delay, make []** the information referred to in points (a) to (f)[43] of paragraph 1 **and in paragraph 2 available electronically** to **all** the competent authorities.

That information may only be used by the competent authorities for the purposes of market surveillance, **market analysis, evaluation and consumer information [in the context of Articles 21, 21a and 22]**[44].

5. The Commission shall**, without delay, make []** the information referred to in paragraph**s** 1 **and 2 available electronically** to poison centres or similar bodies, where established to this end by Member States.

That information may only be used by those bodies for the purposes of medical treatment.

6. Where any of the information set out in paragraph**s** 1, 2 **and 3** changes, the responsible person **and the distributor** shall provide an update without delay.

7. The Commission may, taking into account technical and scientific progress and specific needs related to market surveillance, amend paragraphs 1 to 6 by adding requirements.

Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 27 (3).

℮ 93/35/EEC (new)

~~Each Member State shall designate a competent authority and send details thereof to the Commission, which shall publish that information in the *Official Journal of the European Communities*.~~

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43 DK proposes adding point (g) of paragraph 1.

44 DE reservation.

𝔼 82/368/EEC (adapted) new

Chapter IV
Restrictions for certain substances

Article ~~4~~11

Restrictions for substances listed in the Annexes

1. Without prejudice to Article 3, ~~their general obligations deriving from Article 2, Member States shall prohibit the marketing of~~ cosmetic products shall not contain ~~containing~~ any of the following :

(a) **Prohibited Substances**

- prohibited substances listed in Annex II;

(b) **Restricted Substances**

- restricted substances ~~listed in the first part of Annex III, beyond the limits and outside the conditions~~ which are not used in accordance with the restrictions laid down in Annex III ;

℮ 88/667/EEC (new) new

(c) **Colorants**

i) colorants other than those listed in Annex IV and colorants thereby listed but which are not used in accordance with the conditions laid down in that Annex, except for hair colouring products referred to in paragraph 2~~colorants — colouring agents other than those listed in Annex IV, Part 1, with the exception of cosmetic products containing colouring agents intended solely to colour hair — and colorants which are not used in accordance with the conditions laid down in that Annex —~~;

~~(d) colouring agents listed in Annex IV, Part 1, used outside the conditions laid down, with the exception of cosmetic products containing colouring agents intended solely to colour hair;~~

ii) without prejudice to points (b), **(d)** i) and **(e)** i), substances which are listed in Annex IV but which are not intended to be used as a colorant, and which are not used in accordance with the conditions laid down in that Annex.

Ⓔ 82/368/EEC (adapted)

(d)**Preservatives**

i) preservatives other than those listed in Annex ~~VI, Part 1,~~ V and preservatives **thereby listed but** which are not used in accordance with the conditions laid down in that Annex ;

new

ii) without prejudice to points (b) (c) **i)** and **(e) i)**, 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.

Ⓔ 82/368/EEC (new)

~~(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;~~

𝔼 83/574/EEC (adapted)

(e) UV-filters

i) UV-filters other than those listed in ~~Part 1 of~~ Annex ~~VII~~ VI and UV-filters **thereby listed but** which are not used in accordance with the conditions set out in that Annex ;

ii) without prejudice to points (b) (c) **i)** and **(d) i)**, 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.

~~(h) UV-filters listed in Part 1 of Annex VII, beyond the limits and outside the conditions laid down therein.~~

new

2. Subject to a Commission Decision to extend the scope of Annex IV to hair colouring products, these products shall not contain colorants intended to colour the hair, other than those listed in Annex IV and colorants intended to colour the hair, which are not used in accordance with the conditions laid down in that Annex.

The Commission Decision referred to in the first subparagraph, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 27(3).

𝔼 2003/15/EC Art. 1.2 (adapted) new

Article ~~4b~~12[45]
Substances classified as carcinogenic, mutagenic or toxic for reproduction

(1) The use in cosmetic products of substances classified as carcinogenic, mutagenic or toxic for reproduction, of category ~~1, 2 and~~ [~~3, under Annex I to Directive 67/548/EEC~~] **2, under part 3 of Annex VI of Regulation (EC) No … of the European Parliament and of the Council of … on Classification, Labelling and Packaging of Substances and Mixtures** shall be prohibited. ~~To that end the Commission shall adopt the necessary measures in accordance with the procedure referred to in Article 10(2).~~ However, a ~~A~~ substance classified in category []**2** may be used in cosmetic products ~~cosmetics~~ if the substance has been evaluated by the []**SCCS**[46] ~~SCCNFP~~ and found ~~acceptable~~ safe for use in cosmetic products. To these ends the Commission shall adopt the necessary measures in accordance with the procedure referred to in Article 27(3) [47] .

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45 DE, DK, LT and HU reservation on use of CMR1 and CMR2, but appreciate possible exceptions, concern on estimation of total exposure. NL proposes additional conditions (proven non-existence of alternatives, consideration of overall exposure, SMF 1000, 5-year limitation, investigation in cases of concern, withdrawal of authorisation, individual application). HU: scientific data on chronic exposure to exclude long-term effect.

46 DK highlight possible role of Agency Committee.

47 HU: add: "The Commission shall mandate the SCCS to re-evaluate those substances as soon as safety concerns arise."

new

(2) The use in cosmetic products of substances classified as carcinogenic, mutagenic or toxic for reproduction, of category [~~1 or 2, under Annex I to Directive 67/548/EEC~~] **1A, 1B under part 3 of Annex VI of Regulation (EC) No … of the European Parliament and of the Council of … on Classification, Labelling and Packaging of Substances and Mixtures** shall be prohibited.

However, such substances may be used in cosmetic products **by way of exception** if, subsequent to [] their classification as carcinogenic, mutagenic or toxic for reproduction of category[~~1 or 2 under Directive 67/548/EEC~~] **1A and 1B under part 3 of Regulation (EC) No … of the European Parliament and of the Council of … on Classification, Labelling and Packaging of Substances and Mixtures**, ~~all~~ **one** of the following **set of** conditions **is** ~~are~~ fulfilled ~~**in the following order**~~:

[shifted]

either:

(a) (i) they are complying with the food safety requirements as defined in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety[48];

(ii) there are no suitable alternative substances available, as documented in an analysis of alternatives**;**

(iii) the application is made for a particular use of the product category with a known exposure; and

(iv) they have been evaluated and found safe for use by the []**SCCS** in cosmetic products in particular in view of exposure **to these products and taking into consideration the overall exposure from other sources, as well as under particular consideration of vulnerable population groups[49].**

or, in case (a) (i) does not apply:

(b) (i) there is a history of safe use as ingredients in cosmetic products without safety concerns in regard to their carcinogenic, mutagenic or reproduction toxic properties,

(ii) there are no suitable alternative substances available, as documented in an analysis of alternatives;

(iii) the application is made for a particular use of the product category with a known exposure;

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48 OJ L 31, 1.2.2002, p. 1. Regulation as last amended by […].

49 IT propose adding: "whenever scientific and statistical data is available."; proposes provision for an exchange of ideas on the matter. DK reservation.

(iv) in establishing adequate safety margins, the threshold and specificity of the CMR effect have been taken into account together with possible mixture effects; and

(v) they have been evaluated and found safe for use by the SCCS in cosmetic products in particular in view of exposure to these products and taking into consideration the overall exposure from other sources, as well as under particular consideration of vulnerable population groups.

Specific labelling in order to avoid misuse of the cosmetic product shall be provided in accordance with Article 3, taking into account possible risks linked to the presence of hazardous substances and the routes of exposure.[50]

In order to implement this paragraph, the Commission shall amend the Annexes to this Regulation in accordance with the procedure referred to in Article 27(3) within 15 months at the latest after the inclusion of the substances concerned [~~in Annex I to Council Directive 67/548/EEC~~] **in part 3 of annex VI of Regulation (EC) No … of the European Parliament and of the Council of … on Classification, Labelling and Packaging of Substances and Mixtures**.

On imperative grounds of urgency, the Commission may use the urgency procedure referred to in Article 27(4).

50 DK proposes alternative paragraph : "Specific labelling that enables consumers to identify the presence of CMR category 1 and 2 substances in cosmetic products shall be provided in accordance with article 1(d). This labelling shall additionally in accordance with Article 3 contain warnings to avoid misuse, taking into account possible risks linked to the presence of hazardous substances and the routes of exposure." (MD 33/08). SE proposes deletion of this paragraph as labelling does not address safety concern (MD 24/08).

The Commission shall mandate the [] **SCCS** to re-evaluate those substances as soon as safety concerns arise and at the latest every 5 years after their inclusion in Annexes III to VI.

[51]

[52]

(2a) By [add date: two years after the date of entry into force], the Commission shall ensure that appropriate guidance is developed with the aim of enabling a harmonised approach to the development and use of overall exposure estimates in assessing the safe use of CMR substances. This guidance shall be developed in consultation with the SCCS, the ECHA, the EFSA and other relevant stakeholders, drawing as appropriate on relevant best practice.

(2b) When Community or internationally agreed criteria for identifying substances with endocrine-disrupting properties are available, or at the latest 5 years after this Regulation has entered into force, the Commission shall review the Regulation with regard to substances with endocrine-disrupting properties.

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51 DK, supported by LT, NL, PT and SE proposes additional Article 12 b on extreme sensitizers (see MD 33/08). COM points out ongoing work on non-legislative measures on skin sensitising properties. See new recital 39.

52 BE proposes new Article 12 (3) with detailed provisions for pre-market authorisation for nanomaterials (see MD 50/08)

Article 12 a

Nanomaterials

1. For every product that contains nanomaterials as defined in Article 2, a high level of protection of human health shall be ensured.

1a. The provisions of this Article do not apply to nanomaterials used as colorants, UV-filters and preservatives regulated under Article 11, unless expressly specified.

2. Cosmetic products containing nanomaterials shall be notified by the responsible person to the Commission through electronic means 6 months prior to the placing on the market.

(a) The information notified to the Commission shall contain at least the following:

(i) the identification and specification of the nanomaterial including its chemical name (IUPAC) and other descriptors as specified in paragraph 2 of the Preamble to Annexes II to VI;

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

(iii) the tonnage intended to be placed on the market per year;

(iv) the toxicological profile of the nanomaterial;

(v) its safety data related to the specific category of cosmetic product as used in it;

(vi) the reasonably foreseeable exposure conditions.

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

[The Commission shall provide a reference number to the submission for the toxicological profile which may replace point a (iv) above]

3. In case the Commission has concerns regarding the safety of the nanomaterial, the Commission shall, without delay, request the SCCS to give its opinion on the safety of these nanomaterials for the relevant categories of cosmetic products and the reasonably foreseeable exposure conditions. The Commission shall make this information public ~~inform the responsible person and the Committee referred to in Article 27 (1)~~. The SCCS shall give its opinion within six months of the Commission request. If any missing data are defined by the SCCS, the Commission shall require the responsible person to provide them within one explicitly stated reasonable time, which shall not be extended. The SCCS shall give its final opinion within six months of submission of additional data.

4. The Commission may, at any time, invoke the procedure in the previous paragraph if it has any safety concerns, for example due to new information supplied by a third party.

5. Taking into account the opinion of the SCCS, and where there is a potential risk to human health, including when there is insufficient data, the Commission shall make this information public and may amend Annexes II and III of this Regulation. ~~The Commission shall immediately inform the responsible person, stating the grounds of its decision.~~

6. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 27(3).

7. On imperative grounds of urgency the Commission may use the procedure referred to in Article 27(4).

8. The following information shall be made available by the Commission:

(a) By [add date: forty two months after the date of entry into force of this Regulation], the Commission shall make available a list of all nanomaterials used in cosmetic products, including those used as colorants, UV-filters and preservatives in a separate section, placed on the market, indicating the specific categories of cosmetic products and the reasonably foreseeable exposure conditions. This list shall be regularly updated thereafter and be made publicly available.

(b) The Commission shall submit to the European Parliament and the Council an annual Status report, which will give information on developments in the use of nanomaterials in cosmetic products within the Community, including those used as colorants, UV-filters and preservatives in a separate section. The first report will be presented before the [add date: forty-eight months after date of entry into force]. The report update shall summarise, in particular, the new nanomaterials in new categories of cosmetic products, the number of notifications, the progress made in developing nano-specific assessment methods and safety assessment guides, and information on international cooperation programmes.

9. The Commission shall regularly review the provisions of this Regulation concerning nanomaterials in the light of scientific progress and, where necessary, shall propose suitable amendments to those provisions.

The first review shall be provided at the latest by … [add date: [x years] after the date of application of this Regulation]

82/368/EEC (adapted)

Article 13
Traces of prohibited substances

The **non intended** presence of **small quantity of a** prohibited substance[]**, stemming from impurities of natural or synthetic ingredients, the manufacturing process, storage, migration from ~~transport facilities or~~ packaging**, **which [~~cannot be eliminated by current technology or~~] is** technically unavoidable in good manufacturing practice**,** shall be allowed provided that such presence **is in conformity with Article 3**.

Ⓔ 2003/15/EC Art. 1.2 (adapted)

new

Chapter V
Animal testing

Article ~~4a~~ 14

Animal testing

1. Without prejudice to the general obligations deriving from Article ~~2~~3, the following shall ~~not be allowed~~ **be prohibited** ~~Member States shall prohibit~~:

(a) the ~~marketing~~ placing on the market of cosmetic products where the final formulation, in order to meet the requirements of this Regulation ~~Directive~~, has been the subject of animal testing using a method other than an alternative method after such alternative method has been validated and adopted at Community level with due regard to the development of validation within the OECD;

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

(c) the performance within the Community ~~on their territory~~ of animal testing of finished cosmetic products in order to meet the requirements of this Regulation ~~Directive~~;

(d) the performance within the Community ~~on their territory~~ of animal testing of ingredients or combinations of ingredients in order to meet the requirements of this Regulation ~~Directive~~, no later than the date on which such tests are required to be replaced by one or more validated alternative methods listed in [~~Annex V to Council Directive 67/548/EEC~~] **Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)**[53] ~~of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances~~[54] or in Annex VIII~~IX~~ to this Regulation ~~Directive~~.

~~No later than 11 September 2004 the Commission shall, in accordance with the procedure referred to in Article 10(2) and after consultation of the Scientific Committee on Cosmetic Products and Non-Food Products intended for consumers (SCCNFP) establish the contents of Annex IX~~.

2. The Commission, after consultation of the ~~SCCNFP~~ []**SCCS** and of the European Centre for the Validation of Alternative Methods (ECVAM) and with due regard to the development of validation within the OECD, ~~shall establish~~ has established timetables for the implementation of the provisions under paragraph 1(a), (b) and (d), including deadlines for the phasing-out of the various tests. The timetables ~~shall be~~ were made available to the public on 1st October 2004 ~~not later than 11 September 2004~~ and ~~be~~ sent to the European Parliament and the Council. The period for implementation shall be limited to 11 March 2009 ~~a maximum of six years after the entry into force of Directive 2003/15/EC~~[55] in relation to paragraph 1(a), (b) and (d).

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[53] OJ L 142, 31.5.2008, p. 1

[54] OJ 196, 16.8.1967, p. 1. Directive as last amended by ~~Commission Directive 2001/59/EC (OJ L 225, 21.8.2001, p. 1)~~ […] .

[55] ~~OJ L66, 11.3.2003, p.26.~~

~~2.1.~~ In relation to the tests concerning repeated-dose toxicity, reproductive toxicity and toxicokinetics, for which there are no alternatives yet under consideration, the period for implementation of paragraph 1(a) and (b) shall be limited to 11 March 2013 ~~a maximum of 10 years after the entry into force of Directive 2003/15/EC~~.

~~2.2.~~ The Commission shall study possible technical difficulties in complying with the ban in relation to tests, in particular those concerning repeated-dose toxicity, reproductive toxicity and toxicokinetics, for which there are no alternatives yet under consideration. Information about the provisional and final results of these studies should form part of the yearly reports presented pursuant to Article ~~9~~30.

On the basis of these annual reports, the timetables established in accordance with paragraph 2 , first subparagraph, may be adapted up to 11 March 2009 ~~within a maximum time limit of six years~~ in relation to ~~as referred to in~~ the first subparagraph ~~paragraph 2~~ or 11 March 2013 ~~10 years~~ in relation to ~~as referred to in~~ the second subparagraph ~~paragraph 2.1~~ and after consultation of the entities referred to in the first subparagraph ~~paragraph 2~~.

~~2.3~~ The Commission shall study progress and compliance with the deadlines as well as possible technical difficulties in complying with the ban. Information about the provisional and final results of the Commission studies should form part of the yearly reports presented pursuant to Article ~~9~~30. If these studies conclude, at the latest two years prior to the end of the maximum period referred to in the second subparagraph ~~paragraph 2.1~~, that for technical reasons one or more tests referred to in that subparagraph ~~paragraph 2.1~~ will not be developed and validated before the expiry of the period referred to therein ~~in paragraph 2.1~~ it shall inform the European Parliament and the Council and shall put forward a legislative proposal in accordance with Article 251 of the Treaty.

~~2.~~4 In exceptional circumstances where serious concerns arise as regards the safety of an existing cosmetic ingredient a Member State may request the Commission to grant a derogation from paragraph 1. The request shall contain an evaluation of the situation and indicate the measures necessary. On this basis, the Commission may, after consultation of the []**SCCS** ~~SCCNFP~~ and by means of a reasoned decision, authorise the derogation ~~in accordance with the procedure referred to in Article 10(2)~~. This authorisation shall lay down the conditions associated with this derogation in terms of specific objectives, duration and reporting of the results.

The measures referred to in the first subparagraph, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 27(3).

A derogation shall only be granted if:

(a) the ingredient is in wide use and cannot be replaced by another ingredient able to perform 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.

The decision on the authorisation, the conditions associated with it and the final result achieved shall be part of the annual report to be presented by the Commission in accordance with Article ~~9~~30.

3. For the purposes of this Article and Article 16:

(a) 'finished cosmetic product' means the cosmetic product in its final formulation, as placed on the market and made available to the final consumer, or its prototype.

(b)'prototype' means a first model or design that has not been produced in batches, and from which the finished cosmetic product is copied or finally developed.

𝔼 88/667/EEC (adapted)

~~*Article 5*~~

~~Member States shall allow the marketing of cosmetic products containing:~~

~~(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 colouring agents listed in Annex IV, Part 2, within the limits and under the conditions laid down, until the admission dates given in that 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 that 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 Part 2 of Annex VII, within the limits and under the conditions laid down, until the dates given in column (f) of that Annex.~~

~~At these dates, these substances, colouring 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.~~

~~*Article 5a*~~

~~1. No later than 14 December 1994 the Commission shall, under the procedure laid down in Article 10, compile an inventory of ingredients employed in cosmetic products, on the basis in particular of information supplied by the industry concerned.~~

~~For the purposes of this Article, 'cosmetic ingredient' shall mean any chemical substance or preparation of synthetic or natural origin, except for perfume and aromatic compositions, used in the composition of cosmetic products.~~

~~The inventory shall be divided into two sections: one concerning perfume and aromatic raw materials and the second concerning other substances.~~

~~2. The inventory shall contain informtion on:~~

~~the identity of each ingredient, in particular its chemical name, the CTFA name, the European Pharmacopoeia name, the international non-proprietary names recommended by the World Health Organization, the Einecs, Iupac, CAS and colour index numbers, and the common name referred to in Article 7 (2),~~

~~the usual function(s) of the ingredient in the final product,~~

~~where appropriate, restrictions and conditions of use and warnings which must be printed on the label by reference to the Annexes.~~

~~3. The Commission shall publish the inventory and shall update it periodically under the procedure provided for in Article 10. The inventory shall be indicative and shall not constitute a list of the substances authorized for use in cosmetic products~~

88/667/EEC (adapted)

Chapter VI
Consumer information

Article ~~6~~15

Labelling[56]

93/35/EEC (adapted)

1. ~~Member States shall take all measures necessary to ensure that cosmetic products may be marketed only if the~~ Without prejudice to other provisions in this Article, **cosmetic products shall only be made available on the market if [~~the responsible person shall label~~]** the container and packaging of cosmetic products ~~shall bear the~~ **bear [~~with~~]** the following information in indelible, easily legible and visible lettering~~; the information mentioned in point (g) may, however, be indicated on the packaging alone:~~

88/667/EEC (adapted) new

(a) the name or style and the address ~~or registered office~~ of ~~the manufacturer or~~ the responsible person ~~responsible for marketing the cosmetic product who is established within the Community~~. Such information may be abbreviated in so far as the abbreviation makes it ~~generally~~ possible to identify ~~the undertaking.~~ 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; ~~[~~**~~Member States may require that~~~~]~~ The country of origin shall be specified for imported cosmetic products;**

[56] DE, HU highlight problem with internet sales where ingredients list and labelling in general is not available pre-purchase.

(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 millilitres, 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;

€ 2003/15/EC Art. 1.3 (adapted) new

(c) the ~~date of minimum durability~~ date until which the cosmetic product, stored under appropriate conditions, continues to fulfil its initial function and, in particular, remains in conformity with Article 3 (hereinafter: "date of minimum durability");

The date itself or details of where it appears on the packaging shall be preceded by

the symbol given in point 3 of Annex VII to this Regulation or ~~indicated by~~

the words: 'best used before the end of'. ~~followed by either: the date itself, or~~

~~details of where it appears on the packaging;~~

The date of minimum durability[57] 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.

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[57] PT proposes replacement by "expiry date", concern on confusion between two differing concepts; new recital (38) not clear enough. DE reservation.
See EP am. Nr 85, 86, 87: SE, BE, DE reservation.

Indication of the date of minimum durability shall not be mandatory for cosmetic products with a minimum durability of more than 30 months[58]. 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**[59]. This information shall be indicated, **except when the concept of the durability after opening is not relevant,** by the symbol ~~given in Annex VIIIa~~ set out in point 2 of Annex VII to this Regulation followed by the period (in months and/or years);

93/35/EEC (adapted)

(d) particular precautions to be observed in use, and at least ~~especially~~ those listed in ~~the column 'Conditions of use and warnings which must be printed on the label' in~~Annexes III to VI ~~III, IV, VI and VII, which must appear on the container and packaging,~~ and ~~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 the container and the packaging;~~

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58 HU, LT, PT, SE: Date of minimum durability should always be mandatory. HU proposes indications on minimum durability (or unlimited durability, if applicable) in case of products where the minimum durability is longer than 30 months but PAO is not relevant. SE propose deletion of paragraph to enwiden minimum durability to all products (MD 24/08). See recital 38.

59 LT, supported by ES, proposes: "and fulfils its initial function**.** ". DE suggests explanatory recital.

𝔼 88/667/EEC (adapted)

(e) the batch number of manufacture or the reference for identifying the cosmetic product[60] ~~goods~~. Where this is impossible for practical reasons because the cosmetic products are too small, such information need appear only on the packaging[61];

𝔼 93/35/EEC (adapted)

(f) the function of the cosmetic product, unless it is clear from its ~~the~~ presentation ~~of the product~~;

𝔼 2003/15/EC Art. 1.4 (adapted) new

(g) a list of ingredients ~~in descending order of weight at the time they are added~~. This information may be indicated on the packaging alone. The ~~That~~ list shall be preceded by the term ~~word~~'ingredients'. ~~Where that is impossible for practical reasons, an enclosed leaflet, label, tape or card must contain the ingredients to which the consumer is referred either by abbreviated information or the symbol given in Annex VIII, which must appear on the packaging.~~

[60] BE supported by AT, IE, ES, proposes deletion of "or the reference for identifying the cosmetic product" for the purpose of traceability, as only batch number of manufacture identifies the batch of production (MD 16/08). MT supported by PT proposes using date of minimum durability instead of batch number for tracking. BE reservation.

[61] DE reservation on exception for small products, emphasis on importance of batch number on product, supported by SK.

For the purpose of this article 'ingredient' means any substance or mixture of substances intentionally used [~~added]~~ to the cosmetic product during the process of manufacturing. The following shall not, however, be regarded as ingredients:

(i) ~~-~~ impurities in the raw materials used,

(ii) ~~-~~ subsidiary technical materials used in the preparation but not present in the final product,

~~**(iii) - 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 terms 'parfum' ~~word 'perfume'~~ or 'aroma'. **Moreover**, the presence of substances, the mention of which is required under the column 'Other ~~limitations and requirements~~' in Annex III, shall be indicated in the list **of ingredients in addition to the ~~said~~ terms parfum or aroma..** ~~irrespective of their function in the product.~~

[~~Perfume and aromatic compositions and their raw materials shall be referred to by the terms 'parfum' word 'perfume' or 'aroma'~~[62]~~.~~ **~~However, allergenic fragrances, listed in annex III, if added, as such, at concentrations exceeding 0,01 % by weight, shall be explicitly listed in the list of ingredients.~~]**

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 %.

[62] Note for translators: the words "ingredients, parfum, aroma" are not to be translated as these are to be considered as international common names.

~~Colouring agents~~ Colorants other than colorants intended to colour the hair may be listed in any order after the other cosmetic ingredients~~, in accordance with the colour index number or denomination adopted in Annex IV~~. For decorative cosmetic products marketed in several colour shades, all ~~colouring agents~~ colorants other than colorants intended to colour the hair used in the range may be listed, provided that the words 'may contain'[63] or the symbol '+/-' are added. **The CI (Colour Index) nomenclature shall be used, where applicable.**

~~An ingredient must be identified by the common name referred to in Article 7(2) or, failing that, by one of the names referred to in Article 5a(2), first indent.~~

~~In accordance with the procedure referred to in Article 10(2), the Commission may adapt the criteria and conditions set out in Commission Directive 95/17/EC of 19 June 1995 laying down detailed rules for the application of Council Directive 76/768/EEC as regards the non-inclusion of one or more ingredients on the list used for the labelling of cosmetic products[64] under which a manufacturer may, for reasons of trade secrecy, apply not to include one or more ingredients on the abovementioned list.~~

[63] LT proposes deletion of "the words 'may contain'" (MD 34/08).
[64] ~~OJ L 140, 23.6.1995, p. 26.~~

𝔼 93/35/EEC (adapted)

2. When it is impossible for practical reasons to label the information mentioned in points (d) and (g) of paragraph 1 as provided, the following applies:

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

Unless impracticable, this information shall be referred to by abbreviated information or the symbol given in point 1 of Annex VII, which must appear on the container or packaging for the information referred in point (d) of paragraph 1 and on packaging for the information referred in point (g) of paragraph 1.

~~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 to the cosmetic product.~~

3. In the case of soap, bath balls and other small products where it is impossible for practical reasons ~~impracticable, for reasons of size or shape,~~ for the particulars referred to in point (g) of paragraph 1 ~~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 the container in which the cosmetic product is exposed for sale.[65]

4~~2~~. For 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, Member States shall adopt detailed rules for indication of the particulars referred to in paragraph 1.

[65] DE ponders whether it is possible to include provisions in the regulation for the putting on the market of cosmetic products that are not pre-packaged, in order to achieve a uniform, Community-wide procedure.

5. The language of the information mentioned in points (b), (c), (d) and (f) of paragraph 1 **and in paragraphs (2) to (4)** shall be determined by the law of the Member States in which the product is made available to the end user.

~~6. The **distributors and** persons making the product available to the end user **[] have to make sure/verify that the requirements set out in paragraphs [] 1 to 5 are fulfilled.**~~

7 The information mentioned in point (g) of paragraph 1 shall be expressed by using the common ingredient name set out in the glossary provided for in Article 28. In the absence of a common ingredient name, a term as contained in a generally accepted nomenclature shall be used.

ℂ 88/667/EEC (adapted) Ł 1 2003/15/EC Art. 1.5

Article 16

Product claims

~~3.~~1. ~~Member States shall take all measures necessary to ensure that, i~~In the labelling, ~~putting up for sale~~ making available on the market and advertising of cosmetic products, text, names, trade marks, pictures and figurative or other signs shall ~~are~~ not be used to imply that these products have characteristics **or functions** [66] which they do not have. Ł 1 ---

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new

~~Compliance with the first subparagraph shall be presumed if the cosmetic products are in accordance with the relevant harmonised standards, the references of which have been published in the *Official Journal of the European Union*.~~

66 COM reservation.

2. The Commission, in cooperation with Member States, shall establish an action plan regarding claims used and fix priorities for determining common criteria justifying the use of a claim.

After consultation of the SCCS or other relevant authorities, the Commission shall adopt a list of common criteria for claims which may be used in respect of cosmetic products, in accordance with the regulatory procedure with scrutiny referred to in Article 27(3), taking into account provisions of Directive 2005/29/EC.

Three years after the date of application of the Regulation, the Commission shall submit to the European Parliament and the Council a report [] regarding the use of claims on the basis of the common criteria adopted under the previous subparagraph. If the report concludes that claims used in respect of cosmetic products are not in conformity with the common criteria, the Commission shall take appropriate measures to ensure compliance in cooperation with the Member States.

€ 2003/15/EC Art. 1.5 (adapted)

3[~~2~~]. ~~Furthermore, the manufacturer or~~ The responsible person ~~responsible~~ ~~for placing the product on the Community market~~ may refer ~~take~~ ~~advantage~~, on the product packaging or in any document, notice, label, ring or collar accompanying or referring to the cosmetic product, to ~~of~~ 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. ~~Guidelines shall be adopted in accordance with the procedure referred to in Article 10(2) and published in the *Official Journal of the European Union*~~[67]. ~~The European Parliament shall receive copies of the draft measures submitted to the Committee.~~

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[67] UK proposes that the reference to the guidelines at the end of the paragraph should be retained or made in official Commission guidance accompanying the Regulation.

Ⓔ 2003/15/EC Art. 1.7 (adapted)

Article 17

Access to information for the public[68]

Without prejudice to the protection, in particular, of commercial secrecy and of intellectual property rights, ~~Member States~~ the responsible person shall ensure that the qualitative and quantitative composition of the cosmetic product and, in the case of perfume compositions and perfumes, 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 is ~~information required under (a) and (f) shall be~~ made **easily** ~~easily~~ accessible **to the public** by any appropriate means~~, including electronic means~~.

The quantitative information regarding composition of the cosmetic product required ~~under (a)~~ to be made publicly accessible shall be limited to **hazardous** []substances [~~covered by Directive 67/548/EEC~~] **in accordance with Article 3 of Regulation (EC) No … of the European Parliament and of the Council of … on Classification, Labelling and Packaging of Substances and Mixtures.** [69]

[]

[68] PL proposes indication of language of communication with consumer and addition of list of ingredients.

[69] NL proposes reference to health hazards and to Part 3 of Annex I (GHS); DK reservation.

new

Chapter VII

Market surveillance

Article 18
In-market control

Member States shall survey compliance with this Regulation via in-market controls of the cosmetic products made available on the market. **They shall perform appropriate checks of products and 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.**

Member States shall also survey compliance with good manufacturing practices principles.[70]

Member States shall entrust market surveillance authorities with the necessary powers, resources and knowledge in order to properly perform their tasks. [71]

[70] DE, ES, IE, PT concern on whether GMP principles covers import practices (MD 26/08). PT propose to cover role of distributor: "Member states shall regulate the distribution chains for purposes of market surveillance."(MD 12/08). COM reservation.

[71] See EP amendment 23.

Article 19[72]
Communication of serious undesirable effects

1. The responsible person[73] **and the distributors** shall without delay notify the following to the competent authority **of the Member State where the serious undesirable effect occurred ~~where the product information file is readily accessible~~**[74]:

(a) all serious undesirable effects which are known to him or which should reasonably be expected to be known to him[75],

(b) the [~~complete commercial~~] name of the product concerned, **enabling its specific identification;**

(c) the corrective measures taken by him, if any;

2. **When the responsible person reports serious undesirable effects to t**he competent authority of the Member State where the [~~serious undesirable~~] effect occurred, **this competent authority** shall immediately transmit the information referred to in paragraph 1 [~~concerning the product~~] [~~, together with any other information available on serious undesirable effects coming from consumer or health professionals,~~] to the competent authorities of the other Member States [].

2a. When distributors report serious undesirable effects to the competent authority of the Member State where the effect occurred, this competent authority shall immediately transmit the information referred to in paragraph 1 to the competent authorities of the other Member States and to the responsible person.

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72 PT supported by DE highlight role of other authorities (ex: health authorities and medical practitioners). DK proposes a common communication system; SK propose wider communication of effects to responsible person and distributor.

73 PL reservations on excessive duties on retailers, doubts on qualifications of retailers, asks clarification on distinction of roles.

74 HU propose informing MS where the undesirable effect has taken place. PL reservation.

75 UK proposes deleting: "or which should reasonably be expected to be known to him".

2b. When end users or health professionals report serious undesirable effects to the competent authority of the Member State where the effect occurred, this competent authority shall immediately transmit the information on the product concerned to the competent authorities of the other Member States and to the responsible person.

3. Competent authorities may use the information referred to in this Article [~~only~~] for the purposes of in-market surveillance, **market analysis, evaluation and consumer information in the context of Articles 21, 21a and 22**[76].

Article 20
Information on [~~*concentration of*~~] *substances*

In case of serious doubt regarding the safety of any substance contained in cosmetic products, the competent authority of a Member State where a product containing such a substance is made available on the market may by reasoned request require 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 the cosmetic products.[77]

Competent authorities may use the information referred to in this Article [~~only~~] for the purposes of in-market surveillance**, market analysis, evaluation and consumer information in the context of Articles 21, 21a and 22**[78]**.**

[76] COM reservation. DK propose to add "statistical purposes".
[77] ES would favour a broader formulation reading "list shall indicate all the information deemed necessary". COM reservation, requirement too broad.
[78] COM reservation.

Chapter VIII

Non-compliance, safeguard clause

Article 21 [79]
Non compliance ***by the responsible person***

1. **Without prejudice to paragraph 4,** competent authorities shall require the responsible person to take all appropriate measures, including corrective actions bringing the product into compliance[80], 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:

81

79 AT, DE, DK, PL, PT, specific or partial reservations.
80 DE highlights lack of detail and accuracy as to what provisions are to be subject to penalties.
81 BE propose adding: "(oa) the safety requirements referred to in Article 3;". COM reservation, refers to Article 22.

(c) the good manufacturing practices referred to in Article 5;

(-a) the safety assessment referred to in Article 7;

(a) the requirements for the product information file referred to in Article 8;

(aa) the provisions on sampling and testing referred to in Article 9;

(b) the notification requirements referred to in Article 10;

(d) the restrictions for substances referred to in Articles 11**,** 12 **and 13**;

(g) the animal testing requirements referred to in Article 14.

(e) the labelling requirements referred to in Article 15(1), (2), **(5)** and (**6**);

(f) the requirements related to product claims set out in Article 16;

(h) the access to information for the public referred to in Article 17;

(i) the communication of serious undesirable effects referred to in Article 19;

(j) the information requirements on substances referred to in Article 20.

1a. Where applicable, the competent authority shall inform the competent authority of the Member State where the responsible person is established of the measures which it has required the responsible person to take.

2. The responsible person shall ensure that the measures referred to in paragraph 1 are taken in respect of all the products concerned which are made available on the market throughout the Community.[82]

3. In the case of serious risks for human health, where the competent authority considers that the non-compliance is not limited to the territory of the Member State where the product is made available on the market, it shall inform the Commission and the competent authorities of the other Member States of the measures which it has required the responsible person to take.

4. The competent authority 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 in the following cases:

(a) where an immediate action is necessary in case of serious risk for human health; or

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

In the case of serious risks for human health, that competent authority shall inform the Commission and the competent authorities of the other Member States, without delay, of the measures taken.

[]

[82] ES proposes differentiation between products subject to corrective measures and others (MD 26/08).

4a. **In the absence of a serious risk for human health, in the case where the responsible person does not take all appropriate measures, the competent authority shall inform without delay the competent authority of the Member State where the responsible person is established of the measures taken.**

5. For the purposes of paragraphs 3 and 4 of this Article, the information exchange system provided for in Article 12(1) of Directive 2001/95/EC of the European Parliament and of the Council[83] shall be used.

Article 12 (2), (3) and (4) of Directive 2001/95/EC **and Article 23 of Regulation 765/2008/EC**[84] shall **also** apply.

Article 21 a

Non compliance by the distributors

Competent authorities shall require the distributors to take all appropriate measures, including corrective actions bringing the product into compliance, the withdrawal of the product from the market or its recall within a given reasonable time limit, commensurate with the nature of the risk, where there is non compliance with obligations provided by Article 4b.

[83] OJ L 11, 15.1.2002, p. 4.
[84] COM scrutiny reservation.

Ⓔ 76/768/EEC (new)

~~*Article 12*~~

~~1. If a Member State notes, on the basis of a substantiated justification, that a cosmetic product, although complying with the requirements of the Directive, represents a hazard to health, it may provisionally prohibit the marketing of that product in its territory or subject it to special conditions. It shall immediately inform the other Member States and the Commission thereof, stating the grounds for its decision.~~

Ⓔ 88/667/EEC (new)

~~2. The Commission shall as soon as possible consult the Member States concerned, following which it shall deliver its opinion without delay and take the appropriate steps.~~

Ⓔ 76/768/EEC (new)

~~3. If the Commission is of the opinion that technical adaptations to the Directive are necessary, such adaptations shall be adopted by either the Commission or the Council in accordance with the procedure laid down in Article 10. In that event, the Member State which has adopted safeguard measures may maintain them until entry into force of the adaptations.~~

new

Article 22
Safeguard clause

1. **In the case of products meeting the requirements listed in Article 21 (1), where** **[**~~Where Article 21 does not apply, and~~**]** a competent authority ascertains, **or has reasonable grounds for concern,** that a cosmetic product **or products** [~~placed~~] **made available** on the market present **or could present** a serious risk for 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 otherwise restricted.

2. The competent authority shall immediately communicate to the Commission and the competent authorities of the other Member States of the measures taken and any supporting data.

   For the purposes of the first subparagraph, the information exchange system provided for in Article 12(1) of Directive 2001/95/EC shall be used.

   Article 12 (2), (3) and (4) of Directive 2001/95/EC shall apply.

3. The Commission shall determine**, as soon as possible,**[85] whether the provisional measures referred to in paragraph 1 are justified or not. For that purpose it shall, whenever possible, consult the interested parties, the Member States and the []**SCCS.**

4. If the provisional measures are justified, Article 26(1) shall apply.

85 DE proposes ",within 3 months, ".

5. If the provisional measures are not justified the Commission shall inform the Member States thereof and the competent authority concerned shall repeal the provisional measures in question.

Ⓔ 76/768/EEC (new)

~~*Article 13*~~

~~Precise reasons shall be stated for any individual measures placing a restriction or ban on the marketing of cosmetic products taken pursuant to this Directive. It shall be notified to the party concerned together with particulars of the remedies available to him under the laws in force in the Member States and of the time limits allowed for the exercise of such remedies.~~

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new

Article 23
Good administrative practices

1. Any decision taken pursuant to Articles 21 and 22 shall state the exact grounds on which it is based. It shall be notified **by the competent authority** without delay to the responsible person, who shall at the same time be informed of the remedies available to him under the law of the Member State concerned and of the time limits to which remedies are subject.

2. Except in case where immediate action is necessary for reasons of serious risk for human health, the responsible person shall have the opportunity to put forward his viewpoint 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 Article 21a and 22. [86]

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86 PL, DE and UK scrutiny reservation.

Chapter IX
Administrative cooperation

Article 24
Cooperation between competent authorities

1. The competent authorities of the Member States shall cooperate with each other and with the Commission **to ensure the proper application and due enforcement of this Regulation** and **shall** transmit to each other all information necessary in view of applying this Regulation uniformly.

2. The Commission shall provide for the organisation of an exchange of experience between the competent authorities in order to coordinate the uniform application of this Regulation.

3. Cooperation may be part of initiatives developed at international level.

Article 25[87]

Cooperation regarding verification of product information file

The competent authority of any Member State where the cosmetic product is made available may request the competent authority of the Member State where the product information file is made readily accessible to verify whether the product information file satisfies the requirements referred to in Article 8(2) and whether the information set out therein provide evidence of the safety of the cosmetic product.

The requesting competent authority shall provide a motivation for the request.

Upon that request, the competent authority requested shall, without undue delay **and taking into account the degree of urgency**, carry out the verification and shall inform the requesting competent authority of its finding.

[87] NL proposes the development of guidelines on the functioning of the administrative cooperation

Ⓔ 76/768/EEC (new)

~~*Article 8*~~

~~1. In accordance with the procedure laid down in Article 10 the following shall be determined:~~

~~the methods of analysis necessary for checking the composition of cosmetic products,~~

~~the criteria of microbiological and chemical purity for cosmetic products and methods for checking compliance with those criteria.~~

Ⓔ 93/35/EEC (new)

Ł 1 2003/15/EC Art. 1.8

~~2. The common nomenclature of ingredients used in cosmetic products and, after consultation of the~~ Ł 1 ~~Scientific Committee for Cosmetic Products and Non-Food Products intended for Consumers~~ , ~~the amendments necessary for the adaptation to technical progress of the Annexes shall be adopted in accordance with the same procedure, as appropriate.~~

new

Chapter X
Implementing measures, final provisions

Article 26

Amendment of the Annexes

1. Where there is a potential risk to human health, arising from the use of substances in cosmetic products, which needs to be addressed on a Community-wide basis, the Commission may, after consultation of the []**SCCS**, amend Annexes II to VI accordingly.

   Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 27(3).

   On imperative grounds of urgency, the Commission may use the urgency procedure referred to in Article 27(4).

2. The Commission may, after consultation of the []**SCCS**, amend Annexes III to VI and VIII for the purposes of adapting them to technical and scientific progress.

   Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 27(3).

3. Where it appears necessary, in order to ensure the safety of cosmetic products placed on the market, the Commission may, after consultation of the []**SCCS**, amend Annex I.

   Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 27(3).

2003/15/EC Art. 1.9 (adapted)

Article ~~10~~ 27

Committee

1. The Commission shall be assisted by the Standing Committee on Cosmetic Products.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

new

3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

4. Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply having regard to the provisions of Article 8 thereof.

𝔼 2003/15/EC Art. 1.9 (new)

~~3. The Committee shall adopt its rules of procedure~~

new

Article 28

Glossary of common ingredient names

The Commission shall compile and update a glossary of common ingredient names. **To this end, the Commission shall take account of internationally recognised nomenclatures including the International Nomenclature of Cosmetic Ingredients (INCI).** That glossary shall not constitute a list of the substances authorised for use in cosmetic products.

The common ingredient name shall be applied for the purpose of labelling cosmetic products placed on the market at the latest twelve months[88] after publication of the glossary in the *Official Journal of the European Union*.

Article 29

Competent authorities, poison control centres or assimilated entities

1. Member States shall designate their national competent authorities.

2. Member States shall communicate the details of authorities referred to in paragraph 1 and of the bodies referred to in Article 10(**3**) to the Commission. They shall communicate an update of these details when necessary.

3. The Commission shall compile and update a list of the authorities and bodies referred to in paragraph 2 and make it available to the public.

88 PL: replace "twelve" with "twenty-four". EP amendment 43 "2 years" - DK and UK flexible.

ℂ 82/368/EEC
𝕃 1 2003/15/EC Art. 1.8

~~*Article 8a*~~

~~1. Notwithstanding Article 4 and without prejudice to Article 8 (2), a Member State may authorize the use within its territory of other substances not contained in the lists of substances allowed, for certain cosmetic products specified in its national authorization, subject to the following conditions:~~

~~(a) the authorization must be limited to a maximum period of three years;~~

~~(b) the Member State must carry out an official check on cosmetic products manufactured from the substance or preparation use of which it has authorized;~~

~~(c) cosmetic products thus manufactured must bear a distinctive indication which will be defined in the authorization.~~

~~2. The Member Stats shall forward to the Commission and to the other Member States the next of any authorization decision taken pursuant to paragraph 1 within two months of the date on which it came into effect.~~

~~3. Before expiry of the three-year period provided for in paragraph 1, the Member State may submit to the Commission a request for the inclusion in a list of permitted substances of the substance given national authorization in accordance with paragraph 1. At the same time, it shall supply supporting documents setting out the grounds on which it deems such inclusion justified and shall indicate the uses for which the substance or preparation is intended. Within 18 months of submission of the request, a decision shall be taken on the basis of the latest scientific and technical knowledge, after consultation, at the initiative of the Commission or of a Member State, of the Ł 1 Scientific Committee for Cosmetic Products and Non-Food Products intended for Consumers and in accordance with the procedure laid down in Article 10 as to whether the substance in question may be included in a list of permitted substances or whether the national authorization should be revoked. Notwithstanding paragraph 1 (a), the national authorization shall remain in force until a decision is taken on the request for inclusion in the list.~~

Ȼ 2003/15/EC Art. 1.9 (adapted)

Article ~~9~~ *30*

Annual report on animal testing

Every year the Commission shall present a report to the European Parliament and the Council on:

(~~a~~1) progress made in the development, validation and legal acceptance of alternative methods. The report shall contain precise data on the number and type of experiments relating to cosmetic products carried out on animals. The Member States shall be obliged to collect that information in addition to collecting statistics as laid down by Council Directive 86/609/EEC ~~of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes~~[89]. The Commission shall in particular ensure the development, validation and legal acceptance of alternative test methods which do not use live animals;

(~~b~~2) progress made by the Commission in its efforts to obtain acceptance by the OECD of alternative methods validated at Community level and recognition by third ~~non-member~~ countries of the results of the safety tests carried out in the Community using alternative methods, in particular within the framework of cooperation agreements between the Community and these countries;

(~~c~~3) the manner in which the specific needs of small and medium-sized enterprises have been taken into account.

[89] ~~OJ L 358, 18.12.1986, p. 1.~~

€ 76/768/EEC

~~*Article 11*~~

~~Without prejudice to Article 5 and not later than one year after expiry of the period laid down in Article 14 (1) for implementation of this Directive by the Member States, the Commission shall, on the basis of the results of the latest scientific and technical research, submit to the Council appropriate proposals establishing lists of permitted substances.~~

~~*Article 14*~~

~~1. Member States shall bring into force the provisions needed in order to comply with this Directive within 18 months of its notification and shall forthwith inform the Commission thereof.~~

~~2. Member States may, however, for a period of 36 months from notification of this Directive, authorize the marketing in their territory of cosmetic products which do not conform to the requirements of the Directive.~~

~~3. Member States shall ensure that the texts of such provisions of national law as they adopt in the field governed by this Directive are communicated to the Commission.~~

new

Article 31

Formal objection against harmonised standards

1. When a Member State or the Commission considers that a harmonised standard does not entirely satisfy the requirements set out in the relevant provisions of this Regulation, the Commission or the Member State concerned shall bring the matter before the Committee set up by Article 5 of Directive 98/34/EC, giving its arguments. The Committee shall deliver its opinion without delay.

2. In the light of the Committee's opinion, the Commission shall decide to publish, not to publish, to publish with restriction, to maintain, to maintain with restriction or to withdraw the references to the harmonised standard concerned in the Official Journal of the European Union.

3. The Commission shall inform the Member States and the European standardisation body concerned. It shall, if necessary, request the revision of the harmonised standards concerned.

Article 32

Penalties

Member States shall lay down the provisions on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission on [date to be added: 36 months after publication of this Regulation in the Official Journal of the European Union] at the latest and shall notify it without delay of any subsequent amendment affecting them.

Article 33

Repeal

Directive 76/768/EEC is repealed with effect from [date to be added: 36 months after publication of this Regulation in the Official Journal of the European Union].

References to the repealed Directive shall be understood as references to this Regulation.

This Regulation should be without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law of the Directives set out in Part B of Annex IX.

However, the competent authorities shall continue to keep available the information received pursuant to Article 7(3) and Article 7a(4) of Directive 76/768/EEC and responsible persons shall continue to keep readily accessible the information collected pursuant to Article 7a of that Directive for [7 years] after the date referred to in Article 34(2).

Article 33a

Transitional provisions

By way of derogation from Directive 76/768/EEC, cosmetic products which comply with this Regulation may be placed on the market before the date referred to in Article 34(2).

As from [18 months after entry into force], by way of derogation from Directive 76/768/EEC, notification carried out in accordance with Article 10 of this Regulation shall be considered to comply with Article 7(3) and Article 7a(4) of that Directive.

Article 34[90]

Entry into force ***and date of application***

1. This Regulation shall enter into force on the [twentieth day after its publication in the *Official Journal of the European Union*]

2. It shall apply from [date to be added: 36 months after publication in the Official Journal of the European Union].

[91]

This Regulation shall be binding in its entirety and directly applicable in all Member States.

€ 76/768/EEC

~~*Article 15*~~

~~This Directive is addressed to the Member States.~~

---

new

Done at Brussels, […]

For the European Parliament	*For the Council*
The President	*The President*
[…]	[…]

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90 PL, MT request for clarification on periods of application and effect on products on the market.

91 BE proposes application as from entry into force for the provisions on nanomaterials (MD50/08). See EP amendment nr 28 : "Article 26(2) shall not apply to cosmetic products which contain nanomaterials not yet listed in Annexes III to VIa if they have been placed on the market before the date referred to in paragraph 1 of this Article. These products may remain on the market for two years after the date referred to in paragraph 2. After that date Article 11(h) and Article 26(2) shall apply.".

𝔼 76/768/EEC (adapted)

~~**ANNEX I**~~

~~**ILLUSTRATIVE LIST BY CATEGORY OF COSMETIC PRODUCTS**~~

~~– Creams, emulsions, lotions, gels and oils for the skin (hands, face, feet, etc.).~~

~~– Face masks (with the exception of peeling products).~~

~~– Tinted bases (liquids, pastes, powders).~~

~~– Make-up powders, after-bath powders, hygienic powders, etc.~~

~~– Toilet soaps, deodorant soaps, etc.~~

~~– Perfumes, toilet waters and eau de Cologne.~~

~~– Bath and shower preparations (salts, foams, oils, gels, etc.).~~

~~– Depilatories.~~

~~– Deodorants and anti-perspirants.~~

~~– Hair care products:~~

~~– hair tints and bleaches,~~

~~– products for waving, straightening and fixing,~~

~~– setting products,~~

~~– cleansing products (lotions, powders, shampoos),~~

~~– conditioning products (lotions, creams, oils),~~

~~– hairdressing products (lotions, lacquers, brilliantines).~~

- ~~Shaving products (creams, foams, lotions, etc.).~~
- ~~Products for making up and removing make-up from the face and the eyes.~~
- ~~Products intended for application to the lips.~~
- ~~Products for care of the teeth and the mouth.~~
- ~~Products for nail care and make-up.~~
- ~~Products for external intimate hygiene.~~
- ~~Sunbathing products.~~
- ~~Products for tanning without sun.~~
- ~~Skin-whitening products.~~
- ~~Anti-wrinkle products.~~

new

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 product

~~Description of t~~ **T**he qualitative and quantitative composition of the product, including chemical identity of the substances (incl. chemical name, INCI, CAS, EINECS/ELINCS, **where possible**) and their intended function. In the case of **[~~essential oils,~~]** perfume **and aromatic compositions [~~and perfumes~~]**, 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

~~Description of t~~ **T**he physical and chemical characteristics of the substances **or mixtures**, [~~the raw-material~~] as well as the cosmetic product.

~~Description of t~~ **T**he stability of the cosmetics product under reasonably foreseeable storage conditions.

3. Microbiological quality

~~Description of t~~ **T**he microbiological specifications of the [~~raw material~~] **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

~~Description of t~~ **T**he purity of the substances and **[**~~raw material~~**]** **mixtures**.
In the case of traces of prohibited substances, evidence for their technical unavoidability.
~~Description of t~~ **T**he relevant characteristics of packaging material, in particular purity and stability.

5. Normal and reasonably foreseeable use

~~Description of t~~ **T**he 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 labelling.

6. Exposure to the cosmetic product

~~Description of~~ **Data on the** exposure to 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

~~Description of~~ **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 14, ~~description of~~ 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 sensitisation, 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** ~~and~~, **systemic effects** ~~based on~~ [] ~~NOAEL~~ **and MOS based on NOAEL** shall be **calculated** ~~assessed.~~ The absence of these considerations shall be duly justified.

Particular consideration shall be given to any possible impacts on the toxicological 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

~~Description of~~ **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. ~~description of~~ 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. Labelled warnings and instructions of use

Statement on the need to label any particular warnings and instructions of use in accordance with Article 15(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 ~~calculated~~ **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. ~~If such interaction is not expected, this shall be duly justified.~~

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.

Preamble to Annexes II to VI

(1) For the purposes of the Annexes II to VI:

(a) 'Rinse-off product' means a cosmetic product which is intended **to be removed after application** [~~not to stay in prolonged contact with~~] **on** the skin, the hair or the mucous membranes;

(b) 'Leave-on product' means a cosmetic product which is intended to stay in prolonged contact with the skin, the hair or the mucous membranes;

(c) 'Hair product' means a cosmetic product which is intended to be applied on the hair of head or face, except eye lashes;

(d) 'Skin product' means a cosmetic product which is intended to be applied on the skin;

(e) 'Lip product' means a cosmetic product which is intended to be applied on the lips;

(f) 'Face product' means a cosmetic product which is intended to be applied on the skin of the face;

(g) 'Nail product' means a cosmetic product which is intended to be applied on nails;

(h) 'Oral product' means a cosmetic product which is intended to be applied on teeth or the mucous membranes of the oral cavity;

(i) 'Product applied on mucous membranes' means a cosmetic product which is intended to be applied on the mucous membranes

– of the oral cavity,

– **on the rim** []of the eyes,

– or of the external genital organs;

(j) 'Eye product' means a cosmetic product which is intended to be applied in the vicinity of the eyes;

(k) 'Professional use' means the application and use of cosmetic products by persons in the exercise of their professional activity.[92]

(2) In order to facilitate substance identification, the following descriptors are used:

– The Non-proprietary Names (INN) for pharmaceutical products, WHO, Geneva, August 1975.

– The Chemical Abstracts Service numbers (CAS).

– The **EC number which correspond to either the** European Inventory of Existing Commercial chemical Substances (EINECS) numbers and the European List of Notified Chemical Substances (ELINCS) numbers **or the registration**[93] **number given under Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH);**

– **The XAN which is the name approved by specific country (X), e.g USAN which correspond to the United State approved name;**

– **The name in the Glossary of Common Ingredient Names referred to in Article 28 of this Regulation**.

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92 DE proposes deletion of this point.

93 MT scrutiny reservation on use of registration number.

(3) Substances listed in Annexes III to VI do not cover nanomaterials, except when specifically mentioned.
