European Parliament legislative resolution of 24 March 2009 on the proposal for a regulation of the European Parliament and of the Council on cosmetic products (recast) (COM(2008)0049 – C6-0053/2008 – 2008/0035(COD))

(Codecision procedure: recast)

The European Parliament ,

– having regard to the Commission proposal to the European Parliament and the Council (COM(2008)0049),

– having regard to Article 251(2) and Article 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C6-0053/2008),

– having regard to the Interinstitutional Agreement of 28 November 2001 on a more structured use of the recasting technique for legal acts(1) ,

– having regard to the letter of 21 November 2008 from the Committee on Legal Affairs to the Committee on the Environment, Public Health and Food Safety in accordance with Rule 80a(3) of its Rules of Procedure,

– having regard to Rules 80a and 51 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinion of the Committee on Legal Affairs (A6-0484/2008),

A. whereas, according to the Consultative Working Party of the Legal Services of the European Parliament, the Council and the Commission, the proposal in question does not include any substantive amendments other than those identified as such in the proposal and whereas, as regards the codification of the unchanged provisions of the earlier acts together with those amendments, the proposal contains a straightforward codification of the existing texts, without any change in their substance,

1. Approves the Commission proposal as adapted to the recommendations of the Consultative Working party of the legal services of the European Parliament, the Council and the Commission and as amended below;

2. Takes note of the Commission statements annexed to this resolution;

3. Calls on the Commission to refer the matter to Parliament again if it intends to amend the proposal substantially or replace it with another text;

4. Instructs its President to forward its position to the Council and the Commission.

(1) OJ C 77, 28.3.2002, p.1.

Position of the European Parliament adopted at first reading on xx March 2009 with a view to the adoption of Regulation (EC) No .../2009 of the European Parliament and of the Council on cosmetic products (recast)

P6_TC1-COD(2008)0035

(Text with EEA relevance)

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 ‖ ,

Having regard to the opinion of the European Economic and Social Committee(1) ,

Acting in accordance with the procedure laid down in Article 251 of the Treaty(2) ,

Whereas:

(1) Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products(3) 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 aims at simplifying procedures and streamlining terminology thereby reducing administrative burden and ambiguities. Moreover, 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 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.

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(4) This Regulation comprehensively harmonises the rules in the Community in order to achieve an internal market for cosmetic products while ensuring a high level of protection of human health.

(5) The environmental concerns that substances used in cosmetic products may raise are considered through the application of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a

European Chemicals Agency (4) , which enables the assessment of environmental safety in a cross-sectoral manner.

(6) This Regulation relates only to cosmetic products and not to medicinal products, medical devices or biocidal products. The 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.

(7) 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, face masks, tinted bases (liquids, pastes, powders), make-up powders, after-bath powders, hygienic powders, toilet soaps, deodorant soaps, perfumes, toilet waters and eau de Cologne, bath and shower preparations (salts, foams, oils, gels), depilatories, deodorants and anti-perspirants, hair 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), 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.

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(8) The Commission should define the categories of cosmetic products which are relevant for the application of this Regulation.

(9) Cosmetic products should be safe under normal or reasonably foreseeable conditions of use. In particular, a risk-benefit reasoning should not justify a risk to human health

(10) 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 (5) .

(11) In order to establish clear responsibilities, each cosmetic product should be linked to a responsible person who is established within the Community.

(12) 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.

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

(14) 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.

(15) 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 of 22 July 2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights (6) and Directive 2004/48/EC of the European parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (7) . In-market controls represent a powerful means of identifying products that do not comply with the requirements of this Regulation.

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

(17) 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.

(18) 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.

(19) It should be made clear which information is to be made available to the competent authorities. That 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.

(20) 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.

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

(22) For reasons of effective market surveillance, the competent authorities should be notified of certain information about the cosmetic product placed on the market.

(23) 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.

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

(25) 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.

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(26) 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.

(27) 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.

(28) 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.

(29) 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.

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

(31) The Commission should regularly review the provisions on nanomaterials in the light of scientific progress.

(32) Given the hazardous properties of substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), category 1A, 1B and 2 , pursuant to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (8) , their use in cosmetic products should be prohibited. 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 SCCS and are regulated by the Commission in the Annexes to this Regulation. With regard to substances which are

classified as CMR 1A or 1B substances, there should be a possibility, in the exceptional case where these substances are complying with the food safety requirements, including because they are naturally occurring in food, and no suitable alternative substances exist, to use such substances in cosmetic products if such use has been found safe by the 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 1272/2008 ,. Such substances should be continuously reviewed by the SCCS .

(33) A safety assessment of substances, particularly those classified as CMR 1A or 1B substances, should consider the 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 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 overall exposure estimates for these substances.

(34) 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.

(35) The SCCS should give opinions 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.

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

(37) In order to ensure product safety, prohibited substances should only be acceptable at trace levels if they are technologically inevitable with correct manufacturing processes and provided that the product is safe.

(38) The Protocol on protection and welfare of animals annexed to the Treaty 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.

(39) 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(9) 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.

(40) 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.

(41) 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 should therefore be provided. 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.

(42) 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) and with due regard to the development of validation within the Organisation for Economic Cooperation and Development (OECD). After consulting the 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 should be set for the introduction of a definitive prohibition.

(43) The Commission 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. In view, however, of 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. On the basis of annual reports, the Commission should be authorised to adapt the timetables within the respective abovementioned maximum time limits.

(44) 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 Framework Programmes for research.

(45) The recognition by third 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 countries requiring the repetition of such tests using animals.

(46) Transparency is needed regarding the ingredients employed in cosmetic products. Such transparency should be achieved by indication of the ingredients used in a cosmetic product on its packaging. Where for practical reasons it is impossible to indicate the ingredients on the packaging, such particulars should be enclosed so that the consumer can have access to this information.

(47) A glossary of common ingredient names should be compiled by the Commission to ensure uniform labelling and to facilitate identification of cosmetics ingredients. This glossary should not be intended to constitute a limitative list of substances used in cosmetic products.

(48) In order to inform consumers, cosmetic products should bear 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.

(49) 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. In order to ensure that consumers are adequately informed, 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 improve the diagnosis of contact allergies among such consumers and should 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.

(50) 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.

(51) The consumer should be protected from misleading claims concerning efficacy and other characteristics of cosmetic products. In particular Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market (10) is applicable. Furthermore, the Commission, in cooperation with Member States, should define common criteria relative to specific claims for cosmetic products .

(52) 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 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 also taken 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.

(53) 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.

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(54) 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.

(55) 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.

(56) 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.

(57) 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.

(58) In order to address products which, albeit conforming with the provisions of this Regulation might endanger human health, a safeguard procedure should be introduced.

(59) 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.

(60) 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.

(61) 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 information files located in another Member State.

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(62) The Commission should be assisted by the SCCS , an independent risk assessment body.

(63) 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) .

(64) 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.

(65) When, on imperative grounds of urgency, the normal time-limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to apply the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of certain measures relating to CMRs, nanomaterials and potential risks to human health.

(66) 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.

(67) Economic operators as well as Member States and the Commission need sufficient time to adapt to the changes introduced by this Regulation. 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 .

(68) 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.

(69) 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 still be available for the same period of time.

(70) 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.

(71) 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.

HAVE ADOPTED THIS REGULATION:

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 2

Definitions

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

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

b) (b) "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;

c) "mixture" means a mixture or solution composed of two or more substances;

d) (d) "manufacturer" means any natural or legal person who manufactures a cosmetic product or has such a product designed or manufactured, and markets that cosmetic product under his name or trademark;

e) "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 ;

f) (f) "end user" means either consumers or professionals using the cosmetic product;

g) (g) "making available on the market" means any supply 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;

h) (h) "placing on the market" means the first making available of a product on the Community market;

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

j) "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 of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on information society services(12) on the basis of a request made by the Commission in accordance with Article 6 of that Directive;

k) (k) "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;

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

m) (m) "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;

(n) "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;

o) (o) "undesirable effect" means an adverse reaction for human health attributable to the normal or reasonably foreseeable use of a cosmetic product;

p) (p) "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;

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

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

s) "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.

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 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 (k) 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 32(3).

Safety, responsibility , free movement

Article 3

Safety

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

a) presentation including conformity with Directive 87/357 ;
b) labelling;
c) instructions for use and disposal;
d) any other indication or information provided by the responsible person defined in Article 4.

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

Article 4

Responsible person

1. Only cosmetic products for which a legal or natural person is designated within the Community as responsible person shall be placed on the market.

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

3 . For a cosmetic product manufactured within 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 .

4. 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 .

5. 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 .

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.

Article 5

Obligations of the responsible person

1. The responsible person shall ensure compliance with Articles 3 (safety), 8 (GMP), 10 (safety assessment), 11 (product information file), 12 (sampling and analysis), 13 (notification), 14 (restrictions for substances listed in Annexes), 15 (CMR), 16 (nanomaterials), 17 (traces), 18 (animal testing), 19(1),(2) and (5) (labelling), 20 (claims), 21 (information to the public), 23 (communication of SUE) and 24 (information on substances).

2. Responsible persons who consider or have reason to believe that 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, 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.

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 6

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 19(1)(a), (e) and (g) and Article 19(3) and (4) is present;
- the language requirements provided by Article 19(5) are fulfilled;
- date of minimum durability specified, when applicable in Article 19(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 this 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 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 7

Identification within the supply chain

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 three years following the date when the batch of the cosmetic product was made available to the distributor.

Article 8

Good manufacturing practice

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

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

Article 9

Free movement

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

Safety assessment, product information file, notification

Article 10

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) (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 data from all existing sources;

c) (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 32(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 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 .

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 ECHA .

Article 11

Product information file

1. When a cosmetic product is placed on the market, the responsible person shall keep a product information file for the cosmetic product for which he is the responsible person. 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 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 10(1) ;

c) a description of the method of manufacturing and a statement on compliance with good manufacturing practice referred to in Article 8 ;

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

e) data on any animal testing performed by the manufacturer, his agents or suppliers, relating to the development or safety assessment of the cosmetic product or its ingredients, including any animal testing performed to meet the legislative or regulatory requirements of third countries.

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 contained in the product information file shall be available in a language which can be easily understood by the competent authorities of the Member State.

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

Article 12

Sampling and analysis

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

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.

Article 13

Notification

1. Prior to placing the cosmetic product on the market the responsible person shall submit, through electronic means , the following information to the Commission:

a) the category of cosmetic product and its name or names, enabling its specific identification ;

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

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

d) (d) the Member State where the cosmetic product is placed on the market;

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

f) (f) the presence of substances in the form of nanomaterials and:

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

ii) the reasonably foreseeable exposure conditions ;

g) (g) 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 1272/2008 ;

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

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

2. When the product is placed on the market, the responsible person shall notify the original labelling, and, where reasonably legible, a photograph of the corresponding packaging.

3 . As from the date referred to in Article 40(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;

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.

4. Where a cosmetic product is no longer placed on the market as from the date referred to in Article 40(2), the distributor who introduces that product in a Member State after that date 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 in 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.

5 . The Commission shall, without delay, make the information referred to in points (a) to (g) of paragraph 1 and in paragraph 3 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 25, 26 and 27 .

6 . The Commission shall, without delay, make the information referred to in paragraphs 1 and 3 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.

7 . Where any of the information set out in paragraphs 1, 3 and 4 changes, the responsible person and the distributor shall provide an update without delay.

8. The Commission may, taking into account technical and scientific progress and specific needs related to market surveillance, amend paragraphs 1 to 7 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 32(3).

Restrictions for certain substances

Article 14

Restrictions for substances listed in the Annexes

1. Without prejudice to Article 3, cosmetic products shall not contain any of the following:

(a) Prohibited Substances

- prohibited substances listed in Annex II;

(b) Restricted Substances

- restricted substances which are not used in accordance with the restrictions laid down in Annex III;

(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 ;

ii) (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.

(d) Preservatives

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

ii) (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;

(e) UV-filters

(i) UV-filters other than those listed in Annex VI and UV-filters thereby listed but which are not used in accordance with the conditions set out in that Annex;

ii) (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.

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 32(3) .

Article 15

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 2, under part 3 of Annex VI of Regulation (EC) No 1272/2008 shall be prohibited. However, a substance classified in category 2 may be used in cosmetic products if the substance has been evaluated by the SCCS and found safe for use in cosmetic products. To these ends the Commission shall adopt the necessary measures in accordance with the regulatory procedure with scrutiny referred to in Article 32(3) .

2. The use in cosmetic products of substances classified as carcinogenic, mutagenic or toxic for reproduction, of category 1A and 1B under part 3 of Annex VI of Regulation (EC) No 1272/2008 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 1A and 1B under part 3 of Regulation (EC) 1272/2008 , all of the following conditions are fulfilled:

a) (a) 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(13) ;

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

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

d) 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.

In order to implement this paragraph, the Commission shall amend the Annexes to this Regulation in accordance with the regulatory procedure with scrutiny referred to in Article 32(3) within 15 months at the latest after the inclusion of the substances concerned in part 3 of annex VI of Regulation (EC) No 1272/2008 .

On imperative grounds of urgency, the Commission may use the urgency procedure referred to in Article 32(4) .

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

3. By ...(14) , 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.

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

Article 16

Nanomaterials

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

2. The provisions of this Article do not apply to nanomaterials used as colorants, UV-filters or preservatives regulated under Article 14, unless expressly specified.

3. In addition to the notification in Article 13, cosmetic products containing nanomaterials shall be notified by the responsible person to the Commission through electronic means six months prior to the placing on the market, except when they have already been placed on the market by the same responsible person before ... (15) *.

In this latter case, cosmetic products containing nanomaterials placed on the market shall be notified by the responsible person to the Commission between ...** and ... (16) ** through electronic means, in addition to the notification in Article 13.

The first and the second subparagraph shall not apply to cosmetic products containing nanomaterials in conformity with the requirements set out in Annex III.

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

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

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

c) an estimate of the quantity intended to be placed on the market per year;

d) the toxicological profile of the nanomaterial;

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

f) 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 (d) above.

4. 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. 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. The opinion of the SCCS shall be made publicly available.

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

6. 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 may amend Annexes II and III of this Regulation.

7. The Commission may, taking into account technical and scientific progress, amend paragraph 3 by adding requirements.

8. The measures, referred to in paragraphs 6 and 7, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 32(3).

9. On imperative grounds of urgency the Commission may use the procedure referred to in Article 32(4).

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

(a) By ... (17) , the Commission shall make available a catalogue 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 categories of cosmetic products and the reasonably foreseeable exposure conditions. This catalogue 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 ...(18) . 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.

11. 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 … (19) * .

Article 17

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 packaging, which is technically unavoidable in good manufacturing practice, shall be allowed provided that such presence is in conformity with Article 3 .

Animal testing

Article 18

Animal testing

1. Without prejudice to the general obligations deriving from Article 3, the following shall be prohibited

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

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

c) the performance within the Community of animal testing of finished cosmetic products in order to meet the requirements of this Regulation;

d) the performance within the Community of animal testing of ingredients or combinations of ingredients in order to meet the requirements of this Regulation, no later than the date on which such tests are required to be replaced by one or more validated alternative methods listed in 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) (20) or in Annex VIII to this Regulation.

2. The Commission, after consultation of the 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, 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 were made available to the public on 1 October 2004 and sent to the European Parliament and the Council. The period for implementation shall be limited to 11 March 2009 in relation to paragraph 1(a), (b) and (d).

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.

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 35 .

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 in relation to the

first subparagraph or 11 March 2013 in relation to the second subparagraph and after consultation of the entities referred to in the first subparagraph.

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 35 . If these studies conclude, at the latest two years prior to the end of the maximum period referred to in the second subparagraph, that for technical reasons one or more tests referred to in that subparagraph will not be developed and validated before the expiry of the period referred to therein it shall inform the European Parliament and the Council and shall put forward a legislative proposal in accordance with Article 251 of the Treaty.

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 and by means of a reasoned decision, authorise the derogation. 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 32(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 35 .

3. For the purposes of this Article and Article 20 :

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.

Consumer information

Article 19

Labelling

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

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

b) the nominal content at the time of packaging, given by weight or by volume, except in the case of packaging containing less than five grams or five 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;

c) the 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 the words: "best used before the end of".

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

Indication of the date of minimum durability shall not be mandatory for cosmetic products with a minimum durability of more than 30 months. For such products, there shall be an indication of the period of time after opening for which the product is safe and can be used without any harm to the consumer . This information shall be indicated, except when the concept of the durability after opening is not relevant, by the symbol set out in point 2 of Annex VII to this Regulation followed by the period (in months and/or years);

d) particular precautions to be observed in use, and at least those listed in Annexes III to VI and any special precautionary information on cosmetic products for professional use;

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

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

g) a list of ingredients. This information may be indicated on the packaging alone. The list shall be preceded by the term "ingredients".

For the purpose of this Article 'ingredient' means any substance or mixture of substances intentionally used 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.

Perfume and aromatic compositions and their raw materials shall be referred to by the terms "parfum" or "aroma"(21) . Moreover , the presence of substances, the mention of which is required under the column "Other" in Annex III, shall be indicated in the list of ingredients in addition to the terms parfum or aroma .

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 %.

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

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

2. 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.

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

4. 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.

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. 6 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 33 . In the absence of a common ingredient name, a term as contained in a generally accepted nomenclature shall be used.

Article 20

Product claims

1. In the labelling, making available on the market and advertising of cosmetic products, text, names, trade marks, pictures and figurative or other signs shall not be used to imply that these products have characteristics or functions which they do not have.

2 . The 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 32(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 second 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.

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

Article 21

Access to information for the public

Without prejudice to the protection, in particular, of commercial secrecy and of intellectual property rights, the responsible person shall ensure that the qualitative and quantitative composition of the cosmetic product and, in the case of perfume 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 made easily accessible to the public by any appropriate means.

The quantitative information regarding composition of the cosmetic product required to be made publicly accessible shall be limited to hazardous substances in accordance with Article 3 of Regulation (EC) No 1272/2008.

Market surveillance

Article 22

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.

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

Member States shall periodically review and assess the functioning of their surveillance activities. Such reviews and assessments shall be carried out at least every fourth year and the results thereof shall be communicated to the other Member States and the Commission and be made available to the public, by way of electronic communication and, where appropriate, by other means.

Article 23

Communication of serious undesirable effects

1. The responsible person and the distributors shall without delay notify the following to the competent authority of the Member State where the serious undesirable effect occurred :

a) all serious undesirable effects which are known to him or which should reasonably be expected to be known to him;

b) the 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 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.

3. 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.

4. 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.

5 . Competent authorities may use the information referred to in this Article for the purposes of in-market surveillance, market analysis, evaluation and consumer information in the context of Articles 25, 26 and 27 .

Article 24

Information on 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.

Competent authorities may use the information referred to in this Article for the purposes of in-market surveillance, market analysis, evaluation and consumer information in the context of Articles 25, 26 and 27 .

Non-compliance, safeguard clause

Article 25

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, the withdrawal of the product from the market or its recall, within an expressly mentioned time limit, commensurate with the nature of the risk, where there is non compliance with any of the following:

a) (a) the good manufacturing practices referred to in Article 8;
b) the safety assessment referred to in Article 10;
c) (c) the requirements for the product information file referred to in Article 11 ;
d) (d) the provisions on sampling and testing referred to in Article 12;
e) (e) the notification requirements referred to in Article 13 ;
f) (f) the restrictions for substances referred to in Articles 14–17 ;
g) (g) the animal testing requirements referred to in Article 18;
h) (h) the labelling requirements referred to in Article 19(1), (2), (5) and (6) ;
i) (i) the requirements related to product claims set out in Article 20 ;
j) the access to information for the public referred to in Article 21;
k) the communication of serious undesirable effects referred to in Article 23;
l) the information requirements on substances referred to in Article 24.

2. 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 .

3. 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.

4 . 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.

5 . 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.

6. 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.

7 . For the purposes of paragraphs 4 and 5 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 of 3 December 2001 on general product safety (22) shall be used.

Article 12 (2), (3) and (4) of Directive 2001/95/EC and Article 23 of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products (23) shall also apply.

Article 26

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 6.

Article 27

Safeguard clause

1. In the case of products meeting the requirements listed in Article 25(1), where a competent authority ascertains, or has reasonable grounds for concern, that a cosmetic product or products made available on the market present or could present a serious risk 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, 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 31(1) shall apply.

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.

Article 28

Good administrative practices

1. Any decision taken pursuant to Articles 25 and 27 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 Articles 26 and 27.

Administrative cooperation

Article 29

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 30

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 11(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.

Implementing measures, final provisions

Article 31

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 32(3) .

On imperative grounds of urgency, the Commission may use the urgency procedure referred to in Article 32(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 32(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 32(3) .

Article 32

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.

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.

Article 33

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 after publication of the glossary in the Official Journal of the European Union.

Article 34

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 13(6) 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.

Article 35

Annual report on animal testing

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

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 ‖Directive 86/609/EEC. The Commission shall in particular ensure the development, validation and legal acceptance of alternative test methods which do not use live animals;

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 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;

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

Article 36

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 37

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 ...(24) at the latest and shall notify it without delay of any subsequent amendment affecting them.

Article 38

Repeal

Directive 76/768/EEC is repealed with effect from ...(25) *, except Article 4b which is repealed with effect from 1 December 2010 .

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 seven years after the date referred to in Article 40(2).

Article 39

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 40(2).

As from ... (26) , by way of derogation from Directive 76/768/EEC, notification carried out in accordance with Article 13 of this Regulation shall be considered to comply with Article 7(3) and Article 7a(4) of that Directive.

Article 40

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 ...(27) *, except for:

Article 15(1) and (2) which shall apply from 1 December 2010, as well as Articles 14, 31 and 32 where necessary for the application of Article 15(1) and (2); and

Article 16(2) subparagraph 2, which shall apply from ... (28) **.

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

Done at ‖

For the European Parliament For the Council

The President The President

(1) OJ C 27, 3.2.2009, p. 34.
(2) Position of the European Parliament of xx March 2009.
(3) OJ L 262, 27.9.1976, p. 169. ‖
(4) OJ L 396, 30.12.2006, p. 1. Corrected version in OJ L 136, 29.5.2007, p. 3.
(5) OJ L 192, 11.7.1987, p. 49.
(6) OJ L 196, 2.8.2003, p. 7.
(7) OJ L 157, 30.4.2004, p. 45.
(8) OJ L 353, 31.12.2008, p. 1.
(9) OJ L 358, 18.12.1986, p. 1.
(10) OJ L 149, 11.6.2005, p. 22.
(11) OJ L184, 17.7.1999, p. 23. ‖
(12) OJ L 24, 21.7.1998, p. 37. ‖
(13) OJ L 31, 1.2.2002, p. 1.
(14) * Two years after the date of entry into force of this Regulation.
(15) ** 36 months after the date of entry into force of this Regulation.
(16) *** 42 months after the date of entry into force of this Regulation.
(17) * 48 months after the date of entry into force of this Regulation.
(18) * Fifty-four months after date of entry into force of this Regulation.
(19) ** Five years after the date of application of this Regulation.
(20) OJ L 142, 31.5.2008, p. 1.
(21) Note for translators: the words "ingredients, parfum, aroma" are not to be translated as these are to be considered as international common names.
(22) OJ L 11, 15.1.2002, p. 4.
(23) OJ L 218, 13.8.2008, p. 30.
(24) * 42 months after publication of this Regulation in the Official Journal of the European Union.
(25) ** 42 months after entry into force of this Regulation.
(26) * 24 months after entry into force of this Regulation.
(27) ** 42 months after entry into force of this Regulation.
(28) *** 36 months after date of entry into force of this Regulation.