EUROPEAN PARLIAMENT

2004 *2009*

Session document

A6-0484/2008

8.12.2008

***I
REPORT

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))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Dagmar Roth-Behrendt

(Recast - Rule 80a of the Rules of Procedure)

Symbols for procedures

*	Consultation procedure *majority of the votes cast*
**I	Cooperation procedure (first reading) *majority of the votes cast*
**II	Cooperation procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***	Assent procedure *majority of Parliament's component Members except in cases covered by Articles 105, 107, 161 and 300 of the EC Treaty and Article 7 of the EU Treaty*
***I	Codecision procedure (first reading) *majority of the votes cast*
***II	Codecision procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***III	Codecision procedure (third reading) *majority of the votes cast, to approve the joint text*

(The type of procedure depends on the legal basis proposed by the Commission.)

Amendments to a legislative text

In amendments by Parliament, amended text is highlighted in ***bold italics*.** In the case of amending acts, passages in an existing provision that the Commission has left unchanged, but that Parliament wishes to amend, are highlighted in **bold**. Any deletions that Parliament wishes to make in passages of this kind are indicated thus: [...]. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the legislative text for which a correction is proposed, to assist preparation of the final text (for instance, obvious errors or omissions in a given language version). Suggested corrections of this kind are subject to the agreement of the departments concerned.

CONTENTS

Page

DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

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 80 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. 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;

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

[1] OJ C 77, 28.3.2002, p.1.

Amendment 1

Proposal for a regulation
Recital 25 a (new)

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

Amendment 2

Proposal for a regulation
Recital 25 b (new)

Text proposed by the Commission	*Amendment*
	(25b) At present, there is inadequate information on the risks associated with nanomaterials, regardless of their persistence and solubility. In order to better assess their safety, the SCCP should develop test methods which take into account their specific characteristics.

Justification

Nanomaterials contain specific characteristics due to their small size. Special testing method should be developed so that the potential risks relating to their specificities could be identified and evaluated.

Amendment 3

Proposal for a regulation
Recital 25 c (new)

Text proposed by the Commission	*Amendment*
	(25c) The Commission should regularly review the provisions on nanomaterials, regardless of their persistence and solubility, in the light of scientific progress.

Amendment 4

Proposal for a regulation
Recital 26 a (new)

Text proposed by the Commission	*Amendment*
	(26a) A safety assessment of substances, particularly those classified as CMR 1 or 2 substances, should consider the global exposure to such substances stemming from all sources. At the same time, for those involved in producing safety assessments, it is essential that there be a harmonised approach to the development and use of such global exposure estimates. In consequence, the Commission, in close cooperation with the SCCP, the European Chemicals Agency (ECHA), the European Food Safety Authority (EFSA) and other relevant stakeholders, should, as a matter of urgency, carry out a review and develop guidance regarding the production and use of global exposure estimates for these substances.

Justification

For CMRs in particular, the safety assessment needs to be considered within the context of the global exposure of individuals to the substance from all sources. Guidance needs to be developed for the establishment of global exposure estimates and their use in individual product safety assessments.

Amendment 5

Proposal for a regulation
Recital 31

Text proposed by the Commission	*Amendment*
(31) The safety of finished cosmetic products can already be ensured on the basis of knowledge of the safety of the ingredients that they contain. Provisions prohibiting animal testing of finished cosmetic products should therefore be provided. The application, in particular by small and medium-sized enterprises, of methods which do not involve the use of animals for assessing the safety of finished cosmetic products could be facilitated by Commission guidelines.	(31) The safety of finished cosmetic products can already be ensured on the basis of knowledge of the safety of the ingredients that they contain. Provisions prohibiting animal testing of finished cosmetic products 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.

Justification

It is important to recognize that all relevant available data, whether is stems from in-vitro, in-silico, GLP/non-GLP existing animal studies, existing human data, or other sources should be appropriately considered in the safety assessment of finished cosmetics products.

Amendment 6

Proposal for a regulation
Recital 39 a (new)

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

Justification

The use of existing data from risk assessments in other areas should be possible, but only when it is relevant for the safety assessment of the product in question.-

Amendment 7

Proposal for a regulation
Recital 40

Text proposed by the Commission	*Amendment*
(40) The consumer should be protected from misleading claims concerning efficacy and other characteristics of cosmetic products. In order to ***address specific claims concerning the characteristics of cosmetic products, the possibility to make use of harmonised standards should be provided***.	(40) The consumer should be protected from misleading claims concerning efficacy and other characteristics of cosmetic products. In order to ***assess the validity of specific claims concerning the characteristics of cosmetic products, the Commission should present a report on the use of product claims and the proof given for them and, if appropriate, propose adequate measures to resolve any problems found.***

Justification

It is necessary to ensure that only claims on those characteristics that a product really has can be used in advertising and labelling. The proposal introduces a system of harmonised standards regarding product claims to be developed by a European Harmonisation body (e.g. CEN). While the rapporteur supports a harmonised approach, she does not agree with the proposed solution. Instead, the Commission should review all product claims and the way they are proven by the responsible person and propose, if appropriate, adequate measures to resolve any problems found.

Amendment 8

Proposal for a regulation
Recital 44 a (new)

Text proposed by the Commission	*Amendment*
	(44a) Member States should provide market surveillance authorities with the necessary powers, resources and knowledge to perform their tasks properly.

Amendment 9

Proposal for a regulation
Article 2 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) ‘manufacturer’ means any natural or legal person who designs ***or*** manufactures a cosmetic product or who has such a product designed ***or*** manufactured, under his name or trademark;	b) ‘manufacturer’ means any natural or legal person who designs***,*** manufactures ***or packages*** a cosmetic product or who has such a product designed***,*** manufactured ***or packaged***, under his name or trademark;

Justification

The broad definition of 'manufacturer' should be exhaustive and cover all stages of the process of manufacturing cosmetic products.

Amendment 10

Proposal for a regulation
Article 2 – paragraph 1 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) 'subcontractor' means any natural or legal person who designs, manufactures or packages products on behalf of another natural or legal person who is the main contractor. The main contractor is bound to the subcontractor by specifications and a contract.

Amendment 11

Proposal for a regulation
Article 2 – paragraph 1 – point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) 'distributor' means any natural or legal person who purchases and resells a product unaltered and has no property rights in relation to the trademark.

Amendment 12

Proposal for a regulation
Article 2 - paragraph 1 - point i a (new)

Text proposed by the Commission	*Amendment*
	ia) '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.

Amendment 13

Proposal for a regulation
Article 2 – paragraph 1 – point k

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

Justification

Improvement of clarity and avoiding the use of the word 'harmful'. 'Harmful' has a specific meaning in other EU legislation (e.g. REACH and Classification/labelling legislation).

Amendment 14

Proposal for a regulation
Article 2 – paragraph 1 – point l

Text proposed by the Commission	*Amendment*
(l) 'serious undesirable effect' means an undesirable effect which results in ***temporary or permanent functional incapacity, disability,*** hospitalisation, ***congenital anomalies or an immediate vital risk or death***;	(l) 'serious undesirable effect' means an undesirable effect which results in ***death, threatens the patient's life, requires hospitalisation or prolonged*** hospitalisation***, or results in serious or permanent invalidity or incapacity or in a***

congenital anomaly or malformation;

Justification

For the sake of consistency and to identify serious and rare situations as rapidly as possible, the definition of 'serious undesirable effect' should be brought into line with definitions currently used by the World Health Organisation (WHO) and the International Conference on Harmonisation (ICH).

Amendment 15

Proposal for a regulation
Article 2 - paragraph 1 - point l a (new)

Text proposed by the Commission	*Amendment*
	(la) 'vulnerable population groups' means children under three years of age, elderly people and persons showing compromised immune responses.

Amendment 16

Proposal for a regulation
Article 2 – paragraph 1 – point n a (new)

Text proposed by the Commission	*Amendment*
	(na) 'counterfeit cosmetic product' means any cosmetic product, including the packaging and labelling thereof, bearing a trademark, a marketing name or any other form of trademark identification, a stamp or emblem or any marking of this type, belonging to a manufacturer of cosmetic products other than the person who actually manufactured the product and which thus falsely claims to be the product of another manufacturer of cosmetic products or is depicted as such.

Justification

The European cosmetics sector is one of the main industrial activities to be affected by counterfeiting, with increasing risks for human health. This calls for a concrete response in the regulation to deal adequately with the problem in terms of defining criminal activity,

market control, information in the event of non-compliance and penalties.

Amendment 17

Proposal for a regulation
Article 2 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. 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 adapt, no later than 18 months after the entry into force of this Regulation, the definition in paragraph 1(ia) to ensure that it is in keeping with scientific and technological progress and with definitions subsequently agreed at international level.
	Those measures, designed to amend non-essential elements of this Regulation, inter alia by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 27(3).

Amendment 18

Proposal for a regulation
Article 4 a (new)

Text proposed by the Commission	*Amendment*
	Article 4a
	Obligations of distributors, importers and retailers
	Where a distributor, importer or retailer considers, or has reason to believe, that a product is a counterfeit cosmetic product and therefore does not comply with the rules laid down in this Regulation, he shall not place the product on the market.
	Where a distributor, importer or retailer

	places, or has already placed, a product on the market and subsequently learns that the product is a counterfeit cosmetic product and therefore does not comply with this Regulation, he shall immediately withdraw it from the market and recall any products already sold. Moreover, where a counterfeit cosmetic product has been placed on the market, the distributor shall duly warn the competent national authorities of the Member State where the product has been placed on the market.

Justification

Action to combat counterfeiting is essential for the sake of public health and competitiveness.

Amendment 19

Proposal for a regulation
Article 5 – paragraph 2

Text proposed by the Commission	*Amendment*
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*.	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****, or with other internationally recognised standards.***

Justification

To avoid hindering the operation of international trade.

Amendment 20

Proposal for a regulation
Article 7 - paragraph 1

Text proposed by the Commission	*Amendment*
1. The responsible person shall, prior to placing a cosmetic product on the market,	1. 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.	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. ***Particular consideration shall be given to particle size and more specifically to 'nanomaterials' as defined in Article 2.***
The responsible person shall ensure that 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 responsible person shall ensure that: ***(a) the intended use of the cosmetic product and the anticipated systemic exposure to individual ingredients in a final formulation is taken into account in the safety assessment;*** ***(b) an appropriate weight-of-evidence approach is used in the safety assessment for reviewing relevant data from several sources, including data from in-vitro, in-silico, existing GLP (Good Laboratory Practice) or non-GLP in-vivo and human studies;*** ***c)*** the cosmetic product safety report is kept up to date in view of additional relevant information generated subsequent to placing the product on the market. ***The Commission, in close cooperation with all stakeholders, shall adopt appropriate guidelines to enable enterprises, in particular small and medium-sized enterprises, to comply with the requirements laid down in Annex I. The guidelines shall be adopted in accordance with the regulatory procedure referred to in Article 27(2).***

Justification

Annex 1 collates the cosmetic product safety information and leads to cosmetic safety report. It is important that all responsible persons have a clear understanding of the full obligations and requirements stemming from the Annex and this will be best fulfilled by the availability of appropriate descriptive guidance. It is important to recognise that all available relevant

data, whether from in vitro, in silico, existing animal GLP (good laboratory practice), human studies or other studies, should be taken into account appropriately in assessing the safety of finished cosmetic products.

Amendment 21

Proposal for a regulation
Article 8 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The responsible person shall keep a product information file for the cosmetic product for which he is the responsible person.	1. The responsible person shall keep a product information file for the cosmetic product for which he is the responsible person. ***Should the development and/or manufacturing activities be subcontracted, responsibilities relating to preservation of the product information file may be shared, by written contract, between the person responsible for placing the product on the market and the subcontractors.***

Justification

Account should be taken in this regulation of the frequent cases in which the persons responsible for placing a product on the market resort to subcontracting for the development and/or production of their cosmetic products. In such cases, the information file is shared between the main contractor and his subcontractor for various reasons (updating of details, confidentiality, labelling of address).

Amendment 22

Proposal for a regulation
Article 8 - paragraph 2 - point d

Text proposed by the Commission	*Amendment*
(d) ***where justified by the nature or the effect of the cosmetic product,*** proof of the effect claimed for the cosmetic product;	(d) proof of the effect claimed for the cosmetic product;

Amendment 23

Proposal for a regulation
Article 8 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. The responsible person shall keep the product information file accessible for a period of at least ten years after the last delivery of the cosmetic product.

Justification

A period of time should be laid down during which the product information file must be preserved once the cosmetic product is no longer on the market. Ten years is consistent with the information preservation period laid down in other regulations.

Amendment 24

Proposal for a regulation
Article 9 – paragraph 2

Text proposed by the Commission	*Amendment*
2. In absence of any applicable Community legislation, compliance with paragraph 1 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*.	2. In absence of any applicable Community legislation, compliance with paragraph 1 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****, or with other internationally recognised standards.***

Justification

To avoid hindering the operation of international trade.

Amendment 25

Proposal for a regulation
Article 10 - paragraph 1 - point c

Text proposed by the Commission	*Amendment*
(c) the Member State where the cosmetic product is placed on the market;	(c) the ***first*** Member State where the cosmetic product is placed on the market;

Justification

This aims to clarify that the notification should only be done in the first Member State where the product is placed in the market.

Amendment 26

Proposal for a regulation
Article 10 - paragraph 1 - point e

Text proposed by the Commission	*Amendment*
(e) the presence of substances in the form of ***micronised particles other than substances listed in Annexe III to VI to this Regulation***;	(e) the presence of substances in the form of ***nanomaterials, regardless of their persistence and solubility***;

Amendment 27

Proposal for a regulation
Article 12 – paragraph 2 – subparagraph 2 – introductory part and indent 1

Text proposed by the Commission	*Amendment*
However, such substances may be used in cosmetic products if, subsequent to their classification as carcinogenic, mutagenic or toxic for reproduction of category 1 or 2 under Directive 67/548/EEC, all of the following conditions are fulfilled:	However, such substances may ***exceptionally*** be used in ***specific*** cosmetic products if, subsequent to their classification as carcinogenic, mutagenic or toxic for reproduction of category 1 or 2 under Directive 67/548/EEC ***after entry into force of this Regulation***, all of the following conditions are fulfilled:
- they have been evaluated and found safe for use by the SCCP in cosmetic products in particular in view of exposure;	- they have been evaluated and found safe for use by the SCCP in ***specific*** cosmetic products in particular in view of ***the global*** exposure ***from other significant sources and taking particular account of vulnerable population groups;***

Justification

There has been no problem with regard to the current prohibition of CMR substances that are already classified as such. The future derogation was only proposed by the Commission to anticipate future classifications of certain substances. As such, the derogations should only apply to substances that will be classified CMR in the future. Derogations should also be only

for specific uses, and not for cosmetic products in general.

Amendment 28

Proposal for a regulation
Article 12 - paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. By [two years after the date of publication of this Regulation in the Official Journal], the Commission shall ensure that procedures for the development and use of global exposure estimates for CMR substances are reviewed and that appropriate guidelines are developed with the aim of enabling a harmonised approach to the development and use of such overall exposure estimates in assessing the safe use of cosmetic products containing these substances. This review shall be carried out in consultation with the SCCP, the ECHA, the EFSA and other relevant stakeholders, drawing as appropriate on relevant best practice.

Justification

For certain substances, for CMRs in particular, the safety assessment needs to be considered within the context of the global exposure of individuals to the substance from all sources. Guidance needs to be developed for the establishment of global exposure estimates and their use in individual product safety assessments.

Amendment 29

Proposal for a regulation
Article 12 – paragraph 2 b (new)

Text proposed by the Commission	*Amendment*
	2b. When Community or internationally agreed criteria for identifying substances with endocrine-disrupting properties are available, or at the latest 5 years after this Regulation has entered into force, the

Commission shall review the Regulation with regard to substances with endocrine-disrupting properties.

Amendment 30

Proposal for a regulation
Article 12 a (new)

Text proposed by the Commission	*Amendment*
	Article 12 a
	Nanomaterials
	1. For every product that contains nanomaterials as defined in Article 2, a high level of consumer protection and the protection of human health shall be ensured.
	2. At the latest 12 months before the date of application of this Regulation, the responsible person shall notify the Commission of all existing cosmetic products that contain nanomaterials, identifying the category of each product and the specific nature of the nanomaterials as used in it, as well as the specific exposure conditions.
	At the latest six months before the date of application of this Regulation, the Commission shall publish an initial Status Report on all nanomaterials already used in cosmetic products as well as on the exposure conditions linked to these cosmetic products.
	In the event that the Commission has concerns regarding the safety of the nanomaterials as used, the Commission shall request the SCCP to give its opinion on the safety of these nanomaterials for these categories of products and the specific exposure conditions. The SCCP shall give its opinion within 12 months of the submission of all relevant safety data

and transmit it to the Commission.

The Commission shall urgently adopt a decision on the authorisation of the products of concern in accordance with the regulatory procedure referred to in Article 27(2).

3. 18 months before the date of application of this Regulation, every new product that contains nanomaterials not included in the Status Report or placed on the market before the publication of the initial Status Report referred to in paragraph 2, or nanomaterials used in a new product category or under new exposure conditions, shall be notified by the responsible person to the Commission in accordance with Article 10(1)(e) six months prior to the placing on the market.

The responsible person shall also submit, upon the Commission's request, the safety assessment of the product related to the specific nature of the nanomaterials as used in the product category and the exposure conditions. The Commission may request the SCCP to give its opinion on the safety of these nanomaterials for these categories of products and the specific exposure conditions. The SCCP shall give its opinion within six months of the submission of all relevant safety data and transmit it to the Commission.

If the SCCP assessment does not conclude that the use of nanomaterials in the relevant product category is unsafe, the product may be made available on the market.

If the SCCP assessment concludes that the use of nanomaterials in the relevant product category is unsafe, the Commission shall adopt a decision on the authorisation in accordance with the regulatory procedure referred to in Article 27(2).

4. The Commission shall submit to the European Parliament and the Council an

annual update of the Status Report, which will give information on developments in the use of nanomaterials in cosmetic products within the Community. The report update shall summarise, in particular, the new nanomaterials and the new product categories notified, the number of notifications, the progress made in developing nano-specific assessment methods and safety assessment guides, and information on international cooperation programmes.

5. The Commission shall review the provisions of this Regulation concerning nanomaterials at least every five years in the light of scientific progress and, where necessary, shall propose suitable amendments to those provisions.

Amendment 31

Proposal for a regulation
Article 15 – paragraph 1 – point a a (new)

Text proposed by the Commission	*Amendment*
	(aa) the country of origin, if the cosmetic product was manufactured outside the Community;

Amendment 32

Proposal for a regulation
Article 15 – paragraph 1 – point g – subparagraph 3 a (new)

Text proposed by the Commission	*Amendment*
	All ingredients present in the form of nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be preceded by the word 'nano'.

Justification

Given that nanotechnologies are covered by specific provisions in the revised cosmetic

product legislation, where a cosmetic product contains nanomaterials, this should be specified in the list of that product's ingredients. This will ensure a basic level of information and transparency for all stakeholders (consumers, supervisory authorities, etc.).

Amendment 33

Proposal for a regulation
Article 15 – paragraph 1 – point g – subparagraph 5

Text proposed by the Commission	*Amendment*
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.	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.***

Amendment 34

Proposal for a regulation
Article 16 - paragraph 1 - subparagraph 2

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

Justification

It is necessary to ensure that only claims on those characteristics that a product really has can be used in advertising and labelling. The proposal introduces a system of harmonised standards regarding product claims to be developed by a European Harmonisation body (e.g. CEN). While the rapporteur supports a harmonised approach, she does not agree with the proposed solution. Instead, the Commission should review all product claims and the way they are proven by the responsible person and propose, if appropriate, adequate measures to resolve any problems found.

Amendment 35

Proposal for a regulation
Article 16 – paragraph 1a (new)

Text proposed by the Commission	*Amendment*
	1a. The Commission shall establish, in cooperation with Member States, an action plan regarding claims used in cosmetic products and fix priorities for determining common criteria for the use of a claim.
	After consultation of the SCCP or other relevant authorities, the Commission shall adopt a list of common criteria for claims which may be used in respect of cosmetic products, in accordance with the regulatory procedure with scrutiny referred to in Article 27(3), taking into account provisions of Directive 2005/29/EC.
	Three years after the date of application of this Regulation, the Commission shall submit to the European Parliament and the Council a report regarding the use of claims on the basis of the common criteria adopted under the previous subparagraph. If the report concludes that claims used in respect of cosmetic products are not in conformity with the common criteria, it shall take appropriate measures to ensure compliance.

Amendment 36

Proposal for a regulation
Article 17 - paragraph 1

Text proposed by the Commission	*Amendment*
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	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 ***publicly*** accessible by any appropriate means.	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.

Amendment 37

Proposal for a regulation
Article 18

Text proposed by the Commission	*Amendment*
Member States shall survey compliance with this Regulation via in-market controls of the cosmetic products made available on the market.	Member States shall survey compliance with this Regulation via in-market controls of the cosmetic products made available on the market. ***Member States shall perform controls of adequate scale by assessing the documentation available and, where appropriate, by means of physical and laboratory tests, based on adequate samples.*** ***Member States shall report to the Commission annually on the controls performed for surveying compliance with this Regulation and on the main findings relating to non-compliance.***

Justification

To ensure the safety for the consumers as well as the compliance of the producers with the requirements for the safety report set up in Article 7 as well as Annex I, clear control instruments have to be introduced. The rapporteur therefore asks the Member States to perform adequate controls and in case of non-compliance to report back to the Commission.

Amendment 38

Proposal for a regulation
Article 18 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	Member States shall also use in-market controls as a means of identifying cosmetic products that are counterfeit and therefore do not comply with the requirements set out in Article 21.

Amendment 39

Proposal for a regulation
Article 21 - paragraph 1 - introductory part

Text proposed by the Commission	*Amendment*
1. 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 a given reasonable time limit***, ***commensurate with the nature of the risk,*** where there is non compliance with any of the following:	1. 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 ***without delay***, where there is non compliance with any of the following:

Amendment 40

Proposal for a regulation
Article 22 - paragraphs 1 and 2

Text proposed by the Commission	*Amendment*
1. Where Article 21 does not apply, and a competent authority ascertains that a cosmetic product placed on the market is liable to present a serious risk for human health, it shall take all appropriate provisional measures in order to ensure that a cosmetic product is withdrawn, recalled or its availability otherwise restricted.	1. Where Article 21 does not apply, and a competent authority ascertains that a cosmetic product placed on the market is liable to present a serious risk for human health, it shall take all appropriate provisional measures in order to ensure that a cosmetic product is withdrawn, recalled or its availability otherwise restricted. ***Where Article 21 applies and the***

	responsible person does not agree with the competent authority's interpretation regarding compliance or with the corrective actions proposed, the competent authority and the responsible person shall agree, without prejudice to Article 21, that a dispute has arisen.
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.	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 ***in cases covered by paragraph 1, first subparagraph, or, in cases covered by paragraph 1, second subparagraph, shall forward details of the dispute***.
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.	For the purposes of the first subparagraph *of this paragraph*, 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.	Article 12 (2), (3) and (4) of Directive 2001/95/EC shall apply.

Justification

Allowance needs to be made for disputes arising between the responsible person and the competent authority over the way in which the regulation is interpreted. A procedure needs to be laid down to ensure uniform application of the regulation where such disputes arise.

Amendment 41

Proposal for a regulation
Article 26 - paragraph 1 - subparagraph 1

Text proposed by the Commission	*Amendment*
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 SCCP, amend Annexes II to VI accordingly.	1. Where there is a potential risk to human health ***or to the environment***, 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 SCCP ***and if necessary the Scientific Committee on Health and Environmental Risks (SCHER)***, amend Annexes II to VI

accordingly.

Justification

There have been a number of examples where substances used in cosmetic and hygienic products have been identified as having environmental risks. In case such risks are not properly dealt with in other pieces of legislation, there should be a possibility to add such substances to Annex II of this Regulation. The general public expect cosmetic and hygienic products to be safe also for the environment, and the cosmetics regulation should therefore contain this instrument, to be used in exceptional case. SCHER is the scientific committee for the assessment of environmental concerns.

Amendment 42

Proposal for a regulation
Article 26 – paragraph 1 – subparagraph 2 a (new)

Text proposed by the Commission	*Amendment*
	Where there is an unacceptable risk to the environment assessed under REACH, which arises from the use of substances in cosmetic products, and which needs to be addressed on a Community-wide basis, the Commission may, after consultation of the (SCHER), amend Annexes II to VI accordingly.

Justification

Substances used in cosmetic and hygienic products may present environmental risks. The impact of cosmetic products and their ingredients on the environment is assessed by the EChA and regulated by the REACH Regulation. In exceptional cases where the environmental risks have not already been properly assessed under existing EU legislation, a mechanism should exist for risk assessment by SCHER and for appropriate risk management by the European Commission under annexes II to VI of the Cosmetics Regulation.

Amendment 43

Proposal for a regulation
Article 28

Text proposed by the Commission	*Amendment*
The Commission shall compile and update a glossary of common ingredient names.	The Commission shall compile and update a glossary of common ingredient names ***on***

That glossary shall not constitute a list of the substances authorised for use in cosmetic products.	***the basis of, in particular, 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*.	The common ingredient name shall be applied for the purpose of labelling cosmetic products placed on the market at the latest ***two years*** after publication of the glossary in the *Official Journal of the European Union*.

Justification

Amendment 44

Proposal for a regulation
Article 31 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	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 ***or that an innovation would better satisfy the requirements set out in the relevant provisions of this Regulation and would enable a higher level of protection of human health to be achieved***, 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.

Justification

Objective 3, as set out in the Explanatory Memorandum, is to ensure that cosmetic products placed on the EU market are safe in the light of innovation in this sector. A Member State or the Commission should be entitled to approach the committee set up by Article 5 of Directive 98/34/EC, with a view to the revision of a harmonised standard where it considers that an innovation would ensure more effective compliance with the relevant provisions of the regulation, in particular those on human health protection.

Amendment 45

Proposal for a regulation
Annex I – part A – point 1

Text proposed by the Commission	*Amendment*
Description of the qualitative and quantitative composition of the product, including chemical identity of the substances (incl. chemical name, INCI, CAS, EINECS/ELINCS) and their intended function. In the case of essential oils, perfume compositions and perfumes, description of the name and code number of the composition and the identity of the supplier.	***The*** qualitative and quantitative composition of the product, including chemical identity of the substances (incl. chemical name, INCI, CAS, EINECS/ELINCS) and their intended function. In the case of essential oils, perfume compositions and perfumes, description of the name and code number of the composition and the identity of the supplier.

Justification

The term 'description' is new and very unclear. It does not exist in this context in the current directive. What is needed is the actual information, not a 'description' of it.

Amendment 46

Proposal for a regulation
Annex I – part A – point 2 – subparagraph 1 and 2

Text proposed by the Commission	*Amendment*
Description of the physical and chemical characteristics of the substances, the raw-material as well as the cosmetic product.	***The*** physical and chemical characteristics of the substances, the raw-material as well as the cosmetic product.
Description of the stability of the cosmetics product under reasonably foreseeable storage conditions.	***The*** stability of the cosmetics product under reasonably foreseeable storage conditions.

Justification

The term 'description' is new and very unclear. It does not exist in this context in the current directive. What is needed is the actual information, not a 'description' of it.

Amendment 47

Proposal for a regulation
Annex I – part A – point 3 – subparagraph 1

Text proposed by the Commission	*Amendment*
Description of the microbiological specifications of the raw material and the cosmetic product. Particular attention shall be paid to cosmetics used around the eyes, on mucous membranes in general, on damaged skin, on children under three years of age, on elderly people and persons showing compromised immune responses.	***The*** microbiological specifications of the raw material and the cosmetic product. Particular attention shall be paid to cosmetics used around the eyes, on mucous membranes in general, on damaged skin, on children under three years of age, on elderly people and persons showing compromised immune responses.

Justification

The term 'description' is new and very unclear. It does not exist in this context in the current directive. What is needed is the actual information, not a 'description' of it.

Amendment 48

Proposal for a regulation
Annex I – part A – point 4 – subparagraph 1

Text proposed by the Commission	*Amendment*
Description of purity of the substances and raw material.	***The*** purity of the substances and raw material.

Justification

The term 'description' is new and very unclear. It does not exist in this context in the current directive. What is needed is the actual information, not a 'description' of it.

Amendment 49

Proposal for a regulation
Annex I – part A – point 4 – subparagraph 3

Text proposed by the Commission	*Amendment*
Description of the relevant characteristics of packaging material, in particular purity and stability.	***The*** relevant characteristics of packaging material, in particular purity and stability.

Justification

The term 'description' is new and very unclear. It does not exist in this context in the current directive. What is needed is the actual information, not a 'description' of it.

Amendment 50

Proposal for a regulation
Annex I – part A – point 5

Text proposed by the Commission	*Amendment*
Description of the normal and reasonably foreseeable use of the product. The reasoning shall be justified in particular in the light of warnings and other explanations in the product labelling.	***The*** normal and reasonably foreseeable use of the product. The reasoning shall be justified in particular in the light of warnings and other explanations in the product labelling.

Justification

The term 'description' is new and very unclear. It does not exist in this context in the current directive. What is needed is the actual information, not a 'description' of it.

Amendment 51

Proposal for a regulation
Annex I – part A – point 6 – introduction

Text proposed by the Commission	*Amendment*
Description of exposure to cosmetic product taking into consideration the findings under Section 5 in relation to	***Data on and assessment*** of ***the*** exposure to cosmetic product taking into consideration the findings under Section 5 in relation to

Justification

The term 'description' is new and very unclear. It does not exist in this context in the current directive. What is needed is the data and an assessment of the information, not a 'description' of it.

Amendment 52

Proposal for a regulation
Annex I – part A – point 7

Text proposed by the Commission	*Amendment*
Description of the exposure to the substances contained in the cosmetic product for the relevant toxicological endpoints taking into account the information under Section 6.	***Data on and assessment*** of the exposure to the substances contained in the cosmetic product for the relevant toxicological endpoints taking into account the information under Section 6.

Justification

The term 'description' is new and very unclear. It does not exist in this context in the current directive. What is needed is the data and an assessment of the information, not a 'description' of it.

Amendment 53

Proposal for a regulation
Annex I – part A – point 8 – subparagraph 1

Text proposed by the Commission	*Amendment*
Without prejudice to Article 14, ***description*** of the toxicological profile of all relevant toxicological endpoints. A particular focus on local toxicity evaluation (skin and eye irritation), skin sensitisation, and in the case of UV absorption photo-induced toxicity shall be made.	Without prejudice to Article 14, ***an assessment*** of the toxicological profile of all relevant toxicological endpoints. A particular focus on local toxicity evaluation (skin and eye irritation), skin sensitisation, and in the case of UV absorption photo-induced toxicity shall be made.

Justification

The term 'description' is new and very unclear. It does not exist in this context in the current directive. What is needed is an assessment of the information, not a 'description' of it.

Amendment 54

Proposal for a regulation
Annex I – part A – point 9

Text proposed by the Commission	*Amendment*
Description of the undesirable effects and serious undesirable effects to the cosmetic	***Complete data on*** the undesirable effects and serious undesirable effects to the

product or, where relevant, other cosmetic products. This includes statistical data.	cosmetic product or, where relevant, other cosmetic products. This includes statistical data.

Justification

The term 'description' is new and very unclear. It does not exist in this context in the current directive. What is needed is complete data for this information, not a 'description' of it.

Amendment 55

Proposal for a regulation
Annex I – part A – point 10

Text proposed by the Commission	*Amendment*
Other relevant information, e.g. ***description of*** existing studies from human volunteers.	Other relevant information, e.g. existing studies from human volunteers.

Justification

The term 'description' is new and very unclear. It does not exist in this context in the current directive. What is needed is the information as such, not a 'description' of it.

Amendment 56

Proposal for a regulation
Annex I – part A – point 10

Text proposed by the Commission	*Amendment*
Other relevant information, e.g. description of existing studies from human volunteers.	Other relevant information, e.g. description of existing studies from human volunteers ***or the duly confirmed and substantiated findings of risk assessments carried out in other relevant areas.***

Justification

It should be possible to use existing data from risk assessments carried out in other areas, where such data are of relevance in assessing the safety of the product in question.

Amendment 57

Proposal for a regulation
Annex I – part B – point 3 – subpoint 3

Text proposed by the Commission	*Amendment*
Possible interactions of the substances contained in the cosmetic product shall be assessed. ***If such interaction is not expected, this shall be duly justified***.	Possible interactions of the substances contained in the cosmetic product shall be assessed.

Justification

It is impossible to verify and duly justify a non-existent effect !

EXPLANATORY STATEMENT

As a part of its strategy for simplifying the regulatory environment, the Commission has decided to recast the Council Directive 76/768/EEC on the approximation of the laws relating to cosmetic products. The directive, which has been subject to 55 amendments since its adoption in 1976, has become cumbersome and outdated, and does no longer provide the necessary legal certainty in a rapidly developing field. With the recast, the Commission aims remove legal uncertainties and inconsistencies by introducing a set of definitions and implementation measures. To avoid divergences in national transposition, the Commission has changed the legal form of the act from a directive into a regulation.

Another main objective is to increase the safety of cosmetic products. Since the current Cosmetics Directive does not contain clear requirements for a safety assessment, the Commission now introduces "minimum standards" for it.

The rapporteur strongly supports this goal and further wants to strengthen the safety aspect to ensure the protection and health of all consumers. In total the report focuses on four aspects:

Safety assessment of cosmetic products

According to Article 7, the responsible person has to produce a safety assessment with all the relevant information prior to placing a cosmetic product on the market. Annex I of the Regulation describes the relevant information that has to be included in the safety assessment. It is important that all responsible persons have a clear understanding of the full obligations and requirements stemming from this Annex. Therefore, the rapporteur asks the Commission in close cooperation with all stakeholders to adopt guidance that helps the responsible persons to produce the safety assessments and the product safety report of their products.

To ensure the safety for the consumers as well as the compliance of the producers with the requirements for the safety report set up in Article 7 as well as Annex I, clear control instruments have to be introduced. The rapporteur therefore asks the Member States to perform adequate controls and in case of non-compliance to report back to the Commission.

The use of nanomaterials in cosmetic products

Already today nanomaterials are part of many products on the market. In 2006 the Commission estimated the amount of cosmetic products containing nanoparticles of about 5 %.

There is a wide range of definitions what is to be called a nanomaterial which mostly refer to the size of the substance. To avoid legal uncertainty it is important to make sure what is meant by nanomaterial. Therefore, the rapporteur introduces a definition to this regulation which is based on a definition developed by the Scientific Committee on Consumer Products (SCCP) in December 2007.

Because of their small size nanomaterials contain special characteristics. These characteristics can be very positive but, at the same time there can be new risks, too. Therefore, these products should be evaluated by the SCCP on the basis of a nano-specific safety assessment prior to their placing on the market to ensure the safety for consumers. The rapporteur suggests the introduction of a transitional period for existing products, which contain nanomaterials.

Nanomaterials that are used as colorants, preservatives, UV-filters are already covered in Annex IV, V and VI of this regulation and already have to be positively listed by the Commission after consultation with the SCCP.

To ensure the safety of cosmetic products, an evaluation by the SCCP for all products containing nanomaterials should be required. The rapporteur therefore tables amendments which introduce a congruent procedure for all nanomaterials.

As the research on nanomaterials is still progressing the Commission is requested to regularly review this regulation in the view of nanomaterials.

The use of CMR-substances in cosmetic products

The 7th amendment of the Cosmetics Directive introduced a total ban of CMR 1 and 2 substances in cosmetic products. Still, there might be cases were the use of some of those substances is necessary to produce a cosmetic product. For those cases there may be exemptions from the total ban given that the SCCP finds the substance safe for the use in cosmetics.

The Commission proposal already contains strict requirements that all have to be fulfilled in order to allow the use of a CMR 1 or 2 in a cosmetic product. The rapporteur strengthens this approach by introducing further requirements. Moreover, she introduces the concept of global exposure to this regulation.

Consequently, the global exposure for CMRs from all routes and sources (food sector, cosmetics, other consumer products) has to be taken into account by the SCCP when evaluating the safety of the CMR substance to be used in a cosmetic product.

However, as there is no general methodology for measuring the global exposure of CMRs at the moment and, as it is a matter that should not only be dealt with in the Cosmetics Regulation, the rapporteur asks the Commission to develop estimates for measuring global exposure and subsequently, to review the cosmetics regulation accordingly.

The use of product claims for cosmetic products

It is often the specific characteristics of a cosmetic product that convince the consumer to buy the product. Such product claims are a sensitive issue as the consumers mostly have no possibility to assess their correctness but just to trust what the product promises. Therefore, to protect the consumer it must be ensured that only the characteristics that the product really has

can be used for advertising and labelling that the product.

The Commission proposal underlines in Article 16 that cosmetic products must not contain product claims that are misleading or even false and that the claims have to be proven in the product information file. Apart from that, the Commission proposal introduces a system of harmonised standards regarding product claims. These standards should be developed by a European Harmonisation body, such as the CEN.

While supporting the idea of a harmonised approach for product claims with the aim to ensure product safety and reliable information for consumers, the rapporteur does not agree with the idea to give the responsibility for this to a European Harmonisation body, as described in the Commission proposal.

Private bodies, such as the CEN, which are dominated by the industry sectors concerned, cannot be put in charge of a sensitive matter like product claims, where independent assessment would absolutely necessary.

Therefore, the rapporteur asks the Commission to establish an action plan regarding claims used in cosmetic products and to fix priorities for determining common criteria for the use of a claim. After that, the Commission should adopt a list of common criteria for claims which could be used in cosmetic products.

ANNEX: LETTER FROM THE COMMITTEE ON LEGAL AFFAIRS

COMMITTEE ON LEGAL AFFAIRS
CHAIRMAN

Ref.: D(2008)69152

Mr Miroslav OUZKÝ
Chairman
Committee on Environment, Public Health
and Food Safety
ASP 05F69
Brussels

Subject: ***Proposal for a regulation of the European Parliament and of the Council on cosmetics products (recast version)***
COM(2008)0049 – C6-0053/2008 - 2008/0035(COD)

Dear Chair,

The Committee on Legal Affairs, which I am honoured to chair, has examined the proposal referred to above, pursuant to Rule 80a on Recasting, as introduced into the Parliament's Rules of Procedure by its Decision of 10 May 2007.

Paragraph 3 of that Rule reads as follows:

"If the committee responsible for legal affairs considers that the proposal does not entail any substantive changes other than those identified as such in the proposal, it shall inform the committee responsible.

In such a case, over and above the conditions laid down in Rules 150 and 151, amendments shall be admissible within the committee responsible only if they concern those parts of the proposal which contain changes.

However, amendments to the parts which have remained unchanged may be admitted by way of exception and on a case-by-case basis by the chairman of the above committee if he considers that this is necessary for pressing reasons relating to the internal logic of the text or because the amendments are inextricably linked to other admissible amendments. Such reasons must be stated in a written justification to the amendments".

Following the opinion of the Legal Service of the European Parliament, whose representatives

participated in the meetings of the Consultative Working Party examining the recast proposal, and in keeping with the recommendations of the draftsperson, the Committee on Legal Affairs considers that the proposal in question does not include any substantive changes other than those identified as such in the proposal or in the opinion of the Legal Service and that, as regards the codification of the unchanged provisions of the earlier acts with those changes, the proposal contains a straightforward codification of the existing texts, without any change in their substance.

Furthermore, pursuant to Rules 80a(2) and 80(3), the Committee on Legal Affairs considered that the technical adaptations suggested in the opinion of the Legal Service were necessary in order to ensure that the proposal complied with the recasting rules.

In conclusion, after examining the issue at its meeting of 17 November 2008, the Committee on Legal Affairs, by 17 votes in favour[1] and no abstentions, recommends that your Committee, as the committee responsible, proceed to examine the above proposal in keeping with its suggestions and in accordance with Rule 80a.

Yours faithfully,

Giuseppe GARGANI

Encl.: Opinion of the Consultative Working Party

[1] The following Members were present: Giuseppe Gargani (Chairman), Carlo Casini, Othmar Karas, Klaus-Heiner Lehne, Hartmut Nassauer, Rainer Wieland, Jaroslav Zvěřina, Tadeusz Zwiefka, Lidia Joanna Geringer de Oedenberg, Manuel Medina Ortega, Aloyzas Sakalas, Diana Wallis, Monica Frassoni, Jean-Paul Gauzès, Georgios Papastamkos, Jacques Toubon, Ieke van den Burg

ANNEX: OPINION OF THE CONSULTATIVE WORKING PARTY OF THE LEGAL SERVICES OF THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE COMMISSION

GROUPE CONSULTATIF
DES SERVICES JURIDIQUES

Brussels, 14.11.2008

OPINION

FOR THE ATTENTION OF **THE EUROPEAN PARLIAMENT**
THE COUNCIL
THE COMMISSION

Proposal for a regulation of the European Parliament and of the Council on cosmetic products (recast)
COM(2008) 49 final of 5.2.2008 - 2008/0035 (COD)

Having regard to the Interinstitutional Agreement of 28 November 2001 on a more structured use of the recasting technique for legal acts, and in particular to point 9 thereof, the Consultative Working Party consisting of the respective Legal Services of the European Parliament, the Council and the Commission, met on 13, 20 and 25 February, on 13 March and on 27 May 2008 for the purpose of examining the aforementioned proposal submitted by the Commission.

The discussions continued at the level of the Directors General/Jurisconsults from September 2008 and led to an exchange of letters between the Director General of the Legal Service of the Council (letter addressed to Mr. Pennera and Ms Durand on 4 November), the Jurisconsult of the European Parliament (reply dated 7 November 2008) and the Acting Director General of the Legal Service of the Commission (reply dated 13 November 2008), in which the respective views were made clear.

In all those discussions, the central issue was the question of whether a directive can be

converted into a regulation in the context of a recast exercise.

a) The Legal Services of the European Parliament and of the Commission are of the view that it is possible to have the existing provisions of a directive recast into a new regulation, as long as the provisions of the act addressed to Member States are sufficiently precise and detailed (and therefore only requiring a mere formal transposition) as to be capable of conversion into directly applicable provisions in a regulation. They are of the view that this is the case here, in that the provisions at issue are of a technical nature and have already been fully transposed into national law by all Member States.

In reaching this opinion, the two said Legal Services also accept the relevance of two preceding opinions delivered by the Consultative Working Party as regards directives converted into regulations in the context of a recast exercise[1].

This being said, they are also of the view that the following parts of the text of the recast proposal should have been identified by using the grey-shaded type used for marking substantive changes:

- the title of the proposal;
- the expression "*this Regulation*" appearing in recitals nos. 8, 9, 26 and 46, in the final wording of the preamble, in Article 1, in Article 2(1), in the final wording of Article 3, in Article 6, in Article 14(a), (b), (c) and (d), in Article 15(1)(c), in point 681 of Annex II, and in Annex VIII;
- the first sentence of Recital 13;
- the entire text of Recital 14;

[1] In its opinion relating to Annex XVI to the proposal for a regulation of the European Parliament and of the Council "concerning the Registration, Evaluation, Authorisation and Restrictions of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) on Persistent Organic Pollutants" (COM(2003) 644 final – 2003/0256 (COD)) the Consultative Working Party stated that "*Annex XVI* […] *constitutes a recast version of Annexes I and II to Council Directive 76/769/EEC of 27 July 1976* […]" and that "*examination of the relevant part of the proposal has enabled the Consultative Working Party to conclude, without dissent, that, as regards the aforementioned Annex, the proposal does not comprise any substantive amendments other than those identified as such therein or in the present opinion. The Working Party also concluded, as regards the codification of the unchanged parts of Annexes I and II to Council Directive 76/769/EEC with those substantive amendments, that the proposal contains a straightforward codification of existing texts, without any change in their substance*". In the opinion relating to a proposal for a regulation of the European Parliament and of the Council on common rules for access to the international road haulage market (COM(2007) 265 final of 23.5.2007 - 2007/0099 (COD)) the Consultative Working Party stated that "*an examination of the proposal for a regulation of the European Parliament and of the Council recasting Council Regulation (EEC) No 881/92 of 26 March 1992 on access to the market in the carriage of goods by road within the Community to or from the territory of a Member State or passing across the territory of one or more Member States, Council Regulation (EEC) No 3118/93 of 25 October 1993 laying down the conditions under which non-resident carriers may operate national road haulage services within a Member State, and Directive 2006/94/EC of the European Parliament and of the Council of 12 December 2006 on the establishment of common rules for certain types of carriage of goods by road […] has enabled the Consultative Working Party to conclude, without dissent, that the proposal does not comprise any substantive amendments other than those identified as such therein or in the present opinion. The Working Party also concluded, as regards the codification of the unchanged provisions of the earlier acts with those substantive amendments, that the proposal contains a straightforward codification of the existing texts, without any change in their substance*".

- the entire text of Recital 16;
- the last sentence of Recital 17;
- the entire text of Recital 18;
- the entire text of Recital 20;
- the entire text of Recital 24;
- the entire text of Recital 42;
- in Article 7(1), first subparagraph, the words "*in accordance with Annex I*".

In consequence, the Legal Services of the European Parliament and of the Commission are of the view that the proposal submitted by the Commission constitutes a recast proposal made in compliance with the rules of the Inter-institutional Agreement of 28 November 2001 on a more structured use of the recasting technique for legal acts. According to them, it does not comprise any substantive amendments other than those identified as such therein or in the present opinion. They also are of the opinion that, as regards the codification of the unchanged provisions of the earlier act with those substantive amendments, the proposal contains a straightforward codification of the existing texts, without any change in their substance.

b) The Legal Service of the Council is of the view that it is possible to transform a directive into a regulation, but not by means of a recast proposal. Consequently, it cannot subscribe to the above opinion.

In the view of the Council Legal Service, the transformation of a directive into a regulation implies a substantive change of all provisions of the directive, which, in accordance with Article 249 of the EC Treaty, are no longer binding only as to the result to be achieved, while leaving to the national authorities the choice of form and methods, but become binding in their entirety and directly applicable in all Member States. This change is not *"purely formal or editorial"* (see point 4, second indent of the IIA of 28 November 2001). Hence, the legislative authority should be able to modify all provisions of the act concerned to take account of the fact that they become directly applicable, independently of whether these provisions appear to be "of a technical nature and have already been fully transposed into national law by all Member States". In fact, these elements are subject to a political appreciation by the legislative authority, which cannot be prejudged by the Commission or the Legal Services of the institutions.

However, in the context of a recast, the scope for substantive changes by the legislator to the Commission proposal is limited to those parts which are identified in the proposal as substantive amendments, as opposed to unchanged provisions which, although they may be affected by purely formal or editorial changes, have not undergone any substantive amendment. This presupposes that it is possible to distinguish between substantive amendments and unchanged provisions, which, for the reasons set out above, is not the case if the Commission proposes to transform a directive into a regulation.

The Council Legal Service recalls that, pursuant to point 4, second subparagraph of the Interinstitutional Agreement of 28 November 2001, *"a new legal act shall not constitute a recast if, with the exception of standardised provisions or wordings, it makes substantive amendments to all the provisions of the earlier act, which it replaces and repeals."* This is the case when a directive is transformed into a regulation. The Council Legal Service therefore is of the opinion that the present proposal falls outside the scope of the Interinstitutional Agreement of 28 November 2001[1].

C. PENNERA	J.-C. PIRIS	C.-F.DURAND
Jurisconsult	Jurisconsult	actg. Director General

[1] This position is not contradicted by the two precedents quoted by the Legal Services of the European Parliament and of the Commission which, in the view of the Council Legal Service, are not relevant for the present case.

The proposal COM(2003) 644 (Regulation concerning the Registration, Evaluation, Authorization and Restrictions of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) on Persistent Organic Pollutants) was a new legislative proposal. Only a small part of it, i.e. Annex XVI, followed the rules of the recasting technique.

The proposal COM(2007) 265 (Regulation on common rules for access to the international road haulage market) was seeking to recast the basic Regulation (EEC) 881/92 with Regulation (EEC) 3118/93 and Directive 2006/94/EC. The latter concerns very few provisions of the recast act, and the recast proposal did not change the legal instrument of the basic act.

Hence, the present case is indeed the first proposal aiming to transform an entire directive into a regulation by means of a recast.

PROCEDURE

Title	Cosmetic products (recast version)
References	COM(2008)0049 – C6-0053/2008 – 2008/0035(COD)
Date submitted to Parliament	5.2.2008
Committee responsible Date announced in plenary	ENVI
Committee(s) asked for opinion(s) Date announced in plenary	JURI
Not delivering opinions Date of decision	JURI 17.11.2008
Rapporteur(s) Date appointed	Dagmar Roth-Behrendt 26.2.2008
Discussed in committee	9.9.2008
Date adopted	2.12.2008
Result of final vote	+: 44 –: 0 0: 0
Members present for the final vote	Adamos Adamou, Georgs Andrejevs, Margrete Auken, Pilar Ayuso, Irena Belohorská, Johannes Blokland, John Bowis, Frieda Brepoels, Hiltrud Breyer, Martin Callanan, Dorette Corbey, Magor Imre Csibi, Chris Davies, Avril Doyle, Jill Evans, Anne Ferreira, Matthias Groote, Françoise Grossetête, Satu Hassi, Gyula Hegyi, Jens Holm, Eija-Riitta Korhola, Holger Krahmer, Linda McAvan, Riitta Myller, Miroslav Ouzký, Vladko Todorov Panayotov, Vittorio Prodi, Frédérique Ries, Dagmar Roth-Behrendt, Guido Sacconi, Richard Seeber, Salvatore Tatarella, Antonios Trakatellis, Evangelia Tzampazi, Glenis Willmott
Substitute(s) present for the final vote	Iles Braghetto, Bairbre de Brún, Christofer Fjellner, Johannes Lebech, Kartika Tamara Liotard, Bart Staes, Lambert van Nistelrooij
Substitute(s) under Rule 178(2) present for the final vote	Christel Schaldemose