

PUBLIC CONSULTATION PAPER ON THE SIMPLIFICATION OF COSMETICS DIRECTIVE 76/768/EEC

INTRODUCTION

A simplification of Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products¹ (the “**Cosmetics Directive**”) was announced in the Commission Communication “Implementing the Community Lisbon programme: A strategy for the simplification of the regulatory environment”² and in the Commission’s Annual Policy Strategy for 2007.³ The aim is to simplify the legal framework for economic activities in the EU which was identified as one of the key issues on the better regulation agenda in the Commission Communication “Better regulation for growth and jobs in the European Union”.⁴

The Commission intends to simplify the Cosmetics Directive in the form of a recast, i.e. a legislative technique which enables to codify a legislative text and its amendments and to introduce substantive improvements.⁵

Stakeholders are invited to comment on three main issues:

- codifying and streamlining the legal provisions⁶ with a view to reducing administrative costs (cf. section 1);
- introducing elements of the “new approach” where useful in order to simplify and improve operation of the legislation while maintaining a high level of safety in cosmetics (cf. section 2);
- strengthening certain elements related to chemical safety, in particular with a view to innovative (including “active”) ingredients in cosmetics (cf. section 3).

¹ OJ L 262, 27.9.1976, p. 169, as amended.

² COM (2005) 535 of 25.10.2005.

³ COM(2006) 122 of 14.3.2006.

⁴ COM (2005) 97 of 16.3.2005.

⁵ Cf. whereas 4, 5 of the Interinstitutional agreement of 28 November 2001 on a more structured use of the recasting technique for legal acts (OJ C 77, 28.03.2002, p. 1)

⁶ This also includes some of the items discussed in the Simpler Legislation for the Internal Market (SLIM) initiative launched by the European Commission in May 1996. The “SLIM V team” submitted its “Report and recommendations reviewing legislation on cosmetics” to the Commission in February 2004. This consultation paper takes up the recommendations made in the report on policy issues which are going to be considered by the Commission. For further information, see:

http://ec.europa.eu/internal_market/simplification/slim/2001-phase5_en.htm.

The responses to this consultation are going to be carefully studied by the Commission services to assess:

- to what extent the Cosmetics Directive can be simplified; and
- the socio-economic impact of the changes envisaged.

It shall be emphasised that this simplification exercise is not going to propose any changes to the rules relating to animal testing which were added to the Cosmetics Directive by the “seventh amendment” in 2003⁷ (cf. Article 4a, Article 6(3), second subparagraph, Article 7a(1)(h) and Article 9 of the Cosmetics Directive). The Commission supports these rules. Any opening-up of this sensitive topic would distract attention from the primary aim of this simplification exercise.

1. CODIFYING⁸ AND STREAMLINING THE LEGAL PROVISIONS WITH A VIEW TO REDUCING ADMINISTRATIVE COSTS

The Cosmetics Directive is an example of how a piece of legislation can become “ripe” for simplification: today the Cosmetics Directive is a patchwork of more than 45 amendments with no set of definitions and no coherent terminology. Many of its provisions are unclear or – due to subsequent amendments – appear in the wrong context. This creates legal uncertainty and, as a result, makes application of the Cosmetics Directive a heavier burden and more costly than necessary.

Item 1 considered by the Commission and submitted for public consultation: Which elements in the Cosmetics Directive have given rise to particular legal uncertainty about application? Did this increase administrative costs, e.g. costs to get familiar and to understand the applicable legislation? Can these costs be quantified, e.g. by assessing the necessary man-hours? How can these administrative costs be reduced without compromising the safety of cosmetics placed on the market?

Another aspect concerns international alignment: The cosmetics industry is an international industry with Europe being a very important player. However, the various regulatory frameworks for cosmetic products worldwide are very diverse. This increases costs for European businesses without necessarily contributing to the safety of cosmetic products.

Item 2 considered by the Commission and submitted for public consultation: Can you (roughly) estimate the costs stemming from international regulatory divergences? Which elements in the Cosmetics Directive should be reviewed in order to reach better international alignment? Can you estimate the savings this would bring about for European businesses?

More specifically, the Commission invites comments on the following issues:

⁷ Directive 2003/15/EC of the European Parliament and of the Council of 27 February 2003 amending Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (OJ L 66, 11.3.2003, p. 26).

⁸ “Codification” means replacing the original act and its amending acts by one single text incorporating all amendments.

1.1. Turning the Cosmetics Directive into a Regulation

The Cosmetics Directive provides for exhaustive harmonisation of the national rules on the packaging and labelling of cosmetic products⁹ together with regulation of ingredients for consumer safety reasons. Member States cannot adopt additional rules in this area. Moreover, both the main body of the Cosmetics Directive and the annexes to it are highly detailed and leave little room for manoeuvre in transposition by Member States.

Nevertheless, the Cosmetics Directive and subsequent amendments to it still have to be transposed by the Member States. This can create unnecessary costs for businesses which need to adapt product formulation and packaging to diverging rules if an amending Directive has not (yet) been properly transposed in one or more Member States.

Moreover, transposing highly detailed legal provisions in 27 national laws (plus monitoring by the Commission) creates a heavy and costly burden without adding value.

A regulation would mean that European-wide rules would be directly-applicable without the need of transposition into the national laws of 27 Member States (as it is the case with a Directive). This would create one identical legislative framework as sole reference for economic operators in the entire internal market and address the difficulties set out above.

Item 3 considered by the Commission and submitted for public consultation: Would it be preferable to regulate cosmetics by means of a Regulation (i.e. a directly applicable legal act, cf. Article 249(2) of the EC Treaty)? Two options could be considered:

Option 1: Turn the whole Cosmetics Directive into a Regulation;

Option 2: Turn only the annexes to the Cosmetics Directive into a Regulation.

What would be the socio-economic impact of these options?

1.2. Introducing a set of definitions

A number of definitions are included in various provisions of the Cosmetics Directive,¹⁰ but there is **no coherent list of definitions**. This renders day-to-day administration of the Cosmetics Directive difficult for the industry and competent authorities alike. In response to this lack of definitions, the Commission has developed and published several guidelines. However, these are not legally binding and therefore do not necessarily enhance legal certainty.

Item 4 considered by the Commission and submitted for public consultation: Which terms would need to be included in a set of definitions in order to make the Cosmetics Directive clearer?

⁹ Cf. ECJ cases C-220/98 Lifting ECR 2000 I-117, ground 23; C-150/88 Parfümerie-Fabrik 4711 v Provide ECR 1989 3891, ground 28; C-315/92 Verband Sozialer Wettbewerb v Clinique Laboratories and Estée Lauder ECR 1994 I-317, ground 11.

¹⁰ For example, Articles 1(1) and 5a(1), second sub-paragraph and the preambles to Annexes VI and VII to the Cosmetics Directive.

1.3. Streamlining regulation of substances

Very often regulation of substances in the Cosmetics Directive depends on the purpose for which the ingredient concerned was added. For example, Annexes VI and VII to the Cosmetics Directive relate to the **intended function of the substance** (i.e. “preserving” or “filtering UV radiation”, cf. the preambles to Annexes VI and VII). Some entries in Annex II also refer to certain uses (for example, “when used as a fragrance ingredient”).¹¹

Instead of applying “subjective criteria”, consideration could be given to taking objective criteria as the reference for regulation of substances. This would have two advantages:

- first, it would allow regulation of substances independent of the purpose for which they were added to a cosmetic product;
- second, it would avoid the need to assess the intended function of an ingredient in checks on products on the market.

Item 5 considered by the Commission and submitted for public consultation: Do you agree that objective criteria should apply for defining groups of substances, independent of the purpose for which a substance was added to a cosmetic product?

One example is the term “preservative”. At present, the definition of “preservative” refers to the intention of the manufacturer (“substances [...] added [...] for the primary purpose of inhibiting the development of micro-organisms in such products”, cf. preamble to Annex VI to the Cosmetics Directive). In order to avoid legal uncertainty it might be preferable to define a substance by referring to its *properties* (e.g. anti-microbial), independent of the *reason* why this substance was added to a cosmetic product.

Furthermore, the Cosmetics Directive regulates substances on the “negative lists”¹² and “positive lists”¹³ in the annexes. The disadvantages of listing substances in different annexes are two-fold:

- this could lead to diverging regulation for a substance in different annexes;
- it makes the legislation more difficult to read.

Item 6 considered by the Commission and submitted for public consultation: An alternative approach could be to establish a single list of all regulated substances. With regard to positive lists, it could be specified that substances with specific properties (e.g. anti-microbial, colouring, UV-absorbing or UV-reflecting, etc.) have to be listed in the annex before they can be used as an ingredient in cosmetics.
Would this approach be preferable? Can you see any difficulties which this approach would pose? What would be the impact on the safety of the products containing these substances? What would

¹¹ Annex II, No 432-450 to the Cosmetics Directive.

¹² “Negative lists” place restrictions on substances before the product can be placed lawfully on the Community market (Annexes II and III to the Cosmetics Directive).

¹³ “Positive lists” allow only listed substances as ingredients in cosmetics (hence the term “positive”): Annexes IV (colouring agents), VI (preservatives) and VII (UV filters) to the Cosmetics Directive.

be the socio-economic impacts of this envisaged change? Are there alternative approaches to consider?

1.4. Facilitating updating of the inventory of ingredients

The Cosmetics Directive provides a legal basis for the Commission to adopt an inventory of ingredients (“**the inventory**”, cf. Articles 5a, 6(1)(g), 8(2) and 10 of the Cosmetics Directive). The inventory uses the *INCI*¹⁴ name for each cosmetic ingredient as a *common nomenclature*. The *INCI* name is independent of any national language. It can be indicated on the label independent of the language(s) of the Member State where the product is placed on the Community market.

This concept has been very successful. It labels the packaging with names which (unlike the chemical name) can be easily identified by the consumer and it relieves the industry of the burden of translating much of the obligatory information which has to appear on the container and/or packaging for the different territories in the internal market.

Beyond that, the inventory of ingredients is a useful tool for competent authorities in checks on products on the market.

However, the difficulties lie in updating the inventory. The cosmetics industry is constantly developing new ingredients. The inventory is updated by means of Commission decisions, which inevitably implies a certain time-lag. It also requires translation of the chemical names. As these names are very technical, translation can take years. The result is an inventory which is constantly out of date. This, in turn, makes it less useful for the industry and competent authorities.

Item 7 considered by the Commission and submitted for public consultation: To remedy this situation the Commission could be given a more flexible mandate, which allows for establishing and updating a publicly-available inventory without legislative procedure. Would this approach be preferable? Can you see any difficulties with this approach? What would be the socio-economic impact of this envisaged change? Are there alternative approaches to consider?

2. INTRODUCING ELEMENTS OF THE “NEW APPROACH” IN ORDER TO IMPROVE OPERATION OF THE COSMETICS LEGISLATION

As part of the process of simplification of the Cosmetics Directive, the Commission also intends to assess which elements of the “new approach” to legislation are relevant and should be added to the Cosmetics Directive in order to improve how it works.¹⁵

This would imply, in particular, shifting the focus from detailed regulation of individual substances to tighter checks on products on the market, based on the manufacturer's

¹⁴ International Nomenclature for Cosmetics Ingredients.

¹⁵ Cf. Commission Communication “Implementing the Community Lisbon programme: A strategy for the simplification of the regulatory environment” (COM (2005) 535 of 25.10.2005).

responsibility plus improved technical documentation which would allow better control of the safety of the products on the market.

Unlike new approach regulation (in which harmonisation is achieved by establishing generic - “essential” - requirements rather than laying down technical details), the Cosmetics Directive provides for detailed regulation of chemical substances. It addresses some 500 of the many thousand potential ingredients in cosmetics. For these 500 or so substances, the Cosmetics Directive has become a sort of “cook book” with official “recipes”. The idea underlying the Cosmetics Directive back in 1976 may have been step-by-step total harmonisation of restrictions on every ingredient in cosmetics.

However, despite all the efforts to finalise this “cook book” over the last 30 years this has proven unfeasible: detailed regulation of individual substances has proven too lengthy, burdensome and resource-intensive. The time between identification of a substance which poses a potential risk, evaluation of the risk, regulation through technical adaptation of the Cosmetics Directive and actual changes in the composition of the product sold to the consumer is very long (approximately five years).

Moreover, detailed regulation of individual substances in a “cook book” has serious shortcomings:

- first, it may be perceived as freeing industry of its responsibility to ensure the safety of substances. Once a substance is regulated in detail in the Cosmetics Directive, there is a risk that the industry may refrain from following up the safety aspects in relation to this substance;
- second, there is a danger that, when engaging in detailed assessment of the safety of a specific substance, the regulator might lose the overview and be distracted from the real risks posed by cosmetics placed on the Community market.

Therefore, consideration could be given to turning away from lengthy assessment of individual substances as the means of choice to ensure that cosmetics are safe. Instead, it might be preferable to tighten up safety checks on cosmetic products on the market. Time- and resource-intensive regulation of individual substances would become the exception rather than the rule.

This would imply the following measures:

2.1. Clarifying the principle of the “manufacturer's responsibility”

The Cosmetics Directive is based on the principle of the manufacturer's responsibility for the “uncompromised safety” of cosmetic products. However, the principle of the manufacturer's responsibility is not clearly enshrined in the Cosmetics Directive (cf., for example, Article 3 of the Directive).

<p>Item 8 considered by the Commission and submitted for public consultation: The Cosmetics Directive could clearly stipulate that the person responsible for placing the product on the Community market is responsible for compliance with the Directive, i.e. for the safety of the product.</p>
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2.2. Strengthening the technical documentation required

Stronger technical documentation supporting the safety of the product placed on the market may be needed.

Today there is already a legal requirement to provide a product information file (including information on the safety of the product, based on an assessment of the toxicological profile of the ingredients) for every cosmetic product placed on the market (Article 7a(1) of the Cosmetics Directive), but the documentation requirements may need strengthening to allow improved checks on products on the market.

Item 9 considered by the Commission and submitted for public consultation: The Cosmetics Directive could specify more clearly the information to be made available in the product information file requested via in-market controls to prove the safety of the product. The extent and content of the information required could be based on:

- the SCCP guidelines for safety evaluation of cosmetic ingredients; and/or
- the “technical dossier” and “chemical safety report” requirements in the REACH Regulation 1907/2006 as far as human health risks are concerned.¹⁶

Which concrete information (including safety data) would the product information file need to contain to allow for more efficient in-market controls of the safety of the products/their substances? How does this information compare with what is usually available in product information files today? Would this mean an increase in information as compared to today? What would be the socio-economic impacts of these envisaged changes?

2.3. Strengthening checks on products on the market and “cosmetovigilance”, including clarification of rules on registration

Efficient checks on products on the market and clear rules in case of non-compliance with the Cosmetics Directive are the keys to safe cosmetics. This aspect may need strengthening. For example, the Cosmetics Directive provides no clear rules on product withdrawal if a product information file does not contain the required safety assessment of the product in sufficient detail.

Moreover, in order to make the internal market work, a high degree of cooperation between competent authorities is necessary. This includes clarification how competent authorities support each other regarding verification of the product information file in cases where it is available in another Member State than the one where the in-market control took place. Presently, the Cosmetics Directive addresses this aspect only very much as a side-issue (cf. Article 7a(5), second subparagraph of the Directive).

Item 10 considered by the Commission and submitted for public consultation:

The Cosmetics Directive could provide for clear response mechanisms in the event of non-compliance with the Directive (including rules on product withdrawal).

¹⁶ Articles 10, 14 of “REACH Regulation” 1907/2006 of 18.12.2006 (OJ L 396, 30.12.2006, p. 1).

In addition, the Cosmetics Directive could contain rules on the procedure which would apply for the cases where the product information file is available in another Member State than the one where the in-market control took place.

What is your view on this? What would be the socio-economic impact of such an envisaged mechanism?

Moreover, a flow of information must be ensured between dermatologists, the industry, authorities and the regulator on observed adverse effects (“**cosmetovigilance**”). This is particularly important in connection with allergies to ingredients, as any increase in sensitisation may be detected only over a long period looking at the population as a whole.

While enforcing Community law is primarily the responsibility of the Member States, the Commission can play a useful role in supporting and coordinating their efforts.

Item 11 considered by the Commission and submitted for public consultation:

The Cosmetics Directive could include a mandate for the Commission to assist in coordinating cooperation between the Member States in the field of “cosmetovigilance”.

What is your view on this? How would this information flow need to be organized to ensure an efficient surveillance of the safety of the products? What would be the socio-economic impact?

The Cosmetics Directive provides for a notification requirement of the place of manufacturing and the initial importation of cosmetics products (Article 7a(4) of the Cosmetics Directive).

The notification requirement is meant to facilitate efficient checks on products on the market. Moreover, the notification requirement could be a useful tool to combat importation of counterfeit goods.

However, the notification procedures are unclear. In particular, it is not entirely clear:

- which Member State(s) need(s) to be notified that the product is being placed on the Community market;
- what information has to be notified.

In practice, this leads to diverging requirements for placing a cosmetic product on the Community market.

Item 12 considered by the Commission and submitted for public consultation: Would clarification of the rules on notification help to improve market surveillance? What elements should notification cover? What would this mean in terms of socio-economic impact?

How can the registration requirement best contribute to combating importation of counterfeit goods?

2.4. Addressing individual substances only in exceptional cases

Improved technical documentation of the safety of the product, combined with stronger checks on products on the market and clear mechanisms for product

withdrawal, would make it possible to reserve addressing individual substances for very exceptional cases, such as:

- disagreements between Member States' authorities about whether the data provided in the product information file are adequate to prove the safety of the ingredients used;
- cases where safety concerns attributable to a group of substances are so serious that “authorisation” for these substances is needed (“positive lists”, cf. section 3.2.).

Item 13 considered by the Commission and submitted for public consultation:

The safety of ingredients in cosmetics would be assessed by the competent authorities on the basis of the product information file. Only if the competent authorities of different Member States disagree with this assessment they should refer the matter to the Commission (including the SCCP).

3. STRENGTHENING CERTAIN ELEMENTS RELATED TO CHEMICAL SAFETY, IN PARTICULAR WITH A VIEW TO INNOVATIVE (INCLUDING “ACTIVE”) INGREDIENTS IN COSMETICS

The Commission is not questioning that detailed regulation of an individual substance may be necessary in some cases in order to safeguard operation of the internal market. Indeed, as **the Cosmetics Directive is essentially a special chemicals law**, there may be a need for Community-wide restriction, authorisation or prohibition of a chemical substance in some cases.

This holds particularly true for the trend towards innovative ingredients in cosmetics. Examples include certain “active” substances (sometimes called “dermo-cosmetics”) and micronised particles.

This raises the question whether the chemicals regulation part of the Cosmetics Directive need strengthening in order to secure “uncompromised safety” in this sector in the future.

Item 14 considered by the Commission and submitted for public consultation: Which elements of the Cosmetics Directive need to be strengthened to ensure the safety of innovative products in the future? Are additional regulatory tools required in order to ensure this safety? If yes, what would be the socio-economic impact of these additional regulatory tools?

More specifically, the Commission invites comments on the following issues:

3.1. Stressing the principles of “uncompromised safety” and “no data – no market”

In the cosmetics sector the concept of “uncompromised safety” applies. This means that, in principle, a risk to consumer safety cannot be balanced against the benefit of the product. This is the crucial difference from regulation of medicinal products, where a risk-benefit analysis is conducted.

However, this concept is not reflected clearly enough in the Cosmetics Directive. Instead, a variety of undefined terms are used: Article 2 of the Directive reads “not cause damage to human health”, Article 6 talks about “without any harm to the

consumer”, Article 7a(1)(f) refers to “undesirable effects” and Article 12 mentions “hazard to health”. As safety is a crucial concept for cosmetic products, a coherent terminology is required.

Item 15 considered by the Commission and submitted for public consultation: Clarification could be achieved by explaining and defining the concept of “uncompromised safety”.

What is your view on this clarification? What would be the socio-economic impact?

Moreover, in the vast majority of cases, when assessing individual substances the Commission, as risk-manager, runs into the problem of **lack of data** proving the safety of the substances. In practice, in the bulk of cases the Scientific Committee for Consumer Products (SCCP) concludes that a final risk evaluation is not possible for want of data. There are two explanations for this:

- first, very often the data required to prove the safety of a substance raising safety concerns do not yet exist when the SCCP receives a mandate to conduct a risk evaluation. In particular, the product information file required for checks on products on the market pursuant to Article 7a(1) of the Cosmetics Directive never contains all the data required in the SCCP guidelines;
- second, if the substance is not on a negative list, or if the substance is already on a positive list, there may be a risk of reduced incentive for industry to submit (additional) data.

No provision in the Cosmetics Directive explicitly places on the industry the burden of proof of the safety of ingredients in cosmetics (i.e. no clear enshrining of the basic principle of “no data – no market”). Therefore, if the data for a definitive risk evaluation are missing, **no regulatory action can be taken without invoking the precautionary principle.**

This situation is not going to change when REACH Regulation 1907/2006 enters into force. The obligation imposed by REACH to assess the health risks posed by chemicals does not apply to use as ingredients in cosmetics.¹⁷ In this respect, the Cosmetics Directive continues to provide a separate legal framework.

Therefore, this situation has to be addressed in the Cosmetics Directive itself.

Item 16 considered by the Commission and submitted for public consultation: The Cosmetics Directive could make it clear that, as a consequence of the responsibility of the manufacturer, if data are missing the substance in question will be presumed unsafe.

What is your view on this clarification? Are there alternative approaches to ensure the safety of products? Do you think this clarification would have a socio-economic impact? How?

3.2. Facilitating management of the “positive lists” of authorised ingredients

As explained in section 2.4, the Commission should address individual substances only in two exceptional cases:

¹⁷ Article 14(5)(b) of “REACH Regulation” 1907/2006 of 18.12.2006 (OJ L 396, 30.12.2006, p. 1).

- first, in the case of disagreement between Member States about whether the safety data provided in the product information file are adequate (see section 2.);
- second, in the case of “authorisation” on “positive lists”: past experience has shown that a group of substances may raise safety concerns which are so serious that “authorisation” for these substances as ingredients in cosmetics is needed.

Such “authorisation” is granted by establishing “positive lists”: out of a group of substances, only the substances listed are allowed as ingredients in cosmetics.

Presently positive lists exist for colouring agents (except hair-dyeing substances), preservatives and UV filters. However, a need might emerge for the regulator to establish additional “positive lists” in the Cosmetics Directive, if serious health concerns arise about specific groups of substances in the future. One recent example of the need for this possibility is hair-dyeing substances. In this case a positive list would have greatly helped the regulator to ensure that only hair-dyeing substances which have been assessed by the SCCP are used as ingredients in cosmetics.

“Positive lists” are relatively easy to administer. The difficulties outlined in section 3.1 are less imminent. The industry has a strong interest in quickly submitting a comprehensive set of data in order to obtain authorisation of the substance concerned.

Item 17 considered by the Commission and submitted for public consultation: Apart from a positive list for hair-dyeing substances, the Cosmetics Directive could include a mandate for the Commission, as risk-manager, to compile new positive lists for groups of substances. This would allow it to ensure that only substances which have undergone a safety assessment by the SCCP can be used as ingredients in cosmetics.

What is your view on this? How would this impact on the safety of cosmetic products? What would be the socio-economic impact?

Experience shows that it sometimes proves necessary to reconsider “authorisation” of a substance on a positive list after a certain length of time. The Cosmetics Directive provides no clear mechanism to this end. In order to remedy this, consideration could be given to introducing “sunset clauses” for authorisations.

Item 18 considered by the Commission and submitted for public consultation: The Cosmetics Directive could provide for a mechanism placing an obligation on the regulator to reconsider the listing of a substance on a “positive list”.

What is your view on this? How would this impact on the safety of cosmetic products? What would be the socio-economic impact?

Any comments and information on this public consultation should be submitted by mail, fax or e-mail by Friday evening, 16.3.2007, at the latest to:

European Commission
Unit ENTR F/3, Cosmetics and Medical Devices

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Respondent should indicate whether they are a company, consumer, academic, associations or other. If they are a company, the approximate size (turnover, employees) and the main market (product market and geographical market) should be indicated.

Submissions will be published on the “cosmetics” website of the European Commission. Respondents should indicate whether they wish the Commission to treat their submission as confidential.

Brussels, 12 January 2007