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**Impact assessment report on simplification of the “Cosmetics Directive”
– Directive 76/768/EEC**

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1. PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES

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 It is scheduled in the Commission’s Agenda Planning (under ref. 2007/ENTR/002).

1.1. Consultation of other Commission Services

Work on the impact assessment on this simplification started in late 2006. Three meetings of the Inter-Service Steering Group were held with representatives from Directorates-General SANCO, TRADE, RTD, JRC, ENV and EMPL and from the Legal Service and the Secretariat-General on 15 December 2006, 21 May 2007 and 7 September 2007.

1.2. External studies

To gain additional expertise, the Commission ordered three studies looking at the following aspects of this simplification exercise:⁴

- **A description of the EU cosmetics industry** in order to gain a better understanding of its current performance and characteristics;
- **An assessment of the impact of EU regulation on consumer safety** with the aim of compiling, assessing and presenting information on the impact of the Cosmetics Directive in terms of health protection, in order to define the potential for improvement; and
- **An assessment of the impact of EU regulation on the industry’s competitiveness** in order to obtain more detailed information on the economic impact of the existing EU legislation for cosmetic products and possible changes to it.

1.3. Stakeholder consultation

Moreover, a **stakeholder consultation** was held from 12 January 2007 to 16 March 2007 on the basis of a public consultation document in English, French and German. A press release publicised the launch of this public consultation.

In response to this public consultation the Commission received 72 contributions. Of these, 46 were from industry (fine chemicals, cosmetics and others⁵), 18 from

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

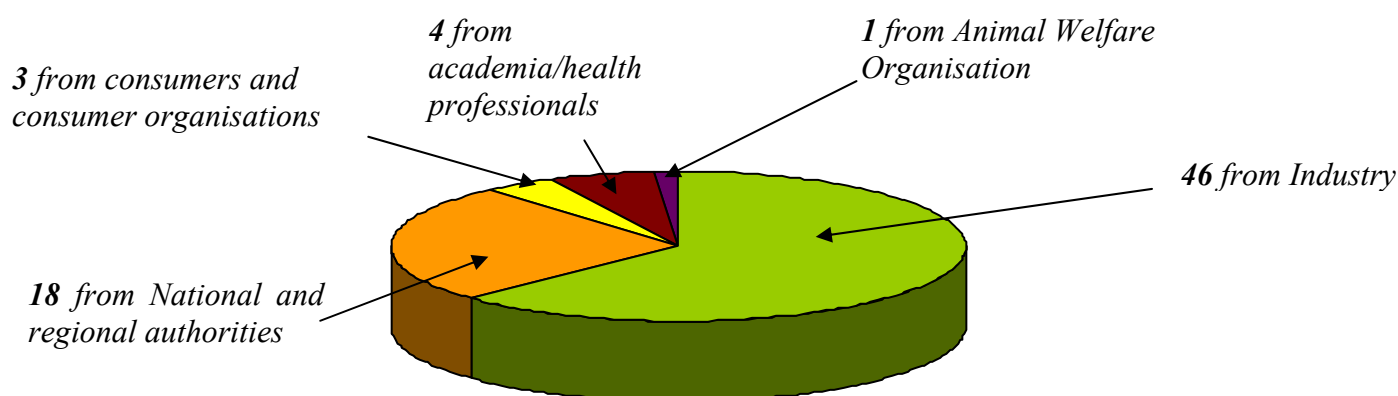
² COM(2005) 535 of 25.10.2005.

³ COM(2006) 122 of 14.3.2006.

⁴ The studies are still under evaluation by the Commission Services. Once the evaluations are finalised and payments are made, the studies are going to be published under http://ec.europa.eu/enterprise/cosmetics/html/cosm_comparative_study.htm

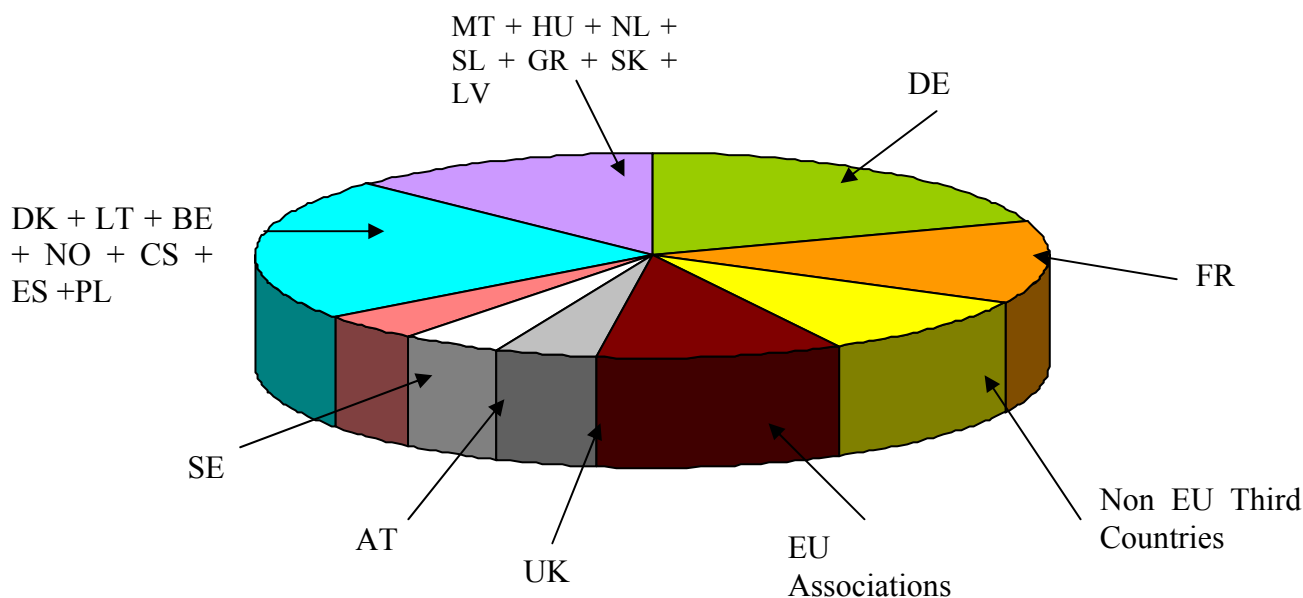
national and regional authorities, 4 from academics/health professionals, 3 from consumers and consumer organisations and 1 from an animal welfare organisation.

Responses to the public consultation – distribution by stakeholders



In terms of regions, 7 contributions were received from EU-wide associations, 15 from Germany, 9 from France, 3 each from the UK, Austria and Sweden, 2 each from Lithuania, Belgium (including Luxembourg), Denmark, Norway, the Czech Republic, Spain, Poland and Ireland, 1 each from Finland, Malta, Hungary, the Netherlands, Slovenia, Greece, Slovakia, Latvia and Switzerland and 7 from Third Countries.

Responses to the public consultation – distribution by country



The main results of the public consultation are summed up in sections 2-5 of the impact assessment report. An overview of the responses to the consultation is attached in Annex 1.

⁵ Including retailers, manufacturers of machinery/equipment, chemists, the hairdressing industry and branding companies.

Seven stakeholders requested that their submission be treated confidentially. The responses of the other stakeholders have been published on the “cosmetics website” of the European Commission.⁶

All the standards set in the “General principles and minimum standards for consultation of interested parties by the Commission”⁷ have been met. In particular, the public consultation was:

- open to all stakeholders for eight weeks and announced by a press release;
- accessible via the single access point on the internet⁸; and
- followed-up with an individual reception notice as well as with a summary of the responses.⁹

1.4. Contacts with Third Countries

In the run-up of the impact assessment, the Commission was in contact with several Third Country authorities and industry associations. For example:

- U.S. Food and Drug Administration (U.S. FDA): In the framework of its bilateral regulatory dialogue the Commission specifically invited U.S. FDA to submit comments during the public consultation. The comments subsequently submitted were carefully studied by the Commission and duly taken into account.
- U.S., Japanese and Australian industry association: All three industry associations submitted comments during the public consultation.

1.5. Scrutiny by the Commission impact assessment board

The impact assessment board of the European Commission¹⁰ assessed a draft version of the impact assessment in August 2007. It issued its opinion on 31 August 2007.¹¹ Apart from some technical comments, the impact assessment board made several substantial suggestions for improvement. In the light of these suggestions, the final impact assessment report:

- Sets out in more detail the impacts of simplification in terms of product safety and costs for businesses (in particular concerning labelling; cf. sections 2.2.1. and 5.1.2.);
- Explains better the impact of a clarified cosmetic product safety report in terms of product safety and costs for businesses (cf. section 5.3.6.a.);
- Addresses the implications for the Community budget (cf. section 5.1.2.)

⁶ http://ec.europa.eu/enterprise/cosmetics/html/cosm_simpl_dir_en.htm.

⁷ COM(2002) 704.

⁸ http://ec.europa.eu/yourvoice/consultations/index_en.htm

⁹ Cf. Annex 1.

¹⁰ http://ec.europa.eu/governance/impact/iab_en.htm

¹¹ Cf. Annex 6.

- Addresses the possibilities of non-legislative measures (cf. sections 4.3.2. and 5.3.2.); and
- Puts a stronger emphasis on procedural matters (public consultation and contacts with Third States; cf. this section 1.)

2. PROBLEM DEFINITION

2.1. Background

The Cosmetics Directive was adopted in 1976. Its aim is to harmonise the restrictions on ingredients and rules on labelling in order to allow free circulation of cosmetic products on the internal market and to maintain a high level of consumer protection.

The Cosmetics Directive¹² is based on the principle of “manufacturer responsibility”, i.e. the “manufacturer”¹³ is responsible for the safety of the cosmetic product placed on the EU market. To this end, the person responsible for placing the product on the market has to prove that the product is safe by means of a “product information file” which is checked on an *ad hoc* basis by the competent authorities in “in-market controls”.

The principle of manufacturer responsibility is supplemented by detailed regulation of selected individual cosmetic ingredients. In fact, in 1976 the objective of the legislator was to establish a “positive list” of all chemical ingredients permitted in cosmetic products along with the relevant concentration limits and any other restrictions. As this was a heavy workload (the cosmetics industry uses approximately 10 000 chemical ingredients), the legislator decided to start with a “negative list” of substances which are restricted or banned and then to move on to address all relevant substances, thereby shifting step by step to a “positive list”.¹⁴

Finally, the Cosmetics Directive is a highly detailed and prescriptive piece of legislation which leaves very little room for varying transposition by Member States. Since 1976 the Cosmetics Directive has been amended 53 times.

Cosmetic products are essentially mixtures of chemicals. The Cosmetics Directive is, in practice, a special chemicals law for products used by every consumer every day.

Industry is constantly re-formulating products and on the quest for substances which could be applied in the cosmetics sector. Studies contracted by the Commission suggest that in average between 20% (SME’s) and 30% (non-SME’s) of product formulations are newly developed or reformulated by the cosmetics industry every year. On its quest for “new” ingredients, industry also uses substances stemming from the pharmaceutical sector – albeit in quantities which do not qualify these products as “medicinal products”.

¹² A more detailed description of the Cosmetics Directive can be found in Annex 6.

¹³ In this context, instead of “manufacturer” it would be more correct to say “person responsible for placing the product on the Community market”.

¹⁴ See the minutes of the first meeting of the Working Group on Economic Matters on the proposal for the Cosmetics Directive, 17 and 18 July 1973, “General observations.”

The EU cosmetics sector is characterised by SMEs: 97% of all EU cosmetic companies are SMEs and 80% have fewer than 19 employees. SMEs account for approximately two thirds of all people directly employed in the cosmetics sector in the EU.¹⁵

In terms of employment, there are approx. 150 000 people employed in the cosmetics industry in Europe. Since 1999, the European sector has been steadily creating new jobs (increase of 1.2% per year). Employment growth has been remarkably pronounced in EU10, with approximately 30% growth in employment over the period 1999-2004, albeit starting from a low base.¹⁶

Apart from direct employment, the cosmetics sector has a strong indirect impact on employment such as retail, distribution and transport. It can be estimated that approx. 350 000 jobs are created indirectly by the cosmetics industry.

The volume and value of intra-community exports of cosmetics has increased year-on-year since 1999 by an average of 5 per cent a year in terms of volume, and by 6.5 per cent a year in terms of value.¹⁷

Cosmetics industry is an international business in which Europe is a very important player.

The global nature of this sector is particularly relevant to the EU as a net exporter. In 2005 exports outside the EU stood at EUR 16 billion with imports at EUR 4.4 billion. For example, 7% of all cosmetic products in the USA are imported from the EU, which adds up to trade of almost EUR 3 billion per year.¹⁸

Moreover, over the period 2000-2005 EU exports grew by 8.7%. This trend is expected to continue, mainly due to the growing markets abroad at a time when the market in the big economies is stagnating. For example, the Chinese market alone is expected to grow by 12.8% per year over the period 2006-2011 and by 11.5% per year over the period 2011-2016. On the other hand, the EU-15 market, including the big economies which generate almost 70% of sales, has been practically stagnant with growth rates in the range of 1-3% (2002-03: 3.5%; 2003-04: 2%; 2004-05: 1%). Consequently, today large EU companies record approximately 30% of their sales in non-EU countries. European SMEs average approximately 10% to 20% of their sales in non-EU countries.¹⁹

¹⁵ Cf. "Study of the European Cosmetics Industry", Global Insight (2007), Chapter II.

¹⁶ Cf. "Study of the European Cosmetics Industry", Global Insight (2007), Chapter II.

¹⁷ Cf. overview in Annex 2.

¹⁸ The value of cosmetic products imported into the EU from the USA totals approximately EUR 1.5 billion; Cf. "Study of the European Cosmetics Industry", Global Insight (2007), Chapter III.

¹⁹ Cf. "Study of the European Cosmetics Industry", Global Insight (2007), Chapter III.

2.2. Problem identification

The Commission has identified four issues to be addressed in a simplification exercise:²⁰

2.2.1. *Legal unclarities/inconsistencies and burdensome management of the Cosmetics Directive*

a) Legal unclarities/inconsistencies

The 53 amendments over a span of more than 30 years have led to numerous conflicting provisions, inconsistent terminology and rules appearing in the wrong context. This is aggravated by the fact that the Cosmetics Directive:

- contains no list of definitions; and
- has never been codified (i.e. all the amendments have never been formally incorporated into a single legal text).²¹

Clarification is required in particular as to the notion of “person responsible for placing the cosmetic product on the market” and the scope of groups of substances, such as “UV-filter”. Moreover, the public consultation revealed that a number of terms used in the Cosmetics Directive needed clarification, including “minimum durability”, “professional use”, “undesirable effect”, “traces”, and “rinse-off product”.²² In addition, the need of more coherent terms in the annexes, which is by and large a scientific and technical exercise, was stressed.

Another example for the need for clarification concerns the labelling regime. The relevant provisions of the Cosmetics Directive²³ have been amended by the co-legislator several times. Some provisions now appear in the wrong context and render the text inconsistent.

This lack of clarity leads to additional costs for businesses as well as for competent authorities.

Costs for businesses

It is very difficult to quantify the costs for businesses stemming from legal unclarities. This holds particularly true for the cosmetics sector. In the public consultation²⁴ stakeholders attributed this to the fact that different regulatory frameworks apply simultaneously to the chemicals employed by the cosmetics industry. These laws address chemical safety from different perspectives, such as worker protection, transport, environment, consumer, waste, etc. It is impossible to “distil” the precise costs incurred from any single piece of legislation. Nevertheless,

²⁰ Note that simplification and recast address the same issue, i.e. a review of the Cosmetics Directive. Recast describes the legal technique, while simplification describes the broad policy aim.

²¹ Note, however, that a consolidated version (i.e. an informal text incorporating all the amendments) was made available by the Office for Publications on 9 August 2006.

²² A summary of the suggested items in the public consultation can be found in Annex 1.

²³ Art. 6 Cosmetics Directive.

²⁴ For a detailed summary of the responses, see Annex 1.

estimates based on the responses submitted during the public consultation suggest that greater legal certainty about various issues in the Cosmetics Directive could cut compliance costs by up to 10%.

According to Commission research, total cost for compliance with the requirements of the Cosmetics Directive lies between 0.5% and 1% of the annual turnover of a cosmetic manufacturer.²⁵

Considering a yearly EU-turnover of EU cosmetics industry of 55 billion EUR²⁶, total costs of compliance for EU businesses is thus approx. 390-400 million EUR.²⁷ This means that legal unclarities stemming from the Cosmetics Directive cost EU-cosmetics businesses approx. 40 million EUR per year.

Example: The Cosmetics Directive does not define the term ‘placing on the market’: Each time a substance is banned/restricted in cosmetic products “placed on the market”, there is considerable legal uncertainty: Companies have to consult public authorities in order to know how this term is interpreted in their jurisdiction. In some cases, extensive discussion and consultation is needed in order to ensure the legality of a product in all Member States of the entire Community market.

The public consultation confirmed that the share of SMEs in new product launches on the Community market is roughly 50%. Based on this figure, and considering that administrative burdens arise usually when a new product is launched, a careful estimation shows that SMEs bear about 20 million EUR of superfluous administrative burden stemming from legal uncertainties every year.

Costs for national competent authorities

Apart from the costs for businesses, legal uncertainties also lead to unnecessary costs for national authorities supervising correct application of the Cosmetics Directive by the industry. Research by the Commission suggests that it takes even small Member States approximately 3 person-years to give extensive explanations of the meaning of the various aspects of the Cosmetics Directive. These costs can be avoided and the resources redirected to market surveillance and in-market control.

b) Complicated and burdensome management of the Cosmetics Directive

Moreover, some aspects of the management of the Cosmetics Directive are very complicated and burdensome without adding value. Examples are:

- The burdensome procedure for the updating of the inventory of cosmetic ingredients used: This aspect relates in particular to the provisions on labelling: According to the Cosmetics Directive, the cosmetic cosmetic ingredients have to be labelled on the product. To avoid the need for translation, an “inventory of ingredients” has been set up by the Commission, which lists “artificial” names of all chemicals which are of interest for the cosmetics industry. These names, established at an international level, are independent of any national language and

²⁵ Cf. “Impact of European Regulation on the EU Cosmetics Industry”, RPA (2007), Chapter 3.3.1.

²⁶ Cf. “Study of the European Cosmetics Industry”, Global Insight (2007), Chapter I.

²⁷ This includes administrative costs count of approx. 80 million EUR. For more details refer to annex 3.

do not need to be translated on the product labelling. However, while there are constantly new chemicals for a potential use as cosmetic ingredient “discovered”, the update of the inventory is a very cumbersome procedure, involving translation of the description of the chemical and its scientific name and Comitology procedure. Translation alone of these highly technical aspects into 22 languages takes several years. This is why there has been only one update of the inventory in the past 11 years;

- The complicated procedure for the development methods for analysis: Methods of analysis are required to assess the concentration of a substance contained in a preparation. Uniform methods of analysis are crucial for companies to have legal certainty about compliance of their product with the regulation of individual substances. At present, methods of analysis – a very technical matter – have to be adopted as Commission Directives under Comitology and subsequently transposed by Member States. This procedure is very lengthy for an issue such as methods of analysis, which are quickly outdated. Methods of analysis in this procedure are in practice very often useless. Consequently, since 1996, no new analytical method in the field of cosmetics was adopted;
- At present, the approx. 10-12 anti-poisoning centres are informed individually for the EU-wide launch of a product.

Costs for businesses:

The cumbersome management of the Cosmetics Directive brings about considerable unnecessary costs for industry: The incomplete inventory obliges industry to label – in order to be compliant with the Cosmetics Directive – certain ingredients in the national language. This leads to considerable additional costs. Industry is trying to avoid these costs by labelling international “artificial” names which are not yet contained in the inventory. In the responses to the public consultation, the need to obtain ingredient names from other sources was identified as one of the most cumbersome aspects in the every-day work for companies, in particular for SMEs which have only limited resources for regulatory aspects available. Another factor contributing to unnecessary costs is the lack of harmonised up-to-date analytical methods to assess compliance with the restrictions for ingredients. Finally, the need to submit information to several anti-poisoning centres individually leads to important increase of administrative costs, which could be reduced considerably: each additional notification increases costs for businesses proportionally (for more details using the standard cost model, see below, 5.1.2.).

Costs for national competent authorities

The difficulties created by the burdensome management of the Cosmetics Directive are also felt by national competent authorities: The incompleteness of the inventory makes in-market controls of products and their ingredients more burdensome and costly. Moreover, authorities, in their in-market control, have to develop their own methods of analysis. This is costly, as it requires considerable technical expertise.

2.2.2. *Incoherent and resource-intensive transposition without adding value*

The Cosmetics Directive provides for exhaustive harmonisation of the national rules on the packaging and labelling of cosmetic products²⁸ together with regulation of ingredients for consumer safety reasons. Member States may not adopt additional rules in this area. Both the enacting terms 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 have to be transposed by Member States. This has led to difficulties for EU businesses, as the national transpositions may be slightly divergent. Moreover, their date of entry into force may vary from country to country. Thus, at any one given time, labelling and ingredient restrictions can differ in the internal market.

While it is true that these consequences are inherent in any EU legislation adopted in the form of a Directive, they are particularly apparent in the case of the Cosmetics Directive because it is:

- highly detailed; and
- frequently amended – in recent years up to five times a year.

The public consultation confirmed that each non/maltransposition of amending Directives to the Cosmetics Directive in a single Member State creates considerable costs for EU-businesses without adding value in terms of safety.

Example: New product launches are often preceded by lengthy discussions between technical managers and Member State authorities in order to track the implementation of changes to the Cosmetics Directive.

Moreover, it reduces the benefits of an internal market and its potential for economies of scale. Transposition in 27 national law does not allow for Europe-wide product launches but requires the staggering of launches: Such launch is only possible once all 27 Member States have transposed amendments to the Cosmetics Directive into their national legal system.

On a different note, it has to be stressed that transposing highly detailed legal provisions into 27 national laws (plus monitoring by the Commission) creates a heavy and costly burden for public authorities without adding value in terms of consumer safety.

2.2.3. *Ensuring the safety of cosmetic products in the light of innovation*

As explained in section 2.1., cosmetic products are essentially applied chemical preparations. These substances could be hazardous and pose a risk to consumer safety.

²⁸ See 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 Laboratoires and Estée Lauder* ECR 1994 I-317, ground 11.

All available statistics suggest that the number of adverse reactions to cosmetic products is very low. For example, figures from the German industry show approximately 1.14 undesirable effects per 1 million units of cosmetic products placed on the market. Older figures published in the 1970s by the Dutch authorities show an incidence rate of 3 cases per 1 million units of cosmetic products placed on the market.²⁹ Considering that each year approximately 10 billion units of cosmetics are sold to final consumers in the EU, the incidence of undesirable effects lies in the range of approximately 10 000 to 20 000 per year in the EU. Most of these undesirable effects are not “serious”, i.e. not “undesirable effects which have caused permanent or significant disability/incapacity, hospitalisation, congenital anomalies, immediate vital risk or death”. According to figures from the French competent authority AFSSAPS, 40 serious undesirable effects were notified by health professionals in 2005.³⁰ These figures were very similar in 2006, when 23% of all cases notified to AFSSAPS were considered serious. The RAPEX database recorded just 49 notifications of cosmetic products posing a “serious risk”³¹ over the period January 2005-May 2007. Most “non-serious” adverse reactions take the form of minor allergic reactions and irritations.

Moreover, since the Cosmetics Directive entered into force the cosmetics industry has had no major safety crisis, unlike, for example, the feed sector.

On the other hand, ensuring and increasing the level of safety of cosmetic products is the key, in particular regarding new and innovative products. Innovation in the cosmetics sector takes three forms:

- A constant change in product formulations: Even if the ingredients used in a given cosmetic product are known, they are constantly applied in new combinations, textures and matrixes. Ingredients – albeit known – may pose new safety challenges when applied in other textures or for other uses.

Example: Penetration of cosmetic ingredients depends on the texture of the product, its pH and its mode of application. Thus, the same ingredient may have different toxicological characteristics in different product types.

- Use of “new” ingredients: The cosmetics industry is constantly on the quest of new ingredients or new preparations used as raw material. The scale of this development can be best illustrated by the attribution of new international ingredient names: Essentially, every ingredient/raw material of interest for the cosmetics industry is attributed an international ingredient name: Each year, approx. 500 names are attributed, i.e. each year, 500 new ingredients/raw materials are used in cosmetic products placed on the market worldwide, including in the EU. Note, however, that these ingredients are not necessarily “new” in terms of chemical molecule. Rather, these substances are often used in other sectors and subsequently “discovered” for the use in a cosmetic product.

²⁹ Keuringsdienst van Waren voor het Gebied Enschede, Cosmetica Report, 25 April 1982.

³⁰ A. Pochet, Actualités réglementaires relatives aux produits cosmétiques, Galénique de dermatologie, 2007, 134:2. Note that these figures relate to France, the second-largest national market in the EU with a market share by volume of approximately 17% based on EU-15 (see Annex 2).

³¹ Note that the definition of “serious risk” in RAPEX is not identical to the one in the French notification system.

Examples are “active” ingredients known in the pharmaceutical sector and applied in concentrations that do not qualify the product as medicinal product as the pharmacological, immunological or metabolic effect is insignificant.³²

- Use of known ingredients in nanosizes: Future innovation is likely to be based on new physical characteristics of existing substances: the most prominent example is the use of particles in micronised forms. Micronised particulars are presently in use as physical UV-filters.³³ As such, their use in cosmetic products has to be authorised by the European Commission. However, other uses in other types of cosmetic products cannot be excluded in the future.

It is not possible to quantify – let alone to quantify in monetary terms – the impact of future innovation in the cosmetics sector on product safety and consumer health.

However, it is clear that the cosmetics sector, which is in constant move, is going to pose increasingly safety-challenges in the future. The Commission has to follow-up this development carefully and to pro-actively respond to it for two reasons:

- The cosmetics sector is characterized by very rapid changes of product formulations. There is a constant quest by industry for new ingredients and new technologies;
- There is a strong public interest in the safety cosmetic products, which are essentially chemical preparations applied by every consumer (including children) every day.

This holds even more true as the definition of “cosmetic product” in the EU is rather wide. A comparison with other jurisdiction reveals that, in the EU, relatively many products fall under the category of “cosmetic products” which elsewhere are considered as “over-the counter drugs” or “quasi drugs”. On the other hand, in those other jurisdictions the requirements for “cosmetic products” are in some cases relatively low, compared to the EU-regime. This concerns in particular provisions on product safety assessment, labelling, and the regulation on individual substances.³⁴

Example 1: Mouth wash products and deodorants are usually cosmetic products in the EU, but regulated as “quasi-drugs” in Japan. Anti-dandruff shampoos, sunscreen products and bleaching products are usually considered as cosmetic products in the EU, but regulated as “over the counter drugs” in the U.S. Anti-wrinkle and skin-bleaching products are usually considered as cosmetic products in the EU, but regulated as “functional cosmetics” (with a stricter regime) in South Korea.

Example 2: The EU Cosmetics Directive regulates approx. 400 cosmetic ingredients in detail. In the U.S., regulation of cosmetics ingredients is very limited, amounting to approx. 12 ingredients and a list of authorised colouring agents.

³² For the determination of the borderline „medicinal product“ and „cosmetic product“ cf. the relevant guidance documents: http://ec.europa.eu/enterprise/cosmetics/html/cosm_borderline_docs.htm

³³ Physical UV-filter *reflect* radiation, while „chemical“ UV-filters act through *absorption*.

³⁴ Cf. “Cosmetics Legislation in the EU and Other Principal Markets with Special Attention to Borderline Products”, RPA (2004).

Apart from the innovation in this field, particular regard has to be paid to issues of sensitisation, i.e. allergic reactions to certain cosmetic ingredients: It can be estimated that approx. 60% of all undesirable effects are cases of allergic reactions.³⁵ Sensitisation is a significant pathology which affects the quality of life of consumers for the rest of their lives. While safety in terms of sensitisation seems to have improved over the last few decades, it remains a major challenge in the field of cosmetics. This was also stressed by some contributions during the public consultation.

It shall be stressed that the new chemicals legislation, the REACH-Regulation 1907/2006, does not address these issues: The Cosmetics Directive is *lex specialis* to REACH: Aspects of human health risks stemming from cosmetic products are excluded from the scope of the chemical safety assessment required under REACH.

2.2.4. *Addressing substances classified as CMR 1 and 2 by considering, in exceptional cases, safe exposure limits*

Carcinogenic, mutagenic and reprotoxic (“**CMR**”) substances are classified based on their intrinsic properties (“hazard”) without taking into account exposure, i.e. future use. The difference between hazard and risk is best explained with an example: A lion is a “hazard” (i.e. a lion as such is dangerous for humans) but a lion is not necessarily a “risk” (e.g. if it is in a guarded zoo, behind a fence, and well-fed).

CMR substances are categorised into 3 categories, “1”, “2” and “3” based on the degree of evidence of their carcinogenic, mutagenic or reprotoxic properties.³⁶

According to the Cosmetics Directive³⁷, CMR 1 and 2 substances are automatically banned in cosmetic products. CMR 3 substances are banned unless the Scientific Committee, on the basis of exposure-data, has found that the substance is safe for use in cosmetics.

The automatic ban without possibility of an exception for CMR 1 and 2 substances makes regulation of cosmetics dependent on a hazard-classification without considering exposure and actual use of the substance. This could lead to situations of incoherence between different legislative regimes for different products. A recent – but not the only – example is ethanol: Ethanol (i.e. alcohol) is widely used in cosmetic products. It was considered for classification as CMR 1 substance in 2006. The dossier is pending. A classification as CMR 1 substance would lead to an automatic ban of all perfumes (representing over 10 billion EUR retail value *per annum*, ie 15 % of value of all cosmetics placed on the EU market), without ever giving the possibility to prove its safe use in cosmetic products based on exposure data. At the same time, ethanol-containing food and beverages would not be affected by the classification and could hence be consumed directly while being banned for application on the skin in perfumes.

³⁵ On the basis of undesirable effects notified in France to the responsible market surveillance authority in 2005.

³⁶ Category 1: “Substances known to be carcinogenic to man”; Category 2: “Substances which should be regarded as if they are carcinogenic to man”; Category 3: “Substances which cause concern for man owing to possible carcinogenic effects but in respect of which the available information is not adequate for making a satisfactory assessment.”

³⁷ Art. 4b Cosmetics Directive.

2.3. Community competence and subsidiarity

The Cosmetics Directive is based on Art. 95 EC Treaty. It aims at establishing an internal market for cosmetic products while ensuring a high level of protection of consumers.

Prior to the adoption of the Cosmetics Directive, the provisions laid down by law, regulation or administrative action in force in the Member States differed from one Member State to another. These differences between these laws obliged the cosmetic industry to vary their production according to the Member State for which the products are intended. Consequently, the different national rules hindered trade in these products and, as a result, had a direct effect on the establishment and functioning of the internal market. To respond to this, it was necessary to determine at Community level the regulations which must be observed as regards the composition, labelling and packaging of cosmetic products. This objective could only be achieved with a very limited efficiency at national level.

This rationale is still valid today: Community action is necessary to avoid a fragmentation of the market and to ensure a high and equal level of protection of the European consumer.

The Cosmetics Directive exhaustively harmonises rules on consumer safety of cosmetic products placed on the Community market. Thus, changes to this legal framework can only be achieved by Community action and are in compliance with the principle of subsidiarity as established in Art. 5 EC Treaty.

3. OBJECTIVES

3.1. Preliminary remark: overall objectives

By way of preliminary remark, it must be pointed out that several overall objectives are being pursued. These are:

- to maintain a high level of consumer safety: One major objective is that the high standard of safety set by the Cosmetics Directive must not be lowered;
- to maintain the rules for phasing out animal testing: This simplification exercise is not going to propose any changes to the rules on animal testing which were added to the Cosmetics Directive by the “seventh amendment” in 2003 (see 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.

This objective was clearly underlined in the public consultation on the simplification exercise. It was also well understood: only five out of the 72 submissions addressed questions concerning animal testing, four of them merely in an auxiliary manner;

- to smoothen the functioning of the internal market: Adoption of the Cosmetics Directive in 1976 brought about real improvements for the free circulation of cosmetic products in the EU. Still today, there is a constant increase in inter-

Community trade. Industry is heavily relying upon the functioning of the internal market for these products, which allows for economies of scale and thereby enhances competitiveness. This holds not only true for the big companies in this sector, but also for SMEs, who characterise the European cosmetics industry (cf. above, 2.1.).

It is a crucial overall-objective for the Commission to further smooth the functioning of the internal market to allow companies to further exploit its potential.

- to ensure international alignment: Cosmetics is an international industry in which Europe is a very important player.

The importance of international trade in this sector leads to a degree of “regulatory competition” between the different markets. In order to assess where EU legislation stands in the international context, in 2004 the Commission ordered a study to assess and appraise international differences in regulation. This concluded that “*the Cosmetics Directive, which combines a wide definition of cosmetics with clear and comprehensive requirements on safety testing, ingredients and labelling, provides a good basis for achieving further alignment, demonstrated by the number of countries and regions already modelling their approach upon it*”.³⁸

The “leadership” given by the Cosmetics Directive was also confirmed by numerous stakeholders from both inside and outside the EU in the public consultation. Asian and South American countries in particular have modelled their regulations on the Cosmetics Directive.

However, the above-mentioned study also stressed that it would be beneficial for EU companies if the existing international divergences between regulations were removed. No new divergences should be introduced. Presently EU companies employ approximately 1% of their personnel solely on assessing divergences between the rules on labelling and other regulatory restrictions. For example, overall costs for duplication of effort if products are developed for both the US and EU markets are 25% higher than for developing products for only one of these markets. Moreover, these costs mount disproportionately if reformulation of a complex formula is required.

Therefore, one overall objective is to maintain the existing convergence with other jurisdictions and to remove divergences, where possible.

Apart from these overall objectives, the following specific objectives are being pursued by the Commission in this simplification exercise:

3.2. Objective 1: Clear and coherent single legal text including facilitated managing of the Cosmetics legislation

“Objective 1” is a clear, structured and coherent legal text with a set of clear definitions where needed (cf. above, 2.2.1.) and a facilitated management of the Cosmetics Directive.

³⁸ “Cosmetics Legislation in the EU and Other Principal Markets with Special Attention to Borderline Products”, RPA (2004), p. 8.

In terms of facilitated management, “objective 1” includes:

- Facilitating updates of the inventory of cosmetic ingredients used (cf. above, 2.2.1);
- Simplifying procedure to develop methods for analysis; and
- Simplifying submissions of information to anti-poisoning centres in the EU.

A set of clear definition, together with a simplified management of the Cosmetics Directive, would have as overall impact a reduction of costs of compliance, including administrative costs, without compromising product safety.

This objective was already set in 2004 in the “SLIM” exercise. The February 2004 “Report and recommendations reviewing legislation on cosmetics”³⁹ contains recommendations on how to address this. It was carefully considered by Commission staff during the impact assessment.

3.3. Objective 2: Removing divergences between national law

Objective 2 is to remove any divergences in transposition in the different Member States.

The overall impact would be a better functioning internal market, thereby reducing costs for businesses by facilitating economies of scale for EU manufacturers.

This objective has not been considered in previous revisions of the Cosmetics Directive.

3.4. Objective 3: Ensuring a high level of safety in cosmetic products in the light of innovation in the industry

Objective 3 is a high level of safety in cosmetic products, in particular in the light of innovation in this sector.

This objective includes considering experience with the shortcomings of the present system which is based on random ingredient-by-ingredient harmonisation by means of detailed legislation.

The overall impact would be safe cosmetic products in the future, taking into account the specifics of each product and innovation in this sector.

This objective has been pursued in several amendments, particularly the “sixth amendment” to the Cosmetics Directive in 1993.⁴⁰ The “sixth amendment” introduced the obligation to indicate the ingredients on the product label in order to facilitate in-market controls plus the requirement to provide a product information file. This was a consequence of the awareness that it was neither feasible nor

³⁹ http://ec.europa.eu/internal_market/simplification/slim/2001-phase5_en.htm.

⁴⁰ Council Directive 93/35/EEC of 14 June 1993 (OJ L 151, 23.6.1993, p. 32).

necessary to establish a “cook book” which would regulate every substance employed in cosmetic products.⁴¹

3.5. Objective 4: Introducing a possibility to regulate CMR 1, 2 substances on the basis of their actual risk

Objective 4 is to have a possibility to address the problems set out under 2.2.4. which are created by a regulation of substances used in cosmetics based on a hazard-classification.

This objective has been under ongoing discussion since the introduction of the hazard-based ban of CMR 1, 2 substances in the “seventh amendment” to the Cosmetics Directive, Directive 2003/15/EC.

4. POLICY OPTIONS

Different policy options in order to achieve each of the four objectives described in sections 3.2. to 3.4. are discussed below.⁴²

4.1. Objective 1: Clear and coherent single legal text allowing easier management of the Cosmetics Directive

Three options can be considered to achieve objective 1: No EU action (section 4.1.1.), adoption of informal guidelines by the Commission to clarify legal provisions (section 4.1.2.) or amending the text of the Directive itself to make it clearer (section 4.1.3.).

4.1.1. Policy option 1 (discarded): No EU action

The “no EU action” scenario cannot meet objective 1. In particular, it is not possible to rely on action by the Member States. The Cosmetics Directive is very detailed *and* provides for exhaustive regulation. It is therefore not possible for Member States to clarify the rules without being in breach of EU law.

Therefore, this policy option was discarded at an early stage.

⁴¹ Cf., for exemple, Commission Working document XI/256/89-FR of March 1989, p. 10 : « *Analyse critique du niveau actuel de protection de la santé et sécurité publique : La manière dont le principe de l’art. 2 susvisé fut concrétisé à ce jour semble assurer une fausse sécurité pour le citoyen. En effet, 13 ans après son adoption, le système actuel n’a pas encore défini toutes les catégories des listes des substances admises. Les substances admises ne constituent qu’une partie infime (environ 300 ingrédients à ce jour) de l’ensemble des substances employées (estimées entre 3000 et 8000). La sécurité du produit fini n’est plus garantie.* » This analysis was supported by Member States. For example the French Republic highlighted in a responding note that « *le système des listes positives s’avère comporter un certain nombre d’inconvénients: fausse sécurité pour le consommateur et pour l’industriel dans la mesure où l’évaluation du risque ne tient compte que des résultats de l’étude toxicologique des matières primaires et ne concerne pas les produits finis et leur champ d’application ; entrave à l’innovation et au développement de l’industrie car inadapté à l’évolution rapide de la technologie ; lenteur de la procédure d’inscription d’une substance.* »

⁴² An overview of the various objectives and policy options is set out in section 6.4.

4.1.2. *Policy option 2: Adoption of informal guidelines by the Commission*

Informal guidelines could be one policy option to achieve objective 1 to the extent that they provide real legal certainty about various aspects of the Cosmetics Directive.

4.1.3. *Policy option 3: Amending the Cosmetics Directive*

A third policy option to achieve objective 1 is to amend the Cosmetics Directive with the aim of clarifying various aspects by:

- introducing a set of definitions;
- removing ambiguities and using identical terms in the legislation if the same thing is meant;
- putting the legal provisions in the right context;
- introducing tools that facilitate management of the cosmetics legislation for both companies and enforcing authorities; and
- reviewing the annexes to the Cosmetics Directive, in particular addressing double entries.

Moreover, this policy-option would allow to (cf. above, 2.2.1.)

- simplify updates of the inventory of cosmetics ingredients;
- make use of standardisation bodies for the development of methods of analysis in the future. Standardising bodies may deliver faster results and gather more expertise; and
- simplify procedures for submission of information to anti-poison centres.

4.2. **Objective 2: Removing divergences between national laws**

4.2.1. *Policy option 1: No EU action*

In a “no policy change scenario” the situation would remain as described above.

4.2.2. *Policy option 2: Turning the entire Cosmetics Directive into a Regulation*

The entire text of the Cosmetics Directive (i.e. enacting terms and annexes) could be turned into a Regulation.

4.2.3. *Policy option 3: Redrafting the enacting terms as a Directive and turning only the annexes into a Regulation*

In order to remove divergences between the national transposing laws, one policy option could be to redraft the enacting terms of the Cosmetics Directive more clearly and to turn only the annexes into a Regulation.

Unlike the option described in section 4.2.2., this policy option would split the existing text of the Cosmetics Directive into two separate legal acts: a Directive (containing the enacting terms of the present Directive) and a Regulation (containing the annexes). The latter would be updated by further Regulations.

4.3. Objective 3: Ensuring a high level of safety in cosmetic products in the light of innovation in the industry

Various policy options may be considered to achieve objective 3:

4.3.1. Policy option 1: No EU action

This option would not address objective 3 at EU level. It would leave the situation as it is.

4.3.2. Policy option 2: Non-binding guidelines and self-regulation

A second option could be to rely on non-binding guidelines and industry self-regulation in order to respond to upcoming safety challenges.

4.3.3. Policy option 3: Restricting the scope of the Cosmetics Directive by reviewing the definition of “cosmetic product”

A third policy option could be to restrict the scope of the Cosmetics Directive so that fewer products are regulated as cosmetics in the EU. They may then be covered by other sectoral legislation, such as on medicinal products, chemicals or biocidal products. Some of these arrangements require authorisation at European or national level prior to placing the products on the EU market.

This policy option can be described as that chosen in several Third Countries, including the U.S.⁴³

4.3.4. Policy option 4: Ex-ante authorisation for all cosmetic ingredients/products

In order to ensure a risk assessment of every ingredient/product, one policy option is to introduce a general requirement for authorisation, as already exists in the Community for medicinal products⁴⁴ and novel foods.⁴⁵

4.3.5. Policy option 5: Introducing additional “positive lists”

“Positive lists” are lists of substances out of a specific group which are allowed as ingredients in cosmetics (hence the term “positive”: the substances in the group concerned must be listed “positively” before they can be allowed for use). As for the introduction of further “positive lists”, the Cosmetics Directive already contains three

⁴³ Cf. above, 2.2.3.

⁴⁴ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

⁴⁵ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

“positive lists” for colorants (Annex IV), preservatives (Annex VI) and UV filters (Annex VII).

One policy option would be to extend the positive lists to other groups of substances.

4.3.6. *Policy option 6: Sharpening the focus on manufacturer responsibility*

Another option would be to sharpen the focus on manufacturer responsibility and how this is documented.

There are already a number of elements in the Cosmetics Directive which aim at ensuring that the manufacturer assesses the safety of the cosmetic product placed on the market. In this policy option, these would be strengthened. More specifically, this option could entail:

- bringing the safety evaluation by the manufacturer of the finished cosmetic products (and the related technical documentation) up to the standard recommended by the Scientific Committee for Consumer Products (see section (a) below);
- making in-market control and cosmetovigilance more effective (see section (b) below); and
- increasing requirements on notification (see section (c) below).

(a) Bringing the safety evaluation by the manufacturer of the finished cosmetic products (and the related technical documentation) up to the standard recommended by the Scientific Committee for Consumer Products⁴⁶

Today the Cosmetics Directive requires the manufacturer to assess the safety of the cosmetic product (based on an assessment of the toxicological profile of the ingredients) and to document this in a product information file prior to placing it on the market.⁴⁷

However, apart from a very general description of this requirement, the Cosmetics Directive says practically nothing about the standards and criteria for this product safety evaluation and how it has to be documented. The only point of reference is Chapter VI of the guidelines of the Scientific Committee for Consumer Products, which addresses the safety of finished cosmetic products.⁴⁸ In this chapter, the Scientific Committee for Consumer Products (an advisory body for the Commission made up of independent experts) sets out how, in its view, the safety of a finished cosmetic product should be assessed by the person responsible for placing the product on the market.

⁴⁶ Chapter VI of the “Notes of Guidance for Testing of Cosmetic Ingredients and their Safety Evaluation by the SCCP”, 6th revision, 19 December 2006.

⁴⁷ Article 7a(1) of the Cosmetics Directive.

⁴⁸ Chapter VI of the “Notes of Guidance for Testing of Cosmetic Ingredients and their Safety Evaluation by the SCCP”, 6th revision, 19 December 2006.

These suggestions of the scientific committee are currently largely ignored. Research conducted for the European Commission suggests that, presently, approx. 40% of all cosmetics safety evaluations of the finished product are considered as insufficient or incomplete by the competent authority.⁴⁹ However, as there is a lack of specification of the content, competent authorities often refrain from taking action in these cases.

A minimum standard for the safety assessment of the finished cosmetic product would include the toxicological criteria to be looked at and the minimum requirement for a substantiation of the reasoning supporting the safety of the product.

(b) Making in-market control and cosmetovigilance more effective

Efficient targeted checks on products on the market and clear rules in cases of non-compliance are the keys to safe cosmetics.

Today the Cosmetics Directive provides no rules on administrative cooperation in in-market controls and cases of non-compliance. In terms of “**cosmetovigilance**”, the Cosmetics Directive places an obligation on the manufacturer to keep a record, in the product information file, of all undesirable effects observed.

These aspects could be strengthened by:

- a mechanism for mutual support in in-market controls: this would be based on bilateral requests from one competent authority (in the country where the product has been made available) to another (in the country where the product information file is located); and
- adding to the passive record-keeping obligatory active notification of the relevant competent authority by the person responsible for placing the product on the market of all *serious* undesirable effects of which the person responsible for placing the product on the market receives or should have received knowledge.

(c) Increasing notification requirements to the market surveillance authorities⁵⁰

In order to make in-market control more efficient, consideration could also be given to increasing the number of addressees notified and the amount of information submitted prior to placing a cosmetic product on the EU market.

Addressees: At present, the only competent authority which has to be notified is the authority of the Member State where the product is manufactured/imported.⁵¹ The number of addressees could be extended to:

- the competent authorities of the Member State where the product is made available to the final consumer; or

⁴⁹ Cf. “Evaluation of the Cosmetics Directive” (GHK, 2007), Chapter 5.1.

⁵⁰ Note, that this notification is different from those to the anti-poison centres of some of the EU Member States.

⁵¹ Article 7a(4) of the Cosmetics Directive.

- all Member States, as a product placed on the Community market can potentially be made available to consumers in every Member State.

Content: Presently, the only information to be notified is the place of manufacture/importation. The scope of information could be extend

- to the list of ingredients; or
- to the full quantitative and qualitative formula of the product.

4.4. Objective 4: Introducing a possibility to regulate CMR 1, 2 substances on the basis of their actual risk

4.4.1. Policy option 1 – no EU action

This policy option would not contribute to addressing the problem and has thus been discarded.

4.4.2. Policy option 2 – taking risk into consideration at the classification stage

One could consider already at the stage of its classification the risk of CMR 1, 2 substances in view of different exposure scenarios in the various downstream uses.

4.4.3. Policy option 3 – giving the possibility to allow, in exceptional cases, the use of a CMR 1, 2 substance provided that the substance is safe

Policy option 3 would give the possibility for the Commission as risk-manager to regulate, under Comitology procedure, a substance classified as CMR 1 and 2. Various conditions would be introduced to ensure that this possibility does not lead to a regular risk-evaluation. Rather, this option would allow for risk-evaluation only in specific circumstances were a hazard-based ban would lead to incoherent situations (cf. section 2.2.4.).

To achieve this, the conditions for use of a CMR 1, 2 substances would be the following:

- Evaluation of the safety of the substance by the SCCP after classification of the substance as CMR 1, 2: This would ensure that the SCCP, in its safety-evaluation, takes into account the data which was the basis of the hazard-classification;
- The substance has been found safe by the SCCP, in particular in view of exposure: This is the crucial element. While it is evident that a safety-evaluation has to consider the exposure to a substance, this is particularly relevant for CMR 1, 2 substances which may have different intrinsic properties for different routes of exposure.
- In order to avoid a situation where the SCCP is systematically seized on the safety of CMR 1, 2 substances, two additional conditions as “gatekeeper” would be introduced:
 - The first condition would be that the substance is legally used in food or as food in the Community. This would ensure coherence with other

regulatory systems in the EU. Moreover, the exposure in food (ie. in a product intended to be ingested) is potentially higher than in cosmetics. Therefore, the use of a substance in food is a useful criteria to “open the path” towards a risk-assessment by the SCCP;

- The second condition would be that there are no suitable alternatives for the substance in question available.

It is important to note that these two conditions would not contribute to safety as such. Rather, they are mere “gatekeepers”: If these two conditions are fulfilled, the path towards a safety evaluation by the SCCP is opened.

- In order to ensure that misuse (which may lead to a different exposure and thus lead to a risk) is prevented, labelling to this effect would be obligatory. It is important to note that such a labelling would not be a labelling of hazard. Rather, it would concretise the general rule already today contained in the Cosmetics Directive aiming at avoiding misuse (and thus contributing to the safety) of cosmetic products.
- In addition, the substance would have to be regulated by the Commission as risk-manager in the Annexes to the Cosmetics Directive. This would be done under Comitology procedure with scrutiny, ie. involving Member States and European Parliament. This would ensure rigid scrutiny of any risk-management measure taken by the Commission.
- Finally, the substance would have to be re-evaluated by the SCCP at the latest after 5 years. This would ensure a regular safety evaluation of the substance in view of evolving scientific knowledge.

5. ANALYSIS OF IMPACT

Commission impact assessments analyse the likely social, economic and environmental impact – be they direct or indirect – of the different policy options.⁵²

With regard to the analysis in this chapter, it must be stressed that it is not an *objective* of the recast to extend the scope of the Cosmetics Directive to issues of environmental safety. Rather, in this respect, the objective was to maintain the *status quo*. According to this *status quo*, issues of environmental safety of cosmetics ingredients are addressed through the general legal framework for environmental risks stemming from chemicals.

The REACH-Regulation 1907/2006 has just recently introduced a far-reaching reform of this legal framework. This reform has further strengthened environmental safety of chemicals used as cosmetic ingredients. For example:

- Suppliers of chemicals used as cosmetic ingredients will have to supply cosmetics manufacturer with information on environmental hazards;

⁵² Commission Impact Assessment Guidelines, pp. 4 and 5.

- If the substance is produced/imported in quantities of over 10 tonnes per year per registrant, a chemical safety assessment for this substance, covering environmental risks, will have to be performed and communicated to the cosmetics manufacturer;
- Cosmetics manufacturers (i.e. downstream users) will be under an obligation to apply the recommended risk-reduction measures communicated by the supplier of the cosmetic ingredient;
- Moreover, REACH provides for the possibility to subject individual substances employed in cosmetic products to a restriction or an authorisation procedure in order to address issues of environmental safety.

The major feature of REACH, however, is its cross-sectoral nature: The various different applications of a substance, which may lead to an accumulation of exposure for the environment, are being looked at as a whole.

Thus, environmental safety issues need to be addressed within this legislative framework. All efforts should now focus on the correct and efficient implementation of REACH.

In view of their prominent role in updates of the impact assessment guidelines, administrative costs have been looked at in particular detail in this analysis. Administrative costs are defined as “*the costs incurred by enterprises, the voluntary sector, public authorities and citizens in meeting legal obligations to provide information on their action or production, either to public authorities or to private parties*”.⁵³ Note that this definition does *not* include the costs incurred by competent authorities to exercise in-market control. Those costs are considered separately in this chapter.

5.1. Objective 1: Clear and coherent single legal text allowing easier management of the Cosmetics Directive

5.1.1. Policy option 2: Adoption of informal guidelines by the Commission

On the positive side, informal guidelines are flexible instruments and allow active participation by all stakeholders. This may lead to more workable results than legal definition by the co-legislator. Therefore, to date, approximately 10 non-binding guidelines have been published by the Commission to explain different aspects of the Cosmetics Directive.⁵⁴ Almost all these guidelines are a consequence of unclear legislation and inconsistent use of legal terms.

On the negative side, informal guidelines have a limited impact on clarifying legal terms. In order to reach a compromise with stakeholders, solutions are not always as satisfactory as they could be. Moreover, experience shows that drafting guidelines on

⁵³ Commission Impact Assessment Guidelines, Annex 10, p. 35.

⁵⁴ These include guidelines on the term “period after opening-labelling”, on the scope of the Cosmetics Directive, on the restriction to professional use, on claims referring to the absence of animal tests, on information on undesirable effects and on the field of application of colorants. Moreover, the Commission is currently working on a guideline on the labelling of perfumery material.

various aspects can take several years and thus ties up substantial resources. Finally, informal guidelines are non-binding and have only de facto, but no legal force. Legal force may, however, be required in critical cases.

Moreover, adoption of informal guidelines would only partly address objective 1. Many issues raised in the problem description are inherent in the text of the Directive which will have to be amended in order to solve them. For example, the complicated updating of the inventory of ingredients cannot be addressed by informal guidelines but only by substantial amendments to the enacting terms of the Cosmetics Directive.

5.1.2. Policy option 3: Amending the Cosmetics Directive

On the positive side, a clear set of definitions and clarification of the legal provisions brings legal clarity with the force of law. This would yield substantial savings for companies on regulatory compliance, including administrative costs. A careful estimate of potential savings for EU cosmetics businesses if legal uncertainties were removed suggests that these add up to approximately EUR 40 million per year (see section 2.2.1.).

Moreover, easier management of the Cosmetics Directive would have a positive impact in terms of costs for both businesses and competent authorities.

One example for the benefits of a simplified management concerns the communication of information about newly launched products to the anti-poison centres in the EU: At present, the economic operator, in order to launch a product EU-wide, has to communicate a frame formulation of this item to these approx. 12-15 different anti-poison centres.⁵⁵ This adds to the notification to the market surveillance authority of the Member State where the product is manufactured/imported. Frequent changes of product formulations (approx. 60.000 products are reformulated or entirely new developed every year), create considerable administrative costs. In application of the standard cost model

$$\Sigma P \times Q$$

where P (for Price) = Tariff x Time

and Q (for Quantity) = Number of entities concerned x Frequency

these costs are approx. 55 Mio EUR for the EU cosmetics industry. These costs could be reduced by approx. 80% to approx. 11 Mio. EUR (detailed assessment⁵⁶ is set out in Annexes 3 and 4), if the communication of information to anti-poison centres was

- based on identical information for each Member State;
- submitted centrally in electronic form through one portal together with the information submitted to the market surveillance authority; and
- free of charge.

⁵⁵ Art. 7 (3) Cosmetics Directive; Note, that the notification to anti-poison centres must not be confused with the notification to surveillance authorities.

⁵⁶ In accordance with chapter 10 of the annexes to the Commission guidelines on impact assessment.

These costs are mainly linked to the launch of new product formulations. As approx. half of all product formulations placed each year on the EU-market stem from SMEs, it can be estimated that SMEs have a share of approx. 50% of these savings.

A change of the notification system as set out above would require the creation of a single electronic portal for submission of information. Such a single portal would be set up and maintained by the European Commission. In the light of previous experiences with IT support tools in other sectors, the costs for setting-up such an electronic single portal are estimated to be approx. EUR 110 000.⁵⁷

Another example for the benefits of an amendment concerns the inventory of ingredients. The inventory of ingredients is a list of “artificial” names of all chemicals which are of interest for the cosmetics industry. These international names are of high practical importance for product labelling: They are independent of any national language and do not need to be translated. However, while there are constantly new chemicals for a potential use as cosmetic ingredient “discovered” (approx. 500 per year), the update of the inventory is a very cumbersome procedure, involving translation of the description of the function and the chemical name of the substance and adoption under Comitology procedure. This process takes several years. This is why there has been only one update of the inventory in the past 11 years: Today, 5 000 cosmetics ingredients of potential interest for the EU Cosmetics industry are not listed in the EU inventory of ingredients. For these ingredients, industry has to research a suitable internationally-recognised name. This creates costs for businesses, in particular for SMEs with limited resources for regulatory aspects, considerably. These costs could be removed if the inventory was updated more regularly. Moreover, the overall objective of international convergence of regulation would be met, as the ingredient’s names follow are identical in many different regulatory systems worldwide.

On the negative side, unless its clarity and impact are carefully considered, any amendment to the Cosmetics Directive could create new legal uncertainties and is likely to bring about regulatory changes to which cosmetics businesses must adapt.

5.1.3. *Comparison of options*

A comparison of the two policy options (informal guidelines or legal amendment) reveals that an amendment is preferable, provided that it takes into account the stakeholders’ needs, previous experiences with existing guidelines and other existing Community legislation in similar fields. This has also been suggested by several contributors during the public consultation.

This approach would ensure legal certainty for issues that have been identified as key by the Commission, Member States and stakeholders. At the same time, it would reduce costs for compliance by 10%⁵⁸ without compromising the overarching policy objectives. Moreover, certain measures facilitating the management of the Cosmetics Directive would bring about important savings for EU-businesses. One example is

⁵⁷ Cf. also the the ex-ante evaluation of implications for the Community budget in the legislative financial statement submitted, in accordance with the Manual of the operating procedures of the Commission together with the Commission proposal.

⁵⁸ Cf. above, 2.2.1.a.

the cut of administrative costs for notification of products (be they re-formulations or entirely new developments). In application of the standard cost model

$$\Sigma P \times Q$$

where P (for Price) = Tariff x Time

and Q (for Quantity) = Number of entities concerned x Frequency

these costs are reduced⁵⁹ by 80% if the information to be submitted to all relevant anti-poison centres was centralised and jointly submitted with the notification to market surveillance authorities.

It is clear that an amended Cosmetics legislation may require cosmetics businesses to adapt to changes in the regulatory environment. Any change of the legal environment may lead to additional costs. To address this, the challenge for the Commission as well as the Community legislator lies in combining

- a careful assessment of the impact of any change as compared to the present situation; and
- a sufficient implementation period for industry in order to react to legislative changes of the Cosmetics legislation.

5.2. Objective 2: Removing divergences between national laws

5.2.1. Policy option 1: No EU action

The Commission has considered this option. In particular, the Commission is aware that any new legislation could create new legal uncertainties and requires adaptation of the business environment. This adaptation is costly – in particular for SMEs when looking at costs on a per item basis.

On the other hand, a no policy change scenario would mean that the rules on the internal market would continue to differ without adding value.

5.2.2. Policy option 2: Turning the entire Cosmetics Directive into a Regulation

On the positive side, a Regulation would mean Europe-wide rules that would be directly applicable without any need for transposition in the national laws of 27 Member States (as is the case with Directives). This would create a single identical legislative framework as the sole reference for operators on the entire internal market and address the difficulties described above. The public consultation also highlighted that a Regulation would ensure uniform interpretation not only by authorities, but also by manufacturers.

This is particularly inherent in chemicals legislation which, compared with other legislation, is highly prescriptive. Not surprisingly, today almost all the Directives on chemical safety have been, or are being, replaced by Regulations. Examples include the Detergents Regulation 648/2004 (replacing the Detergents Directive 73/404/EEC), the REACH Regulation 1907/2006 (replacing several Directives on chemical safety, including Directive 76/769/EEC) and the proposal for a Regulation

⁵⁹ Cf. Annexes 3 and 4.

on the “Global Harmonised System” of classification and labelling – GHS (COM(2007) 355 final).

An important positive aspect concerns the functioning of the internal market: In particular from an industry perspective, removal of the need for transposition would enable simultaneous launches of new products on the entire EU market instead of staggering launches to ensure regulatory compliance in specific Member States. Based on research conducted for the Commission⁶⁰, it can be estimated that waving these verifications of compliance alone would save 40 person-hours per product formulation launched, thus amounting to savings of approx. 50 Mio EUR per year for EU businesses.

Another positive aspect concerns access to the law: In the public consultation, present practices of Member States to transpose the Cosmetics Directive in differing and unrelated pieces of legislation were severely criticised as onerous and costly. A Regulation would provide for one set of legal rules.

At a more general level, in the light of various comments from stakeholders during the public consultation, two issues need clarification:

- first, the choice of the legislative *technique* has no impact on the level of safety provided for by the Cosmetics Directive. In particular, it is wrong to assume that a Cosmetics *Directive* sets only minimum standards to which Member States can “add”. This is not the case. Today’s Cosmetics Directive is exhaustive, and Member States may not adopt additional rules on labelling, ingredients and efficacy. Turning the same content into a Regulation would have no impact on this principle;
- second, the deadlines for implementation are independent of the choice of form of legislation. When setting deadlines for implementation of amending regulations, the regulator would need to take into consideration the time needed today for transposition into national law.

On the negative side, EU legislation by means of Regulations removes the possibility for Member States to introduce EU law into their existing national law, which may be useful in terms of the coherence and comprehensiveness of the national regulatory system.

5.2.3. *Policy option 3: Redrafting the enacting terms as a Directive and turning only the annexes into a Regulation*

On the positive side, reserving the legal form of a Regulation for the annexes to the Cosmetics Directive would make it possible to adapt the body of the Directive to the national peculiarities of each Member State’s legal system. During the public consultation some submissions argued that this was particularly relevant to SMEs.

On the negative side, the disparities between the national laws implementing the enacting terms would persist. While the enacting terms of the Cosmetics Directive provide for detailed rules on labelling, etc., the (small) differences in the transposing

⁶⁰ Cf. “Impact of European Regulation on the EU Cosmetics Industry” (RPA, 2007), chapter 4.2.

laws of Member States lead to considerable increases in the costs for businesses without adding value in terms of consumer safety.

Rephrasing these details in the same type of legislation is not conducive to objective 2, as 30 years' experience with management and implementation of the Cosmetics Directive show.

Moreover, in terms of the burden on national authorities, transposing highly detailed legal provisions in 27 national laws (plus monitoring by the Commission) places a heavy and costly burden on public authorities and regulators without adding value.

5.2.4. *Comparison of the options*

This assessment of the impacts reveals that out of the three options (no EU-action – Regulation – re-drafted Directive) the option of a recast in form of a Regulation is preferable. It is the most effective option to reap the benefits from an internal market for cosmetic products. At the same time, it is wrong to assume that a Regulation would lead to a common lowest denominator in terms of consumer protection: Already today, the Cosmetics Directive is exhaustive.

It shall also be stressed here that it would be incorrect to assume that a Regulation would be less accessible for stakeholders. A Regulation is obviously adopted in all official EU languages and rendered public like in any national official journal. Therefore, access to the law would be ensured if the text was adopted as EU Regulation.

5.3. **Objective 3: Ensuring a high level of safety in cosmetic products in the light of innovation in the industry**

5.3.1. *Policy option 1: No EU action*

“No EU action” would mean continuing with the existing mechanisms to address issues concerning the safety of cosmetic products, mainly by regulating individual ingredients.

The Commission has considered this option. The Commission is well aware that EU action in this field could create new regulatory burdens. Therefore, it is crucial carefully to assess all the consequences of any proposed amendments. In particular, there is a risk that any changes to the rules on product labelling could lead to considerable costs for the industry stemming from the need for new label artwork (which is particularly expensive for aerosol labelling), printing plates, repackaging, packaging write-offs, etc.

Example: The need to relabel products outside the normal cycle of brand rotation leads to additional costs for SME's of up to 50 000 EUR per product formulation.⁶¹

Therefore, no legislative changes may in some cases be preferable to those which are unreflected and disproportionate.

⁶¹ Cf. “Impact of European Regulation on the EU Cosmetics Industry” (RPA, 2007), chapter 3.2.3.

However, as set out above, there are considerable safety-challenges lying ahead which need to be addressed today. As set out above (2.2.3.), it is not possible to quantify or calculate the costs that would arise if these future challenges are not addressed. Yet, it is certain that this damage can be considerable, both in terms of public health as well as consumer trust in the safety of the products purchased on a daily basis.

In a fast-moving sector as the cosmetic one it is not possible to await upcoming safety concerns. In particular, it is insufficient to continue relying on a “cook book approach” which relies heavily on a regulation “substance-by-substance” in annexes to the Cosmetics Directive, as originally envisaged by the Community legislator (cf. above, 2.1.). Reliance on this approach has serious shortcomings, especially for innovative and complex products:

- first, it could be perceived as freeing industry of its responsibility to ensure that substances and products are safe. Once a substance has been regulated in detail in the Cosmetics Directive, there is a risk that the industry might stop following up the safety aspects related to this substance. This responsibility remains particularly crucial when it comes to combination of ingredients;
- second, there is a danger that, when engaging in detailed assessment of the safety of a specific substance, the regulator might lose sight of the real risks posed by cosmetic products placed on the Community market;
- third, the regulation of individual substances, which is practically the only tool to address safety concerns today, is an extremely lengthy process: 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).

Therefore, it is insufficient to continue “business as usual” and to consider regulation of individual ingredients the first choice for addressing product safety issues.

5.3.2. Policy option 2: Non-binding guidelines, self-regulation

Another option would be non-legislative measures and in particular the adoption of non-binding guidelines and self-regulation.

The main difficulty of non-legislative regulation lies in its voluntary compliance and the impossibility for competent authorities to enforce those rules. This is a crucial aspect: Recent RAPEX notifications confirm that the cosmetics sector is prone for “rough traders” who import low quality products into the EU. Incoherent compliance does not only put the consumer at risk – it also distorts competition to the detriment of compliant companies.

Thus, while non-legislative regulation may work well in markets characterised by an oligopolistic industry structure, it is less workable in the cosmetics sector, which is characterised by approx. 3800 EU-cosmetic producers and importers.⁶²

Therefore, in order to ensure safety of *all* products placed on the market, and to avoid a distortion of competition between the players, it was considered crucial to ensure enforceability of these rules.

Another argument is based on historic experience: Already today, the European industry association provides guidance for the safety assessment of cosmetic products.⁶³ Moreover, the “Notes of Guidance for the testing of cosmetic ingredients and their safety evaluation” of the Scientific Committee for Consumer Products address also the safety assessment of a finished cosmetic product.⁶⁴

As set out above (1.1.), despite this existing support, many product safety assessments do presently not live up to the standard competent authorities would need for an efficient in-market control.

Finally, and from a more political perspective, there is still a critical perception in Europe towards non-legislative regulation. This aspect is particular important in the field of consumer goods, such as cosmetic products. A recent example is the Commission’s experience with the industry guidelines on the safe use of fragrance material (so-called “IFRA-guidelines”). Despite these guidelines, there has been heavy political and public pressure on the Commission as regulator to adopt legally-binding rules. The Commission, albeit hesitant, had to give way to this pressure and introduced these guidelines by way of a technical amendment into the Annexes to the Cosmetics Directive.

5.3.3. *Policy option 3: Restricting the scope of the Cosmetics Directive by reviewing the definition of “cosmetic product”*

Presently, any substance which exerts a non-insignificant pharmacological, immunological or metabolic effect falls within the scope of the EU legislation on medicinal products.

The impact of any reduction of the scope of the Cosmetics Directive would depend on the alternative regulation applied. Products which, following any such reduction would fall under the sectoral legislation on medicinal products or biocidal products would require authorisation at European or national level before they could be placed on the EU market. This should ensure that the efficacy and safety of these products are verified, but it would have a huge negative impact on access to the market for innovative or reformulated cosmetic products. Moreover, this option would be a disproportionate means to ensure product safety. Experience with other regulatory systems shows that the European approach of a wider definition of cosmetic products combined with stringent rules on product safety is better suited to ensure both innovation and, at the same time, a high level of protection. One example is the regulation of sunscreen products: these are usually cosmetics in the EU: They are

⁶² Cf. Annex 2.

⁶³ <http://www.colipa.com/site/index.cfm?SID=15588&L0=15604&OBJ=15832>

⁶⁴ Chapter 6 of the guidelines on the SCCP.

subject to rules on labelling and efficacy claims. Moreover, all UV-filter used have to be assessed by the SCCP and listed in the Annexes of the Cosmetics Directive by the Commission as risk-manager. In the U.S., sunscreen products which are not addressed in the respective monograph have to undergo pre-market authorisation as “over the counter drug”. While the end-result is the same (i.e. the UV-filter used has been assessed by the authority), the U.S. approach delays market access, creates additional costs for registration and acts as barrier for innovation in a product group relevant for safeguarding public health.

Apart from that, applying different regulatory frameworks to products which – today – all fall under the Cosmetics Directive would increase legal uncertainty about the legislation applicable.

This conclusion was confirmed by the public consultation. Virtually none of the 72 contributions from stakeholders and Member States was in favour of any substantial rethinking of the scope of the Cosmetics Directive.

5.3.4. *Policy option 4: Ex-ante authorisation for all cosmetic ingredients/products*

Ex ante authorisation of all cosmetic products or their ingredients could ensure a high level of product safety. However, there are numerous negative aspects to this approach. It would be:

- disproportionate to the risk posed by cosmetic products: cosmetic products are not intended to be ingested, inhaled or injected. Exposure is thus very different from medicinal products and novel food. Moreover, cosmetic products, by definition, must have no more than an insignificant impact on the metabolism. Therefore, generally speaking, exposure to and the foreseeable risk stemming from cosmetic products do not justify a regulatory approach similar to that used for medicinal products and novel foods;
- highly burdensome both for regulators and for the industry, considering that every year the EU industry places approximately 60 000 new cosmetic formulations on the EU market;
- a hindrance to innovation and to new products entering the market.

Finally, *ex-ante* authorisation would run counter to all international regulatory systems worldwide.

5.3.5. *Policy option 5: Introducing additional “positive lists”*

“Positive lists” indicate which substances out of a group are allowed for use in cosmetic products.

Today the Cosmetics Directive provides for three “positive lists” (for UV filters, colorants⁶⁵ and preservatives). The Commission aims to extend the system of positive lists to hair-dyeing substances.

Policy option 4 would be to establish further positive lists in the Cosmetics Directive.

Positive lists provide for maximum harmonisation of cosmetic ingredients on the Community market – thereby contributing to the internal market for cosmetic products. Moreover, they create a degree of trust as the SCCP has considered the safety evaluation of these ingredients.

Positive lists give companies strong support, as they provide guidance on the safe concentration limits for substances. SMEs in particular do not have their own research resources but rely heavily on the safety restrictions for substances on the positive lists under the Cosmetics Directive.

The existing positive lists under the Cosmetics Directive have also greatly contributed to international alignment. Many regions in the world have introduced positive lists for the same groups of ingredients as the EU. Often the substances on these lists are the same as in the EU.

Despite these positive aspects, there are a number of arguments against adding new positive lists to the Cosmetics Directive. Many of these were voiced in the responses to the public consultation, which stressed that, rather than adding new positive lists, the *existing* positive lists should be better managed. This includes clarification of their scope (e.g. definition of “preservative” and “UV filter”) and of various restrictions contained therein (e.g. “field of applications” for colorants).

The following negative aspects must be considered:

First of all, the ingredient-by-ingredient approach does not in itself suffice to ensure product safety, as it **takes no account of interactions between ingredients**. In particular, the responses to the public consultation stressed that substances can pose different toxicological risks, depending on the texture, matrix, pH value, solubility, etc. of the final preparation. Positive lists tend to be perceived by companies as a guarantee that the substance is safe under any circumstances. However, positive lists remain substance-related and give no certainty about the safety of the final formulation.

Another impact is on resources. This has been grossly underestimated in the past. As explained in section 2.1., the original approach back in 1976 was to establish a “regulatory cook book” with restrictions for all chemical ingredients employed in the cosmetics sector. This plan has failed. Experience has shown that assessment of individual substances ties up considerable regulatory resources. Despite over 30 years of best efforts, today the Cosmetics Directive provides for detailed regulation of “only” approximately 300 chemical substances of potential interest to the cosmetics industry. Amending the Cosmetics Directive by means of Commission

⁶⁵ Presently this list is restricted to skin-colouring. Hair dyeing substances are excluded. However, in the framework of the hair dyes strategy the Commission aims at extending this positive list to hair dyeing substances.

Directives on each ingredient has proved too lengthy, burdensome and resource-intensive. The time between identification of a substance which poses a potential risk, evaluation of the risk, regulation by means of 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). The Scientific Committee for Consumer Products (“SCCP”) already has an enormous backlog, with almost 100 opinions on the safety of individual substances pending.

Another negative aspect is that the costs to businesses will be increased considerably without necessarily improving the safety of the product as a whole. The costs of positive lists to industry stem from various sources, such as:

- compilation of the evaluation data as set out in the SCCP guidelines. The data submitted to the SCCP are put together by the industry. The SCCP does not perform toxicological tests, but only reviews the results and the conclusions drawn from them. The costs for industry to establish the necessary evaluation data range from EUR 100 000 to EUR 1 000 000 per substance. However, they are usually borne by a consortium of companies to share these costs;
- delayed market access. This is particularly crucial in such a highly innovative sector as cosmetics;
- loss of IP protection. Innovative companies cannot economically exploit an IP-protected molecule on the EU market until the substance has been evaluated by the SCCP and listed by the regulator on a “positive list”.

These important shortcomings had already been detected in the late 1980’s, when the legislator started to turn away from the regulation “ingredient-by-ingredient” by introducing the requirement of a product information file (cf. above, 3.4.).

5.3.6. *Policy option 6: Sharpening the focus on manufacturer responsibility*

As explained in sections 2.1. and 4.3.6., today the Cosmetics Directive is based on the principle of manufacturer responsibility. This is supplemented by regulation of individual substances used as cosmetics ingredients.

Policy option 6 envisages sharpening the focus on manufacturer responsibility and surveillance by means of in-market controls. It would *not* abolish the existing “positive lists” and lists of prohibited substances. Instead, it would strike a better balance between “manufacturer responsibility” and “prescriptive regulation of individual ingredients” by placing greater emphasis on the former.

Generally speaking, the positive side of strengthening the concept of manufacturer responsibility lies in increasing the safety of cosmetic products placed on the Community market, without necessarily regulating individual substances. Another positive aspect concerns the safety of new and innovative products. A sharper focus on manufacturer responsibility allows a rapid reaction to changes in the formulation of cosmetic products - not only if new ingredients are used, but also for reformulations and for new matrices and textures.

A sharper focus on in-market controls would entail a series of complementary measures:

- bringing the safety evaluation of the finished cosmetic products in which the manufacturer has to engage prior to placing a product on the market (and the related technical documentation) up to the standard recommended by the Scientific Committee for Consumer Products (see section (a) below);
- making in-market control and cosmetovigilance more effective (see section (b) below); and
- increasing requirements on notification (see section (c) below).

The advantages and disadvantages of these different measures are discussed below:

(a) Bringing the safety evaluation of the finished cosmetic products by the manufacturer (and the related technical documentation) up to the standard recommended by the Scientific Committee for Consumer Products⁶⁶

On the positive side, clearer requirements for safety evaluations would allow assessing the safety of a product as a whole, rather than its individual ingredients. This is particularly relevant in the cosmetics sector, as many ingredients have different penetration characteristics depending on the matrix and texture they are used in. Indeed, as shown above, it has been a misconception in the early phase of the Cosmetics Directive that issues of safety can be addressed by relying mainly on a “cook book” of individual substances. Rather, it is at least equally important to comprehensively assess the safety of a product, and to look at the interactions, including texture, matrix, ingredients that tend to weaken the skin barrier, etc. The assessment of individual substances is not sufficient in this respect and can only be complementary.

Another positive aspect lies in the possibility for competent authorities to react quickly to safety-concerns stemming from cosmetic products or their constituting ingredients. So far, the possibility to refer to the cosmetics safety assessment in order to assess the safety of a substance/product was limited. Research conducted for the Commission shows that the complete lack of a frame of reference in order to judge compliance with safety requirements has led to a situation where the means of choice to react to concerns has been a referral to the matter to the Commission, who would engage in a years-long evaluation of an individual ingredient. In the future, it will be easier for competent authorities to turn to the manufacturer of the cosmetic and to verify if he has effectively engaged in a thorough safety evaluation of the product, including *inter alia* establishment and assessment of the safety of individual ingredients where necessary. This allows for quick reactions to safety concerns in a sector, which is characterised by constant innovation in particular through re-formulation, without the need to regularly address specific substances in the annexes of the Cosmetics Directive setting out banned/restricted uses.

A further positive aspect concerns effective enforcement. As there is a lack of specification of the extent of the cosmetics safety assessment of the cosmetics manufacturer, competent authorities refrain from its effective enforcement. Rather than verifying cosmetics safety assessment, Member States often limit themselves to

⁶⁶ Chapter VI of the notes of guidance of the Scientific Committee for Consumer Products, 6th revision.

checking the composition and the labelling of a product. Research conducted for the Commission suggests that today, 2 700 cosmetics safety assessments are verified in the EU per year. This compares to approx. 13 000 products/year in the EU, whose product formulations are checked against the detailed restriction of ingredients in the annexes to the Cosmetics Directive. A clarification about the requirements for safety assessments would help to intensify these controls.

Moreover, strengthened requirements for safety evaluations by the manufacturer do not act as barrier to innovation as an introduction of additional positive lists would do (cf. 5.3.5.). This is crucial in a sector which can be characterised by rapid changes in product portfolio and ingredients used.

On the negative side, strengthened requirements are likely to raise costs for companies who have so far neglected the need for a robust product safety assessment. A “correct” cosmetics safety assessment requires in average approx. 240 person-hours for an entirely new product formulation. For product formulations which are merely adapted regarding one aspects of the product (for example, texture, another colour shade, etc.) the person-hours required can decrease considerably: Updates of cosmetics safety assessment require in average approx. 30 person-hours.

Moreover, it was highlighted during the public consultation that even SMEs handle in average 60 product formulations per company. The 3% non-SME’s handle in average approx. 1 000 product formulations per company. While the non-SME’s replace or re-formulate approx. 30% of their formulations *per annum*, SME’s replace or re-formulate approx. 20% of their product formulations every year. 75% of all re-formulations are slight changes to existing formulations which are due to

- Change of supplier;
- Slight change of matrix, texture, or a specific ingredient.

Based on information industry consultation and a Commission-study, the Commission estimates that a correct product safety assessment for a new formulation costs in average approx. 15 000 EUR. The update of a safety assessment for a re-formulated product costs in average approx 1 800 EUR.⁶⁷ Considering that each year approx. 45 000 products are re-formulated, and approx. 15 000 products are newly created, this amounts to costs of approx. 300 Mio EUR for the EU cosmetics industry. As SMEs count for approx. 50% of all new or re-formulated products placed on the EU market, it can be estimated that they also share about a half of these costs for compliance.

It is important to stress that these costs are no new costs. Rather, these costs are today’s costs for a robust cosmetics safety assessment. However, as stated above, there has been a lack of compliance with the obligation to undertake a cosmetics safety assessment – in particular due to a lack of clear requirements about what information a cosmetics safety assessment should contain. If these requirements were specified, costs for non-compliant companies would rise. It is difficult to quantify this rise in costs. A careful estimation would depart from the fact that approx. 40% of all cosmetics safety assessments are considered as insufficient, i.e. they lack

⁶⁷ Cf. “Impact of European Regulation on the EU Cosmetics Industry” (RPA, 2007), pp. 29 *et sequ.*

information considered necessary to prove the safety of the product placed on the market. If one assumes that those safety information files are in average approx. 50% complete, one can deduce that costs for non-compliant companies would rise by approx. 60 Million EUR compared to today.

(b) Rendering in-market control and Cosmetovigilance more effective

Strengthened in-market control

On the positive side, a strengthened in-market control based on the possibility for the competent authority to request the assessment of a product information file would greatly ensure safety of cosmetic products in the future. This was also largely confirmed in the responses to the public consultation. It was in particular pointed out that in-market surveillance needs strengthening in order to ensure fair competition vis-à-vis “rough traders” who deliberately run the risks of sanctions.

On the negative side, strengthened in-market control means more frequent control. This, in turn raises administrative costs. According to research carried out for the Commission, the making-accessible of a product information file takes up approx. 10 person-hours for the manufacturer/importer holding this file. In view of the present density of in-market controls (approx. 2700 controls of product information files in the EU per year), these administrative costs amount presently to approx. 1.6 million EUR for EU cosmetic businesses. Any increase in in-market control would mount these costs proportionally.

Strengthened cosmetovigilance

In terms of a strengthened cosmetovigilance, the concept as set out above (4.3.6.) would add as new element an obligation for the person responsible for placing the product on the market to actively report all *serious* undesirable effects to the competent authority of the Member State concerned (i.e. to the Member State where the product information file is made available to the competent authorities). This Member State would then inform the other market surveillance authorities.

A strengthened cosmetovigilance system along these lines would allow authorities of all Member States to detect rising safety-problems.

On the negative side, reporting these events would constitute administrative costs of approx. EUR 1.5 Million per year for the EU cosmetics industry.⁶⁸

(c) Increasing notification requirements to the market surveillance authorities⁶⁹

In terms of increase of notification requirements, its impact depends largely of the extent of information to be notified and to whom.

⁶⁸ Cf. Annex 4.

⁶⁹ Note, that this notification is different from those to the anti-poison centres of some of the EU Member States.

Today, the Cosmetics Directive requires the manufacturer/importer to notify the product and the place of manufacture/importation to the competent authority of that Member State.

This requirement could be modified in various aspects:

Addressees of notification: In terms of addressees of a notification, if the competent authorities of all Member States were to be notified, (cf. 4.3.6.), the increase of administrative costs would be essentially 27-fold. However, there would be no additional costs if the notification of all Member States was done jointly by one submission through one electronic portal. Moreover, costs could be decreased considerably if the notification was submitted jointly with the communication of information to anti-poison centres. In terms of efficacy, this solution would allow competent market surveillance authorities to gather information:

- that a certain cosmetic product has been placed on the Community market and where this was done for the first time;
- some basic information about this product; and
- which competent market surveillance is responsible for checking the cosmetics safety assessment.

The alternative, i.e. a notification only of those Member States where the product is made available to the final consumer would amount to a tremendous burden for industry: in particular, it is usually not possible for the manufacturer to control on which national territories the product is made available to the final consumer. Therefore, in order for competent authorities to have a complete picture of the products sold on its territory to the final consumer, the notification requirement would need to be extended to wholesalers and intra-EU traders. This would lead to a dramatic increase of administrative burdens for many EU businesses. These additional costs are not proportionate to the improvement of market surveillance: In particular, even this extensive notification requirement would not as such effectively inhibit rough traders to market products which are not compliant with the Cosmetics Directive.

Extent of notification: Today, the Cosmetics Directive requires only the product and the place of manufacture/importation to be notified. If the concept set out above (4.3.6.) was followed (i.e. notification of quantitative/qualitative formula), the increase of administrative costs would be very considerable: Considering that there are approx. 60 000 re-formulated or newly developed products on the EU market every year, notification of their quantitative/qualitative formulas would lead to additional administrative costs in the range of 22 Mio. EUR for EU-industry. This would be an increase by approx. 25% compared to today's administrative costs for EU cosmetics businesses.⁷⁰

⁷⁰ In application of the assumption that extensive notification of a new formulation requires 10 person-hours for an entirely new product and 5 person-hours for a re-formulated product. The total administrative costs at present are approx. 80 Mio EUR (cf. Annexes 2, 3)

This increase in costs would not necessarily lead to an improvement of in-market control: Rather, national competent authorities would be “flooded” with notifications: The notification of 60 000 new or changed product formulations would mean that each national competent authority would receive in average 240 notifications per working day – i.e. one notification per every 2 minutes.⁷¹ It is not possible for competent authorities to process – let alone screen – this information. Therefore, the submitted quantitative/qualitative formula does not as such support in-market control. It still requires competent authorities to verify on their territory if the product is made available there. In this respect, it is clearly sufficient to indicate the basic information in order to identify the product and the place where the product information file is made accessible in the EU.

Moreover, there is a risk that the notification of qualitative/quantitative formulas of product is being perceived as clearance for safety-considerations by the person who places the product on the market.

Finally, in practical terms the notification of a quantitative/qualitative formula bears the risk of an enormous “data-cemetery” with millions of outdated datapoints – a notified list of substances alone would lead to approx. 3 000 000 data-entries.

5.3.7. Comparing the options

A comparison of these impacts reveals that out of the six options (no action – non-binding guidelines – restricting scope – ex-ante authorisation – more positive lists – focus on manufacturer responsibility) the first option is not supportive to reach this objective. Options 3, 4 and 5 would lead to an important increase in regulatory burden for businesses, without necessarily contributing to the safety of the product. Moreover, it would run counter experiences in the past and in other regulatory systems.

With regard to policy option 5, this does not mean that the existing positive lists in the Cosmetics Directive should be scrapped: These positive lists have certainly contributed to some degree to product safety. Abolishing them could be perceived as “rendering products less safe”. Moreover, it would destroy over 30 years of efforts to harmonise rules on certain ingredients which have caused safety concerns in the past.

Policy option 6 is best suited to achieve objective 3. It would ensure safety of cosmetic products without negative impact on innovation and on new developments as it would permit turning to the detailed regulation of individual ingredients only as *ultima ratio*.

It is important to stress that **option 6 is not a change in paradigm** of cosmetics regulation in the EU. Already today the Cosmetics Directive is based on the principle of manufacturer responsibility. This encompasses in particular the obligation to assess the safety of the final product and to document this. However, while this point is crucial, it has been neglected by Community legislation, which has so far largely built on the concept of a prescriptive legislation “ingredient by ingredient”. In other words, the elements set out in option 6 exist already but would be strengthened to

⁷¹ On the basis of an 8-hours working day.

better balance-out the two elements “manufacturer responsibility” and “descriptive regulation of individual ingredients”.

Within option 6, several measures have been considered (cf. section 5.3.6.): In the light of the arguments put forward, the approach to follow shall be a strengthened role of the cosmetics safety assessment, a better system of administrative cooperation and cosmetovigilance and a more far-reaching notification requirement as far as the addressees are concerned.

Regarding the cosmetics safety assessment, this might raise costs for those companies whose products have so far not been sufficiently supported with such an assessment. As set out above (5.3.6.a.), establishing a cosmetics safety assessment means an increase in costs for regulatory compliance for companies, which have so far neglected their obligation to self-assess the safety of their products and to document this. According to Commission research, about 40% of the cosmetics safety assessment made available to competent authorities in the framework of their in-market control are not sufficiently robust, ie. They lack information or do not sufficiently set out the reasoning supporting the safety of the product. Based on that figure, it can be estimated, that this increase in costs is approx. 60 Million EUR for EU cosmetics industry.

However, there are a number of points to be considered:

- First of all, the rules for the cosmetics safety assessment would be sufficiently flexible and generic to not introduce disproportionate requirements: In particular, it is totally wrong to assume that a cosmetics safety assessment would consist of a “tick-box” of various tests to be executed. This would go contrary all overall objectives set out above, including maintaining the rules on animal testing and international alignment. Information would be fundamentally different from risk-assessment data for an individual cosmetic ingredient submitted to the Scientific Committee for Consumer Products. Rather, the cosmetics safety assessment would be a substantiated reasoning based on a large variety of information such as historical data, published data, communicated information from suppliers and read across data from other substances or preparations.
- Secondly, there are several aspects which mitigate costs related to the cosmetics safety assessment: For example,
 - REACH is going to ease access to information on chemicals as more information is going to be passed on from the chemical’s industry to the downstream user.⁷² This should greatly help to assess the toxicological safety of the finished cosmetic products in a strengthened cosmetics safety assessment. While there is some uncertainty as to the portion of cosmetic ingredients falling within the scope of the REACH- registration (i.e. produced/imported in quantities >1 ton per year per manufacturer/importer), figures available to the Commission suggest that about 70% of all cosmetic ingredients are going to be affected by the registration/information-

⁷² Note, that the obligation to pass on safety-data on ingredients to the cosmetics manufacturer is independent from the obligation to assess the safety for the specific use in cosmetic products. The latter aspect is not covered by REACH. In this respect, the Cosmetics Directive is *lex specialis* (cf. above, 2.1.).

obligation of REACH, as they are produced by one or some manufacturers/importers in quantities >1 ton per year;

- the Regulation would provide for sufficient timelines for industry to implement requirements for a cosmetics safety assessment. As products are re-formulated frequently, a sufficient timeline to implement the requirements for a cosmetics safety assessment allows for reduction of costs for compliance.

If, despite these aspects, there is an increase in costs for regulatory compliance, this can be justified with the need to ensure safe products and a possibility to document this in in-market controls.

In terms of administrative costs of a Cosmetovigilance system as discussed above (5.3.6.), it has to be stressed that an active reporting system for serious undesirable effects greatly improves efficacy of in-market control by all competent authorities in the entire internal market. Against this background, a rise in administrative costs for businesses in the scale of EUR 1.5 Mio. per year is justified by the need for competent authorities to be informed of emerging risks to consumer safety through cosmetic products.

Considering a strengthened notification requirement, the arguments brought forward above (5.3.6.c.) support extending the scope of addressees to all competent authorities in the internal market – provided that this is done through a centralised portal in order to not increase administrative costs. In terms of content, additional bureaucratic burdens in form of a rise of administrative costs by approx. 25% (cf. above, 5.3.6.c.) cannot be justified by a slight increase of effectiveness of in-market controls.

5.4. Objective 4: Introducing a possibility to regulate CMR 1, 2 substances on the basis of their actual risk

5.4.1. Policy option 2 – taking risk into consideration at the classification stage

The difficulty of objective 4 lies in the danger that the public – who is not necessarily familiar with the concept of “hazard” and “risk” – perceives it as “rendering products less safe”. Therefore, the positive aspect of policy option 2 would be that the provisions on CMR 1, 2 substances in the Cosmetics Directive would not be amended.

However, there are a number of negative aspects linked to this policy option:

The classification system for chemicals in the EU is based on hazard. It is not intended to assess a risk. Rather, this aspect (which requires consideration of different exposure scenarios) is covered by downstream legislation.

Thus, if one wanted to address issues of risk at the classification stage, it would mean a complete overhaul of the regulatory systems for chemicals in the EU. The negative impact would be even greater, as the classification system is currently being harmonised on a global level.⁷³

⁷³ „Global Harmonised System“, GHS.

Indeed, it would be wrong to “blame” the upstream legislation of hazard classification for inconsistent results in downstream legislation. This aspect has been well summarised by the UK, Sweden and Portugal in a declaration made during the vote on the 2nd adaptation to technical progress of the dangerous preparations Directive: “[t]he proposal [for an amendment to the dangerous preparations Directive] may create unforeseen and unintended problems with downstream legislation. Specifically, we believe that [the amendment to provisions on classification] will in turn trigger the requirements of the Seveso Directive (Directive 96/82 as amended by Directive 2003/105/EC), which is concerned with the prevention of major chemical accidents at fixed installations. [...] This is not a fault of the classification systems under Directive 67/548/EEC or Directive 1999/45/EC but the way the classification system is used to trigger application of Directive 96/82/EC. We therefore request the Commission to address the unintended consequences for downstream legislation with particular reference to Directive 96/82/EC.”⁷⁴

5.4.2. *Policy option 3 – giving the possibility to allow, in exceptional cases, the use of a CMR 1, 2 substance provided that the substance is safe*

This policy option would allow the use of a CMR 1, 2 substance under very strict conditions provided that the use of the substance is safe.

In particular, the requirements set out in policy option 3 ensure that there is no persistent recourse to the Scientific Committee for the safety-evaluation of CMR1, 2 substances. Rather, this would be done only in exceptional cases.

In addition, the use of substances classified as CMR 1 or 2 would only be allowed if their safety has been clearly and unequivocally established.

Moreover, as set out in policy option 3, a labelling aiming at the prevention of misuse (which may lead to a different exposure and thus to a risk) would be obligatory.

On the negative side, it has to be stressed, that the submission of a safety dossier to the Scientific Committee means additional costs for the submitting party, usually industry. These costs may be in average approx. 500.000 EUR. However, they are often borne by a consortium. Moreover, the obligatory labelling to avoid misuse of a product contributes to administrative costs (ie labelling).

5.4.3. *Comparing the options*

A comparison of these impacts reveals that policy option 3 is preferable. It builds upon the well-established classification system but allows, in exceptional cases, some flexibility for the regulator. This flexibility can only be exercised if the substance is safe, is used in food, does not have suitable alternatives and has been regulated by the Commission under Comitology procedure with scrutiny.

⁷⁴ Declaration for the minutes – vote on 4 November 2005 on the 2nd adaptation to technical progress of the dangerous preparations Directive (1999/45/EC).

The increase in administrative costs for the submission of the safety files is an unavoidable consequence and can be justified by the strength and benefits of this option.

6. SYNERGIES, OVERVIEW

6.1. Synergies of the preferred options

The predefined structure of impact assessment requires looking at the various impacts of different options separately. However, it should be pointed out that there are synergies between the four favoured policy options.

This relates in particular to the impact of the options chosen for objective 1 and objective 2 in order to attain objective 3: One can expect that clear rules in an amending legal text, together with the adoption of the recast as Regulation, improve also compliance with the provisions aim at safeguarding a high level of consumer safety.

6.2. Summary of impact on administrative costs of the policy options for objectives 1- 4

Administrative costs are defined as “*the costs incurred by enterprises, the voluntary sector, public authorities and citizens in meeting legal obligations to provide information on their action or production, either to public authorities or to private parties*”.⁷⁵

In its assessment of the impacts of the various policy options to reach objectives 1-4, the Commission has in particular considered the impact on costs defined as “administrative costs”.

This assessment shows that:

- Communication of information to anti-poison centres are going to be reduced by approx. 80%;
- “Objective 3” can be achieved with a minimal increase of administrative costs (Cosmetovigilance and increased market surveillance);

In sum, administrative costs would be reduced by 50% as compared to today.

⁷⁵ Commission impact assessment Guidelines, Annex 10, p. 35.

Impact of policy options to reach objectives 1-4 on administrative costs as compared to option “No EU action”

Objective	1		2		3					4		
	2	3	2	3	2	3	4	5	6	2	3	
Policy option												
Final choice	✗	✓	✓	✗	✗	✗	✗	✗	✓	✗	✓	
Labelling requirements	=	=	↓ (10%, i.e. 2 Mio EUR)	=	=	↑	=	=	=	=	=	=
Notification requirements	=	↓ (80%, ie. 45 Mio EUR)	=	=	=	=	=	=	=	=	=	=
Making safety file available upon request by competent authority	=	=	=	=	↗ (50% , ie. 1.6 Mio EUR)	=	=	=	↗ (50% , ie. 1.6 Mio EUR)	=	=	=
Submitting file for safety evaluation by SCCP	=	=	=	=	=	↑	↑	↑	↘ (20% , ie. 1 Mio. EUR)	=	↗ (depe nding on the numb er of CMR subst ances concern ed)	
Reporting of undesirable events (“cosmetovigilance”)	=	=	=	=	=	=	=	=	↗ (ie. 1.5 Mio EUR)	=	=	=

6.3. Overview

The final policy choices for the four objectives pursued by the Commission can be summarised as:

- Amendment to the Cosmetics Directive in order to clarify legal terms and to facilitate its management;
- Re-cast of the Cosmetics Directive as a whole as Regulation;
- Strengthening the focus on manufacturer responsibility through the three components “cosmetics safety assessment”, strengthened in-market control/improved Cosmetovigilance and extension of the notification requirement to all competent authorities;
- Introducing a possibility, under strict conditions, to regulate CMR 1, 2 substances on the basis of their actual risk.

Overview: objectives and policy options, final choices

Objective	Policy options	Final choice	Positive impacts	Negative impacts
1	1	discarded		No effect, unless breach of EU law by Member States
	2	✗	Flexibility; easier expert input	Less effective
	3	✓	More effective	Less flexibility
2	1	✗	Avoids unforeseeable legislative changes with possibly new costs	No effect
	2	✓	Very effective, as no transposition required; Savings for industry without compromising safety; Allows for fully exploiting economies of scale in the internal market	Less possibility to adopt EC-rules to national legal system
	3	✗	Existing legal systems in Member States remain partly untouched	Less effect
3	1	✗	No increase in costs	Missed opportunity to improve shortcoming of the existing regulatory system to ensure safety of cosmetic products in the future
	2	✗	Flexibility	Enforcement, risk of non-compliance and negative perception
	3	✗	Depending of the legal regime: pre-marketing control, which allows in some cases for official safety/efficacy checks	Disproportionate measure; High burden for industry; increase of legal uncertainty
	4	✗	Pre-marketing control allows for official safety/efficacy check for regulators	Disproportionate; High burden for industry and regulators

			every product	
	5	✘	Targeted approach to certain groups of substances	Disproportionate, High burden for industry and regulators; Does not consider safety of final product
	6	✓	Increase in safety; Relatively moderate increase in costs for compliance; positive for innovation; facilitated market control	Costs of compliance for safety assessment and cosmetovigilance
4	1	discarded		No effect
	2	✘	No need to address issue in Cosmetics Directive	Would require overhaul of internationally-accepted classification system
	3	✓	Allows addressing the issue without changing the principal rule that CMR 1, 2 substances are banned	Slight increase in administrative costs

The data available supports these policy choices. There is only a slight increase in regulatory burden which is off-balanced through

- reductions in administrative costs by approx. 50% as compared to the administrative costs for EU-businesses today. The bulk of these saving result from changes to the rules of communication of information to anti-poison centres as well as to market surveillance authorities which allow savings of approx. 80% as compared to costs of today’s information system;
- better functioning of the Internal market; and
- increase in product safety for the consumer.

Several elements in the re-cast provide for the basis to improve international regulatory alignment, such as the possibility of a swift update of the inventory of ingredients.

Moreover, several accompanying measures facilitate compliance: This includes in particular the ongoing work on an informal platform of enforcing authorities in order to strengthen in-market control and guidance documents for the practical implementation of the strengthened requirements for cosmetics safety assessment and its documentation.

7. MONITORING AND EVALUATION

The proposal, once adopted, is going to be implemented in close cooperation with all stakeholders concerned. To this end, the working party “cosmetic products” has provided for a valuable forum in the past and is going to be used in the future.

Monitoring of the policy will be done through the platform for market surveillance which is currently being set up by the Commission. This platform brings together competent authorities and allows for practical considerations which the new policy might raise.

In order to measure progress, in particular with regard to improvements of product safety, the Commission is going to assess on a biannual basis

- The number of product information files checked by competent authorities in in-market control and the compliance-rate with the minimum requirements set out in the recast legal act; and
- The number and nature of the serious undesirable events notified in accordance with the mechanisms envisaged in the proposed Regulation.

ANNEX 1 - Synthesis of public consultation

This annex shall resume the various replies to the public consultation document and discuss the most relevant ones. The structure of the summary is going to follow *grosso modo* that of the public consultation document. The public consultation document is not reproduced in this synthesis document. The text is available in DE, FR and EN on the “Cosmetics”-website of the Commission.⁷⁶

1. General Comments

Generally speaking, the re-cast/simplification of the Cosmetics Directive was welcomed by all submissions. However, it was also pointed out that any legislative change brings about new legal uncertainties (and, in particular for SME’s, new costs) and that a thorough impact assessment was necessary. The Commission agrees that frequent changes of the regulatory requirements should be avoided. It is aware that any review should be comprehensive enough to pre-empt a re-opening of the discussion a few years later. Indeed, section 3 of the public consultation document has to be seen against this background.

The need to look also at the international impact of changes to the Cosmetics Directive was stressed by many submissions.

Many submissions – including industry submissions – emphasised that reduced administrative and regulatory burden must not lead to a reduction of consumer safety.

Several submissions stressed the importance and success of self-regulation and non-binding guidelines in this sector. Particular reference was made to the guidelines of the international fragrance organisation IFRA.

Some submissions suggested looking closely at existing chemicals and food regulation. The re-cast of the EU Detergents Directive was characterised as a successful simplification initiative. Previous work of the SLIM-working group was widely endorsed.

The public consultation did not bring about much quantifiable data. The Commission regrets this. Several submissions pointed at the difficulty for a company to assess the “legal basis” for regulatory and administrative costs, as the chemical sector is covered by a plethora of regulations looking at identical business and production processes from different perspectives (e.g. worker protection, transport, environment, consumer, waste, etc.).

The few quantifications delivered in the submissions are all taken up explicitly in this synthesis report.

2. Directive vs. Regulation (item 3 public consultation document)

⁷⁶ http://ec.europa.eu/enterprise/cosmetics/html/cosm_simpl_dir_en.htm

A vast majority of the submission supported the re-cast of the enacting terms *and* the annexes to the Cosmetics Directive as Regulation (i.e. option 1 in item 3 of the public consultation document). It was argued that only this option 1 would

- effectively reduce discrepancies in national legislations (very concrete examples were given in several submissions),
- tackle “double banking” and “gold plating”; and
- allow for identical entry into force of amendments.

It was stressed that the (illegal) practice of “gold plating”, combined with relaxed enforcement in Member States, was in particular a problem for companies who try to comply with (transposed) EU-regulation throughout the EU. These companies are disadvantaged vis-à-vis “rough-traders” who are willing to run the risk of sanctions in a particular Member State.

It was also repeatedly stressed that sufficient implementation time for amendments is needed. Clarity of the term “placing on the market” was crucial.

Some submissions argued that option 2 would better take national practices into account, which was favourable for SME’s; however, this argument was not further substantiated.

Two submissions argued that a Directive was preferable as it allowed only for minimum-standards. The Commission would like to stress that this view is wrong. Already today, the Cosmetics Directive is exhaustive. Member States cannot adopt additional rules to those in the Cosmetics Directive. Also, unlike suggested by some submissions, the rules for the language of labelling are independent of the choice of the legal instrument.

3. Issues/concepts and terms needing clarification (items 1 and 4 public consultation document)

The number of issues/concepts and legal terms which need to be defined and clarified according to the submissions amounts to almost one hundred. The Commission stresses that it is not possible to follow-up every suggested clarification. However, some concepts and terms very repeatedly outlined as having created difficulties in application and thus raising costs for compliance without contributing to product safety. These includes:

- “Placing on the market”: Most submissions supported the equation of putting into stock with placing on the market. Others supported the notion of the *first* making-available of the product.
- “Person responsible for placing the product on the market” (including considerations of the role of other economic operators, such as the company in charge of marketing and sub-contracted producers): The peculiarity of the cosmetics sector – which heavily relies on mandated and sub-contracted production – was stressed by many submissions;
- The concept of single access point to the product information file;

- Cooperation in in-market controls;
- Traces and the conditions for their acceptance, incl. thresholds;
- Notification: Extent of information required;
- Safeguard clause: Uncertainties about scope (one product, product line, product group?);
- Labelling: The importance of clarity on the rules of labelling was stressed. The rules for “period-after-opening” were particularly criticised. It was suggested to skip them or to change them according to the respective Commission-guidelines. The minimum-durability-date was also addressed by many submissions, advocating the possibility to label this information with an hourglass. Other issues discussed were the term “decorative cosmetics” and the rules on the +/-, the labelling of the address (extent of detail varies in the national laws) and the possibility to highlight the address where the safety file is made available.

The Commission agrees that the rules on labelling are confuse. However, the Commission is very hesitant in changing the rules on labelling in substance without a thorough assessment of this impact, as costs of labelling are a particularly important factor for administrative costs in particular for SME’s.

Other concept/terms for which more explanation was suggested include: hazard/risk, and “leave on”/“rinse-off” products (in particular for bath-products).

The incoherent use of the terms “cosmetic product”, “finished cosmetic product”, “cosmetic ingredient” “product”, etc. was criticized. Some submissions suggested a clear differentiation between individual product and “product line” (i.e. batch). Annex I to the Cosmetics Directive in the present form was described as being out of date, incoherent with the definition of “cosmetic product” and even superfluous.

While the difficulty was stressed to quantify the costs for these uncertainties, one submission from a smaller Member State suggested that the time spent by an *authority* to explain unclear terms amounted to three man-years.

4. Inventory (item 7 of the public consultation document)

Virtually all submissions characterised a simplified update of the inventory as important measure to facilitate application of the Cosmetics Directive, and reduce costs without compromising product safety. In terms of content of the inventory and its translation, several submissions stressed that the translation of the introductory part of the inventory was sufficient. The bad quality of the translation of the chemical names was highlighted. The Commission agrees that verification of the translated names in 23 languages is an impossible task. Many submissions suggested that listing the INCI-name (not “CTFA-name”) and CAS-no. was sufficient.

Many submissions stressed the need to maintain some key elements of the present system, such as:

- Transparency and free accessibility to the inventory;

- No linking of the inventory to safety checks (which would lead to a pre-market authorisation “through the backdoor”);
- Participation of the regulator in the process of granting international names, in particular for botanical names.

Some submissions questioned whether an informal inventory could be made legally binding.

The need to inform explicitly Member State authorities about any update was raised.

The possibility to use IT-tools was raised. This would allow for swift yearly or bi-annual updates.

The importance of short names, in particular for allergens, was stressed.

5. Notification (item 12 of the public consultation document)

Practically all submissions confirmed the legal uncertainty surrounding the (national transpositions of) the notification requirements. It was stressed that this uncertainty raised administrative costs without adding value: For example, in Poland, alone, 180.000 products are currently notified. As repeated notification is sometimes necessary, this amounts to approx. 540.000 notifications in this Member State alone.

It was suggested that each enterprise employs in average one person full-time during three days to do the notification for a formulation. Other costs stem from fees for registration or fees for subsequent acknowledgement receipts by the competent authority.

There was remarkable agreement amongst all submissions about the features required for a re-shaped notification system. This should be:

- Centralised (“single notification”);
- Based on a simple IT-tool; and
- Not leading to a pre-authorisation.

In terms of content, there was widespread agreement that the notification should be

- Based on a frame-formula as already applied in some Member States (eg. UK, IE, SE); and
- Cover the names and nature of the relevant persons and their name/type of product.

It is remarkable that even some industry submissions spoke in favour of quite some information to be submitted in the notification. This may be explained with the interest of some companies to use notification requirements in order to control parallel trade. Other businesses stressed that quick market developments make overly descriptive notifications burdensome. Different views were expressed on the need to indicate the place of production. However, the Commission considers this helpful to control the respect of good manufacturing practices when producing in the EU.

One submission spoke in favour of a differentiated system for EU-domestic vis-à-vis imported products. The possibility of a voluntary system (as in the U.S.), at least in the early phase, was raised.

No submission agreed with the suggestion in the public consultation document that the notification requirement can contribute to combating counterfeit.

6. Simplifying annexes of substances (items 5 and 6 of the public consultation document)

Many submissions discussed extensively potential for simplifying the annexes. In the Commission's view this shows the practical importance of the annexes and the restrictions set out therein.

Many submissions argued that – rather than re-arranging annexes, it was more important to

- clarify the terminology used therein: for example, it was argued that the “fields of application” of colorants could be reduced to two instead of four categories. The interpretation of column c in Annex III was discussed as well as the definition of “UV-filter”;
- remove substances which are unrelated to cosmetics (in particular the list of CMR substances in Annex II, which is a mere “copy-paste” of the chemicals legislation);
- Identify substances better (in particular with CAS no and INCI name);
- develop an IT-tool to search the annexes; and
- address multiple entries of the same substance in different annexes.

6.1. No regulation of ingredients according to their intended function

Many submissions criticised the approach proposed in the public consultation document. While the merits of the idea were acknowledged, there was widespread agreement that one cannot consider cosmetic ingredients without their intended function, for the following reasons:

- Possible multi-functions;
- Ingredients may have a function only beyond a certain concentration; and
- Exposure is closely linked to function.

It was argued that giving up the concept of intended function would lead to more legal insecurity and thus to more rather than less costs and would run counter international as well as EU (cf. Biocidal products Directive) practice.

On the other hand, many submissions acknowledged that the criteria of the “intended function” has lead to legal uncertainties in the past. Several submission spoke in favour of linking regulation of substances to hazard and exposure rather than to the intended function.

Other submissions suggested to refer to “usual function”, “prevailing function” or “expected functionality”.

The Commission would like to remind that starting point of its consideration was an attempt to

- avoid “loopholes” in the system, i.e. “escaping” the need for “positive listing” by arguing with subjective motivations of the formulator;
- avoid double-listing of one substance in different annexes: All restrictions of the same substance should be listed at the same place to avoid contradictory provisions.

Interestingly, in particular regarding the second point, virtually all submissions agreed that this is a confusing feature in the Cosmetics Directive today.

The Commission is going to assess how these aims can be pursued taking into account the comments submitted in the public consultation.

6.2. Re-organising annexes

Many submissions opposed a re-organisation of the annexes, arguing that their system works well and is easily understood. An important argument referred to international alignment: it was stressed that the annexes as presently presented in the Cosmetics Directive have “model character” and are used worldwide. Re-organising them would put this model-character at risk.

With regard of the suggestion in the public consultation document to arrange all regulated substances in one list, it was argued that the relevant substances would “disappear” amongst the many banned substances. In this context, one submission reminded that currently, out of the many hundred substances listed in Annex II, only approx. 20% are actually relevant for the cosmetics industry. Another interesting argument concerned public perception: It was argued that the present organisation of the annexes can be easily explained to the public, policy-makers and media.

On the other hand, there was a plethora of proposals how the annexes could be re-organised. This includes, apart from a “single list”:

- Re-grouping in two annexes: negative and positive/restricted;
- Re-grouping in three annexes: positive, negative and restricted/provisional;
- Differentiation between substances listed in annex II because of lack of data and substances listed there because of their risk for consumer safety;
- Abolishing all positive lists and replacing this by a well-supervised system of manufacturer responsibility.

The need of an electronic tool to navigate in the annexes was stressed. The Commission is indeed currently working on such a database.

7. Introducing/strengthening “New-approach” elements

The suggestion in the public consultation document to strengthen and introduce some elements of “new approach” legislation in the Cosmetics Directive found particular interest by the interested parties. Some submissions argued that the “new approach” philosophy would not work in the cosmetics field, as

- Causality between a harm and a product is more difficult to establish in the field of toxicology than, say, in case of harms through mechanical hazard; and
- Product withdrawal is not realistic in a sector where products are used off (quickly).

Therefore, these submissions argued that cosmetics legislation should continue to be modelled after chemical’s legislation rather than new approach legislation.

It was also pointed out that standardization is not as quick and swift as sometimes suggested. The fear that standardization leads to reduced consumer protection than descriptive legislation was voiced.

It was pointed out that the “CE-mark” – a particular feature of “new approach” legislation – would lead to increased costs and bureaucracy for the cosmetics industry.

The Commission would like to point out that many elements typical for “new approach” legislation can already today be found in the Cosmetics Directive. This includes

- Manufacturer responsibility for the safety of the products placed on the market (cf. below, 7.1.);
- Technical documentation supporting the safety of the product (cf. below, 7.2.);
- In-market control of regulatory compliance (cf. below, 7.3.).

In the public consultation document the Commission wanted to assess how these elements can be strengthened to avoid recurrence to the regulation of individual as means of choice and to restrict this inflexible and resource-intensive tool to peculiar cases. In this respect, the submissions confirmed that improvements are possible.

7.1. Clarifying manufacturer responsibility (item 8 of the public consultation document)

Most submissions pointed out that the concept of manufacturer responsibility was already well understood in the EU. Uncertainties about role and responsibilities concern rather other actors, such as safety assessor, sub-contracted producers, and professional users.

On the other hand, it was admitted that clarification can be useful, in particular in order to explain the EU-regulatory system in third countries.

7.2. Strengthening product safety assessment (item 9 of the public consultation document)

This issue was rightly considered as a crucial element of the re-cast. The submissions rightly identified a strengthened product safety assessment as a key issue in order to turn away from descriptive legislation as means of choice to address the safety of cosmetic products.

(1) General observations

Practically all submissions agreed on the importance of the cosmetics safety assessment and its documentation for the safety of the product placed on the market. The vast bulk of submission concurred that the present provision in the Cosmetics Directive are insufficient, fail to give guidance and do not reflect the complexity of the exercise. Concrete minimum requirements and standards how to set out the “reasoning” of a safety assessment should be established. It was pointed out that this would help to look closer at toxicological characteristics of substances in their matrix/texture and at combination of substances – thereby addressing the actual toxicological risk stemming from a cosmetic product.

Many submissions stressed that a strengthened safety assessment should not

- Run counter the animal testing provisions;
- Rise regulatory burden: It was emphasised that costs for businesses to establish/maintain product dossiers can be high. For example, one SME reported that it had to handle (ie establish, update, keep accessible) already today approx. 330 product information files; and
- Lead to a “tick-box” approach consisting of simply listing a number of obligatory tests for each ingredient contained in a product.

Moreover, practically all submissions stressed the necessity to continue to look (also) at individual substances and that a product safety assessment cannot in all cases substitute a detailed assessment of an individual substance by the risk-assessor.

It was also pointed out that the concept of “adequate safety substantiation” is a common feature of the regulation in other jurisdictions too and that guidance for cosmetics safety assessments exists already in other regions.

(2) Content of the cosmetics safety assessment

Many submissions discussed the possible content of a strengthened cosmetics safety assessment and the product information file.

There was widespread concern amongst industry that a cosmetics safety assessment may lead to a “tick-box” reasoning. To avoid this, the Commission’s attention was drawn to existing guidelines of various industry associations as well as provisions in transposing national laws. In this respect, most submissions pointed out that existing test catalogues to assess the toxicological safety of individual substances as contained in chemicals legislation are not suitable for establishing a catalogue of criteria for a cosmetics safety assessment. The difference between the two approaches (substance safety – product safety) was stressed.

Submissions highlighted in particular the need to address exposure data, Information/data on sensitisation, stability of raw material, microbiological criteria, impact on renewal of the epidermis, transdermal water loss, and experiences from previous formulations.

The possibility to introduce additional requirements for micronised particles was raised.

Almost all submissions agreed that, apart from a legal description, detailed guidelines were necessary.

(3) Origin of data/qualification of safety assessor

Several submissions highlighted the important role of the safety assessor (qualification, experience) and stressed that requirements differ in the Member States. The idea of a “register” of recognised safety assessors was raised in particular by some submissions from competent authorities and Member States.

The importance of a passing-on of relevant data downstream to the cosmetics producer was stressed.

(4) Access to product information file

Many submissions raised the question of access to product information file. The notion “readily available”, as currently contained in the Cosmetics Directive, was discussed. Many submissions highlighted the importance of the concept of a “single point of access” which should be further clarified in the Cosmetics Directive as this principle is not always respected in practice.

Some submissions raised the need for a possibility to “forward” requests by competent authorities for access to the product information file. In this respect, the difficult position for sub-producers was highlighted: These do not want to give away their know-how to the contractor. On the other hand, the contractor does not want to indicate another producer on its label.

(5) Other remarks

The idea of a standardised, formalised and signed “declaration of conformity” was raised by some contributions. It was stressed that it is important to refer to all ingredients with INCI-name: too often, competent authorities are faced with a cosmetics safety assessment referring to a “mass” of many substances to which the manufacturer had only added some perfume etc. The importance of good laboratory Practices (“**GLP**”) was stressed. However, some submissions underlined that GLP cannot be a prerequisite to every test submitted in the cosmetics safety assessment.

The importance of enforcement was stressed – in particular, rules for cases where the product information file is incomplete are needed. In this respect, there were warnings that capacities of enforcing authorities should not be over-estimated. Cooperation and trust between Member State authorities was necessary to verify the cosmetics safety assessment as contained in the product information file.

7.3. Strengthened in-market control, cosmetovigilance (items 10 and 11 of the public consultation document)

The need for quick reactions of competent authorities was stressed, as cosmetic products use off relatively quickly. Implementation and market surveillance should be stepped up – not at least to discourage “rough traders” who bring the sector as a whole in discredit. There was agreement that cooperation between competent authorities should be enhanced. While legal provisions certainly help, this is also a matter of resources in the Member States.

It was pointed out that non-compliance can have different degrees (labelling – translation etc.) and that responses have to be proportionate.

Many submissions pointed out that the General Product Safety Directive provides for efficient rules for product withdrawal and that a parallel system for cosmetic products should be avoided.

Concerning cosmetovigilance, practically all submissions stressed the importance to follow-up closely developments in (serious) undesirable effects. However, it was emphasised that

- a situation should be avoided where each Member States mounts its own system, with own definitions and requirements. The work of the Council of Europe was referred to frequently as suitable basis for improvements in the EU; and
- any information requirement about undesirable effects should be restricted to serious cases. Otherwise, the system would become too heavy and unmanageable.

Some submissions queried what would happen with reported information. A central register was suggested. It was also suggested to make it available to ingredient manufacturers and independent safety-assessors. On the other hand, the importance of confidentiality of reported data was stressed.

The idea of a yearly industry report was raised.

7.4. Turning to regulation of individual substances only as “last resort” (item 13 of the public consultation document)

Many submissions queried how a strengthened cosmetics safety assessment (and its enforcement in the market) would relate to the existing system of regulating individual substances in the annexes to the Cosmetics Directive.

While many submissions agreed that only significant matters should go before the SCCP and regulated by the legislator, most submissions also stressed the importance of this work, as in particular SME’s did not have the expertise and resources to undertake safety assessments of individual substances. Moreover, national authorities may not be sufficiently independent from their national industries.

There was widespread fear that disagreement over the completeness or conclusions of a cosmetics safety assessment would lead automatically to a general regulation of a substance based on the information contained therein. It was stressed that a product-specific cosmetics safety assessment cannot justify risk-management

measures for this ingredient in general on Community level. Moreover, a situation where one substance is evaluated repeatedly by different Member States should be avoided.

With regard to the interface of cosmetics safety assessment and the work of the SCCP, it was suggested to implicate the SCCP in order to ensure the functioning of the internal market in case where competent authorities of different Member States disagree about the appropriateness of the cosmetics safety assessment.

8. Strengthening safety in view of innovative products

The public consultation document raised also the question on safety of new and innovative products. While this is not a matter of simplification *stricto sensu*, the Commission felt that this point needed to be addressed in the light of the peculiarities of cosmetic products, which are essentially applied chemical preparations.

8.1. General remarks

The vast majority of the submissions pointed out that – all in all – the regulatory principles in the Cosmetics Directive have been successful in ensuring a high level of safety of products placed on the Community market. So far, there has not been – unlike in other sectors - a failure of the system. It was stressed that industry statistics show a rate of approx 1 undesirable effect per 1 million units cosmetic products placed on the Community market.

There was also widespread disagreement with the equation “innovation = new chemical ingredient = higher risk”. Rather, innovation in this sector is not necessarily linked to a new ingredient (but also to new composition, new delivery mechanism, new texture, etc. Moreover, in the case of “new” ingredients their properties may be well known from other sectors. Therefore, all cosmetic products – independent if they are “innovative” or not - should be dealt with within the same regulatory framework.

All submissions agreed that many issues presented for discussion in the public consultation document do already add on in terms of ensuring consumer safety. Moreover, it was pointed out that REACH is going to bring about further improvement in supply of toxicological data to cosmetic manufacturers.

On the other hand, some submissions pointed out that – within the existing system – there should be more consideration of

- Micronised particles;
- Cumulative toxicity;
- Sensitisation;
- “Active” ingredients in “borderline” cosmetic products.

One submission suggested a substitution obligation for CMR substances.

It was also suggested to look at incoherencies of cosmetics legislation with other chemicals or other consumer product legislation, such as toys legislation, as well as food legislation.

One submission proposed that total exposure, including exposure to chemical through food, should be looked at more closely by the SCCP.

8.2. No risk-benefit analysis (item 15 of the public consultation document)

Practically all submissions concurred that the regulatory paradigm for cosmetic products – unlike pharmaceutical products – is not based on risk-benefit reasoning. There was also agreement that similar terms should be used for “safety” throughout the Cosmetics Directive.

However, the term “uncompromised safety” as introduced in the public consultation document was widely criticised as suggesting a “zero risk” requirement. In this context, it was pointed out that “zero risk” was impossible to attain and that it was rather about a minimisation of risk to the largest-possible extent.

It was also suggested that, rather than discussing terminology, risk-management approaches should be reviewed, for example concerning allergies. In this respect, the question was raised whether consumers should be allowed to enter consciously a risk, provided that they are sufficiently informed.

8.3. Dealing with data shortage – “no data – no market” (item 16 of the public consultation document)

All submissions agreed that any cosmetic product placed on the EU market should be sufficiently supported with information proving the safety of the product.

However, many submissions pointed out that the correct paradigm would be “no safety assessment – no market” or “no valid/robust information – no market” rather than “no data – no market”. The latter would lead to a “tick-box approach” for safety assessment of finished products with very negative consequences in particular for SME’s using natural ingredients or ingredients which have been in use for a very long time.

A robust explanation/justification was characterized as crucial. In this respect, historical experience and “read-across” were highlighted as acceptable methods – in particular for so-called “natural” substances. The Commission agrees but stresses that this reasoning cannot be valid for endpoints such as carcinogenicity.

Regarding REACH, some submissions reminded that the registration requirements only applies to substances produced/imported in quantities of >1 ton/manufacturer or importer. Another submission reported that it expects over 70% of the substances purchased to be within the REACH registration obligation.

8.4. More recurrence to “positive lists” (items 17 and 18 of the public consultation document)

(1) General remarks

The vast majority opposed the idea of setting up additional “positive list” or giving the Commission the mandate to do this. It was pointed out that – rather than establishing new positive lists – the existing ones should be better administered. This concerns in particular annex IV (colorants).

It was also stressed that additional positive lists go against international alignment and that the process establishing these is costly and lengthy. In particular, positive lists make it difficult for companies to exploit innovation – albeit patented. In this respect, the possibility of a “bonus” in patent protection – as is the case for medicinal products – was raised. On the other hand, the usefulness of the existing positive lists, in particular for SME’s, was stressed.

(2) Sunset clause

An automatic review of substances listed positively was opposed by the large majority of submissions. Again, it was argued that it was more about good risk-management than legal changes. Review of substances should be based on sound scientific justification (for example, new toxicological data), rather than a calendar-date.

It was also pointed out that a sunset-clause may be counterproductive if it leads to a “shelving” of new scientific information.

On the other hand, some submissions confirmed that the advancement of technical and toxicological knowledge make it necessary more often than it is presently the case to re-view a positively-listed substance. In this respect, the importance of cosmetovigilance was highlighted.

9. International alignment (item 2 of the public consultation document)

Many industry submissions pointed out that the Cosmetics Directive had lost its “model function” due to the changes introduced in the 7th amendment: This concerns not only animal testing, but also fragrance-labelling, period-after-opening and hazard-based regulation of substances.

Despite this, many submissions stressed that the Cosmetics Directive is still an important reference worldwide and that the simplification should not further deepen the gap between it and other jurisdictions. In this respect, the Commission was urged to look into trade-effects of all amendments it intends to propose.

Many industry submissions pointed at the need of international alignment. In terms of costs, the concrete example was given of 1% of the personnel of an SME which is necessary to deal with regulatory differences. It was stressed that many SME’s heavily depend on exports to third countries constituting up to 50% of their turnover. Concerning regulatory alignment, the following areas were raised:

- Aligned common ingredient names: it was stressed repeatedly that this would bring about important savings;
- Aligned substances regulation: in particular concerning colorants. It was stressed that costs mount disproportionately, if re-formulation of complex formula is required;

- Issues of borderlines and acceptable claims for products;
- Use of international bodies, such as ISO;
- Cooperation in risk-assessment.

The possibility of strengthening international alignment and cooperation through an industry-regulator dialogue was raised.

10. Other issues raised

Several issues were raised by the submissions which were not part of the public consultation document.

10.1. Definition of cosmetic product, scope

Virtually no submission argued in favour of a substantial change of the definition of “cosmetic product” in the EU. Some submissions suggested as additional cosmetic function “contributing to personal well-being” or to clarify the meaning of the cosmetic function “protect and maintain”. One submission suggested a clarification of the word “skin” and an explicit exclusion of body-parts affected by “diseases”.

One submission suggested covering cosmetic *articles*, too.

Some submissions suggested including in the scope of the Cosmetics Directive risks to the environment. The Commission would like to point out that this aspect is currently addressed by the general chemical safety law of the EU and that there is no intention to change this.

Some submissions suggested including issues of occupational chemicals safety into the scope of the Cosmetics Directive, as also suggested in the SLIM-recommendations. It was stressed that in particular labelled warnings do not sufficiently take this aspect into account.

10.2. Animal testing

Albeit explicitly excluded from the scope of this re-cast, a small number of submissions addressed the issue of animal testing. This concerned in particular clarification of the amendments in the “7th amendment” such as the term “alternative” method and the scope of the ban of animal testing (incl. the question whether efficacy testing was covered).

10.3. Analytical methods

The importance of harmonised analytical methods for industry as well as competent authorities was stressed. The use of standardising bodies was suggested.

10.4. Efficacy

Some submissions asked for a stronger regulatory focus on efficacy of cosmetic products. This concerns in particular claims such as “natural”, “bio”, “fragrance free” and “preservative free“. The use of standardisation in this area was suggested.

10.5. Risk assessment

Many submissions highlighted the importance of the role of the SCCP's, stressing that its work was closely followed by regulators and industry worldwide. It was argued that the process should be improved and rendered more transparent, incl. possibilities for industry to collaborate closer with the SCCP and to discuss submissions. Procedural tools to avoid bit-by-bit delivery of data were asked for.

Some submissions contemplated a “decentralised” risk assessment system, the possibility for Member States to review SCCP-opinions or mandate for risk-assessment by the newly-created European Chemicals Agency in Helsinki.

10.6. Miscellaneous

One submission suggested a difference to be made between “industrial cosmetics” and “consumer cosmetics”.

One submission criticized the dynamic references in the Cosmetics Directive, which render readability more difficult.

ANNEX 2 - Description of European cosmetics industry and EU cosmetics market

The purpose of this annex lies in describing the European cosmetics industry to the extent necessary to assess administrative costs and other costs for compliance stemming from the Cosmetics Directive before and after re-cast.

The data contained in this annex stems from a variety of sources, including:

- A study contracted by the Commission in 2004: **“Cosmetics Legislation in the EU and Other Principal Markets with Special Attention to so-called Borderline Products”**
- A study contracted by the Commission in 2006: **“Description of the EU cosmetics industry”**
- A study contracted by the Commission in 2006: **“Impact of EU regulation on consumer safety”**
- A study contracted by the Commission in 2006: **“Impact of EU regulation on industry’s competitiveness”**
- Data obtained from EUROSTAT
- Data obtained from COLIPA
- The market size of the EU is approx. 60 billion EUR.
- The yearly EU-turnover of EU cosmetics industry is approx. 70 billion EUR. Of these, approx. 55 billion EUR are generated on the Community market.
- There are approx. 3.800 cosmetics producers in the EU. Out of these⁷⁷:
 - approx. 80% companies (i.e. approx. 3000) have less than 19 employees;
 - approx 9% companies (i.e. approx. 350) have 20-49 employees;
 - approx. 8% companies (i.e. approx. 300) have 50-249 employees;
 - approx. 3% companies (i.e. approx. 100) have more than 250 employees.

Thus, 97% of cosmetic producers in the EU are SME’s. These SME employ approx. 90.000 persons in the EU.

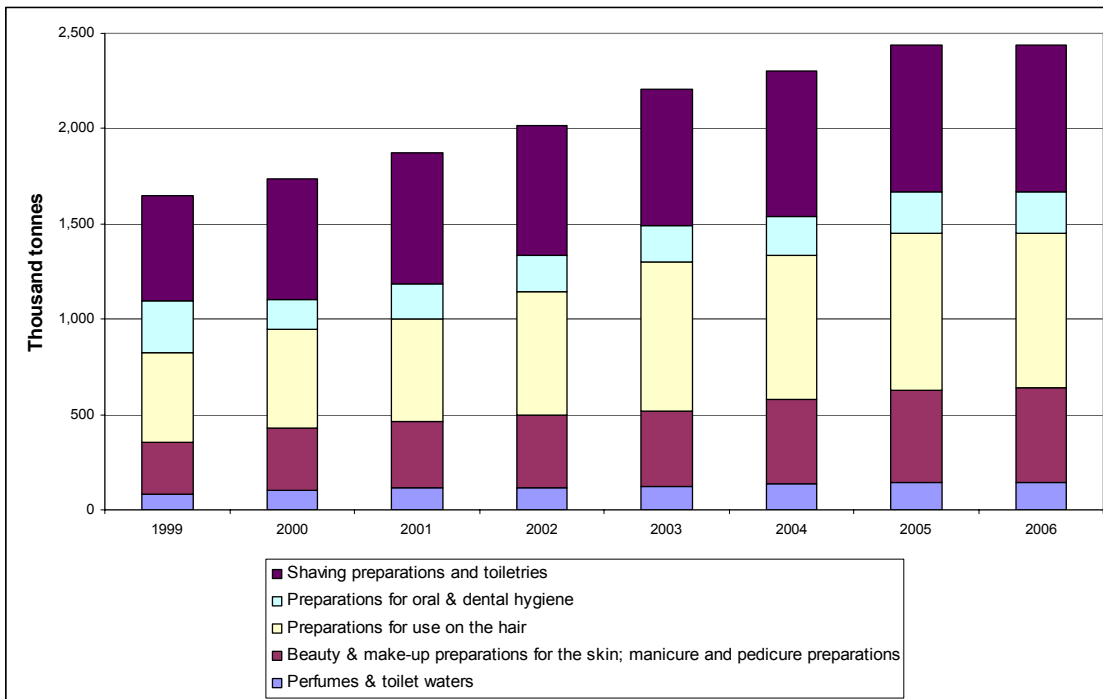
- SMEs handle in average approx. 60 product formulations. The 3% non-SMEs handle in average approx. 1000 product formulations. While in average approx. 30% of their formulations are completely replaced or re-formulated every year, SMEs re-formulate in average approx. 20% *per annum*.
- There are approx. 300.000 product formulations made available to the final user on the EU market by EU companies. Out of these, approx. 60.000 are reformulations or newly

⁷⁷ These figures are based on more generic figures stemming from the 3-digit NACE 245 code.

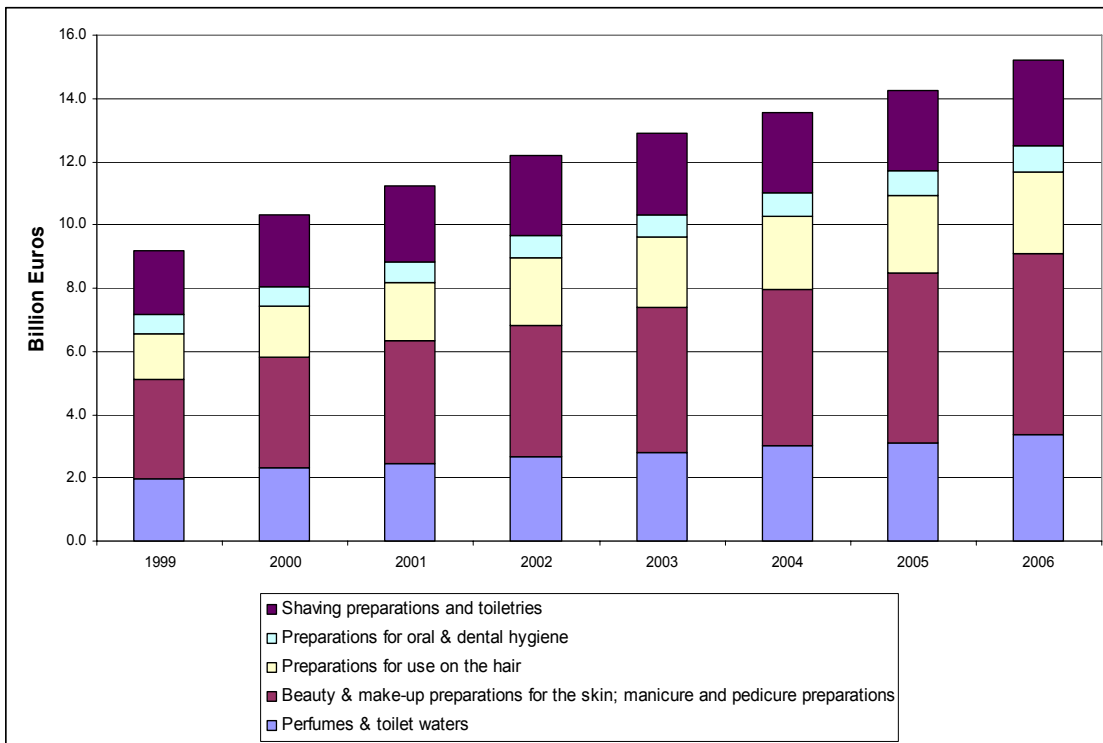
developed each year. Approx. 75% of these re-formulations (i.e. approx. 45.000) are largely based on existing product formulations.

- Total costs of compliance with the Cosmetics Directive lies between 0.5% and 1% of the annual turnover of a cosmetic manufacturer, i.e. approx. 390 million EUR. Of these, approx. 80-90 million EUR are administrative costs, while approx. 300 million EUR are other costs of compliance – in particular establishing a product information file with a cosmetics safety assessment.
- Establishing a safety assessment for a new product formulation requires approx. 240 person-hours. This amounts to costs of compliance of approx. 220 million EUR.
- Establishing a safety assessment for a re-formulation on the basis of an existing product formulation requires in average approx. 30 person-hours. This amounts to costs of compliance of approx. 80 million EUR.
- The costs for a dossier submitted to the SCCP for listing a new cosmetic ingredient in a “positive list” in the annexes to the Cosmetics Directive is approx. 500.000 EUR.
- The product notification fees vary between 0 to 36 EUR per product formulation notified, depending on the transposing laws and regulations in the different Member States.
- The average tariff per person-hour in the field of regulatory compliance with the Cosmetics Directive is approx. 60 EUR.
- Each year, competent authorities verify approx. 2700 safety files of cosmetic products placed on the EU market.

Volume of intra-EU27 cosmetics trade:⁷⁸



Value of intra-EU27 cosmetics trade:⁷⁹



⁷⁸

Source: Eurostat.

⁷⁹

Source: Eurostat.

WESTERN EUROPEAN C&T MARKET 2003-2005
MARKET VOLUME BY COUNTRY
EUROS / RSP BASIS

Country	2003 billion euros	2004 billion euros	2005 billion euros	05/04 +/- %	2005 % share
Germany	11.231	11.078	11.101	0.2	18.5
France	10.272	10.236	10.109	-1.2	16.8
United Kingdom	8.538	9.084	9.176	1.0	15.3
Italy	8.281	8.494	8.492	0.0	14.2
Spain	6.378	6.790	7.113	4.8	11.9
Netherlands	2.424	2.427	2.434	0.3	4.1
Belgium/Luxembourg	1.651	1.682	1.690	0.5	2.8
Sweden	1.268	1.472	1.527	3.8	2.5
Greece	1.230	1.280	1.314	2.7	2.2
Austria	1.190	1.212	1.248	3.0	2.1
Portugal	1.040	1.091	1.100	0.8	1.8
Denmark	0.838	0.877	0.935	6.6	1.6
Finland	0.656	0.672	0.718	6.8	1.2
Ireland	0.514	0.521	0.546	4.8	0.9
EU15	55.512	56.916	57.503	1.0	95.9
Switzerland	1.593	1.647	1.599	-2.9	2.7
Norway	0.821	0.863	0.892	3.4	1.5
Western Europe	57.926	59.425	59.994	1.0	100.0

ANNEX 3 – Assessment of the administrative costs of the Cosmetics Directive (before re-cast)
(NB: to facilitate the understanding, the table differs between SMEs and non-SMEs)

Council Directive 76/768 of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (OJ L 262, 27.9.1976, p. 169)					Tariff (€ per hour)		Time (hour)		Price (per action or equip)	Freq (per year): above SME; below: non-SME	Nbr of entities: above SME; below: non-SME	Total nbr of actions above SME; below: non-SME	Total cost above SME; below: non-SME (Mio €)	Regulatory origin (%)			
No.	Ass. Art.	Orig. Art.	Type of obligation	Target group	i	e	i	e						Int	EU	Nat	Reg
1	6§1		Labelling - new product	Familiarising with the information obligation	Cosmetics industry	60		10	600	3	3.700	11.100	6,7		100%		
										75	100	7.500	4,5				
2	6§1		Labelling - reformulated product	Familiarising with the information obligation	Cosmetics industry	60		3	180	9	3.700	33.300	6		100%		
										225	100	22500	4,05				
3	7§3		Notification anti-poison centre - new product	Filling forms and tables	Cosmetics industry	60		10	600	3	3.700	11.100	6,7		20%	80%	
										75	100	7500	4,5				
4	7§3		Notification anti-poison centre - reformulated product	Filling forms and tables	Cosmetics industry	60		5	300	9	3.700	33.300	10		20%	80%	
										225	100	22.500	6,75				
5	7a§4		Notification competent authority - new product	Filling forms and tables	Cosmetics industry	60		10	600	3	3.700	11.100	6,7		20%	80%	
										75	100	7500	4,5				
6	7a§4		Notification competent authority - reformulated product	Filling forms and tables	Cosmetics industry	60		5	300	9	3.700	33.300	10		20%	80%	
										225	100	22.500	6,75				
7	7a§1		Making safety file available upon request by competent authority	Inspecting and checking (including assistance to inspection by public authorities)	Cosmetics industry	60		10	600			2700	1,62		100%		
8	4§1		Submitting file for safety evaluation to SCCP	Producing new data	Cosmetics industry				500.000			10	5		100%		
Total administrative costs (Mio €)													83,77 (incl. notification: 55,9)				

ANNEX 4 – Assessment of the administrative costs of the Cosmetics Directive (after re-cast)

(NB: to facilitate the understanding, the table differs between SMEs and non-SMEs)

Re-cast Council Directive 76/768 of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products					Tariff (€ per hour)		Time (hour)		Price (per action or equip)	Freq (per year): above SME; below: non-SME	Nbr of entities: above SME; below: non-SME	Total nbr of actions above SME; below: non-SME	Total cost above SME; below: non-SME (Mio €)	Regulatory origin (%)			
No.	Ass. Art.	Orig. Art.	Type of obligation	Target group	i	e	i	e						Int	EU	Nat	Reg
1			Labelling - new product	Familiarising with the information obligation	Cosmetics industry	60		9	540	3	3.700	11.100	6	100%			
										75	100	7.500	4				
2			Labelling - reformulated product	Familiarising with the information obligation	Cosmetics industry	60		2,7	160	9	3.700	33.300	5,3	100%			
										225	100	22.500	3,6				
3			Centralised electronic notification (anti-poison centre and competent authority) - new product	Filling forms and tables	Cosmetics industry	60		3	180	3	3.700	11.100	2	100%			
										75	100	7.500	1,35				
4			Centralised electronic notification (anti-poison centre and competent authority) - reformulated product	Filling forms and tables	Cosmetics industry	60		2	120	9	3.700	33.300	4	100%			
										225	100	22.500	2,7				
5			Making safety file available upon request by competent authority	Inspecting and checking (including assistance to inspection by public authorities)	Cosmetics industry	60		10	600			5.400	3,24	100%			
6			Submitting file for safety evaluation to SCCP ⁸⁰	Producing new data	Cosmetics industry				500000			8 ⁸¹	4	100%			

⁸⁰ This would include the submission of product safety files supporting the use of CMR 1, 2 substances to the SCCP (cf. objective 4).

⁸¹ The Commission assumes that, in the framework of a stronger focus on in-market control and cosmetics safety assessment by the manufacturer, the number of dossiers submitted to the SCCP is going to reduce by approx. 20%.

7	Reporting serious undesirable effects (cosmetovigilance)	Active reporting of serious undesirable events	Cosmetics industry	60	100	6000	250	1,5	100%
Total administrative costs (Mio €)								37,69	(incl. notification: 10,05)

This means: Reduction of administrative costs by approx. 50% from approx. 83 Mio EUR to approx. 37.5 Mio EUR; Reduction of costs for notifications by 80% from approx. 56 Mio EUR to approx. 10 Mio. EUR.

ANNEX 5 – Summary of the Cosmetics Directive

A cosmetic product is any substance or preparation intended to be placed in contact with the various external parts of the human body or with the teeth and the mucous membranes of the oral cavity, with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, and/or correcting body odours, and/or protecting them or keeping them in good condition. Such products, listed in the Annex (illustrative list), must not be liable to cause damage to human health when they are applied under normal conditions of use.

The Cosmetics Directive provides for exhaustive rules in terms of packaging, labelling and chemical safety for the internal market.

1. Product information file/Market surveillance

Cosmetic products are not subject to pre-market approval. Rather, the manufacturer/importer has to assess the safety of the product. The safety is then checked in in-market controls by competent authorities.

The manufacturer/importer must keep product information and safety information available to the competent monitoring authority.

2. Notification to the competent authority

The manufacturer/importer has to notify the product and the place of manufacture or of initial importation to the competent authority of that Member State.

Moreover, he has to notify approx. 12 anti-poison centres in several Member States.

3. Labelling

Containers and/or packaging must bear, in indelible, easily legible and visible characters *inter alia*:

- the name or trade name and address or registered office of the manufacturer or of the person responsible for marketing the cosmetic product within the Community;
- particular precautions for use; and
- the list of ingredients.

This information is to be labelled in the national or official language or languages of the respective Member State.

With regard to the list of ingredients, Member States may require these to be labelled with the name contained in the inventory, as published by the Commission.

4. Ingredients/composition

The Directive sets out a list of substances which cannot be included in the composition of cosmetic products (Annex II) and a list of substances which cosmetic products may not contain, outside the restrictions and conditions laid down (Annex III).

The Directive also contains “positive lists” for colorants (Annex IV), preservatives (Annex VI) and UV filters (Annex VII). Concerning these groups of ingredients, only the substances listed in the respective annex are allowed for use in cosmetics in the EU.



EUROPEAN COMMISSION
IMPACT ASSESSMENT BOARD

Brussels, 31 August 2007

D(2007) 7617

Opinion

Title **Impact Assessment on simplification of the “Cosmetics Directive” – Directive 76/768/EEC**

(Draft of 18 July 2007)

Lead DG **DG ENTR**

Impact Assessment Board Opinion

(A) Context

Simplification of [Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products](#) (the “Cosmetics Directive”) was first announced in the 2005 Commission Communication “Implementing the Community Lisbon programme: A strategy for the simplification of the regulatory environment” and is therefore part of the simplification rolling programme 2005-2008.

(B) Positive aspects

The IA report is well structured and clearly written. It provides a good overview of the relevant Cosmetics Directive issues and contains a very comprehensive synthesis of the public consultation.

(C) Main recommendations for improvements

The recommendations below are listed in order of descending importance. Some more technical comments have been transmitted to the author DG.

General recommendations: The IA report would benefit from a clearer presentation of expected costs and benefits, especially in the context of the simultaneous effects of simplification of the regulatory environment for producers and improved safety for consumers through better implementation. The following recommendations were accepted by DG ENTR in the Board meeting.

(1) The calculation of the costs of "correct cosmetics safety assessments" should be presented in the proper perspective. In the present text it is not sufficiently clear that these costs are incurred by the industry under the preferred option and are not purely additional, but must be seen against the aggregate costs in the current situation, characterised by lack of clarity and transparency and the absence of uniformity across Member States. The report should highlight whether the introduction of a uniform safety regime across the EU would actually produce considerable cost savings for bona fide producers while it should also explain whether the effective overall safety levels could be raised.

(2) It should be clarified whether the desired improvement of cosmetics safety will be achieved without the adoption of more stringent requirements. In view of the dual objective to simplify the regulatory environment without compromising existing levels of consumer protection, the IA report should spell out whether improved security will be entirely accounted for by greater transparency and higher compliance rates or also through the imposition of more stringent de facto requirements.

(3) The overall simplification benefits of this initiative should be better presented. Given that the initiative is part of the Commission's simplification programme, the likely simplification benefits should be presented as clearly as possible, including possible gains from simplification of the labelling regime.

(4) The international context should be better explained. The IA report should incorporate a comparison of the EU regulatory regime with the situation in third countries. It should also refer to consultations that have taken place in the context of existing regulatory dialogues with the US and other countries.

(D) Procedure and presentation

It appears that all necessary procedural elements have been complied with, although the report should state more clearly whether the minimum consultation standards were met. With regard to the presentation, the IA report should aim to more closely respect the maximum length of 30 pages (excluding annexes)

IAB scrutiny process

Reference number	2007/ENTR/002
Author DG	ENTR- F - 3
External expertise used	No
Date of Board Meeting	29 August 2007
Date of adoption of Opinion	31 August 2007