Impact of European Regulation on the EU Cosmetics Industry

Final Report

Prepared for European Commission
Directorate General Enterprise
and Industry

RPA

September 2007

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prepared for

European Commission – Directorate General Enterprise and Industry

by

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1. INTRODUCTION

1.1 Background to the Study

The Cosmetics industry is a global industry within which the EU is a major player. The output of EU cosmetics companies is around twice that of Japanese companies and one third more than those in the USA. Over 350,000 Europeans are employed directly by cosmetics companies or indirectly in retail, distribution and transport. Although the EU market for cosmetics is significant, valued at around €60 billion in 2005 (retail sales prices) by COLIPA[1], exports constitute a significant proportion of the market for EU manufacturers. The major non-EU markets are the USA, Japan and Canada but other markets, such as Russia, China, South Africa and Latin America, are also growing in importance.

The cosmetics sector is characterised by global brands, with most multinational companies selling a high proportion of their products across all key markets. However, the majority of the approximately 4,000 EU cosmetics companies are SMEs. Over five billion cosmetics products (or units) are sold annually in the EU, with the major EU markets being France, Germany, Italy, Spain and the UK. Most cosmetics products have lifetimes below five years, with up to 40% of products being reformulated or replaced each year. The exception is fine fragrances, some of which have remained on the market for 100 years.

Cosmetics products are subject to regulatory controls in all markets, in order to ensure the safety of products and avoid adverse impacts on the health of users. In the EU, the regulatory framework is provided by the Cosmetics Directive[2]. The Directive ensures the safety of chemical products through controls over ingredients, in the form of positive, prohibited and restricted lists and through requirements on manufacturers concerning safety testing and maintenance of data files, information provision and labelling.

A study by RPA (2004)[3] for the European Commission indicated that the EU regulatory framework had enabled innovation and enhanced the competitiveness of the industry, compared to frameworks in other markets. Nevertheless, regulations have the potential to impact on the competitiveness of industry by imposing implementation costs, constraining technological change and innovation or imposing ineffective safety requirements.

As part of its review programme of the impacts of regulation on EU industry sectors, the Commission launched a public consultation on the proposed simplification of the Cosmetics Directive. Before proposing any changes, the Commission will carry out an

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1 The European Cosmetics Toiletry and Perfumery Association (COLIPA)

2 Council Directive 76/768/EEC on the Approximation of the Laws of the Member States Relating to Cosmetics Products and its Subsequent Amendments.

3 RPA (2004): **Comparative Study on Cosmetics Legislation in the EU and Other Principal Markets with Special Attention to so-called Borderline Products**, Final Report, prepared by Risk & Policy Analysts (RPA) Limited for the European Commission, DG Enterprise, August 2004.

Extended Impact Assessment for which information will be required on the economic impacts of the current Directive on the business operations of cosmetics companies and the competitiveness of the European cosmetics industry.

The European Commission (DG Enterprise and Industry) has, therefore, commissioned Risk & Policy Analysts (RPA) to collect and analyse data on the economic impact of the Cosmetics Directive on the competitiveness of the European cosmetics industry.

1.2 Objective of the Study

The objective of this study is to analyse the impact of the Cosmetics Directive on the everyday operation of the cosmetics industry in Europe, focusing on the costs incurred in complying with the Directive and the effects that these have on company operations. In particular, the study should cover:

- the costs of implementing provisions on health and safety, including:
  - total and relative costs for changing labels;
  - total and relative costs for adapting the composition of products to comply with regulation;
  - total and relative costs for the registration of product ingredients in line with the regulatory requirements;
  - the timescale for implementation of regulatory changes;

- the efficacy of regulation for health and safety: in particular, whether the present regulatory framework for health and safety effectively addresses current safety risks and those related to new, innovative products in the future; and

- the effects of regulation on technological change and innovation, for example whether the regulation imposes a barrier to the introduction of new 'active' substances; and

- the impacts of specific possible changes to the Cosmetics Directive.

This Final Report presents the study findings.

1.3 Structure of the Report

The remaining sections of this Report are organised as follows:

- Section 2 sets out the **approach to the study and information on respondents** to the consultation undertaken for this study;
- Section 3 sets out the **impacts of the existing Cosmetics Directive** on the business costs of cosmetics companies, as identified from consultation;
- Section 4 assesses the **impacts of a number of potential changes to the Cosmetics Directive**, as set out in the public Commission Consultation Document; and
- Section 5 sets out the **findings and conclusions** for the study.

2. APPROACH TO THE STUDY AND INFORMATION ON RESPONDENTS

2.1 Approach to Consultation

The main aim of this study was to gather information on the impacts of the existing Cosmetics Directive on the EU industry. In order to achieve this objective, a detailed questionnaire (which was agreed with the Commission services and industry representatives) was developed to obtain the views of cosmetics companies and other industry stakeholders. The questionnaire (attached as Annex 1) was hosted on the RPA web site with a link from the Commission web site. The main industry associations of relevance to the study were also provided with a copy of the questionnaire (and the link) for dissemination to their members.

At the start of the study, it was made clear that the input of the industry associations, both at EU level and their national members, would be crucial in encouraging a high response rate. The Commission set up a steering group comprising representatives of the main EU sector associations (Colipa, EFfCI and EFFA) to facilitate the participation of industry in consultation and case studies.

2.2 Information on Respondents

2.2.1 Responses Received

Responses have been received from 21 companies in total:

- 17 from cosmetics manufacturers/companies; and
- 4 from manufacturers of cosmetics ingredients.

Table 2.1 provides an overview of the size or scale of operations of companies which responded to the consultation, while Table 2.2 provides an indication of the geographical locations of the business operations of the cosmetics companies.

Table 2.1: No. of Employees and Annual Turnover of Companies Responding to Consultation

Size of Enterprise		Cosmetics Companies	Cosmetics Ingredients Manufacturers
	No. of Employees		
Small	<50	4	
Medium	<250	5	
Large	>250	8	2
	Annual Turnover		
Small	≤€10m	3	
Medium	≤€50m	4	
Large	>€50m	8	2

Not all of the companies responded to both the questions on employees and that on annual turnover. Some companies did not fall into the same category based on the number of employees and annual turnover.

Table 2.2: Geographical Location of Business Operations of Responding Cosmetics Companies			
Countries	**Headquarters**	**Manufacturing**	**Sales**
Austria	0	0	5
Bulgaria	1	1	6
Belgium	1	0	6
Cyprus	0	1	9
Czech Republic	2	4	10
Denmark	0	0	7
Estonia	0	0	9
Finland	0	0	6
France	1	4	8
Germany	2	4	8
Greece	0	1	10
Ireland	0	0	3
Hungary	0	0	8
Italy	6	7	8
Latvia	0	1	5
Lithuania	0	0	9
Luxembourg	0	0	2
Malta	0	0	4
Netherlands	0	0	7
Poland	0	2	9
Portugal	0	0	8
Romania	0	0	9
Spain	0	3	9
Slovakia	0	0	10
Slovenia	0	1	7
Sweden	0	1	7
United Kingdom	2	3	8
All EU-27	0	0	2
EFTA/EEA	0	0	6
Far East	0	7	12
North America	3	6	8
Other Country	0	5	11
Total	**18**[1]	**51**	
[1] One company indicated that it had headquarters both in North America and in Europe			

Responses were received from cosmetics companies based in the countries with the largest cosmetics markets (France, Germany, Italy, Spain and the UK) and from those based in the new Member States. The small and medium-sized enterprises (SMEs) responding had their headquarters and/or manufacturing facilities in Italy, Bulgaria and the Czech Republic.

2.2.2 Business Operations of Respondents

Companies were asked to indicate the percentage of their sales that fall into the main cosmetics product categories. Table 2.3 provides an overview of the product portfolios of the cosmetics manufacturing companies while Table 2.4 summarises the responses to other key questions relating to the manufacture of cosmetics and ingredients.

Table 2.3: Percentage of Annual Sales of Cosmetics Manufacturing Companies Accounted for by Different Product Categories

Product Category	% Average Annual Sales			Average Across all Companies	Maximum % per Company
	Small Companies	Medium Companies	Large Companies		
Skin care*	55%	26%	33%	36%	99%
Hair care	2%	46%	14%	21%	95%
Toiletries	5%	12%	25%	17%	90%
Perfumes and fragrances	20%	0%	10%	9%	80%
Sun care products	7%	13%	3%	7%	50%
Decorative cosmetics	11%	3%	9%	8%	40%
Other	0%	0%	7%	3%	38%
	100%	**100%**	**~100%**	**~100%**	

* excluding sun care products

Table 2.4: Information on Cosmetics Ingredients and Cosmetics Manufacturers

Questions asked in the questionnaire:	Range of Responses Received		Average Across Respondents
	Minimum	Maximum	
Approximately what percentage of your total sales is obtained from **outside the EU**?			
• Small	20%	24%	12%
• Medium	10%	20%	15%
• Large	1%	70%	29%
• **ALL**	**1%**	**70%**	**22%**
Approximately how many **different product formulations** do you currently place on the market in the EU?			
• Small	80	200	160
• Medium	10	100	59
• Large	160	3,000	810
• **ALL**	**10**	**3,000**	**480**
Approximately how many **different ingredients** do you currently use across your company's cosmetics products portfolio?			
• Small	200	400	288
• Medium	100	500	325
• Large	400	2,000	1,298
• **ALL**	**100**	**2,000**	**802**
Approximately what **percentage of the ingredients** used across your company's cosmetics products portfolio is used *solely* or *mainly* in cosmetics products?			
• Small	60%	100%	94%
• Medium	20%	100%	92%
• Large	1%	100%	64%
• **ALL**	**1%**	**100%**	**81%**
What percentage of your product formulations do you **replace or reformulate** each year?			
• Small	10%	25%	19%
• Medium	5%	60%	26%
• Large	10%	50%	25%
• **ALL**	**5%**	**60%**	**24%**
Approximately **what proportion of ingredients will be changed** when a product formulation is reformulated?			
• Small	5%	80%[1]	45%
• Medium	10%	20%	15%
• Large	5%	30%	19%
• **ALL**	**5%**	**80%**	**25%**

[1] Two small companies indicated that they re-formulated products infrequently but, when they did, a large percentage of ingredients is changed

The responses indicate that:

- skin care products, hair care products and toiletries are the three most important cosmetics product groups for the responding companies, accounting for around 70% of the product types identified by respondents as being of relevance. This is broadly consistent with the market shares of these product categories in Western Europe, according to COLIPA statistics;

- the responding cosmetics companies focus their activities on specific product groups. Hence, hair care products and toiletries account for over 90% of the annual cosmetics sales for two of the companies (the first an SME and the second a large company) while perfumes and fragrances account for 80% of the annual sales of one small company. Skin care products account for between 60% and 70% of annual turnover for three companies and around 99% for another small company overall;

- over 20% of total annual sales of cosmetics products per company are obtained from outside the EU. As would be expected, the average for SMEs is lower (at around 12%) than that for large companies (around 29%). The maximum sales outside the EU indicated by any company was 70%, by a large company;

- large companies place almost 1,000 different product formulations per company on the EU market, compared with SMEs which place less than 100 product formulations per company on the market. Similarly, large companies have on average over 1,000 different ingredients per company across their portfolio, while SMEs have less than 350 ingredients on average;

- for most cosmetics companies, around 80% of the ingredients in their portfolios are used solely or mainly in cosmetics products; and

- most companies reformulate around 25% of their product formulations every year, although the percentage is lower for small companies. In the process, on average around 25% of ingredients in a product will be changed.

2.2.3 Representativeness of Sample

The aim of the consultation was to obtain responses representative of the EU cosmetics industry as a whole. In practice:

- the *overall sample size* (21 companies) is very small when compared with the estimated 4,000 cosmetics companies across the EU. However, based on previous studies for the cosmetics industry and discussions with industry, this is not an unusual response rate. In our experience, large cosmetics companies and ingredient manufacturers respond directly to these consultation exercises (with assistance from the EU-wide associations) while national associations collate and submit a joint response on behalf of the SMEs;

- eight out of the seventeen questionnaires received from cosmetics companies were from *large companies and multinationals*. One large company also responded to the survey but did not complete the questionnaire. Around 25 large companies participate in the European cosmetics market; the respondents therefore account for nearly 33% of the total number and, as such, the results of this survey are likely to be representative for the large companies;

- nine out of the seventeen questionnaires received from cosmetics companies were from *small and medium-sized enterprises (SMEs)* with four from small companies. This is only a very small proportion of the almost 4,000 cosmetics companies across the EU which are SMEs. However, SMEs account for nearly 40% of the total responses from cosmetics companies, which is a high percentage for surveys of this type. On this basis, the responses received provide a useful counterbalance to the views of large companies in assessing the total costs to the sector as well as providing some insight into the impacts of the Cosmetics Directive on SMEs.

  Normally, responses from national associations mostly representing SMEs (who were sent the questionnaire by COLIPA) would have been used to verify the impacts of the Cosmetics Directive on SMEs. However, the specific nature of the information required in the questionnaire meant that industry associations were unlikely to be in a position to provide a response. Thus, although one industry association response was received, this response was for one large company which responded anonymously through its industry association; the data provided has, therefore, been input as an individual company response.

3. IMPACTS OF THE EXISTING COSMETICS DIRECTIVE

3.1 Introduction

The EU approach to regulation of cosmetics products is set out within the Cosmetics Directive (Directive 76/768/EEC) and its subsequent amendments. The comparative study of cosmetics regulations (RPA, 2004) identified this as the preferred model from an industry competitiveness viewpoint. However, there were a number of aspects of the EU regulatory framework identified by industry as having potential impacts on costs and overall competitiveness. This Section discusses these aspects in detail, in particular:

- the costs of implementing the Cosmetics Directive provisions on health and safety (Section 3.2);
- the overall costs and benefits of compliance with the existing Cosmetics Directive (Section 3.3);
- the effectiveness of the Cosmetics Directive for health and safety (Section 3.4); and
- the effect of the Cosmetics Directive on technological change and innovation (Section 3.5).

In the following sections, the costs identified by manufacturers of cosmetics are set out separately from those identified by manufacturers of cosmetics ingredients, except where no costs have been identified by the latter or the questions/issues are relevant for cosmetics products only.

3.2 Costs of Implementing Provisions on Health and Safety

3.2.1 Costs of Complying with the Labelling Requirements

The Cosmetics Directive requires manufacturers to include a range of information on the labels of cosmetics products, including:

- the name and address of the manufacturer or person placing the product on the market and the address where the product safety information is kept within the EU;
- the batch number, nominal net content and function of the product;
- the date of minimum durability (if up to 30 months) or period after opening within which the product can be used safely, usage precautions and warnings for regulated ingredients; and
- a list of ingredients in descending order (including any of a list of 26 fragrance allergens).

Ingredient listing is required only on the outer packages of cosmetics products, using the International Nomenclature of Cosmetics Ingredients (INCI) which aims to establish a single name for each cosmetics ingredient. Warning statements (on the outer and inner packages and in the respective national languages of all Member States) are required for products containing certain ingredients listed in the Annexes of the Directive.

Companies were asked to provide an indication of the costs of complying with changes to the information requirements of the Cosmetics Directive as a result of the 7th amendment (which introduced specific requirements for cosmetics companies to make available to the public a range of product information, covering product composition and related adverse effects, animal testing, durability and declaration of the presence of 26 fragrance allergens). Table 3.1 shows respondents' estimates of the man-hours and costs required to make these changes.

Table 3.1: Man-hours and Cost per Hour of Complying with Changes to Information Requirements

Company	Range of man-hours	Average no. of man-hours	Cost per hour	Average cost per hour	Average total cost[1]
Small	200 – 500	350	€7 - €30	€20	€7,000
Medium	2 – 1,200	600	€17 - €35	€26	€15,600
Large	200 – 6,100	2,775	€20 - €135	€80	€222,000
All	**2 – 6,100**	**1,625**	**€7 - €135**	**€50**	**€81,250**

[1] Calculated by multiplying average number of man-hours by average cost per hour across respondents

The estimated number of man-hours required to comply with changes to the information requirements ranged from 2 to 6,100 per company while the average cost per hour ranged from €7 to €135. The overall average cost across all respondents was around **1,625 man-hours** (around 210 man-days) **per company per year** at an average cost of around **€50 per hour** (€375 per day). This is roughly equivalent to one employee (at graduate or similar level) working full-time for one year. It also exceeds the maximum number of man-hours and cost per hour indicated by any of the SMEs.

One reason for the difference in the costs of complying with labelling changes between small and large companies is the number of different product formulations placed on the market, as each formulation may have a separate label. As Table 2.4 shows, the average number of formulations varies from 160 for small and 59 for medium companies to 810 for large companies responding to the survey.

Companies were also asked to indicate the average one-off cost per formulation incurred in complying with the latest changes to the labelling requirements. Table 3.2 summarises the responses.

Table 3.2: Average One-off Cost per Formulation of Complying with the Latest Changes to the Information Requirements

Range of Costs	No. of Respondents			Percentage of All Respondents
	Small	Medium	Large	
Below €500	1	0	0	7%
€500 - €1,499	1	1	1	21%
€1,500 - €4,999	2	1	2	36%
€5,000 - €9,999	0	0	1	7%
€10,000 - €24,999	0	3	1	29%
€25,000 - €99,999	0	0	0	0%
Over €100,000	0	0	0	0%
Total	**4**	**5**	**5**	**100%**

For most companies, the one-off cost to comply with the latest changes to the labelling requirements was less than **€5,000 per formulation**. Four companies (three medium and one large) indicated costs per formulation of €10,000 to €25,000. This contrasts with the costs obtained by dividing the average total man-hour cost (from Table 3.1) by the average number of product formulations (from Table 2.4). These are shown in Table 3.3 and average €169 per formulation. The difference may be due to the inclusion in Table 3.2 of non-manpower costs, but this is not clear from the responses.

Table 3.3: Calculated Average Cost Per Formulation of Complying with Changes to Information Requirements

Company	Average no. of man-hours	Average cost per hour	Average total cost[1]	Average number of formulations	Calculated average cost per formulations[2]
Small	350	€20	€7,000	160	€44
Medium	600	€26	€15,600	59	€264
Large	2,775	€80	€222,000	810	€274
All	**1,625**	**€50**	**€81,250**	**480**	**€169**

[1] Calculated by multiplying average number of man-hours by average cost per hour across respondents
[2] Calculated by dividing the average total cost by the average number of formulations

Companies were also asked to indicate the total annual cost to the company of complying with changes in labelling requirements. Responses are shown in Table 3.4.

Table 3.4: Total Annual Cost per Company of Complying with the Latest Changes to the Information Requirements

Range of Costs	No. of Respondents			Percentage of All Respondents
	Small	Medium	Large	
Below €1,000	0	0	0	0%
€1,000 - €49,999	2	0	0	17%
€50,000 - €249,999	0	4	2	50%
€250,000 - €499,999	0	0	1	8%
€500,000 - €749,999	0	0	1	8%
€750,000 - €999,999	0	0	0	0%
Over €1 million	0	0	2	17%
Total	**2**	**4**	**6**	**100%**

Small companies indicated annual costs of less than €50,000 and medium companies less than €250,000 to comply with changes in labelling requirements. Larger companies indicated costs of above €250,000, with two large companies indicating costs of over €1 million per company. This is again significantly higher than the man-hour costs indicated in Table 3.2, implying that factors other than staff time account for the majority of costs. In explaining their high-end estimates, the two large companies noted that, to comply with the requirements to label the period after opening, hundreds of artworks had to be changed and new artwork developed (at a cost of around €1 million), old packaging had to be destroyed, equipment/components written off (at around €1 million) and new information generated. Further information is provided in the Case Study in Box 3.1.

Only one of the manufacturers of cosmetics ingredients provided quantitative data on the cost of complying with changes to the information requirements. The company noted that its total annual cost were between €1,000 and €49,999, with man-hour costs of €15,000, based on 100 man-hours per year at an average cost of €150 per hour.

Other impacts identified by respondents as resulting from changes in labelling requirements include:

- impacts on export markets: where the company produces multilingual and/or multiregional packs, labelling changes to meet EU requirements result in labelling changes to products sold in non-EU markets. Consumers or regulators in these markets may not understand that labels on packs have changed, but the product has not, and this could raise concerns. Some impacts were also identified in non-EU markets aligning with EU regulatory requirements. In some cases, authorities in these markets were not able to keep up with changes to the EU Cosmetics Directive, resulting in regulatory inconsistencies between the two markets;
- adding greater complexity to warehousing and the supply chain and making higher demands on logistics to ensure full compliance with the changes;
- the need to brief consumer care staff on product information changes, and updating the website which provides home and personal care product ingredient lists to consumers; and
- generating waste packaging materials, especially where the time period for change means that existing packaging cannot be re-used (see Section 3.2.3).

Box 3.1: Case Study 1: Example of Costs to Industry Resulting from Changes in Labelling Requirements - Large Company

Company X is a large global manufacturer of consumer products with a turnover of around €4 billion for its range of personal care products in Europe only. It has manufacturing sites in four EU countries and undertakes contract manufacture in eight other EU countries, as well as in the Far East and North America. It sells its products globally and manufactures mainly antiperspirants and deodorants, oral care, skin care and hair care products. Under the 7th Amendment, the introduction of period after opening (PAO) and fragrance allergen labelling required that every product variant label needed amending.

Direct Costs Incurred: Typically, the cost to generate new label artwork is around €1,400 per bottle label, whilst new artwork for aerosol cans is around €2,800 per product variant. Similar costs are incurred when INCI lists need amending following changes to the Directive Annexes. Company X has around 1,000 formulations; based on the above costs and assuming 50% of formulations are in aerosol format, the cost of artwork generation alone was around €2.2 million. (A second company had indicated costs relating to new artwork development of €1 million; however, this company has only around 200 formulations).

Indirect Costs Incurred: These include:
- packaging write-off costs;
- component write-off costs, estimated at €1million;
- product portfolio management activities (including man-hour costs of generating information) to ensure compliance within the Directive, estimated at €2million.

Key Factors Affecting Cost: These include:
- timescales for compliance, including delays in implementing legislation and producing guidance; and
- specific company product portfolios and commercial arrangements (e.g. where the products are manufactured contractually for a brand name or in pre-determined/agreed batches).

Box 3.2: Case Study 2: Example of How Changes to the Labelling Requirements Under the Existing Cosmetics Directive Resulted in Costs to Industry – Small Company

Due to the delay in agreeing guidance on the application of the period after opening provisions, a significant proportion of stock will need over-labelling.

The company's premium product range consists of six different products. Minimum production runs for each product variant are 25,000 units. On average, 13,890 units of each variant will need over-labelling at an average cost of 29 cents per unit. This is comprised of the following elements:

- cost of label including printing plates: 14 cents per unit
- cost of unpacking stock and applying label and re-packing: 11 cents per unit
- transport from warehouse: 0.8 cents per unit
- originating artwork: 2.2 cents per unit
- cost of cutter tools used to cut out the labels: 1 cent per unit
- **Total: 29 cents per unit (€24,500 for all 83,340 units requiring re-labelling)**

In addition, approximately 10,000 printed but unfilled cans will need to be written off (at a cost of €3,640) or over-labelled (at a cost of **23.8 cents per unit, total cost €2,380**)

The total cost of re-labelling this product range is therefore €26,880

Source: UK Department of Trade and Industry (2004): Final Regulatory Impact Assessment, the Cosmetics Products (Safety) Regulations 2004[4].

3.2.2 Costs of Adapting the Composition of Products and Registration of Product Ingredients to Comply with Regulatory Requirements

Cost of Including an Ingredient on a Positive List

Certain product ingredients (colorants, preservatives and UV-filters) are the subject of positive lists under the Cosmetics Directive[5]. A new substance can only be added to a positive list following an evaluation of the risk of the substance by the Scientific Committee on Consumer Products. The Committee may also review the positive (and the prohibited/restricted) lists in response to technical progress and/or concerns about the impacts of particular ingredients on safety. The final decision on addition (or removal) of substances from the lists is taken by the Commission and the Member States.

Companies were asked to provide an indication of the average one-off cost per ingredient and/or the total annual cost per company of listing an ingredient in the Cosmetics Directive. There was wide variation in the responses provided by the companies, as shown in Table 3.5. In explaining the wide range of the cost estimates provided, respondents noted that the costs are substance-specific. A number of key factors influence the costs per ingredient or company, in particular the extent of safety testing required and whether the company acts as part of a consortium or lists the ingredient alone.

[4] These costs are currently being reviewed by the UK CTPA and will be updated if necessary

[5] Annex IV is a positive list of over 150 cosmetics colourants permitted for use in cosmetics products. Annex VI is a positive list of over 50 preservatives that are permitted in cosmetics products. Annex VII is a positive list of over 20 ultraviolet (UV) filters that are permitted in cosmetics products.

Table 3.5: Indicative Costs of Listing an Ingredient in the Cosmetics Directive				
Range of Costs	**No. of Respondents**			**Percentage of All Respondents**
	Small	**Medium**	**Large**	
Average One-off Cost per Formulation				
Below €500	1	1	1	25%
€500 - €1,499	0	1	0	8%
€1,500 - €4,999	0	0	0	0%
€5,000 - €9,999	0	1	2	25%
€10,000 - €24,999	0	1	0	8%
€25,000 - €99,999	1	0	0	8%
Over €100,000	0	0	3	25%
Total	**2**	**4**	**6**	**100%**
Total Annual Cost per Company				
Below €1,000	1	0	1	25%
€1,000 - €49,999	0	1	0	13%
€50,000 - €249,999	0	2	1	38%
€250,000 - €499,999	0	0	0	0%
€500,000 - €749,999	0	1	0	13%
€750,000 - €999,999	0	0	0	0%
Over €1 million	0	0	1	13%
Total	**1**	**4**	**3**	**100%**

One respondent indicated that its estimate included only the manpower costs associated with listing, comprising literature/information searches, evaluation of existing data and preparation of the safety dossier and risk assessment. It did not include any additional costs of conducting toxicity studies to address potential data gaps. In the event that toxicity testing is necessary and a full testing package is required, the estimated one-off cost per ingredient could increase up to €1 million. This could help to explain the variation in responses, with the high end of the range including the costs of additional studies whilst the lower end of the range excludes such studies. The only company which indicated costs of over €1 million specifies toxicity testing, repeat testing for safety, efficacy and consumer acceptance and expert resource as key factors driving the high costs.

Two of the four responding cosmetics ingredient manufacturers indicated that the total annual cost of listing an ingredient in the Cosmetics Directive was in the range of €250,000 to €500,000 per company. A one-off cost of over €100,000 per ingredient was also indicated.

Costs to Companies When an Ingredient is Added to Restricted or Prohibited Lists

The Cosmetics Directive also includes a list of ingredients prohibited for use in cosmetics (Annex II) and a list of ingredients with restricted uses (Annex III)[6]. Companies were asked to provide an indication of the average one-off cost per ingredient

[6] Annex II lists over 1,300 substances that are prohibited for use in the composition of cosmetics products (negative list). The 7th Amendment also prohibited the use of substances with category 1 and 2 carcinogenic, mutagenic or reprotoxic (CMR) properties, with the potential for risk assessment based exemption for Category 3 CMRs. Annex III lists over 90 substances which cosmetics products may only contain subject to the restrictions and conditions laid down (restricted list).

and/or the total annual cost per company of adapting the composition of products when ingredients are added to the prohibited or restricted lists. Table 3.6 provides a summary of the responses provided by cosmetics companies.

Table 3.6: Indicative Costs of Adapting the Composition of Products when an Ingredient is Added to the Prohibited or Restricted List

Range of Costs	No. of Respondents			Percentage of Respondents
	Small	Medium	Large	
Average One-off Cost per Formulation				
Below €500	1	1	0	12%
€500 - €1,499	1	2	0	18%
€1,500 - €4,999	0	0	2	12%
€5,000 - €9,999	0	1	2	18%
€10,000 - €24,999	2	1	1	24%
€25,000 - €99,999	0	0	2	12%
Over €100,000	0	0	1	6%
Total	**4**	**5**	**8**	**100%**
Total Annual Cost per Company				
Below €1,000	0	0	0	0%
€1,000 - €9,999	1	0	0	10%
€10,000 - €99,999	1	2	2	50%
€100,000 - €249,999	0	2	1	305%
€250,000 - €499,999	0	0	0	0%
€500,000 - €999,999	0	0	0	0%
Over €1 million	0	0	1	10%
Total	**2**	**4**	**4**	**100%**

Again, there was significant variation in the responses; one respondent noted that the ease of substitution, and thus the costs, will depend largely upon:

- whether the ingredient to be replaced is a key functional component of the product or included as the basis of product claim. If this is the case, the costs of substitution will increase; and

- the availability of suitable alternative ingredients with identical or similar performance/function. If such ingredients are available, the costs of substitution will decrease.

Five cosmetics manufacturers indicated that the addition of ingredients to the prohibited or restricted lists had caused them to withdraw products from the market; 10 had not experienced such impacts. Only one large company had experienced such an impact while 50% of the responding SMEs had done so. This may be because, as noted by one respondent, large companies pay particular attention to, and have more resources for, managing their products and public profiles and keeping up-to-date with regulatory developments. Interestingly, 75% of large companies had suffered 'other impacts' (see Box 3.3) as a result of the addition of a substance to the prohibited or restricted lists, while only half of the SMEs had suffered 'other impacts' beyond the withdrawal of their product.

Other factors identified by respondents which could significantly affect the costs include:

- whether any changes in processing and manufacturing are associated with handling the new ingredient;
- packaging or ingredient write-off costs and generation of new label artwork to reflect the change in ingredient labelling (see Section 3.2.1);
- potential loss of sales, implications for global supply and disruption to business (e.g. where resources are transferred from innovation);
- the time available to implement an ingredient restriction/ban following Commission decision; and
- difficulties associated with the generation of stability data, testing, research and development and formulation development.

Costs to Companies from Product Formulation Changes Due to Changes in Ingredient Listing

Companies were asked to provide an indication of the average one-off cost per ingredient and/or the total annual cost per company to put on the market products with a new (or modified) composition due to changes in ingredients (such as administrative, marketing or labelling costs). Again, there was significant variation in the estimates provided by the cosmetics companies, as shown in Table 3.7.

Table 3.7: Indicative Costs to Put a Product on the Market with a New or Modified Composition Due to Changes in Ingredients

Range of Costs	No. of Respondents			Percentage of Respondents
	Small	Medium	Large	
Average One-off Cost per Formulation				
Below €500	0	0	0	0%
€500 - €1,499	2	1	0	20%
€1,500 - €4,999	1	2	1	27%
€5,000 - €9,999	0	0	3	20%
€10,000 - €24,999	0	2	0	13%
€25,000 - €99,999	1	0	2	20%
Over €100,000	0	0	0	0%
Total	**4**	**5**	**6**	**100%**
Total Annual Cost per Company				
Below €1,000	0	0	0	0%
€1,000 - €49,999	2	1	0	30%
€50,000 - €249,999	0	1	2	30%
€250,000 - €499,999	0	1	1	20%
€500,000 - €749,999	0	0	0	0%
€750,000 - €999,999	0	1	0	10%
Over €1 million	0	0	1	10%
Total	**2**	**4**	**4**	**100%**

One cosmetics ingredient manufacturer indicated that the total annual cost to the company of adapting the composition of products when ingredients are added to the prohibited or restricted lists was over €1 million, while a medium company indicated a cost range of €750,000 to €999,999.

Box 3.3 below provides some specific examples of costs incurred by companies associated with controls on ingredients.

Box 3.3: Specific Examples of Other Costs Incurred by Companies Associated with Controls on Ingredients Under the Cosmetics Directive

Company A lost annual sales of around €1 million for a skin whitening cream which contained hydroquinone. This product had to be withdrawn after the listing of hydroquinone in the Directive.

Company B experienced some indirect impacts from the inclusion of phthalates DEHP and DBP in Annex II as part of the CMR ban under the 7th Amendment. Although not directly include in cosmetics formulations, these two substances are present in sealing gaskets used in aerosol valves. In the presence of alcoholic formulations, the phthalates tend to leach out from the gaskets into the final product. Considerable difficulty was experienced in obtaining suitable alternative valve gaskets that were phthalate-free, due to the need to ensure that safety was not compromised by product leakage as a result of ill-fitting valve seals.

Company C incurred costs in the development of a tooth whitening product containing hydrogen peroxide - the Cosmetics Directive currently limits the concentration permitted in oral care products. The costs incurred included the preparation of a human safety dossier (as part of an industry consortium) and clinical trials to support a request to amend the hydrogen peroxide entry in Annex III. In order to continue selling the product until the Directive is amended, the company has been obliged to register this product as a medical device in Europe which has also incurred costs. External costs associated with use of consultants, undertaking clinical studies, medical device certification and representation activities as part of the industry consortium are around €440,000. Internal costs which include the preparation of several human safety dossiers and subsequent reviews by expert toxicologists, preparation and submission of medical device registration documents are around €275,000.

Company D incurred costs of around €500,000 as a result of the safety data required by the SCCP to add a UV-filter to the positive list. As there is no globally harmonised method for UV-filter testing, further costs of around €500,000 were incurred in Australia and €10 million in the US.

In the EU, further costs associated with the SCCP were incurred, resulting from:

- delays in approval (e.g. for zinc oxide). The dossier was submitted in September 2005 and to date, no decision has been reached by the SCCP and consequently the substance has not been included in the positive list. This results in lost opportunities for business;
- lack of clarity regarding the approval granted for Diethylamino Hydroxybenzoyl Hexyl Benzoate which was given for "maximum 10% in sunscreen products", whereas for other UV-filters in the positive list there is no such restriction regarding the application. This resulted in questions from cosmetics companies whether this UV-filter could not be used in non-sunscreen products such as daily care products or for product protection. Upon addressing this issue, the applicant was informed that this was a misunderstanding; and
- change of SCCP Notes of Guidance. As a result of the above situation, the applicant submitted the dossier a second time to SCCP, this time for other skin care applications (other than sunscreens). By this time, the SCCP Notes of Guidance had changed and additional testing became necessary. This had severe consequences with financial impact, even though these are difficult to assess, for instance:
    - a delay for approval of skin care products (other than sunscreens);
    - a damaged reputation in the market; and
    - Diethylamino Hydroxybenzoyl Hexyl Benzoate being in a disadvantaged position compared with other UV-filters.

This company is of the opinion that cost savings could be achieved if the manufacturer of a cosmetics ingredient (positive list) has the opportunity to discuss options for safety testing with the SCCP beforehand in order to optimise and reduce the number of tests/animals. The TGA in Australia uses this approach.

Company E: A skin cleansing product developed and manufactured in the USA, to be introduced onto the European market, was found to contain a dye whose purity did not meet the strict criteria laid down in

Box 3.3: Specific Examples of Other Costs Incurred by Companies Associated with Controls on Ingredients Under the Cosmetics Directive

Annex IV. Although satisfactory for the USA market, the level of trace contamination indicated by the supplier was not deemed to meet the Cosmetics Directive Article 4.2 'unavoidable trace contamination' requirements. As a consequence, the product was not launched in Europe. Similar difficulties were also encountered with tooth whiteners.

Company F: One cosmetics ingredient manufacturer indicated that it had been forced to withdraw a deodorant product from the market as a result of the restrictions on 4-methylbenzylidene camphor.

Box 3.4: Case Study 3: Example of where Changes to the Ingredients Under the Existing Cosmetics Directive Resulted in Costs to Industry

Company Y is a large manufacturer of consumer products with a turnover of around €500 million relating to cosmetics products only. It has manufacturing sites in four EU countries as well as the Far East and North America and specialises mainly in toiletries and skin care products, to a far lesser extent.

Regulatory Requirement: Companies are required to comply with positive, prohibited and restricted lists of substances under the Cosmetics Directive.

Direct Costs Incurred:

Option 1 (Product Withdrawal): Company Y decided to replace a UV-filter (included in skin care products) because its supplier had withdrawn it from the market rather than fund additional testing to support an SCCP dossier. 12 formulations were affected at a cost of between €5,000 and €10,000 per formulation, equivalent to between €60,000 and €120,000.

Option 2 (Product Reformulation): Company Y decided to replace a thickening ingredient in 70 formulations, 30% of which were produced by a contract manufacturer, which increased the reformulation costs. The cost of this was between €1,500 and €5,000 per formulation, equivalent to between €100,000 and €350,000.

Indirect Costs Incurred:

These include:
- loss of sales;
- manufacturing or costs associated with any processing changes (including component write-off costs);
- costs of handling the new ingredient and old ingredient write-off costs;
- new packaging and packaging write-off costs;
- generation of new label artwork to reflect the change in ingredient labelling; and
- product portfolio management activities (including man-hour costs of generating information) to ensure compliance within the Directive).

Key Factors Affecting Cost:

These include:
- timescales provided for implementing changes (see next Section);
- specific company product portfolios and commercial arrangements (e.g. consortia).

3.2.3 Impacts of the Timescale for Implementation of Regulatory Changes

Changes to the Cosmetics Directive must be implemented within specified time periods. Companies were asked whether they thought the timescale for implementation of changes was adequate. Five companies thought that the timescales were adequate while 10 companies disagreed. No specific costs directly linked to timescales were identified in response to this question. However, responses to other questions indicated that the timescale could have a significant impact on costs. For example, as noted in Section 3.2.1, the costs of re-labelling, in particular the extent to which waste packaging materials are generated will be influenced by the time period for change.

The following viewpoints were expressed by respondents:

- a period of 24 months is the minimum needed to manage company and market complexities. A longer timescale of two to three years should be permitted (except for provisions which are linked to critical consumer safety issues) with no limitations for selling to the consumer;

- a period of 24 months should be included after publication of the restriction in the OJ to the point of 'placing on the market' to avoid companies spending a disproportionate amount of resource reformulating products in anticipation of possible future ingredient restrictions within the Directive. In the event of a serious human safety concern this timescale can be reduced;

- where a company does not hold all the required data but needs further data from suppliers, then additional time to comply may be required (e.g. obtaining information from suppliers on potential substance traces);

- it would be helpful to standardise the various enforcement points in the Directive. With some changes to the Annexes, the deadline refers to 'placing on the market', (a term that still needs defining), whilst others talk of 'supply to the final consumer'; and

- where there is ambiguity and/or further clarification/guidance is required on interpretation, such as was the case for PAO, then sufficient additional time should be allowed for the development of clear guidance and the clock should start from the availability of that guidance. Box 3.5 provides further information on this point.

Box 3.5: Examples of the Impacts of Timing of the Availability of Guidance on the Costs of Re-labelling
Given sufficient time, industry normally phases the 'facelift' of its brands in rotation, so that they are not all done at once. Artwork is revised regularly over a two or three year cycle. As a result of the 7th Amendment, 20% - 30% of brands will have had artwork changes outside of this normal cycle – at significant cost. Those companies that waited for publication of the guidance on period after opening are worse off, in that they have a very much shorter time in which to make the changes but at least they will not have to label certain product excluded by the guidance. Conversely, those companies which decided to label period after opening early, to minimise costs, will find that the guidance does not require certain of these product to be labelled at all
Source: UK Department of Trade and Industry (2004)

One cosmetics ingredient manufacturer noted that the timescale for implementation of changes to the Cosmetics Directive was not sufficient, as alternatives to the animal testing ban will not be in place in time to launch new ingredients once the animal test ban is effective (the Directive assumes that by 2009/2013 adequate alternative test methods will be available). The respondent suggests that there are still not sufficient validated and recognized alternative test methods available and this situation is unlikely to change by the set deadlines. Hence, the deadlines set in the 7th amendment may have impacts on innovation.

3.3 Overall Costs and Benefits of Compliance with the Cosmetics Directive

3.3.1 Costs

In order to provide a robust assessment of the costs of compliance with the Cosmetics Directive, companies were asked to indicate the significance of a number of factors to the total cost of placing a cosmetics product on the market. Companies were also asked to indicate which aspects of these cost factors were most affected by the requirements of the Cosmetics Directive. The results are shown in Tables 3.8 and 3.9 below.

Table 3.8: Ranking of the Importance of Cost Factors for Placing a Cosmetics Product on the Market (in Descending Order of Importance)

Cost Factor	Size of Company			All
	Small	Medium	Large	
Product marketing	1	2	1	1
Research and development	3	1	3	2
Product manufacture	2	3	2	2
Product safety testing	3	4	4	4
Product labelling	2	4	5	4
1 indicates the most important cost factor				

It is interesting to note that small companies ranked product labelling as much more important in determining costs that medium or large companies; medium companies rank the costs of research and development more highly than small or large companies.

Table 3.9: Impact of the Cosmetics Directive on Specific Cost Factors

	% of Respondents				
Impact	**Research & development**	**Safety testing of product**	**Product labelling**	**Product manufacture**	**Product marketing**
Very High	47%	29%	18%	6%	6%
High	35%	47%	59%	19%	25%
Moderate	18%	24%	24%	63%	44%
Low	0%	0%	0%	13%	19%
Negligible	0%	0%	0%	0%	6%

Table 3.9 indicates that:

- *research and development, product labelling* and *safety testing of products* appear to be the most highly affected by the Cosmetics Directive, with over three-quarters of respondents indicating that the Directive has a very high or high impact on costs;
- *product manufacture* is impacted moderately, according to 63% of respondents; and
- there is least agreement on the impacts of the Directive on *product marketing*, with 25% of respondents (all small companies) indicating that the Directive has a high or very high impact on costs, but 25% (large companies) indicating that it has low or negligible impact.

Companies were asked to indicate the total annual cost to their company of complying with the current requirements of the Cosmetics Directive, as a percentage of their annual sales. As shown in Table 3.10 below, nearly 70% of respondents indicated that the existing Cosmetics Directive resulted in costs of between 0.1% and 1% of their annual sales (with nearly 50% indicating costs of 0.5% to 1%). Two large companies indicated that the cost was over 1% of their annual turnover while three companies (two large and one small) indicated that it was below 0.1%.

Table 3.10: Indicative Total Costs Per Company of Complying with Requirements of the Cosmetics Directive as a Percentage of Annual Sales

As a % of Total Annual Sales	No. of Respondents			Percentage of Respondents
	Small	Medium	Large	
Below 0.05%	0	0	0	0%
Between 0.05% and 0.1%	0	1	2	19%
Between 0.1% and 0.5%	2	1	1	25%
Between 0.5% and 1%	2	3	1	44%
Over 1% (please specify)	0	0	2	12%
Total	**4**	**5**	**7**	**100%**

Companies were asked to indicate the number of man-hours required each year to ensure compliance with the Cosmetics Directive. Table 3.11 provides a breakdown of the responses by company size.

Table 3.11: Man-hours and Cost per Hour of Complying with the Cosmetics Directive

Company	Range of man-hours	Average no. of man-hours	Range of cost per hour	Average cost per hour	Average total cost[1]
Small	100 - 500	300	€7 - €30	€19	€5,700
Medium	300 – 1,600	900	€5 - €30	€17	€15,300
Large	14,000 – 63,000	39,900	€20 - €200	€100	€3,990,000
All	**100 – 63,000**	**20,300**	**€5 - €200**	**€60**	**€1,218,000**

[1] Calculated by multiplying average number of man-hours by average cost per hour across respondents

The number of hours indicated by respondents ranged from 300 to 63,000 per company per year, at an average cost per hour ranging from €5 per hour to €200 per hour. Overall, the average across all respondents was around **20,300 hours (or nearly 2,700 man-days) per company per year**; this is equivalent to more than ten people working full time on ensuring compliance with the Directive, with the average cost of around **€60 per hour**. The company which indicated the highest figure of 63,000 man-hours manufactures and sells mainly toiletries (90% of annual sales).

The respondent whose response was closest to the average (i.e. 14,000 man-hours/year and €60/hour) indicated that its costs were based on the company having technical managers in 18 countries, covering the cosmetics regulatory and technical activities in all 27 Member States. The respondent noted that the number of hours per year varies between Member States, from 37 to 1,700 hours, with an average of 450 hours/country technical manager.

The data from the large companies significantly skews the overall figures. Small and medium-sized companies spend much less time; on average, 300 and 900 man-hours respectively (equivalent to less than one man-day per week for a small company and three man-days per week for a medium-sized company) on ensuring compliance with the Cosmetics Directive.

3.3.2 Benefits

Respondents were asked to rank the benefits of the Cosmetics Directive for their company. Table 3.12 provides a summary of the responses.

Table 3.12: Ranking of Benefits Resulting from the Cosmetics Directive

Types of Potential Benefits	Rating on Scale of 1 – 8 (where 1 is most significant)			% (or No.) of Respondents that ranked the benefit
	Maximum Rating	Minimum Rating	Average Rating	
Increased access to global markets	1	5	2.4	64% (7)
Increased customer trust	1	7	2.4	73% (8)
Increased access to markets in EU Member States	1	6	2.7	82% (9)
Safer products and reduction in incidents involving cosmetics	1	8	3.1	64% (7)
Increased customer satisfaction	1	7	3.3	73% (8)
Reduced competition from non-EU manufacturers	1	8	4.2	82% (9)
Increased competitiveness of the EU cosmetics industry	1	8	4.3	55% (6)
Increased sales and product exports	1	9	4.5	55% (6)
Other (please specify)	1	4	1.7	55% (6)

There was considerable variation in the ranking given to the different types of benefits. However, both SMEs and large companies agreed that the three key benefits from the Cosmetics Directives are:

- increased access to global markets;
- increased customer trust (although one SME disagreed); and
- increased access to markets in EU Member States (although one large company disagreed).

Additional benefits mentioned by companies which indicated 'other' include:

- a harmonised Directive across the EU;
- less complexity in dealings with the new EU Member States;

- enhancing a common understanding across industry and a standard set of ingredients; and
- the removal of misunderstandings between the original CE Directive and national transpositions.

Most companies preferred to provide a qualitative rather than quantitative indication of the annual value of these benefits (in the form of additional revenue or reduced costs), as shown in Table 3.13 below. As a guide, the companies which indicated 'low' benefits also indicated that the potential annual value of these benefits were between €10,000 and €100,000 per year. Similarly, two of the companies which indicated 'medium' benefits quantified these at between €100,000 and €250,000 per year, while another quantified these 'medium' benefits at between €500,000 and €750,000 (the difference may reflect the size of operations of the companies).

Table 3.13: Annual Benefits to Cosmetics Companies Resulting from the Cosmetics Directive

	Size of Company		Total No. of Respondents	Percentage of Respondents
	SMEs	Large		
Annual Value to the Company				
< €10000	1	1	2	25%
€10000 - €99999	2	1	3	38%
€100000 - €249999	2	0	2	25%
€250000 - €499999	0	0	0	0%
€250000 - €499999	0	0	0	0%
€500000 - €749999	0	1	1	13%
€750000 - €999999	0	0	0	0%
€1 million and above	0	0	0	0%
Total	**5**	**3**	**8**	**100%**
Indicative Value				
Very High	0	0	0	0%
High	0	1	1	8%
Medium	2	2	4	31%
Low	2	1	3	23%
Negligible	4	1	5	38%
Total	**8**	**5**	**13**	**100%**

Over 60% of respondents indicated that the annual benefits of the Directive to the company were either low or negligible. This is not in line with the types of benefits identified in Table 3.12, nor the comments made by industry in the previous comparative study on cosmetics regulation. It perhaps reflects the length of time the Directive has been in place and the consequent difficulty in comparing with the situation before it was introduced.

3.4 The Efficacy of Regulation for Health and Safety

None of the respondents raised concerns about the ability or suitability of the present regulatory framework to address both current safety risks and those related to new,

innovative products in the future. However, they provided suggestions for changes to the Cosmetics Directive which may improve its efficacy and reduce costs. These included:

- clearer definitions and guidelines would reduce uncertainty and potentially reduce costs. This includes guidance on access to product information and definition of placement of product on the market. These guidelines should also be drawn in partnership with industry;

- ensure appropriate standards and harmonisation of product safety assessments, for example through the Intelligent Testing Strategy (an integrated approach, recommended by one company, comprising of various evaluation methods including human exposure data, data from other sources, and toxicological risk assessments), which should be issued and training provided where appropriate;

- missing data should not automatically be interpreted as a lack of safety information. Safety assessments should take into account historic data and data from other sources. There should not be a requirement for increased technical documentation as this would increase costs and restrain innovation;

- national authorities should concentrate on ensuring compliance with the Cosmetics Directive as regards product safety, recognising the validity of different types of information on the products such as confirmatory safety studies, experience from safe-use histories; and

- cross referencing of chemical names in annexes to the Directive to INCI names, as this would help facilitate tracking of ingredient restrictions.

Other concerns centred on the international harmonisation of labelling, product development and standards, with specific comments by respondents relating to:

- the lack of global harmonisation on standards for ingredients, in particular colours approved for use in cosmetics;

- duplication of effort in product development between EU and US for 'global' formulations, which increases development costs by 25%;

- labelling provisions on a global scale - product names that are understood internationally or by which the function of the product is obvious from the presentation of the product (e.g. Eau de Toilette); and

- the REACH Regulation, which is seen as a threat to EU cosmetics industries as it will reduce the ingredients available for cosmetics formulations, and thus increase the cost for research and reformulation.

3.5 The Effects of Regulation on Technological Change and Innovation

Companies were asked whether the requirements of the Cosmetics Directive prevented them from introducing any technological changes or innovations to their products (for example whether the regulation imposes a barrier to the introduction of new 'active' substances). Less than half of the respondents thought that the Directive had hindered innovation, while the remaining respondents did not think so. However, there was a difference between the responses of companies of different sizes, with three out of five large companies indicating that the Directive had hindered innovation but only three out of nine SMEs thinking this was the case.

Table 3.14 shows the responses of companies in attempting to quantify the impacts of the Cosmetics Directive on innovation. The companies which indicted lost sales of less than €100,000 were SMEs and they quantified these impacts as 'medium'. Box 3.6 provides a specific example from one respondent.

Table 3.14: Estimated Loss of Sales as a Result of Technological Changes or Innovations Being Prevented

Annual costs/lost sales to Company	**No. of Respondents**			**Percentage of Respondents**
	Small	**Medium**	**Large**	
> €1 million	0	0	2	33%
€500,000 - €999,999	0	0	1	17%
€250,000 - €499,999	0	0	0	-
€100,000 - €249,999	0	1	0	17%
€10,000 - €99,999	0	2	0	33%
< €10,000	0	0	0	
Total	**0**	**3**	**3**	**100%**
Indicative costs	**No. of Respondents**			**Percentage of Respondents**
	Small	**Medium**	**Large**	
Very High	0	0	0	-
High	0	0	1	20%
Medium	0	3	0	60%
Low	0	0	0	-
Negligible	0	0	1	20%
Total	**0**	**3**	**2**	**100%**

Box 3.6: The Cosmetics Directive and Innovation

Company G: The Cosmetics Directive currently restricts the maximum concentration of hydrogen peroxide in oral care products to 0.01%. Industry has made a number of submissions to SCCP concerning the safety of products containing up to 6% hydrogen peroxide with a view to a future amendment to the Directive to allow the sale of these products on the EU market as cosmetics. However taking into account the ambiguity in the SCCP opinions, the commission has not been able to progress amendments to legislation.

Development costs (lost): €6 million

Lost sales: €70 million over 3 years

4. POTENTIAL IMPACTS OF SUGGESTED CHANGES TO THE COSMETICS DIRECTIVE

4.1 Introduction

In addition to providing a baseline of the economic impacts of the current Directive on the everyday business operations of cosmetics companies, this study is intended to assess the impacts of a limited number of (the most important) potential changes to the Directive set out in the public Commission Consultation Document (CCD). These changes are:

- changing the Directive to a regulation (consultation item 3);
- specifying data required in the product information files (consultation item 9);
- introducing harmonised notification requirements (consultation item 12); and
- introducing a standardised system for cosmetovigilance (consultation item 11).

These changes are discussed further below.

4.2 Changing the Directive to a Regulation

As stated in the CCD, the Cosmetics Directive and the annexes to it are highly detailed and leave little room for variation in transposition by Member States. However, unnecessary costs may be incurred by businesses through the need to adapt product formulation and packaging to divergent rules if an amending Directive has not (yet) been properly transposed in one or more Member States. Converting the Cosmetics Directive into a regulation would mean that EU-wide rules would apply directly without the current need for transposition into the national laws of 27 Member States. This should result in one identical legislative framework as a sole reference for economic operators in the EU. Companies were asked what the potential implications of this change would be.

Seven out of the 14 cosmetics companies which responded indicated that costs would be reduced, while the other seven companies disagreed (five of the eight large companies thought costs would be reduced, whilst only two of the six SMEs agreed). Three out of the four responding manufacturers of cosmetics ingredients also indicated that there would be reduced costs. Table 4.1 shows respondents' estimates of the man-hours and costs savings likely to be incurred as a result of such a change.

Table 4.1: Range of Man-hours and Cost Savings from Converting Directive to Regulation

Company	Range of man-hours	Average no. of man-hours	Range of cost per hour	Average cost per hour	Average total cost saving[1]
SMEs	0-50	25	€17	€17	€425
Large	6 - 20,000	7,235	€10 - €135	€98	€710,000
All	**0 – 20,000**	**5,440**	**€17 - €135**	**€78**	**€424,250**

[1] Calculated by multiplying average number of man-hours by average cost per hour across respondents

The number of man-hours that may be saved as a result of this change, as indicated by cosmetics companies, ranged from 6 to 20,000 man-hours per year, with the cost saving per hour ranging from €17 to €135 per hour. The overall average cost saving across all respondents was around **5,440 man-hours (725 man-days) per year** at an average cost saving of around **€80 per hour**. This is roughly equivalent to three to four employees working full-time for one year[7].

Respondents also noted that changing the legislative framework from a Directive to a regulation would:

- ensure uniformity in implementation and interpretation of requirements not only between Member States, but also between cosmetics manufacturers. In theory, such a change should eliminate mistakes in translations, reduce divergences in implementation and allow for a consistent interpretation in relation to content and timings of the Directive;

- imply that there is no longer a need to track the implementation of changes to the Directive and potential divergences in Member States by Technical Managers (whose role involves holding discussions with national trade associations and Competent Authorities to review and ensure a harmonised approach to transposition); and

- from a new product launch perspective, it should enable products to be simultaneously launched Europe-wide rather than the need to stagger launches to ensure regulatory compliance in specific Member States.

4.3 Specifying the Data Required in the Product Information File

4.3.1 Introduction

The existing Cosmetics Directive does not require information on the safety of cosmetics products to be submitted to Member State competent authorities before a product is placed on the market. However, manufacturers/importers must retain information, accessible to Member State competent authorities on request at all times, which proves the safety of their products. Under the existing Directive, the product information file (PIF) should contain information on:

- the qualitative and quantitative composition of the product;
- physicochemical or microbial specifications of ingredients and finished product;
- manufacturing method;
- safety assessment by qualified person;
- existing data on any undesirable effects; and
- proof for certain claims made.

[7] As noted in Section 3.3.1, more than ten full-time employees per company are currently required on average to ensure compliance with the Cosmetics Directive.

The Commission (as set out in the CCD) considers that stronger technical documentation may be needed to allow improved checks on products on the market. The Cosmetics Directive could, therefore, specify more clearly the information (including safety data) to be made available in the PIF. In order to identify the potential impacts of this change, companies were asked to identify the current costs of producing a PIF and, following that, the potential impacts of specifying the data requirements further.

4.3.2 Costs of Producing a Product Information File

Table 4.2 shows respondents' estimates of the man-hours and costs required to produce PIFs, or the safety aspects of PIFs.

Table 4.2: Man-hours and Cost per Hour of Producing PIFs, or the Safety Aspects Only of PIFs

Company	Range of man-hours	Average no. of man-hours	Cost per hour	Average cost per hour	Average total cost[1]
Cost of Producing PIFs					
Small	200 - 250	225	€7 - €30	€20	€4,500
Medium	300 - 500	400	€5 - €30	€17	€6,800
Large	150 - 20,000	7,000	€20 - €160	€100	€700,000
All	150 - 20,000	4,000	€5 - €160	€64	€256,000
Cost of Producing the Safety Aspects Only of PIFs					
Small	50	50	€10 - €50	€30	€1,500
Medium	250 - 300	275	€17 - €30	€24	€6,600
Large	75 - 10,000	3,875	€20 - €160	€100	€387,500
All	50 - 10,000	2,500	€10 - €160	€75	€187,500

[1] Calculated by multiplying average number of man-hours by average cost per hour across respondents

Cosmetics companies estimate that the number of man-hours currently required to prepare PIFs range from 150 to 20,000 man-hours per year, at an average cost of between €5 and €160 per hour. The safety aspects included in the PIF were indicated to account for between 75 and 10,000 man-hours per year, at an average cost of between €10 and €160 per hour. Overall, the average number of hours required to prepare PIFs was indicated to be around **4,000 man-hours (530 man-days) per company per year**, with the safety aspects accounting for around **2,500 man-hours (or 330 man-days) per company per year, 62% of the total man hours**. The average cost per hour of producing PIFs was **€64 per hour,** or **€75 per hour** for the safety aspects only. These averages exceed the maximum number of man-hours indicated by any of the SMEs, of 500 man-hours and €30 per hour.

One reason for the difference in the costs of producing PIFs between small and large companies is the number of different products placed on the market, which is likely to be higher for large companies (similar to the number of formulations) compared with SMEs.

Companies were also asked to indicate the average one-off cost per formulation incurred to produce a PIF, or the safety aspects only of a PIF. Table 4.3 summarises the responses.

Table 4.3: Average One-off Cost per Formulation of Preparing a PIF, or the Safety Aspects Only of a PIF				
Range of Costs	**Number of Respondents**			**Percentage of Respondents**
	Small	**Medium**	**Large**	
Average One-off Cost per Formulation of Preparing a PIF				
Below €500	1	0	0	7%
€500 - €1,499	1	1	2	27%
€1,500 - €4,999	1	1	3	33%
€5,000 - €9,999	0	1	1	13%
€10,000 - €24,999	0	1	1	13%
€25,000 - €99,999	0	0	0	0%
Over €100,000 (please specify)	0	0	1	7%
Total	**3**	**4**	**8**	**100%**
Average One-off Cost per Formulation of Preparing the Safety Aspects Only of a PIF				
Below €500	2	0	0	13%
€500 - €1,499	0	2	0	13%
€1,500 - €4,999	1	1	4	40%
€5,000 - €9,999	0	0	2	13%
€10,000 - €24,999	0	1	1	13%
€25,000 - €99,999	0	0	1	7%
Over €100,000 (please specify)	0	0	0	**0%**
Total	**3**	**4**	**8**	**~100%**

For most companies, the average one-off cost incurred for preparing a PIF was **below €4,999 per formulation**. SMEs, in general, indicated lower costs per formulation/PIF compared with large companies; no reason was indicated for this difference. The costs of preparing only the safety aspects were in the same range as the costs of preparing a PIF (suggesting that this is the most significant cost factor in preparing a PIF). This contrasts with the costs obtained by dividing the average total man-hour cost (from Table 4.2) by the average number of product formulations (from Table 2.4). These are shown in Table 4.4 below and average €391 per formulation. The difference may be due to the inclusion of non-manpower costs in Table 4.3, but this is not clear from the responses.

Table 4.4: Calculated Average Cost Per Formulation of Preparing a PIF, or the Safety Aspects Only of a PIF						
	Preparing a PIF			**Preparing the Safety Aspects Only**		
Size of enterprise	**Average total cost[1]**	**Average number of formulations**	**Calculated average cost per formulation[2]**	**Average total cost[1]**	**Average number of Formulations**	**Calculated average cost per formulation[2]**
Small	€4,500	80	€56	€1,500	160	€9
Medium	€6,800	70	€97	€6,600	59	€112
Large	€700,000	917	€763	€387,500	810	€478
All	**€256,000**	**610**	**€420**	**€187,500**	**480**	**€391**

[1] Calculated by multiplying average number of man-hours by average cost per hour across respondents
[2] Calculated by dividing the average total cost by the average number of formulations

Companies were also asked to indicate the total annual cost to the company to produce PIFs, or the safety aspects only of PIFs. Table 4.5 summarises the responses

Table 4.5: Total Annual Cost per Company of Preparing PIFs, or the Safety Aspects Only of PIFs				
Range of Costs	**Number of Respondents**			**Percentage of Respondents**
	Small	**Medium**	**Large**	
Average One-off Cost per Formulation of Preparing PIFs				
Below €1,000	0	0	0	0%
€1,000 - €49,999	2	1	1	36%
€50,000 - €249,999	0	1	1	18%
€250,000 - €499,999	0	2	0	18%
€500,000 - €749,999	0	0	1	9%
€750,000 - €999,999	0	0	0	0%
Over €1 million	0	0	2	18%
Total	**2**	**4**	**5**	**~100%**
Total Annual Cost per Company of Preparing the Safety Aspects Only of PIFs				
Below €1,000	0	0	0	0
€1,000 - €49,999	2	0	0	18%
€50,000 - €249,999	0	3	1	36%
€250,000 - €499,999	0	1	1	18
€500,000 - €749,999	0	0	0	0
€750,000 - €999,999	0	0	0	0
Over €1 million	0	0	3	27%
Total	**2**	**4**	**5**	**~100%**

There was a large variation in the total annual cost indicated per company for preparing PIFs, ranging from less than €50,000 (indicated by four companies) to over €1 million (indicated by two companies), possibly due to differences in the number of formulations. Interestingly though, the maximum total annual cost indicated by small and medium companies were €50,000 and €500,000 respectively, compared to large companies with costs of over €1 million per company. This is again significantly higher than the man-hour costs indicated in Table 4.3, implying that factors other than staff time account for the majority of costs. It was not possible to obtain further information from cosmetics companies to explore these factors in detail.

One manufacturer of cosmetics ingredients indicated that the number of man-hours required per year was 200, at an average cost of €150 per hour. The estimated total cost annual cost to the company was between €500,000 and €750,000.

4.3.3 Costs of Suggested Change to the Directive

Companies were asked to indicate whether they expected an increase or decrease in costs from specifying the data required in product information files (according to the SCCP guidelines for safety evaluation of finished cosmetics products[8]).

Most companies preferred to provide a qualitative indication of the potential costs of this change, as shown in Table 4.6, rather than quantitative data. As a guide, however, the companies which indicated a 'very high' cost also indicated that the potential annual

[8] http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_03j.pdf; chapter 6, page 84.

value of these costs was over €1million, while two of the companies which indicated a 'medium' cost gave a cost range of between €10,000 and €100,000 per company.

Table 4.6: Potential Cost of Specifying the Information in the PIF				
Indicative Value	**Number of Respondents**			**Number of Respondents**
	Small	**Medium**	**Large**	
Very high	0	1	2	27%
High	1	0	2	27%
Medium	0	4	1	45%
Low	0	0	0	0%
Negligible	0	0	0	0%
Total	**1**	**5**	**5**	**~100%**

Key points raised by most respondents are that:

- the SCCP Guidelines relate to safety evaluation of ingredients and not of finished cosmetics products;

- there also appears to be some misunderstanding between some regulatory authorities on the difference between the two safety assessments, i.e. the safety risk assessment for placing a finished product on the market, conducted by the manufacturer, and the full scientific review of the human safety of an individual ingredient by the SCCP, which involves data from both raw material suppliers and end users in the cosmetics industry;

- the SCCP Guideline requirements for data for ingredient dossiers far exceeds the data available to individual cosmetics companies and it is not entirely feasible for companies to have access to safety data for each ingredient. Much of this data is confidential and lodged with the suppliers, who provide summaries of relevant data for company toxicologists to utilise as part of their finished product assessments. If full data were required, this would restrict sourcing flexibility, increase costs and restrict import of ingredients;

- current practice for undertaking a safety evaluation of finished cosmetics products takes account of sources of information (including historic data, actual use data, etc) not currently recognised by the SCCP Guidelines. Safety evaluators also determine on a case-by-case basis, taking into account their own experience, which data are most important for proving the safety of a given cosmetics product. If more specific information is required, this could result in unnecessary administrative data and costs, at the risk of missing out important information; and

- while such detailed safety assessment (e.g. confirmatory skin testing in groups of volunteers) may provide health benefits for consumers, it will increase costs for a company before the product is marketed and it will give rise to significant time delay.

4.4 Costs of Complying with the Notification Requirements

4.4.1 Introduction

There is currently no requirement under the EU Cosmetics Directive for the registration of cosmetics manufacturers or importers, or for pre-market approval for cosmetics products imported into or manufactured within the EU. Article 7 of the Directive requires a simple notification to the relevant Member State authority of the place of manufacture or of initial importation into the EU of cosmetics products. This notification requirement is meant to facilitate efficient checks on products on the market and could be a useful tool to combat import of counterfeit goods. It is considered, however, that the notification procedures are unclear (particularly relating to what information has to be notified and which Member State(s) need(s) to be notified) and clarification of the rules in a revision of the cosmetics Directive could help to improve market surveillance.

4.4.2 Costs of Notification under the Existing Directive

Table 4.7 shows respondents' estimates of the man-hours and costs required to comply with the notification requirements.

Table 4.7: Man-hours and Cost per Hour of Complying with Notification Requirements

Company	Range of man-hours	Average no. of man-hours	Cost per hour	Average cost per hour	Average total cost[1]
Small	30 - 50	28	€5 - €50	€40	€1,120
Medium	300 - 3,200	1,750	€17 - €25	€21	€36,750
Large	100 - 1,700	1,042	€20 - €100	€70	€72,940
All	**30 - 3,200**	**968**	**€5 - €100**	**€47**	**€45,500**

[1] Calculated by multiplying average number of man-hours by average cost per hour across respondents

The number of man-hours currently required to comply with the notification requirements, as indicated by respondents, ranged from 30 to 3,200 man-hours per year, at an average cost of between €5 and €100 per hour. The average was around **1,050 man-hours (or 150 man-days) per company per year**, at an average cost of **€47 per hour**. The top-end figure of 3,200 man-hours per year was provided by an SME, manufacturing and selling mainly hair care products (95% of annual sales). Companies were also asked to indicate the average one-off cost per formulation incurred to comply with the notification requirements. Table 4.8 summarises the responses.

Table 4.8: Average One-off Cost per Formulation of Complying with Notification Requirements

Range of Costs	Number of Respondents			Percentage of Respondents
	Small	Medium	Large	
Below €500	1	0	4	42%
€500 - €1,499	1	2	1	33%
€1,500 - €4,999	1	1	0	17%
€5,000 - €9,999	0	0	0	0%
€10,000 - €24,999	0	1	0	8%
€25,000 - €99,999	0	0	0	0%
Over €100,000	0	0	0	0%
Total	**3**	**4**	**5**	**100%**

The average one-off cost incurred by responding cosmetics companies to comply with the notification requirements was less than **€1,500 per formulation** for 75% of the respondents. This contrasts with the costs obtained by dividing the average total man-hour cost (from Table 4.7) by the average number of product formulations (from Table 2.4) as shown in Table 4.9 – resulting in an average of **€95 per formulation**. The difference may be due to the inclusion of non-manpower costs, but this is not clear from the responses.

Table 4.9: Calculated Average Cost Per Formulation of Complying with Notification Requirements

Company	Average total cost[1]	Average number of formulations	Calculated average cost per formulation[2]
Small	€1,120	160	€7
Medium	€36,750	59	€623
Large	€72,940	810	€90
All	**€45,500**	**480**	**€95**

[1] Calculated by multiplying average number of man-hours by average cost per hour

[2] Calculated by dividing the average total cost by the average number of formulations

Companies were also asked to indicate the total annual cost to the company of complying with the notification requirements. Responses are shown in Table 4.10.

Table 4.10: Total Annual Cost per Company of Complying with Notification Requirements

Range of Costs	Number of Respondents			Percentage of Respondents
	Small	Medium	Large	
Below €1,000	1	0	2	25%
€1,000 - €49,999	0	1	2	25%
€50,000 - €249,999	1	2	2	42%
€250,000 - €499,999	0	1	0	8%
€500,000 - €749,999	0	0	0	0%
€750,000 - €999,999	0	0	0	0%
Over €1 million	0	0	0	0%
Total	**2**	**4**	**6**	**100%**

The total annual cost per company to comply with the notification requirements ranged from less than €1,000 to €250,000. Respondents indicated total annual costs of less than €250,000 to comply with the notification requirements. This can be considered to be consistent with the man-hour costs indicated in Table 4.7, as the total costs for medium and large companies were between €36,000 and €72,000 and around €1,100 for the small company; thereby implying that staff time accounts for the majority of costs.

Companies were also asked whether they had incurred any costs associated with divergences in transposition or enforcement of the Cosmetics Directive by Member States. Although the question related to all aspects of transposition and enforcement, the responses mainly concerned the notification requirements. Five respondents indicated they had incurred such costs, while nine had not.

In explaining the costs they had incurred, the respondents noted that:

- different systems and processes for notification require multiple entry and therefore additional resources and, in some markets, payments of fees (e.g. Belgium);

- while some Member States follow the Cosmetics Directive and require notification of manufacturing sites only, with no associated fees, others require detailed product and ingredient information and levy a charge per product, which can vary from €5 to €36 per product variant. In Sweden, the total per product notification fee for 2007 is 45,300SEK (around €4,900). In Belgium, the estimated notification cost is around €1,000; and

- the different and more bureaucratic notification procedures in some Member States (e.g. Portugal, Hungary) result in additional costs, either directly in fees or indirectly in administration.

4.4.3 Costs of Proposed Clarification of Notification Requirements

Companies were asked to indicate whether they expected an increase or decrease in costs from a harmonised approach to the notification requirements being set out clearly in the Cosmetics Directive.

Six companies believed that there would be an increase in costs while four companies expected a decrease. Those respondents who believed there would be a decrease noted that, with clearly set out notification requirements, producers would save a lot of time and money from having to meet varying requirements across Member States. One respondent suggested that a single EU notification system without any specific product information should be sufficient to satisfy the requirements of the Directive. This could be achieved through a simple secure on-line process indicating the EU countries where the product is marketed and the address where product information can be assessed.

The current situation appears to be that some countries closely follow the requirements laid down in the Directive for notification of manufacturing site or site of first importation. Others have more detailed notification requirements. Indeed, in a few Member States, the product notification also includes payment of a notification fee per product. If notification were harmonised and restricted to the current requirements, costs would decrease. According to one company, the costs would certainly not increase even if the current notification requirements were extended, but harmonised and included the creation of an electronic tool to facilitate notification. However, if a fee was introduced for each product notification, then costs would increase significantly.

The explanations provided by those anticipating a cost increase actually indicates that they expect a decrease in costs. It is likely that they did not fully understand the question.
One company, however, noted that the actual impact would depend on the level of harmonisation. Notification of specific product information would significantly increase the costs, compared to notification of place of manufacture only.

4.5 Introducing a Standardised System for Cosmetovigilance

Having an efficient system of checking cosmetics products placed on the market for compliance with the Cosmetics Directive, as well as clear rules in cases of non-compliance, is important for ensuring the safety of consumers. As set out in the CCD, the Commission considers that this aspect of the cosmetics Directive may require strengthening, for instance, by providing clear rules on product withdrawal if a PIF does not contain sufficient information; actively encouraging cooperation between Member States competent authorities; and ensuring a flow of information between dermatologists/toxicologists, industry and the authorities on any observed adverse effects (cosmetovigilance).

While enforcing Community law is primarily the responsibility of the Member States, the Commission can play a useful role in supporting and coordinating their efforts. It is considered that the Cosmetics Directive could include a mandate for the Commission to assist in coordinating cooperation between the Member States in the field of 'cosmetovigilance'.

Companies were asked to indicate whether they felt that a harmonisation of enforcement and surveillance approach across the EU would reduce costs to businesses.

Only two respondents indicated that such a change would reduce costs. One respondent noted that the savings would be significant if a harmonisation of the approach to product withdrawal, cosmetovigilence and product notification (particularly if the latter included poison centres notification) could be achieved. The company noted that there would be potential for more significant savings if one European centralised electronic tool for these activities were to be developed, with companies then adopting a similar centralised resource approach for the various notifications.

Twelve respondents did not anticipate any cost savings, noting that:

- compliance with the COLIPA Guideline on Management of Adverse Events should be sufficient;
- if there was a requirement to hold a PIF in every Member State where the product is sold, there would be a significant increase in costs for industry; and
- national interpretation of data and documents has always been possible.

5. FINDINGS AND CONCLUSIONS

The aim of this study was to provide an in-depth analysis of the ways in which regulatory requirements affect the competitiveness of the cosmetics industry. By describing the actions required to achieve compliance with a particular aspect of regulation, the study provides a better picture of the relevance of regulation in terms of innovation, technological change, profitability and competitiveness.

Table 5.1 gives a summary comparison of the resource requirements (in man-hours and €/hour) associated with particular aspects of the existing Cosmetics Directive. **It should be noted that this table excludes the resource requirements associated with including ingredients on a positive list and adapting the composition of products when an ingredient is added to the prohibited or restricted list, as no data on resource requirements was provided for these aspects.**

Table 5.1: Summary Comparison of Resource Requirements per Company (in Man-hours and €/hour) Associated with Various Aspects of the Existing Cosmetics Directive

Size of Enterprise	Range of man-hours	Average no. of man-hours	Cost per hour	Average cost per Hour	Average Cost per company
Overall Cost of Compliance with the Cosmetics Directive					
• Small	100 - 500	300	€7 - €30	€19	€5,700
• Medium	300 - 1,600	900	€5 - €30	€17	€15.300
• Large	14,000 - 63,000	39,900	€20 - €200	€100	€3,990,000
• **ALL**	**100 - 63,000**	**20,300**	**€5 - €200**	**€60**	**€1,218,000**
Compliance with Changes to Information/Labelling Requirements					
• Small	200 - 500	350	€7 - €30	€20	€7,000
• Medium	2 - 1,200	600	€17 - €35	€26	€15,600
• Large	200 - 6,100	2,775	€20 - €135	€80	€222,000
• **ALL**	**2 - 6,100**	**1,625**	**€7 - €135**	**€50**	**€81,250**
Complying with the Notification Requirements					
• Small	30 - 50	28	€5 - €50	€40	€1,120
• Medium	300 - 3,200	1,750	€17 - €25	€21	€36,750
• Large	100 - 1,700	1,042	€20 - €100	€70	€72,940
• **ALL**	**30 - 3,200**	**968**	**€5 - €100**	**€47**	**€45,400**
Preparing Product Information Files					
• Small	200 - 250	225	€7 - €30	€20	€4,500
• Medium	300 - 500	400	€5 - €30	€17	€6,800
• Large	150 - 20,000	7,000	€20 - €160	€100	€700,000
• **ALL**	**150 - 20,000**	**4,000**	**€5 - €160**	**€64**	**€256,000**
Preparing the Safety Aspects only of Product Information Files					
• Small	50	50	€10 - €50	€30	€1,500
• Medium	250 - 300	275	€17 - €30	€24	€6,600
• Large	75 - 10,000	3,875	€20 - €160	€100	€387,500
• **ALL**	**50 - 10,000**	**2,500**	**€10 - €160**	**€75**	**€187,500**

Table 5.2 summarises information on the total costs to companies calculated on the basis of the cost ranges indicated by companies.

Table 5.2: Costs and Benefits per Company of the Cosmetics Directive, Based on Questionnaire Responses		
Annual Costs of Compliance with Various Aspects of the Existing Cosmetics Directive		
Size of Enterprise	**Minimum Total Annual Cost[1]**	**Maximum Total Annual Cost[2]**
Overall Cost of Compliance with the Cosmetics Directive		
• Small	€50,000[3]	€500,000[3]
• Medium	€250,000[3]	€2,500,000[3]
• Large	€1,000,000[3]	€10,000,000
Compliance with Changes to Information/Labelling Requirements		
• Small	€1,000	€49,999
• Medium	€50,000	€250,000
• Large	€50,000	>€1 million
Listing an ingredient in the Cosmetics Directive		
• Small	0	€1,000
• Medium	€1,000	€749,999
• Large	€1,000	>€1 million
Adapting the Composition of Products When an Ingredient is Added to the Prohibited or Restricted List		
• Small	€1,000	€99,999
• Medium	€10,000	€249,999
• Large	€99,999	>€1 million
Putting a Product on the Market with New or Modified Composition due to Changes in Ingredients		
• Small	€1,000	€49,999
• Medium	€49,999	€999,999
• Large	€50,000	>€1 million
Complying with the Notification Requirements		
• Small	€1,120	<€1,000
• Medium	€36,750	<€250,000
• Large	€72,940	>€250,000
Preparing Product Information Files		
• Small	€4,500	<€50,000
• Medium	€6,800	<€500,000
• Large	€700,000	>€1 million
Preparing the Safety Aspects only of Product Information Files		
• Small	€1,500	<€50,000
• Medium	€6,600	<€250,000
• Large	€387,500	>€1 million
Annual Benefits to Cosmetics Companies Resulting from the Cosmetics Directive		
Size of Enterprise	**Minimum Total Annual Benefit[4]**	**Maximum Total Annual Benefit[4]**
• Small	<€10,000	€249,999
• Medium	<€10,000	€749,999
• Large	<€10,000	€749,999

[1] Based on the lower end of the specified range in Tables 3.10, 3.4, 3.5, 3.6 and 3.7.
[2] Based on the upper end of the specified range
[3] Calculated by multiplying the 0.1% and 1% (from Table 3.10) by total annual sales of €50 million for a small company, €250 million for a medium company and €1 billion for a large company
[4] Based on the lower and upper ends of the specified range in Table 3.13

Because of the small number of responses on which Tables 5.1 and 5.2 are based, any estimate of the overall cost of the Cosmetics Directive will be subject to a great deal of uncertainty. Nevertheless, in order to provide an indicative estimate of the costs and benefits to the cosmetics industry as a whole, Table 5.3 presents lower and upper-bound estimates, based on the following assumptions regarding the number of small, medium and large companies, together with the costs derived from tables 5.1 and 5.2:

- there are between 2,000 and 3,500 small companies, the costs of the Cosmetics Directive are between €5,700 per year (based on Table 5.1) and €50,000 per year (based on Table 5.2);

- there are between 500 and 2,000 medium-sized companies and the costs of the Directive are between €15,300 (based on Table 5.1) and €2,500,000 per year (based on Table 5.2); and

- there are 25 large companies and the costs of the Directive are between €3,990,000 per year (based on Table 5.1) and €10 million per year (based on Table 5.2).

Table 5.3: Estimated Overall Annual Costs of the Cosmetics Directive

Company	Average Cost per Company	Number of Companies	Overall Cost
Lower Bound Estimate			
Small	€5,700	3,500	€19,950
Medium	€15,300	500	€7,650,000
Large	€3,990,000	25	€99,750,000
Total	**-**	**4,025**	**€127,350,000**
Upper Bound Estimate			
Small	€50,000	2,000	€100,000,000
Medium	€2,500,000	2,000	€5,000,000,000
Large	€10,000,000	25	€250,000,000
Total	**-**	**4,025**	**€5,350,000,000**

[1] Calculated by multiplying average number of man-hours by average cost per hour
[2] Calculated by dividing the average total cost by the average number of formulations

The Table indicates that the total cost of the Cosmetics Directive lies between €127 million and €5.4 billion per year. These costs are offset by the benefits of the Directive. Table 5.4 presents the overall benefits of the Directive, based on the following assumptions:

- there are between 2,000 and 3,500 small companies, the benefits of the Cosmetics Directive are between €10,000 per year and €249,999 per year (based on Table 5.2);

- there are between 500 and 2,000 medium-sized companies and the benefits of the Directive are between €10,000 (based on Table 5.1) and €749,999 per year (based on Table 5.2); and

- there are 25 large companies and the benefits of the Directive are between €10,000 (based on Table 5.1) and €749,999 per year (based on Table 5.2).

Table 5.4: Estimated Overall Annual benefits of the Cosmetics Directive			
Company	**Average Benefit per Company**	**Number of Companies**	**Overall Benefit**
Lower Bound Estimate			
Small	€10,000	3,500	€35,000,000
Medium	€10.000	500	€5,000,000
Large	€10,000	25	€250,000
Total	**-**	**4,025**	**€40,250,000**
Upper Bound Estimate			
Small	€249,999	2,000	€499,998,000
Medium	€749,999	2,000	€1,499,998,000
Large	€749,999	25	€18,749,975
Total	**-**	**4,025**	**€2,018,745,975**

[1] Calculated by multiplying average number of man-hours by average cost per hour

[2] Calculated by dividing the average total cost by the average number of formulations

The Table indicates that the benefits of the Directive to industry range from around €40 million per year to over €2 billion per year. Given the uncertainties around the estimates of both costs and benefits, this indicates in broad terms that the costs of the Directive to industry are balanced by the benefits.