Executive Summary

Conclusions

If the marketing ban comes into effect for the 2013 safety endpoints, it will have a major impact on the EU cosmetics industry, specifically on innovation and on knowledge that is of benefit to the consumer, but it will have little impact on global animal welfare. The absence of alternative methods to animal testing means that it would not be possible to develop new ingredients or new uses of existing ingredients specifically for the EU market; nor could the industry defend existing ingredients if the EU required new safety data that is not yet available from other sources.

Also the EU would lose its leadership on safety assessment regulatory standards.

The scale of the consequences will depend on how the ban is implemented. It may mean that businesses operating solely within the EU are put at a competitive disadvantage, as for them, unlike multi-nationals, it will be more difficult to have access to data developed specifically for non-EU markets for use in the EU. Under the strictest implementation, it may mean that no new ingredients at all can enter the EU market until alternative tests are available for all endpoints.

In view of these negative impacts on the EU industry, together with little or no impact on animal welfare, the most logical way forward would be to implement the 2013 endpoint bans depending on the availability of validated and ECVAM accepted alternatives. Well established processes such as the EU Commission's annual progress reports and platforms such as EPAA will ensure full transparency to all stakeholders. Such a scheme would ensure all efforts continue towards developing the necessary alternatives, thus promoting animal welfare globally.

Data on the Cosmetics Market and the Industry

The data in this report are based on replies to a detailed consultation of all Colipa members (individual companies and national associations). Twenty-four (24) large companies (accounting for a major part of EU cosmetics production) and one hundred (100) SMEs responded, from the main cosmetics-producing countries (France, Italy, Spain Germany and the UK) and other member states (such as Poland and Bulgaria).

The EU cosmetics industry was worth €66.6bn in 2010[1]. The estimated SME market share is 30%. The EU represents almost half of the global market (with the US and Japanese markets estimated at € 37.8 bn and € 29.4 bn respectively). A high proportion of products placed on the market by EU manufacturers are exported; exports in 2010 totalled €12.5bn with up to 62% of products placed on the export market.

Impacts on Animal Welfare/Environmental

[1] Data Source Euromonitor

The cosmetics industry is committed to providing safe products. To do this, it needs tools to ensure an ever higher standard of consumer safety. Animal testing is limited to ingredients (cosmetic products are not tested on animals) and is used only under the following circumstances:

- **To assess the safety of new ingredients and/or new uses of existing ingredients**, following demands from member states' competent authorities and the Scientific Committee on Consumer Safety (SCCS);
- **To 'defend' existing ingredients** following demands for additional safety information from member states and the SCCS. Full implementation of the 2013 ban would mean that demands are made for information to ensure product safety and regulatory compliance without permitting use of the tools to provide this information.

Impacts on number of animals affected

The Commission estimates that 12 million animals were used in 2008 for experimental and other scientific purposes in the EU[2]. Of these, 1,500 were used for testing of cosmetics ingredients[3] (0.0125% of the total). From 2009, no animal tests have been carried out in the EU in the context of the EU cosmetics legislation. Cosmetics manufacturers still carry out a small number of animal tests outside the EU to ensure the safety of products in line with SCCS guidance, or in response to requests for further information. But these take place only after trying first to use all existing data. Currently, cosmetic manufacturers are commissioning animal tests for 2013 endpoints: essentially, contact allergy (both non-SMEs and SMEs), sub-chronic and reproductive toxicity (non-SMEs only).

Cosmetics companies also commission animal testing outside the EU to meet the regulatory requirements of other markets. Before the 2009 ban, 90% of testing was performed outside the EU, with the welfare of animals conforming to European companies' internal standards (as there is no equivalent to the Directive 86/609).

The 2013 ban will have little impact on overall animal welfare globally (and no impact in the EU). Animal testing is likely to continue at the same level globally to meet non-EU cosmetics laws (in emerging markets such as China); it may even increase if the Safe Cosmetics Act in the US was enacted into law, through REACH and the emergence of the Global Harmonised System, transposed into EU law by the Classification, Labelling and Packaging (CLP) Regulation[4].

Incentive function for research into alternatives

The cosmetics industry has led investment into the development of alternatives for more than two decades – through significant financial input, its own research, and support of a growing academic network, including the industry's response to the EU's Framework Programmes for research and technological development. Through these efforts testing

[2] COM (2010) 511

[3] COM (2010) 480

[4] Regulation (EC) 1272/2008.

methods were developed which enabled the 2009 deadlines to be met. In addition, the benefits have been shared with other industry sectors, where these alternative methods are now also used for safety assessment.

Developing alternatives for the 2013 endpoints is an enormous scientific challenge, and requires the development of fundamental biological understanding, through basic academic research. For the 2013 endpoints, this knowledge is lacking, and so a full set of testing methods will not be available before 2013. If the marketing ban goes ahead, the EU may lose its leadership role on alternatives methods; research and development (R&D) facilities are likely to move to expanding markets (US, China, India), taking AAT research with them.

IMPACT ON CONSUMERS

Consumer safety

Nearly every person in Europe uses cosmetic products daily (skin care, sun protection products, toiletries including oral care products, hair care and colorants, fragrances and perfumes and decorative cosmetics). To ensure a high level of consumer safety, a thorough safety assessment of products and ingredients is required. Cosmetics companies are committed to this process and accept the burden of proof to show that products are safe and that their use will not lead to any reasonably foreseeable adverse effects.

The current 'state of the art' safety assessment toolbox is largely made up of animal tests recommended by regulatory authorities including the Scientific Committee for Consumer Safety's Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation. Without these tools, companies may stop using or introducing ingredients for which no satisfactory safety assessment can be performed – including ingredients that may improve human health and protection (sunscreens, preservatives) – or replace existing ingredients that can no longer be used for several reasons.

Consumer Choice Amount of new substances between 2000 and March 2009

A large cosmetics manufacturer has an ingredients/raw materials portfolio of around 2,000 (600 for an SME). Across the industry, new ingredients are introduced at an annual rate of around 4% of the total portfolio, with a proportion of these thought to be 'new to all uses'. For most companies, less than 10% of the new ingredients introduced are covered by the Cosmetics Regulation Annexes. Most new ingredients are used in a few formulations at first and their use expanded to other formulations over time.

For most companies (both large and small), new ingredients have a significant effect on profitability. New raw materials are introduced for many reasons, e.g. to improve performance in response to consumer demands, or for improved caring and health protection. These new ingredients might, for example, have anti-ageing properties; be more natural; be biological/organic; be needed for new categories (e.g. sprays); offer better skin tolerance; have a better ecological profile; as well as being needed to replace ingredients removed for regulatory or safety reasons.

Overall, the number of ingredients/raw materials in companies' portfolios is far below what is seen in the Inventory, CosIng and the INCI lists. Manufacturers select only the safest, best performing, most environmentally-friendly and cost-effective ingredients. Few new ingredients are introduced, and several old ones are abandoned.

On average, large companies removed 120 ingredients from their portfolios in 2010; SMEs removed 10. Over the past decade, the annual average figures were 24 and 6 respectively. The main reason for removal was regulatory constraints. Most companies expect the number of new ingredients available within the EU to reduce over the next five years, with significant implications for innovation, and so growth and profitability.

Ultimately, companies may not be able to formulate some products, resulting in a loss of products and diminished consumer choice.

Impacts on Innovation Capability and Future Availability of Cosmetic Products

Cosmetics companies' portfolios range from more than 20,000 products for large companies to 160 for SMEs. Many products are formulated and re-formulated annually (90% for some companies, with an average of more than 25% for most large companies and more than 50% for most SMEs). For most companies, around 10% of (re)formulations involve new ingredients; this figure is much higher for some companies. The loss of ingredients without full replacement could affect tens, hundreds or even thousands of products depending on how often the ingredient is used.

Colipa (since 2004) has submitted seven dossiers for new UV filters and preservatives and defended 58 ingredients which were assessed by the SCCS; this corresponds to 20 dossiers for which "2013 tests" had to be generated: skin allergy, reprotoxicity, sub-chronic studies, toxicokinetics and carcinogenicity.

In the context of the Commission decision to review the safety hair dyes used in the EU, 45 commonly used hair dyes which represented around 95% of what is used in the EU had to be reassessed with "2013 tests". These data benefit the whole sector, including SMEs. If this request had been made after 2013, the need for data from animal tests would have meant that almost no hair colorants would be left on the EU market.

Labelling

Companies can label products with an 'animal testing-free' label if they follow the Commission's Guidelines. In practice, most companies do not use this label, as most ingredients used have been, at some point, tested on animals.

A 'tested on animals' label to indicate that they contain ingredients tested on animals is likely to raise several legal and practical obstacles. In particular, it could be discriminatory and misleading as consumers may conclude that only cosmetics (and not other consumer goods) are tested on animals.

Impacts on Competitiveness

It is difficult to judge the impact of the current provisions as ingredients introduced over the past five years will have been developed and tested prior to introduction of the testing

ban. Had the ban already been in place for all endpoints for the past five years, respondents envisage that:

- there would have been no development in the EU of products containing ingredients for which the SCCS has requested animal test information, or for ingredients where the full data required for the Product Information File was not available from other sources;
- 50 to 100 ingredients per year would have been lost in addition to those already withdrawn;
- fewer new products would have been introduced in the EU, with impacts on sales and profitability and the viability of cosmetic manufacturer and ingredient supplier SMEs.

Depending on the implementation of the 2013 ban, companies expect that the EU cosmetics industry will face significant losses in turnover and profitability (3-20% in the short term; 7-20% in the medium term; 1-25% in the long term) and damage to its global market position and reputation. The EU would lose its leading role in innovation, with a lack of new products and a reduced quality and variety of products on the global market. The EU cosmetics market would become increasingly commoditised, with "offshoring" of manufacturing and a loss of member state revenue (VAT, as well taxes on industry profits, currently estimated at €10bn per year). The EU would lose its leadership on safety assessment regulatory standards; for example, there may be no further updates to the Cosmetics Regulation Annexes.

Investment by multinationals would switch outside the EU, and American, Japanese and Chinese manufacturers would be favoured in non-EU markets because they can ensure the safety of their ingredients and products more effectively.

Impacts on SMEs

SMEs have a market share of around 30% (€20bn). In some member states, 98% of cosmetic companies are SMEs, and they generate a substantial annual average employment growth. They employ around 62,000 people in the EU.

SMEs anticipate similar impacts to those expected by larger companies. However, they are likely to be more significant for companies only operating within the EU. They also anticipate significant adverse impacts on R&D and academic partnerships within the EU.

The impact on SMEs is likely to be disproportionate; the smaller the company, the greater the socio-economic impact of the ban. This is because SMEs rely on data generated by their suppliers and/or larger companies (or consortia), which may no longer be available for use within the EU. SMEs will also be unable to reach niche markets for highly differentiated, innovative cosmetics, both in the EU and globally.

SMEs manufacturers will increasingly lose supply of ingredients, especially from SME suppliers. The move to a commodity business will hit SMEs hardest as they lack economies of scale. They will not have access to non-EU innovation and will be unable to compete equally in global markets outside the EU. Some SMEs may be able to relocate outside the EU, but this would cause substantial damage to economic development and employment at national level (in R&D, marketing, advertising and communications).

Impacts on Employment

The EU cosmetics industry directly employs more than 177,000 people (around 137,000 in manufacturing of which 17,000 are in R&D, and 39,000 in distribution). Indirect employment (including retail and salons) is estimated to be about 1.5 million people.[5]

Most large companies expect a negative impact on jobs resulting from the 2013 ban, particularly in R&D, as multinationals move this outside the EU to continue to develop new products for non-EU markets. The reduction in EU-based R&D would affect research into alternative tests and result in a transfer of academic partnerships outside the EU; in effect, a 'brain drain'. There are currently around 17,000 scientists employed by the EU cosmetics industry, and some respondents consider that a significant number of these jobs could be relocated, with Europe losing its leading role in R&D.

Impacts on Trade

Exports are a significant source of business and employment for the EU cosmetics industry. The 2013 ban will lead to a reduction in the innovative capacity of the EU industry compared to companies operating outside the EU. Multinationals are likely to switch product development (and possibly production) outside the EU. Companies operating solely in the EU will be at a competitive disadvantage in markets outside Europe as they will not be able to test and introduce new ingredients into their products. With increasing innovation outside Europe, products exported from the EU will become less attractive for consumers in foreign markets.

Imports may also be affected, as non-EU companies would have to develop separate product ranges for the EU, increasing the costs of marketing in the EU, and so reducing the range and volume of imports. Consumers seeking innovative products may look to parallel imports, or internet sales.

[5] Euromonitor, 2009

Annex 2

QUESTIONS IMPACT ASSESSMENT
2013 IMPLEMENTATION DATE MARKETING BAN COSMETICS DIRECTIVE

1. EXISTING DATA ON THE COSMETICS MARKET AND THE INDUSTRY

The recent revision of the Cosmetics legislation, which led to the adoption of Regulation 1223/2009/EC, was preceded by an extensive impact assessment. The Commission services intend to make reference to much of the data generated in that context and in particular the RPA study "Impact of European Regulation on the EU Cosmetics Industry" September 2007 (http://www.rpaltd.co.uk/documents/J574Cosmetics2.pdf) and the work done by Global Insights "Study of the European Cosmetics Industry" of October 2007 (http://ec.europa.eu/enterprise/newsroom/cf/document.cfm?action=display&doc_id=4561&userservice_id=1).

We would therefore request your input as to whether the data reflected in the above referenced reports changed or remains valid. **Should you be aware of any significant changes to the data provided in these reports you are invited to inform us of those changes.** The issues and questions addressed in the above mentioned RPA report that are considered particularly relevant here are covered in the following tables of the RPA report: Table 2.3 (page 5), Table 2.4 (page 5), Table 3.5 (page 14), Table 3.6 (page 15), Table 3.7 (page 16), Table 3.14 (page 25), Table 4.2 (page 29) and Table 4.3 (page 29).

The data in the previous 2007 RPA report were based on a relatively small sample of 21 cosmetics companies and did not cover the issue of safety testing. The responses included in this questionnaire are based on replies to a detailed consultation exercise of all Colipa members (individual companies and national associations). Information was provided from 24 large companies, accounting for a high proportion of EU cosmetics production, and 100 SMEs from across the EU, including the major producers (France, Italy, Spain Germany and the UK) and newer Member States including Poland and Bulgaria. Table 2.5 in the RPA report should therefore be replaced by the information provided in responses to questions 3.2.4, 3.2.7, 3.2.8, 3.2.9, 3.2.12; the data in Table 3.14 in the RPA report should be supplemented by the information in the response to question 4.3.

The findings in the Global Insights report that are considered particularly relevant are information relating to market size and structure, market forecasts, Research & Development (R&D) spending and export figures.

Additional information on the innovative nature of the industry and the importance of R&D to the industry is given in response to questions 2.3.2, 3.2.8 to 3.2.14 and 6.3. Further information on exports from the EU is given in response to questions 7.1 to 7.5.

2. IMPACTS ON ANIMAL WELFARE/ENVIRONMENTAL IMPACTS

The aim of the **provisions on animal testing** in the Cosmetics Directive is to provide a **high level of animal welfare**. They contain a **clear political and ethical choice against animal testing for cosmetics purposes**. With regard to quantifiable impacts on animal

welfare, impacts can be measured by the number of animals affected by testing for cosmetics purposes.

Animal tests for cosmetic purposes were possible in the EU until March 2009. From then on **any testing in order to meet the requirements of the Directive is prohibited**. There is no intention to propose any changes in relation to the testing ban. Any future direct impacts on animal welfare will therefore be impacting animal welfare outside the EU.

An important aim of the provisions is equally the function as an **incentive to the development of alternatives to animal testing** that would ultimately also benefit other sectors.

2.1. IMPACTS ON NUMBER OF ANIMALS AFFECTED

In relation to number of animals used, there are currently at Community level two mechanisms in place to collect statistics. One is the reporting under the Cosmetics Directive on the number and type of experiments relating to cosmetics products carried out on animals. The 1997, 2004, 2005, 2007 and 2008 reports are available on our website under http://ec.europa.eu/consumers/sectors/cosmetics/documents/animal-testing/index_en.htm. For 2008 a total of 1510 animals was reported to the Commission.

Another important source in relation to animals used in the EU are the statistics under Directive 86/609/EEC on the protection of animals used for experimental and other scientific purposes. The statistics collected in this framework on the use of animals for experimental purposes in the EU are published under http://ec.europa.eu/environment/chemicals/lab_animals/statistics_en.htm.

Finally, apart from the total numbers, Regulation 1907/2006/EC can provide background information on the number of animals normally to be used in the respective tests falling under the 2013 deadline.

The table below sets out the assumptions used to answer Questions 2.1.1 and 2.1.2 on the number of animals used in testing.

Endpoints	**Animals per Test**	**Assumptions for calculating animal numbers used in 2010 – assumes that underlined protocols are followed**
Skin corrosion	1	OECD 404
Skin irritation	2	OECD 404
Skin absorption/penetration	4	OECD 427 (4 – 16)
UV-induced toxic effects – photogenotoxicity	25	OECD 474 : micronucleus –N=25 Rarely done – nowadays in vitro 3T3 NRU
UV-induced toxic effects - acute phototoxicity	10	Acute test only See also Photosensitization
Eye irritation	3	OECD 405
Acute toxicity	10	OECD 420: 5 to 20 OECD 423: 6 to 12 OECD 425: 5/doses - nb of doses: 1 to 5
Skin sensitisation	20	LLNA OECD 429: 20 OECD 406: 32
Sub-acute and sub-chronic toxicity	80	OECD 407: 40 OECD 408: 80
Genotoxicity and Mutagenicity	25	OECD 474 (Micronucleus): 5/group, 3 dose levels, 2 controls = 25 OECD 486 (UDS): 3/group, 2-3 dose levels, 2 controls = 12 to 15 OECD 478 (lethal dominant test): test rarely performed but at least

Endpoints	Animals per Test	Assumptions for calculating animal numbers used in 2010 – assumes that underlined protocols are followed
		240 animals
UV-induced toxic effects, photo-allergy	30	Photosensitization : see above
Toxicokinetics and metabolism	12	OECD 417 (4 per dose/ 1 pilot plus 2 doses = 12)
Carcinogenicity	240	OECD 452: 160 and if interim sacrifice 80 additional OECD 453: at least 400
Reproductive and developmental toxicity	100	OECD 414: 80 to 100 OECD 416: 120
Inhalation toxicity/allergy/sensitisation	40	OECD 412::Sub-acute Inhalation Toxicity: 28-Day Study: 40 OECD 413: Sub-chronic Inhalation Toxicity: 90-day Study: 80

Animal Testing by Large Cosmetics Manufacturers

The following table sets out the number of animal tests carried out, and the number of animals used, by **large cosmetics manufacturers** for all endpoints in 2010.

Animal Tests and Animals Used in the EU for Cosmetics Purposes by Large Companies in 2010				
Endpoints	**All Animal Tests**	**Tests for EU Cosmetics**		
		Animals per Test	**Total Number of Tests**	**Total Animals Used**
Skin corrosion	0	1	0	0
Skin irritation	6	2	0	0
Skin absorption/penetration	0	4	0	0
UV-induced toxic effects - photogenotoxicity	0	25	0	0
UV-induced toxic effects - acute phototoxicity	5	10	0	0
Eye irritation	6	3	0	0
Acute toxicity	5	10	0	0
Skin sensitisation	150	20	125	2,500
Sub-acute and sub-chronic toxicity	49	80	34	2,720
Genotoxicity and Mutagenicity	10	25	0	0
UV-induced toxic effects, photo-allergy	25	30	0	0
Toxicokinetics and metabolism	3	12	1	12
Carcinogenicity	0	240	0	0
Reproductive and developmental toxicity	28	100	25	2,500
Inhalation toxicity/allergy/sensitisation	0	40	0	0
Totals for All Endpoints	***287***		***185***	***7,732***
Totals for 2013 Endpoints	***230***		***185***	***7,732***

The next table separates out the numbers of animal tests by large companies, and the number of animals these involved, for the 2013 end points.

Animal Tests and Animals Used in the EU for Cosmetics Purposes by Large Companies in 2010 – 2013 Endpoints Only			
Endpoints	**Animals per test**	**Total number of tests**	**Total Animals Used**
Skin sensitisation	20	125	2,500
Sub-acute and sub-chronic toxicity	80	34	2,720
Toxicokinetics and metabolism	12	1	12
Carcinogenicity	240	0	0
Reproductive and developmental toxicity	100	25	2,500
Totals for 2013 Endpoints		***185***	***7,732***[6]

[6] The large company animal number may be overestimated - many tests are performed by consortia – individual consortia members may have reported the same tests

The following table also provides information on the annual average of animal tests for all endpoints for the previous 10 years.

Animal Tests Conducted in the EU for Cosmetics Purposes by Large Companies (Annual Average over Previous 10 Years)	
Endpoints	**Total number of tests**
Skin corrosion	<1
Skin irritation	6
Skin absorption/penetration	1
UV-induced toxic effects - photogenotoxicity	0
UV-induced toxic effects - acute phototoxicity	1
Eye irritation	50
Acute toxicity	53
Skin sensitisation	151
Sub-acute and sub-chronic toxicity	36
Genotoxicity and Mutagenicity	19
UV-induced toxic effects, photo-allergy	26
Toxicokinetics and metabolism	6
Carcinogenicity	<1
Reproductive and developmental toxicity	20
Inhalation toxicity/allergy/sensitisation	2
Totals for All Endpoints	***372***
Totals for 2013 Endpoints	***213***

The next table separates out the annual average numbers of animal tests carried out for the 2013 end points by large companies for the previous 10 years.

Animal Tests Conducted in the EU for Cosmetics Purposes by Large Companies (Annual Average over Previous 10 Years) – 2013 Endpoints	
Endpoints	**Total number of tests**
Skin sensitisation	151
Sub-acute and sub-chronic toxicity	36
Toxicokinetics and metabolism	6
Carcinogenicity	<1
Reproductive and developmental toxicity	20
Totals for 2013 Endpoints	***213***

Animal Testing by SME Cosmetics Manufacturers

The data analysis of SME animal testing data are based on a relatively small sample (18 companies) and should be taken as indicative only. The majority of SMEs cosmetics manufacturers do not carry out animal testing.

The following table sets out the number of animal tests carried out, and the number of animals used, by the 18 responding SME cosmetics manufacturers for all endpoints in 2010.

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Animal Tests and Animals Used for Cosmetics Purposes by SMEs in 2010				
Endpoints	**All Animal Tests**	**Tests for EU Cosmetics**		
		Animals per Test	**Total Number of Tests**	**Total Animals Used**
Skin corrosion	0	1	0	0
Skin irritation	5	2	0	0
Skin absorption/penetration	0	4	0	0
UV-induced toxic effects - photogenotoxicity	0	25	0	0
UV-induced toxic effects - acute phototoxicity	0	10	0	0
Eye irritation	0	3	0	0
Acute toxicity	0	10	0	0
Skin sensitisation	49	20	8	160
Sub-acute and sub-chronic toxicity	0	80	0	0
Genotoxicity and Mutagenicity	0	25	0	0
UV-induced toxic effects, photo-allergy	11	30	0	0
Toxicokinetics and metabolism	0	12	0	0
Carcinogenicity	0	240	0	0
Reproductive and developmental toxicity	0	100	0	0
Inhalation toxicity/allergy/sensitisation	0	40	0	0
Totals for All Endpoints	***65***		***8***	***160***
Totals for 2013 Endpoints	***49***		***8***	***160***

The next table separates out the numbers of animal tests by SMEs, and the number of animals these involved, for the 2013 end points in 2010.

Animal Tests and Animals Used for Cosmetics Purposes by SMEs in 2010 – 2013 endpoints			
Endpoints	**Animals per Test**	**Total Number of Tests**	**Total Animals Used**
Skin sensitisation	20	8	160
Sub-acute and sub-chronic toxicity	80	0	0
Toxicokinetics and metabolism	12	0	0
Carcinogenicity	240	0	0
Reproductive and developmental toxicity	100	0	0
Totals for 2013 Endpoints		***8***	***160***

The next table provides information on the annual average number of animal tests by SMEs or all endpoints for the previous 10 years.

Animal Tests Conducted in the EU for Cosmetics Purposes by SMEs (Annual Average over Previous 10 Years)	
Endpoints	**Total number of tests**
Skin corrosion	<1
Skin irritation	0
Skin absorption/penetration	<1
UV-induced toxic effects - photogenotoxicity	0
UV-induced toxic effects - acute phototoxicity	0
Eye irritation	<1
Acute toxicity	4
Skin sensitisation	7
Sub-acute and sub-chronic toxicity	0
Genotoxicity and Mutagenicity	<1
UV-induced toxic effects, photo-allergy	<1
Toxicokinetics and metabolism	0
Carcinogenicity	0
Reproductive and developmental toxicity	0
Inhalation toxicity/allergy/sensitisation	0
Totals for All Endpoints	***16***
Totals for 2013 Endpoints	***7***

The following table separates out information on the annual average number of animal tests by SMEs for the previous 10 years for the 2013 end points.

Animal Tests Conducted in the EU for Cosmetics Purposes by SMEs (Annual Average over Previous 10 Years)	
Endpoints	**Total number of tests**
Skin sensitisation	7
Sub-acute and sub-chronic toxicity	0
Toxicokinetics and metabolism	0
Carcinogenicity	0
Reproductive and developmental toxicity	0
Totals for 2013 Endpoints	***7***

2.1.1. Please provide any **additional information to the one referenced above in relation to the number of animals used for cosmetics testing** in the EU that you consider relevant.

(type of answer expected: any additional data considered relevant and the exact source of the data)

From 2009, no animal tests have been carried out in the EU in the context of the EU cosmetics legislation. Cosmetics manufacturers still carry out a small number of animal tests outside the EU to ensure the safety of products in line with SCCS guidance, or in response to requests for further information. But these take place only after trying first to use all existing data.

Large companies

Large cosmetic product manufacturing companies responding to the questionnaire conducted approximately 185 animal tests in total in 2010 for EU Cosmetics purposes. This is compared to an annual average over the previous 10 years of 372 tests. It is estimated that the tests required an estimated 7,732 animals in 2010.
All 185 animal tests in 2010 were undertaken for 2013 endpoints. This compares to annual average of approximately 213 animal tests over the previous 10 years.

SMEs

SME cosmetic product manufacturing companies responding to the questionnaire conducted approximately 8 animal tests in total in 2010, this is compared to an annual average over the previous 10 years of 16 tests. It is estimated that these tests required around 160 animals in 2010.

In 2010, all 8 of the animal tests were undertaken for 2013 endpoints. This compares to annual average of approximately 7 animal tests over the previous 10 years.

2.1.2. Is testing for cosmetic purposes carried out **exclusively on rodents (including rabbits)** or are you aware of any other species used?
(type of answer expected: qualitative)

All animal testing carried out in 2010 for cosmetics purposes involved rodents (rats and mice)

2.1.3. Please provide information about the **number of animals that would in your view potentially be saved from testing** over the next 10 years in case the 2013 implementation date is kept? *(type of answer expected: any founded explanation of numbers plus reasons)*

The answer to this question could depend upon the nature of the test ban imposed on the EU. Therefore, this question has been considered under three different assumptions:

A: Assuming that animal tests performed for other purposes than meeting the requirements of the EU cosmetics legislation do not trigger the ban and you can subsequently rely on these test data for cosmetic purposes in the EU provided these test were for non cosmetic purposes but in addition you can also rely on test data developed for cosmetic purposes outside the EU.
B: Assuming that animal tests performed for other purposes than meeting the requirements of the EU cosmetics legislation do not trigger the ban and you can subsequently rely on these test data for cosmetic purposes in the EU provided these test were for non cosmetic purposes.
C: Assuming that animal tests performed for other purposes than meeting the requirements of the EU cosmetics legislation do not trigger the ban, but you can never rely on these data.

Large Companies.

Under Assumption A, large companies considered that it is likely that animal test data available from obligatory testing required for legislation outside of the EU would largely suffice to substantiate safety of novel ingredients. The numbers of animal tests would not therefore be expected to fall significantly from the 2010 figures. No animal tests

would be conducted in response to SCCS requests for data relating to Annex substances; however, it is rather unlikely that this will significantly reduce animal testing as tests done in support of non-EU cosmetic purposes are usually then also used for SCCS dossier submissions...

The impacts are likely to be similar under Assumption B.

Under Assumption C, large companies considered that no animal tests would be carried out to satisfy EU legislation; this would include animal tests to satisfy data requests from SCCS. However, as most companies are global, they will continue to innovate for cosmetics markets outside of the EU, including for the growing Chinese market, it is likely that, there would be no reduction in animal tests worldwide.

SMEs

SMEs have stressed the importance of data supplied by their ingredient manufacturers, or generated by large companies' consortia. They themselves commission very few tests so there would be very little impact on animal tests from their part. Therefore, testing may continue at the same level under all assumptions

2.1.4. Do you consider that the **numbers of animals used in the EU for testing for cosmetics purposes prior to the testing ban** can be used as a basis to determine the number of animals that will not be used in the future outside the EU? Or are you aware that already before the testing ban testing for cosmetic products manufactured in the EU market was carried out outside the EU? *(type of answer expected: any founded explanation and numbers plus reasons)*

Before 2009, at least half of the **large companies** commissioned animal tests outside the EU for the critical 2013 endpoints. It is estimated that 90% of testing was performed outside the EU, with the welfare of animals conforming to European companies' internal standards (as there is no equivalent to the Directive 86/609). Data on animal tests in the EU do not therefore provide a robust basis upon which to determine the number of animals that will be used in the future.

Most importantly, as discussed in response to questions 4.5 and 6.3, the innovation of cosmetic ingredients and products containing these ingredients is likely to continue for markets outside of the EU. Therefore, globally animal tests will continue at the same level or may even increase to meet the demands of non-EU cosmetics legislation. (e.g. China and US)

Of the five **SMEs** that provided information on this point, two have commissioned animal tests outside the EU for the critical 2013 endpoints in the past 10 years but only one SME commissioned such tests in 2010. Some SMEs have stressed their dependence on test data supplied by ingredients manufacturers. Therefore, SME testing is likely to represent only a very small fraction of overall testing. Furthermore, the innovation of cosmetic ingredients and products containing these ingredients is likely to continue for markets outside of the EU. Therefore, globally animal tests will continue at the same level or may even increase to meet the demands of non-EU cosmetics legislation.

2.1.5. Please provide us with any **cosmetics specific data on public opinion** in relation to animal testing and specifically animal testing for cosmetics **that you consider could be of interest** as well as information on the source of the data. *(type of answer expected: any surveys that could be of additional value here with exact source information)*

The cosmetics industry monitors trends in public opinion (as published in the media) on a daily basis. It can be assessed that there is a large amount of confusion or lack of information on the subject : ignorance of existing regulations and requirements, confusion on species used for testing, or on numbers involved, assumptions that testing is not needed for cosmetics.

2.2. Testing data in relation to 2013 endpoints

2.2.1. Inclusion in the **Annexes** of the Cosmetics Directive is preceded by a dossier review by the Scientific Committee on Consumer Safety (SCCS) or its predecessors. In how many cases/dossiers was **data on the endpoints covered by the 2013 implementation date** submitted to the SCCS (or its predecessors), respectively requested by the SCCS (or its predecessors) between 2000 and March 2009? *(type of answer expected: out of the XXX substances data on these endpoints was expected for XXX)i*

This question is primarily for the SCCS. However, large companies indicated that a large number of 'opinions' have been issued by the SCCS over the last five years on key ingredients which are essential either for their categories or for all cosmetics, such as hair dyes (the majority), fragrance components, UV filters, preservatives and other ingredients for which submissions had been made (e.g. CMR III substances). In about 50% of these opinions, additional information has been requested, a substantial proportion of which has required animal testing (mostly in-vivo sensitisation, genotoxicity/mutagenicity studies and reproductive toxicity but also other study types such as toxicokinetics.

In addition to individual companies interactions with SCCS, Colipa (since 2004) has submitted 7 dossiers for new UV filters and preservatives and defended 58 ingredients which were assessed by the SCCS ; this corresponds to 20 dossiers for which "2013 tests" had to be generated : skin allergy, reprotoxicity, sub-chronic studies, toxicokinetics and carcinogenicity.

In the context of the Commission decision to review the safety hair dyes used in the EU , non SMEs companies organised in a consortium and shared existing data on 45 commonly used Hair dyes which represented 89 % of the HD defended by Colipa and around 95% of what is used in the EU. Among all the studies submitted it can be seen that there were 203 animal studies covering the 2013 endpoints with 101 studies which had to be specifically generated while the others already existed .Out of these 101 studies, 34 were done to study skin allergy, whereas the remaining 67 covered essentially reproduction and sub-chronic tests.If this request of the Commission had been done after 2013 , almost no hair colorants would have been able to be marketed any more.

2.2.2. Out of the data under question 2.2.1. **in how many cases was data needed on**: a) Repeated-dose toxicity (please specify in case it concerned skin sensitisation or

carcinogenicity) b) Reproductive toxicity c) Toxicokinetics *(type of answer expected: out of the XXX, for a) XXX, for b) XXX …)*

This is a question for the SCCS but please refer to previous question's answer.

2.2.3. Please provide information on in how many cases between 2000 and March 2009 animal testing data on the endpoints covered by 2013 was **specifically generated for the dossier submission** to the SCCS (or its predecessors), thus not available from other uses or upstream? *(type of answer expected: out of the XXX for XXX)*

33% of the **large companies** responding undertook animal tests to provide information to the SCCS in 2010, this is down from an average of 56% companies undertaking such tests over the previous 10 years. Studies dates may help to respond with the help of SCCS.

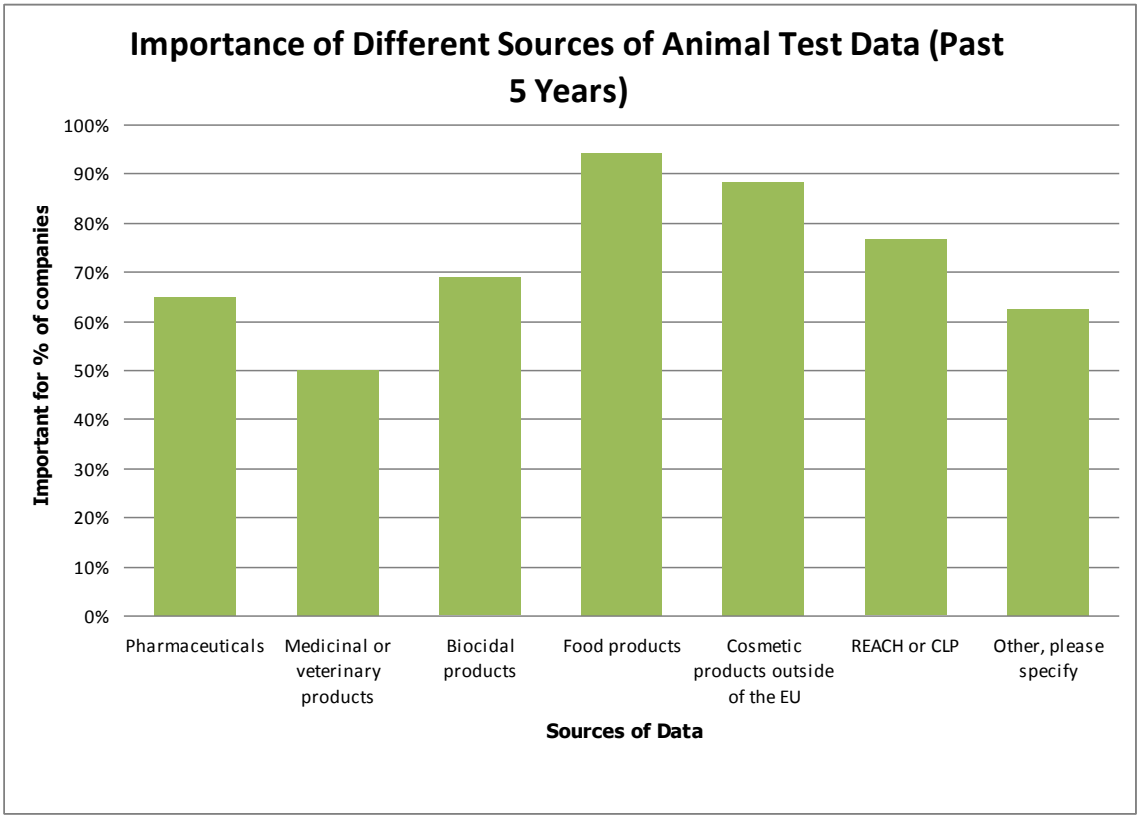
Only two **SMEs** undertook animal tests to provide information to the SCCS in 2010 and only the same SMEs undertook such tests over the previous 10 years (see 2.2.7).

2.2.4. In case testing data was not specifically generated for this purpose, **from which source was it available?** a) Chemicals Legislation/REACH b) Sectorial EU legislation (such as food, pharma etc.), please specify c) Regulatory testing for cosmetics products outside the EU d) Other, please specify If data comes from another source is it usually **clearly identifiable for which reason** this data was generated? *(type of answer expected: out of the XXX of tests needed, in XXX cases data was available from testing for purpose …, in XXX cases data was available from …)*

Large Companies

Large companies noted that, with regard to data from other sources, is **not generally clearly identifiable** for which reasons these have been generated, in particular in relation to data from the literature. However, this may change in future.

The chart below shows the percentage of responding large companies that considered the different sources of animal test data shown to be important to them. The reasons given refer to all animal testing and not just to those for 2013 endpoints. It is important to note that importance is not necessarily equivalent to the volume of data obtained from a particular source. Overall it is clear that all sources are important as they will provide relevant toxicological information which can be used and avoid conducting animal tests, although additional information may be needed in some few cases.

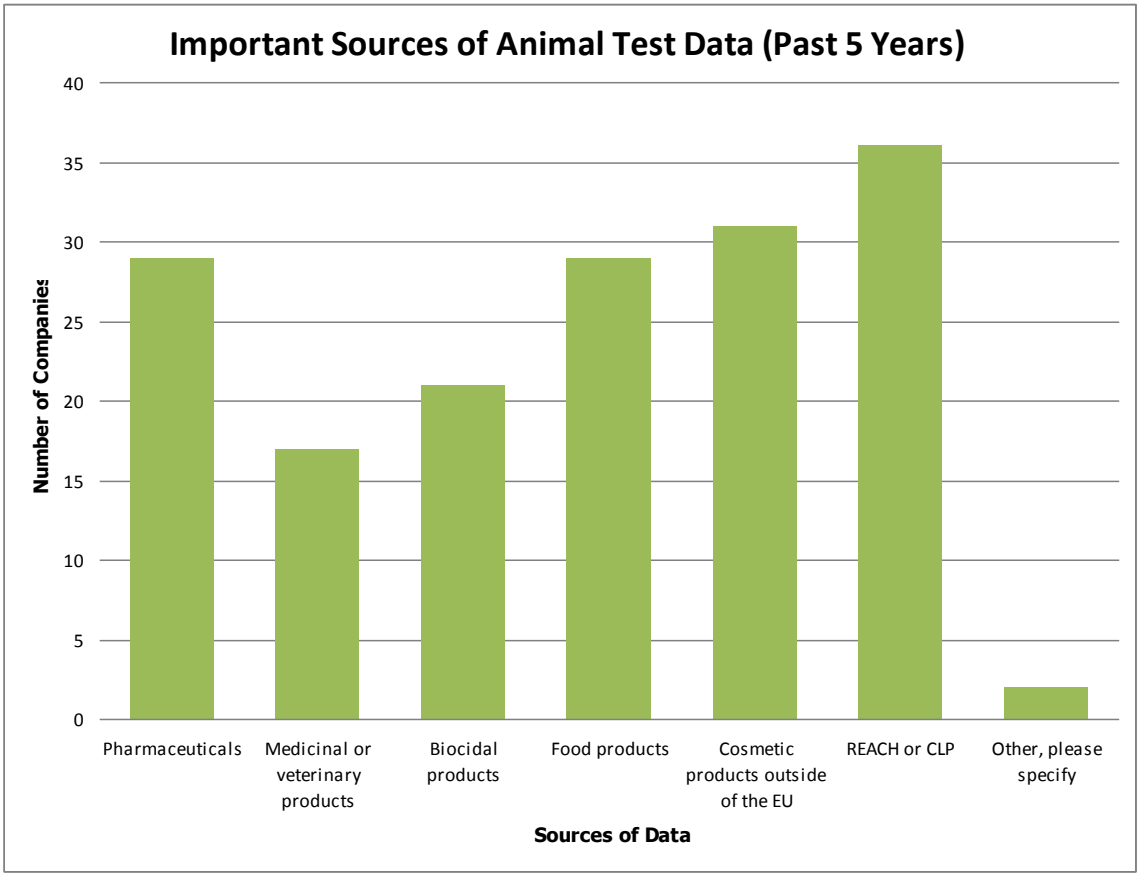


Importance of Different Sources of Animal Test Data to Large Companies (Past 5 Years)			
Animal test data source	**Number of companies**		
	Not important	Moderately important	Very important
Pharmaceuticals	6	4	7
Medicinal of veterinary products	8	2	6
Biocidal products	5	7	4
Food Products	1	5	11
Cosmetic products outside the EU	2	7	8
REACH or CLP	4	5	8
Other	3	1	4

The "Other" data sources shown in the chart include environmental toxicity data, data from other product categories, (e.g. aerosols and personal care consumer products) and from the literature. The importance of different information sources varies greatly, depending upon the ingredient and product exposure scenario.

SMEs

The chart below shows the percentage of SME companies that found the different sources of animal test data shown to be important to them. The reasons given refer to all animal testing and not just to those for 2013 endpoints.



Importance of Different Sources of Animal Test Data to SMEs (Past 5 Years)			
Animal test data source	**Number of companies**		
	Not important	Moderately important	Very important
Pharmaceuticals	5	11	18
Medicinal of veterinary products	13	7	9
Biocidal products	11	10	9
Food Products	6	12	16
Cosmetic products outside the EU	5	16	15
REACH or CLP	5	15	21
Other	1	0	1

The "Other" data sources shown in the chart include old data on ingredients and data from the ingredient supplier. Indeed, a proportion of the data represented in the above chart may have been provided by ingredients manufacturers.

SME companies also state that although these sources of information are important to them, the main source of animal test data was from suppliers (tests may have been performed by suppliers or large companies)

2.2.5. **For substances not covered by the Annexes** and not subject to SCCS review, please provide information on in how many cases animal testing **data on the three 2013 endpoints was needed for the cosmetics safety assessment** of products containing these substances? *(type of answer expected: out of the XXX substances data on these endpoints was expected for XXX)*

The **large companies**' response to question 2.2.3 shows that the primary reasons for large cosmetics companies undertaking tests were to meet requirements of legislation other than the cosmetics EU legislation and to ensure that products are safe (which is a regulatory requirement and legal obligation in virtually every market globally). This can be necessary when chemical legislation does not request data under a certain tonnage or when classification and labelling data are not sufficient to establish a no effect level for safety assessment needs.

The primary reasons for **SME** cosmetics companies undertaking tests were also to complete the product information file and to ensure that products were safe (beyond regulatory requirements). However, this does not enable us to draw conclusions on the proportion of the animal tests undertaken in 2010 for 2013 endpoints which were for substances covered by the Annexes or subject to SCCS review.

2.2.6. Out of the data under 2.2.5. **in how many cases was data required on**: a) Repeated-dose toxicity (please specify if it concerned skin sensitisation or carcinogenicity) b) Reproductive toxicity c) Toxicokinetics *(type of answer expected: out of the XXX, for a) XXX, for b) XXX …)*

Large Companies

The numbers of tests for the 2013 endpoints in 2010 and in the past ten years by large cosmetics companies are set out in the table below. The table represents all animal tests undertaken for these endpoints, not just for substances not covered by the Annexes nor those subject to SCCS review. However, as noted in answer to Question 2.2.5, the majority of the tests shown will be relevant to this question.

Number of Animal Tests Carried out for 2013 Endpoints – Large Companies		
Endpoint	**No. Tests 2010**	**Average Annual no. Tests over Previous 10 Years**
Skin sensitisation	125	151
Sub-acute and sub-chronic toxicity	34	36
Toxicokinetics and metabolism	1	6
Carcinogenicity	0	<1
Reproductive and developmental toxicity	25	20

Animal tests for carcinogenicity were conducted by large companies over the previous 10 years but only at a frequency of one test every three years. This would suggest that carcinogenicity tests are only infrequently conducted as a last resort but this does not mean that they would never be needed in the future.

SMEs

In 2010 and over the previous 10 years SMEs only conducted tests for skin sensitisation (out of the 2013 endpoints). This involved 8 tests in 2010, using 160 animals, and an average of 7 tests per year in the previous 10 years.

2.2.7. For substances **not covered by the Annexes** and not subject to SCCS review, please specify in how many of these cases animal testing data was **specifically generated** for the cosmetics safety evaluation? *(type of answer expected: out of the XXX for XXX)*

Large Companies

The figures set out in the table below refer to animal test data specifically generated for the cosmetics safety evaluation. This is, however, also relevant for cosmetic safety purposes outside the EU which, in the vast majority of cases, require the same safety data and build on the same data sets as substances subject to SCCS review.

Animal Tests for 2013 Endpoints – Large Companies		
2013 Endpoints	**Number of Tests**	
	Previous 10 Years (Rounded Annual Average)	**2010**
Skin sensitisation	151	125
Sub-acute and sub-chronic toxicity	36	34
Toxicokinetics and metabolism	6	1
Carcinogenicity	<1	0
Reproductive and developmental toxicity	20	25
Totals for 2013 Endpoints	***213***	***185***

SMEs

All of the SMEs that undertake animal testing indicated that they use the data to complete their product information file, with a small proportion of these (two companies) also undertaking animal tests to provide information at the request of SCCS. These findings were the same for 2010 and the previous 10 years.

2.2.8. In case it was not specifically generated **from which source was it available**? a) Chemicals Legislation/REACH b) Sectorial EU legislation (such as food, pharma etc.), please specify c) Regulatory testing for cosmetics products outside the EU d) Other, please specify If data comes from another source is it usually **clearly identifiable for which reason** this data was generated? *(type of answer expected: out of the XXX of tests needed, in XXX cases data was available from testing for purpose …, in XXX cases data was available from …)*

See response to question 2.2.4.

Several **SMEs** have stated that they cannot undertake animal testing due to the high cost. Therefore, these companies will seek to source data for the 2013 endpoints from the sources set out in 2.2.4. SMEs that provided additional comment stressed that a key source of test data (animal and non-animal) is their supplier.

2.2.9 On **which endpoints do you expect testing data to be most needed** in the next 10 years?

Large companies consider that the greatest need for testing data will be for skin sensitisation, sub-acute and sub-chronic toxicity and reproductive toxicity endpoints. A small number of tests are likely to be needed for toxicokinetic endpoints. Although only a small number of animal tests for carcinogenicity have been carried out over the past 10 years, large companies stressed that such tests could be critical in the case of an

important ingredient with carcinogenicity safety questions, which cannot be addressed *in vitro*.

SMEs consider that the greatest need for testing data will be for skin sensitisation.

2.2.10. Do you expect that the availability of testing data from other sources (see questions 2.2.4. and 2.2.8.) to remain the same or change in the coming 10 years? If you expect changes please explain which ones and the reasons. *(type of answer expected: data availability is expected to be similar/different for the following reasons)*

The answer to this question will depend upon the nature of the test ban. Therefore, this question has been answered under three different assumptions:

A: Assuming that animal tests performed for other purposes than meeting the requirements of the EU cosmetics legislation do not trigger the ban and you can subsequently rely on these test data for cosmetic purposes in the EU provided these test were for non cosmetic purposes but in addition you can also rely on test data developed for cosmetic purposes outside the EU.

B: Assuming that animal tests performed for other purposes than meeting the requirements of the EU cosmetics legislation do not trigger the ban and you can subsequently rely on these test data for cosmetic purposes in the EU provided these test were for non cosmetic purposes.

C: Assuming that animal tests performed for other purposes than meeting the requirements of the EU cosmetics legislation do not trigger the ban, but you can never rely on these data.

The responses were the same for large companies and SMEs

Under Assumption A, animal test data generated to satisfy non-EU cosmetics legislation may become more available with the likelihood of data generated for Japan and China becoming particularly important. Data generated to meet the requirements of other EU legislation would be available to approximately the same degree as currently. However, more data may become available as a result of additional testing for REACH.

Under Assumption B, animal test data generated outside of the EU for cosmetic purposes would not be available for cosmetic purposes in the EU. Data generated to meet the requirements of other EU legislation would be available to approximately the same degree as currently. However, more data may become available as a result of additional testing for REACH.

Under Assumption C, no new animal test data would be available for cosmetic purposes. However, it is expected that animal test data will still be generated for non-EU cosmetic purposes, in more or less the same order of magnitude. This would mean that the marketing of these novel ingredients would be prohibited in the EU only, albeit without any effect on animal testing worldwide.

2.2.11. In which market segment **do you expect the highest testing data need in relation to data covered by the endpoints covered by the 2013 implementation** date in the next 10 years? a) fragrances and perfumes b)

decorative cosmetics c) skin care d) sun protection products e) hair care (other than hair colorants) f) hair colorants g) toiletries h) Other, please specify *(type of answer expected: sector X is expected to have the highest data need because…, followed by)*

The level of data need will be dependent upon both the level of innovation (see responses to Section 3) and the extent to which ingredients need to be defended (for example in response to SCCS requests).

2.3. INCENTIVE FUNCTION FOR RESEARCH INTO ALTERNATIVES

In the last 20 years an estimated 200 million were spent on alternatives by the EU RTD programme (see recent report: ftp://ftp.cordis.europa.eu/pub/fp7/docs/alternative-testing-progress-report-2009_en.pdf)

Industry has contributed (with its ongoing work on research for alternatives, but also for example with the commitment to contribute 25 million to an RTD call http://www.colipa.eu/news-a-events/news/19--cosmetic-industry-funding-for-commission-call-for-proposals.html). Other initiatives, such as the European Partnership for Alternative Approaches to Animal Testing (EPAA) (http://ec.europa.eu/enterprise/epaa/index_en.htm) or the International Cooperation on Cosmetics Regulation (ICCR) also play an important role (http://ec.europa.eu/consumers/sectors/cosmetics/animal-testing/index_en.htm#h2-international-cooperation).

2.3.1. Please provide information on the **impact the provisions in the Cosmetics Directive had on research in alternative methods** to replace animal testing.
(type of answer expected: this is an open qualitative question)

The industry has invested in AAT research for more than 30 years and together under the Colipa structure they created the Steering Committee on Alternatives to Animal Testing (SCAAT) in 1992 – long before the 2003 decision on the 2013 ban – however investment in terms of funding research and method development and (pre) validation have increased overtime as research objectives have become even more complex and life sciences has provided more and more insight into biological pathways of toxicological effects especially in the area of allergy – this availability of basic knowledge has allowed us to invest in method development and prevalidation of promising methods, resulting in a large portfolio of projects and 3 methods .under prevalidation with ECVAM

Developing alternatives for the 2013 endpoints is an enormous challenge, and requires the development of fundamental knowledge on toxicological pathways, through academic research. For the 2013 endpoints, this knowledge is lacking, and so a full set of testing methods will not be available before 2013. If the marketing ban goes ahead, the EU may lose its leadership role on alternatives: research and development (R&D) facilities are likely to move to expanding markets (US, China, India), taking AAT research with them.

2.3.2. Please provide information **on the general research and development spending** in **the cosmetics/ cosmetics ingredients industry** in the last 10 years.
(type of answer expected: quantitative data on spending, either total or if not available based on examples of small/large companies spending)

Spending on R&D accounts for 0.5% to 3.5 % of the net sales of companies.

Another indication of the significance of R&D spend is given by the proportion of scientists amongst the staff of cosmetics companies. Euromonitor data indicates that almost 17,000 scientists were employed by the sector in 2009, out of a total of 177,000 direct employees – nearly 10%. In addition, some companies invest a significant amount of money in external research, for example through partnerships with academic institutes.

2.3.3. Please provide information on the amounts **spend by the cosmetics/cosmetics ingredients industry** on **research in alternatives to animal testing** in the last 10 years.

(type of answer expected: quantitative data on spending, either total or if not available based on examples of small/large companies spending)

Under the 7th Framework Programme for R&D, several large Colipa companies matched the European Commission's funding, which made €50 million available for research into alternatives. The focus of this programme is on systemic toxicity, yet another industry effort of €12 million covers method development/improvement and validation in the area's of genotoxicity, skin allergy and eye irritation. Individual companies are investing in non-animal testing as well, often in partnership with academic institutes the size of this research effort is not exactly known. Recent interviews in the press have indicated that one company has invested 30 Millons € in the past 25 years, that another has spent an overall 285 Million $, and that another company is investing 3 Million € a year for external research in addition to their own internal activities.

2.3.4. How do you **expect these amounts** spent on research in relation to alternatives to animal testing **to develop in the future**? Would they increase, remain the same/decrease? Please provide information on whether they would increase, remain the same/decrease compared to total R&D expenses.

(type of answer expected: expectation on whether these would augment, remain the same or be reduced and reasons)

Despite the fact that the cosmetic sector is facing economic and regulatory challenges (REACH, New Regulation on cosmetics), it has maintained a high level of investments in the area of research on replacement solutions to animal testing .This unique effort started in the '80s and made it possible to face the 2009 ban with methods which had been developed 10 or 15 years earlier. However, despite current significant efforts full scientific knowledge is not there for a large number of areas covered by 2013, which means that setting deadlines is not a satisfactory mechanism but that more time and funding are also required.

Developing alternatives for the 2013 endpoints is an enormous challenge, and requires the development of fundamental knowledge on toxicological pathways, through academic research. For the 2013 endpoints, this knowledge is lacking, and so a full set of testing methods will not be available before 2013. If the marketing ban goes ahead, the EU may lose its leadership role on alternatives: research and development (R&D) facilities are likely to move to expanding markets (US, China, India), taking AAT research with them, providing new opportunities.

So funding of alternatives would continue for some companies, outside the EU.

2.3.5. Please provide information on the **amounts spend by Member States on research in alternatives to animal testing** in the last 10 years? If you refer to a specific Member State please specify.

(type of answer expected: total figures for specific Member States)

This question is aimed at the Member States, not industry

2.3.6. Do you consider that maintaining the 2013 implementation date **would have impacts on the incentive function** of the provisions? Please specify.

(type of answer expected: this is an open qualitative question)

In addition, the EU would lose its leadership in this area of research, subsequent to no industrial & EU academic research, nor EU start-ups : shift and strong support to US or China labs

2.3.7. Which do you consider would be the best **approach/what type of mechanism would have the highest incentive function** in terms of research into alternative methods?

(type of answer expected: this is an open qualitative question)

The best incentive would be to allow science to deliver – yet there should be sufficient pressure to make the research programmes move as quickly as possible (knowing that scientific development cannot be fully predicted). The type of research requires a multidisciplinary approach; this should be possible through the EC's framework programmes but only if it the research area is politically marked as a high priority for the EU.

Delivery of the science could be achieved through a controlled, monitored research and development effort, high level investments from the public (EU and Member States) and private sectors (several industry sectors) with synergies between the different regions of the world, and a progressive approach to ensure safe use of scientifically developed robust non animal new methods alongside current in vivo tests.

This could happen if the current 2013 provisions apply with a realistic transition, introducing bans in a partial way in order to allow science to deliver. High levels of investments are required with transparency on the few tests which would still be needed to allow sound safety assessments.

3. QUESTIONS ON IMPACTS OF THE IMPLEMENTATION OF THE MARKETING BAN IN 2013 ON CONSUMERS

The main objective of the Cosmetics Directive is to **ensure that cosmetics products are safe for the consumer and that the internal market functions well for these products**. Possible impacts on consumers could be potential impacts on safety, availability of cosmetic products and price.

3.1. CONSUMER SAFETY

3.1.1. Will it be possible to **ensure the same level of consumer safety** in relation to cosmetics products once the 2013 implementation date applies, in the absence of alternatives to animal testing?

(type of answer expected: yes/no and explanations)

The cosmetics industry is committed to providing safe products. To do this, it needs tools to ensure an ever higher standard of consumer safety. Animal testing is limited to ingredients (cosmetic products are not tested on animals) and is used only under the following circumstances:

- **to assess the safety of new ingredients and/or new uses of existing ingredients**, following demands from member states' competent authorities and the Scientific Committee on Consumer Safety (SCCS);
- **to 'defend' existing ingredients** following demands for additional safety information from member states and the SCCS. Full implementation of the 2013 ban would mean that demands are made for information to ensure product safety and regulatory compliance without permitting use of the tools to provide this information.

Colipa (since 2004) has submitted 7 dossiers for new UV filters and preservatives and defended 58 ingredients which were assessed by the SCCS. This corresponds to 20 dossiers for which 2013 tests had to be generated; skin allergy, reprotoxicity, subchronic studies, toxicokinetics and carcinogenicity.

If the ban is implemented, a limited number of new products would be introduced in the EU (mainly reformulations that do not require additional safety data). For ingredients where new concerns arise (e.g. because of new insights in risk assessment) there is no possibility to support these ingredients if relevant data cannot be generated. As manufacturers will not place products on the market that are not proven to be safe, the ingredients will be lost. This could include ingredients that may improve human health and protection (sunscreens, preservatives) or replace existing ingredients that can no longer be used for several reasons. The loss of ingredients, without replacement, would gradually lead to higher formulation costs. Ultimately, companies may not be able to formulate some products, resulting in a loss of products and diminished choice.

3.1.2. Do you consider that **Member State authorities will be able and sufficiently equipped** to pick up on manufacturers that may rely on insufficient data packages in their safety assessment?

(type of answer expected: yes/no and explanations)

This is not a question for industry. However, all manufacturers are ready to assist national competent authorities as best as they can to provide the necessary information.

3.1.3. Are you aware of **existing substances** in any of the Annexes or not being regulated that are in your view **likely to be reviewed/should be reviewed** in the coming 10 years? How many and which ones? *(type of answer expected: expected number and possibly type of substances for review)*

This is not a question for industry. However, there could be future needs in relation to endocrine modulation, nanos and mixtures evaluation, amongst others. Existing ingredients face ever increasing additional safety information.

3.2. CONSUMER CHOICE

The Commission services would like to establish whether in case the marketing ban provisions remain unchanged in the absence of alternatives by 2013 impacts on availability of cosmetic products and on the possibility to innovate are to be expected. Possible impacts would depend on future events (how many new substances will be placed on the market, data needs for these substances etc.) which may be difficult to predict. In the following, information is therefore first requested looking backwards for the time **between 2000 and March 2009** (=the entry into force of the testing and marketing ban) and then **looking forward.**

PLEASE NOTE:
For all questions below we are looking for information that **distinguishes between large and small and medium sized (SME's) companies**. This is important to establish specific SME impacts. Therefore please differentiate in your answer wherever possible between SME's and larger companies. For details on the SME definition please refer to: http://ec.europa.eu/enterprise/policies/sme/facts-figures-analysis/sme-definition/index_en.htm

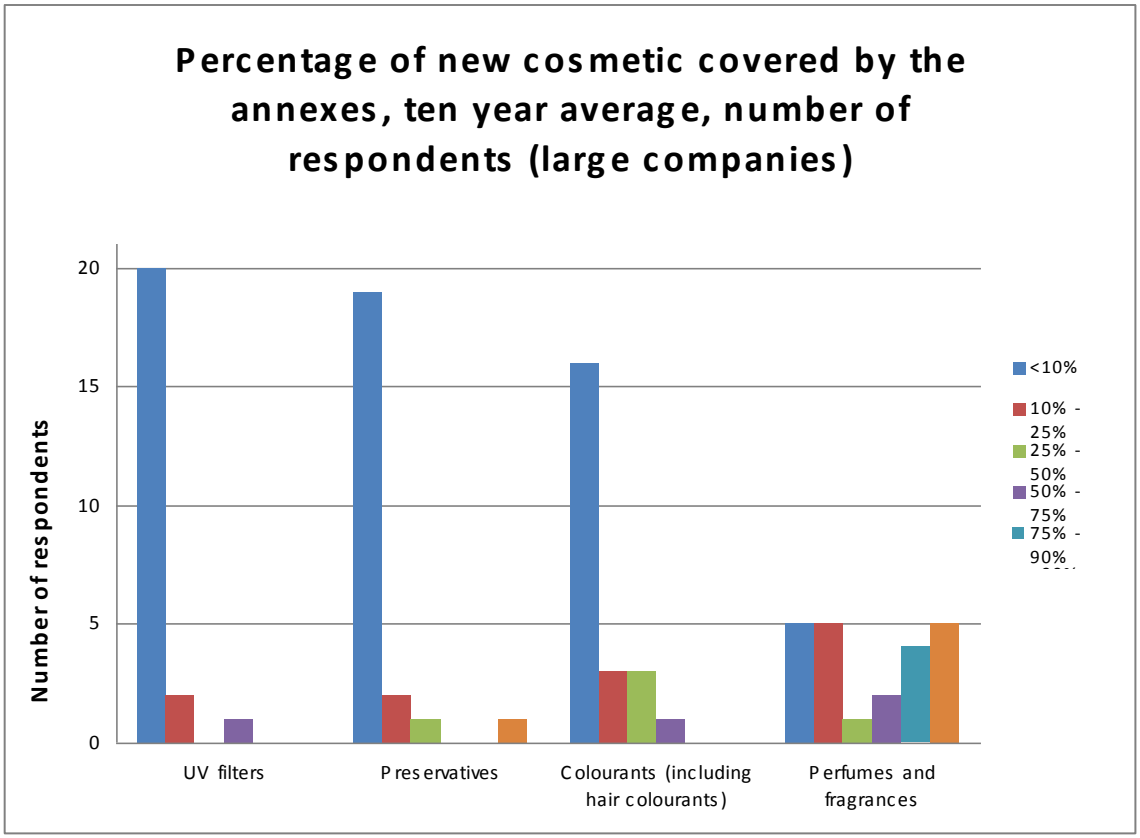
Please also differentiate between the type of company concerned, notably whether the information provided concerns **cosmetics manufacturers or cosmetics ingredients manufacturers.**

AMOUNT OF NEW SUBSTANCES BETWEEN 2000 AND MARCH 2009

3.2.1. Please provide information on how many substances have been **newly used in cosmetic products between 2000 and March 2009**? Please differentiate the information for substances covered by the Annexes to the Cosmetics Directive and those that are not covered. *(type of answer expected: total number, XXX substances covered by Annexes, XXX not covered by Annexes)*

Large cosmetics companies on average introduced around 70 new ingredients each per year in the period 2000 to 2009 (range: 0 to 734). This represents around 4% of the total ingredient portfolio. It is not possible to derive the total number of new ingredients by multiplying the average by the number of companies, as each new ingredient is likely to be used by a number of companies. The average number of new ingredients introduced in 2010 by larger companies was 60 (range: 0 to 677). This represents around 3.5% of the total ingredient portfolio and is a minor reduction compared to the previous 10 years.

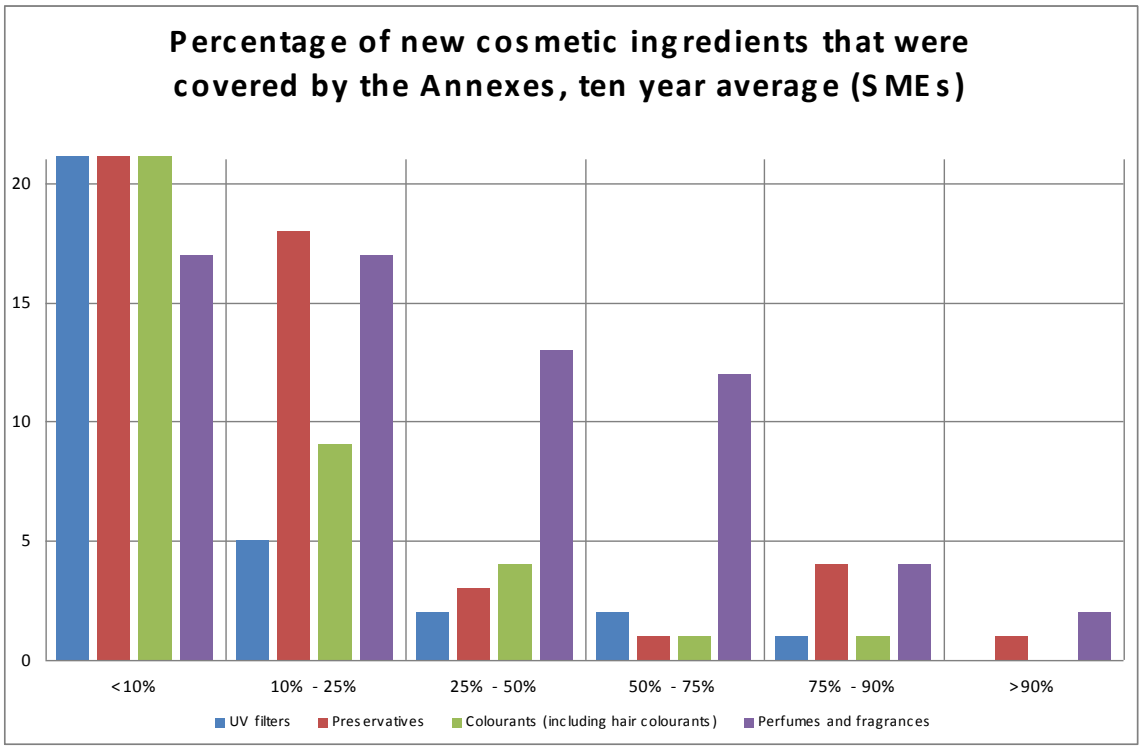
For large companies, the percentage of ingredients newly used in cosmetic products that are covered by the Annexes is shown in the chart below. The chart shows that, for several companies, less than 10% of new ingredients were covered by the Annexes. However, perfumes and fragrances, represented a higher proportion of new ingredients/raw materials.



Percentage of New Cosmetic Ingredients Covered by the Annexes – Large Companies						
Type of ingredient	**No. companies specifying percentage of new ingredients**					
	<10%	10% - 25%	25%-50%	50%-75%	75%-90%	>90%
UV filters	20	0	0	1	0	0
Preservatives	19	0	1	0	0	1
Colourants	16	0	3	1	0	0
Perfumes	5	0	1	2	4	3

SME cosmetics companies responding to the questionnaire on average introduced around 22 new ingredients each per year in the period 2000 to 2009. (The range was 0 to 370, but only 6 of the SMEs introduced more than 100 new ingredients per year). This represents around 4% of the total ingredient portfolio on average. It is not possible to derive the total number of new ingredients by multiplying the average by the number of companies, as each new ingredient is likely to be used by a number of companies. The average number of new ingredients introduced in 2010 by SME companies was around 26 (range: 0 to 370). This also represents around 4% of the total ingredient portfolio, and is not a significant change compared to the previous 10 years.

The percentage of ingredients newly used in cosmetic products by SMEs that are covered by the Annexes is shown in the chart below. The chart shows that, in most cases, between 0 and 10% of new ingredients were covered by the Annexes. However, for perfumes and fragrances, a higher proportion was covered by the Annexes.



Percentage of New Cosmetic Ingredients Covered by the Annexes – SMEs						
Type of ingredient	**No. companies specifying percentage of new ingredients**					
	<10%	10% - 25%	25%-50%	50%-75%	75%-90%	>90%
UV filters	49	5	2	2	1	0
Preservatives	39	18	3	1	4	1
Colourants	37	17	13	12	4	0
Perfumes	17	17	13	12	4	2

3.2.2. Do you consider that the number of **new INCI names** generated can give an indication of the amount of new substances?
(type of answer expected: yes/no and explanations)

While the number of new INCI names provides a broad indication of the number of new substances, not all substances nominated by ingredient suppliers to the list are widely used in cosmetic products in the EU. The number of ingredients/raw materials in companies' portfolios is far below what is seen in the Inventory, CosIng and the INCI lists. Only a proportion of ingredients on the INCI list meet the criteria for safety, performance and environmental impacts to an extent that allows for their widespread adoption by the industry.

3.2.3. Please provide information on how many of the new substances under 3.2.1. **were new to market (= not at all used before, also not in other sectors)**? Please differentiate the information for substances covered by the Annexes to the Cosmetics Directive and those that are not covered. *(type of answer expected: of the XXX new substances XXX were new to market and out of these XXX are covered by the Annexes)*

Most new ingredients used by cosmetics manufacturers are sourced from cosmetics ingredients suppliers. Cosmetics manufacturers do not therefore have detailed information on which of these ingredients are completely new and which have been used in other sectors.

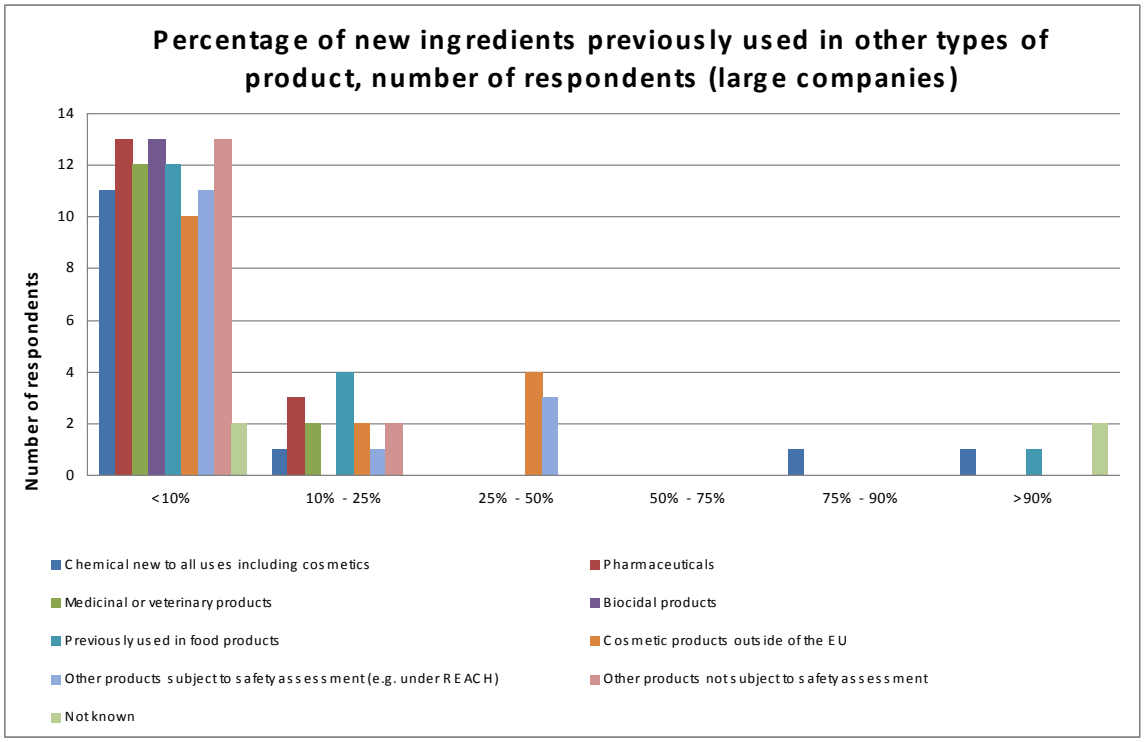
Based on the information available to them, **large** cosmetics manufacturers estimated that, on average, around 10% or less of the new ingredients used by large cosmetics manufacturers were new to market (i.e. have not previously been used in other product sectors). The response from SMEs was similar.

As noted in response to question 3.2.1, in most cases, less than 10% of new ingredients were covered by the Annexes. However, for perfumes and fragrances, a higher proportion was covered by the Annexes.

3.2.4. Please provide information on how many of the new substances under 3.2.1. were **new to the use in cosmetics** (= not used in cosmetics before, **but used in other sectors**)? Please differentiate the information for substances covered by the Annexes to the Cosmetics Directive and those that are not covered. *(type of answer expected: of the XXX new substances XXX were new to use in cosmetics and out of these XXX are covered by the Annexes)*

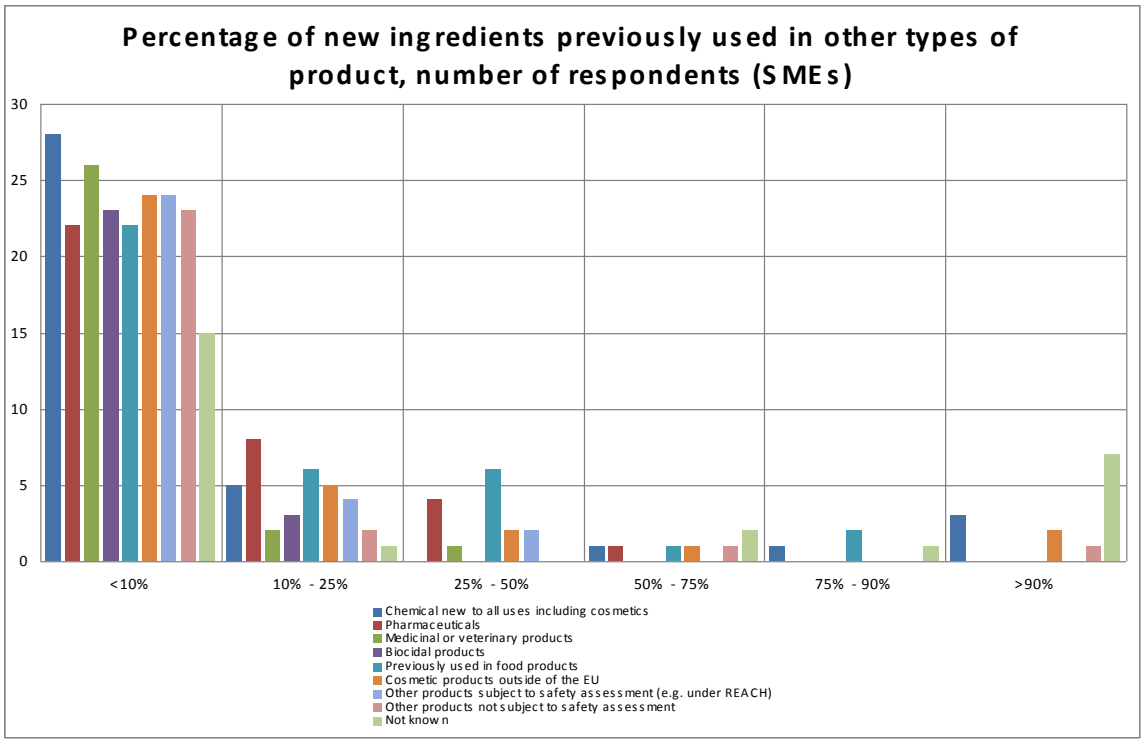
Most new ingredients used by cosmetics manufacturers are sourced from cosmetics ingredients suppliers. Cosmetics manufacturers do not therefore have comprehensive information on which of these ingredients are completely new and which have been used in other sectors.

Based on the information available to them, **large** cosmetics manufacturers estimated that, on average, more than 90% of the new ingredients they use have previously been used in other product sectors. The chart below shows in which sectors ingredients new to cosmetics products have previously been used.



Percentage of New Cosmetic Ingredients Previously used in Other Types of Product – Large Companies						
Type of product	**No. companies specifying percentage of new ingredients**					
	<10%	10% - 25%	25%-50%	50%-75%	75%-90%	>90%
Chemical new to all uses	11	1	0	0	1	1
Pharmaceuticals	12	2	0	0	0	0
Medicinal or veterinary	12	2	0	0	0	0
Biocidal	13	0	0	0	0	0
Food	12	3	0	0	0	0
Cosmetic producs outside the EU	10	2	4	0	0	0
Other products subject to safety assessment (e.g. REACH)	11	1	4	0	0	0
Other products not subject to safety assessment	11	1	3	0	0	0
Not known	2	0	0	0	0	2

Based on the information available to them, **SME** cosmetics producers also indicated that more than 90% of the new ingredients they use have previously been used in other product areas. Food products and pharmaceuticals were the most often-cited previous uses of ingredients new to cosmetics, as shown in the chart below.



Percentage of New Cosmetic Ingredients Previously used in Other Types of Product – SMEs						
Type of product	**No. companies specifying percentage of new ingredients**					
	<10%	10% - 25%	25%-50%	50%-75%	75%-90%	>90%
Chemical new to all uses	28	5	0	1	1	3
Pharmaceuticals	22	8	4	1	0	0
Medicinal or veterinary	26	2	1	0	0	0
Biocidal	23	3	0	0	0	0
Food	22	6	6	1	2	0
Cosmetic producs outside the EU	24	5	2	1	0	2
Other products subject to safety assessment (e.g. REACH)	24	4	2	0	0	0
Other products not subject to safety assessment	23	2	0	1	0	1
Not known	15	1	0	2	1	7

As noted in response to question 3.2.1, in most cases, less than 10% of new ingredients were covered by the Annexes. However, for perfumes and fragrances, a higher proportion was covered by the Annexes.

3.2.5. Please provide information on how many of the new substances under 3.2.1. added since 2000 are **used in several cosmetic products** and could be considered to be of **wide use in the cosmetics sector** (eg. a preservative is likely to be used in many different cosmetic products)? If total numbers are not available, please give examples of such substances and indications of the number of products they are used in. Please differentiate the information for substances covered by the Annexes to the Cosmetics Directive and those that are not covered. *(type of answer expected: of the XXX new substances XXX are of wide use because … and out of these XXX are covered by the Annexes)*

The majority of new ingredients are used initially in more than one product formulation by each company (75% for large companies, 60% for SMEs). The number of products in which a new ingredient is used will increase over time; within an individual company, a new ingredient may first be used in premium product lines, for example, then later extended to other product lines. Similarly, an ingredient may be used initially by a small number of cosmetic product manufacturers but then adopted by a wider range of product manufacturers if it proves successful (and, potentially, as the price reduces). Thus, over time, a new ingredient can become widely disseminated amongst product formulations.

Ingredients introduced under the Annexes, or assessed by SCCS are often submitted by one or several companies only but ultimately most are then used by all the companies, including SMEs. This can be illustrated by a recent example with the dossier prepared for TiO2 which is used by almost all the industry.

3.2.6. Please provide information on how many of the new substances under 3.2.1. **are multi-use substances**, meaning that they are **not exclusively used in cosmetics**

products (but also in other uses, eg. chemicals, food, biocides, etc.)? Please differentiate the information for substances covered by the Annexes to the Cosmetics Directive and those that are not covered. *(type of answer expected: out of the XXX new substances XXX are multi-use substances, out of these XXX are covered by the Annexes)*

See response to question 3.2.4

Impacts on Innovation Capability and Future Availability of Cosmetic Products

3.2.7. Please provide information on how many **different cosmetic products (= product formulations)** cosmetic companies offer. *(type of answer expected: total number of products, eg a large company offers XXX different cosmetics products, an SME offers XXX different cosmetic products)*

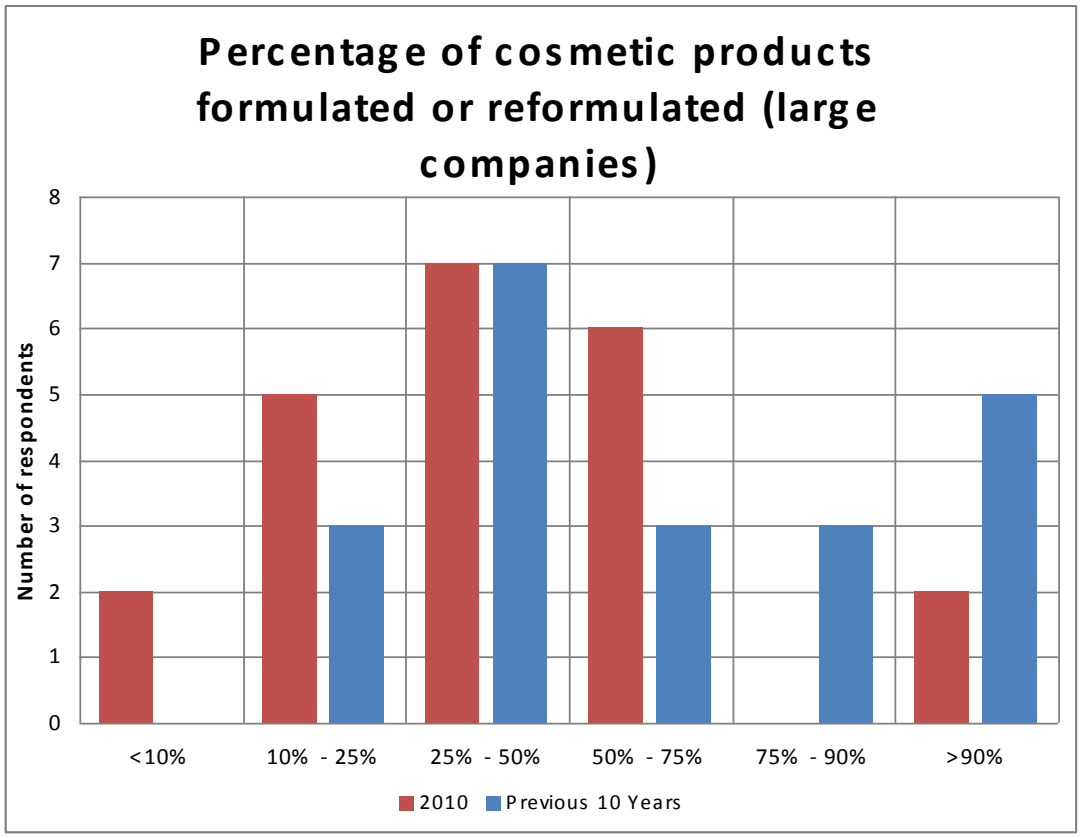
On average, a large company offers around 10,000 different product formulations (range: up to 20,000).

On average, an SME offers around 160 different product formulations

3.2.8. Please provide information on **how many new cosmetic products are added to the product portfolio** on average per year. Which **market value** do these new products represent in percentage compared with the total products? *(type of answer expected: total number of new products, eg a large company adds each year XXX new products, these represent X% of the total market value, an SME adds XXX new products, these represent X% of the market value)*

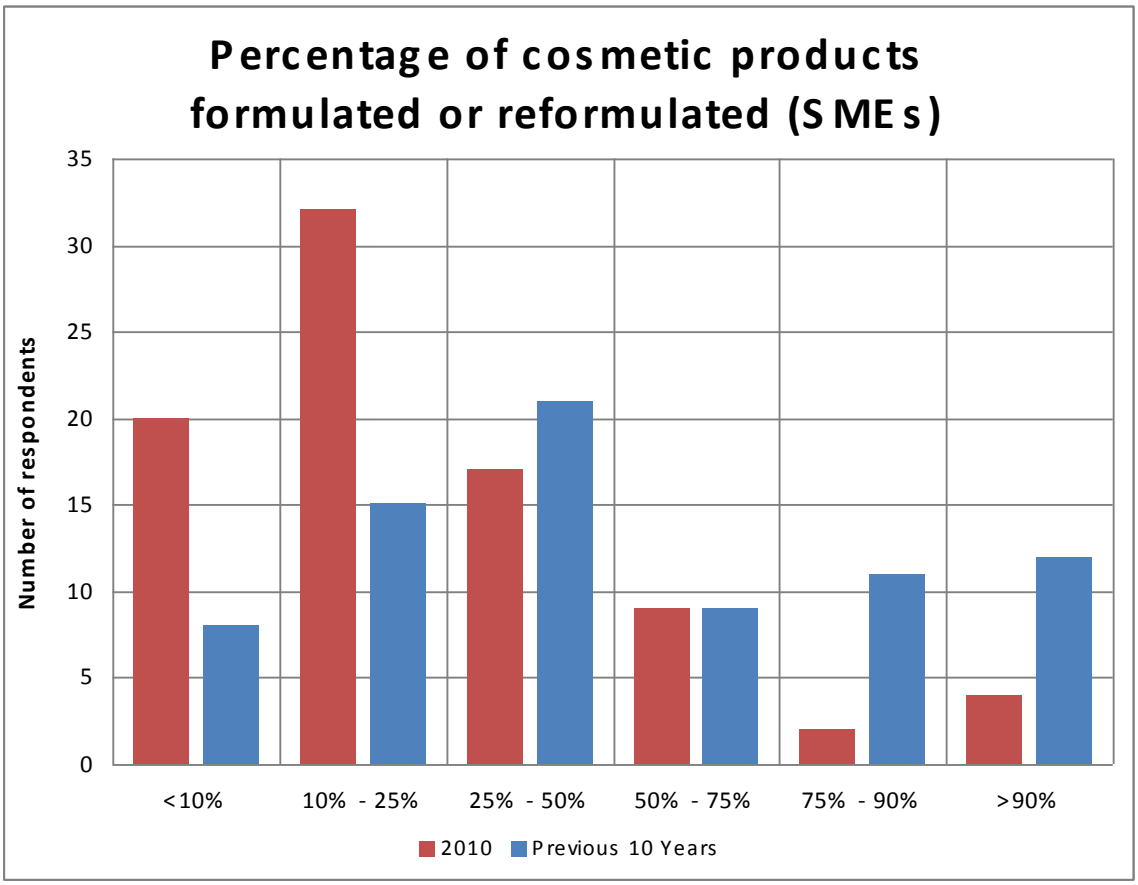
New cosmetic products comprise both new formulations and re-formulations of products. A high proportion of cosmetic products is formulated or re-formulated each year.

The chart below illustrates the percentage of the number of companies that newly- or re-formulate different percentages of their products each year. Most companies newly- or re-formulate over 25% and some companies over 90% each year. It is not possible to specify precisely the percentage of total market value represented by new- or re-formulations as this is confidential business information.



Percentage of new Cosmetics Products Formulated or Reformulated Each Year – Large Companies						
Time	**No. companies specifying percentage of products (re)formulated**					
	<10%	10% - 25%	25%-50%	50%-75%	75%-90%	>90%
2010	2	5	7	6	0	2
Previous years	0	3	7	3	3	5

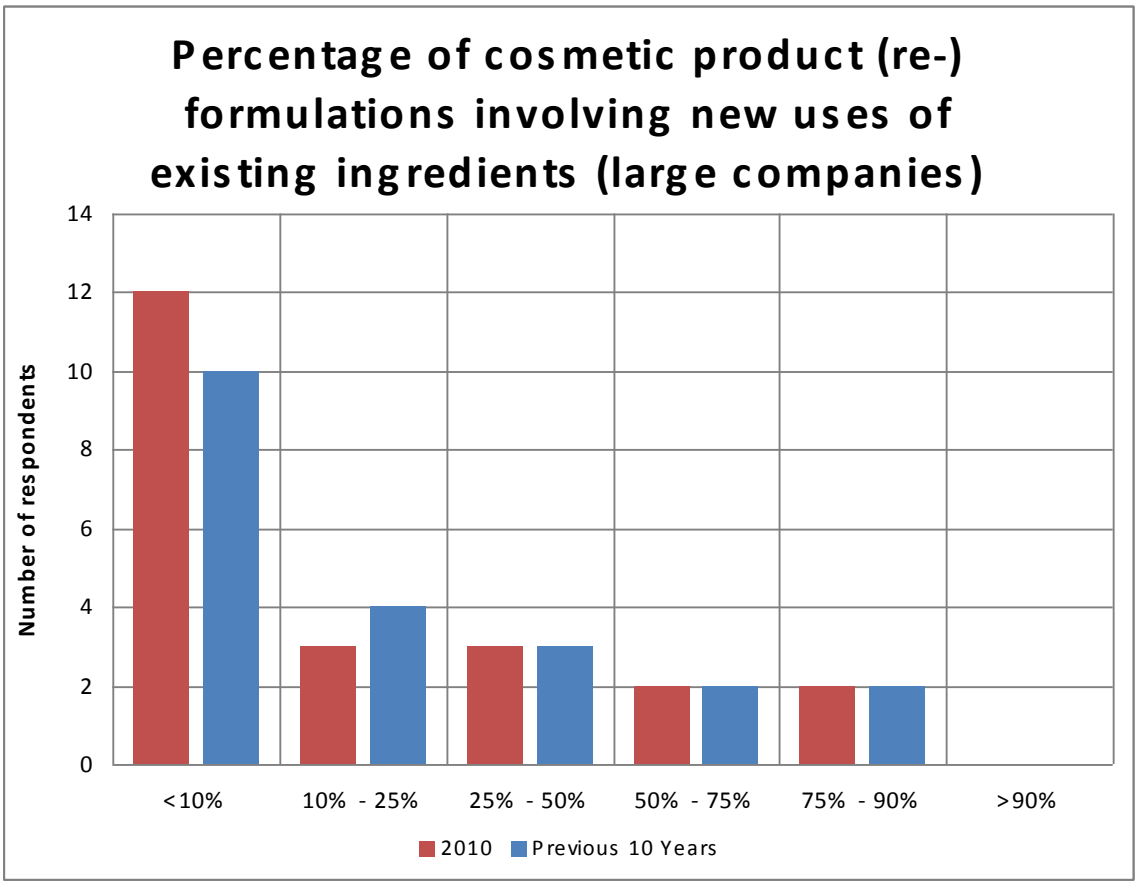
Most SMEs newly- or re-formulate less than 50% of their product formulations each year but a small percentage (nearly 8% of companies responding to this question) newly- or re-formulated over 90% of their product formulations in 2010 and 24% had newly- or re-formulated over 90% of their product formulations in 2000-2009.



Percentage of Cosmetics Products Newly Formulated or Reformulated Each Year – SMEs						
Time	**No. companies specifying percentage of products (re)formulated**					
	<10%	10% - 25%	25%-50%	50%-75%	75%-90%	>90%
2010	20	32	17	9	2	4
Previous years	8	15	21	9	11	12

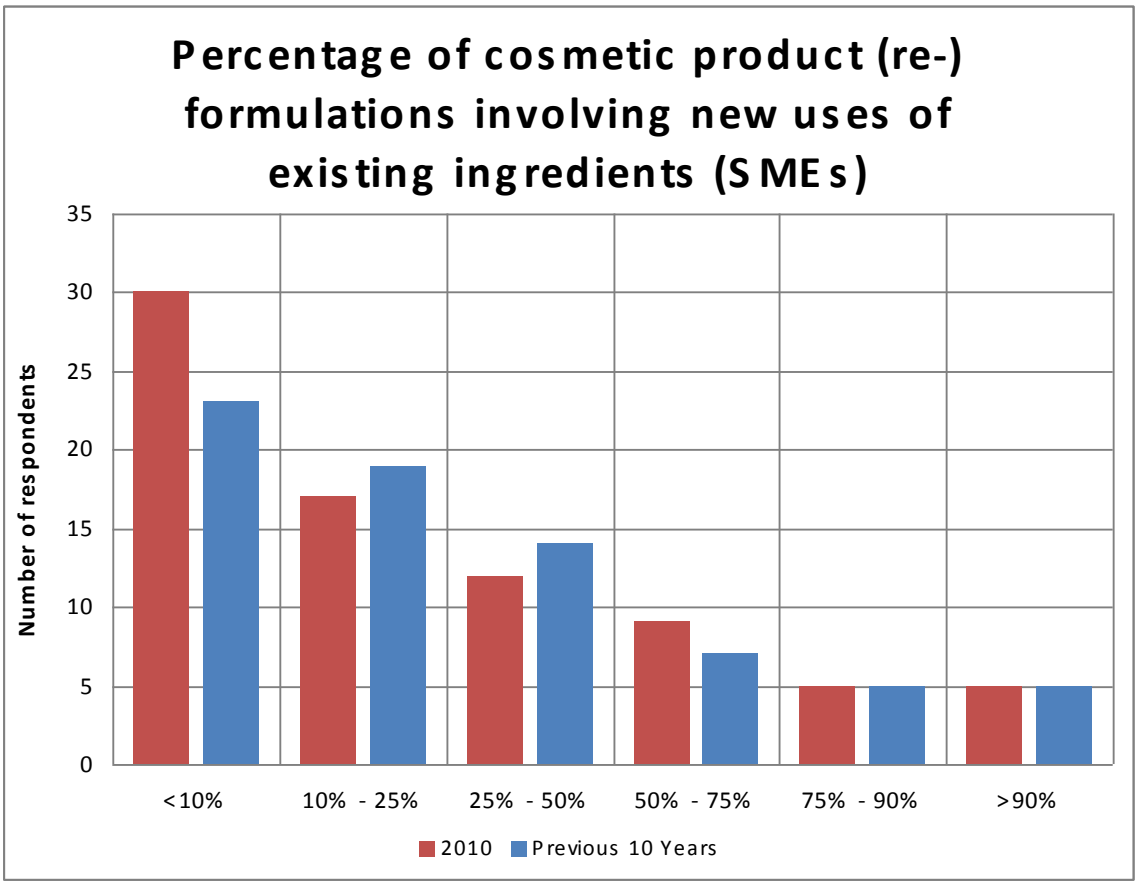
3.2.9. Please provide information on **how many of the new products under 3.2.8. are reformulations**, thus rely on substances already in use for cosmetics by the manufacturer? *(type of answer expected: out of the XXX new products XXX are reformulations)*

In 2010 half of the large manufacturers, (re)formulations relying on new uses of substances already in use for cosmetics accounted for less than 10% of the total, For the other companies the proportion was much higher (see response to question 3.2.10). The chart below shows the proportion of new- or re-formulations by large companies that involve novel uses of existing ingredients. For one company re-reformulations including novel uses of existing ingredients account for between 75% and 90% of all reformulations.



Percentage of New Cosmetics product (Re)-Formulations involving New Uses of Existing Ingredients – Large Companies						
Time	**No. companies specifying percentage of new uses of existing ingredients**					
	<10%	10% - 25%	25%-50%	50%-75%	75%-90%	>90%
2010	9	6	3	1	1	0
Previous years	10	5	3	1	1	0

In 2010, for 37% of SMEs, less than 10% of re-formulations involved the novel use of existing ingredients. However, for others, this could be as high as 90% (13% of respondents).

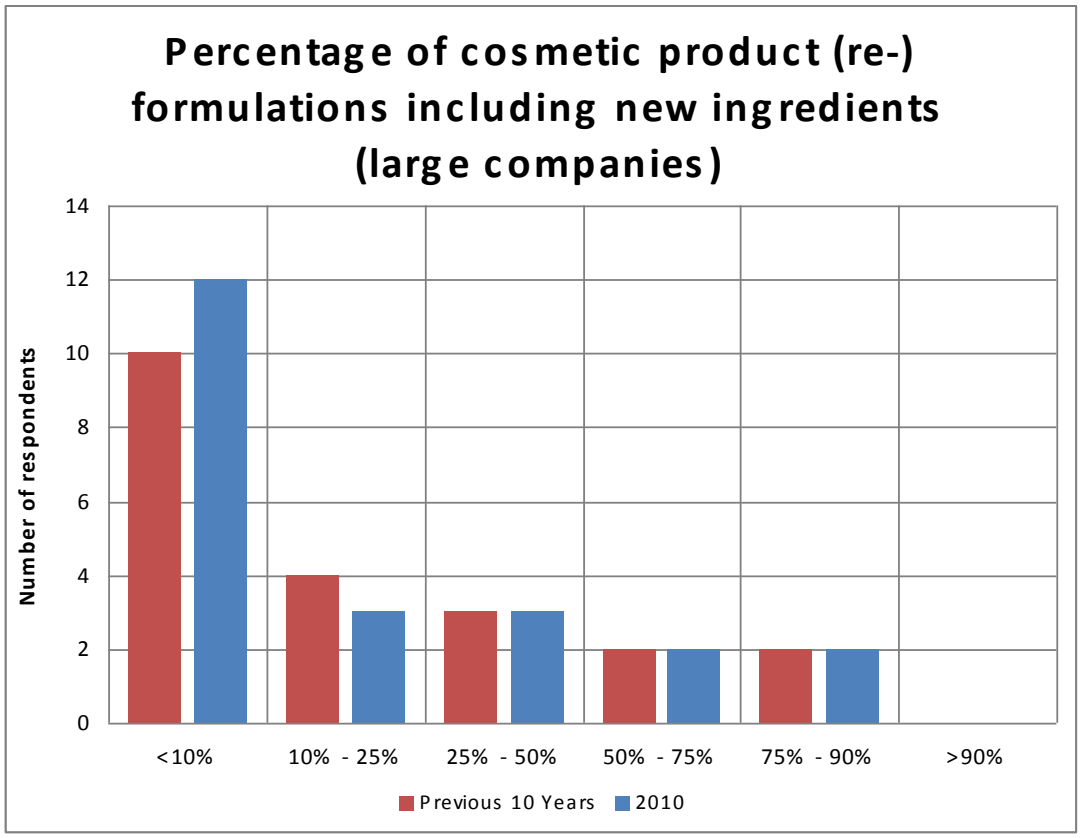


Percentage of New Cosmetics product (Re)-Formulations involving New Uses of Existing Ingredients – SMEs						
Time	**No. companies specifying percentage of new uses of existing ingredients**					
	<10%	10% - 25%	25%-50%	50%-75%	75%-90%	>90%
2010	28	13	9	9	7	10
Previous years	21	16	5	8	12	6

3.2.10. Please provide information on how many of the **new products under 3.2.8. rely on new to the market substances** (= not at all used before, also not in other sectors)?

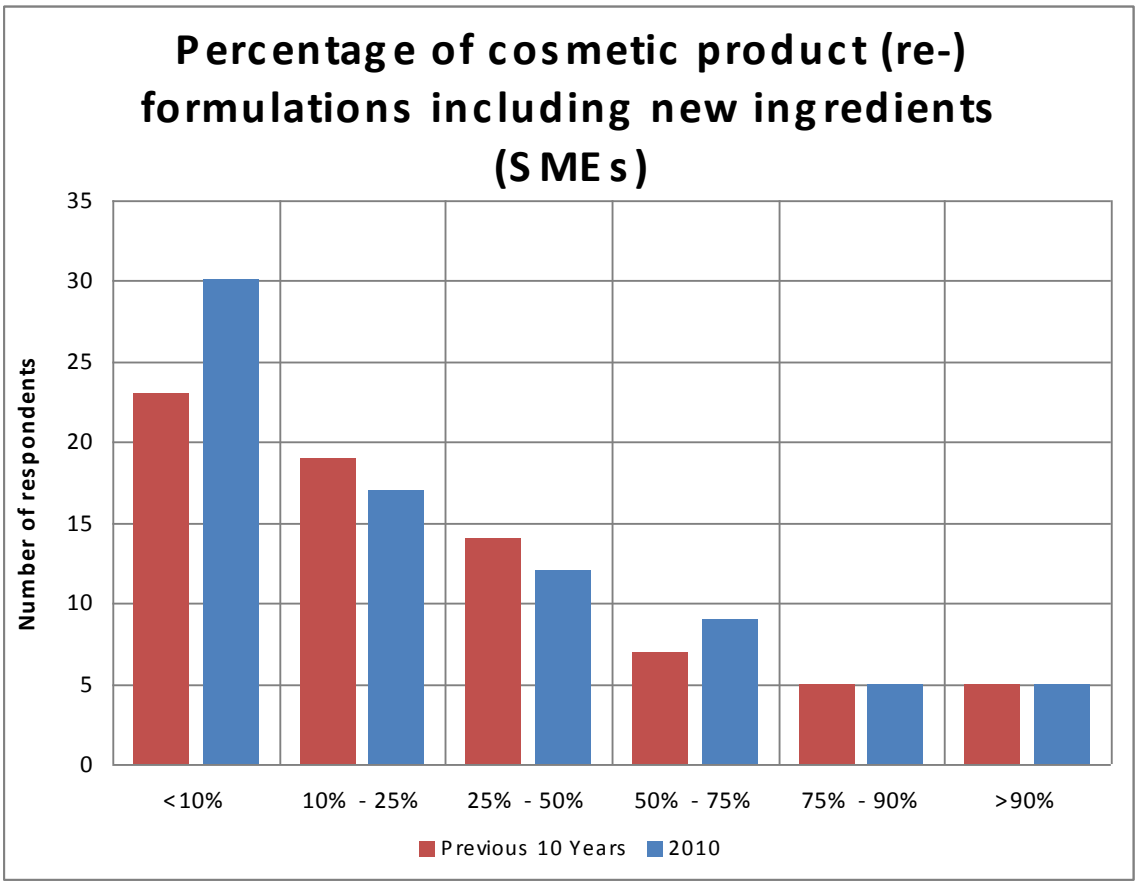
(type of answer expected: of the XXX new product XXX are relying on new to market substances, eg. for an SME XXX products rely on new to market substances, these represent X% of the total market value)

The chart below shows the proportion of new- or re-formulations by large companies that use new ingredients. In 2010 for 12 companies, these comprise less than 10% of total new- or re-formulations, but for 10 companies the proportion is much higher. As noted in response to question 3.2.5, a new ingredient may be used initially in a small proportion of formulations and then extended to further formulations over time.



Percentage of Cosmetics product New- or Re-Formulations involving New Ingredients – Large Companies						
Time	**No. companies specifying percentage of new ingredients**					
	<10%	10% - 25%	25%-50%	50%-75%	75%-90%	>90%
2010	12	3	3	2	2	0
Previous years	10	4	3	2	2	0

The chart below shows the proportion of new- or re-formulations by SMEs that use new ingredients. In 2010 for 30 SMEs, these comprise less than 10% of total (re)formulations, but for 48 companies the proportion ranges from 10 to 90% of (re)formulations. As noted in response to question 3.2.5, a new ingredient may be used initially in a small proportion of formulations and then extended to further formulations over time.



Percentage of Cosmetics product New- or Re-**Formulations involving New Ingredients – SMEs**						
Time	**No. companies specifying percentage of new ingredients**					
	<10%	10% - 25%	25%-50%	50%-75%	75%-90%	>90%
2010	30	17	12	9	5	5
Previous years	23	19	14	7	5	5

It can be concluded that as a general rule most cosmetics companies including SMEs rely on new ingredients for new products , alongside innovating formulations based on new uses of existing ingredients.

Which **market value** do these products represent in percentage compared with the total products?

It is not possible to specify precisely the percentage of total market value represented by new- or re-formulations containing new ingredients, as this is confidential business information. However, it is likely to be equivalent or superior to at least the same percentage as the products newly- or re-formulated – i.e. for companies where 50% of (re)formulations contain new ingredients, these would represent over 50% of total market value.

New cosmetic ingredients are also significant to cosmetic manufacturers that also develop their own ingredients; 67% of large companies responding to the questionnaire

who also manufacture ingredients said new ingredients were very significant to profitability..

More than half of the responding SMEs indicated that (re)formulated products in total accounted for less than 10% of their turnover. However, for one group of respondents (nearly 20%), (re)formulated products accounted for over 50% of turnover.

3.2.11. How many of these new products under 3.2.8. **rely on new to the cosmetics market** (= not used in cosmetics before, **but used in other sectors**) **substances?** *(type of answer expected: of the XXX new products XXX rely on new to cosmetics market substances, these represent X% of the total market value)*

As noted in response to question 3.2.4, most new ingredients used by cosmetics manufacturers are sourced from cosmetics ingredients suppliers. Cosmetics manufacturers do not therefore have detailed information on which of these ingredients are completely new and which have been used in other sectors.

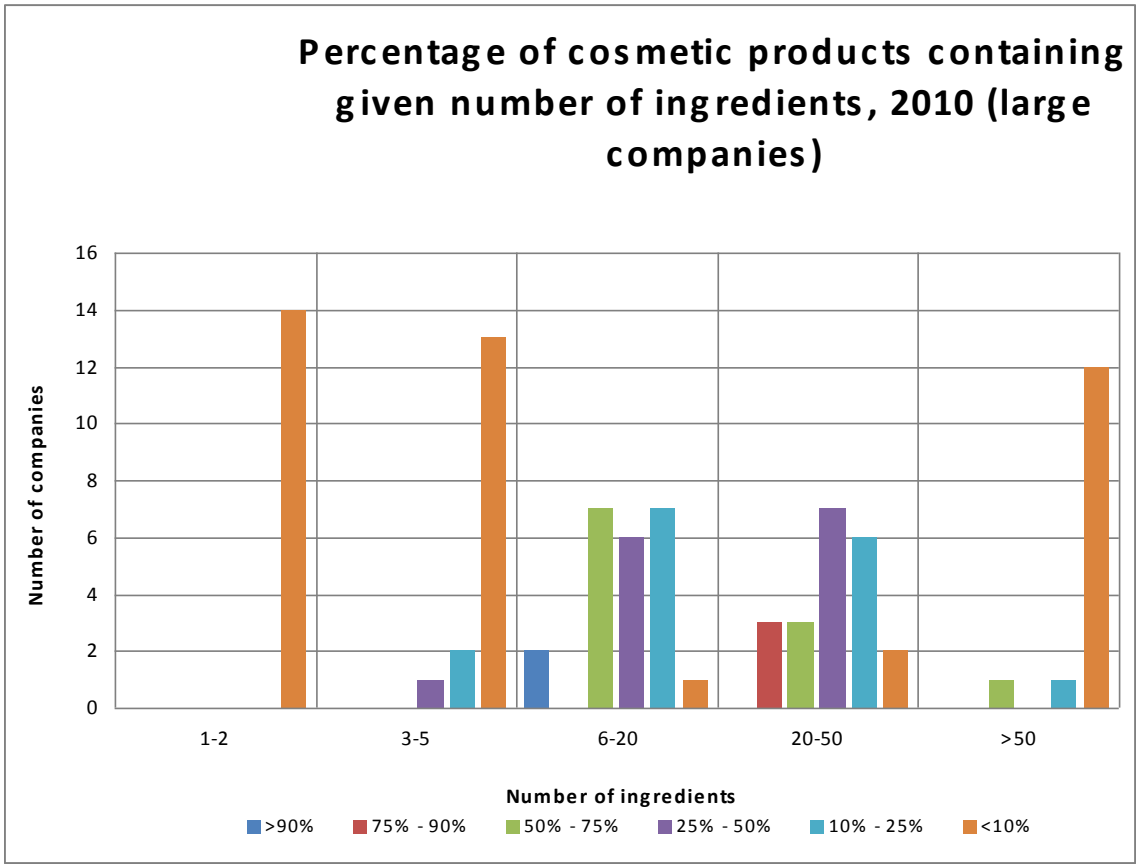
37% of SMEs and 21% of large companies use totally new ingredients .However, on average, less than 10% of the new ingredients used by large cosmetics manufacturers have previously been used in other product sectors, so it can be concluded that they are new and intended for several sectors, although not yet used. It is not possible to say what proportion of (re)formulations involving new ingredients rely on ingredients new to the cosmetics market but used in other sectors,

Which **market value** do these products represent in percentage compared with the total products?

It is not possible to specify precisely the percentage of total market value represented by (re)formulations containing ingredients new to cosmetic but previously used in other products., However, it is likely to be equivalent to at least the same percentage as the products newly- or re-formulated.

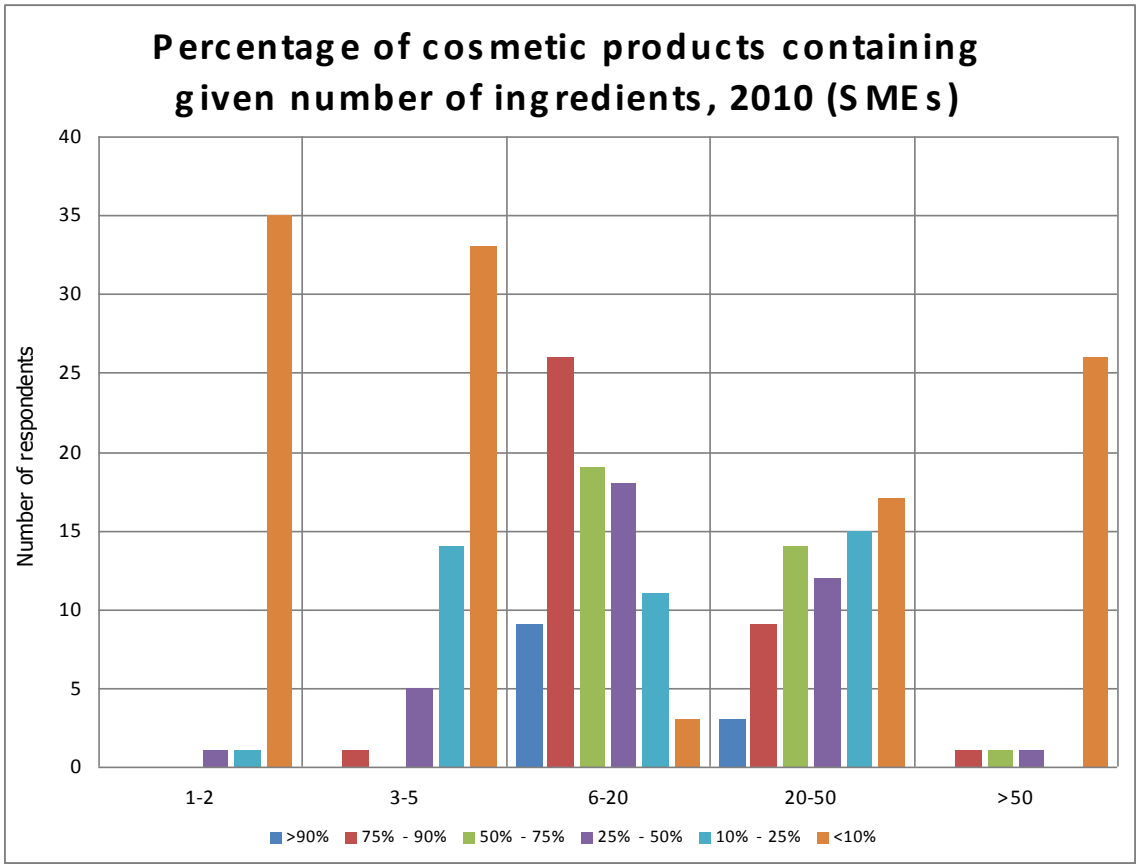
3.2.12. Please provide information on the **size of the ingredients portfolio** (total numbers of ingredients used) and of the **combination of ingredients portfolio** (= combinations of ingredients include several substances)? *(type of answer expected: total number of ingredients, eg a large company uses XXX different cosmetics ingredients)*

The average number of ingredients in the portfolio of a large cosmetics manufacturer is 2,000. Information on the number of ingredients per product is given in the chart below. Products generally contain between 6 and 50 ingredients, with only one company indicating that the majority of its products contained over 50 ingredients.



Average Number of Ingredients in Cosmetics Products – Large Companies						
Number of ingredients	**No. companies specifying percentage of ingredients**					
	<10%	10% - 25%	25%-50%	50%-75%	75%-90%	>90%
1-2	14	0	0	0	0	0
3-5	13	2	1	0	0	0
6-20	1	6	6	7	3	3
20-50	2	9	7	3	3	0
>50	12	1	0	1	0	0

The average number of ingredients in the portfolio of a SME cosmetics manufacturer is around 600. SME company products also generally contain between 6 and 50 ingredients.



Average Number of Ingredients in Cosmetics Products – SMEs						
Number of ingredients	**No. companies specifying percentage of ingredients**					
	<10%	10% - 25%	25%-50%	50%-75%	75%-90%	>90%
1-2	35	1	1	0	0	0
3-5	33	14	5	0	1	0
6-20	3	11	18	19	26	9
20-50	17	15	12	14	9	3
>50	26	0	1	1	1	0

3.2.13. Please provide information on how **many new ingredients and combinations of ingredients are added** to an ingredient portfolio per year? *(type of answer expected: SME adds XXX new ingredients per year)*

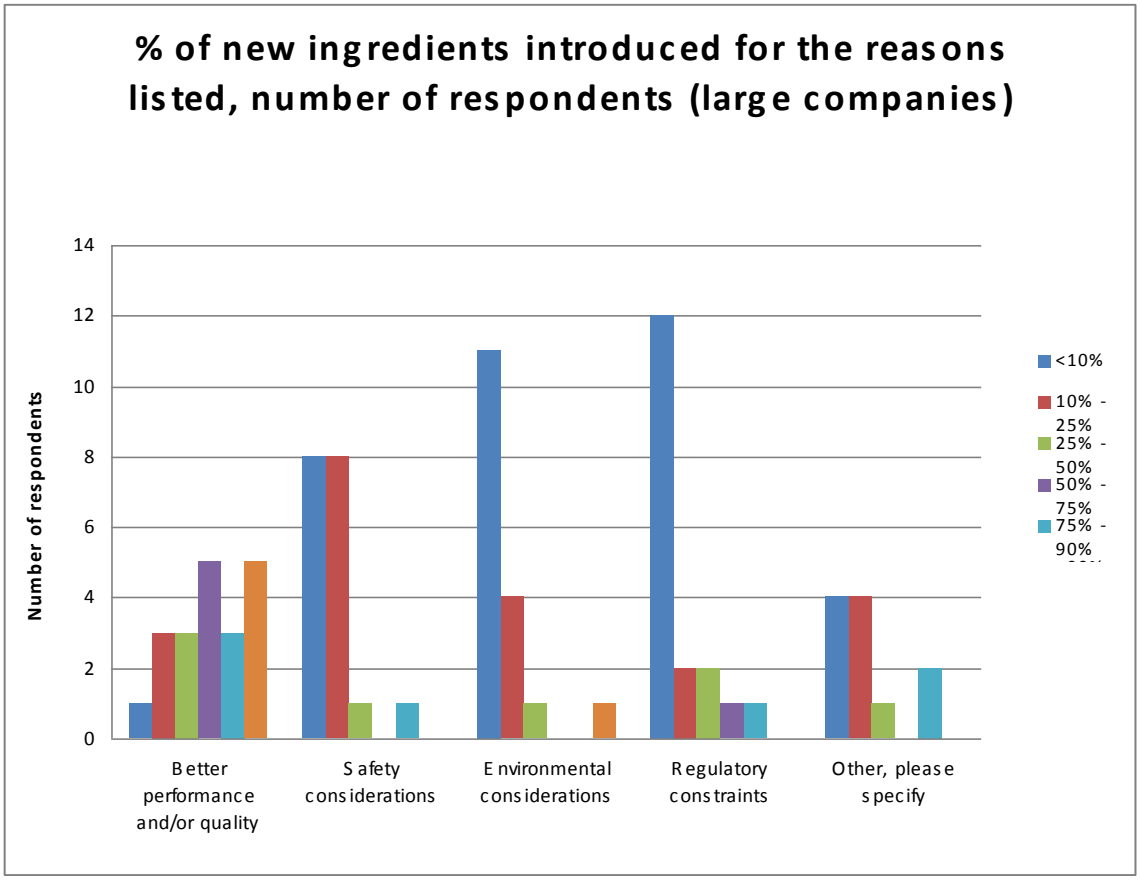
On average, large cosmetic manufacturers indicated that they each introduced 60 new ingredients to their portfolio in 2010 (see also 3.2.1). These new ingredients are sourced mainly from cosmetic ingredient manufacturers and may come from a number of different suppliers. The same new ingredients may have been added to the portfolios of a number of different cosmetics manufacturers, so it is not possible to determine the total number of new ingredients adopted each year. One new ingredient may be present in a large number of raw materials (new combinations of ingredients) which are offered to cosmetics manufacturers

3.2.14. What are the **main reasons for introducing new ingredients and combinations of ingredients** into the portfolio?

a) Better performance and/or quality
b) Safety considerations
c) Environmental considerations
d) Regulatory constraints
e) Other, please specify

(type of answer expected: in XX% the reason is a) in XX% the reason is b) etc.)

The chart below sets out the percentage of new ingredients introduced for different purposes by large companies.

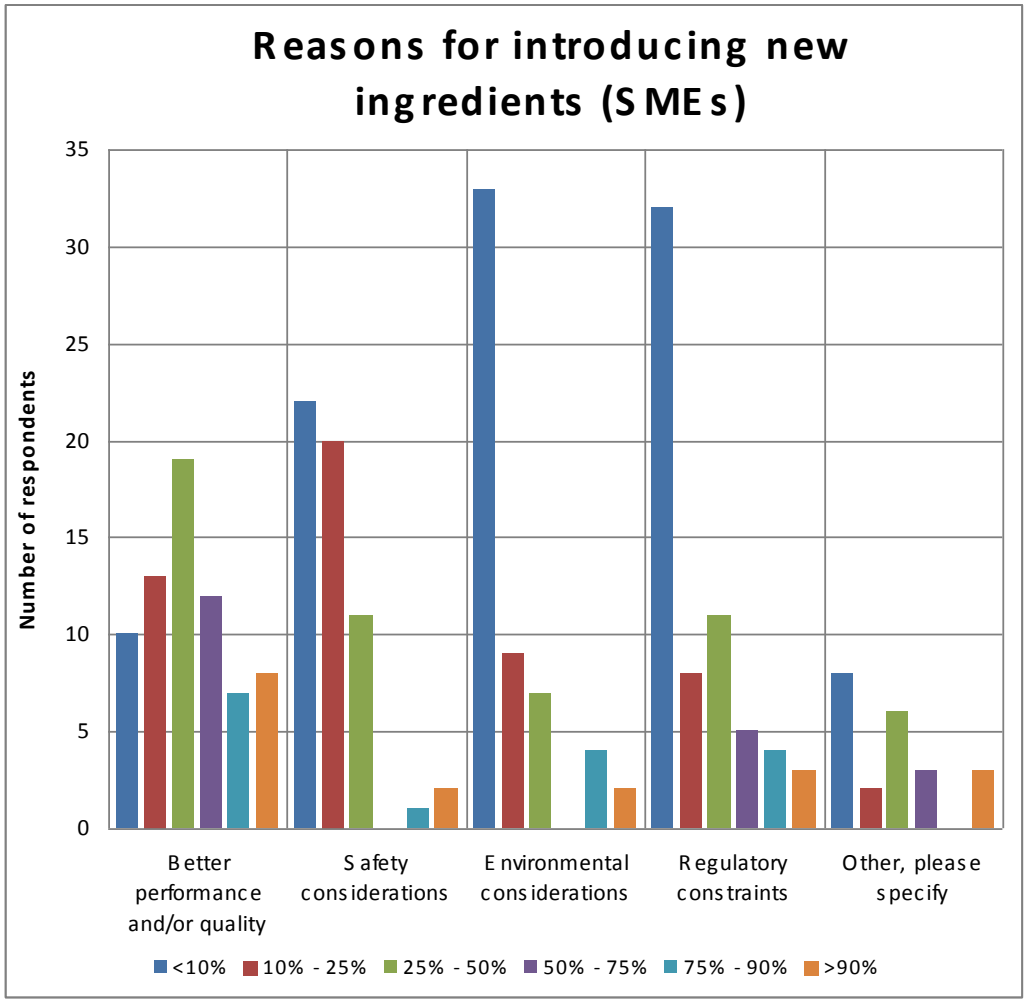


Reasons for Addition of New Ingredients to the Portfolio in Last 10 Years – Large Companies						
Reason	**No. companies specifying percentage of each reason**					
	<10%	10% - 25%	25%-50%	50%-75%	75%-90%	>90%
Better performance	1	2	3	5	3	5
Safety considerations	8	8	1	0	1	0
Environmental considerations	11	4	1	0	0	1
Regulatory constraints	12	2	2	1	1	0
Other	4	4	1	0	2	0

The most widely-given reason for introducing new ingredients by large companies was to provide better performance and/or quality products (e.g. anti-ageing properties; more natural; biological/organic; new categories (e.g. sprays); better tolerance (less susceptible to induce allergy)). Most companies indicated that this reason accounted for over 50% of reformulations. However, environmental and safety considerations were also important.

The other reasons given for introducing new ingredients included:

- cost savings
- introduction of changes in advance or in anticipation of regulatory changes
- product innovation
- to allow local purchasing
- in response to a market or customer request
- global harmonisation of formulations
- improvement of product aesthetics.



Reasons for Addition of New Ingredients to the Portfolio in Last 10 Years – SMEs						
Reason	**No. companies specifying percentage of each reason**					
	<10%	10% - 25%	25%-50%	50%-75%	75%-90%	>90%
Better performance	10	13	19	12	7	8
Safety considerations	22	20	11	0	1	2
Environmental considerations	33	9	7	0	4	2
Regulatory constraints	32	8	11	5	4	3
Other	8	2	6	3	0	3

The most widely-given reason for introducing new ingredients by SMEs was also to provide better performance and/or quality products (i.e. to meet customer needs), with nearly half the responding companies indicating that this reason accounted for over 50% of reformulations. However, regulatory requirements were a more important reason than for large companies, with nearly a quarter of companies saying that this accounted for more than 50% of new ingredient introductions.

3.2.15. Please indicate in terms of percentage of the total number of new ingredients and combinations of ingredients **which are the main supply sources**:

a) SME's specialized in cosmetics supplies
b) SME's not specialized
c) Large suppliers
d) Own R&D

(type of answer expected: XX% the total of new substances are sourced from a),…)

Companies were unable to respond to this question, for reasons of business confidentiality. However, in relation to own R&D, 60% of large companies produce some cosmetic ingredients themselves, each of these introduced between 1 and 5 new ingredients in 2010. Furthermore, companies indicated that SME suppliers were particularly important for the provision of new ingredients, and for innovation in the development of new ingredients. New raw materials are largely perfume compositions, but others improve performance in response to consumer demands: anti-ageing properties; more natural; biological/organic; new categories (e.g. sprays); better tolerance (less susceptible to induce allergy); and better ecological profile, as well as to replace ingredients discarded for regulatory or safety reasons.

3.2.16. Please provide information on how **many ingredients and combinations of ingredients are eliminated from** a substance portfolio per year?

(type of answer expected: SME eliminates XXX substances per year)

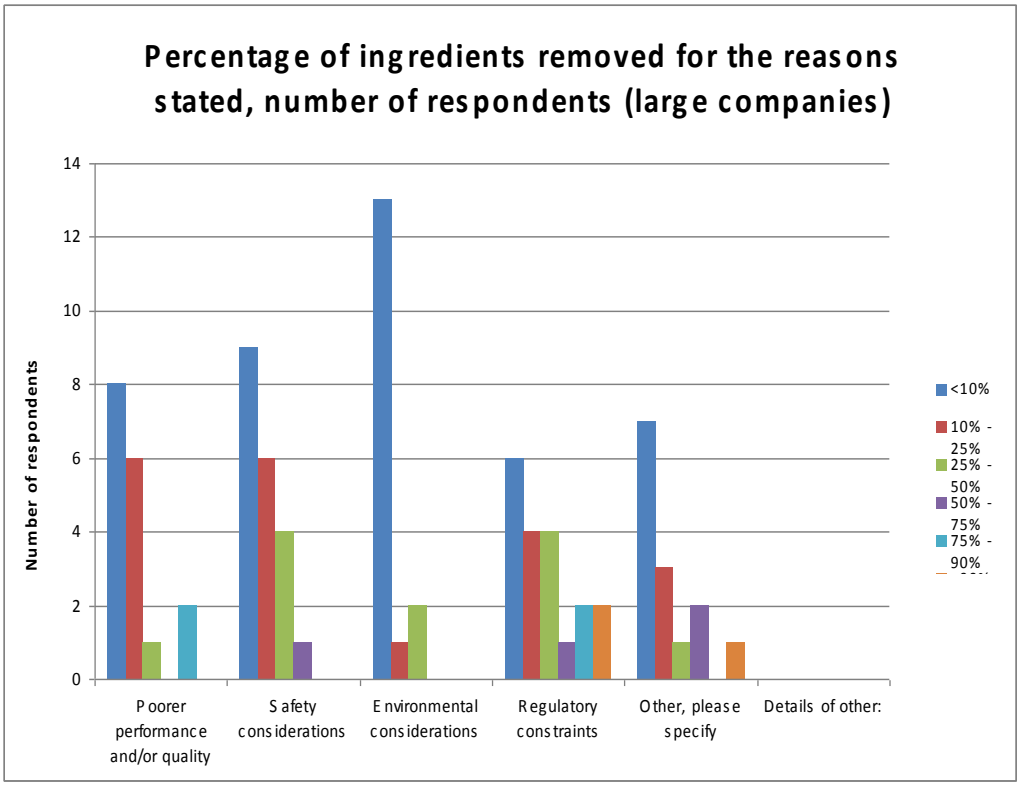
On average, large companies removed 120 ingredients from their portfolios and SMEs removed 10 ingredients from their portfolios in 2010. This compares to annual average numbers removed over the previous 10 years of 24 for large companies and 6 for SMEs. The same ingredients may have been removed from the portfolios of a number of different cosmetics manufacturers, so it is not possible to determine the total number of ingredients removed each year.

3.2.17. What are the **main reasons for eliminating ingredients and combinations of ingredients** from the portfolio?

a) Better performance and/or quality
b) Safety considerations
c) Environmental considerations
d) Regulatory constraints
e) Other, please specify

(type of answer expected: in XX% the reason is a) in XX% the reason is b) etc.)

The chart below shows the reasons why large companies removed ingredients from their portfolios.



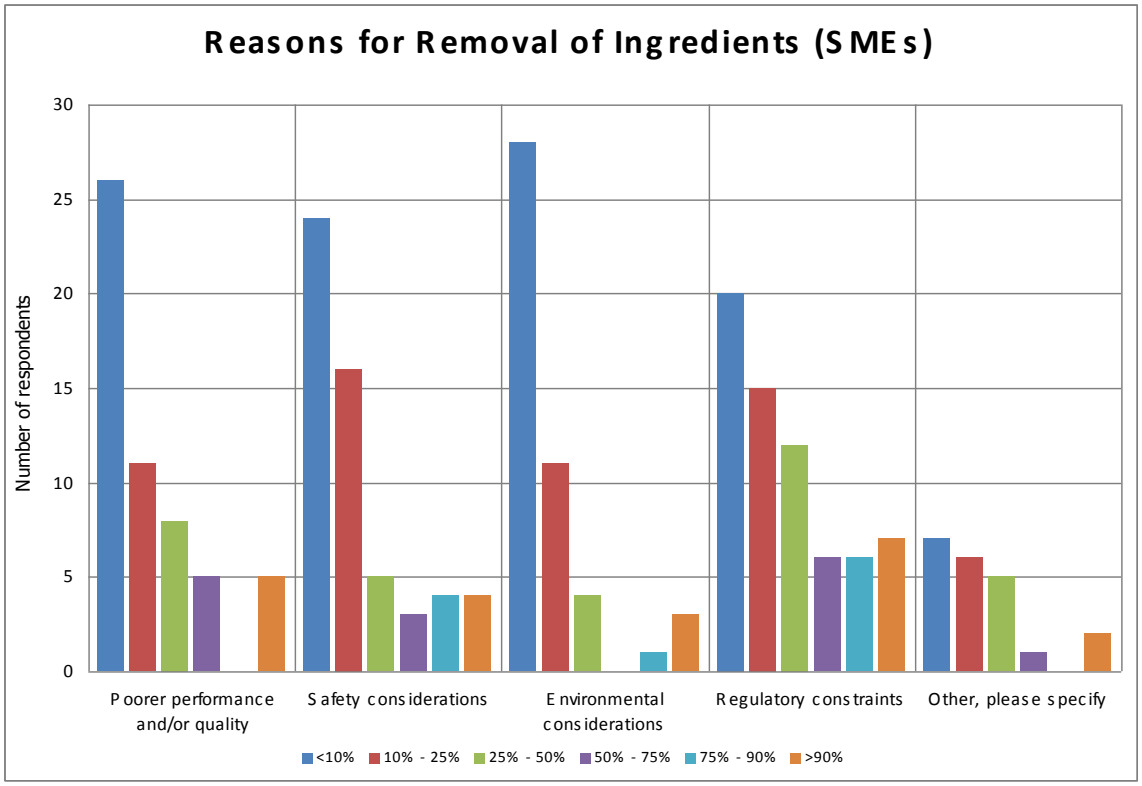
Reasons for Removal of Ingredients from the Portfolio in Last 10 Years – Large Companies						
Reason	**No. companies specifying percentage of each reason**					
	<10%	10% - 25%	25%-50%	50%-75%	75%-90%	>90%
Poorer performance	8	6	1	0	2	0
Safety considerations	9	6	4	1	0	0
Environmental considerations	13	1	2	0	0	0
Regulatory constraints	6	4	4	1	2	2
Other	7	3	1	2	0	1

The chart indicates that the most important driver for the removal of ingredients by **large companies** is regulatory constraints, with over half of the respondents indicating that this accounted for more than 25% of total removals of ingredients. Safety considerations and poor performance and/or quality were also important reasons for removal of ingredients.

The other reasons given for removal of ingredients included:

- to improve or increase product claims
- introduction of changes in advance or in anticipation of regulatory changes
- global harmonisation of formulations
- in response to negative PR
- in response to market forces
- reducing complexity of formulations
- discontinuation of supply
- to adjust to the portfolio of new acquisitions

Regulatory constraints were also the most common driver for **SMEs** to remove ingredients from their portfolios, with 14% of respondents indicating that this accounted for over 90% of removals, followed by poorer performance and/or quality.



Reasons for Removal of Ingredients from the Portfolio in Last 10 Years – SMEs						
Reason	**No. companies specifying percentage of each reason**					
	<10%	10% - 25%	25%-50%	50%-75%	75%-90%	>90%
Poorer performance	26	11	8	5	0	5
Safety considerations	24	16	5	3	4	4
Environmental considerations	28	11	4	0	1	3
Regulatory constraints	20	15	12	6	6	7
Other	7	6	5	1	0	2

3.2.18. Please provide information on the **likely number of new to market substances used in cosmetics** (= not at all used before, also not in other sectors) in the **coming 10 years**? Which **market value** do you expect to depend on these substances?

(type of answer expected: expect XXX new to market substances in next10 years)

As noted in response to question 3.2.1, large cosmetics companies have on average introduced 70 new ingredients per year over the past 10 years and SMEs on average 22 new ingredients per year. On the basis of information available to them (see response to question 3.2.3), cosmetics manufacturers consider that less than 10% of these new ingredients are 'new to market' (i.e. have not been used in other sectors).

Companies were not able to specify the likely number of new to market substances/ingredients used in cosmetics in the coming 10 years as most cosmetic manufacturers obtain new substances from cosmetic ingredients suppliers. However, they were able to indicate whether they considered that number of new to market substances will be likely to change in future. The answer to this question will depend upon the nature of the test ban. Therefore, this question has been answered based on three different assumptions:

- Assumption A: animal tests performed for other purposes than meeting the requirements of the EU cosmetics legislation do not trigger the ban and you can subsequently rely on these test data for cosmetic purposes in the EU provided these test were for non cosmetic purposes but in addition you can also rely on test data developed for cosmetic purposes outside the EU.
- Assumption B: animal tests performed for other purposes than meeting the requirements of the EU cosmetics legislation do not trigger the ban and you can subsequently rely on these test data for cosmetic purposes in the EU provided these test were for non cosmetic purposes.
- Assumption C: animal tests performed for other purposes than meeting the requirements of the EU cosmetics legislation do not trigger the ban, but you can never rely on these data.

The tabel below shows how many **large companies** expect the number of ingredients available to change under each of the scenarios. All expected the number of ingredients available to **reduce**.

Large Company Expectations about Future Ingredient Availability

Expectation of Change	Assumption A	Assumption B	Assumption C
Yes	12	19	22
No	11	4	1

Most large companies expect the number of ingredients available in the EU to change under both assumptions B and C, with almost all large companies expecting the number to reduce under assumption C. Under assumption A, there is less agreement on whether the number of ingredients will change or not. Outside the EU, it is unlikely that the number of ingredients will go down, thus innovation will continue globally, but the EU will fall behind (see response to question 4.5).

Most SMEs also expect the ban to result in a reduction in the number of ingredients available in the next five years.

Which **market value** do you expect to depend on these substances?

It is not possible to specify precisely the percentage of total future market value that would be associated with new ingredients. However, it is expected that a significant reduction in the number of new ingredients available in the EU will lead to a loss of products and consequently have a very serious impact on EU market value.

Some companies have given examples on the market value represented by the introduction of new ingredients for which "2013 endpoints" tests had to be generated in order to go on the EU market .This loss of potential profitability could be used as an illustration .The Commission could get access though RPA under confidentiality ie no public disclosure .

3.2.19 Please provide information on the **likely number of new to cosmetics sector** substances (= not used in cosmetics before, **but used in other sectors**) **in the coming 10 years**?

(type of answer expected: expect XXX new to cosmetic sector substances in next 10 years)

As noted in response to question 3.2.1, large cosmetics companies have on average introduced 70 new ingredients per year over the past 10 years and SMEs on average 22 new ingredients per year. On the basis of information available to them (see response to question 3.2.4), cosmetics manufacturers consider that around 90% of these new ingredients have been/will be used in other sectors.

Companies are not able to specify how many substances new to the cosmetics sector but previously used in other sectors will be introduced over the next 10 years, as most substances new to the cosmetics sector are provided by cosmetic ingredients suppliers. However, most expect the number of ingredients available in the EU to reduce dramatically, especially under assumptions B and C

Which **market value** do you expect to depend on these substances?

It is not possible to specify precisely the percentage of total future market value that would be associated with new ingredients. However, it is expected that a significant reduction in the number of new ingredients available in the EU would lead to loss of products and consequently have a very serious impact on EU market value. For example,

one cosmetics manufacturer gave the example of a superior skin moisturisation ingredient which had been introduced. Four different formulations were launched in the EU using technology based on this ingredient and, since it clearly met a consumer demand, this resulted in very significant growth for the brand.

Some companies have given examples on the market value represented by the introduction of new ingredients for which "2013 endpoints" tests had to be generated in order to go on the EU market .This loss of potential profitability could be used as an illustration .The Commission could get access though RPA under confidentiality ie no public disclosure .

3.2.20 Please provide information on **how many substances are likely to be submitted for inclusion into the Annexes** III, IV, VI and VII to the Cosmetics Directive (respectively then Cosmetics Regulation) in the coming 10 years?

(type of answer expected: expect XXX new substances for the Annexes in next 10 years)

Companies are not able to specify how many substances are likely to be submitted for inclusion in Annexes III, IV and VII over the next 10 years.

Under Assumption A, substances may be submitted for these Annexes providing that the applicant had necessary test data that had been generated to satisfy non-cosmetics EU legislation or to satisfy non-EU legislation. However, this would rely on the SCCS not requesting additional in vivo data..

Under Assumption B, substances may be submitted for these Annexes providing that the applicant had necessary test data that had been generated to satisfy non-cosmetics EU legislation. However, this would rely on the SCCS not requesting additional in vivo data.

Under Assumption C, it would be unlikely that any substances would be submitted for any of these annexes, although data is likely to be available to address cosmetic safety obligations outside the EU.

3.2.21 Please provide information on **which sector is likely to be most prone to innovation and use of new substances** (the sector grouping is the one used in Global Insights, see A, with the addition of hair colorants and sun protection products):

a) fragrances and perfumes
b) decorative cosmetics
c) skin care
d) sun protection products
e) hair care (other than hair colorants)
f) hair colorants
g) toiletries
h) Other, please specify

(type of answer expected: sector X is expected to be most prone because…, followed by sector X)

Innovation

Innovation takes place across the range of cosmetics industry product categories. The Global Insight report notes that:

Today's cosmetic market is driven by innovation including new colour pallets, treatments targeted to specific skin types and unique formulas concentrating on different needs….Many of the latest advancements include cosmetics that are designed to treat multiple problems with faster acting formulations. The growing men's cosmetic market has also led to a new direction in innovation for many companies. Hair and skin care products targeted to the needs of specific ethnic groups are also growing in popularity, specifically aimed at the fast growing markets in Asia. Building new lines based on ingredients derived from sustainable development practices are also part of this trend taking into account what consumers want in the name of environmental preservation and minimizing societal impacts of new manufacturing procedures and ingredients.

This remains the case today.

It is difficult to allocate the amount of innovation between the different sectors, as this will vary from company to company, based on their areas of expertise and business model. Some ingredients, for example preservatives, are used in many different formulations so will have an impact across many different sectors of the business.

RPA collected some information on research on product categories - this can be made available upon request.

Use of New Ingredients

In terms of new ingredients, around 75% of **large companies** indicated that the proportion of reformulations that involve new ingredients varies between product types. They indicated that reformulations of fragrances, skin care, sun care and decorative products are most likely to use new ingredients. However, new ingredients can also be significant in other sectors, such as oral care, where a single new ingredient may be used in a product with very large sales volumes. Only 30% of SMEs indicated that the proportion of reformulations involving new ingredients varied by product types.

3.2.22 Do you consider that the amount of new ingredients substances introduced over the last 10 years **could also give an indication of the number of substances to be introduced for the coming 10 years**? *(type of answer expected: qualitative answer)*

See response to question 3.2.18. Depending on the assumption, most companies expect that the number of new substances introduced in the EU in future will be much lower than the number introduced over the last 10 years, in addition, existing ingredients which are no more used will be sometimes not replaced.

Labelling

3.2.23 Please provide information on the frequency of the use of the **animal testing free label** foreseen in the Cosmetics Directive? By how many manufacturers and for how many products is this label used?

(type of answer expected: the label is used by XXX companies and for XXX products)

Companies can label products with an 'animal testing-free' label if they follow the Commission's Guidelines. In practice, companies do not use this label, as most ingredients used have been, at some point, tested on animals.

For most large companies, they do not use the 'animal test free' label.

SMEs also make limited use of the 'animal test free' label, with 86% responding that they use it on 0 to 10% of products (this percentage has not changed over the past 10 years). However, 6% of SMEs use the label on over 90% of their products.

3.2.24 Do you have information on whether **the use of the label has an impact on consumer behaviour** in terms of encouraging the purchase of products with the label? Have you noticed an increase in sales for products using the animal testing free label? Please provide impact in terms of sales before and after the introduction of the label.

(type of answer expected: for brands which used the label sales increased/decreased)

Large companies made a number of comments on the impact of the label on consumer behaviour. These are summarised in the table below.

A relevant proportion of consumers in the EU are concerned about the safety of the cosmetic products they are using and about animal welfare at the same time. The respective target groups will presumably appreciate a credible "animal testing free" label provided the criteria are meaningful and transparent for them (communication challenge). The need for animal safety studies is more likely to be accepted by lay persons in case of product categories perceived as challenging for a safety assessor (e.g. sunscreens or hair colorant products) as compared to e.g. decorative cosmetics
"Animal testing free" implies responsibility and is interesting for all who are not aware of actual requirements; level depends on necessity to use a category, frequency and whether it is for home use…
Consumers may be more sensitive in the case of decorative cosmetics or anti aging products, but do not change their behaviour in the case of personal care, hair dyes and perfumes
Some…consumers may be attracted by "animal testing free". Some consumers who know safety assessment well may hesitate to buy as these words imply either "less safe" or "not new technology".
If consumers can chose between two different products with equal performance and price they may prefer the one with an animal free-testing claim. This may have lower relevance for products or brands with a high personal individuality profile, like fine fragrances.
Currently only a minority of consumers would be encouraged. In a future of a complete marketing ban, such label would be senseless as every product would then bear it and no differentiation would be given.
"Animal testing free"-type labelling is of limited commercial value currently and will diminish over time. (a) 'Product not tested on animals' claims. It has been unlawful to market cosmetic products tested on animals since 2004, so such a statement would presumably be true for all products introduced to the EU market since that date. Given the high rate of innovation and renovation of cosmetic products on the EU market, we will quickly reach a point (if not already reached) where the majority of products on the market have been introduced after 2004. So such a claim will be increasingly less meaningful to distinguish one product from another. At some point, when the vast majority of products on the market have been introduced after 2004, it will become potentially misleading to use such a claim, if its use created the false impression that this feature was unique or particularly characteristic of the product on which it is used, when in fact all or most other cosmetics could make a similar claim. (b) Ingredients not tested on animals' claim: at the level of use of ingredients we are of the opinion that it will be difficult to state that a product is free from ingredients that have been tested in animals, as almost all cosmetic product formulations contain ingredients that have been animal tested in the past. As a company we are committed to the elimination of animal testing. We are equally committed to consumer health and safety, and to the safety of our workforce and the environment. Where some testing is required by law or currently unavoidable, we aim to minimise the number of animals used. In line with this policy, currently we do not think it is appropriate for us to use labels such as 'animal testing free'.
Preference of consumers varies widely across the countries. UK most sensitive

Few SMEs considered that the label had a lot of influence on consumer purchases; the remainder of respondents were split between those considering that it had no influence at all and those considering it had moderate influence. There was little difference in responses across product types. The reasons given for not making wider use of the label were similar to those given by the larger companies.

3.2.25 Do you consider that the use of an **"animal tested" label** (thus a label that requires to expressively state if animal testing is relied on) could be an option? Would it be practicable and add value for consumers?

(type of answer expected: qualitative view on practicability and added value on such a label…)

A 'tested on animals' label to indicate that they contain ingredients tested on animals is likely to raise several legal and practical obstacles. In particular, it could be discriminatory and misleading as consumers may conclude that only cosmetics (and not other consumer goods) are tested on animals. Overall companies are not in favour of this initiative.

3.2.26 Do you have information on the **importance and value consumers attach** to cosmetics and cosmetics ingredients not being subject to animal testing?

(type of answer expected: any specific studies/figures on this…)

See response to question 3.2.24

3.3. Impacts on Costs and Price

3.3.1. Please provide information on whether you expect any **impacts on costs** if the marketing ban was to enter into force as such, which ones and why?

(type of answer expected: describe expectation and give reasons why, possibly based on concrete example)

Companies are not able to provide any information on whether the marketing ban will lead to increases in costs, as this is confidential business information. However, for international companies, the marketing ban may lead to the development of two different product ranges, one for the EU and one for the rest of the world, with potentially significant impacts on costs : different formulations, packaging, labelling etc. Also it could be foreseen that some ingredients prices will be going up, driving costs up for the companies. The inability to formulate out of costly ingredients will be an aggravating factor (as currently seen on Foods RMs) and the final result will be volatility rather than a generic overall cost increase. This will be happening at the same time with commoditization which could lead to lower prices for the consumer, but not for all products categories.

3.3.2. **Do you envisage passing any increase/decrease in costs on consumer prices?** Whenever available please provide an estimation of the impact in %.

(type of answer expected: describe expectation and give reasons why, possibly based on concrete example)

Companies are not able to provide any information on whether any changes in costs will be passed on to consumers, as this is confidential business information.

4. Competitiveness of cosmetics and cosmetics Ingredients manufacturers

PLEASE NOTE:
For all questions below we are looking for information that **distinguishes between large and small and medium sized (SME's) companies**. Please differentiate in your answer wherever possible between SME's and larger companies.

Please also differentiate between the type of company concerned, notably whether the information provided concerns **cosmetic manufacturers or cosmetic ingredients manufacturers.**

4.1. To which extent have the current provisions in the Cosmetics Directive in relation to animal testing have **already impacted – positively or negatively - business decisions in the cosmetics industry in the last 5 years**?

(type of answer expected: qualitative explanation of current impacts)

The impacts of the current provisions are difficult to determine because of the timescale for introduction of new ingredients. New ingredients introduced over the last five years will generally have been developed and tested prior to introduction of the testing ban. However it should be pointed out that the introduction of the testing ban already has some impact, in the sense that even if companies can still commission some testing for EU specific purposes these need to be carried out outside EU, which in itself is already more difficult for companies only operating in the EU.

The cosmetics industry worked for 30 years successfully on "2009 endpoints" and thanks to this the companies could meet the 2009 ban deadline .This cannot be compared to the 2013 ban where we do not have the tools to assess safety in a comprehensive and satisfactory way.

However, data gathered for the study indicates that the number of new ingredients introduced into the industry may have reduced slightly over the past 10 years (see response to question 3.2.1).

The table below shows the average number of substances added to and removed from the portfolios of cosmetics manufacturing companies in 2010 and over the previous 10 years.

Number of Ingredients Added to and Removed From Cosmetic Manufacturers' Portfolios		
	Large Companies	SMEs
Average number of ingredients added per company - 2010	60	22
Average number of ingredients removed per company - 2010	120	10
Net change in number of ingredients	-60	+12
Average number of ingredients added per company – annually over previous 10 years	70	26
Average number of ingredients removed per company – annually over previous 10 years	24	6
Net change in number of ingredients	+46	+20

4.2. **Assuming** the full testing and marketing ban would have been in place for all endpoints **already for the last 5 years**, what would have been the impact for the cosmetics and cosmetics ingredients manufacturers?

(type of answer expected: where possible quantative estimations, possibly based on examples)

The answer to this question would depend on how the marketing ban would be implemented.. Therefore, this question (and subsequent questions on the future impacts of the ban) was answered under three different assumptions:

- Assumption A: animal tests performed for other purposes than meeting the requirements of the EU cosmetics legislation do not trigger the ban and you can subsequently rely on these test data for cosmetic purposes in the EU provided these test were for non cosmetic purposes but in addition you can also rely on test data developed for cosmetic purposes outside the EU.
- Assumption B: animal tests performed for other purposes than meeting the requirements of the EU cosmetics legislation do not trigger the ban and you can subsequently rely on these test data for cosmetic purposes in the EU provided these test were for non cosmetic purposes.
- Assumption C: animal tests performed for other purposes than meeting the requirements of the EU cosmetics legislation do not trigger the ban, but you can never rely on these data.

Under Assumption A, **large** companies identified a number of potential impacts. These included:

- Fewer innovative products in the EU due to the possible lack of new entries in the Annexes and loss of existing ingredients. In this respect the greatest impact would have been on EU operating producers and manufacturers and for ingredients/products most reliant on innovation. This would lead to less exports from the EU.

- Product and ingredients manufacturers based outside of the EU would have a competitive advantage in markets outside the EU because they continued to be able to test and introduce new ingredients into their products. This will induce more costs for EU based companies. The world market share of EU producers would have fallen;

- Centres of creativity and development would have relocated outside of the EU in order to avoid these restrictions

- A significant proportion of EU companies would have moved most R&D (and potentially production) outside of the EU to be closer to the markets outside of the EU that will be driving product innovation. Probably only the larger companies would have re-located; others may not have been able to re-locate and so would have stopped trading;

- Much ingredient innovation is currently undertaken by EU SMEs. Large companies estimated that these companies would be less able to relocate outside of the EU and thus would lose much of their ability to innovate for non-EU markets. As a consequence of the loss of innovation by EU SME ingredient manufacturers, some large product manufacturers would have been significantly less able to innovate, whether based in the EU or elsewhere.

- Product manufacturers would have maintained product ranges for the EU market separate from those supplied to the rest of the world, adding to the cost of supplying to the EU.

- **Under Assumption B,** the level of impact would be somewhat greater and the impacts would arise sooner. Innovation in the EU cosmetic industry will depend fully on data developed for non-cosmetic purposes and access to such data. No development would have taken place in the EU for those products or products containing ingredients for which animal tests have been requested by SCCP/S that are not available from non-cosmetic sources, for example:

  - hair dyes (most);
  - UV filters;
  - preservatives; and
  - other ingredients for which submissions have been made (e. g. CMR III substances).

  One company estimated that this would have resulted in the loss of between 50 and 100 ingredients, resulting in a significant reduction in sales in the EU.

Under Assumption C, there was consensus that the impacts would have been far more severe and their onset very much faster, with more companies moving all R&D and production outside of the EU.

SME respondents shared similar views on the impacts. Most companies expected that there would have been adverse effects under all of the assumptions, with the worst impacts under assumption C and the least impacts under assumption A. The table below indicates the percentage of SME respondents anticipating adverse effects under each of the three scenarios.

Assuming the full testing and marketing ban would have been in place for all endpoints already for the last 5 years, what would have been the impact? – % SME responses			
	Negative effects	**Little or No effect**	**Don't know**
Assumption A	66%	17%	13%
Assumption B	74%	14%	12%
Assumption C	76%	11%	6%

The types of impacts anticipated were similar to those anticipated by the larger companies:

- reduction in the numbers of new ingredients on the market, particularly for substances covered by the Annexes. Estimates of the extent of reduction ranged from 10% to 'drastic'. This is because, where data from suppliers did not contain all the information needed specifically for cosmetics purposes, no new data could have been generated;
- the loss of new ingredients would have reduced innovation and hence the numbers of new products, resulting in a more uniform market and making it difficult for SMEs to stay in business. One SME estimated that 65% of the increased net sales due to new products would have been lost, another estimated a 20% reduction in sales;

- significant costs and loss of competitiveness due to the need to reformulate products to replace ingredients where the SCCS requested additional data that could not be provided due to the non-availability of tests (or removal of the products from the market);
- closure of testing laboratories in the EU, which are already experiencing tough competition, reducing the potential for and reliability of European testing.

SMEs which indicated that the impacts on them would have been more limited generally did not give reasons for this belief (although some commented that they do not test products on animals, which perhaps indicates a misunderstanding of the issue). One commented, though, that development of new ingredients would focus on those with "limited toxicological risks".

4.3. Please provide information on the possible yearly **economic impact on annual sales and profitability for the cosmetics industry in case the 2013 implementation date** is maintained in the short term (2013 - 2015), medium term (2015-2018) and long term (2018 and beyond).

(type of answer expected: where possible quantative estimations, possibly based on examples, for the time spans mentioned)

Under Assumption A, large companies considered that the overall impact on the EU cosmetics industry would be losses to turnover and profitability, estimated by one company at 1% in the short term, 3% in the medium term and 5% in the long term. Most expected the scale of losses to increase over time, although one company expected losses to reduce over time, from 20% in the short term to 10% in the medium term and 1% in the long term. One company considered that there would be a reduction in annual growth rates rather than an absolute reduction, but another again considered that there would be a significant loss of turnover and a total loss of profitability in the longer term. Large companies considered that the EU would lose its leading role for innovation under this assumption, leading to reduced R&D expenditure and a movement of the most highly-qualified R&D staff away from the region.

Under Assumption B large companies expected the overall impact on the EU cosmetics industry to show significant losses in turnover and profitability, with losses ranging from 3% to 20% in the short term, 7% to 20% in the medium term and 1% to 25% in the long term. Most expected the scale of losses to increase over time, although one company expected them to reduce, presumably through adaptation to new market conditions.

The losses are likely to vary by product type, with skin care the most affected and decorative products also seriously reduced. One company estimated losses of 50% to 70% in the most affected categories. These losses could equal reductions in turnover of several billion Euro and at worst a complete loss of profitability in certain product categories. For example, one company considered that its skincare business in Europe might no longer be viable.

Other impacts would include significant reductions in R&D investment in Europe with R&D and production moving to other markets. The range of products marketed in the EU would change towards conventional, mass market and lower price products with a gradual reduction in sales and profitability for all cosmetics companies.

Under Assumption C, the overall impact on the EU cosmetics industry would occur as under the other assumptions, but large companies considered that the impacts would be more severe and the onset faster. Reductions in turnover and profitability could be 5% to 15% in the short term, 12% to 20% in the medium term and 15% to 25% in the long term. These losses would amount to billions of Euro in turnover and one company predicted a total loss of profitability over 10 years. As with assumption B, sales of skincare products would be most affected, but there would be effects on sales of other cosmetic products as well (e.g decorative cosmetics). There would be significant cuts to R&D expenditure in Europe under this assumption, with relocation of R&D facilities to support the growth of non-EU markets.

Most **SMEs** responding to this question were unable to quantify the impact on sales or profitability, but most expected an adverse impact (although some anticipated no impacts). As with the larger companies, the impacts were expected to be most severe under assumption C and least severe under assumption A.

Where companies were able to quantify the impacts, estimates ranged from a 5% to a 20% reduction in turnover. One anticipated losses under assumption C of nearly €11 million in the short term, over €14 million in the medium term and nearly €22 million in the longer term. Another company expected losses to be reduced in the longer term, on the assumption that alternatives would have been developed by then. Others anticipated a 'sharp' fall in profitability and one predicted that its business would close.

There would also be a loss of member state revenue (VAT, as well taxes on industry profits are currently estimated at € 10 billion per year).

4.4. Please provide information on the **percentage of yearly turnover in the years since 2000 that depended on products newly introduced**.

(type of answer expected: XX% of turnover in 2000 depended on products introduced the year before, XX% of turnover in 2004 depended on product introduced in 2003 etc.)

For most large companies, the percentage of turnover accounted for by newly (re)formulated products was below 25% (70% of respondents). However, for 10% of respondents the figure was over 90% of turnover.

More SMEs than large companies depended on new products for a significant proportion of their turnover. The percentage of turnover accounted for by newly (re)formulated products was below 25% for just over one third of respondents. For 14% of respondents, over 50% of turnover was accounted for by new products.
Some companies have given examples on the market value represented by the introduction of new ingredients for which "2013 endpoints" tests had to be generated in order to go on the EU market .This loss of potential profitability could be used as an illustration .The Commission could get access though RPA under confidentiality ie no public disclosure .

4.5. Which impacts do you think would the implementation of the ban in 2013 have on the **positioning of the European cosmetics and cosmetics ingredient manufacturers globally**?

(type of answer expected: qualitative answer)

Under Assumption A, all responding large companies agreed that the following impacts on the positioning of European cosmetics and ingredients manufacturers in the global market were likely:

- Strengthening of companies located outside the EU and weakened competitive position of EU products;
- Loss of the EU industry's leading role in innovation within five years, with a lack of new products;
- Severe damage to the market position and reputation of the European industry as leadership and innovation move elsewhere;
- Loss of shareholder confidence and reduction in share value;
- Disappearance of EU cosmetic ingredients manufacturers and suppliers, leading to further weakening of EU cosmetic product manufacturers;
- Switch of investment and production by multinational companies to the growing markets outside the EU, primarily in Asia.

Under Assumption B, most large companies considered that the types of impact would be similar to those under assumption A, but would be stringer and their onset somewhat quicker (especially for companies without businesses outside the EU). Competitiveness would be more damaged further and the EUs leading position in innovation would be lost; there could be particularly adverse impacts on SMEs and companies without non-EU businesses. However, three companies believed there would be no impacts and one that the impacts would be marginal. [see comment on this issue in question 4.2]

Under Assumption C, large companies expect similar types of effect to those under assumption B, but more severe and with a faster onset. Impacts could include no application of new raw materials and no new technologies, neither technology transfer. The market position and reputation of EU companies as innovative would be severely damaged, with a negative effect on global competitiveness. Shareholders will lose confidence, company values will reduce and some large companies may consider moving out of Europe.

The global lead for innovation would move from the EU to other regions where it will remain possible to generate the required safety data. In addition, the EU market will be deprived of these new developments/innovations. This will result in the EU market for cosmetics becoming commoditized, with less product differentiation and consumer choice, but which will be less attractive for companies to invest in. The negative impacts on cosmetic ingredients suppliers would be more severe and faster than under Assumption B; the European SME network specialising in cosmetic products and ingredients would be lost.

Another consequence could be to open the doors of the cosmetic market, particularly at its higher end, to pharmaceutical/food/other companies which could benefit from the animal testing that they are allowed to perform, to accelerate the creation of innovative skincare products, against which pure cosmetic companies which have no capacity to compete, either in R&D and regulatory processes.

Large companies considered that a further impact could be on the EU's leading position in the regulation of cosmetics products. As previous studies for the European Commission show, developing cosmetics markets have increasingly modelled their regulation on the EU Cosmetics Regulation. However, the impact of the ban could reduce the influence of the EU model, if it is seen as providing an inadequate and no

more relevant/updated basis to assure the safety of cosmetic products and/or as a barrier to innovation.

Most SMEs anticipated similar impacts on the global positioning of EU manufacturers to the large companies (although a small proportion anticipated no impacts). The impacts anticipated included:

- a reduction in the global market share of EU producers, with EU-located producers losing out to multinationals who are still able to innovate outside the EU;
- a general reduction in competitiveness, with reduced quality and variety of EU products on the global market;
- US, Japanese and Chinese manufacturers favoured in non-EU markets because they can ensure the safety of their ingredients and products more effectively;
- There would be a gradual decline in the EU's position over time.

4.6. Please provide information on the **time to market for a new cosmetic product** and a description of the **product development cycle timing**?

(type of answer expected: average time to market for example X years and description of steps)

The time to market varies with the nature of the product and the degree of innovation. It can take over five years of innovative research and formulation to bring a new product to the market. This is not changed since the 2007 RPA Report.

CASE STUDIES/EXAMPLES

1. Can you give an example of a direct impact on safety, innovation and product availability of the entry into force of the 2009 implementation date?

the introduction of the testing ban already has some impact, in the sense that even if companies can still commission some testing for EU specific purposes these need to be carried out outside EU, which in itself is already more difficult for companies only operating in the EU.

2. The Commission has over the last years embarked on an extensive review of hair dyes (see for information on the hair dye strategy: http://ec.europa.eu/consumers/sectors/cosmetics/cosmetic-products/hair-dye-products/index_en.htm).
Looking at this example and doing this under the assumption that the deadlines would have already been in force could give valuable information on possible impacts of the 2013 implementation date. Can you in relation to the hair dye strategy - or picking a couple of concrete examples from it - specify what would have been the possible economic impact and the impact on availability of products to consumers?

In the context of the Commission decision to review the safety hair dyes used in the EU , non SMEs companies organised in a consortium and shared existing data on 45 commonly used Hair dyes which represented 89 % of the HD defended by Colipa and around 95% of what is used in the EU. Among all the studies submitted it can be seen that there were 203 animal studies covering the 2013 endpoints with 101 studies which had to be specifically generated while the others already existed .Out of these 101 studies, 34 were done to study skin allergy, whereas the remaining 67 covered essentially

reproduction and subchronic tests.If this request of the Commission had been done after 2013 , almost no hair colorants would have been able to be marketed any more .

These data, generated by a few companies benefit the whole cosmetic sector, including SMEs who do not need to generate any animal tests.

3. Are you aware of another case/example that could help the Commission services in evaluating possible impacts of the 2013 implementation date? For example sunscreens? Oral care?

In a similar way , since 2004 and in addition to individual companies responses to the SCCS, Colipa has submitted 7 dossiers for new UV filters and preservatives and defended 58 ingredients which were assessed by the SCCS ;This corresponds to 20 dossiers for which 2013 tests had to be generated ; skin allergy, reprotoxicity, subchronic studies, toxicokinetics and carcinogenicity.

5. Impacts on Small and Medium sized Enterprises (SME's)

A large number of enterprises in the cosmetics sector are SME's, impacts on them therefore are of particular importance and differences should already be taken into account in the questions above, notably under 3.2 and 4 above.

5.1. Please provide information on the **total number of SME's in the cosmetics sector in the EU** in relation to the total number of cosmetics manufactures. Please specify for cosmetics manufacturers and cosmetic ingredient manufacturers.

(type of answer expected: overall XXX cosmetics/cosmetics ingredients manufacturers in EU of which XXX SME's)

Euromonitor data for 2009 published on the Colipa web site[7] indicates that there were 3,041 SME cosmetic product manufacturers in the EU27. In some Member States 98% of cosmetic companies are SMEs.

- *SMEs – 3041(70%)*
- *Larger companies – 1322(30%)*

5.2. Please provide information on the **percentage of the overall yearly sales** that are realized by **SME's** in the cosmetics sector.

(type of answer expected: overall yearly turnover XXX of which XXX for SME's)

The EU cosmetics industry was worth €66.6 billion in 2010[8]. The estimated SME market share is 30%.

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7 http://www.colipa.eu/about-colipa-the-european-cosmetic-cosmetics-association/facts-and-figures-colipa-the-european-cosmetic-cosmetics-association.html

8 Data source: Euromonitor

5.3. Please provide information on the **number of employees** of the SME's in the cosmetics sector in the EU compared to the overall number of employees in the cosmetics sector.

(type of answer expected: total number of employees is XXX, number of SME employees is XXX)

The overall number of direct employees in the cosmetics sector in 2009 was estimated by Euromonitor at around 176,940 (137,362 in manufacturing, 39,578 in distribution and 17,000 in R&D). Indirect employment (including retail and salons) is estimated to be about 1.5 million people.[9]

Based on Eurostat data from 2005[10], SMEs in the cosmetics sector might be expected to account for around 35% of total employment in the sector. This would be equivalent to nearly 62,000 direct jobs. SMEs generate significant annual average employment growth (eg. Italy 2002-2008 employment growth of Italian SMEs showed an overall increase of 9%)[11].

Large companies responding to the questionnaire employed over 140,000 staff in total in the EU, with 75,000 of these working in development (including R&D), manufacture, import or supply of cosmetic products and 1,200 in development (including R&D), manufacture, import or supply of cosmetic ingredients.

SMEs responding to the questionnaire employed over 19,000 staff in total in the EU, with 9,600 of these working in development (including R&D), manufacture, import or supply of cosmetic products and 325 in development (including R&D), manufacture, import or supply of cosmetic ingredients.

5.4. Please describe any **particular impacts you expect for SME's** in case the marketing ban deadline is maintained.

(type of answer expected: qualitative reply describing particular SME impacts)

Impacts on SMEs are described separately from impacts on larger companies in response to all the questions in previous and following sections of the questionnaire, so that particular impacts for SMEs can be readily identified.

The impact on SMEs is likely to be disproportionate; the smaller the company, the greater the socio-economic impact of the ban. This is because SMEs rely on data generated by their suppliers and/or larger companies (or consortia), which may no longer be available for use within the EU. SMEs will also be unable to reach niche markets for highly differentiated, innovative cosmetics, both in the EU and globally.

SMEs manufacturers will increasingly lose supply of ingredients, especially from SME suppliers. The move to a commodity business will hit SMEs hardest as they lack economies of scale. They will not have access to non-EU innovation and will be unable to compete equally in global markets outside the EU. Some SMEs may be able to

[9] Euromonitor, 2009

[10] http://epp.eurostat.ec.europa.eu/cache/ITY_OFFPUB/KS-SF-08-031/EN/KS-SF-08-031-EN.PDF

[11] EC SBA fact Sheet 2009

relocate outside the EU, but this would cause substantial damage to economic development and employment at national level (in R&D, marketing, advertising and communications).

SME respondents confirmed that the impacts are likely to be more significant for companies located only within the EU, as opposed to multinationals, especially in relation to the non-EU market. They also anticipate significant adverse impacts on R & D collaborations with local academic institutes .

6. IMPACTS ON EMPLOYMENT

6.1. Do you consider that the 2013 implementation date may have **impacts on employment** in the cosmetics industry in the EU? If yes, please specify?
(type of answer expected: explanation on the possible impacts on employment)

The answer to this question would depend upon the nature of any test ban imposed on the EU. Therefore, this question (and subsequent questions on the future impacts of the ban) was answered under three different assumptions:

- Assumption A: animal tests performed for other purposes than meeting the requirements of the EU cosmetics legislation do not trigger the ban and you can subsequently rely on these test data for cosmetic purposes in the EU provided these test were for non cosmetic purposes but in addition you can also rely on test data developed for cosmetic purposes outside the EU.
- Assumption B: animal tests performed for other purposes than meeting the requirements of the EU cosmetics legislation do not trigger the ban and you can subsequently rely on these test data for cosmetic purposes in the EU provided these test were for non cosmetic purposes.
- Assumption C: animal tests performed for other purposes than meeting the requirements of the EU cosmetics legislation do not trigger the ban, but you can never rely on these data.

Large Companies

The table below shows the number of large company respondents expecting impacts of the ban on employment under the three assumptions. Most large companies expect a negative impact on jobs resulting from the 2013 ban, particularly in R&D, as multinationals move this outside the EU to continue to develop new products for non-EU markets.

Large Company Expectations about Impacts on Employment – Large Companies			
Expectation of Change	**Assumption A**	**Assumption B**	**Assumption C**
Negative impact on employment	13	16	15
No impact on employment	3	2	1

Under Assumption A, 81% of large company respondents considered that the ban would have impacts on employment in the cosmetics industry in the EU.
The impacts would include:

- Reductions in highly-qualified R&D jobs in Europe as research into new products is moved outside the EU and because research in certain product areas (such as hair

dyes) would be discontinued because it will not be possible to assure the safety of products. There are currently around 17,000 scientists employed by the EU cosmetics industry and some respondents consider that the majority of these jobs could be relocated;

- Longer-term reductions in production staff as production facilities are moved outside the EU to follow R&D and to focus on growth markets and because of the reduced turnover and profitability of the industry in Europe (see response to questions 4.3 and 4.5);

- Reductions in jobs in supporting functions (HR, marketing, logistics, sales) as a result of relocations, reduced turnover and profitability in Europe.

As raw materials will be tested outside the EU, contract laboratories may close or reduce manpower. Ingredient suppliers may also shift outside the EU. Some R&D facilities would continue to relocate outside the EU, leading particularly to the loss of highly educated and leading scientists. For some companies, this would also mean the re-location of multi-functional new product development teams. If new products for the EU market are sourced from elsewhere, this can also result in the loss of supply-chain jobs.

Under Assumption B, 89% of large company respondents considered that the ban would have impacts on employment in the cosmetics industry in the EU. The types of impacts would be similar to those for assumption A, but the reduction in jobs could be slightly higher and the onset somewhat faster compared to assumption A.

Under Assumption C, 94% of large company respondents considered that the ban would have impacts on employment in the cosmetics industry in the EU. The types of impacts would be similar to those under assumption A, but would be more severe and the onset would be faster:

- No new raw materials would be developed for cosmetics. This would not only lead to a drastic reduction in R&D employment but also to knock-on effects on employment in all other functions. The majority of the current 17,000 R&D jobs in the industry would be moved outside Europe and these losses could be tripled in manufacture, supply chain, marketing and administration jobs;

- R&D employment would begin to reduce immediately the ban was introduced, other employment would reduce after a lag time of 2-3 years;

- Loss of innovation would lead to cosmetics becoming a commodity market in the EU. This is likely to result in global corporate management functions being moved outside the EU with only marketing and sales offices remaining. This would lead to a further reduction in jobs and significant reductions in tax payments in Europe;

- Once the shift of excellence (and related jobs) outside the EU has occurred, it is unlikely to be reversed.

SMEs

55% of SME respondents expected an adverse impact on employment under scenario 1, 56% expected an adverse impact under assumption A and 73% expected an adverse impact on employment under assumption C.

Most respondents were not able to quantify the impact on employment, but one SME quantified the number of jobs that would not be created if the 2013 ban proceeds as 53 jobs in the short term, 70 jobs in the medium term and over 100 jobs in the long term. Other views on the impacts ranged from limited impacts to a 'devastating' effect.

Impacts expected by SMEs included:

- Fewer impacts on businesses selling only within the EU, although jobs would also be lost to these companies because of falling sales and an inability to innovate (particularly in R&D);
- Significant losses of jobs in EU testing laboratories;
- Potential relocation of some businesses outside the EU, with the loss of all or most EU jobs in those businesses.

6.2. Do you consider that there would be specific employment impacts **for SME's**? If yes, please specify?

(type of answer expected: explanation on specific impacts for SME's)

The majority of SMEs anticipate adverse impacts on employment from the ban. SMEs could be particularly affected by job losses, because they do not have the option to move outside the EU. Large companies rely on SME manufacturers for a significant proportion of innovative new ingredients. This business would be significantly reduced by the ban and could lead to closure of these companies or their takeover by non-EU multinationals.

6.3. Do you consider that the implementation could lead to the **relocation of R&D or production facilities?**

(type of answer expected: explanation on the likelihood of relocation)

As noted in response to questions 4.3, 4.5 and 6.1, respondents consider that the ban would have a significant impact on the location of R&D facilities. The reduction in EU-based R&D would affect research into alternative tests and result in a transfer of academic partnerships outside the EU; in effect, a 'brain drain'. There are currently around 17,000 scientists employed by the EU cosmetics industry, and some respondents consider that the majority of these jobs could be relocated, with Europe losing its leading role in R&D.

- **Under Assumption A**, 75% of responding large companies predict some relocation of R&D is predicted. There could also be a threat to the cosmetic industry's strong academic networks in the EU, with new networks being developed outside the EU. One large company alone currently collaborates with around 60 academic groups and funded over €3.5 million in external research in 2010. 53% of SMEs expected R&D facilities to relocate under this assumption;

- **Under Assumption B**, 76% of responding large companies predicted that R&D would be relocated. The amount of R&D located could be up to 50%, depending upon company, to locations closer to emerging markets (e.g. China). The R&D activities affected would be those focused at developing innovative products, such as skin care, where the ban would result in a lack of data from specific tests. Only large companies would be able to relocate R&D. Probably for this reason, only 45% of SMEs considered that R&D facilities would relocate under assumption B;

- **Under Assumption C**, 87%% of responding large companies expect relocation of R&D, and it is predicted that the majority of EU R&D will relocate outside the EU, to Asia and the Americas. There will also be very severe impacts on academic networks. 61% of SMEs also expected R&D facilities to relocate under this assumption.

6.4. Has the **2009 implementation date already had impacts** on employment? Which ones?
(type of answer expected: explanation on the impacts already experienced)

The cosmetics industry worked for 30 years successfully on "2009 endpoints" and thanks to this the companies could meet the 2009 ban deadline .This cannot be compared to the 2013 ban where we do not have the tools to assess safety in a comprehensive and satisfactory way.
Re-location of testing is costly and difficult for a lot of EU companies;

7. Impacts on Trade

7.1. Can you provide **figures** in relation to the **import and export of cosmetic products and cosmetics ingredients** from and to the EU in the last 5 years? Please provide breakdown by country if available.
(type of answer expected: figures in relation to import and export, figures should be expressed both in quantity and value.)

The EU represents almost one-third of the global market (with the US and Japanese markets estimated at € 37.8 bn and € 29.4 bn respectively). A high proportion of products placed on the market by EU manufacturers are exported; exports in 2010 totalled €12.5bn with up to 62% of products placed on the export market.

The total numbers of product formulations exported by large companies responding to the questionnaire in 2010 was 17,565 (compared to 28,364 placed on the EU market). No data are available on the breakdown of exports by country, or on imports. For SMEs, the figures for 2010 were 14,200 and 8,874.

7.2. Do you expect **impacts on trade** in case the marketing ban for the remaining three endpoints is implemented in 2013? Which impacts do you expect?
(type of answer expected: explanation on the expected impacts)

As explained in the response to question 4.5, the development and production of innovative products will move outside the EU to continue to serve emerging markets, particularly in Asia. These markets will be supplied increasingly from local facilities,

rather than by export from Europe. Overall, the majority of large companies expect that there will be a significant reduction in the competitiveness of the EU industry.

The types of impacts expected by **large company** respondents include:

- changes in the amount of cosmetic products imported into the EU. This could comprise a reduction in legal imports, as manufacturers do not develop new products which can be sold the EU due to the ban, but an increase in non-legal imports (including products bought on the internet) as consumers seek access to innovative products developed outside the EU;

- reductions in the amount of cosmetic products exported from the EU, as these may be less innovative than products developed elsewhere;

- some reductions in the amount of cosmetic products sold in the EU, as market increases due to innovative products will not be realised; and

- a reduction in the range of products sold on the EU market.

Large companies expect these impacts to be most likely under assumption C, with around 75% of respondents expecting them to arise.

SMEs expect similar impacts to large companies, although a higher proportion of SMEs did not feel able to comment on impacts on trade.

7.3. Which impacts do you expect on **imports**?
(type of answer expected: explanation on the possibility to import)

Companies responding to the questionnaire anticipated significant impacts on imports of cosmetics into the EU if the ban is implemented in 2013, Depending on the assumptions made (see response to question 6.1), between 52% and 64% of responding large companies and SMEs expect imports of cosmetic products to be reduced and 67% expect exports of cosmetics ingredients to be reduced.

Businesses will increasingly develop separate product ranges for EU and non-EU markets, increasing the costs of marketing in the EU, which is likely to reduce the range and volume of imports. However, consumers seeking innovative products may be able to access these through parallel imports and via the internet.

7.4. Which impacts do you expect on **exports**?
(type of answer expected: explanation on the possibility to export)

Exports are up to now a significant source of business and employment for the EU cosmetics industry. Companies responding to the questionnaire anticipated significant impacts on exports of cosmetics from the EU if the ban is implemented in 2013, Depending on the assumptions made (see response to question 6.1), between 43% and 73% of responding large companies expect exports of cosmetic products to diminish and 67% expect exports of cosmetics ingredients to be reduced

This is because the ban will lead to a reduction in the innovative capacity of the EU industry compared to companies operating globally or outside the EU. Multinationals are likely to switch product development (and possibly production) outside the EU. Companies operating solely in the EU would have a competitive disadvantage in markets outside Europe because they will not be able to test and introduce new ingredients into their products. European operating brands will thus be less able to bring innovation to the market, in Europe With increasing innovation outside Europe, products exported from the EU will become less attractive for consumers in foreign markets.

The ban will also not stop companies to comply with the safety requirements of other markets, where animal testing is required for certain endpoints or in context of cosmetic manufacturers' general legal obligation in virtually every country to only market products which are safe. Overall, the world market share of EU producers will fall.

Impacts on exports are particularly significant for EU producers, as the EU market is nearing saturation and future growth will be focused in non-EU markets, particularly in Asia.

7.5. With which **countries would trade be most affected** in your view?
(type of answer expected: explanation on the possibility to import and export and reasons)

Trade with countries where the cosmetics market is growing, particularly in Asia, will be most affected. China is predicted to be not only a major growth market, but also a centre of innovation if the ban is implemented, with R&D increasingly relocated there. This would reduce EU exports not only to China but also to other markets in Asia which could be more easily served from China.

In addition, the Chinese market requires animal testing of ingredients for certain endpoints, which will make the impact of the ban more significant for exports to China.

However, regulators in most non – EU countries require animal test data and some will accept data from alternative tests as additional information. So it can be foreseen that many companies, due to non-EU regulations will not be able to market in EU the same products and similarly the EU companies will have to provide animal tests data when they want to market in non-EU countries (USA, Japan, China, Russia).* * *

Annex 3

Specific Privacy Statement

Targeted stakeholder consultation "2013 IMPLEMENTATION DATE MARKETING BAN COSMETICS DIRECTIVE"

1. OBJECTIVE

The objective of this consultation is to receive the views of stakeholders and potentially to publish them on the Internet, under the responsibility of Ms Sabine Lecrenier, Head of the Unit B2 – Cosmetics and Medical Devices, Health and Consumers Directorate-General (DG SANCO), acting as the Controller.

As this service collects and further processes personal data, Regulation (EC) 45/2001, of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data, is applicable.

2. WHAT PERSONAL INFORMATION DO WE COLLECT AND THROUGH WHICH TECHNICAL MEANS?

Identification Data
The personal data collected and further processed are data necessary for the participation in the consultation, such as name/surname/profession/postal & e-mail addresses/phone number/fax number of the contributors, including their views on the topics concerned. The processing operations on personal data linked to the organisation and management of this consultation are necessary for the management and functioning of the Commission, as mandated by the Treaties, and more specifically Articles 244 to 250 of the Treaty on the Functioning of the European Union.

Technical information
Your reply and personal data will be collected through e-mail. The e-mail system of the European Commission abides by the Commission's security decisions and provisions established by the Directorate of Security.

3. WHO HAS ACCESS TO YOUR INFORMATION AND TO WHOM IS IT DISCLOSED?

Received contributions, together with the identity of the contributor, may be published on the Internet, unless the contributor objects to publication of the personal data on the grounds that such publication would harm his or her legitimate interests. In this case the contribution may be published in anonymous form. Otherwise the contribution will not be published nor will, in principle, its content be taken into account. Any objections concerning publication of personal data should be sent to the service responsible for the consultation (see contact information below).

4. HOW DO WE PROTECT AND SAFEGUARD YOUR INFORMATION?

Your replies, together with your chosen language used for drafting the reply, are recorded in a secured and protected database hosted by the Data Centre of the European Commission, the operations of which abide by the Commission's security decisions and provisions established by the Directorate of Security for this kind of servers and services. The database is not accessible from outside the Commission. Inside the Commission the database can be accessed using a UserId/Password.

5. HOW CAN YOU VERIFY, MODIFY OR DELETE YOUR INFORMATION?

In case you want to verify which personal data is stored on your behalf by the responsible controller, have it modified, corrected or deleted, please contact the Controller by using the contact information below and by explicitly specifying your request.

6. HOW LONG DO WE KEEP YOUR DATA?

All replies to the consultation will remain in the database until the results have been completely analysed, and they will be archived for reference purposes thereafter. Your personal data will be part of a list of contact details shared internally amongst the staff under the responsibility of the Controller for the purpose of contacting you in the future in the context of further activities related to the consultation. If you do not agree with this, please indicate this in your reply. If you have already sent your reply, please contact the Controller by using the contact information below specifying your request.

7. CONTACT INFORMATION

In case you wish to verify which personal data is stored on your behalf by the responsible Controller, have it modified, corrected, or deleted, or if you have questions regarding the consultation, or concerning any information processed in the context of the consultation, or on your rights, feel free to contact the support team, operating under the responsibility of the Controller, using the following contact information:

European Commission
Health and Consumers Directorate-General (DG SANCO)
Unit SANCO B2, Cosmetics and Medical Devices
B-1049 Brussels, Belgium
Fax: 00 32 (0) 2 296 64 67
e-mail: SANCO-COSMETICS-REPORT@ec.europa.eu

8. RECOURSE

Complaints, in case of conflict, can be addressed to the European Data Protection Supervisor (http://www.edps.europa.eu/EDPSWEB/).