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COMMISSION STAFF WORKING DOCUMENT

**IMPACT ASSESSMENT ON THE ANIMAL TESTING PROVISIONS IN
REGULATION (EC) 1223/2009 ON COSMETICS**

Accompanying the document

**COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN
PARLIAMENT AND THE COUNCIL**

**on the animal testing and marketing ban and on the state of play in relation to
alternative methods in the field of cosmetics**

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Disclaimer:

This Impact Assessment report only commits the Commission's services involved in its preparation and does not prejudice the final form of any decision to be taken by the Commission.

1. PROCEDURAL ISSUES

The Cosmetics Directive¹ foresees a phasing-out of animal testing for cosmetic products. A ban of animal testing of finished cosmetic products has been in force since September 2004 and a testing ban on ingredients or combinations of ingredients since March 2009. As from March 2009, it is also prohibited in the EU to market cosmetic products and their ingredients which have been tested on animals in order to meet the requirements of the Directive, irrespective of the origin of these products. This marketing ban applies to all but the most complex human health effects to be tested to demonstrate the safety of cosmetic products (repeated-dose toxicity including skin sensitisation and carcinogenicity, reproductive toxicity and toxicokinetics), for which the legislator extended the deadline to March 2013².

The assessment of the 2013 marketing ban is foreseen in the Cosmetics Directive itself. Article 4a (2.3) of the Cosmetics Directive obliges the Commission to study the progress and compliance with the implementation deadlines in relation to animal testing and to report to the European Parliament and the Council. In particular, the Directive provides that if alternatives to animal testing in relation to the endpoints covered by the 2013 marketing ban are not developed and validated by the 2013 implementation date, the Commission shall inform the European Parliament and the Council and put forward a legislative proposal.

The Commission has monitored the progress of the development of alternative methods to animal testing on a yearly basis and presented its final report to the European Parliament and the Council³ on 13 September 2011. It concluded that alternatives to animal testing in relation to the endpoints in question will not yet be available by 2013.

1.1. First Phase of Stakeholder Consultation on the Evaluation of the Availability of Alternative Methods

The Commission services evaluated the availability of alternative methods between April 2010 and May 2011. The evaluation exercise aimed at gaining a broad and objective picture of the scientific and technical issues related to establishing alternative test methods for the human health-related effects falling under the 2013 deadline. To this end the Commission services selected scientific experts proposed by the various stakeholders. The work was carried out under the co-ordination of the European Centre for the Validation of Alternative Methods (ECVAM)⁴, hosted by the Institute for Health and Consumer Protection of the European Commission's Joint Research Centre.

In total 39 experts contributed, nominated from amongst proposals received by Cosmetic Regulators (Member States as represented in the Standing Committee operating under the Cosmetics Directive), the Scientific Committee on Consumers Safety (SCCS), the European Cosmetics Association (Colipa⁵), the European Federation for Cosmetic Ingredients (EFFCI) and the European Coalition to End Animal Experiments (ECEAE).

The draft expert report was open to public consultation between 23 July and 15 October 2010. The consultation was accessible on the Commission's "Your Voice in Europe" as well as

¹ Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products, OJ L 262, 27.9.1976, p. 169.

² See for the grouping of endpoints under the 2013 marketing ban: Commission Staff Working Document, Timetables for the phasing-out of animal testing in the framework of the 7th Amendment to the Cosmetics Directive (Council Directive 76/768/EEC), 1.10.2004, SEC(2004) 1210

³ Report on the Development, Validation and Legal Acceptance of Alternative Methods to Animal Tests in the Field of Cosmetics (2009), 13.9.2011, COM(2011) 558 final

⁴ Now the European Union Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM)

⁵ Now named Cosmetics Europe

Directorate-General SANCO's cosmetics website⁶. Known stakeholders were in addition directly informed by e-mail and in stakeholder meetings. The consultation was carried out in accordance with the Directorate-General SANCO's "Code of Good Practice For Consultation of Stakeholders"⁷. The contributions of the stakeholders, a summary report of the consultation as well as the final report, are published on the Directorate-General SANCO's cosmetics website⁸.

The large majority of stakeholders agreed with the draft reports findings. Some stakeholders from the animal welfare side considered the report as too conservative⁹. While they based themselves on the same alternative methods as those described in the expert report, they considered that these methods could already today be relied on for the safety assessment. However, the overall findings of the expert report and the consultation do not support this view. The findings of the expert report are also consistent with the findings of the SCCS¹⁰ and with other evaluations in relation to the availability of alternative methods carried out within the Commission¹¹. The expert report findings were overall also confirmed by an expert panel review¹².

This technical and scientific analysis was necessary in order for the Commission to be able to report to the European Parliament and the Council on the availability of alternative methods.

1.2. Second Phase of Stakeholder Consultation on the Impacts of the 2013 Deadline

In order to obtain information on the potential impacts of the entry into force of the 2013 deadline the Commission services consulted targeted stakeholders and cosmetic regulators (Member States as represented in the Standing Committee operating under the Cosmetics Directive) between December 2010 and April 2011. The list of stakeholders consulted included besides the cosmetic regulators the cosmetics industry, cosmetic ingredient manufacturers, animal welfare organisations, a consumer organisation, the Scientific Committee for Consumer Safety (SCCS), and trading partners. The consultation document, as well as a list of stakeholders consulted, is available on the Directorate-General SANCO's cosmetics website. The contributions of the stakeholders to the targeted stakeholder consultation are published on the same website¹³. The consultation was carried out in

⁶ See: http://ec.europa.eu/consumers/sectors/cosmetics/documents/public_consultation/index_en.htm All Internet links provided in the footnotes of this report were last accessed on 24 August 2012

⁷ Directorate-General SANCO's "Code of Good Practice For Consultation of Stakeholders", see http://ec.europa.eu/dgs/health_consumer/dgs_consultations/docs/code_good_practices_consultation_en.pdf

⁸ See: http://ec.europa.eu/consumers/sectors/cosmetics/documents/animal-testing/index_en.htm

⁹ See European Coalition to End Animal Experiments contribution to the consultation and BUAV publication: *Meeting the Deadline of the 2013 EU Marketing Ban. A Scientific Review of Non Animal Tests for Cosmetics*, 2011

¹⁰ Memorandum on "Alternative Test Methods in Human Health Safety Assessment of Cosmetic Ingredients in the European Union", SCCS/1294/10, see: http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_s_001.pdf

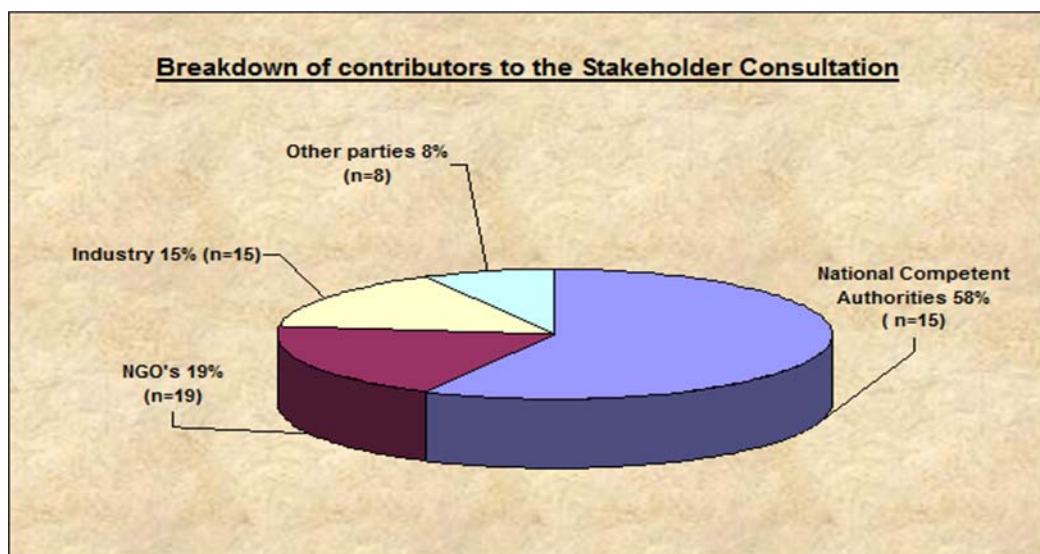
¹¹ EFSA: Existing approaches incorporating replacement, reduction and refinement of animal testing: applicability in food and feed risk assessment, Opinion of the Scientific Committee/Scientific Panel, Question No EFSA-Q-2005-231, See: <http://www.efsa.europa.eu/en/efsajournal/doc/1052.pdf> Echa: 'The Use of Alternatives to Testing on Animals for the Reach Regulation', 2011 http://echa.europa.eu/documents/10162/13639/alternatives_test_animals_2011_en.pdf

¹² An Expert Consortium Review of the EC-commissioned Report "Alternative (Non-Animal) Methods for Cosmetics Testing: Current Status and Future Prospects – 2010", Altex 28, 3/11

¹³ See:

http://ec.europa.eu/consumers/sectors/cosmetics/documents/animaltesting/stakeholders_consultation_en.htm

accordance with Directorate-General SANCO's "Code of Good Practice For Consultation of Stakeholders"¹⁴. A summary of the consultation is contained in Annex 1.



A targeted stakeholder consultation was chosen as it was considered to be the consultation at the most appropriate level to obtain the information required to assess the impacts of the 2013 deadline. This choice was confirmed by the large sample size on which the industry input was based. The Colipa submission was based on input from 24 large and 100 small companies, while in a public consultation carried out in 2007 in relation to the revision of the Cosmetics Directive¹⁵ a total of 47 industry stakeholders replied.

The consultation document outlined the option to postpone the deadline (including sub-options, such as postponing for certain endpoints only, and the possibility to have no fixed cut-off date) and the option to maintain the deadline irrespective of availability of alternatives (thus not to make a proposal). It included a questionnaire that was aimed at obtaining data to allow the Commission services to assess the likely impacts of the 2013 marketing ban.

As a result of the input received an additional option was added to the considerations by the Commission, the introduction of a derogation mechanism. The targeted stakeholder consultation was therefore followed up and further detailed in relation to the derogation option (Option 3, below 4.3) through bilateral consultation with stakeholders and through detailed presentations in the Cosmetics Committee and Working Group on 9 November 2011 and 23 March 2012. In these meetings, as well as in several bilateral meetings, the details of the derogation option were described to stakeholders and discussed. All stakeholders that were part of the targeted consultation were provided with an outline of the derogation and had the opportunity to comment.

In the overall debate all stakeholders support the long term objective to replace animal testing for cosmetics. Animal testing is a tool to ensure consumer safety but has in itself no specific interest or value for the stakeholders involved. The question at stake is therefore how to deal with the situation until alternative methods become available. Here, the stakeholder consultation showed diverging views as to the expected impacts of the entry into force of the 2013 marketing ban and the best way forward. Industry, several Member State Competent Authorities (Czech Republic, Denmark, France, Germany, Greece, Italy and Poland) and the

¹⁴ Directorate-General SANCO's "Code of Good Practice For Consultation of Stakeholders", see http://ec.europa.eu/dgs/health_consumer/dgs_consultations/docs/code_good_practices_consultation_en.pdf

¹⁵ See: http://ec.europa.eu/consumers/sectors/cosmetics/documents/revision/index_en.htm

SCCS expected significant negative impacts on the availability of cosmetic ingredients and products, the competitiveness of the cosmetics industry and on employment. They considered an extension of the deadline the most logical way forward. Animal welfare organisations and some Member State Competent Authorities (Austria and Sweden) by contrast considered that the bans were based on an ethical decision, that possible negative economic and social impacts play no role in the decision-making and were clearly opposed to any change in the deadline. They considered that in any case such impacts were unlikely as manufacturers could rely on existing data and ingredients.

Some stakeholders, in particular Colipa, EFfCI and ECEAE, collected data from their members for a consolidated submission of their respective organisation to the consultation. When this data is relied on in the following impact assessment, reference is made to the respective data (Colipa data¹⁶, EffCI data, ECEAE data based on companies taking part in the Leaping Bunny¹⁷).

The input and data received in this consultation is one of the main pillars of the following assessment and reference is made to the received data throughout the assessment.

Stakeholders were in addition informed and consulted in the framework of regular meetings of the Standing Committee and the Working Group¹⁸ on Cosmetics. Targeted meetings took place at senior level with representatives from industry associations and animal welfare organisations on various occasions.

1.3. Other contacts with stakeholders

Since the beginning of its assessment, the Commission services have received a large amount of e-mails, faxes and letters from citizens requesting it to maintain the 2013 deadline. A petition of one of the animal welfare organisations alone resulted in 350 000 signatures in favour of maintaining the ban¹⁹. The European Parliament's Intergroup on the Welfare & Conservation of Animals²⁰ also called for no extension to the deadline.

1.4. Contacts with Third Countries

The Commission services work actively with its counterparts from the United States, Japan and Canada in the framework of the "International Cooperation on Cosmetic Regulation" ("ICCR"). Animal testing has been a key issue for ICCR since its inception. In this context, the International Cooperation on Alternative Test Methods (ICATM) started in September 2008, was implemented in April 2009 and has in the meantime become well established. ICATM members cooperate actively on the validation of alternatives and provide regular reporting to the ICCR. The targeted stakeholder consultation document was sent to ICCR partners, however no input was received. This may have various reasons, from not having specific data to provide to political reasons. In the first phase of consultations a reaction from the United States Food and Drug Administration (FDA) was received.

The issue has also been raised in the framework of bilateral contacts by the Commission, such as with Chinese authorities, who submitted their support for a postponement of the 2013

¹⁶ The Colipa submission is based on the input of 24 large companies (accounting for a major part of EU production) and 100 SMEs (from France, Italy, Spain, Germany and UK as main producing countries, as well as other countries such as Poland and Bulgaria)

¹⁷ The Leaping Bunny trademark certifies compliance with the criteria of the Humane Standards, which are in the EU managed by ECEAE; 25 cosmetic and personal care companies from the UK, France, Germany, Sweden and Denmark were consulted – 2 of them were large, the rest SMEs.

¹⁸ Cosmetics Committee: 08.02.2010, 08.11.2010, 08.02.2011, 14.06.2011, Working Group: 23.06.2010, 08.02.2011, 14/15.06.2011

¹⁹ Humane Society International, Cruelty Free 2013

²⁰ Letter from Intergroup to Commissioner Dalli of 16 February

deadline in the framework of the targeted stakeholder consultation. China has over the last years overhauled its cosmetics legislation and requires in many instances animal testing data for the cosmetics safety assessment.

1.5. External studies

For the preparation of this impact assessment no specific external studies have been mandated, as it was considered that an external contractor would not have had access to additional data and would have consulted the same stakeholders. In addition, the recent revision of the Cosmetics legislation, which led to the adoption of Regulation 1223/2009/EC²¹, was preceded by an extensive impact assessment²². The Commission services took the data generated in that context and in particular the RPA study "Impact of European Regulation on the EU Cosmetics Industry" of September 2007²³ and the work done by Global Insight "Study of the European Cosmetics Industry" of October 2007²⁴ into account for this assessment. For some of the data in these two reports the targeted stakeholder consultation provided updated or more accurate data.

1.6. Inter-Service steering group on the impact assessment

Commission inter-service steering group meetings took place at the different stages of the assessment (20 July 2010, 21 September 2010, 23 June 2011 and 3 February 2012). The following Directorate-Generals were invited and regularly informed of the progress of the assessment: DG ENV, DG ENTR, DG RTD, DG TRADE, DG MARKT, SG, LS, BEPA and JRC.

1.7. Follow-up to Impact Assessment Board recommendations

The Impact Assessment Board issued its Opinion on 25 May 2012 (Reference 2011/SANCO/025). On the basis of this opinion the final report was adapted, in particular in line with the Board's recommendation to:

- Improve the presentation of the problem;
- Better explain the options;
- Strengthen the assessment of impacts;
- Improve the comparison of options;
- In relation to procedure and presentation, to better present the stakeholder's different views.

A number of more technical comments made by the Board were equally taken into account and the draft report was adapted accordingly.

²¹ Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, OJ L 342, 22.12.2009, p. 59-2009

²² Impact assessment - Report on simplification of the "Cosmetics Directive" – Directive 76/768/EEC (COM(2008)49 final) (SEC(2008)118) /SEC/2008/0117 final, also accessible under http://ec.europa.eu/consumers/sectors/cosmetics/documents/revision/index_en.htm#h2-impact-assessment-report

²³ See: <http://www.rpaltd.co.uk/documents/J574Cosmetics2.pdf>

²⁴ See: http://ec.europa.eu/enterprise/newsroom/af_getdocument.cfm?doc_id=4562

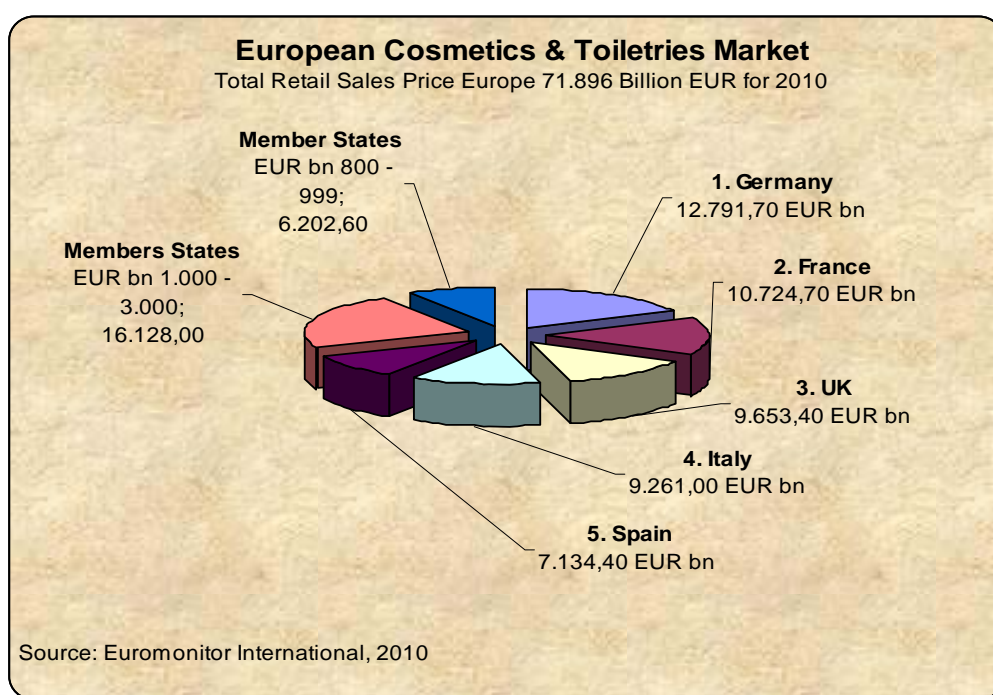
2. PROBLEM DEFINITION

2.1. General Policy Context

2.1.1. Cosmetics sector

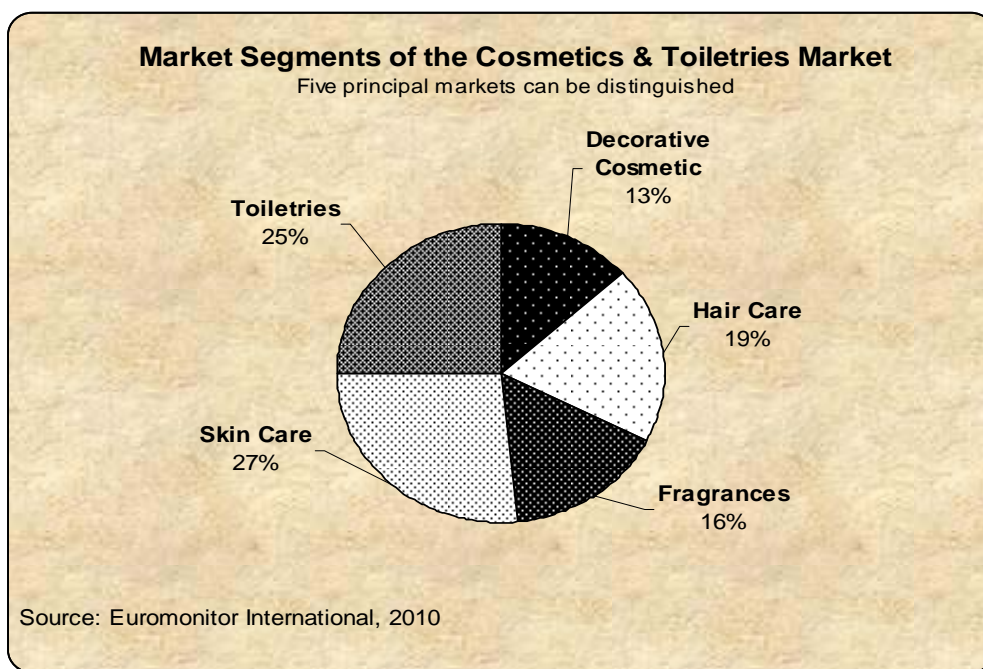
Cosmetics range from everyday hygiene products, such as soap, shampoo, deodorant and toothpaste to luxury beauty items including perfumes and decorative cosmetics.

The European Cosmetics and Toiletries industry recorded a total retail sales price of EUR 71.8 billion in 2010²⁵. These figures are based on more recent Euromonitor data provided by the cosmetics industry than the one provided to the targeted stakeholder consultation. There the market was estimated at EUR 66.6 billion This represents almost half of the global market. The market is led by Germany and France, followed by the United Kingdom, Italy and Spain. These five Member States make up 69% of the total retail sales price, the remaining 31% are shared between two groups of Members States, those with a turnover ranging from EUR 800 to 999 and those between 1 000 to 3 000 billion.



The cosmetics industry is composed of five main sub-sectors and market segments that can be distinguished as follows:

²⁵ Cosmetics Europe, Report of Euromonitor International, 2010



The two main segments, i.e. the skin care and toiletries segment, account for around 52% of the total market. The segments hair care, fragrances and decorative cosmetics cover the remaining market share of 48%. Almost all segments, especially decorative cosmetics and toiletries products, recorded a positive growth over the past years.

The structural conditions of the European industry are on the one hand characterized by multinational conglomerates. There are a significant number of major international cosmetic firms in Europe, mainly in France and Germany. The leading companies are L'Oreal, Beiersdorf, Henkel, Procter & Gamble, Unilever, Johnson & Johnson, Sara Lee and Colgate. European leader is the French company L'Oréal, which is also the world's leading cosmetics manufacturer. Large companies are estimated to have a market share of about 70%. On the other hand the clear majority of companies in number in the cosmetics field are small- and medium-sized companies (SMEs), with several hundred of them in most Member States²⁶.

Overall, the EU cosmetics industry comprises approximately 4 576 companies, including over 4 072 SMEs²⁷. It is estimated to directly employ more than 184 000 people, indirect employment of retail and beauty salons is estimated to about 1.7 million employees²⁸.

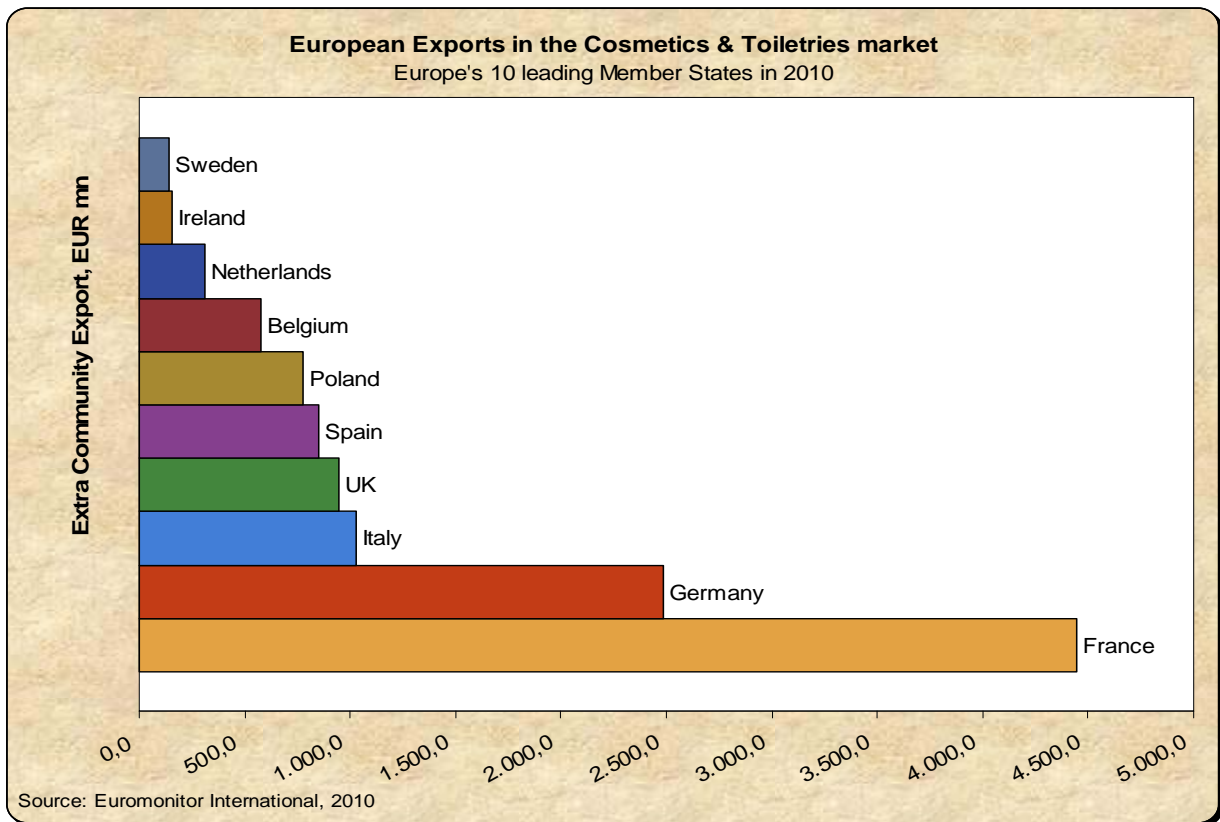
Many of the SME's in the Cosmetics and Toiletries industry have fewer than 10 employees and thus qualify as microenterprises. For example, there are an estimated 855 firms with fewer than 10 employees in France and Italy.

Extra community exports of cosmetic products from the EU totalled EUR 12.4 billion in 2010, with France and Germany being the largest exporters. Exports play a particularly important role for larger cosmetic manufacturers, as well as for cosmetic ingredient manufacturers. Exports clearly outweigh imports within the Cosmetics market.

²⁶ Global Insight, A Study of the European Cosmetics Industry

²⁷ COLIPA, Euromonitor International, 2010

²⁸ COLIPA, Euromonitor International, 2010



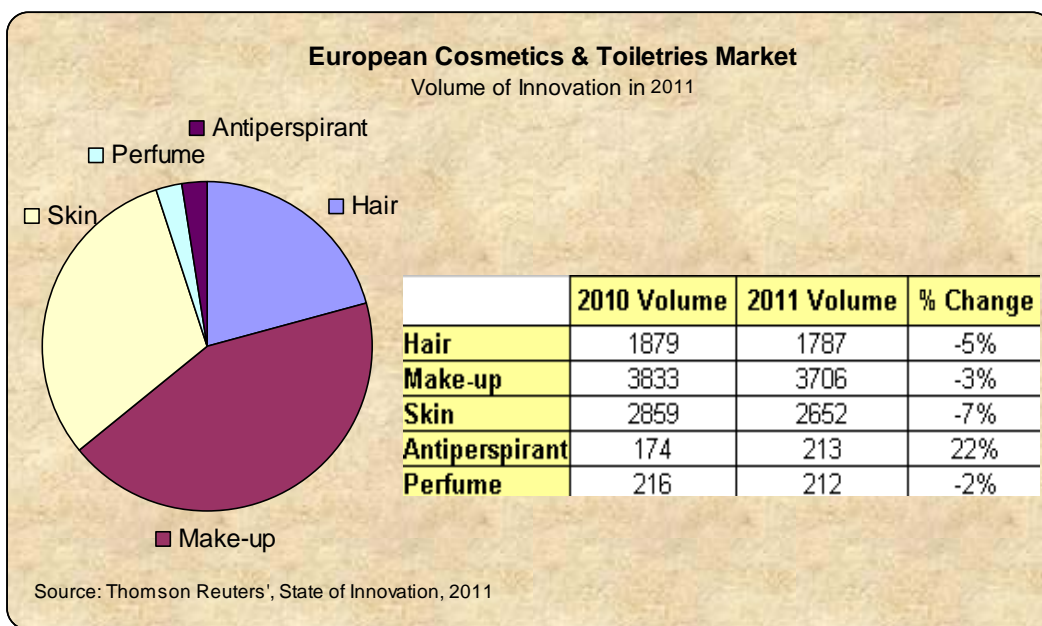
The European Cosmetics & Toiletries market faces new challenges in the highly competitive global market. There is increased competition and simultaneously potential growth in the overall saturated global market from emerging markets. China's premium cosmetics market is for example expected to double by 2015 to reach \$7 billion and Latin America's industry value in 2015 is expected to be the third largest globally.

The innovation potential of Europe's Cosmetics and Toiletries market is highly important for trade and growth. Product innovation is a major driver for growth of the cosmetics industry in the EU; several thousand new or improved products are placed on the market each year with major companies, on average, reformulating or replacing around 25% of their cosmetics products annually²⁹.

Patent activity is one indicator for innovation. The cosmetics industry is responsible for a large part of the overall patent activity in the EU, with a total of 6 082 patents filed in 2011, compared to a volume of 6 438 inventions in 2010. While there was a growing demand for patent protection in relation to ingredients for cosmetics and perfumes, with a steep increase since 2000³⁰, there is a decline of 6% between 2011 and 2010.

²⁹ Comparative Study on Cosmetics Legislation in the EU and Other Principal Markets with Special Attention to so-called Borderline Products, DG ENTR, 2004 and Colipa submission to Targeted Stakeholder Consultation

³⁰ Union for Ethical Bio Trade, A review of patent activity in the cosmetics sector in the context of the ethical sourcing of biodiversity, 2010



The sectors with the highest patent volume remain, despite a general decline in all subsectors with the exception of antiperspirants, hair, make-up, skin antiperspirant and perfumes.

Ingredients play the key role in product and technology innovation in cosmetics and perfumes, and are consequently the focus of significant patent activity. Ingredients and extracts for cosmetics and perfumes may be drawn from a variety of sources, including synthetic compounds, botanicals or minerals, such as mica used to add sheen and glitter. Among the main European players for patent assignees for extracts and ingredients is L'Oreal, followed by Unilever, Henkel and Beiersdorf. As regards the range of materials and technologies involved in patent applications for the cosmetics and perfumes sectors peptides play an important role, but biochemistry and more recently emerging areas such as nanotechnology play a role as well. Often fields referenced in cosmetics patents are also referenced in the pharmaceutical field.

2.1.2. Cosmetics Regulatory Framework

The Cosmetics Directive 76/768/EEC is the regulatory framework for the placing on the market of cosmetic products. Its key objectives are to ensure consumer safety and to secure an internal market for cosmetic products. It is based on manufacturer responsibility for the safety of products. For certain ingredients - colorants, preservatives and UV-filters - only ingredients included in positive lists (Annexes IV, VI and VII to the Cosmetics Directive) can be used. Also, a large number of ingredients are either prohibited or restricted (Annexes II and III) and manufacturers need to take account of this in their product formulation. Inclusion in the Annexes is preceded by a scientific risk assessment by the Scientific Committee.

In order to ensure the safety of products manufacturers must carry out a safety assessment, which includes a study of the intrinsic properties of all ingredients contained in the product. A number of key endpoints need to be addressed, such as whether the ingredient can cause allergies or whether it otherwise causes damage to the human body as a result of repeated use, such as cancer. To assess these questions currently animal testing data is often relied on. The testing to obtain such data does not have to be carried out by the manufacturer - in many cases such safety data is available upstream from the ingredient manufacturer or through other data sources. Testing does not need to be carried out for each batch or each product, it is sufficient to have determined the profile of an ingredient once. Such testing would typically be carried out relatively early on in the product development, in most cases around 2 to 3 years before

the product actually reaches the market. Testing must comply with the principles of good laboratory practice³¹ and follows defined testing protocols set out in Council Regulation (EC) 440/2008³² and in most cases based on OECD Testing Guidelines. Whether animal testing data is relied on or not becomes evident in the manufacturers safety assessment – which needs to be documented and kept available to the authorities.

The Cosmetics Directive aims at phasing out animal testing for cosmetic purposes. Besides the complete testing ban for cosmetic products and their ingredients, a marketing ban has applied since 11 March 2009 for all human health(-related) effects with the exception of repeated-dose toxicity (including skin sensitisation and carcinogenicity), reproductive toxicity and toxicokinetics, for which the deadline is 11 March 2013. As a result no testing for cosmetic purposes can be carried out inside the EU, but for the endpoints covered by the 2013 deadline testing can be carried out outside the EU and the results of tests performed before that date can be relied on in the safety assessment. There is a possibility for Member States to request a derogation from these provisions in case a human health problem is substantiated for an ingredient that is in wide use and cannot be replaced by another ingredient capable of performing a similar function.

The provisions in relation to animal testing were not changed by the recast of the Cosmetics Directive by Regulation (EC) 1223/2009. The Cosmetics Regulation did however further strengthen the requirements for the safety assessment and will thus rather lead to an increased need for toxicological data. It also introduced specific provisions for nanomaterials, requiring manufacturers to inform the Commission about the toxicological profile and the safety data of the material before placing the cosmetic product on the market. The Cosmetics Regulation repealing the Cosmetics Directive as of 11 July 2013, any proposal would amend the Cosmetics Regulation only.

2.1.3. Previous Legislation in relation to the Marketing Ban

The first provisions in relation to the marketing ban of cosmetic ingredients or combinations of ingredients tested on animals in order to meet the requirements of the Directive were introduced to the Cosmetics Directive by Directive 93/35/EEC³³ with an application date of 1 January 1998. The introduction of the marketing ban was based on the political objective to end animal testing for cosmetics. The '3R' principle – aiming to replace, reduce and refine animal testing wherever possible – had earlier on been integrated in Directive 86/609/EEC³⁴. The introduction of the ban at the time was not based on a science based assessment that alternative methods would be available by 1998. Indeed, the European Centre for the Validation of Alternative Methods (ECVAM) had only been founded in 1992 and no validated alternative methods were in place yet. The provisions foresaw that, in case alternative methods would not be available in time, the Commission would propose the postponement of the ban by 1 January 1997 for no less than 2 years.

The ban was postponed for the first time by Commission Directive 97/18/EC³⁵ to June 2000, essentially stating that alternative methods were not yet available and that the scientific developments were difficult to foresee, but that given the need of close follow-up of the issue the next scientific re-assessment should not be pushed out too far.

³¹ See Article 10 (3) of Regulation (EC) 1223/2009 of the European Parliament and the Council on cosmetics products, 22.12.2009, OJ L 342, p. 59 - 209

³² See Article 10 (3) of Regulation (EC) 1223/2009 of the European Parliament and the Council on cosmetics products, 22.12.2009, OJ L 342, p. 59 - 209

³³ Directive 93/35/EEC, OJ L 151, 23.06.1993, p. 0032-0037

³⁴ Council Directive 86/609/EEC regarding the protection of animals used for experimental and other scientific purposes OJ L 358, 18.12.1986, p. 1–28

³⁵ Directive 97/18/EC, OJ L 114, 01.05.1997, p. 0043-0044

The second postponement was an interim Commission measure. In 2000 the Commission had already made the co-decision proposal that eventually lead to Directive 2003/15/EC³⁶, the third postponement. But it was clear that this proposal would not be adopted before the lapse of the deadline in 2000. The Commission therefore proposed by Commission Directive³⁷ to postpone the deadline until 30 June 2002. Directive 2003/15/EC, the third postponement which sets the current deadlines, was adopted in February 2003.

With the proposal for Directive 2003/15/EC the Commission intended to move from a marketing to a testing ban, first for products and later for ingredients. It also proposed to postpone the entry into force of the testing ban for ingredients in the absence of alternatives. These changes were proposed in order to address enforcement difficulties and the unavailability of alternative methods. However, in the co-decision procedure the testing and marketing ban were both imposed and the 2009 deadline for the full testing ban and the partial marketing ban was clearly made independent of alternatives being available.

A number of elements are therefore different in the situation under consideration now compared to the earlier postponements. These are:

- The European Parliament and the Council made it clear that it is willing to set fixed cut-off dates, even in the absence of alternatives. The testing and part of the marketing ban accordingly apply since 2009 in the absence of alternatives with respect to some endpoints;
- The European Parliament and the Council made it clear that a constant review process with postponements by the Commission is not the acceptable way forward and did not provide this right to the Commission in Directive 2003/15/EEC (any change now requires co-decision);
- Considerable progress has been made in the development of alternatives since 2003. The extensive expert review carried out in the above described first phase of stakeholder consultation made it however also clear that for most endpoints covered by the 2013 deadline it will take at least 10 years and most likely more to fully replace animal testing. This puts the overall policy approach of recurrent postponements in question.

One of the options considered in this assessment is a postponement similar to the ones before (see option 2 (a) below). However, as described above, the current situation does not necessarily require the same policy response as before.

2.1.4. Implementation of the 2009 Testing and Marketing Ban and Impacts

The implementation and enforcement of the testing and marketing ban is the responsibility of Member States. The Commission annual reports³⁸ cover certain aspects of the implementation and enforcement. They address the availability of alternative methods and the progress in research, the number of animals used in the EU for testing until the 2009 ban entered into force and technical difficulties in complying with the bans. Endpoints falling under the 2009 deadline of the marketing ban are: skin corrosivity, skin irritation, dermal absorption, phototoxicity, mutagenicity/genotoxicity, acute toxicity and eye irritation. Not all endpoints falling under 2009 can be fully replaced by alternative methods yet. For the last three endpoints full replacement is not yet possible, respectively limitations exist. The 2009 marketing ban applies irrespective of this unavailability and appears not to have caused major

³⁶ Directive 2003/15/EC, OJ L 66, 11.03.2003, p. 0026-0035

³⁷ Directive 2000/41/EC, OJ L 145, 20.06.2000, p. 0025-0026

³⁸ Available under: http://ec.europa.eu/consumers/sectors/cosmetics/documents/animal-testing/index_en.htm

negative impacts so far. The Commission services are not aware of products being taken from the market by Member State authorities as a result of the marketing ban and the stakeholder consultation did not result in concrete information on negative impacts, even though this question was raised. Nevertheless the Commission services are faced with first cases in which the SCCS cannot provide a conclusive opinion on the safety of a substance as data on the 2009 endpoints is missing or not sufficient for the assessment. These situations are expected to become more frequent.

Impacts of the 2009 ban are therefore not excluded and the fact that not many were reported so far in no way prejudices the possible impacts of the 2013 deadline. A number of elements have to be taken into account here:

- Since the animal testing data is needed at the early stage of the product development, any impacts would most likely become more evident later. The deadline was known and industry prepared;
- The endpoint acute toxicity plays in practice a limited role for the cosmetics industry. Ingredients used in this sector essentially do not raise the risk of acute toxicity and sufficient information is often available from repeated dose studies;
- As regards mutagenicity/genotoxicity alternative tests are available, but come with some drawbacks in that they appear to be oversensitive. However in many cases they will be sufficient to exclude certain properties;
- As regards eye irritation, again some judgements can be made using existing alternative approaches, eg. existing alternatives provide the possibility to eliminate severe irritants;
- Another aspect why the 2009 deadline has apparently not had negative impacts is the uncertainty in relation to the interpretation (see below under 2.1.5.).

These elements also explain why the derogation for Member States has only been requested one time so far.

2.1.5. Legal clarity in relation to the scope of the testing and marketing ban

The current provisions on animal testing have been subject to diverging interpretations by different stakeholders. The main discussions on the scope centre on the wording used in the testing as well as the marketing ban "*in order to meet the requirements of this Directive*".

Starting point for the discussion is the fact that the majority of ingredients used in cosmetic products are ingredients that are equally in use in many other consumer and industrial products, such as in pharmaceuticals, detergents and food, and animal testing may be necessary to ensure compliance with the legal frameworks applicable to these products. Ingredients used in cosmetics will generally also be subject to the horizontal REACH³⁹ requirements and animal testing may be necessary as a last resort to complete the respective data packages.

Shortly after its adoption, the relevant provisions of Directive 2003/15/EC were challenged by the French Republic before the European Court of Justice in case C-244/03. However, the

³⁹ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, Official Journal L 136, 29.5.2007, p. 3.

case was held inadmissible. Currently, there is no jurisprudence of the Court of Justice of the European Union ('the Court') on the interpretation of the scope of the 2013 marketing ban. Only the Court can provide a legally binding interpretation of Union law. The Commission services role is to oversee, under the control of the Court, the application of the provisions by Member States.

The Commission services consider that data from animal testing generated before the respective deadlines can be used and relied on after the deadline and do not trigger the marketing ban.

The Commission services also consider that animal testing that has clearly been motivated by compliance with non-cosmetics related legislative frameworks should not be considered to have been carried out *'in order to meet the requirements of this Directive/Regulation'*. The resulting animal testing data should not trigger the marketing ban and could subsequently be relied on in the cosmetics safety assessment.

Independent of the option chosen, it is necessary to provide clarification on the interpretation in order to ensure a coherent application of the legal framework by Member States and to provide a clear and predictable legal framework for the economic operators.

2.1.6. Provisions in relation to Animal Testing in other Union legislation

The protection and welfare of animals is an area covered by a wide range of Union legislation. It is covered by Article 13 of the Treaty on the Functioning of the European Union, which requires the Union and Member States to pay full regard to the welfare requirements of animals when formulating policies. Prior to that, the issue was addressed in a Protocol to the Amsterdam Treaty.

Already in 1986 the EU introduced specific legislation covering the use of animals for scientific purposes, Directive 86/609/EEC. In September 2010 Directive 2010/63/EU⁴⁰ was adopted, which updates and replaces the existing legislation. The aim of the new Directive is to strengthen the legislation and to improve the welfare of those animals still needed to be used, as well as to firmly anchor the principle of the '3Rs', to replace, reduce and refine the use of animals, in Union legislation. Directive 2010/63/EU has taken full effect since 1 January 2013. Member States must accordingly ensure that, wherever possible, a scientifically satisfactory method or testing strategy, not entailing the use of live animals, is used instead of animal testing. If replacement is not possible reduction and refinement have to be ensured.

Toxicological data requiring animal testing is needed under many pieces of Union legislation for the regulatory safety assessment. This is for example the case under REACH⁴¹ for chemical substances, which are a major ingredient source for cosmetics. REACH has several provisions in place to reduce animal testing for its purposes. It requires companies to share data in order to avoid unnecessary animal testing. If testing is needed and depending on the tonnage a testing proposal must be submitted to the European Chemicals Agency. Under REACH, animal testing is to be avoided in favour of alternative methods and registrants can only carry out tests involving the use of animals as a last resort. Similarly, the proposal for a

⁴⁰ Directive 2010/63/EU on the protection of animals used for scientific purposes, OJ L 276, 20.10.2010, p.33

⁴¹ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, Official Journal L 136, 29.5.2007, P. 3

new Regulation on Biocides⁴² will require toxicological data including animal data, but animal testing is allowed as a last resort only and data sharing is required.

In summary, Union legislation recognises that animal testing is still needed to ensure the protection of human health and the environment and thus acknowledges that animal testing will be carried out to fulfil the legislative requirements. Union legislation at the same time sets very high animal welfare standards for such testing and requires that whenever possible this testing is replaced, reduced and refined. The Cosmetics legislation is the only legislation that prohibits animal testing irrespective of the availability of alternative methods.

2.1.7. Animal Testing Requirements for Cosmetics in non-EU Countries

In the United States cosmetics are regulated by the Federal Food, Drug & Cosmetics Act, which prohibits the use of any unsafe substance in a cosmetic product. There is no list of toxicology test methods for use in determining the safety of cosmetic ingredients and cosmetic products. It is the manufacturer who is under an obligation to verify whether the cosmetics he places on the market present any risk to consumer health, but it is up to him to decide on the data (literature, tests on animals or humans, alternative tests etc.) used as the basis for proving harmlessness. Otherwise the product must bear the statement 'The safety of this product has not been determined'. New active ingredients in Over-The-Counter (OTC) products (anti-acne, anti caries/anti-plaque, anti-hair loss, anti-dandruff, anti-perspirant products, skin whiteners, sun protection products etc.) must prove their safety on the basis of tests on animals and also clinical tests.

The United States, while not prohibiting animal testing, are also working towards the '3R's'. In 1997, the United States created the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) to reduce animal testing. Once ICCVAM recommends that an alternative method has been adequately validated and the relevant test recommendations are accepted or endorsed by Federal regulatory and other agencies, it becomes available for all toxicology purposes in the United States.

In Japan a number of products that are qualified as cosmetics in the EU are qualified as quasi-drugs. Quasi-drugs include hair dyes and decolourants, anti-hair loss products, hair permanents/straighteners, depilatories, anti-perspirants, deodorants, anti-acne, skin whiteners, bath treatment products, medicinal cosmetics such as anti-dandruff shampoos etc. and are subject to the regulations on pharmaceutical products. A toxicological dossier is required for approval of a new quasi-drug ingredient, including tests for which no alternatives are in place yet. The Act on Welfare and Management of Animals was revised in 2006 incorporating basic consideration for animal testing, handling of animals and introducing the '3Rs' principle. Japan also set up the Japanese Centre for the Validation of Alternative Methods (JaCVAM) in 2005.

In China, the control of cosmetic products and new cosmetic ingredients is since 2008 under the responsibility of the Chinese State Food and Drug Administration (SFDA). For finished cosmetics, depending on the type of product, a hygiene license or record-keeping certificate from the Health Administrative Department of the State Council is required. The hygiene license would for example be required for hair dye or sun protection products or for deodorants. Obtaining the hygiene license requires a testing report from a cosmetics testing institution approved by the SFDA, including animal data. China is starting to consider the acceptance of alternative methods.

⁴² Commission Proposal for a Regulation of the European Parliament and the Council concerning the placing on the market and the use of biocidal products, COM (2009) 267 of 12.06.2009

In conclusion, animal testing data will in many cases be needed to ensure the safety of cosmetic products internationally. If alternative methods are available these will often be acceptable, however levels of acceptance vary between countries. Notably methods included in OECD Test Guidelines will often be accepted.

2.2. Problem Description

According to the expert report on the availability of alternatives (see 1.1), alternative methods to fully replace animal testing for the endpoints covered by the 2013 deadline will not be available by 2013. No specific timeline could be estimated in the areas of toxicokinetics, repeated-dose toxicity, carcinogenicity and reproductive toxicity due to the underlying scientific challenges. The timelines estimated for full replacement of animal tests in the area of skin sensitisation pointed to a further 7-9 years (i.e. 2017-2019) for scientific development. Another 3 to 6 years are likely to be needed for validation and regulatory acceptance of the alternative methods. However, alternative methods able to simply discriminate between skin sensitisers and non-sensitisers are expected to become available earlier.

The problem is therefore in a nutshell that the marketing ban would apply as of 11 March 2013 in the absence of alternative methods, thus effectively limiting the tools needed for compliance with the Cosmetics Regulation. This would have several consequences:

2.2.1. Animal Welfare

The entry into force of the marketing ban in 2013 would be positive in relation to animal welfare, in that it would end animal use for EU cosmetic purposes. This was the objective of the provisions when they were first introduced in 1993. This objective was based on overall ethical considerations and not on animal numbers. Nevertheless animal numbers are an important indicator of the impacts of the 2013 bans on animal welfare.

Since 11 March 2009, animal testing for cosmetic purposes is no longer allowed in the EU. In the reports under the Cosmetics Directive the number of animals used for cosmetic purposes in the EU were highest in 2004 with 8 988 animals and came down to 1 510 in 2008 and 344 in 2009. Animals used for testing for cosmetic purposes include rats, mice, guinea-pigs and rabbits. Any animal testing currently done for EU cosmetic purposes is done outside the EU. Animals spared would therefore be animals of these species outside the EU. Annex 2 provides further data on animal use.

Currently, toxicological animal data is still needed for the cosmetics safety assessment. Whether or not ingredients can be used in cosmetic products depends on whether their safety can be demonstrated. Toxicological data needs arise in two scenarios, the manufacturers own safety assessment and the review by the SCCS, either with a view to the ingredient being added to one of the positive lists or to being prohibited or restricted in use. The highest data need for cosmetic manufacturers exists for skin sensitisation tests, second for repeated dose, third for reproductive toxicity and then for toxicokinetics and carcinogenicity. Information on the need for toxicological data for the cosmetics safety assessment is included in Annex 3.

Over the last ten years large cosmetics companies together carried out on average 213 animal tests for the 2013 endpoints per year, out of which 151 addressed skin sensitisation and 36 repeated dose, thus these two endpoints represent 87% of all testing⁴³. For all of these endpoints the complete replacement of animal tests is not yet possible.

These figures relate to testing carried out for cosmetic purposes. By far not all testing data relied on for the cosmetics safety assessment has been generated for this purpose. The data used so far for the cosmetics safety assessment is indeed in many cases not generated

⁴³ Colipa and EFFCI submissions to the Targeted Stakeholder Consultation

specifically for this purpose. About 90% of ingredients are used in other areas as well. In many cases testing data is provided by the ingredient supplier, who offers the ingredient also for other purposes. Testing data may also be available in publications, databanks, etc. Often the original reason for the testing will not be obvious from the testing data itself. Information on testing data sources is contained in Annex 4.

Large cosmetics companies considered testing data from food, cosmetic products outside the EU and REACH as most important to them⁴⁴. This does not necessarily indicate that this data is available in most cases, as the question was only how important it is considered to be, not in how many cases it was available. However, while there remains uncertainty, it is likely that the importance given also reflects the availability.

As regards the possible total number of animals used outside the EU for EU cosmetic purposes that could be spared as a result of the implementation of the 2013 marketing ban, there is no reliable statistical data. Simply taking EU numbers before the bans as a baseline does not work because 1) in a number of Member States testing for cosmetic purposes was banned before the EU ban (eg. in the United Kingdom in 1998), 2) many manufacturers already moved outside the EU for testing many years ago and 3) older animal numbers can not really give a reliable baseline as some of the tests that were still carried out 10 years ago were using more animals and might now not be needed as such.

While there are no reliable statistics, the information supplied by stakeholders in the targeted stakeholder consultation allow a reasonably solid estimate.

On the one hand, industry contributors confirm that tests were already done outside EU, also ahead of the 2009 testing ban deadline in the EU. About 90% of the testing for cosmetics took place outside the EU in 2008⁴⁵. Given that testing inside the EU for cosmetic purposes in 2008 was at 1 510 this would indicate about 13 590 animals were used outside the EU in 2008. Since after 2009 all testing for cosmetics purposes has to take place outside the EU, around 15 000 animals are likely to be used. Large cosmetic companies carried out in 2010 185 tests for 2013 endpoints using a total of 7 732 animals. They indicated that over the last ten years they carried out in average 213 tests per year. SMEs reported 8 tests in 2010 and a total of 160 animals and a yearly average of 7 tests over the last 10 years⁴⁶. Taking into account that in addition testing is also done or commissioned by ingredient manufacturers, this data suggests that the overall estimate of a minimum of 15 000 animals used outside the EU for EU cosmetic purposes per year is reasonable.

On the other hand, animal welfare organisations provided an estimate for 2005, according to which 58 339 972 animals are used in actual animal testing procedures outside the EU annually⁴⁷. Assuming that the percentage of cosmetics testing in relation to the overall testing would be the same as inside the EU, the respective animal welfare organisation estimates that about 26 836 animals were used for cosmetics testing in 2005 worldwide. This estimate relates to cosmetics specific testing. In contrast to the information supplied by industry above, this information does however not specifically relate to cosmetic specific testing done for EU cosmetic purposes, which could explain why the estimate is higher than the industry figures.

Overall the data provided indicates that between 15 000 and 27 000 animals are used for EU cosmetics specific testing outside the EU yearly.

⁴⁴ Colipa submissions to the Targeted Stakeholder Consultation

⁴⁵ Colipa submissions to the Targeted Stakeholder Consultation

⁴⁶ Colipa submissions to the Targeted Stakeholder Consultation

⁴⁷ Taylor, K., Gordon, N., Higgins, W. and Langley, G. (2008) *Estimates for worldwide laboratory animal use in 2005. Alternatives to Laboratory Animals (ATLA)*. 36 (3); 327-42

These figures remain comparatively limited in relation to the overall number of animals used in the EU for experimental purposes per year (about 12 million)⁴⁸.

However, not all of these 15 000 to 27 000 animals per year would be spared once the 2013 marketing ban comes into force. Cosmetic specific testing outside the EU may be for two reasons at the same time. One is testing for non-EU cosmetics regulatory requirements. While the EU is working with trading partners in order to accelerate acceptance of validated alternative methods, it is unlikely that other countries would ban testing irrespective of the availability of alternatives or even accept alternative methods for regulatory purposes to the same extent as the EU in the short term. The other important reason for testing outside the EU is testing to meet the EU cosmetics requirements.

There is no reliable data that would allow determining exactly which part of the testing outside the EU is carried out for EU cosmetics purposes only and would not take place beyond 2013. Testing is often carried out at the supplier level to establish the safety dossier of an ingredient, without specifically targeting only a certain market. Equally, testing carried out by international cosmetic companies will be geared at establishing the safety of the ingredient, but not necessarily only with a view to a specific market. Testing carried out in line with OECD Test Guidelines can be relied on then in all OECD countries and beyond.

To which extend testing outside the EU would diminish as a result of the ban depends largely on business decisions of companies. It concerns cases in which the data is needed to ensure the safety of the product and cannot be obtained through alternative methods. In the EU the ingredient could therefore not be used. Essentially the question is whether a cosmetics company would forego the testing for third countries in these cases. This depends on several criteria and strategic decisions of companies and manufacturers, e.g. how important the ingredient for manufacturers or companies is; how profitable it is to invest in a certain test (animal testing can be costly, from EUR 4 000 for a skin sensitisation test to about EUR 780 000 for a carcinogenicity test⁴⁹), whether or not the manufacturer considers that the non-EU market alone warrants the investment or if the company considers a possible shift of investment into other non-EU markets.

Due to these underlying uncertainties making further assumptions (such as all animals currently used would be spared, versus none of them or a certain percentage of them) will not lead to a more reliable estimate. In addition, the exact number of animals spared is likely to play a limited role for the political decision-making. Animal welfare stakeholders recognise that the number of animals used for cosmetics is comparatively low, but consider that the question is one of principle. For the purposes of this impact assessment it is therefore considered that a sub-set of the 15 000 to 27 000 will be spared.

The ban would have no immediate positive impacts in relation to the number of animals used in other sectors overall in the EU for the respective 2013 endpoints, which amounted in 2008 to 257 350 animals⁵⁰ and was estimated by animal welfare stakeholders to be 134 180 in 2005 outside the EU. In the absence of alternative methods animal testing will still need to be carried out to comply with other applicable legislative frameworks. On the longer run, the

⁴⁸ Sixth Report from the Commission to the Council and the European Parliament on the Statistics on the number of animals used for experimental and other scientific purposes in the member states of the European Union COM(2010) 511/final 2, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2010:0511:REV1:EN:PDF>

⁴⁹ 'Food for Thought ... on the Economic of Animal Testing', Bottini and Hartung, Altex

⁵⁰ Sixth Report from the Commission to the Council and the European Parliament on the Statistics on the number of animals used for experimental and other scientific purposes in the member states of the European Union COM(2010) 511/final 2, see: <http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2010:0511:REV1:EN:PDF>

marketing ban in the Cosmetics Directive is expected however to also have kick-off effects on the use of animals in other sectors. Alternative methods developed in the cosmetics context can and are used to replace animal testing in other sectors as well and *vice-versa*. All methods validated and accepted at regulatory level are included in Commission Regulation (EC) 440/2008, and not specifically in Annex IX to the Cosmetics Directive. Also, while the Cosmetics Directive only looks at replacement, the path to developing a full replacement often leads first to refinement and reduction and thus already benefits animals.

As mentioned, the number of animals used is not the sole indicator of animal welfare: the existing provisions represent a clear political and ethical choice to value animal welfare higher than economic and “lifestyle” driven interests. They result from many years of very engaged public and political discussions, going back more than 20 years.

Most information on public opinion in relation to animal testing for cosmetics was presented by the animal welfare organisations in the framework of the targeted stakeholder consultation. The information provided indicates that, depending on the poll, between 60 and 88% of the citizens favoured a complete ban on animal testing for cosmetics. A 2009 "You Gov" poll showed that 79% of respondents were against testing that does not relate to serious or life-threatening human conditions.

A Eurobarometer⁵¹ study showed that the majority (66%) of respondents find that scientists should be allowed to do research on animals, like mice, if it produces new information about human health problems, while only 18% of respondents disagree. However, the purpose of the testing is critical for the decision.

The overall long-term objective to end animal testing for cosmetics is shared by all stakeholders. Stakeholders have no interest in animal testing as such, other than as a tool to ensure and demonstrate consumer safety. Indeed alternative methods may turn out to be beneficial for industry. A recent example of an ECVAM validated method to address *in vitro* carcinogenicity testing – while it only presents a partial replacement - shows that the costs of the alternative (EUR 12 000 to 35 000 per substance) were low in comparison to the animal test (EUR 1 to 1.5 million per substance). With 2-7 weeks required per substance compared to 3 years in the animal test the alternative would also be faster.⁵²

Stakeholders hold however diverging views on the impacts of the ban on animal welfare. Animal welfare groups consider the effects on animal welfare to be very high and point also to the kick-off effects for other sectors. They underline that actual numbers are in any case not decisive for their view, but the underlying basic ethical decision against animal testing. Industry stakeholders point out that the overall number of animals to be saved is very small in relation to overall animal use for scientific purposes. They also consider that the animal use would continue for outside EU use in any case.

2.2.2. Research into Alternatives to Animal Testing

The implementation of the ban is expected to have overall positive impacts in relation to research into alternative methods.

Considerable amounts of funding have been made available to find and validate new alternative test methods. For this purpose the Commission made about EUR 238 million available between the years 2007 to 2011 alone. The major part of this budget, around EUR

⁵¹ Special Eurobarometer 340 / Wave 73.1 – TNS Opinion & Social, June 2010

⁵² EURL ECVAM Recommendation of 14.03.12 on three Cell Transformation Assays (CTA)

Using Syrian Hamster Embryo Cells (SHE) and the BALB/c 3T3 mouse fibroblast cell line, see: http://ihcp.jrc.ec.europa.eu/our_labs/eurl-ecvam/eurl-ecvam-recommendations/EURL-ECVAM%20-Recommendation.pdf

198 million, was spent on projects through the 6th and 7th Framework Programmes and the LIFE + Programme. The second most important tranche, about EUR 38 million, was spent on the European Reference Laboratory (EURL) for Alternative Methods to Animal Testing (ECVAM).

At Member State level the funding available varies strongly from Member State to Member State.

Examples (Note that these figures are not always representative of the entire funding in the Member State concerned):

Austria: Average for 1992 -2005 EUR 250 000 per year;

Belgium: Between 2005 and 2013 EUR 1 395 847;

Denmark: Between 2005 and 2008 EUR 47 million;

France: In 2010 EUR 2.75 million;

Germany: Between 2000 and 2009 EUR 42.5 million and in 2010 EUR 7.4 million;

Netherlands: In 2010 EUR 2 million;

Sweden: From 2004 onwards around EUR 1.6 million per year.

On the industry side equally there have been significant efforts. In the recently launched research project Seurat-1⁵³ on methods for repeated dose systemic toxicity, the EUR 25 million which come from the EU research framework programme are matched with EUR 25 million from the European cosmetics industry, represented by Colipa.

This is in addition to various projects at association and company level. Individual companies often work in partnerships with academic institutions.

Examples: One company invested EUR 30 million in the last 25 years, another has spent an overall of 285 million USD and another gave the figure of EUR 3 million a year for external research on alternatives in addition to own research. There are no overall figures available for the industry investments.

The percentage of cosmetics and cosmetic ingredients industry's investment in research and development (general, not alternative method related) ranged from 0.5 to 3.5% of net sales. The German industry association IKW estimates that about 2.5 to 5% of the turnover are used for R&D. EFfCI assumes that up to 1% of the annual turnover achieved in the cosmetic ingredients business by larger companies is used to develop alternative testing methods.

The majority of the answers received in the stakeholder consultation highlight the positive impact the provisions in the Cosmetics Directive and in particular the setting of the 2013 deadline had on research into alternative methods to replace animal testing. The provisions are generally seen as a crucial accelerator of research and validation of alternative methods by all stakeholders. Indeed many projects in this area make explicit reference to the provisions in the Cosmetics Directive. Stakeholders also point out that the number of validated methods has greatly increased since 2003 when the current deadlines were set (13 methods between 2003 and 2009 compared to 6 in the period between 1998 and 2002). The search for alternative methods is by now also more and more recognized as the search for better science and forms part of an overall shift of paradigm in safety assessment. Maintaining the deadline is expected by many to lead to a continuation or even acceleration of these developments. Certainly the

⁵³ See: <http://www.seurat-1.eu/>

deadline leaves industry with no other choice than research into alternatives to bring new cosmetic ingredients on the European market.

Industry stakeholders however point out that while the research investments were motivated by and linked to the deadlines, letting the marketing ban apply without alternatives would risk leading to less funding available for research into alternatives. The main argument brought forward is that the expected negative impacts from the marketing ban on competitiveness (see below under 2.2.5) will also weaken the industry's ability to invest in alternatives. Industry also cautions that research might move outside the EU.

2.2.3. Consumer Safety

Specific impacts on consumer safety are not expected from the 2013 deadline. Consumer safety is the key objective of the Cosmetics Directive. Manufacturers can only place cosmetic products on the market if they are safe. Manufacturers must not place products with ingredients for which insufficient safety data is available on the market. Market surveillance authorities must ensure that the requirements of the Directive are complied with. Most Competent Authorities in the replies to the targeted stakeholder consultation confirmed that in the course of market surveillance manufacturers that would rely on insufficient data would be identified.

There is no pre-market authorisation for placing cosmetic products on the market. Compliance with the Directive, such as for example not using ingredients that are prohibited, is ensured through market surveillance, thus in market product spot-checks. Market surveillance is always linked to resources available, only a sample of products will come under scrutiny. These limitations apply to all provisions of the Directive.

Nearly all stakeholders agree that while it is clear that a full safety assessment solely based on alternative methods is not possible yet, this will result in not being able to place certain products on the market, not in placing unsafe products on the market. Stakeholders agree that consumer safety is not put at risk through the 2013 deadline.

2.2.4. Consumer Choice and Product Innovation

Overall negative effects are expected from the 2013 marketing ban for consumer choice and product innovation compared to the situation before the ban. The cosmetics industry is highly innovative. On average large cosmetic companies have a product portfolio of around 10 000 different cosmetic products, SMEs of around 160 products⁵⁴. Companies working under the Leaping Bunny label had a smaller product portfolio. They have, for large companies, 592 products on offer and, for SMEs, 40.

Industry stakeholders indicate the product life of a cosmetic product at 3 years⁵⁵. There is an estimated 25% - 30% renewal of cosmetic products on the market per year. Out of the 25% to 30% of reformulations, 90% rely on ingredients already used in the cosmetics sector, 10% depend on new to market (= ingredients not yet used in any other sector) or new to cosmetics market (= ingredients already in use in other sector, but new to cosmetics use) ingredients⁵⁶. Information on cosmetic products and their lifecycle is contained in Annex 5.

Cosmetic products consist of between 5 to 60 ingredients each. Large cosmetics companies have an ingredient portfolio of 2 000 ingredients and SMEs of 600 ingredients. This toolbox is constantly evolving.

⁵⁴ Colipa submission to Targeted Stakeholder Consultation

⁵⁵ ECEAE submission to Targeted Stakeholder Consultation

⁵⁶ Colipa submission to Targeted Stakeholder Consultation

Large companies introduced around 80 new ingredients per year between 2000 and 2009 (SMEs 22), representing around 4% of their ingredient portfolio⁵⁷. Only 10% of these ingredients introduced into the portfolio are estimated to be new to the market. 90% are/have been used in other sectors, including cosmetic products outside the EU, food, pharmaceuticals, detergents, and will partially be covered by REACH. Information on cosmetic ingredients portfolios and changes to it are included in Annex 6.

Negative impacts of the 2013 deadline are first expected in relation to ingredients that are new to the market – thus ingredients that are cosmetic specific and have not been used in other areas. For such new cosmetic specific ingredients at least part of the data necessary for the safety assessment will not be available. Since these are new cosmetic specific ingredients it is not possible to rely on existing data or data from other regulatory frameworks. 4% of the ingredients portfolio are renewed each year and 10% of these 4% new ingredients introduced are new to the market. When calculating this down to total numbers per manufacturer a large manufacturer with an ingredient portfolio of 2 000 ingredients could lose 8 of the 80 ingredients it would normally introduce per year.

Second, negative impacts are expected, though to a lesser extent, for ingredients that are new to the cosmetics market, but have been used in other sectors. This is the case for 90% of the 4% newly introduced ingredients, in total numbers this represents about 72 ingredients per large manufacturer per year. For these ingredients in the majority of cases data from other regulatory frameworks will be available, however not in all cases and not always on all relevant endpoints. In 50 to 70% of the cases submitted to the SCCS, data from other sources has been relied on in the past. The availability of such data from other sectors depends however on many factors. Data may not have been necessary for other uses (for example low tonnage under REACH), it may not be accessible to the cosmetics manufacturer or the data may not be sufficient to address the use (eg. different exposure routes). If this is calculated down to total numbers per manufacturer this would mean that a large manufacturer with an ingredient portfolio of 2000 ingredients would in the worst case loose another 21 to 36 of the 72 new to cosmetics ingredients it would normally introduce per year. However, this is a worst case scenario. The SCCS review will often require more data than the manufacturer's safety assessment. The majority of ingredients are not reviewed by the SCCS. This means that, realistically, the loss of ingredients from other sectors would likely be considerably lower but uncertainty remains.

Example: Nanomaterials

Nanomaterials are chemical substances or materials manufactured and used at a very small scale. Over the past years, the cosmetics industry has focused on nanomaterials and they play an important role in innovation. The number of patents in the cosmetics field involving nanotechnology grew by 103% over the last seven years.

Nanomaterials display improved functionalities in UV filters, but also in dental care, appearance enhancement and skincare.

Under the Cosmetics Regulation, nanomaterials come under special scrutiny. Products containing nanomaterials need to be notified to the European Commission and information on their toxicological profile is to be provided. The Commission may request an opinion of

⁵⁷ Colipa submission to Targeted Stakeholder Consultation, Note: the total number of ingredients introduced per manufacturer provided there is 70, 4% of 2 000 is however 80 – the higher number of taken as a basis here

the SCCS. The SCCS has issued guidance for the safety assessment of nanomaterials in cosmetics⁵⁸, which clearly underlines the specific challenges of this assessment in the light of the marketing ban, which will make the introduction of new nanomaterials only possible in very limited cases in which data is already available.

Third, negative impacts are also expected for existing ingredients. This can be the case if ingredients already in cosmetic use come under scrutiny and new safety concerns arise. Also, using existing ingredients in new types of products (e.g. spray) can raise new safety questions that cannot be addressed by animal testing after 2013. As regards existing ingredients, the SCCS delivered between 2000 and 2009 opinions on 220 substances, thus an average of 24 per year. In at least 154 cases a full toxicological data set was provided. However, the activity in the last 10 years is not entirely representative, because the majority of cases concerned hair dyes. Nevertheless an important number of areas of future concern in relation to existing substances were pointed out by stakeholders. Some of these cases could be addressed by the existing derogation for Member States, however this has only been requested one time so far. Uncertainty remains therefore in how many cases existing ingredients would be impacted.

Examples:

Parabens are widely used as preservatives in cosmetics. They have come under review as they were considered to have endocrine disrupting effects. The SCCS has recently reviewed the safety of parabens⁵⁹. This review was based on animal data. Without the relevant data to support the safety the SCCS can not provide a conclusive opinion.

The negative impacts described above are expected certainly until the time when alternatives for skin sensitisation tests would become available, but also well beyond as for the other endpoints no clear timeline for replacement exists. These impacts would aggregate over the years, but would start diminishing once alternatives become available.

This loss of ingredients will also have negative impacts on the availability of cosmetic products. There is no linear link between ingredients and cosmetic products. 25% to 30% of the cosmetic products are on average reformulated per year. 90% of these reformulation rely on existing ingredients, 10% rely on new to market or new to cosmetics ingredients.

Three situations can be differentiated. The first one concerns cases in which reformulations rely on new to market ingredients extensively used in cosmetics. These are unlikely to be possible after 2013 as the safety of these ingredients cannot be demonstrated. Second, the cases in which the reformulation depends on new to cosmetics ingredients. Also here in a number of cases the reformulation will not be possible if existing data from other fields is not sufficient. Third, cases in which reformulation concerns ingredients used already in other cosmetic products. This should in most cases remain possible, but different uses may lead to different types of exposure and therefore different data needs. Overall, while it is difficult to give a clear indication of the total number of products concerned, the data implies that in the worst case up to 10% of the total 25 to 30% of annual reformulations will be affected (= 2.5%), mainly those relying on new to market ingredients. Assuming a total number of 300 000 products on the market this could mean that up to 7 500 products could be lost per year. Assuming the lower estimate of a total of 100 000 products on the market it could mean a loss of about 2 500 products.

Example:

⁵⁸ Opinion SCCS/1484/12, see: http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_s_005.pdf

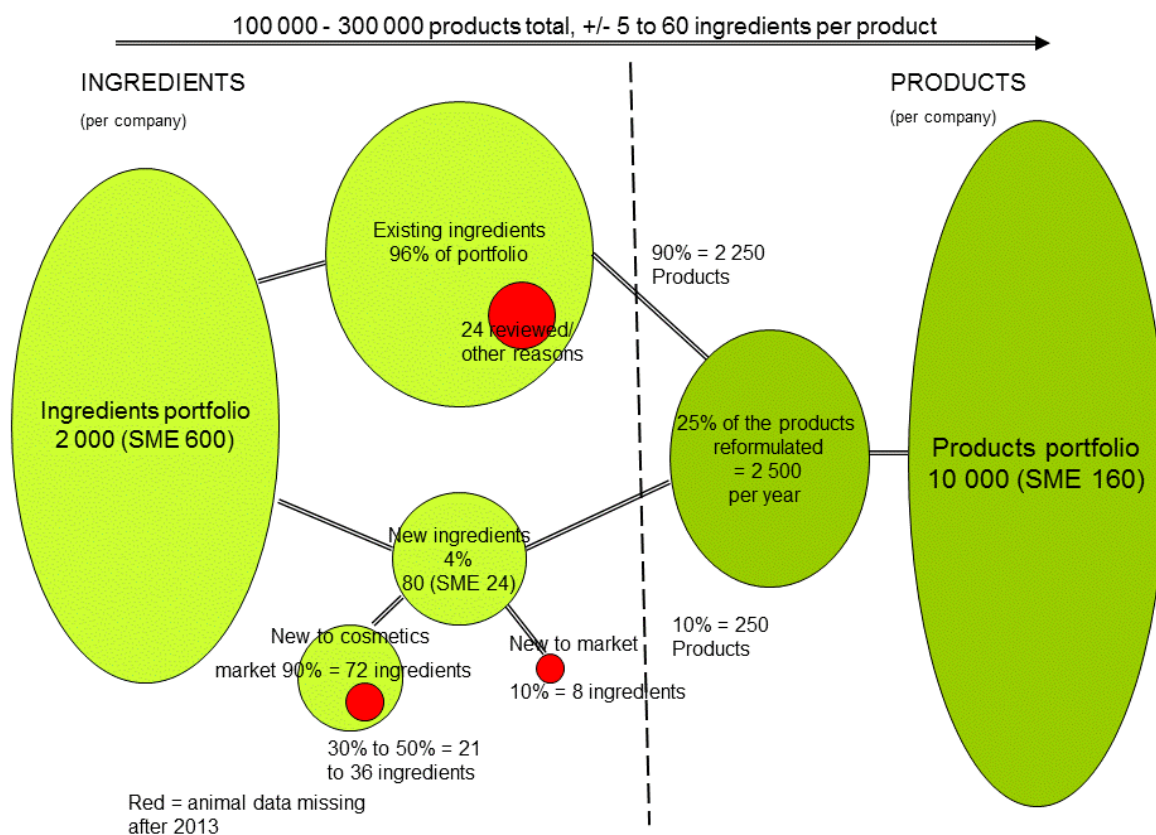
⁵⁹ Opinion SCCS/1348/10, see:

Company A (=ingredient manufacturer) develops after 2013 an ingredient with better anti-ageing properties. Company B (=cosmetics manufacturer) would like to bring a new skin care product on the market using this ingredient. To do so it needs to comply with the Cosmetics Regulation and carry out the required safety assessment. This requires information on the toxicological profile of the new ingredient. While the Cosmetics Regulation contains no tick-box of data required, at a minimum information on skin sensitisation (= can the ingredient cause allergies) and repeated dose toxicity (= are there other negative effects on the body as a result of repeated use) will be needed. Currently no alternative methods exist for these endpoints and since the ingredient is new and not used in other areas, no data is available. As a result Company B would not be able to place the new skin care product on the market.

Impacts would likely not be immediate in 2013. Due to the product development cycle and the fact that the deadline has been known for a long time it is expected that the impacts will mainly kick-in by 2014/2015 and continue over the following years. It is also assumed that the cosmetics industry is likely to be able to counteract some of these developments by innovating using existing ingredients or new ingredients supported by sufficient data. As mentioned above impacts would start diminishing as alternatives become available.

Stakeholders have different views on the likely impacts on ingredient and product availability. Industry stakeholder provided the figures discussed above and summarized in the table below and consider that the impacts will be serious. An argument made by some animal welfare stakeholders on the other hand is that if some companies can innovate and reformulate without animal testing, others should be able to do so as well. The argument here is essentially that the existing ingredient pool is sufficient.

The graph below summarises the figures discussed above and the likely impacts:



2.2.5. The Competitiveness of the EU Cosmetics Industry

The impacts of the 2013 deadline on the competitiveness of the EU cosmetics and cosmetics ingredients industry are expected to be overall negative compared to the situation before the ban. This assessment concentrates on the impacts on product innovation and turnover resulting from a limited access to ingredients. These impacts could be mitigated by other measures taken by the industry to maintain its role and turnover, such as marketing and new ways of innovation. While ingredients clearly are key to innovation, to some extent also other factors, such as product presentation, product application (brushes, form of delivery etc.) play a role in innovation. It is also assumed that this innovation would be extended if the innovation capacity from ingredients is limited.

The innovation capacity of the cosmetics industry is linked to the availability of innovative ingredients and the possibility to reformulate products. The European cosmetics industry has a leading role in product innovation. The EU is home to some of the most advanced and luxurious cosmetic products brands. Limits on the ability of the European industry to reformulate products and to introduce innovative ingredients could reduce its overall role as driver of future developments. Such a development is expected by industry to lead to more conventional, mass market and lower priced products, which in turn could lead to a reduction in sales and profitability for the cosmetics companies.

Along with a loss in innovation capacity, industry also expects potential impacts on turnover. The cosmetics industry had a turnover of EUR 71 billion in 2010. New ingredients have a significant impact on profitability as it is often these ingredients and the products formulated with them that lead to the greatest profit. There is however considerable uncertainty as to the exact impacts. The estimates provided by the Colipa respondents were that large companies expected an overall significant loss in turnover and profitability, with losses ranging from 3 to 20% in the short term (2013-2015), 7 to 20 % in the medium term (2015 – 2018) and 1 to 25% in the long term (2018 and beyond).

Turnover and profitability may also be affected by the costs of loss of existing ingredients. The examples below show the costs that could be occurred as a result.

Examples of direct costs incurred in past in case of re-formulation:

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

Product Reformulation: Company Y decided to replace a thickening ingredient in 70 formulations, 30% of which were produced by a contract manufacturer, which increased the reformulation costs. The cost of this was between EUR 1500 and EUR 5000 per formulation, equivalent to between EUR 100 000 and 350 000.

Impacts are expected in particular for ingredient manufacturers. In particular ingredient manufacturers specialised in cosmetics are expected to face difficulties. EFfCI data suggests that in the medium term (2015 to 2018) reductions in sales of up to 20% are expected.

However, stakeholder views on the effects on competitiveness diverge enormously. While industry and some Competent Authorities share the expectations above, animal welfare stakeholders on the other hand point out that maintaining the ban provides the opportunity for the EU industry to be the leader in implementing animal free safety assessment strategies. Companies following the 'Leaping Bunny' label and ECEAE considered to 57% that it would have a positive impact on sales and to 43% that it would have no impact. 65% of the

participating companies considered that it would have a positive impact on the EU marketing position and its global positioning.

Finally, the development of alternative methods in itself is innovation and leads to business opportunities. An example is the development of reconstructed skin by a cosmetic company now used in place of animal testing for skin irritation and which is being tried for other uses as well. It is by now also marketed outside the company and has become a business in itself.

2.2.6. Regional and Sectorial Impacts

Member States with the largest cosmetics industry are Germany, France, the United Kingdom, Italy and Spain. These make up 69% of the total sales. It is these Member States that would likely be most impacted by the 2013 marketing ban. These countries are also the largest exporters of cosmetics.

The largest market segments are skin care and toiletries (52% of the market share), overall all market segments had a positive growth over the last years. There is no clear indication which segments would be most impacted, but a number of assumptions can be made. Products which rely most on cosmetic specific ingredients, such as UV filters, hair dyes or specific skin care, are likely to be impacted most. It could also be assumed that sectors which currently have a high innovation activity based on the patents activity described under 2.1.1., such as make-up and skin care could be particularly impacted.

Depending on the ingredient the supply chain starts with either raw material producers or ingredient manufacturers. Some ingredients are also produced by the cosmetics manufacturers themselves. As regards the distribution channels for the cosmetic products they generally fall under four main categories: mass distribution, specialised distribution, pharmacy sales and direct sales. In France the breakdown in 2007 was 54% mass distribution, 28% specialised distribution, 10% pharmacy sales and 7% direct sales, while in Italy it is 41% mass distribution, 40% specialised distribution, 13% pharmacy sales and 6% sales⁶⁰. While the impacts on the ingredient manufacturers and the cosmetics manufacturers were described above, there is no clear indication on how these impacts may affect the distribution chain.

2.2.7. Trade Impacts

The deadline on export and import of cosmetic products could also have a certain negative impact. The EU cosmetics market represents almost half of the global market, with the United States and Japanese market estimated respectively at EUR 37.8 billion and EUR 29.4 billion.

In relation to exports, industry stakeholders expect export losses. One reason brought forward in the targeted stakeholder consultation is that less innovative EU products would be less attractive for export. Also, around 76% of the larger Colipa companies expect the development and production of innovative products to move outside the EU to continue to serve emerging markets, particularly in Asia.

Similarly, it is feared that ingredient manufacturers based outside of the EU would have a competitive advantage. EU based manufacturers fear no longer being able to drive demand for new ingredients which could result in the drivers for innovation in cosmetic ingredients moving away from the EU.

Another problem EU products are expected to face is that many trading partners – such as China – still require animal testing data for certain endpoints. While it is possible to have different product lines or safety assessments for inside and outside the EU and production in the EU could therefore still take place for export only, this is likely to be an option only for a

⁶⁰ Global Insight, A Study of the European Cosmetics Industry

few larger companies. Larger companies may formulate more innovative products for export with ingredients for which they cannot show the safety purely based on alternative methods yet and which can therefore not be placed on the EU market.

The 2013 deadline is also expected by industry stakeholders to lead to impacts on imports. At the moment, the EU is the only region with such stringent bans in place. New products developed outside the EU will still mainly rely on animal data for the safety assessment and are likely in many cases to fall under the marketing ban. Between 52% and 64% of responding large Colipa companies expect imports to be reduced. Similarly, between 60% and 69% of EFfCI companies expect such impacts. In the short term this could lead to a competitive advantage for EU companies on the EU market. While this may be a short-term advantage for industry there could be a growing risk of non-compliant products being imported to the EU to meet consumer demands.

2.2.8. Employment

In relation to employment, while future developments are difficult to predict and to quantify, the cosmetics industry and the ingredients industry expect that the 2013 marketing ban could lead to negative impacts on employment though again it needs to be stressed that the data basis is rather uncertain.

The overall number of direct employees in the cosmetics industry in 2009 was approximately 177 000, around 137 000 of whom were in manufacturing, including 17 000 in Research & Development, and around 40 000 in distribution. In 2010 direct employment had grown to 184 000. In addition, indirect employment, including retail and salons, is estimated to be about 1.7 million. SMEs are estimated to employ around 35% of the total direct employees, thus around 62 000. However, figures supplied from Germany indicate that in Germany alone 45 000 employees work in the cosmetics industry and that of these 85% to 90% work in SMEs.

In addition, large ingredient manufacturers (cosmetics and cosmetic and other ingredients) employ about 110 000 people overall in the EU with approximately 5% of these employed in the development, manufacture, import or supply of cosmetic ingredients, thus about 5 500 employees. Taking cosmetics and cosmetic ingredients manufacturer together, this leads to total of 182 500 employees based on 2009 data. The average number of employees in SME's according to EFfCI data is 90, with 71 of them employed in the development (including R&D), manufacture, import or supply of cosmetic ingredients.

The main impacts on employment could occur as a result of possible relocation of activities in reaction to the marketing ban. Industry expects that a limited possibility to develop new products in the EU will favour R&D and product development to move closer to emerging markets. Industry also points out that this could be a threat to the cosmetic industry's strong academic networks in the EU as well, with new networks being developed outside the EU.

Example:

One large company alone currently collaborates with around 60 academic groups and funded over EUR 3.5 million in external research in 2010.

76% of responding large Colipa cosmetic companies predict that R&D would be relocated. The amount of R&D relocated could be up to 50%, depending on the company. 45% of SMEs considered that R&D facilities would relocate.

The ingredient manufacturers have similar expectations; 53% predict that up to 50% of R&D could relocate. The development of innovative new raw materials and finished ingredients is expected to move more outside the EU. Relocation of R&D is however not a necessary

impact, since R&D could remain in the EU, even for products that can as a result of the marketing ban not be placed on the EU market, but only exported.

Besides the relocation of R&D, industry considers that production facilities could also move outside the EU to focus on growth markets and because of the reduced turnover and profitability of the industry in Europe. This could in the longer run also impact jobs in supporting functions and management. 89% of large cosmetics company respondents from Colipa considered that the ban would have such impacts on employment. It is estimated that a considerable part of the 17 000 scientists' posts would be endangered. In addition, the loss of jobs in the production and supporting functions is expected. More than 66% of EFfCI large company respondents considered that the ban would have impacts on employment. It was also pointed out that once the shift of excellence (and related jobs) outside the EU has occurred, it is unlikely to be reversed.

It needs to be stressed once again that there is considerable uncertainty about the exact impacts on employment. The figures above are forward looking industry expectations. According to these expectations, the majority of industry stakeholders expects an impact that would affect several thousand R&D staff, up to 8 000, as well as other staff.

However, many of the target markets for European manufacturers are already today outside the EU. The highest market growth is expected to take place by 2015 in South America and Africa. The market for premium cosmetics in China is expected to double by 2015. Relocation may therefore take place in any case.

2.2.9. Specific Impacts on SMEs and Micro-Enterprises

Particular attention has been given to the situation of SMEs⁶¹ and micro-enterprises⁶² in the assessment. Around 100 SME's provided input to the Colipa response to the targeted stakeholder consultation and the Commission services met with a number of national associations and small manufacturers to complement the information.

The marketing ban applies to large and small companies alike and the cosmetics industry has a high percentage of SMEs. SMEs are therefore clearly among those affected by the ban. According to data provided by Euromonitor for 2010, there were about 4 072 small and medium sized cosmetic product manufacturers in the 27 EU Member States. In some Member States, SMEs represent more than 80% of the overall cosmetic manufacturers, as reported by Colipa and EFfCI. In Germany, in 2008 SMEs represented 76% of the total number of cosmetic manufactures (but the statistics do not cover all sectors, so the percentage for the whole cosmetic sector is probably even higher). Figures from Germany also indicate that the overall number of SMEs in the cosmetics field is much higher than the Euromonitor data suggests. The European Organization of Cosmetics Ingredients Industries and Services (UNITIS), representing companies in the field of botanical natural complex substances is made up of 50 member companies, all of them SME's.

Specific data on the number of micro-businesses is not available, however data collected in the context of the earlier impact assessment⁶³ indicated that there were 855 firms with fewer

⁶¹ Medium-sized: less than 250 employees, equal to or less than € 50 m turnover or equal to or less than € 43 m balance sheet total

⁶² Micro enterprise: less than 10 employees, equal to or less than € 2 m turnover or equal to or less than € 2 m balance sheet total

⁶³ Impact assessment - Report on simplification of the "Cosmetics Directive" – Directive 76/768/EEC (COM(2008)49 final) (SEC(2008)118) /SEC/2008/0117 final, also accessible under http://ec.europa.eu/consumers/sectors/cosmetics/documents/revision/index_en.htm#h2-impact-assessment-report

than 10 employees in France in 2004 and that Italy had over 1000 firms with fewer than 10 employees. These figures would indicate that the share of micro-businesses is very high.

Colipa estimates that the SME market share is about 30% (about EUR 20 billion) of the total EU cosmetics industry. This is confirmed by figures received from Germany, where SMEs have 36% of the market share in this sector.

SMEs and micro-enterprises were not excluded from the testing and marketing ban when it was introduced. Exempting SMEs and micro-enterprises would run counter the animal welfare objective and is therefore also not considered in this assessment.

SMEs and micro-enterprises face in principle the same impacts as those described above, ie. less access to ingredients and thus limited possibilities of product re-formulations. However, the impacts are not expected to be the same for all SMEs.

SMEs and micro-enterprises specialised in cosmetics with a high rate of innovation could feel the impacts of the marketing ban. They often consider that the bans will have no impacts on them since they do not themselves test or commission tests. However stakeholders also underline (eg. the input received from UEAPME) that SMEs might be the least aware of these impacts. SMEs depend to a large extent on toxicological data being provided to them by their suppliers and may not be aware of the extent to which this data will not be available in the future. They will also often have less access to data from other sectors than larger companies with a varied product portfolio. Also, a more commoditised market/mass market that competes more on price is likely to disadvantage SMEs that can less easily compete on economies of scale rather than in niche markets. SMEs are also less likely to relocate or to focus on exports.

Another group of SMEs and micro-enterprises that is likely to be affected are small and specialised ingredient manufacturers. UNITIS in particular underlined in its submission to the targeted stakeholder consultation impacts on its around 50 SME specialised member companies. Ingredient manufacturers and especially small and specialised ones depend on constant ingredient innovation.

There are however also a number of niche market SME's and micro-enterprises that might be less negatively affected by the ban or even benefit from it. This would include companies already working under the 'animal testing' free label. Around 115 companies are part of the Leaping Bunny label in Europe (400 worldwide) alone, many of whom SME's. This would also apply to SMEs that work with well-established product lines, such as traditional soaps or other products less prone to product innovation.

2.3. Subsidiarity

The use of Union competences is governed by the principles of subsidiarity and proportionality (Article 5 TEU). The current EU legislation on cosmetics is based on Article 114 TFEU (ex-article 95 TEC) and its aim is to ensure a high level of protection of human health as well as the proper functioning of internal market. Article 13 of the TFEU contains the obligation to pay full regard to the welfare requirements of animals when implementing the internal market policies.

The Cosmetics Directive/Regulation exhaustively harmonises rules on consumer safety of cosmetic products placed on the EU market. Thus, changes to this legal framework can only be achieved by EU action. The marketing ban directly addresses the free movement of cosmetic products in the Union. This is already subject to harmonized legislation and cannot be addressed at Member State level without leading to a serious fragmentation of the market. It can therefore only be achieved at Union level. Besides the testing and marketing ban, the

Cosmetics Regulation also harmonised the possibility to grant derogations from the bans and provided such a possibility under Article its 18 (2).

All previous legislation in relation to the marketing ban was adopted at Union level. The first provisions in relation to the marketing ban of cosmetic ingredients or combinations of ingredients tested on animals in order to meet the requirements of the Directive were introduced to the Cosmetics Directive in 1993 with an application date of 1 January 1998, first postponed to June 2000, then to 30 June 2002 and finally for the endpoints in question here to March 2013. These extensions of the deadline were essentially due to the non-availability of alternative methods to animal testing, however the last extension made the testing ban and the 2009 marketing ban independent of the availability of alternatives (see for more details above 2.1.3.).

3. OBJECTIVES

3.1. General objective

The general objective is to ensure a proper functioning of the internal market and maintaining a high level of protection of human health, while paying full regard to the welfare requirements of animals.

3.2. Specific objectives

The specific objectives followed are accordingly on the one hand linked to the functioning of the internal market (3.2.1. and 3.2.2., Article 114 TFEU) and on the other hand to the animal welfare objective (3.2.3. and 3.2.4., Article 13 TFEU).

3.2.1. To maintain consumer safety and consumer choice (specific objective 1 – Consumer Safety and Choice)

For more than 30 years, the Cosmetics Directive has provided a legal framework that ensures consumer safety. The Cosmetics Regulation strengthens this framework. The Cosmetics legislation has favoured a broad, varied and innovative offer of cosmetic products to European consumers. Consumer choice is likely to be impacted by a limited access to certain cosmetic ingredients and thus products. The objective is to maintain the current level of consumer safety and consumer choice.

3.2.2. To maintain innovation and competitiveness of the European cosmetics industry (specific objective 2 – Innovation and competitiveness)

The Europe 2020 strategy for smart, sustainable and inclusive growth⁶⁴ called for an ‘Innovation Union’ to improve the framework conditions for innovation⁶⁵. The regulatory framework for cosmetics should therefore be supportive of innovation. The current framework has contributed to a thriving cosmetics industry that has also largely been able to resist the economic crisis. The cosmetics and cosmetic ingredients industry also plays an important role in creating jobs - direct and indirect. A reduced access to cosmetic ingredients and the resulting limited product innovation could impact the competitiveness of the industry. The objective is to maintain industry's capacity to innovate and its competitiveness. The EU is an important trading partner for third countries when it comes to cosmetics, with the EU representing almost half of the global market, followed by the United States and Japan. The objective is to maintain this trade.

⁶⁴ Communication from the Commission of 3 March 2010, COM(2010)2020

⁶⁵ Communication of the Commission on Europe 2010 Flagship Initiative Innovation Union, 6.10.2010, COM(2010)546final

3.2.3. To provide animals with a high level of protection and welfare (specific objective 3 - Animal Welfare)

Animal welfare is enshrined in Article 13 of the Treaty on the Functioning of the European Union, which is part of its provisions with general application. The objective is to pay full regard to animal welfare in implementing the Union's policies. While currently animals are still used outside the EU for the purposes of the EU cosmetics legislation, once the 2013 deadline enters into force such testing data cannot be relied on, leading to a likely reduction in animal use. Animal welfare is also served through a proper enforcement of the current provisions. Legal clarity in relation to the scope of the provisions and additional tools for Member State authorities to carry out the necessary checks in relation to the compliance with the marketing ban will help ensure the effectiveness of the provisions in place. The Commission Communication on the European Union Strategy for the Protection and Welfare of Animals 2012-2015⁶⁶ in particular underlined the need for better implementation and enforcement of existing provisions in relation to animal welfare.

3.2.4. To maintain the incentive for continued research on alternative methods to animal testing (specific objective 4 – Research into alternatives)

A safety assessment of cosmetics without using animals can only be achieved if alternative methods are in place. Considerable funding has been made available to develop and validate new alternative methods to animal testing by the Commission, Member States and the cosmetics industry. These efforts have contributed to validated alternative methods for several endpoints. Significant advances have been made in reducing the number of animals used in tests. These findings have not only benefited the cosmetics industry, but help to reduce the number of animals used across sectors. The objective is to keep up or step up the momentum for the remaining endpoints, not only out of animal welfare considerations, but also because this work allows to better understand the toxic pathways and to make better safety assessments in the long run. Development of alternatives is itself innovation and creates new opportunities for industry. Continued efforts in research into alternatives is also in line with the Commission's international co-operation in the International Cooperation on Alternative Test Methods (ICATM).

4. POLICY OPTIONS

4.1. Option 1: Baseline/No Action

Option 1 is the scenario in which the Commission does not present a proposal in relation to the 2013 deadline of the marketing ban to the European Parliament and the Council. The legal framework will remain unchanged, resulting in an entry into force of the marketing ban in relation to the 2013 endpoints on 11 March 2013, irrespective of the availability of alternative methods to animal testing. The rationale behind option 1 is that it is the most effective way to obtain the overarching political objective that lead to the current provisions - to abolish animal testing for cosmetic purposes.

4.2. Option 2: Postpone the 2013 deadline

In the absence of alternative methods by the 2013 deadline, the deadline could be postponed. This has already been done on several occasions (see above 2.1.3.). Option 2 foresees three sub-options for a postponement of the 2013 deadline. The overall rationale behind the different sub-options under 2 is to maintain the overall objective to end animal testing for cosmetic purposes, but to take account of the finding that alternatives are not yet available and

⁶⁶ COM(2012) 6 final/2, 15.2.2012, see: http://ec.europa.eu/food/animal/welfare/actionplan/docs/aw_strategy_19012012_en.pdf

to thus make reaching the objective one way or the other dependant on the availability of alternative methods.

4.2.1. Option 2 (a): Postpone the 2013 deadline with fixed deadline

Option 2 (a) foresees the postponement of the deadline for a fixed time. Given that it is not clear when alternatives will be available, any postponed deadline would serve mainly as a review deadline, by which progress and efforts in research and development of alternative methods would be evaluated. This option therefore would envisage a postponement of 7 years and then a review exercise similar to the one recently carried out, with the possibility of a further postponement should alternatives not have been found despite the demonstration of serious research efforts. The rationale behind option 2(a) is that it follows the logic of the earlier interventions. It sets a deadline after which a review will take place, is thus not based on the assumption that at that point in time all alternatives will be available. The 7 years are chosen because the indication of the first phase of stakeholder consultation is that – in the best case – at least alternatives for skin sensitisation could be validated by then (experts expected the alternative methods to be available the earliest by 2017, in addition at a minimum 3 years are needed for validation, which would lead to 2020), so that a possible subsequent postponement could exclude this endpoint.

4.2.2. Option 2 (b): Postpone the 2013 deadline in relation to certain endpoints only and maintain for others

Option 2 (b) would be similar to Option 2 (a), but restrict the postponement to certain endpoints only. Essentially this would foresee no extension for tests used less frequently (carcinogenicity, toxicokinetics and reproductive toxicity), a one-off extension for skin sensitisation and extension for repeated dose toxicity subject to review. The rationale behind option 2 (b) is to limit the postponement only to those endpoints most needed to demonstrate the safety of the cosmetic products, ie. skin sensitisation and repeated dose.

4.2.3. Option 2 (c): Postpone the 2013 deadline without fixed deadline

Option 2 (c) would do away with the fixed deadline, but maintain the current mechanism according to which the ban applies as soon as an alternative method has been validated and adopted at EU level, with due regard to the developments of validation within the OECD. The ban would clearly apply once a method would be validated and included either in Regulation 440/2008/EC or in Annex VIII of the Cosmetics Regulation. It would also be possible to already require replacement earlier, e.g. as soon as a satisfactory scientific method or testing strategy is available⁶⁷. In the future, alternative methods will not be one-to-one replacements, but rather integrated testing strategies. The process for validation and regulatory acceptance of these strategies is only being developed. Option 2 (c) would be most coherent with the overarching provisions in Directive 2010/63/EC or the approach in REACH to use animal testing as a last resort. The rationale behind option 2 (c) is essentially to let science deliver.

4.3. Option 3: Maintain the deadline and introduce an additional derogation mechanism

Option 3 aims at maintaining the deadline while allowing access to market for innovative cosmetics with clear benefits when the safety assessment requires animal testing for cosmetics purposes. To this end, it foresees the introduction of a derogation, complementing the one already existing for Member States⁶⁸. Given that uncertainty remains about the actual impacts of the 2013 deadline, option 3 would be a kind of safety valve to allow key innovation. It will

⁶⁷ Such as in Article 4 of Directive 2010/63/EU on the protection of animals used for scientific purposes

⁶⁸ See Article 4a, 2.4. of Directive 76/768/EEC

also make the problematic cases in which data is missing and the industry considers that the ingredient is of significant benefit transparent and will thus allow a better re-assessment of the policy in the future.

The derogation could apply both to the testing and the marketing ban. Applying it to the testing ban is not considered as the testing ban has applied in full since March 2009 and the review clause does not refer to the testing, but only to the marketing ban. In addition, there was no call to do so by stakeholders. It was further considered whether the derogation should apply to innovative ingredients only or to existing ingredients as well. This latter possibility was however discarded as in these cases, the derogation for Member States is in place. It is also considered that data from other legal frameworks may help.

The provisions envisaged would allow a cosmetics/ingredients manufacturer (or associations of manufacturers) to request a derogation from the marketing ban for specific ingredients or combinations of ingredients under limited circumstances.

- (1) A request would need to contain a demonstration that the ingredient in question would bring innovation and a significant benefit to consumer health, consumer well-being and/or the environment. Whether the conditions would be fulfilled would be a case-by-case assessment of the Commission. Innovation would be demonstrated by comparison with existing ingredients and their functions. Significant benefits could be shown for example in the case of an ingredient that is less likely to induce allergies than ingredients currently used, in the case of a new preservative (a limited number of preservatives creates the risk of microbial cross-resistance), in the case of a new sun protection ingredient with better environmental properties, in the case of an ingredient that would help to address needs of specific parts of the population. These criteria would not be fulfilled in the case of lower cost or greater accessibility of ingredients, in the case of ingredients that facilitate the production process, ingredients that only bring incremental product improvements, such as better emulsifier, product aesthetics or new colour shades. Since it would be a derogation, the cases in which it applies should represent the exception, not the rule.

The operational application would clearly be very challenging. Examples exist in other areas of similar evaluations and the criteria developed there could be partly drawn on. This is notably the case under the authorisation procedure under REACH⁶⁹, which requires the evaluation of socio-economic benefits of substances for which an authorisation is requested and the exemptions under Directive 2011/65/EU in relation to restrictions of hazardous substances, which allows an exemption taking into account '*the availability of substitutes and the socioeconomic impact of substitution*', taking also account of adverse impacts on innovation⁷⁰.

However, under the current legislation there is only a limited requirement to document the effect claimed for the cosmetic product under Article 11, 2, (d) of the Regulation. Article 20 of the Regulation requires that claims must relate to actual characteristics and functions of the product. Specific benefits of new ingredients as such do not need to be demonstrated. Nevertheless, the decision

⁶⁹ Extensive guidance on the Socio-Economic Analysis in these cases exists: http://echa.europa.eu/documents/10162/13637/sea_authorisation_en.pdf

⁷⁰ Article 5 of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, L 174, 1.7.2011, p. 8 ff.

whether or not to change the formulation of a product and whether to introduce a new ingredient assumingly are based on company internal considerations on the expected benefit of the ingredient. These would need to be documented for the application.

- (2) Manufacturers would need to demonstrate that toxicological data needed for the safety assessment is not available and cannot be obtained using alternative methods to animal testing, in a reasonable timeframe. This verification would in any case be part of the safety assessment process, here it would need to be documented.
- (3) Manufacturers should demonstrate their commitment in relation to their investments in research for alternative methods. Such a commitment could e.g. be demonstrated by contributions to Framework Programmes, own research activities or contribution to academic research work. It will be evaluated on a case-by-case basis. SMEs and micro-businesses will be exempted from this requirement. The objective is to ensure that the derogation is not used as a way to avoid research into alternatives, a logic similar to the requirement of a substitution plan under REACH.

In the application, the manufacturer would need to provide details on the proposed place of testing, the protocol followed, the number of animal involved and the animal welfare standards applied. This will include information on the test protocol followed, such as reference to OECD protocol. It would also include information on the purpose for which the testing was carried out and a description of the test that can be made public together with the description of the ingredient.

Consideration would also be given to avoid on the one hand that the derogation excludes others than the applicant from the use of the ingredient (= not the create 'monopolies') and on the other hand to avoid that the derogation allows for duplicate animals testing.

In terms of procedure, such a derogation would be granted in the form of a Commission Decision. This would allow for the fastest decision-making. In terms of time between 6 month and 1 year are expected to be needed for the decision-making. Appropriate expertise , notably the SCCS, could be consulted on the questions whether the toxicological data is needed and whether the test in question is appropriate to provide it.

5. ANALYSIS OF IMPACTS

5.1. Methodology and possible impacts identified

The following assessment of the impacts is focused on the analysis of each option in its entirety, focusing on the environmental, economic and social impacts. The environmental impacts are limited to the impacts on animal welfare and research into alternatives and are dealt with upfront. The environmental concerns that substances used in cosmetic products may raise are considered through the application of REACH, which enables the assessment of environmental safety in a cross-sectoral manner.

5.1.1. Impacts Policy Option 1 - Baseline/No Action

The effects of the no action scenario have been described and analysed in detail above in the problem description and will only be summarized here. In the absence of an amendment to the Cosmetics Regulation, option 1 will apply as of 11 March 2013.

As regards environmental impacts the application of the deadline is expected to spare a subset of 15 000 to 27 000 animals per year. This concerns animals used for testing outside the

EU only, as the testing ban applies and is not put into question. Option 1 fully meets the overall political objective to end animals testing for cosmetics. It is also the option that is expected to contribute most to the development of alternatives methods.

As regards economic impacts, option 1 is expected to lead to a certain reduction of cosmetic ingredients. A large cosmetics manufacturer with an ingredient portfolio of 2 000 ingredients could lose 8 of the 80 new ingredients normally introduced per year as these would be new to the market. Also access to ingredients already used in other sectors would be limited. In the worst case a large cosmetic manufacturer could lose another 21 to 36 ingredients per year. In addition, existing ingredients come under review regularly and might not be sufficiently defended. This could in total concern up to 24 existing ingredients per year. The data implies that in the worst case up to 10% of the total 25 to 30%, i.e. 2,5 to 3%, of annual reformulations will be affected, mainly those relying on new to market ingredients. This could impact between 2 500 and 7 500 products per year in total.

This loss of ingredients could lead to a loss of competitiveness. It is estimated by industry stakeholders that large companies could face losses in turnover ranging from 3 to 20% in the short term (2013-2015), 7 to 20 % in the medium term (2015 – 2018) and 1 to 25% in the long term (2018 and beyond). Member States with the largest cosmetics industry are Germany, France, the United Kingdom, Italy and Spain. Exports and imports would also be affected given that animal data is needed for the safety assessment in third countries.

The impacts on availability of ingredients and the resulting impacts on turnover could also lead to lower employment of R&D staff, up to 8 000 in the worst case, as well as other staff. It has to be stressed that these are estimates from the industry stakeholders and that no independent data is available to verify these impacts and that views of stakeholders diverge enormously.

5.1.2. Impacts Policy Options 2 (a), (b) and (c) – Postpone the 2013 deadline

Environmental Impacts

All sub-options discussed under option 2 maintain the overall objective to phase-out animal use for cosmetics. They do however allow for more time to achieve this objective as they make it one way or the other dependant on the availability of alternative methods. Under all sub-options of option 2 animal testing outside the EU for EU cosmetics purposes could therefore continue beyond 2013, meaning the continuous use of 15 000 to 27 000 animals per year. In relation to the ethical considerations and expectations of European citizens any extension of the deadline is likely to be seen negatively.

There are some differences in the impacts on animal numbers between the sub-options. Option 2 (a) would lead to the continuation of the use of between 15 000 and 27 000 animals per year for the coming 7 years. Any further prolongation would require an amendment of the legislation.

Option 2 (b) would limit the number of animal used compared to the situation now by at least 12%, this represents the percentage of the less used tests excluded under this option. This would mean that at least 1 800 to 3 240 animals less would be used. However, this number is likely to be somewhat higher because in cases in which a reproductive toxicity study would be needed for the assessment and cannot be carried out it does also not make sense then to carry out the skin sensitisation test.

Option 2 (c) would continue the use of animals as now and as under option 2 (a) per year. The difference is that there would be no fixed deadline, but that the ban would kick in once alternatives become available. It would still mean that the number would diminish. Assuming that alternatives for skin sensitisation become available by 2020 this should mean a 70%

reduction of testing (this is the percentage of skin sensitisation testing now). This would mean that beyond 2020 the numbers would go down to about 4 500 to 8 100 animals per year, until further alternatives become available.

All options under 2 are generally expected to have somewhat negative impacts in relation to research in that the postponement takes away the immediate need for research in alternatives. In particular option 2 (c) would make the ban dependant on the availability of alternative methods and but would not set a fixed deadline. Many stakeholders considered that it was exactly the deadline that led to intensified research funding.

Economic Impacts

Under options 2 (a), (b) and (c) the deadline would be postponed, with the result that also beyond 2013 new cosmetic-specific animal data could be relied on for the safety assessment of cosmetics. This would maintain the availability of ingredients and the possibility to reformulate products as it is now before the entry into force of the marketing ban. There would be therefore overall no economic impacts expected under option 2, the cosmetics market could continue to develop as described under 2.1.1.

Slight differences exist however depending on the sub-option. Options 2 (a) and 2 (c) both foresee a postponement for all endpoints. Option 2 (b) foresees the postponement for certain endpoints only. Therefore option 2 (b) would have negative impacts in the few cases in which this data is needed, thus in about 12%.

Also in relation to trade the situation will essentially remain as it is now, and export and import activities can continue. Under option 2 (b) slightly negative impacts are however expected in cases in which data on endpoints for which the deadline was not prolonged are in question.

Social Impacts

As for the economic impacts, essentially the situation will remain the same to the current situation. Of the sub-options, option 2 (c) would have possibly positive impacts compared to the situation now, as it takes away a fixed deadline and thus provides most confidence in the future ability of the cosmetics industry to innovate and this stability could lead to more employment. Under this option industry can be sure that innovation can be continued either based on animal data or based on alternatives.

Stakeholders have split views on option 2 and its sub-options. Animal welfare stakeholders and some Competent Authorities clearly oppose any postponement, independent of the sub-option. They consider that enough time has passed since the bans were first introduced 20 years ago and that no further postponement is acceptable. As described above under 2.2.4 and 2.2.5, they also do not consider that the marketing ban leads to considerable negative impacts, and therefore do not see the need of a postponement. The wish to maintain the 2013 deadline also seems to reflect the views of many citizens, as evidenced by the large number of letters and mails against any postponement directed to the Commission. Industry stakeholders on the other hand and several Competent Authorities generally support a postponement, with option 2 (c) being the preferred option that is considered to be the most science based approach. They consider that a postponement is the best way to avoid the negative impacts expected from the marketing ban and consider that the impacts on animal welfare are limited.

5.1.3. Impacts Policy Option 3 - Maintain the deadline and introduce an additional derogation mechanism from the marketing ban

Environmental Impacts

Option 3 would essentially lead to similar positive impacts as option 1 in relation to animal welfare. It maintains the deadline and thus ends the use of a sub-set of the currently used 15 000 to 27 000 animals per year.

It would, however, lead to the possibility to request derogations and, thus, in a limited number of cases to testing outside the EU for EU cosmetics purposes beyond 2013. A derogation would be sought in relation to the safety assessment of a specific ingredient. The number of animals impacted would depend on how often such a derogation would be granted.

There is uncertainty about the overall number of ingredients introduced for the total industry. The data provided in the targeted stakeholder consultation indicates that in total there may be at a minimum around 150 new ingredients introduced for the cosmetics industry per year in Europe. At a maximum the number of new INCI codes indicates that up to 500 new ingredients could be introduced to the cosmetics industry per year. Both figures include new to the market and new to the cosmetics market. Therefore it is likely that only about 10% of these would be new to the market and most likely to require a derogation, thus somewhere between 15 and 50 ingredients per year. Other ingredients are more likely to have data sets from other uses. However, also for at a maximum for half of the new to cosmetics market at least some data may be needed (see above 2.2.4.). This would mean that between 82 and 275 new ingredients would be likely to require animal data per year.

Only assumptions can be made to the possible number of derogations requested and granted based on these figures. One assumption could be that the use would be similar to the use of the current Member State derogation, which has been applied for one time since 2009. This is however for various reasons not likely to be a valid assumption (see above 2.1.4.). Another assumption could be that a derogation would be requested for nearly all new ingredients, thus at the high end up to 275 times per year. The derogation is however designed to apply only in exceptional circumstances and the aim is not to turn the ban into an authorisation scheme. This assumption is therefore not likely to be valid either. The third assumption would be that the derogation would only apply in a small percentage of the newly introduced ingredients and would probably only be used in about 10 to 15 cases per year. This appears the most likely assumption.

In the majority of cases testing on skin sensitisation and repeated dose would be needed. The data in Annex 2 implies that, per derogation granted, a minimum of 100 animals would be used. This figure could in some cases be higher, depending on the testing needed. Based on these estimates the derogation could lead to a use of about 1 000 to 1 500 animals per year. It would in each case depend however which data is already available. It should be noted that the derogation could, and is likely to be, also sought in order to rely on testing data which already exists, but which is covered by the marketing ban, e.g. testing done to meet third countries cosmetics legislation. In these cases the testing would not be triggered by and not be a direct impact of the derogation.

Option 3 will lead to a similar need for alternative methods as option 1 and thus equally have positive impacts on research. However, this effect may be somewhat limited by the possibility to request a derogation.

Economic Impacts

Under option 3 the situation is to some extent similar to the one under option 1, thus the ban enters into force and similar negative impacts can be expected than the ones described under 2.2.4 and 2.2.5. However, option 3 would allow limiting the negative impacts of option 1 in that it provides the possibility for industry to request a derogation on a case-by-case basis. Most of the new ingredients would not fulfil the criteria for a derogation, as they may be

added for example for reasons of better availability, price or other rather incremental innovation reasons. The derogation would therefore most likely cover only a small number of the cases. Nevertheless, Option 3 would provide the possibility to introduce the derogation for the most valuable ingredients and product innovations with particular benefit for consumers. It would therefore allow mitigating the most serious impacts. It is not possible to provide an estimate of to which extent the derogation would limit the impacts on turnover in quantitative terms. While the derogation may only apply in a few cases in terms of numbers, they are expected to concern the ingredients with the biggest impact on innovation and competitiveness. So even if it would be granted as assumed above in only about 10 to 15 cases, the economic impact would be mitigated to a higher extent as the ingredients in question are likely to have a comparatively higher value.

The derogation would apply to large and small companies essentially the same way. However the derogation mechanism would also foresee a number of ways to take account of the specific needs of SMEs. First, the derogation could also be applied for by a group of applicants. Second, it could allow for ingredient manufacturers to apply. Third, the decision could not only apply to the direct applicant, but to anyone which whom a data sharing agreement is in place. SMEs and micro-business can therefore benefit from derogations requested by others, notably further up the supply chain. Indeed in most cases SME's do rely on data from the supply chain in any case. Fourth, SMEs could be exempted from the requirement to demonstrate their commitment to research.

In relation to trade option 3 would allow to mitigate some of the trade impacts. In relation to export, because the derogation would still allow for key innovations within the EU and for the EU market, which could then be exported. In relation to imports, because the possibility to request a derogation would also be open to third country manufacturers and would allow them access to the EU market with innovative products.

Social Impacts

As regards employment, the situation is essentially similar to option 1 (see above under 2.2.8). To which extent the derogation could mitigate the expected negative impacts cannot be quantified.

Stakeholders had mixed views on option 3. Animal welfare stakeholders reiterated in the consultation on the derogation that they wish to maintain the deadline as is, thus not to introduce a derogation. As described earlier, their concern is less the potential number of animals used under the derogation, but letting the marketing ban apply in full is a question of principle. Industry stakeholders recognised that – should no postponement be considered - the derogation could offer a solution at least for a few innovative ingredients. Given that industry considers that most of the testing would be done in any case for third countries, the impacts on animal welfare were considered to be very limited. Industry stakeholder underlined that the derogation would by far not mitigate all negative economic impacts of the 2013 marketing ban. In comparison to a postponement it is clearly seen as less favourable by industry. It also comes with delays and administrative costs (see below 5.2). Administrative Costs

Administrative costs are defined as "the costs incurred by enterprises, the voluntary sector, public authorities and citizens in meeting legal obligations to provide information on their action or production, either to public authorities or to private parties".⁷¹

The options 1 and 2 do not raise any specific additional administrative costs for the industry, Member States or the Commission. Option 3 however does raise substantial administrative costs at industry level.

⁷¹ Impact Assessment Guidelines (SEC(2009)92, Part III, page 45

These costs would arise on the industry side for the preparation and the follow-up of a derogation file. This would not involve a fee, but would consist of the time needed to compile and substantiate the derogation file. To some extent, the information needed for the derogation file would be information industry would need to consider in any case when introducing a new ingredient. The elements to be covered in the derogation file were described above under 4.3. and are:

- (a) A detailed argumentation and substantiation of the innovation and the benefits of the ingredient in question. This is as such not required under the Cosmetics Regulation, with the exception of the cases in which due to the nature or effect of the cosmetic product proof of the effect needs to be included in the Product Information File (see Article 11, 2 (d));
- (b) Detailed reasoning in relation to the need for animal data in the safety assessment versus relying on alternative methods (description of possible existing alternatives routes, such as Threshold of Toxicity Concern (TTC). While this does not require documentation currently, already now under the '3 R's' policy manufacturers must reflect on whether animal testing cannot be avoided by other approaches. Information on any testing carried out or planned (numbers, place, protocol etc.) must also be provided. This information is readily available and the current legislation requires that the source of toxicological information must be clearly identified (Annex I, Part A, 8 of the Regulation);
- (c) Demonstration of the financial commitment to research into alternatives (funding provided to EU Framework Programmes, own research activities, contribution to academic research work etc.). This is a new element.

Apart from the financial commitment to research, the costs for such a derogation file can be estimated to some extent by looking at the costs of two types of files existing under the Cosmetics Directive, the costs for the safety assessment file on the one hand and the costs for submission to the SCCS on the other hand. For both cost information was provided in the impact assessment preceding the adoption of the Cosmetics Regulation⁷².

The costs were determined using the administrative costs the EU Standard Cost Model⁷³:

$$\sum P \times Q$$

where P (for price) = tariff x time

Q (quantity) = number of business and frequency

Accordingly, the costs for industry to establish the necessary safety evaluation data for a SCCS submission range from EUR 100 000 to EUR 1 000 000 per substance. These costs are usually borne by a consortium of companies to share these costs. The costs for a correct product safety assessment (for the product safety file) for a new formulation were estimated to in average be approximately EUR 15 000.

⁷² Impact assessment - Report on simplification of the “Cosmetics Directive” – Directive 76/768/EEC (COM(2008)49 final) (SEC(2008)118) /SEC/2008/0117 final, also accessible under http://ec.europa.eu/consumers/sectors/cosmetics/documents/revision/index_en.htm#h2-impact-assessment-report

⁷³ The underlying cost elements are described in the Impact assessment - Report on simplification of the “Cosmetics Directive” – Directive 76/768/EEC (COM(2008)49 final) (SEC(2008)118) /SEC/2008/0117 final and partly based on the RPA study "Impact of European Regulation on the EU Cosmetics Industry" of September 2007

The costs to prepare the derogation dossier are likely to be closer to the second case, ie. the costs for the product safety assessment.

Unlike the dossier for the SCCS, the derogation dossier would not have to address the safety of the substance. It would also not address all endpoints, but only the ones for which the additional data is needed. The costs for the derogation dossier would also not include the costs arising for producing testing data to demonstrate safety. These were included in the cost estimates above and constitute a large part of the costs. Therefore the costs for the derogation file would not be comparable to the SCCS dossier.

The derogation dossier would be rather comparable in overall complexity and likely cost to the product safety assessment file. It would not include certain elements of the product safety assessment, but on the other hand include additional ones. Overall it is therefore in balance considered comparable. It would only address one ingredient and not all ingredients of the product, as does the product safety assessment. It would also not have to argue the safety of the ingredient. It would however have to include information and demonstration on the four elements above.

6. COMPARING THE OPTIONS

6.1. Comparing the options on Effectiveness

When looking at the extent to which the options achieve the objectives, option 1 – maintaining the deadline – clearly makes the animal welfare objective paramount and is the most effective option in this respect. The number of animals spared as of 2013 would be a sub-set of the estimated 15 000-27 000 animals used for cosmetic specific testing outside the EU per year. Option 1 also clearly best reflects the ethical considerations of many EU citizens that animal welfare is not only about numbers, but about a basic ethical value decision. The expectation is that no animal should suffer because of a cosmetic product. In relation to the internal market objectives, option 1 is however less effective. It can lead to a more limited consumer choice and to less competitiveness of the European industry compared to the current situation.

Option 2 and its sub-options – the postponement options - are least effective in relation to the animal welfare objective of the considered options. While the long-term objective to end animal use is kept, under all sub-options the animal use outside the EU for EU purposes would continue, even though with some differentiation in relation to number of animals or time depending on the sub-option. Option 2 also meets the ethical consideration of citizens the least of the options. A further postponement of 7 years would mean a total postponement of 22 years after the first foreseen deadline. In addition, given that for several endpoints alternatives are not expected to be available then either it would already foreshadow a further postponement. On the other hand option 2 is the most effective of the options in relation to the internal market objectives, as it essentially maintains the current situation, which has allowed the industry to provide a wide range of safe and innovative cosmetics to the market and to maintain a competitive position. Of the sub-option under option 2, sub-option 2 (c) is the most effective in this regard, it makes the ban dependant on the scientific criteria of availability of alternatives and thus would not leave industry in a situation in which the tools for the safety assessment of cosmetics would not be available.

Option 3 – the derogation - is less effective than option 1, but more effective than option 2 in relation to the animal welfare objectives. The overall ban remains in place and only a limited number of animals would be used under the derogation. The derogation would be granted under exceptional conditions only. In relation to the internal market objectives option 3 is more effective than option 1, but less effective than option 2. Option 3 at least allows a certain

amount of innovation and could mitigate possible negative impacts of option 1 to some extent. The likely challenging application, which would each time raise the same ethical debate and would have to involve considerable judgement on the Commission side, would however limit the effectiveness of the option.

6.2. Comparing the options on Efficiency

In relation to efficiency, option 1 scores lowest of the options considered in that achieving the animal welfare objective can have an impact on the internal market objectives. The sub-set of 15 000 to 27 000 animals spared could come at the cost of a certain reduced availability of innovative ingredients, thus leading to less product innovation. It could equally lead to difficulties in relation to the assessment of existing ingredients, even though the existing derogation for Member States may help. Option 1 could lead to a somewhat more commoditised and less innovative market and is likely to impact the competitiveness of the EU cosmetics industry. Also, certain consumer demands could possibly not be met.

Option 2, and specifically option 2 (c), comes with no drawbacks in relation to the internal market objectives. However, while it maintains the long-term objective in relation to the animal welfare, it comes at the price of continued animal use at the same level as now for the coming years and the drawback of the 'ethical defeat' and of being considered to lose the animal welfare objective out of sight.

Option 3 maintains the deadline and thus adheres to the animal welfare objective, but at the same time provides the possibility of using the most significant innovative ingredients and thus mitigating some of the drawbacks of the deadline. The derogation would be subject to a Commission decision, and thus to a judgement whether in the case at hand the benefits offered by the ingredient can outweigh the drawback of the animal use. Option 3 is not likely to reduce the negative impacts of the marketing ban on the internal market objectives completely, but could limit them in some specific cases.

In quantitative terms the differences in efficiency between the options are limited. In relation to the animal welfare objective, because in comparison with other sectors the total number of animals involved is relatively low anyhow and because the differences in animal use between the options are difficult to quantify beyond the overall estimates. Also, under all options the animal numbers would decrease in time as alternative methods become available. In the best case this could be the case for skin sensitisation by 2020, leading then independent of the option chosen to a reduction of animal use of 70%. In relation to the internal market objective because while there will be undoubtedly a reduced access to existing and new ingredients and economic and social impacts are expected, they remain difficult to quantify and figures given were to a large extent based on industry estimates. In addition, counterbalancing measures such as EU support for research for research and development of alternative test methods could not be taken into account due to a lack of solid data.

6.3. Comparing the options on Coherence

Option 1 scores high in coherence with the overall animal welfare objectives of the Union, but low in coherence with the way the same question is addressed in other Union legislation.

All sub-options under option 2 score well in relation to coherence with overarching policies, in particular relating to innovation and competitiveness orientated objectives. Option 2 (c) could be seen as the most coherent approach compared to the way the same issue is addressed in other areas of EU legislation. On the other hand option 2 is least coherent with the animal welfare objective.

Option 3 comes with trade-offs and advantages on overarching objectives. It aims in

	Environmental Impacts	Economic Impacts	Social Impacts
Option 1	Sub-set of 15 000 to 27 000 animals per year spared (for EU cosmetic purposes) Acceleration of development of alternative methods with impacts beyond the cosmetics sector	Certain limitations in access to new ingredients, leading to a certain reduced product innovation. Possible loss of existing ingredients. Possible negative impacts on competitiveness of the cosmetics and cosmetics ingredients industry and trade.	Possible loss of R&D and other jobs as a result of the economic impacts.
Option 2 (a)	Sub-set of 15 000 to 27 000 continues to be used per year for the next 7 years	The current situation is maintained.	The current situation is maintained.
Option 2 (b)	Sub-set of 15 000 to 27 000 animals continues to be used per year, but minus 12% for tests excluded (- 1 800 to 3 240)	The current situation is maintained, but in a number of cases negative impacts (+/- 12%)	The current situation is maintained, but in a number of cases negative impacts
Option 2 (c)	Sub-set of 15 000 to 27 000 animals continues to be used per year, no fixed cut-off, but probably reduced as off 2020 by 70%, so beyond that sub-set of 4 500 to 8 100 animals per year	The current situation is maintained, but more planning safety is provided.	The current situation is maintained, but more planning safety is provided.
Option 3	Animal use stopped as under option 1, but possible to request derogation. Certain number of animals used under derogation about 100 animals, total number depends on number of derogations granted, estimated to about 1 000 to 1 500 per year.	Negative impacts as under option 1, but certain mitigation through the derogation for the most beneficial ingredients.	Negative impacts as under option 1, but certain mitigation through the derogation for the most beneficial ingredients.

particular at ensuring the innovation related objectives under the EUROPE 2020 strategy, but it clearly is in some contradiction to the animal welfare objective.

Looking at the stakeholder views, all stakeholders share the overall objective to end animal testing for cosmetics. Stakeholders have no interest in animal testing as such, other than as a tool to ensure and demonstrate consumer safety. Indeed alternative methods may turn out to be beneficial for industry.

The question remains however what to do in the cases in which alternatives are not available. Here, the views of stakeholders on the options are split. Animal welfare stakeholders took throughout the process a clear position against any proposal in relation to the 2013 deadline, thus clearly supporting option 1. Their position is one of principle and focussed on the animal welfare objective, irrespective of potential negative impacts on other objectives. Industry stakeholders have underlined that they expect significant negative impacts on them from the 2013 deadline and limited positive impacts for animal welfare. They have therefore overall supported the approach to let science deliver, thus supporting option 2 (c). Industry has nevertheless provided input on the derogation in option 3, recognising that - as a fallback position if a postponement is not proposed - the derogation is better than option 1. Member States appear to have split views, some (Denmark, Italy, France, Greece and the Czech Republic) expressed their support for a postponement (for one of the sub-options under 2) and others (Austria, Sweden and the Netherlands) are supporting option 1. However, not all Member States have expressed a view and, given that the issue has a clear political dimension, views taken at working level may not be representative for positions that would be taken in Council.

6.4. Preferred Option

The preferred policy option is in this case not a decision based on numbers only. It involves ethical questions of principle. There is a long history of political decision-making on this issue, with the bans first introduced going back as far as 1993. The objective of the legislator has clearly been ending animal use for cosmetics. Any decision will therefore have to take the political background into account.

6.5. Financing

In case a proposal by the Commission was made scheduled, an adoption of the legislative act by the co-legislator could not be expected before the end of 2013, with the application of the derogation starting in 2014 so that credits for its implementation would need to be foreseen as of 2014 which would go hand in hand with the start of the next Multiannual Financial Programme (MFF) 2014-2020.

Costs for the Commission would arise under Option 3 as it would require additional resources to assess derogation requests, in the Cosmetics Unit as well as in the Unit administering the SCCS.

While there is uncertainty as to the number of derogation request, it is estimated that about 10 to 15 ingredients would be eligible per year. The staff required will depend on the number of derogations to deal with.

Estimated budgetary needs

The average staff costs for the Commission are taken as a basis of the calculation, i.e. EUR 127 000/year for one AD/AST (2011 prices)	
Commission (Operational Unit for Cosmetics Regulation/Unit responsible for the Scientific Committee)	EUR 254 000 /year (for 2 FTE with overhead)

7. MONITORING AND EVALUATION

Monitoring and evaluation can be assured through existing mechanisms under the Cosmetics Regulation.

The Cosmetics Regulation foresees a mechanism of yearly reports to the European Parliament and the Council in its Article 35. These reports address the progress made in the development, validation and legal acceptance of alternative methods, statistical data on animals used and progress in international acceptance of alternative methods. While the yearly reporting is considered as too frequent, these regular reports provide a valuable tool to determine to which extent the safety assessment for cosmetics can already be based on alternative methods.

The last reports have equally addressed the implementation and enforcement of the testing and marketing ban. The enforcement of the rules is the task of the Competent Authorities and is part of their overall market surveillance activities. Market surveillance has been reinforced by the Cosmetics Regulation, in particular in its Article 22, which foresees that the Member States should at least every 4 years periodically review and assess the functioning of their market surveillance activities and inform the Commission and the Member States and make their assessment publicly available. This would present an additional monitoring tool. Cooperation on market surveillance is also supported through the Cosmetics Committee, the Working Group on Cosmetics and the Platform of European Market Surveillance Authorities (PEMSAC).

In case option 3 is chosen, the enforcement of the marketing ban would be further strengthened and a reporting on the derogation scheme would be foreseen. The reporting on the derogation would look in particular at the following aspects:

- Number of derogations requested and granted;
- Number of animals used under the derogation;
- Test protocols requested under the derogation;
- Time required for the derogation process;
- Types of ingredients covered by the derogations (granted and non-granted) and benefits put forward.

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ANNEX 1: SUMMARY SECOND PHASE STAKEHOLDER CONSULTATION

1. Introduction

A first phase stakeholder consultation on the availability of alternative methods by 2013 was carried out between April 2010 and May 2011. Information on this exercise, the contributions of the stakeholders, a summary report of the consultation as well as the final report, have been published on the Directorate-General SANCO's cosmetics website⁷⁴.

The result of the first phase of the consultation showed that alternatives to animal testing for the 2013 endpoints will not be available by 2013. The Commission services therefore started a second phase of stakeholder consultation in order to obtain information on the potential impacts of the entry into force of the 2013 deadline in the absence of alternatives. The Commission services consulted targeted stakeholders and Member States. The list of stakeholders consulted included the cosmetics industry, ingredient manufacturers, animal welfare organisations and the Scientific Committee for Consumer Safety (SCCS), as well as trading partners.

The consultation questionnaire, as well as a list of stakeholders consulted, is available on the Directorate-General SANCO's cosmetics website⁷⁵. The consultation took place between 7 December 2010 and 11 April 2011. The contributions of the stakeholders to the targeted stakeholder consultation have been equally published on the same Directorate-General SANCO's cosmetics website. None of the respondents claimed confidentiality.

The main purpose of this second consultation was to obtain information and data allowing the analysis of the impacts of the 2013 deadline in the absence of alternatives.

The Commission services received 14 answers from Member States (Austria, Belgium, Denmark, Finland, France, Germany, Greece, Italy, Netherlands, Poland, Portugal, Slovakia, Spain and Sweden) plus an answer from Norway; 4 industry association replies (Colipa, EDfCI, UEAPME and UNITIS); 5 replies from animal welfare associations (Eurogroup for Animals, ECEAE, Four Paws, Animal Defenders and PETA); a reply on behalf of the SCCS and a reply from the Chinese SFDA.

Some stakeholders, in particular Colipa, EFfCI and ECEAE, each collected data from their members for a consolidated submission of their respective organisation to the consultation.

2. General Findings

The consultation resulted in diverging views in relation to the possible impacts of the entry into force of the 2013 marketing ban and the best way forward. Industry, several Member States (Denmark, Italy, France, Greece and the Czech Republic) and the SCCS expected significant negative impacts on availability of cosmetic products, the competitiveness of the cosmetics industry and on employment, and considered a prolongation of the deadline the most logical way forward. Animal welfare organisations and some Member States (Austria, Sweden and the Netherlands) by contrast were clearly opposed to any proposal in relation to the deadline. Other stakeholders mainly described the expected impacts without taking a clear position. In particular industry stakeholders underlined to which extent the impacts depend on the interpretation of the existing provisions.

3. Comments and information supplied on specific items of the Questionnaire

⁷⁴ See: http://ec.europa.eu/consumers/sectors/cosmetics/documents/public_consultation/index_en.htm All Internet links provided in the footnotes of this report were last accessed on 24 August 2012

⁷⁵ See: http://ec.europa.eu/consumers/sectors/cosmetics/documents/animal_testing/stakeholders_consultation_en.htm

The questionnaire was organised according to seven groups of questions.

1) Existing Data on the Cosmetics market and the industry

Industry respondents provided additional data on the cosmetics market to complement existing data from earlier impact assessments.

2) Impacts on Animal Welfare/Environmental Impacts

Respondents provided information on the number of animals affected (in and outside the EU), the needs in relation to testing data as well as the impacts on research and the incentive role the provisions play.

Information on number of animals affected was received predominantly from industry and animal welfare group respondents. The answers highlighted that the testing in question is testing outside the EU (testing ban already in place in EU since 2009 and much earlier in some Member States) and thus not covered by existing reporting requirements in the EU on animal use. Animal welfare groups and industry provided different elements to allow a quantification of the possible number of animals concerned. These included information on the number of tests carried out by cosmetic companies, estimates based on extrapolations of the number of animals that were used in the EU for cosmetic testing in the past, testing and animal numbers normally necessary for the safety assessment of an ingredient and on the number of animals used in tests submitted to the SCCS.

In relation to research into alternatives, several respondents provided information on funding of such research, either through Member States, industry or other. There was overall agreement between all respondents that the provisions in the Cosmetics Directive had an important incentive function. Respondents had however split views on what will be the better incentive for research going ahead. Industry respondents maintained that the deadline will negatively impact the available funding for research and may even lead to a relocation of research into alternatives, while several Member States and the animal welfare respondents considered the deadline to be the best incentive for research into alternatives.

3) Impacts on Consumers

Respondents provided information on impacts on consumer safety and product availability. The clear majority of respondents underlined that there would be no impacts on consumer safety since ingredients for which no sufficient data is available would not be allowed to be placed on the market. Some Member States pointed nevertheless to difficulties in market surveillance.

The clear majority of respondents considered that animal data on the endpoints in question will be necessary for the safety assessment of cosmetics. The highest data needs identified were skin sensitisation, second repeated dose, reproductive toxicity and toxicokinetics. In particular industry respondents provided data on the testing carried out over the last 10 years to substantiate the main data needs. In relation to data used from other sectors many respondents – and particularly the industry – confirmed that data from the food sector, from cosmetics testing for outside EU regulatory requirements, from REACH/CLP, from biocidal products and from pharmaceuticals field were important.

Respondents from Member States underlined that data will in the future not only be needed for new ingredients, but that also existing ingredients are likely to come under review. Often mentioned substances expected as future candidates for assessment were: colorants also used in food (this is expected to mainly impact decorative cosmetics), nanomaterials, endocrine disrupters, sun protection products in general, and skin care in particular in relation to preservatives.

While in particular animal welfare stakeholders considered that the actual impact on availability of ingredients and thus cosmetics products would be negligible or should in any case be accepted because of an overriding ethical interest, industry and other stakeholders considered that there are likely to be considerable impacts. Industry, as well as one animal welfare respondent, provided detailed information on ingredient and product portfolio size and changes to allow quantification of the possible impacts.

4) Impacts on Competitiveness of Cosmetic and Cosmetic Ingredients Manufacturers

In particular industry respondents, but also some Member States, voiced clear concerns that the deadline will lead to a loss in competitiveness of the cosmetics and cosmetics ingredients industry. While industry provided data on the expected impacts, any quantification remained approximative and based on forward looking expectations.

5) Impacts on Small and Medium sized Enterprises (SMEs)

Overall respondents underlined the high percentage of SMEs in the cosmetics sector and their importance in terms of employment. Some Member State and industry responses highlighted that SMEs sometimes may not be sufficiently aware of the possible impacts, but are in reality likely to be hit harder than large companies. SMEs typically rely on less ingredients and less products, and may have more difficulties to offset loss of ingredients. On the other hand it was also pointed out that SMEs often use the animal testing free label.

6) Impacts on Employment

Industry and some Member States provided information on the current employment in the cosmetics industry. Industry respondents expressed the fear of relocation of research and development, which may also lead to a loss of employment in production and marketing.

7) Impacts on Trade

In particular industry respondents underlined the role of trade for the cosmetics industry and its current global role. They considered that the deadline may lead to reduced imports and exports.

4. Follow-up contacts in relation to derogation

The consultation on impacts was followed-up and further detailed in relation to a derogation option through bilateral consultation with targeted stakeholders and through a detailed presentation in relation to this option in the Cosmetics Committee and Working Group on 9 November 2011 and on 23 March 2012.

Animal welfare stakeholders reiterated in this context their position to maintain the deadline as is, without any derogation. Some industry and Member State stakeholders saw the benefits of a derogation approach as offering a possible balanced approach, but questioned the criteria to be applied, the practicalities of granting the derogation and the possible timeframes.

* * *

ANNEX 2: NUMBERS OF ANIMALS USED FOR TOXICOLOGICAL TESTING

1) Cosmetic Specific Animal Testing Data EU:

Year	Cosmetics Reports	Commission
2009	344	
2008	1510	
2007	1818	
2006	1329	
2005	2276	
2004	8988	
2003	1618	
2002	2153	
2001	2592	
2000	3138	
1999	3630	
Estimated total 1999-2008	29396	

Source: Reports as published on SANCO website (http://ec.europa.eu/consumers/sectors/cosmetics/documents/animal-testing/index_en.htm)

2) EU Animal Numbers for the endpoints covered by 2013 deadline not cosmetic specific 2008:

2008 – overall per testing area		
Skin sensitisation	38437	
Carcinogenicity	20807	
Sub-chronic and chronic toxicity testing	103005	
Developmental and reproductive toxicity	31286 63815	

Total	257350	
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Source: 6th Statistical report, compiled by Eurogroup and submitted to the Targeted Stakeholder Consultation

3) Estimated animal numbers per endpoint:

Endpoints	Animals per Test	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 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

Source: compiled by Colipa, based on OECD Guidelines and submitted to the Targeted Stakeholder Consultation

ANNEX 3: THE NEED FOR TOXICOLOGICAL DATA FOR THE COSMETICS SAFETY ASSESSMENT

Whether or not ingredients can be used in cosmetic products depends on whether their safety can be demonstrated. Essentially toxicological data needs arise in two scenarios:

The first is the manufacturer's safety assessment of cosmetic products he places on the market. This assessment is based on the safety of the ingredients. In line with Annex I of the Cosmetics Regulation the cosmetics safety report must contain the toxicological profile of each substance contained in the cosmetics product for all relevant toxicological endpoints. A particular focus is on local toxicity evaluation (skin and eye irritation), skin sensitisation, and in the case of UV absorption photo-induced toxicity. All significant routes of absorption must be considered as well as the systemic effects and margins of safety (MoS) based on a no observed adverse effects level (NOAEL) must be calculated.

The highest data need for the cosmetic manufacturers exists for skin sensitisation tests, second for repeated dose, third for reproductive toxicity and then for toxicokinetics and carcinogenicity. Skin sensitisation, i.e. allergic reactions to certain cosmetic ingredients plays an important role from a consumer safety point of view. An estimated 60% of all undesirable effects are cases of allergic reactions.⁷⁶ Sensitisation is a significant pathology which affects the quality of life of consumers for the rest of their lives. Colipa data shows that over the last ten years large companies carried out on average 213 animal tests for the 2013 endpoints per year, out of which 151 addressed skin sensitisation and 36 repeated dose, thus these two endpoints represent 87% of all testing. EFfCI confirmed the order of importance of the different tests. SMEs participating in the Colipa response carried out on average 7 tests per year over the last 10 years and tested only on skin sensitisation.

The second scenario is ingredients that are reviewed by the SCCS, either with a view to be added to one of the positive lists or to be prohibited or restricted in use. It can not be assumed that all ingredients in use now will remain available to the cosmetics industry after 2013. A number of Member States pointed out that many ingredients in use now are not supported by sufficient toxicological data. Often mentioned substances expected as future candidates for assessment were: colorants also used in food (this is expected to mainly impact decorative cosmetics), nanomaterials, endocrine disrupters, sun protection products in general, and skin care in particular in relation to preservatives. Preservatives in particular could become a sensitive area as a number of substances in this field are under review (such as parabens) and the list of available preservatives is likely to reduce.

Example Hair Dyes:

In Europe more than 60% of women and 5-10% of men colour their hair with a mean frequency of use by 6-8 times per year. The average age of majority of hair colour users is 30-60 years.

The hair dye market in the EU was EUR 2.6 billion in 2004, i.e. some 8% of the value of output of the cosmetics industry in Europe.

In the context of the Commission decision to review the safety of 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".

⁷⁶ On the basis of undesirable effects notified in France to the responsible market surveillance authority in 2005

According to the SCCS Notes of Guidance⁷⁷ if a substance is submitted to the SCCS the minimum data set that needs to be provided includes two endpoints that fall under the 2013 deadline: skin sensitisation and repeated dose toxicity.

When considerable oral intake is expected or when the data on dermal/percutaneous absorption indicates a considerable penetration of the ingredients through the skin (taking into account the toxicological profile of the substance and its chemical structure), data on carcinogenicity, reproductive toxicity and toxicokinetics becomes necessary. A review of data submitted to the SCCS between 2000 and 2009 shows that of 220 substances reviewed 154 had data intended to determine a full toxicological profile. All but 5 had repeated dose data and 137 had data on reproductive toxicity⁷⁸.

For all of these endpoints a full replacement of animal tests is not yet possible. For skin sensitisation alternatives are however expected to be scientifically available by 2017-2019; validation and regulatory acceptance is expected to take another 3 to 6 years.

Example: *When the negative effects of UV-A became more known companies developed over the last 10 to 15 years several new UV-A filters. The approval of these filters to be added to the Annexes of the Cosmetics Directive was also based on animal testing data.*

However, this does not automatically mean that all new ingredients would be blocked from the market or that no existing ingredients could be defended. Data may be already existing and it may be possible to rely on such old data. Data may also be available from other sectors. To some extent the existing derogation for Member States could be used in case data needs arise. Finally data may not always be needed and other tools may be able to be used for the assessment. Data on carcinogenicity, reproductive toxicity and toxicokinetics is as explained above not always required. The Cosmetics Regulation also supports the use of a weight-of-evidence approach and allows in duly substantiated and justified cases a read-across. Also, the scientific committees jointly adopted guidance in relation to the use in certain cases the Threshold of Toxicological Concern (TTC)⁷⁹.

In a number of cases it will therefore be possible to carry out a safety assessment in line with the legal requirements even in the absence of toxicological animal data. Since the safety assessment is a case-by-case evaluation it is difficult to assess in how many cases such other approaches will be sufficient. A recent review under REACH⁸⁰ showed that read-across and weight of evidence was used quite extensively in the absence of animal data. For repeated dose toxicity 28.1% of the dossiers relied on read-across and 6.6% on weight of evidence. For skin sensitisation 20.8% relied on read-across and 13.7% on weight-of-evidence. These figures are however considered to be high and it is likely that in a number of these cases additional data will need to be requested. Also, these figures all related to existing substances for which data allowing read-across was available.

⁷⁷ The SCCS's Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation, 7th http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_s_004.pdf

⁷⁸ Safety Assessment of Cosmetics in Europe. Rogiers V and Pauwels M (Eds), Current Problems in Dermatology Vol. 37 (2008). S. Karger, Basel, CH, ISBN 978-3-8055-8655-9

⁷⁹ The TTC concept aims to establish a human exposure threshold value below which there is a very low probability of an appreciable risk to human health, applicable to chemicals for which toxicological data are not available and based on chemical structure and toxicity data of structurally related chemicals. Opinion SCCP/1171 on the Use of the Threshold of Toxicological Concern (TTC) Approach for Human Safety Assessment of Chemical Substances with focus on Cosmetics and Consumer Products, http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_092.pdf

⁸⁰ 'The use of alternatives to testing on animals for the REACH Regulation 2011', ECHA-11-R-004.2-EN

ANNEX 4: TESTING DATA SOURCES

The data used so far for the cosmetics safety assessment is in most cases not generated specifically for this purpose. In about 90% of the cases cosmetic ingredients are used in other areas as well. The testing data required for cosmetics testing is general testing data following OECD guidelines that is equally used for other purposes.

However, this does not mean that in all these cases no additional data would be needed specifically with a view to the cosmetics use. To which extent existing data from other sectors is sufficient and to which extent cosmetic specific data is needed is a case-by-case question that depends on a number of factors (which data is already available, is it an SCCS assessment or not, etc.). While there is no clear data allowing to say exactly in how many cases existing data is sufficient, estimates can be made based on the information supplied below.

Colipa informed that in about 50% of the cases in which a substance was under SCCS review and supported by Colipa additional information including animal testing had to be provided to the SCCS. Colipa itself supported since 2004 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 animal data had to be generated (skin allergy, reproductive toxicity, sub-chronic studies, toxicokinetics and carcinogenicity).

Example: *In the case of the hair dye strategy, industry submitted 203 animal studies, out of which 101 had to be specifically generated.*

33% of Colipa companies responding informed that in 2010 they undertook animal testing to provide information to the SCCS, in earlier years on average 56% of the companies undertook such specific animal tests.

This data does not allow a clear quantitative determination in how many cases additional data may be needed. From this it would nevertheless roughly appear that in relation to substances under SCCS assessment in 50 to 70% of the cases sufficient data from other sources is available. The SCCS review is a very in depth and general evaluation of the safety of the ingredients and it is likely that more in depth data is needed than for the manufacturer safety assessment. Only 10 % of the new substances fall under SCCS review.

In many cases testing data is provided by the ingredient supplier. Testing data may also be available in publications, in databanks, etc. Often the original reason for the testing will not be obvious from the testing data itself.

According to the Colipa information, large companies considered testing data from food, cosmetic products outside the EU and REACH as most important to them. This does not necessarily reflect that this data is available in most cases, as the question was only how important it is considered to be, not in how many cases it was available. However, while there remains uncertainty, it is likely that the importance given also reflects the availability to some extent. The difference with the views expressed by SMEs is notably that they consider third country data less important and give more importance to REACH. SMEs are less likely to act internationally and will therefore in fewer cases have access to data generated for third countries.

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

Source: Colipa submission to the Targeted Stakeholder Consultation

A similar evaluation of important data sources was provided by EFfCI.

Generally nearly all comments received on the question of the key data sources and on how they are likely to develop in the future indicate a higher availability of toxicological testing data as a result of REACH requirements. However, it was also pointed out that, although for substances above 100 tons/year data will be available in June 2013, for substances between 1 to 100 tons/year data may only be available as of 1 June 2018 and may thus not be available for the first 5 years of the full ban.

Example: Existing cosmetic ingredients may need to undergo animal testing under REACH. A recent example of a substance widely used in cosmetics that underwent testing is calcium carbonate (used in toothpaste).

So far a total of 1849 animal tests were conducted since 2009 for REACH registration purposes and 711 testing proposals were submitted to ECHA, the clear majority of them relating to repeated dose and reproductive toxicity testing.

ANNEX 5: COSMETIC PRODUCTS AND THEIR LIFE CYCLE

On average large cosmetic companies have a product portfolio of around 10 000 different cosmetic products, SMEs of around 160 products according to data supplied by Colipa. Companies that participated in the ECEAE survey had for large companies 592 products on offer and SMEs 40. The difference between these figures is likely to be due to a higher percentage of small and specialised companies providing data to ECEAE (only 2 large companies participated). Overall it is estimated that there are between 100 000 and 300 000 different cosmetic products on the market, but there is no reliable data on European level so far⁸¹. Sweden provided the information that there were 35 000 products in total notified in Sweden in 2009 and 8700 new products were notified to be placed on the market in Sweden in 2009. In Portugal about 23 000 new notifications for new cosmetics products are received per year.

Industry stakeholders indicate the product life of a cosmetic product at 3 years. There is an estimated 25% - 30% renewal of cosmetic products on market per year.

The development cycle of a new product is described by UEAPME to be between 9 months to 1 year, however for very innovative products it may take up to 5 years. While this pace of innovation holds true for many, some manufacturers re-formulated a much higher percentage of their products per year, up to 90%. Large companies participating in the ECEAE survey added 5 products per year, representing 6% of the market value of their overall products, SMEs added 4 products, representing 22% of the market value of their overall products.

Out of the 25% to 30% of reformulations, 90% rely on ingredients already used in the cosmetics sector, 10% depend on new to market or new to cosmetics market ingredients.

Overview Cosmetic Products	
Product portfolio per manufacturer:	Colipa 10 000 (SME 160) ECEAE 592 (SME 40)
Total products:	Estimated between 100 000 and 300 000
Products reformulated:	25-30% per year
Reformulation depending on new to market and new to cosmetics market ingredients:	10% (of the 25-30%) = 2.5% to 3%

Source: Colipa, ECEAE and UEAPME submission to Targeted Stakeholder Consultation

⁸¹ This will change with the full implementation of the Cosmetic Products Notification Portal (CPNP) by July 2013

ANNEX 6: OVERVIEW OF COSMETIC INGREDIENTS PORTFOLIO AND CHANGES

Cosmetic products consist of between 5 to 60 ingredients each. Overall it can be estimated that there are more than 19 000 cosmetic ingredients globally. CosIng lists 19 391 ingredients and 2099 substances⁸². Looking at the INCI numbers over the last years approximately 500 new International Nomenclature of Cosmetic Ingredients (INCI) names are introduced per year. As regards the positive lists in the Cosmetics Directive they currently contain 29 UV filters, 58 preservatives and 153 colorants. However, in reality the number of ingredients actually used by manufacturers is far lower than these numbers would suggest. According to data submitted by Colipa in the stakeholder consultation, large cosmetics companies have an ingredient portfolio of 2000 ingredients and SMEs of 600 ingredients. This makes up the toolbox companies use for product formulation.

According to Colipa data, large companies introduced around 80 new ingredients per year between 2000 and 2009 (SMEs 22), representing around 4% of their ingredient portfolio. This represents the key innovation pool for industry. In 2010, 60 new ingredients were introduced by the participating large companies (SMEs 26). Less than 10% of these new ingredients are covered by the Annexes of the Cosmetics Directive.

However, the number of new ingredients introduced varies considerably between companies. The range given by large companies was between 0 and 734. While some cosmetic manufacturers may have more 'conservative' product lines or may innovate and/or grow more based on marketing strategies, others very much depend on innovative ingredients and products.

According to data supplied by ECEAE in the stakeholder consultation, large companies have a portfolio of 11500 ingredients⁸³, small companies have a portfolio of 151 ingredients. Large companies participating in the ECEAE survey added 15 ingredients per year, SMEs added 9 to their portfolio.

From this data it is not possible to deduce a total number of new ingredients introduced per year for the entire industry (the numbers above relate to manufacturers), as each ingredient can and will be used by several companies and in a variety of products. Proprietary ingredients developed by cosmetic companies themselves would typically be used first exclusively and then be provided to the wider market under license.

However, data from EffCI gives a minimum indication of total numbers; it estimates that from the ingredient manufacturer side in last 10 years around 1100 new substances – thus about 100 per year - were supplied by large companies to the cosmetics market, including substances used already in other sectors. A large supplier is estimated to introduce on average 5 new ingredients per year. In addition SME's introduce 2 to 3 new ingredients per year. In particular for botanical natural complex substances the European Organization of Cosmetic Ingredients Industries and Services (Unitis) informed that each company produced since 2000 each year several new ingredients from known or new plants. Hundreds of new botanical natural complex substances were made available to the cosmetics industry. These substances are in particular in demand as there is a strong consumer demand for more natural cosmetics. Ingredients are mostly sourced from ingredient suppliers. However 60% of large companies produce at least some ingredients themselves - according to Colipa data between 1 and 5 new

⁸² See: <http://ec.europa.eu/consumers/cosmetics/cosing/> , Substances are those that are regulated under one of the Annexes of the Cosmetics Directive, ingredients are not.

⁸³ Note: this figure is not coherent with overall information available and may be based on a mistake

ingredients a year per company. Taken together, this would indicate that at a minimum approximately 150 new ingredients are introduced per year.

On the other hand, up to 500 new INCI codes are introduced per year. This represents the maximum of new ingredients per year. It is however likely to be a very high estimate and most stakeholders considered that the actual number of new cosmetics ingredients in the EU is lower than that. The reasons were that INCI is not exclusive to cosmetics, covers ingredients worldwide and also mixtures.

To illustrate the link between ingredients and products, below the example of a frame formulation for a sunscreen cream is provided and an example of a formulation. Frame Formulations detail the type of ingredients and their maximum concentration for most cosmetic products on the European market. They are used to provide information to poison centres and are included in the new Cosmetic Products Notification Portal (CPNP).

EXAMPLE SUNSCREEN CREAM:

Frame formulation Number: 9.1 - 2011
SUNSCREEN CREAM, LOTION

Ingredients Maximum

	<u>levels (% w/w)</u>
Oils (e.g. vegetable and/or mineral), waxes and fats (e.g. long chain alcohols)	70
UV filters	40
Silicones including volatile silicones (e.g. <i>cyclopentasiloxane, dimethicone</i>)	30
Humectants (e.g. <i>glycerin, propylene glycol</i>)	30
Ethanol (<i>alcohol, alcohol denat.</i>)	25
Emulsifying agents (e.g. <i>glyceryl stearate, PEG-100 stearate</i>)	10
Bulking agents (e.g. <i>talca, silica, nylon powder</i>)	10
Additional ingredients (e.g. <i>bisabolol, vitamins</i>)	6
Film forming polymers (e.g. <i>PVP</i>)	5
Thickeners (e.g. <i>carbomer, xanthan gum</i>)	5
<i>Parfum</i>	3
Preservatives, antimicrobials	2
Colorants	2
<i>Aqua</i>	to 100

ACTUAL PRODUCT EXAMPLE:

Ingredient (from example)	Use (according to COSING)
Aqua	Solvent
C12 C15 Alkyl benzoate	Antimicrobial, Emollient, Skin conditioning
Glycerin	Denaturant, Humectant, Masking, Perfuming,

	Skin protecting, Viscosity controlling
Ethylhexyl salicylate	UV absorber, UV filter
Titanium dioxide	Opacifying, UV absorber, UV filter
Butyl methoxydibenzoylmethane	UV absorber, UV filter
Bis-ethylhexyloxyphénol Methoxyphenyl triazine	Skin conditioning, UV absorber, UV filter
Alcohol Denat	Antiforming, Antimicrobial, Astringent, Masking, Solvent, Viscosity controlling
Pentylène glycol	Skin conditioning, Solvent
Octocrylene	UV absorber, UV filter
Cyclopentasiloxane	Emollient, Skin conditioning, Solvent
Stearic acid	Cleansing, Emulsifying, Emulsion stabilising, Masking, Refatting, Surfactant
Potassium cetyl phosphate	Surfactant
Dimethicone	Surfactant, Antifoaming, Emollient, Skin conditioning, Skin protecting
Methyl methacrylate crosspolymer	Film forming
Myristyl myristate	Emollient, Opacifying, Skin conditioning
Nylon-12	Bulking, Opacifying, Viscosity controlling
Petrolatum	Antistatic, Emollient
Ethylhexyl triazone	UV absorber, UV filter
Aluminium hydroxide	Cosmetic colorant, Emollient, Humectant, Opacifying, Skin Protecting, Viscosity controlling
Ammonium Polyacryloyldimethyl taurate	Emulsion stabilising, Viscosity controlling
Caprylyl glycol	Emollient, Humectant, Skin conditioning
Cassia alata leaf extract	Astringent
CI 77491 (IUPAC Name: iron oxides)	Cosmetic colorant
CI 77492	Cosmetic colorant
CI 77891 (INN Name: Titanium Dioxide)	Cosmetic colorant
Disodium edta	Chelating, Viscosity controlling

Drometrizole trisiloxane	UV absorber, UV filter
Glyceryl stearate	Emollient, Emulsifying
Hydroxypropyl methylcellulose	Antistatic, Binding, Emulsion stabilising, Film forming, Surfactant, Viscosity controlling
Maltodextrin	Absorbent, Binding, Emulsion stabilising, Film forming, Skin conditioning
PEG 100 Stearate	Surfactant
Phenoxyethanol	Preservative
Stearyl alcohol	Emollient, Emulsifying, Emulsion stabilising, Foam boosting, Masking, Opacifying, Refatting, Surfactant, Viscosity controlling
Terephthalylidene dicamphor sulfonic acid	UV Absorber, UV Filter
Tocopherol	Antioxidant, Masking, Skin conditioning
Triethanolamine	Buffering, Emulsifying, Masking, Surfactant

Only 10% of the ingredients introduced into the portfolio are estimated to be new to the market. 90% are/have been used in other sectors, including cosmetic products outside the EU, food, pharmaceuticals, detergents and are covered by REACH.

Ingredients do not all have the same importance and value. While no data was provided by stakeholders on actual individual ingredient value, it is clear that some ingredients, such as preservatives, are used in a large portion of cosmetic products, have a key functionality and are therefore much more difficult to replace. Equally, new ingredients with a specific and innovative function, eg. in anti-ageing products, may produce a much higher industry value than a new colorant.

Ingredients are added to and taken out the portfolio for various reasons. In 2010 according to Colipa data more ingredients were taken out of the portfolio than added to it. On average large companies removed 120 ingredients from their portfolio in 2010 and SMEs removed 10. The main reasons for removing ingredients were regulatory constraints, followed by safety considerations, poor performance and/or quality. The reason to introduce new ingredients is in over 50% of the cases better performance and quality, including better tolerance (e.g. anti-ageing properties, more natural, biological/organic, new categories (sprays), better tolerance). However, environmental reasons were also considered important. In an effort towards more sustainability the cosmetics industry replaces e.g. more and more silicon, mineral oils and synthetic alcohol. Very often a new ingredient will lead to a better performance eg. better consistency, innovation is therefore often rather incremental.

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

Source: Colipa Submission to Targeted Stakeholder Consultation

Examples of innovation:

- A superior skin moisturisation ingredient has been introduced by company A. Four different formulations were launched in the EU using technology based on this ingredient and this resulted in significant growth for the brand.
- Development of ingredients to obtain odourless self-tanning.
- A natural ingredient to formulate silicone-free products (highly soluble, absorbs oil at higher levels, enhancing its emulsifying effect). It contains an extremely low microbial count reducing the need for preservatives, is low cost and has enhanced anti-irritant properties.
- A large part of the patent activity in the cosmetics industry appears to be in the field of peptides. Peptides stimulate skin regeneration, but in order to be effective, a high concentration of peptides is needed, without causing any irritation to the skin. Peptides are already in use, so here innovation would mainly mean enhancements.

Overview Ingredients	
Ingredients portfolio per manufacturer:	Colipa 2000 (SME 600), ECEAE 11 500 (SME 151)
Ingredients added per year per manufacturer:	Colipa 70 (SME 22) = 4%, ECEAE 15 (SME 9)
New to market ingredients:	Out of these 4% added ingredients only 10% new to market = 90% used in other sectors, thus new only to cosmetics market
Total ingredients added per year:	Overall at least 100 (EfFCI)
Ingredients removed:	Removed: Between 2000 and 2009 Colipa 24 (SME 6), but in 2010 120 (SME 10)

Source: Colipa, EfFCI and ECEAE submissions to the Targeted Stakeholder Consultation

ANNEX 7: GLOSSARY

Alternative methods:

Methods that provide the same or higher levels of information as those obtained in procedures using animals, but which do not involve the use of animals or use fewer animals or which entail less painful procedures. In the context of the Cosmetics Directive only methods that do not involve the use of animals are relevant (not reduction and refinement).

Carcinogenicity:

A specific endpoint on repeated dose toxicity is carcinogenicity. Carcinogenesis is a complex long-term multi-factorial process, and consists of a sequence of stages. Carcinogens have conventionally been divided into two categories according to their presumed mode of action: genotoxic carcinogens that affect the integrity of the genome by interacting with DNA and/or the cellular apparatus, and non-genotoxic carcinogens that exert their carcinogenic effects through other mechanisms.

Cosmetic ingredients:

‘ingredients’ means any chemical substance or preparation of synthetic or natural origin, including perfume and aromatic compositions used in composition of cosmetic products (see Commission Recommendation Establishing guidelines on the use of claims referring to the absence of tests on animals pursuant to Council Directive 76/768/EEC, (2006/406/EC)).

Cosmetic product:

‘cosmetic product’ means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours; (see Article 2, 1 (a) of Regulation 1223/2009)

Marketing ban:

As from March 2009, it is prohibited in the EU to market cosmetic products and their ingredients which have been tested on animals, irrespective of the origin of these products. This marketing ban applies to all but the most complex human health effects to be tested to demonstrate the safety of cosmetic products (repeated-dose toxicity including skin sensitisation and carcinogenicity, reproductive toxicity and toxicokinetics), for which the legislator extended the deadline to March 2013 (see Article 4a,1 (a) and (b) of Directive 76/768/EEC and Article 18 1 (a) and (b) of Regulation 1223/2009).

New to cosmetics market ingredient:

A cosmetic ingredient that is new to use in the cosmetics sector, but has been used already in other sectors.

New to market ingredient:

A cosmetic ingredient that has not been used in other sectors before either, thus is completely new.

Repeated-dose toxicity:

Repeated dose toxicity occurs if a persistent or progressively deteriorating dysfunction of cells, organs or multiple organ systems, results from long-term repeated exposure to a chemical.

Reproductive toxicity:

Reproductive toxicity refers to a wide variety of adverse effects that may occur in different phases within the reproductive cycle, as a consequence of one or more exposures to a toxic substance, including effects on fertility, sexual behaviour, embryo implantation, embryonic/foetal development, parturition, postnatal adaptation, and subsequent growth and development into sexual maturity.

Skin sensitisation:

One specific endpoint to assess repeated dose toxicity is skin sensitisation. This is the toxicological endpoint associated with chemicals that have the intrinsic ability to cause skin allergy.

Toxicokinetics:

Toxicokinetics informs about the penetration into and fate within the body of a toxic substance, including its absorption, distribution, metabolism (producing less toxic metabolites (detoxification) or in some cases more toxic metabolites) and excretion.

Testing ban:

A ban of animal testing of finished cosmetic products has been in force since September 2004 and a testing ban on ingredients or combinations of ingredients since March 2009 (see Article 4a,1 (c) and (d) of Directive 76/768/EEC and Article 18 1 (c) and (d) of Regulation 1223/2009).

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