April 15, 2011

To: European Commission
DG SANCO, Unit B2 - Cosmetics and Medical Devices

Subject: Stakeholder Consultation on the 2013 Implementation date of the Marketing Ban - Cosmetics Directive

On behalf of the European Coalition to End Animal Experiments (ECEAE), we are pleased to submit the following responses to the questionnaire received in December 2010. We welcome the opportunity to provide our input to the European Commission’s impact assessment on the 2013 deadline for the implementation of the Cosmetics Marketing Ban.

The ECEAE is the only European organisation exclusively representing animals used in scientific procedures and represents 17 animal welfare member organisations across Europe. The ECEAE is an umbrella lobbying organisation with considerable legal, campaigning and scientific expertise.

Originally, the ECEAE was created in 1990 to campaign for a total ban on cosmetics testing on animals in Europe. Today, the ECEAE focuses on all EU legislative and policy developments relating to animal experimentation with a view to enhance the protection of animals in European laboratories and raise awareness of the use of animal in experiments.

We consider that the deadline should be maintained, since:

- The ban on the sale of cosmetics tested on animals reflects the clear will of EU citizens and the European institutions
- The current position disadvantages European companies, especially SMEs, compared with overseas competitors
- An extension to a specific new deadline would not be based on evidence suggesting that the position will change significantly in the near future
- A removal of any specific deadline would subvert the policy altogether and represent a substantial change rather than a review, requiring a major new debate on the issue.

- The scientific position makes it possible to achieve the deadline with negligible negative impact, as set out in this response.

We look forward to ongoing dialogue with the European Commission and other stakeholders on developments affecting animals used in cosmetic testing.

Sincerely,

Michelle Thew
Chief Executive
European Coalition to End Animal Experiments
British Union for the Abolition of Vivisection

QUESTIONS IMPACT ASSESSMENT
2013 IMPLEMENTATION DATE MARKETING BAN COSMETICS DIRECTIVE

1. EXISTING DATA ON THE COSMETICS MARKET AND THE INDUSTRY

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

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

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

2. IMPACTS ON ANIMAL WELFARE/ENVIRONMENTAL IMPACTS

The aim of the provisions on animal testing in the Cosmetics Directive is to provide a high level of animal welfare. They contain a clear political and ethical choice against animal testing for cosmetics purposes. With regard to quantifiable impacts on animal welfare, impacts can be measured by the number of animals affected by testing for cosmetics purposes.

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

An important aim of the provisions is equally the function as an incentive to the development of alternatives to animal testing that would ultimately also benefit other sectors.
2.1. IMPACTS ON NUMBER OF ANIMALS AFFECTED

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

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

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

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

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

The number of animals reported under the EU Directive 86/609 and the Commission reports on the Cosmetic Directive are for easy reference given in the table below. In addition we provide an estimate of the numbers of animals used in non-recorded years (based on an average of the years either side) to give an estimate of the total number of the period of interest; 1999-2008 inclusive.

**Table 1.** The number of animals reported to have been used for cosmetic testing according to reports under Directive 86/609 and the Commission Reports on the implementation of the Cosmetic Directive. Numbers in italics are extrapolated numbers.

<table>
<thead>
<tr>
<th>Year</th>
<th>Total use for cosmetics reported under Directive 86/609</th>
<th>Total used for cosmetics reported in Commission Reports</th>
</tr>
</thead>
<tbody>
<tr>
<td>2008</td>
<td>1,967</td>
<td>1,510</td>
</tr>
<tr>
<td>2007</td>
<td>3,167</td>
<td>1,818</td>
</tr>
<tr>
<td>2006</td>
<td>4,369</td>
<td>1,329</td>
</tr>
<tr>
<td>2005</td>
<td>5,571</td>
<td>2,276</td>
</tr>
<tr>
<td>2004</td>
<td>4,611</td>
<td>3,480</td>
</tr>
<tr>
<td>2003</td>
<td>3,651</td>
<td>1,618</td>
</tr>
<tr>
<td>2002</td>
<td>2,691</td>
<td>2,153</td>
</tr>
<tr>
<td>2001</td>
<td>2,910</td>
<td>2,592</td>
</tr>
<tr>
<td>2000</td>
<td>3,128</td>
<td>3,138</td>
</tr>
<tr>
<td>1999</td>
<td>3,347</td>
<td>3,630</td>
</tr>
<tr>
<td>Estimated total 1999-2008</td>
<td><strong>35,412</strong></td>
<td><strong>23,544</strong></td>
</tr>
</tbody>
</table>
It must be noted that in both the reporting under the statistics for the laboratory animals directive (86/609/EEC) and the Commission reports of the implementation of the Cosmetics Directive, consideration is not given to the number of animals used to test chemical substances that subsequently end up in cosmetics. This is because in neither report is a full definition of ‘testing for cosmetics purposes’ given.

It is up to the person completing the statistical report form for their institution to decide what ‘testing for cosmetics purposes’ is; they may do this based on legislative purpose of the testing (where known) or the first or primary use the substance is likely to have.

This is therefore likely to omit a great many chemical substances that have a minor or even major use in cosmetics. In our view testing on animals of these chemicals would also constitute ‘cosmetics testing’.

Until the REACH dissemination website is more complete, we are not aware of a database that will identify how many chemicals tested under chemicals legislation are also used for cosmetics purposes.

However, it is thought that the majority of ‘cosmetics ingredients’ are in fact tested on animals for human safety under other legislation (see Rogiers, W. and Pauwels, M. 2008. Safety assessment of cosmetics in Europe Curr. Prob. Dermatol. 36. Karger; Basel, Switzerland. p 150), although it is our opinion that this is also no longer lawful under the animal testing bans of the Cosmetics Directive (see answer to 2.2.10).


2.3.2. Details of difficulties encountered by Member States
Some Member States elaborated on their replies by mentioning the difficulties they had in collecting the information. As pointed out in the previous reports, chemicals are rarely tested on animals solely for their use as ingredients in cosmetics, and the majority of animal tests are conducted for multiple uses by manufacturers of chemical substances (industry assumes that approximately 80-90% of cosmetic ingredients are tested for multiple uses). Therefore, some Member States acknowledged that it is difficult to determine which testing has been carried out with a view to cosmetic purposes.

It is likely therefore that both the statistical reports under Directive 86/609 and the Commission Reports on the implementation of the Cosmetics Directive are significantly under-reporting ‘cosmetics testing’.

The fact that in each year there is a difference in number of animals reported to have been used for cosmetics purposes between the two types of report, even though the same Member States are reporting, reinforces that there is an issue with definitions and some under-reporting.

Another source of information on the numbers of animals used for cosmetics testing can be found in the evaluation of the tests conducted under the dossiers submitted to the SCCS1.

These opinions are only on certain ingredients of concern (such as tanning ingredients) or those listed in the Annexes of the Cosmetic Directive (hair dyes, preservatives, UV

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filters). However, these do give a good idea of the number of animals used to demonstrate cosmetics safety for these types of ingredients. According to the SCCS analysis of their opinions, 103,683 animals were used in 119 opinions published in 2002 and 2006, leading to a ‘rudimentary figure of about 21,000 animals per year’ (see Rogiers, W. and Pauwels, M. 2008. Safety assessment of cosmetics in Europe. Curr. Prob. Dermatol. 36. Karger; Basel, Switzerland).

We understand the SCCS will be providing you with an additional analysis covering the years 2006-2009; however, in case this is incomplete we provide our own analysis of SCCS published opinions from 2009 and 2010, including those open for comment. In these we found a total of 221 recent animal tests reported in 42 out of 50 opinions. Recent animal tests were defined as those listed as conducted or published in 2000 or later. The estimated number and species of animals for the tests is given in Table 2. The total estimated number of animals used in these opinions in tests conducted between 2000 and 2010 was 48,502.

It should be noted that within these opinions there was a high level of repeat testing even since 2000. It appeared that 48 of the 221 animal tests were essentially duplicated animal tests on the same endpoint using either the same species or another species.

<table>
<thead>
<tr>
<th>Test</th>
<th>Max number of animals used per test, according to OECD TG</th>
<th>Number of substances tested (number of duplicate tests within the same period)</th>
<th>Species reported in the opinions</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin irritation</td>
<td>3</td>
<td>15 (2)</td>
<td>Rabbits, guinea pigs</td>
<td>45</td>
</tr>
<tr>
<td>Eye irritation</td>
<td>3</td>
<td>20 (6)</td>
<td>rabbits</td>
<td>60</td>
</tr>
<tr>
<td>Acute oral</td>
<td>20</td>
<td>7</td>
<td>Dogs, rats</td>
<td>140</td>
</tr>
<tr>
<td>Acute dermal</td>
<td>20</td>
<td>1</td>
<td>rats</td>
<td>20</td>
</tr>
<tr>
<td>Acute inhalation</td>
<td>40</td>
<td>2</td>
<td>rats</td>
<td>80</td>
</tr>
<tr>
<td>Phototoxicity</td>
<td>25</td>
<td>3 (1)</td>
<td>Guinea pigs</td>
<td>75</td>
</tr>
<tr>
<td>Skin sensitisation (LLNA)</td>
<td>25</td>
<td>36 (6)</td>
<td>mice</td>
<td>900</td>
</tr>
<tr>
<td>Skin sensitisation (GPMT)</td>
<td>30</td>
<td>5 (2)</td>
<td>Guinea pigs</td>
<td>150</td>
</tr>
<tr>
<td>Mutagenicity</td>
<td>50</td>
<td>41 (15)</td>
<td>Rats, mice</td>
<td>2,050</td>
</tr>
<tr>
<td>Repeated dose 7 or 28 day oral/inhalation/dermal</td>
<td>60</td>
<td>11 (2)</td>
<td>Mice, rats, hamsters, dogs</td>
<td>660</td>
</tr>
<tr>
<td>Repeated dose 90 day oral</td>
<td>100</td>
<td>21 (2)</td>
<td>rats</td>
<td>2,100</td>
</tr>
<tr>
<td>Repeated dose 90 day oral</td>
<td>48</td>
<td>1</td>
<td>dogs</td>
<td>48</td>
</tr>
<tr>
<td>Neurotoxicity</td>
<td>80</td>
<td>1</td>
<td>mice</td>
<td>80</td>
</tr>
<tr>
<td>Enzyme induction</td>
<td>158</td>
<td>1</td>
<td>rats</td>
<td>158</td>
</tr>
<tr>
<td>Chronic toxicity</td>
<td>160</td>
<td>2 (1)</td>
<td>rats</td>
<td>320</td>
</tr>
<tr>
<td>Developmental</td>
<td>200 (incl pups)</td>
<td>6</td>
<td>rats</td>
<td>1,200</td>
</tr>
<tr>
<td>toxicity screening study</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>--------------------------</td>
<td>-----------------</td>
<td>----------------</td>
<td>------------------</td>
<td></td>
</tr>
<tr>
<td><strong>Toxicokinetics</strong></td>
<td>224</td>
<td>14 (6)</td>
<td>Mice, rats</td>
<td>3,136</td>
</tr>
<tr>
<td><strong>Carcinogenicity</strong></td>
<td>400</td>
<td>2 (1)</td>
<td>Rats</td>
<td>800</td>
</tr>
<tr>
<td><strong>Developmental toxicity</strong></td>
<td>1056 (incl pups)</td>
<td>24 (2)</td>
<td>Rats</td>
<td>25,334</td>
</tr>
<tr>
<td><strong>One generation reproductive toxicity study</strong></td>
<td>1152 (incl pups)</td>
<td>6 (2)</td>
<td>Rats, mice</td>
<td>6,912</td>
</tr>
<tr>
<td><strong>Two-generation reproductive toxicity study</strong></td>
<td>2112 (incl. pups)</td>
<td>2</td>
<td>rats</td>
<td>4,224</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td></td>
<td></td>
<td></td>
<td><strong>48,502</strong></td>
</tr>
</tbody>
</table>

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

Rabbits are not rodents and should, therefore, not be included as rodents here. The question appears to imply that testing on “rodents (including rabbits)” is less controversial, either in terms of animal welfare or public opinion. There is nothing to support this statement.

It is well recognised that rodents and rabbits have the same capacity as other mammals to suffer pain in procedures in addition to stress from the barren laboratory environment.

Public opinion opposed to animal experiments is also not limited to so-called higher species such as dogs, cats and non-human primates. A poll conducted by YouGov for the ECEAE in relation to the revision of the laboratory animals directive (86/609/EEC) in 2009 found that 79% of people agreed or strongly agreed that the new law should prohibit all experiments on animals which do not relate to serious or life-threatening human conditions.

According to the analysis of SCCS opinions conducted by the SCCS; rats (64,105), mice (28,597), guinea pigs (5,640), rabbits (3,823), hamsters (1,262) and even dogs (256) featured in the dossiers submitted to the SCCS between 2002 and 2006 (see Rogiers, W. and Pauwels, M. 2008. *Safety assessment of cosmetics in Europe*. Curr. Prob. Dermatol. 36. Karger; Basel, Switzerland. p 150)

Our own analysis of the SCCS opinions published in 2009 and 2010, including those open for comment found that; of 50 substances, there were 221 animal tests conducted in recent years (defined as 2000 or later) for 42 substances. Animals involved in these tests included mice, rats, rabbits, guinea pigs, hamsters and dogs.

According the Commission reports on the implementation of the Cosmetics Directive (with data from 1998 to 2008); rabbits, guinea pigs, mice, rats, fish, hamsters were used.

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Whilst, ecotoxicology studies are not covered under the scope of the Cosmetic Directive, animal testing of cosmetic ingredients under other EU legislation such as REACH and Biocides is a major issue (see answer to question 2.2.10). Under such legislation cosmetic ingredient testing could include tests on fish, guinea pigs, rats, mice, rabbits, birds and dogs. The fact that, in the Commission reports on the implementation of the Cosmetics Directive, Member States have reported the use of fish supports this premise.

2.1.3. Please provide information about the number of animals that would in your view potentially be saved from testing over the next 10 years in case the 2013 implementation date is kept?

(type of answer expected: any founded explanation of numbers plus reasons)

We assume the question relates to how many animals would be spared from testing outside the EU for products and ingredients that are sold in the EU (as the 2013 deadline relates only to marketing).

This is difficult to answer because we do not know the extent of animal testing outside the EU of cosmetic ingredients. Reporting of animal testing in general is poor outside of Europe, with large animal testing countries such as the USA and Japan only providing reports of total numbers by species and not by area of research. In addition the USA does not report the use of rodents, fish or birds in its annual figures.

However, we can make an assessment based on available estimates of animal use worldwide. One reliable estimate has been produced, based upon 2005, which is 58,339,972 animals used in actual procedures annually. This can be found in the paper, Taylor, K., Gordon, N., Higgins, W. and Langley, G. (2008) Estimates for worldwide laboratory animal use in 2005. Alternatives to Laboratory Animals. 36 (3); 327-42.

Assuming the proportion of cosmetics testing outside the EU is the same as in the EU in 2005 (0.05%) then we can make an estimate that the annual numbers of animal used for cosmetic testing worldwide (that may result in products being imported in the EU) is 26,836. Over ten years this would be 268,360; i.e. over a quarter of a million animals.

However, this is likely to be an underestimate for at least two reasons:

1. Based on the SCCS opinions alone, an estimate of 21,000 animals per year was given which is not much less than the worldwide estimate above. The testing in the SCCS opinions only covered a fraction of cosmetic ingredients and is also only likely to have covered testing in the US and the EU (not Japan or China or South America).

2. The worldwide estimate only includes testing specifically of cosmetic ingredients for cosmetics purposes and will therefore not cover testing of chemical substances that are also used in cosmetics or testing of cosmetics ingredients done under other legislation such as chemical or worker safety.

If 80% of cosmetics are tested for other legislative purposes such as chemical or worker safety (see 2.3.2 in EC Report on the Development, Validation and Legal Acceptance of
Alternative Methods to Animal Tests in the Field of Cosmetics (2008)), then one could assume that the figure of 26,836 constitutes the remaining 20% of cosmetic testing which is purely for cosmetic purposes. Extrapolating would then give us a figure of 134,180 animals each year. This would amount to 1,341,800 animals over ten years.

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

We anticipate industry providing detail here. The most transparent source of information on cosmetic testing, SCCS opinions, does not provide location of testing.

There are, however, a number of reasons to support the contention that the proportion of testing of cosmetics on animals is likely to be higher outside the EU:

- Negotiations for a ban on animal testing for cosmetics have been underway in the EU since the 1990s – this is likely to have had an effect on company practices before the ban. For example the Humane Cosmetics Standard (the global certification standard for products not tested on animals) launched in 1998 has seen a number of large national and multinational companies join the programme and end animal testing within the EU. This, together with other corporate response to consumer pressure, is likely to have had an impact on animal testing in the EU.

- There is no legislation prohibiting animal testing of cosmetics in countries outside the EU and less debate on the issue; this may suggest that testing itself is less rigorously controlled.

- If patents filed with the EU patent office in 2005 can be used as a proxy for development of new products (and ingredients) then Japan as the submitter of 43% of cosmetics patents is likely to be a significant animal tester (the EU (27) constituted 37%, the US 10%, Japan 43%, China 10% of cosmetics patents filed in Europe according to the Global Insight 2007 report referred to section 1).

- Some countries require repeat testing on products imported into the country, e.g. China. This is likely to significantly increase the proportion of testing outside the EU.

There is, however, also some evidence from the Global Insight 2007 report that the EU is the main producer and exporter of cosmetics. In 2005, the EU was by far the largest exporter of cosmetics at 23.1 billion euros, followed by the USA (3.8), Japan (0.6) and China (0.8).

Out of the total exports by these countries, 81% were from the EU (page 14 of Global Insight report). This may therefore suggest that the EU was more likely to be a greater tester than other countries (prior to the ban).
Global companies, however, control over half the share of the EU market (page 5 of Global Insight report). They can export their animal testing with their production based in the EU whilst the testing is not. In any event, the fact that the EU is an exporter of cosmetics, rather than an importer, supports the statement that the testing ban was of arguably far greater impact than the import ban is likely to be.

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

Public opinion appears solidly opposed to the testing of animals for cosmetic products. Examples of surveys:

- UK (1999): 88% of women want a complete ban on animal testing for cosmetics, and 96% think there should be compulsory labelling.
- UK (2001): 83% of women in the UK are in favour of a Europe-wide ban on the sale of cosmetics and make-up that are tested on animals.
- UK (2004): 79% of people said they would be likely to swap to a brand that was not animal tested if they discovered that their existing brand was tested on animals.
- France (2003): 60% of French citizens favour a total ban on cosmetics animal testing.
- Czech Republic (2006): 72% of respondents agree with the use of alternatives instead to animal tests for cosmetics.
- Norway (non-EU country) (2002): 81% of respondents have a negative opinion about cosmetics testing.

2.2. Testing data in relation to 2013 endpoints

2.2.1. Inclusion in the Annexes of the Cosmetics Directive is preceded by a dossier review by the Scientific Committee on Consumer Safety (SCCS) or its predecessors. In how many cases/dossiers was data on the endpoints covered by the 2013 implementation date submitted to the SCCS (or its predecessors),

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3 Opinion Research Business for BUAV and RSPCA, 1999
4 BUAV and Co-Op Retail, 2001
5 Opinion Research Business for BUAV, 2004
6 Enquête Ipsos for One Voice 2003, « Les Français et l’expérimentation animale »
7 The Public Opinion Research Centre (CVVM) for Svoboda zvírat, 2006
8 Opinion for Dyrevernalliansen, "Holdninger til bruk av dyr", landsomfattende omnibus av 2002
respectively requested by the SCCS (or its predecessors) between 2000 and March 2009?

(type of answer expected: out of the XXX substances data on these endpoints was expected for XXX)

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

(type of answer expected: out of the XXX, for a) XXX, for b) XXX ...)

Question 2.2.2.a is not, in our view, a valid question as it includes skin sensitisation and carcinogenicity under ‘repeated dose’.

Despite objections from animal welfare groups, the Commission, has since 2004, assumed in its reports that that the extension for ‘repeated dose’ tests also includes two further animal tests: skin sensitisation and carcinogenicity. The argument appears to be that these tests can also be considered repeated-dose toxicity, because animals may be subjected to more than one dose of the substance in question.

The ECEAE’s very strong legal advice is that this is unsustainable. Carcinogenicity and skin sensitisation are always listed in EU legislation as discrete endpoints (in the text of REACH, the Test Methods Regulation, the Pesticides Directive, the Biocides Directive, the Medicines Directive and the Veterinary Medicinal Products Directive, for example). The Commission’s own Scientific Committee on Consumer Safety (SCCS), in its notes on guidance for the testing of cosmetic ingredients and their safety evaluation, also considers these endpoints separately.

There is no written evidence from the time to suggest that the European Parliament and Council of Ministers intended that the term ‘repeated dose’ be used to cover several animal tests as the Commission claim. The effect of including animal tests not previously included is to reopen the debate already concluded by the European institutions and to subvert the previous decision. In our view it is clear that the discussion should be limited in scope to the tests specified by the Directive.

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

(type of answer expected: out of the XXX for XXX)

2.2.4. In case testing data was not specifically generated for this purpose, from which source was it available?

   a) Chemicals Legislation/REACH
   b) Sectorial EU legislation (such as food, pharma etc.), please specify
   c) Regulatory testing for cosmetics products outside the EU
   d) Other, please specify
If data comes from another source is it usually **clearly identifiable for which reason** this data was generated?  
(type of answer expected: out of the XXX of tests needed, in XXX cases data was available from testing for purpose ..., in XXX cases data was available from ...)  

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

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

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

2.2.8. In case it was not specifically generated from which source was it available?  
   a) Chemicals Legislation/REACH  
   b) Sectorial EU legislation (such as food, pharma etc.), please specify  
   c) Regulatory testing for cosmetics products outside the EU  
   d) Other, please specify  

If data comes from another source is it usually **clearly identifiable for which reason** this data was generated?  
(type of answer expected: out of the XXX of tests needed, in XXX cases data was available from testing for purpose ..., in XXX cases data was available from ...)  

2.2.9. **On which endpoints do you expect testing data to be most needed** in the next 10 years?  
   a) On repeated-dose toxicity (including skin sensitisation and carcinogenicity)  
   b) On reproductive toxicity  
   c) On toxicokinetics  

Please specify further by **making reference to the respective OECD test protocols**.  
(type of answer expected: most data will be needed on X) because ..., followed by)  

It is not clear why reference should be made to OECD test protocols as the suitable methods according to the Cosmetics Directive (recast) are those listed in the EU Test Methods Regulation (Regulation (EC) No 440/2008 plus amends), those listed in Annex VIII of the Cosmetic Directive and those that the SCCS considers appropriate.
We consider that for:

1. **Repeated dose** (which does NOT include skin sensitisation and carcinogenicity see answer to 2.2.2): the TTC approach can be used to waive repeated dose testing for many non-toxic ingredients used in low levels. In addition, a number of cell-based tests already exist so all that is required is a testing strategy to incorporate these into a meaningful prediction for longer term toxic risk.


3. **Toxicokinetics**. This is not considered a core requirement for cosmetic ingredients under the Cosmetic Directive and may only be conducted if “considerable oral intake or dermal absorption is expected”. In many cases in vivo testing can be avoided through the use of in vitro skin absorption studies and computer based pharmacokinetic models. In a review of dossiers made by the SCCS between 2000 and 2006, less than 50% of dossiers had toxicokinetic data and the SCCS never requested the conduct of an in vivo test (Pauwels, M. et al. 2009: *Critical analysis of the SCCNFP/SCCP safety assessment of cosmetic ingredients* (2000-2006) Food Chem. Toxicol. 47, 898-905).

Skin sensitisation:
This should not fall under the 2013 deadline, see answer to 2.2.2. Nonetheless three different models have just completed pre validation by ECVAM and should be considered suitable for full replacement by 2013.

Carcinogenicity:
This test should not fall under the 2013 deadline, see answer to 2.2.2. Nonetheless the cell transformation assays have just completed pre validation by ECVAM and should be considered suitable for full replacement by 2013.

In addition, carcinogenicity is not considered a core requirement for cosmetic ingredients under the Cosmetic Directive and may only be conducted if “considerable oral intake or dermal absorption is expected”.

In fact, in most cases companies do not perform carcinogenicity studies in vivo per se but use other sources of data to evaluate the likelihood of an ingredient being carcinogenic. In a review of dossiers made by the SCCS between 2000 and 2006, less than 40% of dossiers had carcinogenicity studies. In our own analysis of the opinions from 2009 and 2010, only 2 in vivo carcinogenicity studies were conducted between 2000 and 2009 so this test is extremely uncommon.

We attach our report which provides a scientific review of the status of non-animal tests for cosmetics, which elaborates upon these points and provides evidence to support them.
2.2.10. Do you expect that the availability of testing data from other sources (see questions 2.2.4. and 2.2.8.) to remain the same or change in the coming 10 years? If you expect changes please explain which ones and the reasons.

(type of answer expected: data availability is expected to be similar/different for the following reasons)

Availability of data from other sources, e.g. REACH, is likely to increase significantly as companies submit their registration dossiers in deadlines of 2010, 2013 and 2018. It is likely that many/most cosmetics ingredients will be registered under REACH during this time period and data on the safety of these substances will become available to cosmetics companies. It is possible that within these dossiers will be old animal test data that can be used to also satisfy the safety of the cosmetic substance for consumers.

However, it is our position that the conduct of animal testing in the EU from 2009 of a cosmetic ingredient for any purpose would fall foul of the animal testing bans in the Cosmetic Directive. Cosmetics companies may therefore not rely on the data from animal testing conducted since 2009. This is because it is our interpretation that ‘testing for cosmetic purposes’ refers to not the purpose of testing but the substance. If a substance is used as a cosmetic ingredient and animal test data is relied on then this constitutes ‘testing for cosmetic purposes’.

In 2005, France challenged the validity of the Cosmetics Directive animal testing bans at the European Court of Justice (ECJ). The Advocate-General (AG), advising the ECJ stated that, if an ingredient was tested on animals after the deadlines referred to above under other legislation, it could not subsequently be used in cosmetics.

This was his interpretation of the animal testing bans in the Cosmetics Directive. Although the case pre-dated REACH, the latter had already been under discussion for some time and there is no reason why the principle the AG laid down would not extend as much to animal testing under REACH as under other legislation.

On this basis, animal testing on an ingredient under REACH would prevent its subsequent use in cosmetics, even though it had previously been used in cosmetics. In addition, REACH is expressed to be subject (or ‘without prejudice’) to the animal testing bans in the cosmetics directive. Alerted by the BUAV (leader of the ECEAE) and others, EU legislators were alive to the need to clarify the relationship between the two pieces of legislation. So, the animal testing bans in the Cosmetics Directive take priority over any requirement to test on animals under REACH.

It appears from recent parliamentary answers that the Commission’s position is close to the ECEAE’s and the AG’s. The main points emerging from the answers are:

- 25 February 2009: Mr Verheugen said that the Commission saw no contradiction between the Cosmetics Directive and REACH

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9 Case C-244/03, French Republic v European Parliament and Council of the European Union
- 6 May 2009: Mr Verheugen made it clear that a dye animal-tested under REACH (after March 2009) – the example given by Mr Caspary – could not subsequently be used in cosmetics\(^\text{11}\)

- 26 May 2009: in his question, MEP Daniel Caspary said, in response to Mr Verheugen’s reply to his first question: ‘It follows that, from 11 March 2009, substances that have been tested on animals may no longer be used in cosmetic products under any circumstances, despite the fact that, as the Commission points out in its most recent report, not all the alternative testing methods that were to have been available by the 2009 deadline have been developed and validated’.\(^\text{12}\)

Mr Verheugen did not contradict him and pointed out that marketing ban applied to ‘cosmetic products which have been tested on animals or whose ingredients have been tested on animals’ (save at present for repeated-dose toxicity, reproductive toxicity and toxicokinetics). He made no exception for substances tested under REACH or any other legislation.

2.2.11. In which market segment do you expect the highest testing data need in relation to data covered by the endpoints covered by the 2013 implementation date in the next 10 years?

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

(type of answer expected: sector X is expected to have the highest data need because..., followed by)

2.3. INCENTIVE FUNCTION FOR RESEARCH INTO ALTERNATIVES

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

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


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

Deadlines to phase out animal testing for cosmetics have served as an added impetus for the cosmetics industry to invest and speed up research and development of alternative methods to the animal tests associated with the deadlines.

The cosmetics industry has worked since the 1980s to replace animal tests; however specific steps have been taken since the adoption of the 7th Amendment to the Cosmetic Directive, to accelerate the development of non-animal alternative methods and to meet the 2009 and 2013 deadlines. For instance, companies such as Unilever have invested large sums of money since 2004 to research alternatives and targeted their resources to meet the requirements of the Cosmetics Directive. Unilever states that “Our research is currently focused on finding alternatives for skin allergy and skin cancer which are associated with the 2013 deadline on cosmetic ingredient testing of the EU Cosmetics Regulation”13.

It is difficult to assess quantitatively the direct impact the animal testing bans have had on research on alternative methods. However, we can identify a number of factors that could be used as a measure of impact.

1. Number of validations since 2003

As a measure of the impact of the animal testing bans on validation of alternative methods we can look at the number of completed validation studies since 2003. These are listed in Table 1., which draws directly from the ECVAM Technical report of 2008-2009. There were 13 completed validations of relevant methods between 2003 and 2009. This compares to 6 in the period preceding this (1998-2002).

Table 1. Number ECVAM validations of non-animal methods suitable for cosmetic regulatory purposes between 1998 and 2009 (according to ECVAM Technical Report on the status of alternative methods for cosmetics testing 2008-2009, Table 1.)

<table>
<thead>
<tr>
<th>Test method</th>
<th>Date of completion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bovine Corneal Opacity and Permeability (BCOP)</td>
<td>ESAC statement 2007</td>
</tr>
<tr>
<td>Isolated Chicken Eye (ICE)</td>
<td>ESAC statement 2007</td>
</tr>
<tr>
<td>Fluorescein Leakage assay</td>
<td>ESAC statement 2009</td>
</tr>
<tr>
<td>Cytosensor Microphysiometer assay</td>
<td>ESAC statement 2009</td>
</tr>
<tr>
<td>Neutral Red Release assay</td>
<td>ECVAM validation 2009</td>
</tr>
<tr>
<td></td>
<td>(negative outcome)</td>
</tr>
<tr>
<td>Red Blood Cell test</td>
<td>ECVAM validation 2009</td>
</tr>
<tr>
<td></td>
<td>(negative outcome)</td>
</tr>
<tr>
<td>Low Volume Eye Test</td>
<td>ESAC statement 2009</td>
</tr>
<tr>
<td>CORROSITEX Skin Corrosivity Test</td>
<td>ESAC statement 2000</td>
</tr>
<tr>
<td>EpiSkin Skin Corrosivity Test</td>
<td>ESAC statement 1998</td>
</tr>
</tbody>
</table>

13 Unilever’s research investment: [http://www.unilever.com/sustainability/consumer/testing/]
2. Reports of EU Framework Projects on alternative methods

According to the AXLR8 Progress report of 2010, “almost 150 million euros has been spent in the EU’s 6th and 7th Research Framework Programmes to advance the development and validation of 3Rs methods and testing strategies for regulatory purposes”.

The AXLR8 Progress report of 2010 details the FP6 and FP7 projects that have involved the development of alternative methods and on page 13 makes it clear that; “these funding activities have been ‘policy driven’ by the former Directive 86/609/EEC (soon to be replaced by Directive 2010/63/EU) for the protection of animals used for scientific purposes, as well as the 7th Amendment of the EU Cosmetics Directive and the REACH regulation- all of which provide legislative mandates to replace regulatory toxicity testing in animals with non-animal approaches.”

3. Other research

A number of key papers detailing alternative methods quote the animal testing bans in the Cosmetic Directive as a major driver for the effort:

- Hettwer, M. et al. 2010. Metabolic activation capacity by primary hepatocytes expands the applicability of the embryonic stem cell test as alternative to experimental animal testing. Reproductive Toxicology 30, 113–120.
A number of popular sources also describe the impact the deadline has had on alternatives development:


It appears from these sources that most effort (development and validation) has been on the acute endpoints – skin and eye irritation and skin sensitisation. This could be argued that this is because these are easier to replace or that these are most heavily required for cosmetics. However, it could also be argued that this was because these had the shorter (immovable) deadlines under the Cosmetics Directive. Efforts to replace the remaining three endpoints with the longer deadlines have been less evident until very recently, with the announcement of the 50 million euro project by the Commission and COLIPA.

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

2.3.3. Please provide information on the amounts spend by the cosmetics/cosmetics ingredients industry on research in alternatives to animal testing in the last 10 years.
(type of answer expected: quantitative data on spending, either total or if not available based on examples of small/large companies spending)

2.3.4. How do you expect these amounts spent on research in relation to alternatives to animal testing to develop in the future? Would they increase, remain the
Assuming that the marketing ban is fully implemented in 2013, we can expect that the cosmetics industry will continue to allocate resources to develop alternative methods to animal testing.

For the L’Oreal group, the R&D budget has consistently increased over the last three years (in 2008 it was 588 million Euros, in 2009, 609M Euros and in 2010, 665M Euros). We would expect that the amounts allocated to the research of alternative methods would also increase, in order to meet the 2013 deadline.

As stated in our answer to question 2.3.1, the deadlines set in the Directive constitute a clear target for the industry. If the 2013 deadline is either postponed or worse, removed, we could expect that the amounts spent on research for alternatives would decrease as the sense of urgency is removed.

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

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

According to a survey carried out in 2006/2007 in 16 EU countries\(^\text{14}\), the annual total cost of publicly funded research into alternative methods (including methods that still use animals but use fewer animals or less severe testing) – not restricted to cosmetics testing—was estimated as 17 million Euros The study shows that only a minority of European countries have national alternative funding strategies in place (France, Germany, the Netherlands, Sweden, Switzerland and the UK).

<table>
<thead>
<tr>
<th>Country</th>
<th>Amount in Euros</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>(in 2006) 200,000</td>
</tr>
<tr>
<td>Belgium</td>
<td>(in 2005) 400,000</td>
</tr>
<tr>
<td></td>
<td>(in 2006) 116,000</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>(in 2006) 2,000</td>
</tr>
<tr>
<td>Denmark</td>
<td>(in 2005) 3.3 million</td>
</tr>
<tr>
<td>Finland</td>
<td>(in 2005) 40,000</td>
</tr>
<tr>
<td>France</td>
<td>(in 2006/2007) on average 2.75 million per year</td>
</tr>
<tr>
<td>Germany</td>
<td>(in 2006/2007) over 4 million per year</td>
</tr>
<tr>
<td>Hungary</td>
<td>(in 2005) 40,000</td>
</tr>
<tr>
<td>Italy</td>
<td>No public funds directly allocated for alternatives to animal testing</td>
</tr>
<tr>
<td>Netherlands</td>
<td>(in 2006) 797,000</td>
</tr>
<tr>
<td>Norway</td>
<td>(in 2006) 70,000 via the Norwegian Food Safety Authority</td>
</tr>
<tr>
<td>Slovakia</td>
<td>On average between 28,000 and 280,000 a year</td>
</tr>
</tbody>
</table>

Spain | On average 4,000  
Sweden | From 2004, on average 1,6 million  
Switzerland | On average 270,000  
UK | (in 2005) 1,5 million

2.3.6. Do you consider that maintaining the 2013 implementation date would have impacts on the incentive function of the provisions? Please specify.  
(type of answer expected: this is an open qualitative question)

The cosmetics industry has been collectively affirming its commitment to end the use of animals for cosmetics safety testing since the 1990s. It is however clear that more research activity on the development of alternatives has taken place since 2004 because the 7th amendment to the Cosmetics Directive was adopted (see answer to question 2.3.1).  
Assuming that the 2013 deadline is maintained, it is unlikely that efforts to research alternatives will grind to a halt, in fact we expect the reverse. We expect that the full implementation of the marketing ban will actually promote the rapid validation of existing alternatives, and the development of new ones, to the remaining tests associated with the 2013 deadline.  
We believe that the 2013 deadline should be maintained primarily because alternative methods and approaches can be available by 2013, provided that enough resources are made available to facilitate their validation and acceptance. Removing or postponing the 2013 deadline would undermine the objective the 7th Amendment to the Cosmetics Directive and slow down the development of new alternative methods.  
In addition, speakers from China, Japan and Korea at the First International Symposium on Alternatives to Animal Experimentation for Cosmetics held in Beijing from April 11-12 2011 stated that the anticipation of the EU marketing ban in 2013 had prompted an acceleration of efforts to accept alternatives and provide an effective validation process. The event itself was sponsored by the Chinese Food and Drug Administration and reflects the increased sense of urgency now felt by China in preparing for the new situation: it is expected that further steps will follow in the coming months, probably including the establishment of a Chinese counterpart to ECVAM, as already exists in Korea and Japan. It is likely that this impetus would be slowed were the EU to reconsider the 2013 deadline.

2.3.7. Which do you consider would be the best approach/what type of mechanism would have the highest incentive function in terms of research into alternative methods?  
(type of answer expected: this is an open qualitative question)

Maintenance of the 2013 deadline is the best approach to maximise the incentive to research alternatives. As stated in question 3.2.1 more progress has been made with the acute endpoints, with the expectation of a 2013 deadline in view. One could argue that because the 2013 was extendable that there has been less research on these endpoints and therefore less significant developments than would have been the case if the deadline had been certain.
3. QUESTIONS ON IMPACTS OF THE IMPLEMENTATION OF THE MARKETING BAN IN 2013 ON CONSUMERS

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

3.1. CONSUMER SAFETY

3.1.1. Will it be possible to ensure the same level of consumer safety in relation to cosmetics products once the 2013 implementation date applies, in the absence of alternatives to animal testing? (type of answer expected: yes/no and explanations)

The testing ban is already in place and yet there is no ban on the sale of new products in the EU. To this effect discussions about safety in relation to the marketing ban are irrelevant.

There are currently nearly 20,000 registered substances used in cosmetics in the CosIng database. It should be assumed that their presence on the list means that basic safety information is already available for these ingredients.

The marketing (and associated testing) ban does not equate to a risk to consumer safety. If the regulatory bodies such as the SCCS (or companies in the case of unregulated ingredients) decide that the safety of cosmetic ingredients old and new cannot be determined without animal testing then the choice is not between allowing the product on the market or withdrawing the ingredient. If companies cannot demonstrate its safety, then they simply cannot sell the ingredient. Companies are aware of the regulations and are very risk averse. We believe it is very unlikely that companies will be selling cosmetic products that have not been suitably tested because they know they will be acting unlawfully and are liable to legal action if they do. Fear of non-compliance with the legislation is not a valid reason to fail to legislate.

There should be no question over the suitability of alternative methods that are currently available or that may become available in the near future. This is because ‘available methods’ are those that have been shown scientifically to be reliable and valid, i.e. they have gone through a validation process. It should not be forgotten that most animal tests have not gone through this process, so non-animal tests have met a higher standard than is effectively the case for animal tests. It is unlikely that companies will use un-validated/unapproved alternative methods in their dossiers for the same reasons above. The SCCS review of opinions between 2000 and 2006 found that very few alternative methods were used, even those that are validated, so it is unlikely that companies will use un-validated methods.

Finally, the use of the Threshold of Toxicological Concern (TTC) approach suggests that for many cosmetic ingredients, the risk to consumers is likely to be limited since they are used in such small amounts in the cosmetic product. The TTC is likely to be able to be applied to at least: antioxidants, UV filters, chelating agents, foam stabilizers, thickeners, preservatives, humectants, pearlescing/opacifying agents and fragrances. *
*This statement is based on an analysis of a representative selection of cosmetic products using the TTC for skin sensitisation (TSC) provided by Keller, D, Krauledat, M, Scheel, J. 2009. Feasibility study to support a threshold of sensitisation concern concept in risk assessment based on human data. Archives of Toxicology 83; 1049-1060. They provide % concentrations of ingredients for various products below which there is little risk for skin sensitisation.

We provide here the TTC for skin sensitisation being more protective to consumers than the TTC values for repeat dose or reproductive toxicity. We compared the values of TSC-derived acceptable concentration in different cosmetic products in Keller with example concentrations of products found in the website resource; http://www.specialchem4cosmetics.com/formulations/guides/recipe.aspx?id=1

<table>
<thead>
<tr>
<th>Product (ingredients)</th>
<th>% concentration in product</th>
<th>Within range for TSC ok to be applied?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Face cream</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Essential ingredients</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emulsifiers</td>
<td>2-6%</td>
<td>Out of range</td>
</tr>
<tr>
<td>Emollients</td>
<td>10-35%</td>
<td>Out of range</td>
</tr>
<tr>
<td>Thickener</td>
<td>0.1-1%</td>
<td>Partly in range</td>
</tr>
<tr>
<td>Deionized Water</td>
<td>variable</td>
<td>n/a</td>
</tr>
<tr>
<td><em>Usual ingredients</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preservatives</td>
<td>0.2-1%</td>
<td>Partly in range</td>
</tr>
<tr>
<td>Humectants</td>
<td>1-8%</td>
<td>Out of range</td>
</tr>
<tr>
<td>Consistency factors</td>
<td>1-6%</td>
<td>Out of range</td>
</tr>
<tr>
<td>Antioxidants</td>
<td>0.01-0.05%</td>
<td>In range</td>
</tr>
<tr>
<td>UV filters</td>
<td>0.01-0.5%</td>
<td>In range</td>
</tr>
<tr>
<td><em>Optional ingredients</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chelating Agents</td>
<td>0-0.02 %</td>
<td>In range</td>
</tr>
<tr>
<td>Fragrance</td>
<td>0.1-1 %</td>
<td>Partly in range</td>
</tr>
<tr>
<td>Active agents</td>
<td>0.1-2%</td>
<td>Partly in range</td>
</tr>
<tr>
<td>Colouring agents</td>
<td>Variable</td>
<td>Not known</td>
</tr>
<tr>
<td>Aesthetic enhancers</td>
<td>0.1-5%</td>
<td>Partly in range</td>
</tr>
<tr>
<td><strong>Shampoo</strong></td>
<td></td>
<td>1.63 (Keller et al. 2009)</td>
</tr>
<tr>
<td><em>Essential ingredients</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surfactants</td>
<td>15-30%</td>
<td>Out of range</td>
</tr>
<tr>
<td>Foam Stabilizers</td>
<td>1-4%</td>
<td>In range</td>
</tr>
<tr>
<td>Thickener</td>
<td>0-5%</td>
<td>In range</td>
</tr>
<tr>
<td>Deionized Water</td>
<td>Variable</td>
<td>Not known</td>
</tr>
<tr>
<td><em>Usual ingredients</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preservatives</td>
<td>0.1-1%</td>
<td>In range</td>
</tr>
<tr>
<td>Humectants</td>
<td>1-5%</td>
<td>In range</td>
</tr>
<tr>
<td>PH Buffers</td>
<td>Variable</td>
<td>Not known</td>
</tr>
<tr>
<td>Chelating Agents</td>
<td>0-0.02 %</td>
<td>In range</td>
</tr>
<tr>
<td><em>Optional ingredients</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pearlescing/ opacifying agents</td>
<td>0.2-2%</td>
<td>In range</td>
</tr>
<tr>
<td>Perfume</td>
<td>0.5-1%</td>
<td>In range</td>
</tr>
<tr>
<td>Active agents</td>
<td>0-2%</td>
<td>In range</td>
</tr>
<tr>
<td>Colouring agents</td>
<td>Variable</td>
<td>Not known</td>
</tr>
<tr>
<td>Conditioning agents</td>
<td>Variable</td>
<td>Not known</td>
</tr>
<tr>
<td>UV Filter</td>
<td>0.01-0.1%</td>
<td>In range</td>
</tr>
<tr>
<td>Lipstick</td>
<td>0.04 (Keller et al. 2009)</td>
<td></td>
</tr>
<tr>
<td>----------</td>
<td>--------------------------</td>
<td></td>
</tr>
<tr>
<td><strong>Essential ingredients</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Consistency factors/ Waxes</td>
<td>20-55%</td>
<td>Out of range</td>
</tr>
<tr>
<td>Emollients (liquid)</td>
<td>25-70%</td>
<td>Out of range</td>
</tr>
<tr>
<td>Pigments (color)</td>
<td>0.5-10%</td>
<td>Out of range</td>
</tr>
<tr>
<td><strong>Usual ingredients</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thickeners/ stabilizers</td>
<td>0-1%</td>
<td>Partly in range</td>
</tr>
<tr>
<td>Preservatives</td>
<td>0-1%</td>
<td>Partly in range</td>
</tr>
<tr>
<td>Antioxidants</td>
<td>0.05-1%</td>
<td>Out of range</td>
</tr>
<tr>
<td>Pigments (special effects)</td>
<td>5-25%</td>
<td>Out of range</td>
</tr>
<tr>
<td><strong>Optional ingredients</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sunscreens/ UV filters</td>
<td>0-2%</td>
<td>Partly in range</td>
</tr>
<tr>
<td>Fragrances/ Flavoring agents</td>
<td>0-1%</td>
<td>Partly in range</td>
</tr>
<tr>
<td>Active agents</td>
<td>0-1%</td>
<td>Partly in range</td>
</tr>
</tbody>
</table>

3.1.2. Do you consider that Member State authorities will be able and sufficiently equipped to pick up on manufacturers that may rely on insufficient data packages in their safety assessment?  
*(type of answer expected: yes/no and explanations)*

Yes. Member state authorities are already required to consider whether data packages are sufficient. Eliminating animal tests conducted overseas from the range of aspects that they are required to consider will not make the task more difficult.

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

3.2. CONSUMER CHOICE

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

**PLEASE note:**
For all questions below we are looking for information that distinguishes between large and small and medium sized (SME's) companies. This is important to establish specific SME impacts. Therefore please differentiate in your answer wherever possible between SME's and larger companies. For details on the SME definition please refer to: http://ec.europa.eu/enterprise/policies/sme/facts-figures-analysis/sme-definition/index_en.htm
Please also differentiate between the type of company concerned, notably whether the information provided concerns cosmetics manufacturers or cosmetics ingredients manufacturers.

**AMOUNT OF NEW SUBSTANCES BETWEEN 2000 AND MARCH 2009**

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

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

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

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

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

3.2.6. Please provide information on how many of the new substances under 3.2.1. are multi-use substances, meaning that they are not exclusively used in cosmetics products (but also in other uses, e.g. chemicals, food, biocides, etc.)? Please differentiate the information for substances covered by the Annexes to the Cosmetics Directive and those that are not covered.
(type of answer expected: out of the XXX new substances XXX are multi-use substances, out of these XXX are covered by the Annexes)

**IMPACTS ON INNOVATION CAPABILITY AND FUTURE AVAILABILITY OF COSMETIC PRODUCTS**
3.2.7. Please provide information on how many different cosmetic products (= product formulations) cosmetic companies offer.
(type of answer expected: total number of products, e.g. a large company offers XXX different cosmetics products, an SME offers XXX different cosmetic products)

Preliminary note:

The following questions have been answered following consultation with 25 cosmetic and personal care companies in Europe. The companies represented are manufacturers & brand owners. They only use non-animal tested materials in their products, and as such are certified under the Humane Cosmetics Standard, managed by the ECEAE. Country breakdown: 12 UK, 8 France, 3 Germany, 1 Sweden, 1 Denmark. 2 are large companies and 23 are SMEs. Some companies prefer to remain anonymous; others are listed below.

The Co-operative Group UK
SA Hyteck Aroma Zone France
Santaverde GmbH Germany
Calder Valley Soap Co. Ltd UK
Provida Organics Germany
Yes Pure Intimacy Ltd UK
Bio Aromes France
Rosenserien Sweden
The Hemp Co. Ltd UK
Montagne Jeunesse UK
Alvin Connor Ltd UK

<table>
<thead>
<tr>
<th></th>
<th>Average no of products on offer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Large</td>
<td>592</td>
</tr>
<tr>
<td>SMEs</td>
<td>40</td>
</tr>
</tbody>
</table>

*25 companies answered this question

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

<table>
<thead>
<tr>
<th></th>
<th>Average no of products added 00-09</th>
<th>market value as % of total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Large</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>SMEs</td>
<td>4</td>
<td>22</td>
</tr>
</tbody>
</table>

*21 companies answered this question
Because of these companies’ commitment to the Humane Cosmetic Standard for no-animal testing in cosmetics, all new products make use of existing materials only or new materials which have been tested for safety through alternative test methods.

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

3.2.10. Please provide information on how many of the new products under 3.2.8. rely on new to the market substances (= not at all used before, also not in other sectors)? Which market value do these products represent in percentage compared with the total products?
(type of answer expected: of the XXX new product XXX are relying on new to market substances, eg for an SME XXX products rely on new to market substances, these represent X% of the total market value)

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

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

<table>
<thead>
<tr>
<th></th>
<th>Average no of ingredients used</th>
</tr>
</thead>
<tbody>
<tr>
<td>Large</td>
<td>11500</td>
</tr>
<tr>
<td>SMEs</td>
<td>151</td>
</tr>
</tbody>
</table>

*19 companies answered this question

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

<table>
<thead>
<tr>
<th></th>
<th>Average no of ingredients added</th>
</tr>
</thead>
<tbody>
<tr>
<td>Large</td>
<td>15</td>
</tr>
<tr>
<td>SMEs</td>
<td>9</td>
</tr>
</tbody>
</table>

*16 companies answered this question
3.2.14. What are the main reasons for introducing new ingredients and combinations of ingredients into the portfolio?

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

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

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

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

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

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

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

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

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

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

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

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

3.2.19 Please provide information on the likely number of new to cosmetics sector substances (= not used in cosmetics before, but used in other sectors) in the coming 10 years? Which market value do you expect to depend on these substances?

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

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

(type of answer expected: expect XXX new substances for the Annexes in next 10 years)
3.2.21 Please provide information on which sector is likely to be most prone to innovation and use of new substances (the sector grouping is the one used by Global Insight, see A, with the addition of hair colorants and sun protection products):

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

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

3.2.22 Do you consider that the amount of new substances introduced over the last 10 years could also give an indication of the number of substances to be introduced for the coming 10 years?

(type of answer expected: qualitative answer)

LABELLING

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

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

Recommendation 2006/406/EC states that it is possible for a manufacturer, on a voluntary basis, to claim that a cosmetic product is free of animal testing only if:

“the manufacturer and his suppliers have not carried out or commissioned any animal tests on the finished product, or its prototype or any of the ingredients contained in it, or used any ingredients that have been tested on animals by others for the purpose of developing new cosmetics products”

Point 3 of the Recommendation offers a strict interpretation of the requirement of Article 6(3) of the Directive, in particular, point a) specifies that:

“ (a) ‘no animal tests have been carried out’ means that no animal test whatsoever was carried out in relation to the development or safety evaluation of a cosmetic product or its ingredients. Only the full replacement of the animal tests by an alternative method, and therefore not a reduction or a refinement of animal tests, allows the claim to be made. Furthermore, it does not matter where the test (including re-testing) is performed (in the Community or in third countries) or when the test has been performed.

It appears that some cosmetics and toiletries manufacturers have misused the label “not tested on animals” by claiming that their finished products have not been tested on animals, while individual ingredients have been.

The only voluntary scheme which provides the consumer with genuine information about animal testing, going further than the requirements of Recommendation 2006/406/EC, is the Humane Cosmetics Standards (HCS) represented by the leaping bunny label
The scheme was created in 1998, and to date, nearly 400 large, medium and small companies worldwide have joined the HCS. Only companies which commit not to buy or use ingredients that have been tested on animals by themselves or along their supply chain after a set date, meet the criteria to claim that their products are “cruelty-free”.

There is no evidence that any other voluntary labelling system has enabled consumers to make an informed choice about cosmetics products, nor any guarantee that it would do so in future.

3.2.24 Do you have information on whether the use of the label has an impact on consumer behaviour in terms of encouraging the purchase of products with the label? Have you noticed an increase in sales for products using the animal testing free label? Please provide impact in terms of sales before and after the introduction of the label.
(type of answer expected: for brands which used the label sales increased/decreased)

<table>
<thead>
<tr>
<th></th>
<th>Average sales own-label cosmetics 2004</th>
<th>Average sales own-label cosmetics 2009</th>
<th>Average increase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Large</td>
<td>2808000</td>
<td>4329000</td>
<td>154%</td>
</tr>
<tr>
<td>SMEs</td>
<td>653963</td>
<td>1664763</td>
<td>255%</td>
</tr>
</tbody>
</table>

8 companies answered this question

These companies are licensed to use the Leaping Bunny trademark as they conform to the Humane Cosmetics Standard criteria for no animal tested cosmetic products or ingredients. This shows above industry average sales increases for companies using the label.

3.2.25 Do you consider that the use of an "animal tested" label (thus a label that requires to expressively state if animal testing is relied on) could be an option? Would it be practicable and add value for consumers?
(type of answer expected: qualitative view on practicability and added value on such a label...)

Labelling cannot be seen as an alternative option to maintaining the 2013 deadline. The institutions have already made a clear decision of principle not to allow products to be marketed if their ingredients have been tested on animals; to substitute a policy that such products should after all be marketed, so long as they have a label, would be a substantive change in policy, going well beyond questions of implementation.

There is no evidence to suggest that EU citizens would accept this

3.2.26 Do you have information on the importance and value consumers attach to cosmetics and cosmetics ingredients not being subject to animal testing?
(type of answer expected: any specific studies/figures on this...)

30
See the poll data in section 2.1.5 on public attitudes. Below are the responses from 25 companies which adhere to the Humane Cosmetics Standards:

<table>
<thead>
<tr>
<th>Very much</th>
<th>Much</th>
<th>Little</th>
<th>Very little</th>
</tr>
</thead>
<tbody>
<tr>
<td>68%</td>
<td>24%</td>
<td>8%</td>
<td>0%</td>
</tr>
</tbody>
</table>

The company Marks & Spencer states that:

“With over 80% of consumers concerned about animal testing, being able to clearly label all our beauty and household ranges with the Leaping Bunny logo gives customers added peace of mind and is their guide to cruelty free shopping.”

3.3. Impacts on Costs and Price

3.3.1. Please provide information on whether you expect any impacts on costs if the marketing ban was to enter into force as such, which ones and why? (type of answer expected: describe expectation and give reasons why, possibly based on concrete example)

3.3.2. Do you envisage passing any increase/decrease in costs on consumer prices? Whenever available please provide an estimation of the impact in %.
(type of answer expected: describe expectation and give reasons why, possibly based on concrete example)

4. Competitiveness of cosmetics and cosmetics ingredients manufacturers

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

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

4.1. To which extent have the current provisions in the Cosmetics Directive in relation to animal testing have already impacted – positively or negatively - business decisions in the cosmetics industry in the last 5 years? (type of answer expected: qualitative explanation of current impacts)

4.2. Assuming the full testing and marketing ban would have been in place for all endpoints already for the last 5 years, what would have been the impact for the cosmetics and cosmetics ingredients manufacturers? (type of answer expected: where possible quantitative estimations, possibly based on examples)

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

<table>
<thead>
<tr>
<th></th>
<th>Positive impact</th>
<th>Negative impact</th>
<th>No impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sales</td>
<td>57%</td>
<td>0%</td>
<td>43%</td>
</tr>
<tr>
<td>Profitability</td>
<td>45%</td>
<td>0%</td>
<td>55%</td>
</tr>
</tbody>
</table>

*23 companies answered this question

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

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

See 3.2.8.

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

*type of answer expected: qualitative answer*

Implementing the full marketing ban will have a positive impact, reaffirming the EU’s status worldwide as a leader in this field and signalling clearly that EU citizens consider testing cosmetic ingredients on animals to be unacceptable.

<table>
<thead>
<tr>
<th></th>
<th>Positive impact</th>
<th>Negative impact</th>
<th>No impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>EU market positioning</td>
<td>65%</td>
<td>0%</td>
<td>35%</td>
</tr>
<tr>
<td>Global positioning</td>
<td>65%</td>
<td>0%</td>
<td>35%</td>
</tr>
</tbody>
</table>

*20 companies answered this question

According to an SME consulted on this question, “*the impact will be positive since it will be easier for the consumer to trust in cosmetics free of animal testing when there exists strict rules/legislation. Since we already guarantee that our products are free of animal testing, there will be no great impact for us regarding sales, profit, marketing etc. but we think that raw material suppliers will concentrate on new innovative ingredients produced without animal testing, which will help us to launch new, innovative products as well.*”

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

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

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

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

This question is designed to assess the impact of the 2013 deadline on the availability of hair dyes, which have been subjected to increased animal testing in recent years due to concerns about carcinogenicity and skin sensitisation for these products.

Experts for the Commission in their draft report on the ‘status of alternatives for cosmetics testing’ highlighted the impact of the risk of detecting false positives with the in vitro genotoxicity assays using the example of a review of hair dyes from Speit (2009). In this review the sole use of in vitro tests may have resulted in a number of false positives and therefore withdrawal from the market of these products.

However, it should also be considered that the application of the over-protective criteria may not be regarded as a limitation, indeed it is better that the public are protected than new hair dyes are produced. In the absence of human data it is indeed possible that these false positives are not ‘false’ at all. It should also be pointed out that in this assessment a significant proportion of the hair dyes were deemed safe.

Nonetheless, the report authors did not appreciate the impact of a new strategy to reduce percentage of false positive in vitro genotoxicity tests thus increasing test predicitvity, with respect to the need of in vivo genotoxicity/carcinogenicity testing (Fowler, P., Smith, K., Jong, J. et al. (in press). Reduction of misleading (false) positive results in mammalian genotoxicity assays. I. Choice of cell type. Mutat Res.; Kirkland, D. and Fowler, P. (2010). Further analysis of Ames-negative rodent carcinogens that are only genotoxic in mammalian cells in vitro at concentrations exceeding 1 mM, including retesting of compounds of concern. Mutagenesis 25, 539-553).

Hair dyes have also been subjected to other animal tests in recent years for which the TTC could have been applied. We have conducted a review of recent SCCS opinions to establish whether the TTC could have in fact been used to waive testing of repeated dose tests, reproductive toxicity tests and skin sensitisation tests. Exposure data taken from recent (2009/10) SCCS opinions on 33 hair dyes were compared with TTC values for repeated dose/genotoxicity/carcinogenicity (Norwegian Scientific Committee for Food Safety (2006)).


Cramer classes of potential toxicity (I to III) were applied based on the use of the Toxtree database. If there was no information available, Cramer class III (most toxic) was applied.

The review (detail available on request) found that the exposure to hair dyes was within TTC values for repeated dose in 21% (7 out of 33), in 18% (6 out of 33) for reproduction toxicity and in 9% (3 out 33) for skin sensitisation. And yet, animal tests for some of these endpoints were conducted.

The TTC could have been used more widely if the Cramer class for toxicity was able to be lowered from class III (worst case) to II. Since hair dyes are naturally reactive substances it is protective to apply the Cramer class III and yet this shows that with less potentially toxic substances the TTC may be more widely applied.

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

For the self-tanning ingredient Dihydroxactone (Cramer class I – Toxtree) the TTC approach could have been used to waive repeated dose testing since the ingredient is used in quantities of 10 µg/kg bw/day (Systemic Exposure Dosage - SED from SCCS dossier) and the TC for repeated dose (Norwegian Scientific Committee for Food Safety, 2006) is 30 µg/kg bw/day for Cramer class I.

Similarly, for the colourant CI 45430 (Erythrosine) (Cramer class not available), the TTC approach could have been used to waive repeated dose testing, reproductive toxicity testing and skin sensitisation tests since the ingredient is used in quantities of 0.2 µg/kg bw/day (SED from SCCS dossier) that is well below the TC of 1.5 µg/kg bw/day for Cramer class III (taken as worst case) for repeated dose (Norwegian Scientific Committee for Food Safety, 2006) and of 1.5 µg/kg bw/day and 1 µg/kg bw/day for fertility and developmental toxicity respectively (oral route) (Bernauer et al., 2008).

For skin sensitisation the exposure, assuming a mouth surface area of 215 cm2 (Collins and Dawes 1987) and 60 kg body weight, is equal to 0.05 µg/cm2 (0.2 µg/kg bw/day x 60 kg bw/ 215 cm2), thus well below the TC of 0.91 µg/cm2 for rinse-off products (Keller et al., 2009) and thus of no sensitisation concern.

5. IMPACTS ON SMALL AND MEDIUM SIZED ENTERPRISES (SME's)

A large number of enterprises in the cosmetics sector are SME's, impacts on them therefore are of particular importance and differences should already be taken into account in the questions above, notably under 3.2 and 4 above.
5.1. Please provide information on the **total number of SME's in the cosmetics sector in the EU** in relation to the total number of cosmetics manufactures. Please specify for cosmetics manufacturers and cosmetic ingredient manufacturers.

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

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

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

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

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

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

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

Many companies already have a policy of not using animals at any stage of the development of their products, in anticipation of the deadline and the reasonable expectation that it would be implemented. They would be disadvantaged by any delay, since by seeking to follow the requirements of the Directive they will be on an unequal playing field: companies who are continuing to introduce new ingredients with animal tests potentially have a competitive advantage.

This applies particularly to SMEs, since they do not have the capacity to resume and then cease animal testing at short notice. If, for example, the 2013 deadline were extended to 2015, there would be a further period of five years during which the SME would be competing with companies introducing new animal-tested products and therefore would be penalised for having implemented stated European policy. If the deadline was extended without any specific new date, the position would worsen further, since there would be no certainty when and even whether the marketing ban would apply.

6. **IMPACTS ON EMPLOYMENT**

6.1. Do you consider that the 2013 implementation date may have **impacts on employment** in the cosmetics industry in the EU? If yes, please specify?

*(type of answer expected: explanation on the possible impacts on employment)*

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

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

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

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

7. IMPACTS ON TRADE

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

7.2. Do you expect **impacts on trade** in case the marketing ban for the remaining three endpoints is implemented in 2013? Which impacts do you expect?
(type of answer expected: explanation on the expected impacts)
See 7.3 and 7.4.

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

At present, companies based outside the EU, or EU companies with the financial muscle to commission testing outside the EU, have a potential competitive advantage, in that they have a wider range of testing options than companies inside the EU without such muscle.

This will level the playing field for companies, such as SMEs, who are unable to afford to commission testing outside the EU.

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

If the deadline is maintained, all EU exporters - those who currently have the financial muscle to commission animal testing outside the EU and those, such as SMEs, who do not - will be in same position. They will also be in the same position as non-EU companies with the EU as one of their intended markets.

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