Annex 2

QUESTIONS IMPACT ASSESSMENT
2013 IMPLEMENTATION DATE MARKETING BAN COSMETICS DIRECTIVE

Eurogroup for Animals appreciates the European Commission’s offer to participate in the impact assessment on the 2013 implementation date of the marketing ban laid down in the 7th Amendment (Directive 2003/15/EC) to the Cosmetics Directive 76/768/EC, followed by the Cosmetics Product Regulation No. 1223/2009. We would like to invite the European Commission to take the following comments into consideration in its further deliberations. These comments were prepared in collaboration with our member organisations Animalfree Research (lead authorship), Deutscher Tierschutzbund and the RSPCA.

Our interest is not in creating new deadlines for the full introduction of the marketing ban, but in ensuring that the 2013 deadline remains in place regardless of the availability of alternative methods. Our position on this issue remains: we believe that the pain, distress and suffering caused to animals used in cosmetics tests cannot be justified. A complete ban on the use of new cosmetics ingredients tested on animals will not affect the safety of consumers because existing safe ingredients can be used and reformulated without the need for further testing. Moreover, consumers will still be able to choose between thousands of existing products, as well as those using newly formulated existing ingredients. Our opposition to animal testing of cosmetics is therefore not dependent on the availability of alternative test methods and remains an ethical position.

1. EXISTING DATA ON THE COSMETICS MARKET AND THE INDUSTRY

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

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

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

Eurogroup for Animals considers the data reflected in the mentioned RPA and Global Insights Studies to be relevant. Both studies highlight that the European cosmetics industry is a major player of the global cosmetics industry. In consequence, the European Community has the
opportunity and also the responsibility to lead the way internationally in implementing legislative provisions on non-animal risk assessment strategies for cosmetic ingredients, formulations and products that assign high significance to animal welfare issues without impeding the goal of human health protection.

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.

Eurogroup for Animals fully agrees with the statements that the provisions on animal testing in the Cosmetics Directive aim at providing a high level of animal welfare and that they contain a clear political and ethical choice against animal testing for cosmetics purposes. It is against this background that we would like to emphasize that the number of animals affected by testing for cosmetics purposes should not be a major criterion in determining, let alone in quantifying the impact of the marketing ban on animal welfare.

The provisions on animal testing in the Cosmetics Directive provide a – currently – unique legal proof-of-evidence of the high significance that the European Union assigns to animal welfare. The animal testing provisions in the Cosmetics Directive clearly state that economic and “lifestyle”-driven interests are only second to the welfare of sentient beings. Therefore they are a benchmark for the harm-benefit analysis of animal experiments, as it is called for in Article 38(2)(d) of the new Directive for the Protection of Laboratory Animals 2010/63/EC. Leading the way to a profound ethical balancing of the acceptability of animal testing, the unambiguous statement of the animal testing and marketing ban has implications that far exceed the scope of the Cosmetics Directive. Therefore its significance cannot be established on the grounds of animal numbers used for the testing of cosmetic ingredients and formulations alone.

It should be noted that this ethical balancing of the welfare of sentient beings over economic and “lifestyle”-driven interests – and not mainly the number of animals used in this sector - was the main motivation for the citizens of Europe in calling for the animal testing and marketing ban for cosmetic ingredients, formulations and products in the nineties of the last century. Therefore any deliberations regarding the maintenance of the 2013 marketing ban should not be founded mainly on calculations regarding the numbers of animals used.

Since animal welfare is weighed higher than economic interests in the animal testing provisions of the Cosmetics Directive, the marketing ban should be implemented regardless of the availability of non-animal test methods. In its annual Reports in accordance to the Cosmetics Directive (e.g.: Report on Animal Testing, 2007), the European Commission has repeatedly and explicitly confirmed this provision: “A deadline of 10 years after entry into force of the Directive is foreseen, i.e., 11 March 2013, irrespective of the availability of alternative non-animal tests.”

Likewise, the Cosmetics Products Regulation (EU Regulation No. 1223/2009) contains a firm statement that the 2013 marketing ban is unshiftable. Point 43 of the Preamble, final sentence, reads: “On the basis of annual reports, the Commission should be authorised to adapt the timetables within the above mentioned maximum time limit” (accentuations by Eurogroup).
Both of these statements unambiguously confirm the 2013 date for the complete marketing ban.

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.

As stated in our general comments to Chapter 1, considering that the European cosmetics industry is a major player of the global cosmetics industry, the European Community has the opportunity and also the responsibility to lead the way internationally in implementing legislative provisions on cosmetics risk assessment strategies that are both ethically sound and adequate in ensuring a high level of human safety.

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.

In our comments to question 2.3, we will go into further detail regarding the issue of “incentive to develop alternative methods”.

2.1. IMPACTS ON NUMBER OF ANIMALS AFFECTED

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

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

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

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)

Eurogroup for Animals is not aware of any additional publicly available information regarding the use of animals for the testing of cosmetic ingredients, formulations or products.

Notwithstanding our general comment to Chapter 2 that animal numbers are not the sole, let alone the decisive issue for determining the animal welfare impact of the animal testing or
marketing bans, we would like to point to the significant decrease in the number of animals used for the testing of products for cosmetics and toiletries that has been taking place from 1998 until today. In accordance to the respective Annual Animal Testing Reports from the European Commission (COM(2005)175 final, COM(2007)232 final, COM(2008)416 final and COM(2010)480final), the numbers have dropped from about 4,200 per year in 1998 to below 2,000 in 2003, and subsequently, with an interim peak of approximately 9,000 animals in 2004, to 1,510 in 2008. This overall decrease has to be seen in the light of the legal requirement to phase out animal testing for cosmetics and indicates that the ban is indeed a valuable incentive for a rapid development, implementation and application of alternative methods.

In addition, all endeavours to develop alternative methods with a view of the animal testing and marketing bans also help replace animal test methods in other legislative areas, such as chemicals legislation. Therefore the animal testing provisions of the Cosmetics Directive have implications for reducing animal numbers that by far exceed the area of testing of cosmetic substance (see our comments to question 2.1.3).

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

According to Table 3.1 (page 27) of the Commission Staff Working Document accompanying the sixth EU Statistical Report on the Numbers of Animals Used for Scientific Purposes (SEC(2010) 1107 final/2), altogether 722 fish were used for the toxicological and other safety evaluation of products and substances intended to be used mainly as cosmetics or toiletries. 422 of the fish were used in the Czech Republic and 300 in France, in both cases with the aim of determining LC50 values. The tables do not reveal for which specific reasons these tests were considered necessary or by whom they were requested.

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)

Eurogroup for Animals expects a widespread effect on avoiding animal testing that by far exceeds the avoidance of those animal tests performed under the scope of the Cosmetics Directive. Non-animal test methods that are developed for the purpose of safety assessment of cosmetics ingredients can also be adapted for application in other product areas. All non-animal test methods developed so far for regulatory toxicological testing purposes have been considered applicable to a variety of areas of use. To discuss possible implications of maintaining the 2013 marketing ban, we therefore would like to refer to the respective overall numbers of animals used for the testing of skin sensitisation, repeated-dose toxicity, carcinogenicity, reproductive toxicity and toxicokinetics published in the Sixth Report on the Statistics on the Number of Animals Used for Experimental and Other Scientific Purposes in the EU (COM(2010) 511/final 2) and its accompanying Staff Working Document (SEC(2010) 1107 final/2; Table 7.1). In 2008, 38,437 animals were used to test skin sensitisation, 20,807 for carcinogenicity testing, 103,005 for sub-chronic and chronic toxicity testing, 31,286 and 63,815 animals for developmental and reproductive toxicity testing, respectively. There is no separate entry for data on toxicokinetics testing in the statistical report.

Notwithstanding the fact that we can recognize no scientific justification whatsoever to include the endpoints “skin sensitisation” or “carcinogenicity” under the endpoint “repeated-
dose toxicity” (the EU statistics back up this criticism by requesting and presenting three distinct figures for these endpoints), the numbers presented in the statistical report underline the importance of maintaining the 2013 marketing ban: A replacement of the respective in vivo tests in all product areas, initiated and accelerated through the incentive of the ban, could possibly save ten times these numbers over the next 10 years, in the European Union alone, and that not even taking into account the expected increases in animal numbers triggered by implementation of the REACH legislative procedure. Irrespective of these considerations, we would like to re-emphasize that animal numbers are not the main incentive for the provisions on animal testing in the Cosmetics Directive.

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)

Considering that only 17 cosmetic manufacturers and companies (and 4 manufacturers of cosmetic ingredients) out of an estimated total of 4,000 EU cosmetic companies participated in the RPA Study (see page 1 and page 3 of the RPA Study), concrete information on research activities of the cosmetics industry within the European Union apparently is scarce and incomplete. As a result, even less confidence can be placed in the accuracy of any calculations regarding research and testing activities of companies located outside the EU.

Furthermore, it has to be remembered that a first animal testing ban was already introduced in the 6th Amendment to the Cosmetics Directive with an implementation date of 1998, which was then postponed until 2000, and again until 2002. In 2003, this original ban was replaced by the separate phased-in bans implemented in the 7th Amendment, to be effective from 2004 (finished products), 2009 (all but 3 tests) and 2013 – the latter being the marketing ban under investigation in the questionnaire at hand.

Due to this long history of animal testing and marketing bans, is difficult to establish a baseline level of testing which existed before bans were even anticipated. Already well before 1998, due to ongoing legislative discussions, it was to be expected that some form of testing ban would eventually be introduced. Therefore any estimations of animal numbers used for the testing of cosmetics before any bans were anticipated have to turn to the early 90ies. Reliable data from that time are scarce. However, the 1st EU statistical report on the use of animals for scientific purposes (COM (1994) 195 final) reveals that 27,337 animals were used to test cosmetics in France alone in 1990 – and overall approximately 30,000 for all of the 10 EU Member States (1991, apart from France) that submitted information for the first EU statistical report (Spain 2036, Netherlands 248).

UK figures report 16,989 animals for the year 1988, falling to 559 animals in 1998, just before animal testing for cosmetic ingredients was banned in the UK. Interestingly, well over half of the animals used were guinea pigs, which, in accordance with the corresponding standard test guidelines, most likely were used in skin sensitisation tests. According to the latest EU Commission’s Animal Testing Report (COM(2010)480 final), the overall EU animal numbers in the area of cosmetics have dropped to approximately 1,500 animals per year. Also here, by far the greatest numbers of animals are reported for the testing of skin sensitization (1,283 of 1,510).
Considering the extent of decrease of animal use in the area of cosmetics testing, we would expect this decline to have been caused by several different effects. The development and application of non-animal test methods is surely to be mentioned, but most likely also the reason that animal testing was indeed moved to countries outside the European Union. Animal testing performed outside the European Union obviously can only be prevented by enforcing an unshiftable date for a marketing ban.

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)*

In 1999, an opinion poll on animal testing for cosmetics (see **Annex I to our comments** at the end of this submission) was carried out in 6 of the member states (France, Germany, Italy, Spain, Sweden, UK). The results strongly indicated public support for a ban with 71% supporting. At present, a similar poll is being conducted, the results of which, however, will only become available later in 2011. Eurogroup for Animals will welcome the opportunity to provide the European Commission with the results from this ongoing poll as soon as it is published.

**2.2. Testing data in relation to 2013 endpoints**

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

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

Eurogroup for Animals would like to leave any detailed evaluations of animal testing data submitted in the SCCS dossiers to other parties. Briefly, a number of the SCCS dossiers do contain information on the 2013 endpoints. Oftentimes, however, this information has been compiled from so-called “existing data” i.e. the tests were not conducted for the purpose of compiling the SCCS dossiers. Use of such information for safety assessment, evidently, will continue to be permissible even after implementation of the 2013 marketing ban.

According to the sixth European Statistical Report on the Number of Animals Used for Scientific Purposes, no animals were used in the European Union for chronic and sub-chronic toxicity, developmental or reproductive toxicity, mutagenicity or carcinogenicity in 2008 in the field of cosmetics and toiletries.

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 …*)

see above
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)*

see above

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 …)*

Eurogroup for Animals is not in a position to answer this question.

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)*

Eurogroup for Animals would appreciate clarification of the intention behind question 2.2.5. We would expect that in no case animal testing on the three 2013 endpoints was requested for the safety assessment of cosmetic products – as suggested by the wording of the question, since such animal testing has been prohibited since the year 2004. In case this question refers to the number of animal tests performed on substances to enable a risk assessment to be made for the product, we are not in a position to provide the respective information.

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 …)*

see above

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 …)

Eurogroup for Animals is not in a position to answer this question.

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)

Considering that usually data on the endpoints toxicokinetics, teratogenicity, reproduction
toxicity and carcinogenicity are only collected in case of expected considerable oral intake or
considerable skin absorption\(^1\) and that no such testing was performed for cosmetics or
toiletries in 2008 in accordance to the sixth EU Statistical Report on the Number of Animals
Used for Scientific Purposes, it is likely that most new data will be needed to determine
possible skin sensitising effects. This presumption is backed up by the information on animal
numbers provided under question 2.1.4.

It should be noted that from a scientific point of view the endpoint skin sensitisation should
not have been part of the 2013 endpoints, since skin sensitisation tests do not investigate
cumulative effects of substances as repeated-dose toxicity tests do, to which they were
subsumed. Instead skin sensitisation tests evaluate whether a substance elicits an allergic
reaction during the first challenge exposure to the substance, which, for biological reasons can
only occur when preceded by an inductive phase. Thus, the twofold application of a substance
during skin sensitisation tests is by no means comparable to the cumulative application of
substances during repeated-dose toxicity tests. Instead both applications form two unique and
different parts of one single elicitation of the reaction under investigation.

Currently OECD Test Guideline 429 is the accepted OECD test protocol for skin sensitisation
testing. However three promising in vitro methods, the Direct Peptide Reactivity Assay
(DPRA), the human Cell Line Activation Test (h-CLAT) and the Myeloid U939 Skin
Sensitisation Test (MUSST), were sufficiently optimised by industry and, in 2009, were

\(^1\) http://ec.europa.eu/enterprise/epaa/3_events/3_3_workshops/wg4_cosmetics_workshop_pres_200609.pdf  (presentation
Gerald Renner, COLIPA)
accepted by ECVAM for entering pre-validation. Recently, the in vitro KeratinoSens Assay has undergone a ring-trial in preparation for an ECVAM review.

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)*

We expect the REACH legislative procedure, which encompasses a huge collection of data for a large number of chemical substances for a broad variety of different areas of use, to improve the applicability of read-across and weight-of-evidence approaches. The abundance of data becoming available should be processed to further refine in silico and mathematical non-testing approaches with the aim to further reduce the need to rely on data from new *in vivo* test methods for safety assessment.

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)*

Eurogroup for Animals is not in a position to answer this question.

2.3. INCENTIVE FUNCTION FOR RESEARCH INTO ALTERNATIVES

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

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

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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.

Since implementation of the animal testing and marketing bans, efforts increased to develop, validate and accept in vitro methods for the safety testing of cosmetic ingredients. A number of examples confirm the significance of the animal testing provisions in the Cosmetics Directive as an incentive to develop non-animal test methods: For instance, both the Re-Pro-Tect and the Sens-It-Iv EU projects spell out the 7th Amendment of the Cosmetics Directive 76/768/EEC as an incentive for initiating the project\(^3\). Likewise, the 2009 European Commission Call for Proposals on the development of a strategy towards alternative solutions to animal testing in the field of repeated dose systemic toxicity, which was backed up by the European Cosmetics Industry Association, has the 2013 marketing ban as a main incentive\(^5\).

Between 2008 and the first quarter of 2010 alone, ECVAM has received a total of 30 pre-submissions and submissions for human health effect test methods (see: ECVAM Technical Report on the Status of Alternative Methods for Cosmetics Testing, 2008-2009). Undoubtedly, the pending cosmetics marketing ban has been an important trigger for all of these research initiatives.

Test methods that have received regulatory acceptance or are currently in the process of (pre)validation include tests for the endpoints skin corrosion and irritation – the EpiSkin and EpiDerm Skin Irritation Tests and the SkinEthic Reconstituted Human Epidermis Assay, for eye irritation – e.g. the Bovine Corneal Opacity and Permeability Test, the Isolated Chicken Eye Test, the HET-CAM Test, the EpiOcular Assay, for skin absorption/penetration – the In Vitro Diffusion Method, for skin sensitisation – the h-CLAT and MUSST Assays and the Direct Peptide Reactivity Assay, for acute phototoxicity the 3T3 NRU Phototoxicity Test, for acute toxicity different in vitro cytotoxicity tests just as, for genotoxicity/mutagenicity different in vitro assays, for carcinogenicity – Cell Transformation Assays, for toxicokinetics – in vitro hepatic biotransformation models, and for reproductive toxicology – in vitro Embryonic Stem Cells Tests.

In addition to developments on the European level, the marketing ban has also had an important impact on improving international cooperation, the harmonisation of validation and peer review processes and the international acceptance of alternative methods e.g. by intensifying bilateral co-operations between the EU and the United States (e.g. on the level of ECVAM and ICCVAM), and, on a global scale between the EU, Japan, the US and Canada, via the International Cooperation on Cosmetics Regulation, ICCR. In recognition of the importance of alternative test methods for cosmetics safety assessment also in the light of the pending European animal testing and marketing bans, in 2008, the ICCR established ICATM, the International Cooperation on Alternative Test Methods. These international developments underline the extent of the impact the provisions in the Cosmetics Directive had on research in alternative methods to replace animal testing.

The animal welfare provisions of the Cosmetics Directive have also exerted positive effects on an international scale at the level of individual companies and institutes: Concern about the

\(^{1}\) http://www.reprotect.eu/files/home/ReProTect_Flyer.pdf


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7th Amendment bans has improved laboratory animal welfare in China as well as evoked recognition of the significance of the 3Rs in that country\textsuperscript{6}. Likewise, the Japanese cosmetics company Shiseido recently cited the 2013 sales ban as a reason for stopping animal testing\textsuperscript{7}.

The animal testing provisions in the 7th Amendment to the Cosmetics Directive have shown further beneficial effects: In the last decade, the reporting of animal testing issues from the Member States with the goal of improving and judging animal welfare provisions throughout Europe, could be vastly improved thereby considerably contributing to transparency in this area. The animal testing provisions have certainly contributed to this progress, by raising awareness for animal welfare issues. Most likely this has also contributed to firmly establishing the goal of avoiding animal testing and developing alternative methods in EU legislation, such as in the recently adopted Directive 2010/63/EC on the protection of laboratory animals.

Overall the animal welfare impact of animal testing and marketing bans is not restricted to the cosmetics sector, but extends to other areas of toxicological testing as well, areas with much higher numbers of animal testing than the cosmetics sector. Even if alternative methods are developed for the safety testing of cosmetics, they can be developed further for application in the entire chemicals sector. Therefore, the role of the animal testing provisions of the Cosmetics Directive as an animal welfare incentive on other sectors of regulatory animal testing, such as under the provisions of the REACH chemicals legislation, cannot be overestimated.

Nevertheless, scientific progress not only depends upon the establishment of research programmes, but also upon the amount of money dedicated to meeting their respective scientific goals. Therefore, in spite of all previous efforts, the funding programmes established should not only be kept up, but intensified to speed up the process of developing and validating comprehensive non-animal testing strategies.

Notwithstanding these observations, we would like to re-emphasize that maintenance of the 2013 marketing ban is not an issue of availability of alternatives.

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)

Eurogroup for Animals is not in a position to answer this question.

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)

Eurogroup for Animals is not in a position to answer this question.

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

\textsuperscript{6} http://www.mondaq.com/article.asp?articleid=79142
\textsuperscript{7} http://www.japantoday.com/category/national/view/shiseido-tells-activists-of-efforts-to-stop-animal-testing
same/decrease? Please provide information on whether they would increase, remain the same/decrease compared to total R&D expenses.

Eurogroup for Animals would like to see the proportion of research on alternatives to animal testing to increase in comparison to the total R&D expenses. Compared to *in vivo* research, *in vitro* methods are still not receiving an adequate amount of funding, let alone sufficient funding to achieve a paradigm change in regulatory toxicology moving away from *in vivo* to *in vitro* testing.

2.3.5. Please provide information on the **amounts spent 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.

Please refer to **Annex II to our comments** at the end of this submission regarding a survey of public funded research specifically targeting alternatives to animal testing that was conducted over 2006/2007 with responses received from 16 European countries (14 EU, 2 non-EU). Please note, however, that the data from the different countries cover different time periods and that some of the data might no longer be up-to-date. Secondly, the figures in the report do not distinguish between the funding of replacement methods versus reduction or refinement methods, or between the funding of alternatives to regulatory test methods versus other types of research. Nevertheless, the figures reveal that funding alternative methods is indeed taking place, however not at the same level as funding allocated to *in vivo* research. Furthermore, as also revealed in the 2008 Animal Testing Report published in autumn 2010, so far the amount is insufficient to bring about a true paradigm change in regulatory toxicology turning from *in vivo* to *in vitro* methods.

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

It goes without saying that maintaining the 2013 implementation date would have a strong positive impact on keeping up its incentive function. Only when retaining one’s credibility, one can exert an incentive function. To even consider any contrary options would have a detrimental effect on the meaningfulness and reliability of European legislation.

Commissioner John Dalli, DG SANCO himself has underlined the importance of maintaining credibility. When asked about the maintenance of the 2013 marketing ban for cosmetics at the 2010 Eurogroup for Animals Plenary Meeting (on 23 June 2010 in Brussels), he confirmed: “**There will be no extension of this deadline. Once you get into the habit of giving extensions, it never stops. There is no credibility.** “

The example of the animal testing provisions in the 7th Amendment to the Cosmetics Directive reveals the effectiveness of a legal ban in comparison to mere voluntary recommendations. As long as the use of alternative methods was recommended, but not mandatory, a decided and dedicated impact on the reduction of animal testing was not observable. It was only the 7th Amendment to the Cosmetics Directive laying down a concrete testing and marketing ban for cosmetics - brought about and supported by an enduring and broad public consensus of requesting “cruelty-free” cosmetic products - that gave sufficient impetus to the development and validation of non-animal test methods, which in return led to the progress discernible today. These developments show that a legal ban with transition

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periods, fulfilling citizen concerns and giving industry time to adapt, and the laying down of corresponding unshiftable deadlines are necessary and effective tools in bringing about a paradigm change from animal experimentation towards ethically sound and scientifically validated non-animal testing strategies.

It is invaluable to maintain deadlines once they have been decided on, in order to keep up one’s credibility and the need to fulfil the corresponding obligations. As pointed out by Commissioner Dalli in June 2010, once a deadline has been postponed, it becomes increasingly difficult to justify not postponing it again.

Spurred by the 2013 deadline, consortia made up of scientists from academia, authorities and industry have worked together to meet the challenge of developing non-animal test methods. The high scientific quality of the outcomes of these co-operations is very encouraging. If the deadline would now be postponed, this could have a very negative effect on all involved. Efforts in developing and validating alternative methods would inevitably wane, and the psychological impact in general could be devastating.

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)

For the reasons stated in our comments to 2.3.6, only by maintaining the 2013 marketing ban, a high incentive function on research into non-animal test methods can be kept up. This is the only option that prevents the European legislative procedure from losing credibility, which evidently would have a detrimental effect on any incentive function.

Eurogroup for Animals would like to suggest combining maintenance of the 2013 marketing ban with an explicit and dedicated commitment to a stepwise regulatory acceptance and application of a comprehensive non-animal testing strategy specifically developed for the purpose of safety assessment of cosmetic ingredients: Allowing breaking down the task to develop, accept and apply such a non-animal tiered testing strategy into smaller and clearly arranged steps, would further increase the incentive to develop and validate alternative methods. In the following we would like to outline the rationale behind such an approach.

A tiered scheme should be laid down for the hazard assessment of cosmetic substances, which not only calls for an endpoint-by-endpoint testing, but makes interrelations between the endpoint specific test batteries, while at the same time taking into account the specific nature of cosmetic ingredients and the type of their exposure to humans. Tier 1 of such a scheme should prescribe collecting all available data on the respective substance and then continuing to performing simple in vitro test methods and in vitro mechanistic investigations in the 2nd tier. The following tiers should consist of specific in vitro test methods, chosen in accordance to the outcome of the previous tiers. After each tier, all information gathered so far is evaluated to determine if a scientifically sound safety assessment is already possible.

For the assessment of skin sensitisation, toxicokinetics, repeated dose toxicity, and

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11 Grindon C, Combes R, Cronin MTD, Roberts DW, Garrod JF (2008). An integrated decision-tree testing strategy for repeat dose toxicity with respect to the requirements of the EU REACH legislation. ATLA 36 Suppl. 1, 139-147.
reproductive toxicity\textsuperscript{12} of chemical substances, concrete schemes have been put forward how such integrated decision-tree testing strategies should be performed. The testing strategy for skin sensitisation consists of 11 steps, with only steps 9 and 10 calling for the performance of \textit{in vivo} tests. The combined acute toxicity – toxicokinetics testing strategy consists of 10 steps with only the final step calling for the performance of \textit{in vivo} tests. The repeated-dose testing strategy consists of 6 steps with only the final step calling for the performance of \textit{in vivo} tests. Finally, the reproductive toxicity testing strategy consists of 12 steps with steps 9, 11 and 12 calling for the performance of \textit{in vivo} tests.

For manufactured nanomaterials, the EU Commission’s Joint Research Centre JRC, together with the Netherlands Environmental Assessment Agency RIVM and BASF SE have put forward a tiered testing strategy that also meets the above-mentioned requests. In the 1\textsuperscript{st} tier of the JRC/RIVM/BASF testing strategy, \textit{in vitro} local effects and primary biological effects on the one hand and the kinetic translocation of nanomaterials on the other hand are tested separately. Due to this splitting, \textit{in vivo} testing can be avoided in the initial stage of the testing strategy. If nanomaterials do not show any biological effects \textit{in vitro}, they are unlikely to have effects \textit{in vivo}; and further toxicity testing is considered unnecessary. Likewise, if tier 1 kinetic evaluations do not reveal ENM translocation, they are assumed to be unlikely to have systemic effects, and again further studies for systemic effects are not necessary\textsuperscript{13}.

Due to the ethically-motivated reasons underlying the animal testing and marketing bans for cosmetics, only non-animal testing steps should be permissible for the testing of cosmetic substances. Since tiered testing strategies call for an evaluation of the data collected so far and for consideration of the possibility to classify the substance under investigation after each step of the testing strategy, it should be possible to determine the safety of a number of substances already after early, i.e. non-animal, steps of such a testing strategy. Already today, the cosmetics industry declares to only perform the 2013 endpoints in case of expected considerable oral intake or considerable skin absorption\textsuperscript{14}, an observation, which underlines the meaningfulness and acceptance of such a tiered testing strategy. Overall, the precautionary principle should be applied in a manner that inconclusive non-animal test results do not lead to \textit{in vivo} testing, but to rejection of the test substance – at least until their safety can be assessed with \textit{in vitro} test methods as they become available.

An international consortium should be convened and entrusted with the task compile tiered decision-tree testing strategies for the specific purposes and circumstances of the safety testing of cosmetic substances. To promote confidence in such an approach, the tiered testing strategy should be accepted and thus become applicable for regulatory purposes on a step-by-step basis over the course of time whilst the respective \textit{in vitro} test methods become validated and accepted. In consequence, the cosmetics industry would no longer be dependant upon an “all or nothing” position regarding the acceptance of non-animal testing strategies and thus also regarding the availability of new substances.

Notwithstanding these suggestions we would like to re-emphasize that the legal provisions of the 2013 marketing ban are intended to come into effect regardless of the availability of non-animal test methods.


\textsuperscript{14} http://ec.europa.eu/enterprise/epaa/3_events/3_3_workshops/wg4_cosmetics_workshop_pres_200609.pdf (presentation Gerald Renner, COLIPA)

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?

The 2013 marketing ban does not compromise consumer safety. It does not affect or derogate Article 3 of the Cosmetics Products Regulation, which states that a cosmetic product made available on the market shall be safe for human health when used under normal or reasonably foreseeable conditions of use.

Hence, as long as non-animal testing strategies have not been implemented for the 2013 endpoints, the 2013 marketing ban will result in no further new cosmetic ingredients being put on the market in the form of pure substances, formulations or products, unless their safety can be determined without performing new animal tests. Until non-animal testing strategies, as depicted in our comments to 2.3.7 will have been developed, validated and accepted for the testing of cosmetic ingredients, the cosmetics industry continues to be able to develop new cosmetic products with the abundance of cosmetic ingredients that are already recognized as safe (see also comments to 3.2.1).

On the contrary, in the longer term, human health protection will improve due to the animal testing provisions of the Cosmetics Directive, since non-animal test methods and non-animal testing strategies validated as to their reliability and relevance in detecting effects on humans, are better able to ensure human health protection than scientifically flawed animal test methods that were never validated.

The National Academy of Sciences (2007) points to the scientific deficiencies of animal test methods15: “Using the results of animal tests to predict human health effects involves a number of assumptions and extrapolations that remain controversial. Test animals are often exposed to higher doses than would be expected for typical human exposures, requiring assumptions about effects at lower doses or exposures. Test animals are typically observed for overt signs of adverse health effects which provide little information about biological changes leading to such changes leading to such health effects. Often controversial uncertainty factors must be applied to account for differences between test animals and humans. Finally, use of animals in testing is expensive and time consuming, and it sometimes raises ethical issues.” Accordingly, the US National Research Council has spelled out a paradigm change from in vivo to in vitro testing strategies as a vision for the 21st century16.

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"The committee envisions a new toxicity-testing system that evaluates biologically significant perturbations in key toxicity pathways by using new methods in computational biology and a comprehensive array of in vitro tests based on human biology."

The animal testing provisions of the Cosmetics Directive are appropriate, state-of-the-art legal tools that serve to fulfil these scientific provisions.

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?

It is important that Member State authorities decide on common rules on how to efficiently pick up on manufacturers that might rely on insufficient data packages in their safety assessment and that the authorities are adequately equipped and staffed in order to fulfil their obligations. In this context, the legal framework for an inventory of already accepted cosmetic ingredients has already been established (96/335/EC, Commission Decision of 8 May 1996 establishing an inventory and a common nomenclature of ingredients employed in cosmetic products – and its subsequent amendments). Furthermore, in the case of colorants, preservatives and UV filters, lists of allowed substances are continuously updated as Annexes to the Cosmetics Directive and likewise the subsequent Cosmetics Products Regulation – just as lists of prohibited substances. When making use of these already established tools, the task of following up on the marketing and safety of future new cosmetic ingredients – and taking into account the low annual numbers of new chemical substances or cosmetic ingredients (see comments to 3.2.1) - does seem realistic.

Besides, in the 2007 RPA Study manufacturers reported that the total annual costs resulting from compliance with the current requirements of the Cosmetics Directive, in percentage of their annual sales, were calculated to lie between 0.1 and 1%, with only two exceptions over 1%, which were large companies. Considering the risk of harming customers with resulting liability claims and ensuing loss of revenue, there is no economic incentive to cut down on the issue of safety assessment.

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)

Eurogroup for Animals is not in a position to answer this question.

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](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)*

Eurogroup for Animals has no company-specific information on the number of substances that were newly used in cosmetic products in the last decade. However, whereas more than 6,000 of commonly used cosmetic ingredients are listed on the INCI list, with 17,000 names on the list, the RPA Study (Table 2.4) reveals that cosmetics companies use an average of 800 different ingredients for their company’s cosmetics products portfolios and that an average of 80 % of these ingredients are used only in cosmetic formulations and products. Additionally, according to the RPA Study an average of approximately one fourth of the products are replaced or reformulated every year and an average of one fourth of the ingredients are replaced when a product is reformulated or replaced. Further considering that in accordance to the European Commission’s Annual Animal Testing Reports, 80 – 90 % of cosmetic ingredients are being used for multiple purposes other than cosmetics, the conclusion seems plausible that the cosmetics industry in fact relies on a very limited number of well-known ingredients – and in consequence on existing safety data – when formulating and even reformulating their products.

This estimation is backed up by evidence from the area of “regular” chemical substances where the number of existing substances is by far greater than the few truly new substances that enter the market every year. Another figure supporting our estimations is the fact that companies ranked product safety testing among the least important cost factors for placing a product on the market in the RPA Study.

Altogether these observations underline the proportionality of the ethically motivated 2013 marketing ban in comparison to economic interests and thus back up the request to retain it – as a firm ethical standpoint leading to a strong incentive to encourage the further development, validation and acceptance of alternative methods.

All in all, the 2013 marketing ban is to be implemented for ethical reasons and thus irrespective of the availability of alternative methods and irrespective of its economic implications.
As regards consumer choice (the title of section 3.2) and consumer confidence in cosmetic products, it should be noted that a large proportion of European citizens requested and backed up the animal testing and marketing ban for cosmetic products. The current situation of stepwise implementation of the bans leaves these consumers confused about whether cosmetics are still tested on animals or not. These consumers expect an unambiguous assurance that all cosmetics will indeed be cruelty-free after 2013. Hence, the selling of cruelty-free products is to be regarded as an economic incentive and a marketing advantage by improving consumer confidence in cosmetic products.

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)

Eurogroup for Animals is not in a position to answer this question.

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)

Please refer to our answer to question 3.2.1.

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)

Please refer to our answer to question 3.2.1.

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)

Please refer to our answer to question 3.2.1.

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.
Please refer to our answer to question 3.2.1.

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.

Eurogroup for Animals is not in a position to answer 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?

Please refer to our answer to question 3.2.1.

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?

Please refer to our answer to question 3.2.1.

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?

Please refer to our answer to question 3.2.1.

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?

Eurogroup for Animals is not in a position to answer this question.
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, e.g. a large company uses XXX different cosmetics ingredients)

Eurogroup for Animals is not in a position to answer 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)

Eurogroup for Animals is not in a position to answer 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.)

Eurogroup for Animals is not in a position to answer this question.

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),…)

Eurogroup for Animals is not in a position to answer this question.

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)

Eurogroup for Animals is not in a position to answer this question.

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
Eurogroup for Animals is not in a position to answer this question.

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 in Global Insights, see A, with the addition of hair colorants and sun protection products):

a) fragrances and perfumes
b) decorative cosmetics
c) skin care
d) sun protection products
e) hair care (other than hair colorants)
f) hair colorants
g) toiletries
h) Other, please specify
(type of answer expected: sector X is expected to be most prone because…, followed by sector X)

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)

Eurogroup for Animals has no figures regarding the number of products containing the animal testing free label. In the context of such labelling, however, we find it important to note that, for transparency reasons, any claim referring to the absence of animal testing should specify its concrete basis. In addition to any of the registered “common” claims or logos (i.e. ‘against animal testing’, ‘cruelty-free’, etc.), such labelling therefore must contain the following...
statement: *The producer/company and/or its suppliers have not carried out or commissioned any animal testing for this product or its ingredients, nor used any ingredients that have been tested on animals after date x*. 

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)*

Eurogroup for Animals has no market surveillance figures regarding the impact of the labelling of cosmetic products on consumer behaviour. Our opinion polls however (see comments to 2.1.5 together with Annex I to our comments), do point to the significance that consumers assign to animal testing free cosmetic products. Additionally, we would like to re-emphasize (see our comments to 3.2.1) that the current situation of stepwise implementation of the bans leaves consumers confused about whether cosmetics are still tested on animals or not. These consumers expect an unambiguous assurance that all cosmetics will indeed be cruelty-free after 2013.

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…)*

As repeatedly stated, the only option Eurogroup for Animals considers acceptable regarding the 2013 marketing ban is its implementation without further delays. Therefore we cannot recognize any grounds for an “animal tested” label.

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…)*

Please refer to our answer to question 2.1.5 in combination with Annex I of our comments.

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
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?**

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?

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).**

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?**

Again, we would like to point to the ethical motivation for the implementation of the 2013 marketing ban, which implies that in the case of life-style driven products, any economic issues are only second to the welfare of sentient beings.

Additionally, Eurogroup for Animals would like to question whether the competitiveness of the cosmetics and cosmetics ingredients manufacturers is affected at all or to a significant extent. Evidently, the ban applies to all companies alike (and even non-EU countries and companies are adhering to it, see our comments to 2.3.1). Considering, that, in accordance to the results from the RPA Study, smaller enterprises use smaller numbers of ingredients, any possible impacts of the 2013 marketing ban on the competitiveness of manufacturers of cosmetic ingredients or products do seem balanced and proportional.

On the contrary, the selling of cruelty-free products is to be regarded as an economic incentive and a marketing advantage by improving consumer confidence in cosmetic products. Thus, the 2013 marketing ban is to be seen as an incentive promoting the innovative potential of the cosmetics industry. Furthermore, the 2013 marketing ban is an important incentive in the economic sector of developing and validating non-animal test methods and thus has resulted in the creation of an abundance of new jobs and new companies, including SME’s, in this sector.

Finally, we would like re-emphasize that the European Commission has already conceded to economic interests by adding the endpoints “skin sensitisation” and “carcinogenicity” to the 2013 marketing ban, for which there are no scientific grounds. From the point of view of animal welfare, there is no justification to make any further concessions to economic interests beyond this final deadline.

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

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.

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

Again, we would like to point to the ethical motivation for the implementation of the 2013 marketing ban, which implies that in the case of life-style driven products, economic interests are only second to the welfare of sentient beings.

In the case of the competitiveness of SME’s, Eurogroup for Animals cannot recognize any particular negative impacts resulting from the 2013 marketing ban. Evidently, the ban applies to all companies alike (and even non-EU companies are adhering to it, see our comments to 2.3.1). Considering, that smaller enterprises apparently use smaller numbers of ingredients (RPA Study), any possible impacts of the 2013 marketing ban on the competitiveness of manufacturers of cosmetic ingredients or products do seem balanced and proportional.

The selling of cruelty-free products is to be regarded as an economic incentive and a marketing advantage by improving consumer confidence in cosmetic products. Thus, the 2013 marketing ban is to be seen as an incentive promoting the innovative potential of the cosmetics industry. Furthermore, the 2013 marketing ban is an important incentive in the economic sector of developing and validating non-animal test methods and thus has resulted in the creation of an abundance of new jobs and new companies, including SME’s, in this sector.

### 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?

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

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

6.4. Has the 2009 implementation date already had impacts on employment? Which ones?

Again, we would like to point to the ethical motivation for the implementation of the 2013 marketing ban, which implies that in the case of life-style driven products, economic interests are only second to the welfare of sentient beings.

Regarding impacts on employment, Eurogroup for Animals cannot recognize any particular negative impacts resulting from the 2013 marketing ban. Instead, the selling of cruelty-free products is to be regarded as an economic incentive and a marketing advantage by improving consumer confidence in cosmetic products. Thus, the 2013 marketing ban is to be seen as an incentive promoting the innovative potential of the cosmetics industry. Furthermore, the 2013 marketing ban is an important incentive in the economic sector of developing and validating non-animal test methods and thus has resulted in the creation of an abundance of new jobs in this sector.
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.

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?

Again, we would like to point to the ethical motivation for the implementation of the 2013 marketing ban, which implies that in the case of life-style driven products, economic interests are only second to the welfare of sentient beings.

As regards possible impacts on trade, considering that the European cosmetics industry is a major player of the global cosmetics industry, the European Community has the opportunity and also the responsibility to lead the way internationally in implementing legislative provisions on cosmetics risk assessment strategies that are both ethically sound and adequate in ensuring a high level of human safety. That this is indeed taking place can be seen by the developments on the level of the ICCR and ICATM as well as by the fact that also non-European cosmetics companies are adhering to the animal welfare provisions of the European Cosmetics Directive (see our answers to 2.3.1). In consequence, Eurogroup for Animals does not expect any negative impacts from implementation of the 2013 marketing ban.

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**Annex I (re. question No. 2.1.5)**

**Opinion poll on animal testing for cosmetics, May 1999, commissioned by the RSPCA and BUAV, carried out by Opinion Research Business (ORB)**

Countries: France, Germany, Italy, Spain, Sweden, UK

**Question 1:**
Do you think animal tests for cosmetics and toiletries should be banned throughout the European Union?

**Question 2:**
Do you think consumers should be told if a cosmetic or toiletry product has been tested on animals?

<table>
<thead>
<tr>
<th>Country</th>
<th>% who want a ban on animal testing</th>
<th>% who think animal tested products should be labelled</th>
</tr>
</thead>
<tbody>
<tr>
<td>France</td>
<td>56% (27% no)</td>
<td>87% (9% no)</td>
</tr>
<tr>
<td>Germany</td>
<td>87% (10%)</td>
<td>93% (6%)</td>
</tr>
<tr>
<td>Italy</td>
<td>63% (26%)</td>
<td>92% (4%)</td>
</tr>
<tr>
<td>Spain</td>
<td>51% (24%)</td>
<td>79% (6%)</td>
</tr>
<tr>
<td>Sweden</td>
<td>79% (10%)</td>
<td>96% (2%)</td>
</tr>
<tr>
<td>UK</td>
<td>88% (10%)</td>
<td>96% (3%)</td>
</tr>
<tr>
<td>Average</td>
<td>71% (18%)</td>
<td>91% (5%)</td>
</tr>
</tbody>
</table>
ANNEX II (re. question No. 2.3.5)
Information on public funding of alternative methods in Europe

**Austria**

Public supported alternatives research in Austria in 2006 is estimated at €200,000. The average for 1992 - 2005 was reported as €250,000 per annum. The Federal ministries responsible for research support are the Ministry of Education, Science and Research, the Ministry for Health and Women, the Ministry for Economics and Labour and the Ministry for Agriculture, Forestry, Environment and Water. No other sources of funding were highlighted by the respondent. There is no existing national strategy in Austria with regards to coordination of research into 3R alternatives. Multi-stakeholder consultation takes place with regards to priority setting. There is no preference with regards to the magnitude of funding of the projects to be supported by public research support. No project funding limits are placed on the proportion of research that will be supported (i.e., up to 100%). There is a national consensus platform, ZET. There is partial overlap between the competent authorities for chemical management (i.e., the Federal Ministry of Agriculture, Forestry, Environment and Water) and those responsible for animal testing procedures (i.e., the Ministry of Education, Science and Research, the Ministry for Health and Women, the Ministry for Economics and Labour and the Ministry for Agriculture, Forestry, Environment and Water).

**Belgium**

No public funds specifically aimed at 3Rs research are available in Belgium. Recent financing of research on 3Rs was possible through Public Contract Research. The funding, as far as research on alternatives is concerned, is allocated upon a project basis and selected by the National Research Committee. The amount of funds released depends on the nature and “lifespan” of the project. In 2005, an amount of €400,000 was allocated to one project for duration of 3 years and in 2006 two projects were selected for a total amount of €116,000 for one year. This process of selection for projects will continue in 2007. In addition, some NGO's (such as BPAM\textsuperscript{17}, APMA\textsuperscript{18} etc.) occasionally promote research or application of alternative methods in research or education. Belgium has no general national strategy as such. Research on alternative methods is promoted through a public contract committee (the Public Contract Research) at the Federal Public Service Health, Food Chain Safety and Environment. Topics of projects may be selected through collaboration with local ethical committees of private, academic and public laboratories and the animal welfare officers in the laboratories. Replacement is the main focus of the research, but all three Rs are considered when public funds are made available. Once a project is underway cooperation and coordination between research groups is possible, although there is no particular cooperation with other stakeholders. The contracts for research are approved by a specific evaluation committee of the Public agency, namely the Federal Public Service Health, Food Chain Safety and Environment. The control of chemical management and control of animal testing procedures lies with two other distinct departments of the same Federal Public Service.

**Czech Republic**

17 Belgian Platform for Alternative Methods to animal testing
18 Action préventive contre le martyre des animaux de laboratoire
Public supported research into alternatives in the Czech Republic was estimated at €2,000 in 2006. The Ministry of Health and Ministry of Education have responsibility for research support. No other sources of funds or funding were highlighted. There is currently no provision to match EU research support or indeed any indication of cooperation with other EU in this respect. There is a national strategy with regards to coordination of research into alternatives (although this is somewhat at odds with the estimate of public funded research into alternatives). This strategy is apparently focused on replacement. Priority setting is based on a consideration of societal and legislative needs and does entail an element of public consultation. There is no preference with regards to the magnitude of funding of the projects to be supported by public research support. No project funding limits are placed on the proportion of research that will be supported (i.e., up to 100%). There is a national consensus platform, Czecopa. The competent authority for chemical management is the same as that responsible for animal testing procedures (i.e., UKOZ, the Ministry of Agriculture).

**Denmark**

In 2005 the Danish Government’s Research Council for Independent Research (DFF) spent €120 million on research of which €3.3 million went on alternatives. Between 2005 and 2008 the Danish Research Council for Strategic Research (DSF) plan to spend some €47 million. It appears that there is no national strategy as such, although the two bodies DFF and DSF cooperate in setting research priorities. Project funding will vary depending on the project and other factors but can be up to 100%. Stakeholder co-operation and coordination does take place, but the extent of the involvement will depend on the project. The two research councils (DFF and DSF) fall under the Ministry of Science and it is clear that Denmark has a strong commitment to funding research into alternatives. The commitment in monetary terms is second only to the United Kingdom and Germany. The Ministries of Health and Environmental Protection share the legal responsibility for controlling chemical management and animal testing procedures. A Danish platform (Dacopa) has been recently set up and is seeking to improve communications with the Ministry of Science (Danish Research Coordination Committee).

**Finland**

In the year 2004 - 2005 the total amount of public funds spent on research into alternatives was €40,000. Of this some €34,000 came from the Ministry of Agriculture and about €6,000 from the Julia von Wendt Foundation (in some years this sum can be up to €8,000). The Ministry of Agriculture will fund research into all the three Rs, but the Foundation will only fund research into Replacement. Other funding can come from the National Technology Agency (TEKES). This funding is used to develop in-vitro methods for studies of drug development and safety, but no figures are available. No national strategy exists beyond a government policy that requires that the number of animal experiments be reduced. All the 3Rs are given as priorities, but the greatest emphasis is on replacement. Stakeholder consultation takes place with the pharmaceutical industry in particular (representatives sit on the advisory board of TEKES), but also with academia in the development and planning of in vitro studies. There is also a national consensus platform for promoting alternatives, Fincopa. The Ministry of Agriculture and Forestry is responsible for supporting research and animal welfare and it also controls animal testing procedures. Chemical management is divided between the Ministry of Social and Health Affairs (pharmaceuticals), the Ministry of Environment plus the Ministry of Social and Health Affairs (biocides and industrial chemicals) and the Ministry of Trade and Industry (cosmetics). Two recent government reports have suggested that financing of research into alternatives should be considerably
increased and that there should be better co-ordination of replacement research. A National Centre for the Studies of Alternatives to Animal Experimentation has also been proposed.

**France**

Current national funding of alternatives in France is potentially of the order of €2.75 million (€0.3 million from AFFSAPS\(^{19}\), €2 million from ANR\(^{20}\) and €0.45 million from funds to support “Pôles de Compétitivité”). It appears that there is national strategy coordinated by the national platform (established in the form of a GIS or Groupement d’Intérêt Scientifique) that has an apparent focus on replacement. Project funding will vary depending on the project and other factors but can be up to 100% for the public sector, but lesser amounts for the private sector (i.e., 30%). The Ministries of Agriculture and Research has responsibility for animal testing procedures and the Health, Industry and Environment for chemical management.

**Germany**

In Germany, the Federal Ministry for Education and Research has spent 86.1 Mio EUR for the funding of alternative method development over the first 20 years of its alternative methods funding programme, i.e. from the mid 80ies until 2004\(^{21}\). For the period of 2000 until 2009 a total of 41.5 EUR is being reported\(^{22}\). In 1986, the German Government established the German National Centre for Documentation and Evaluation of Alternatives to Animal Experiments (ZEBET), in response to the EU Council Directive 86/609/EC. ZEBET has an additional yearly budget for the funding of alternative test development of currently 300,000 – 440,000 EUR\(^{23}\). Furthermore the German government allocates 15,000 EUR per year to an animal welfare award. Additionally, in Germany, government, industry and animal welfare organisations jointly founded SET (Foundation for the Promotion of Research on Replacement and Complementary Methods to reduce Animal Testing), which, so far, has spent 4 Million Euros on projects in the field of 3R. Currently approximately 220,000 Euro are provides by industry and additional 100,000 by the Federal Ministry of Consumer Protection every year.

**Hungary**

In Hungary, public funds specifically targeted at research into alternatives are estimated at €40,000 in 2005. Other potential sources were also highlighted by the respondent i.e., National Office for Research & Technology (NKTH) and Hungarian Scientific Research Foundation (OTKA). There is no existing national strategy in Hungary with regards to coordination of research into alternatives. There is a national consensus platform, Hucopa.

**Italy**

In Italy, there are no public funds specifically available for alternatives to animal testing. However, there are non-profit organizations, such as CELLTOX (Italian Association of *in vitro* Toxicology) or IPAM (Italian platform on Alternative Methods) which provide financial support by means of fellowships or other initiatives to promote research on alternative

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\(^{19}\) Agence française de sécurité sanitaire des produits de santé  
\(^{20}\) French National Research Agency  
methods. Private enterprise generally supports the annual national meetings of IPAM and CELLTOX (with contributions varying between €500 to €4,000 per meeting). There is no existing national strategy in Italy with regard to funding for research into alternative methods. The responsibility for research support lies with the Ministry of University and Research. The Ministry of Health has regulatory responsibilities, including implementation of Directive 86/609. Apparently, there is no formal cooperation or coordination between the different authorities on this issue. According to the chair of the Italian platform IPAM, ‘the willingness’ towards alternative methods needs to be encouraged in Italy.

**Netherlands**

Public funds for alternatives in the Netherlands were estimated at €797,000 in 2006 and €1,297,000 for 2007-2009. The majority of this estimated budget corresponds to the Dutch research programme on alternatives to animal testing (“Dierproeven Begrensd II”). The budget for DB II is provided by the Ministries of Health, Education and Defence. Only earmarked national budgets are included, as there are no figures available for the investments by industry and academia in the development of alternative methods. Within DB II there is encouragement to cooperate as much as possible with other European institutions (EP, and ECVAM) and OECD. The national strategy in the Netherlands focuses on the 3Rs with an emphasis on guideline testing and development of research models. The priority setting is undertaken by the Dutch National Platform (Platform for Alternatives to Animal testing) & ZonMW, an Independent National Health Council. Key persons of industry, welfare & academia are consulted. There is no preference for either large or small projects. Projects are selected on the relevance for the programme DB II and the scientific quality. Limitation is only related to the size of the budget. The maximum percentage of funding is 75% of the total project costs. To ensure the commitment of the research organisation to the project, a financial contribution of the research organisation is required. Grants range from €20,000 to €350,000. Stakeholder cooperation and coordination is present, including a consultative role for the Dutch Platform. In the Netherlands, the Institute(s) responsible for research support on alternatives to animal testing are mainly embedded within the Ministry of Health, Welfare & Sport; Ministry of Education, Culture & Science; Ministry of Defence; Ministry of Spatial Planning, Housing and Environment; Ministry of Agriculture, Nature & Food Quality. The competent authority (CA) for Chemical Management lies with the Ministry of Environment, whilst the CA for animal testing procedures is to be found with the Ministry of Health.

**Norway**

Norway is not a member of the European Union. No public funds are made available specifically for research into alternatives, but there are other sources. In 2006 the Norwegian Food Safety Authority (FSA) spent approx. €70,000 to continue the work of establishing a National Platform for Alternatives in Norway in 2007. Some of this money will be used to fund research projects within the 3Rs. A state fund for alternatives is being planned. The Norwegian Research Council provides information about the availability of EU funding for research projects. This body also sets the priorities for research in Norway. There is no national strategy as yet. There is regular stakeholder consultation involving industry, academia and animal welfare. A national consensus platform is in the process of being formed. The FSA comes under the Ministry of Agriculture and Food and is responsible for supporting research. The Ministry of Environment is responsible for chemical management, but delegates the work to the Pollution Control Agency. Control of animal testing procedures is delegated to the Norwegian Animal Research Authority and the FSA by the Ministry of Agriculture and Food.
**Slovakia**

Slovakia has allocated public funding of between €28,000 and €280,000 a year to the development of alternatives. There is no set amount and it obviously varies noticeably from year to year. No national strategy is in place. Most funding is allocated to reduction and replacement. Refinement is addressed more at an ethical and legislative level. Stakeholders may be consulted although, no defined procedure exists. When stakeholders are consulted, they are usual representing research institutes and universities with occasional participation by industry. When allocating funding for projects, smaller projects are generally preferred and these projects are funded up to 100%. There are a number of institutes responsible in providing research support and they include the Agency for support of Science and Technology, Slovak Academy of Science, Agency of Universities and Minister of Education, Scientific Agency of the Ministry of Health and the Ministry of Environment. The Ministry of Environment is responsible for both chemical management and animal testing procedures.

**Spain**

There is no specific programme within the national agencies dedicated to funding research on alternative methods. Research projects specifically dedicated to alternatives are a minority. However, many research projects make use of alternative methods, and are thus financed by other rationale. The total expenditure on all general research is estimated at €4,000 million per year. An estimation of the total annual budget for *in vitro* alternatives is €500,000. No systematic policy exists in Spain to match EU supported projects. There are some additional funds (“Complimentary Actions”) available to support research teams participating in European projects. There is no national strategy for alternatives. A systematic procedure for priority setting and for allowing stakeholder consultation in priority setting is also lacking. Most basic research projects receive 100% funding support. Technological projects with the participation of industries normally receive partial funding. The project funding limits are a function of the number of researchers and FTE dedicated to the project. Most bio-research projects exclusively involve academic institutes (research institutes and universities) with a low participation from industry. Research is mainly governed and supported by the National Research Programs Authority (General Directorate of Research and Technology in the Ministry of Education and Research). The responsibility for chemical safety of new and existing chemicals, biocides, cosmetics, food additives and food safety, and drugs lies with different Ministries. The Environmental Health sub-directorate deals with the evaluation of new and existing chemicals, biocides, testing methods (EU and OECD). Agrochemicals (under Directive 91/414) are dealt with by the Ministry of Agriculture, although the human health effect evaluation is conducted by the Ministry of Health. Conversely, when the Ministry of Health is the competent authority, the evaluation of ecotoxicity and environment safety is delegated to the Ministry of Environment. Responsibility for animal experimentation falls under a specific sub-directorate in the Ministry of Agriculture which also deals with other veterinary aspects.

**Sweden**

In Sweden public funds are distributed for research into alternatives by the Swedish Animal Welfare Agency (SAWA). Each year from 2004 onwards the amount has been in the order of €1.6 million (15 million SEK). In addition, annually, about €100,000 comes from the

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24 Since 2006, the responsibility for allocating research funding for alternatives in Sweden no longer lies with SAWA.
Swedish Pharmaceutical industry and a similar sum from the Swedish Fund for Research to Animal Experiments. There is a national strategy and research has been focussed on all 3Rs. The intention is to bring about a decrease in the use of laboratory animals. The SAWA sets the priorities for this research and consults stakeholders through a scientific advisory committee. This committee is made up of experts in different biomedical fields, representatives from government agencies, animal welfare representatives and the pharmaceutical industry. Some projects have been jointly funded by both the Swedish government and the European Union. The amount of funding will vary depending on the project but can be as high as 100%. SAWA is responsible for research. Chemical management falls under the Swedish Chemical Inspectorate and control of animal testing procedures under the Swedish Medical Products Agency.

**Switzerland**

Switzerland is not a member of the European Union. The amount allocated to the funding has remained consistent for the past two decades. Approximately €270,000 is specifically allocated to the development of alternative methods. Funding is also made available through other sources, mainly from industry and private foundations. This amount has also remained consistent in recent decades. All 3Rs are supported when funding allocation is decided, mostly with projects focusing on research and drug development. The priorities are set by the 3R Research Foundation at the national level. Stakeholders from all related sectors are actively consulted and are represented on a Scientific Expert Board. There is no preference as to the size of projects funded, but generally those funded would receive between 80 and 100% support. Switzerland has a national platform, the 3R Research Foundation. The Institutes responsible for research support are the Bundesamt für Veterinärwesen and Interpharma. The Competent Authority responsible for chemical management being Bundesamt für Gesundheit (Ministry for Health) and for animal testing procedures, Bundesamt für Veterinärwesen.

**United Kingdom**

In the United Kingdom, government funding for research to develop 3Rs methods is available from the National Centre for the Replacement, Refinement, and Reduction of Animals in Research (NC3Rs), Research Councils such as BBSRC\(^\text{25}\) and MRC\(^\text{26}\) and some other government institutes and departments. Funding is also provided through a number of other sources including industry, professional associations, private foundations and NGOs, sometimes in collaboration. The respondents indicated that it was difficult to provide an estimate of total public funds dedicated to alternatives research. This is partly because there is no single specific department responsible for the allocation of funding for alternatives research. From 2004 to 2010, the NC3Rs provided direct funding for 3Rs projects to a total of approximately €20 million. Both large and small projects are considered. Funding decisions are dependent upon the scientific quality of proposals and their likely impact on the 3Rs. Public funding providers usually allocate a total of up to 80% of the amount requested. NC3Rs has a strategic plan which focuses on all 3Rs. In setting priorities, the NC3Rs consults stakeholders representing all relevant fields (i.e. animal welfare, industry, academia and the government). The Home Office is responsible for the regulation of animal testing procedures.

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\(^{25}\) Biotechnology and Biological Sciences Research Council

\(^{26}\) Medical Research Council