

# **Lush Lobbying Prize 2014**

## **Background Paper**

## 1 Executive Summary

Lobbying is an essential part of the campaign to end animal testing. The continued use of animals is often entrenched by legal requirements or regulatory reluctance to accept the scientific superiority of non-animal testing methods.

The Lush Prize, now in its third year, rewards initiatives in five areas of working for an end to animal testing: three science categories, public awareness and lobbying.

The latter prize aims “to reward the work of exceptional individuals, groups or organisations pushing for change, focusing on policy interventions promoting the use of alternatives”<sup>1</sup>.

The definition of the Lobbying Prize is:

“Scientific innovation needs to go hand-in-hand with policy change to ensure that end-users of new testing approaches – industry and regulators – are receptive and responsive to the new methods.

Such change requires a multifaceted, global approach, including science-based lobbying at the national level or supra-national level to:

- Entrench non-animal testing methods in national, EU or OECD programmes of test guidelines
- Revise existing guidelines to reflect best practices, including the removal of animal tests, or
- Achieve a mandatory requirement for non-animal testing in legislation, regulatory policies, testing guidance, etc.”

This paper examines some of the key issues relating to animal testing in several countries that are of particular relevance to the Lush Prize, which focuses on toxicity testing for consumer products and ingredients. Those key issues relate to cosmetics testing and chemical testing. Recent lobbying initiatives are discussed as well as several recent successes. This is a crucial time for lobbying on these issues and important results have been achieved, such as the EU ban on marketing animal testing cosmetics, which are making waves around the world.

Also included is a table of organisations around the world active in lobbying, either locally, nationally or internationally, on animal experimentation.

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<sup>1</sup> Lobbying Prize. Lush Prize. <http://www.lushprize.org/awards/lobbying-prize/>. Accessed 30.7.14

## 2 Introduction

A great deal of progress has been achieved over the past twenty years in helping change legislation to encourage non-animal testing methods. These changes not only meet the expectations and demands of a public concerned about animal protection but, given the unreliability of experiments on animals, provide safer methods of testing new products for the consumer market.

The biggest recent success has of course been the EU-wide ban on testing cosmetics on animals and the marketing of any animal-tested cosmetics (even if those experiments were conducted outside the EU). The marketing element of the ban came into force in March 2013.

Israel also introduced a marketing ban in 2013<sup>2</sup>, having first banned using animals to test personal care and household products in 2007.

The Drug Controller General of India announced in June 2013 that the testing of cosmetics and their ingredients on animals will no longer be permitted in India and NGOs are now urging for a ban on the marketing of cosmetics or their ingredients tested on animals, in line with the EU and Israel.

Countries that require cosmetics to pass animal tests before being allowed on the market are being robustly challenged to implement effective non-animal testing methods and end animal use entirely. This is being done by a skilful combination of public awareness and lobbying campaigns as well as training of scientists and regulators. China and Brazil have been in the spotlight for their mandatory animal testing, but from June 2014 China removed that requirement for some products made in the country and in January 2014 the State of São Paulo became the first region in Brazil to sign a bill prohibiting cosmetics testing on animals in the state.

In the USA, the Humane Cosmetics Act was introduced in 2014, to ban the testing of cosmetics on animals and the sale of products that have been tested elsewhere. This could be seen as a challenge to the Safe Cosmetics and Personal Care Products Act which many have stated would increase animal testing.

The use of animals in chemicals testing still remains high on the lobbying agenda for several NGOs. In Europe, toxicity tests required under REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) usually involve the poisoning of guinea pigs, rabbits, fish, birds, rats and mice<sup>3</sup>. Lobbying has helped to significantly reduce the number of animals used in testing for REACH, but scrutiny needs to be applied to limit animal use as much as possible.

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<sup>2</sup> Import ban on animal-tested products goes into effect. Gabe Fisher, Times of Israel, 1.1.13. <http://www.timesofisrael.com/import-ban-on-animal-tested-products-goes-into-effect/>

<sup>3</sup> REACH. ECEAE. <http://www.eceae.org/en/what-we-do/campaigns/reach>. Accessed 15.8.12

Organisations opposed to animal testing are becoming increasingly skilled at lobbying at a variety of levels and are accepted by regulatory and legislative bodies as informed and reliable stakeholders.

NGOs have formed coalitions such as the International Council on Animal Protection in OECD Programmes, which was formed to incorporate alternative methods that can replace, reduce, and refine animal use in OECD (Organisation for Economic Co-operation and Development) guidelines and programmes.

The European Coalition to End Animal Experiments (ECEAE) has a stakeholder seat on several committees relating to the European Chemicals Agency.

PETA India has an official seat on committees which has been instrumental in their lobbying to successfully ban cosmetics testing on animals.

As this paper notes later, forming a coalition shows a common cause which can have a greater impact on policy makers.

## 3 Lobbying

### 3.1 What is lobbying?

“Lobbying is the process of seeking to shape the public policy agenda in order to influence government (and its institutions) and the legislative programme.”<sup>4</sup>

Public policy is dictated and influenced by a range of bodies and individuals, from local government to the media, groups which are home to Key Decision Makers and Key Opinion Formers.

### 3.2 What is effective lobbying?

Whilst each country has a different political system and governing operations, some lobbying techniques are universal and just need adapting to meet conditions on the ground. Equally, “you will need to tailor your approach to accommodate the personal and political sensibilities of a wide range of politicians”, even within an individual political body<sup>5</sup>.

There are several key factors to making lobbying effective:

1. Be credible: the message has to be based on evidence and withstand scrutiny and criticism.
2. Understand what you want and how to achieve it: Have a short-term and long-term strategy and fully understand what your objectives are.
3. Get involved at the earliest stage: This can be as early as political parties’ policy reviews or responding to government consultations on policy proposals. Research shows that one in five MEPs believe that lobbyists do not provide information in a timely enough manner<sup>6</sup>.
4. Understand how policy is made at various levels (local, national, international): “it helps to ensure that you arrive with the right arguments at the right time.”<sup>7</sup>

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<sup>4</sup> *Lobbying: The art of political persuasion*. Lionel Zetter. Harriman House, 2011

<sup>5</sup> A Common Sense Guide to Effective Lobbying on Capitol Hill. Pete Levitas. Antitrust, Vol. 21, No. 2, Spring 2007. The American Bar Association. <http://www.dicksteinshapiro.com/files/Publication/f5fbc125-8854-4218-9572-1c9a669aa557/Presentation/PublicationAttachment/061e73e9-718e-4272-82d5-28c4bfdc491e/Spring07LevitasC%20%282%29.pdf>

<sup>6</sup> Quoted in Robert Mack 2005. Lobbying effectively in Brussels and Washington – Getting the right result. Journal of Communication Management. Vol. 9, 4, 339-347. <http://web.efzg.hr/dok/MAR/mfuduric/Lobbing%20in%20Bruxelles%20and%20Washington-getting%20the%20right%20result.pdf>

<sup>7</sup> A Guide to Effective Lobbying In Europe 2009. Burson-Marsteller, 2009. [http://www.burson-marsteller.com/Innovation\\_and\\_insights/blogs\\_and\\_podcasts/BM\\_Blog/Lists/Posts/Post.aspx?ID=143](http://www.burson-marsteller.com/Innovation_and_insights/blogs_and_podcasts/BM_Blog/Lists/Posts/Post.aspx?ID=143)

5. Prepare a list of key stakeholders: keep this updated so you know who to lobby. Few people actually influence a decision, so strategic communication with them is far better than mass briefings to people with little influence.

6. Establish relationships with Key Decision Makers and Key Opinion Formers: Being on relevant consultation lists ensures that government seeks your input at an early opportunity. This is known as ‘insider campaigning’. “This status as an insider will have been established through longevity, having developed a track record of being a trusted source of policy and opinion”<sup>8</sup>. (Outsider campaigning “involves attempting to influence decision-makers through the participation of the general public in lobbying action.”<sup>9</sup>)

7. Know your opponent’s arguments: formulate what their strategy would be and what you need to put together a stronger case than theirs.

8. Use the media to impact both political and public opinion on your issue: a change in public opinion often leads to a corresponding change in political opinion rather than the other way around.

9. Form a coalition: this shows a common cause which can have a greater impact on policy makers, who crave consensus. Managing the differing key messages and ‘rivalries’ amongst coalition organisations can be difficult, so “ad hoc and temporary issue-specific coalitions can be just as influential as longstanding partnerships.”<sup>10</sup>

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<sup>8</sup> *Lobbying: The art of political persuasion*. Lionel Zetter. Harriman House, 2011

<sup>9</sup> A Guide to Effective Lobbying for Women’s Groups in Ireland. The National Women’s Council of Ireland, 2006. [http://www.womensaid.ie/download/pdf/nwci\\_effective\\_lobbying\\_for\\_womens\\_groups\\_in\\_ireland.pdf](http://www.womensaid.ie/download/pdf/nwci_effective_lobbying_for_womens_groups_in_ireland.pdf)

<sup>10</sup> A Guide to Effective Lobbying In Europe 2009. Burson-Marsteller, 2009. [http://www.burson-marsteller.com/Innovation\\_and\\_insights/blogs\\_and\\_podcasts/BM\\_Blog/Lists/Posts/Post.aspx?ID=143](http://www.burson-marsteller.com/Innovation_and_insights/blogs_and_podcasts/BM_Blog/Lists/Posts/Post.aspx?ID=143)

## 4 Key Issues

There are several key issues subject to ongoing lobbying campaigns relevant to the Lush Prize:

- Cosmetics animal testing
- REACH
- Individual species

### 4.1 Cosmetics animal testing

#### 4.1.1 European Union

In Europe, the progress on banning animal testing for cosmetics has seen public awareness and lobbying working together to ensure that the widespread public support for a ban has underpinned political negotiations.

Due to this sustained campaigning the testing of cosmetics and their ingredients on animals was banned in the UK in 1998. The campaign on an EU level resulted in a ban on the testing on finished cosmetic products in 2004 and a testing ban on ingredients since 2009. A marketing ban followed, prohibiting the import and sale of products and ingredients tested on animals outside Europe after March 2009, with the exception of testing for three 'toxicological endpoints' which were considered harder to replace. In March 2013 a full marketing ban was introduced, meaning that cosmetics tested on animals can no longer be sold in Europe, even if the testing happened outside the EU.

Implementation of the 2013 marketing deadline is the result of effective lobbying at Member State and EU-level. The ban applies even though non-animal testing methods are not yet available in all cases. The EC states<sup>11</sup> that "this reflects a sector-specific political choice by the European Parliament and the Council" and that a ban was not "dependent on the availability of a full set of replacement methods."

It has long been clear that setting a deadline for the marketing ban has acted as an incentive for companies to work harder towards finding and implementing non-animal methods of testing. The EC states<sup>12</sup> that it did not delay the 2013 marketing ban as it "could seriously diminish determination to swiftly develop alternative test methods", noting that the proposed ban has "been a key accelerator in relation to the development of alternative methods and have sent a strong signal far beyond the cosmetics sector and far beyond Europe."

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<sup>11</sup> Communication from the Commission to the European Parliament and the Council on the animal testing and marketing ban and on the state of play in relation to alternative methods in the field of cosmetics. Brussels, 11.3.2013. [http://ec.europa.eu/consumers/sectors/cosmetics/files/pdf/animal\\_testing/com\\_at\\_2013\\_en.pdf](http://ec.europa.eu/consumers/sectors/cosmetics/files/pdf/animal_testing/com_at_2013_en.pdf)

<sup>12</sup> Communication from the Commission to the European Parliament and the Council on the animal testing and marketing ban and on the state of play in relation to alternative methods in the field of cosmetics. Brussels, 11.3.2013. [http://ec.europa.eu/consumers/sectors/cosmetics/files/pdf/animal\\_testing/com\\_at\\_2013\\_en.pdf](http://ec.europa.eu/consumers/sectors/cosmetics/files/pdf/animal_testing/com_at_2013_en.pdf)

#### 4.1.2 Taking the EU ban to a global level

The EC considers the ban can be used as an opportunity for the EU “to set an example of responsible innovation in cosmetics with positive impact beyond Europe. Impacts go beyond the cosmetics sector – the objective is to develop strategies that will lead to better and more predictive, faster and cheaper tools to assess consumer safety of chemical substances.” It is eager to ensure that its new requirements are adopted by other countries around the world, being “convinced that the overall long-term objective to replace animal testing wherever possible and to move to new ways of improved safety assessment will eventually be shared by many of the Union’s trading partners, even though different regions may be at different steps of the process and the approaches to achieve the objective may differ.” It is “convinced that the issue of alternative test methods for cosmetics merits a prominent place on the EU’s trade and international cooperation agenda. It will endeavour to put these issues on the agenda of all relevant multi and bilateral meetings in the cosmetics field in 2013, notably with the United States and China, but also in contacts with Brazil and India. The Commission will in this effort look for synergies with the international initiatives of industry and animal welfare organisations”<sup>13</sup>.

Animal protection blogger Hans Gutbrod comments<sup>14</sup> on ‘expanding from the best constituency’: The EU ban is likely to have a global impact, “since global manufacturers will adapt to the rules of the world’s single largest market. The EU thus has an impact far beyond its borders”. Yet the data suggests that levels of concern about animal experimentation varied within the EU and “engaged countries seem to have brought others along”. In this way “Britain’s ban on testing cosmetics on animals in 1998, as well as a number of similar measures in other countries, helped to bring about a broader change across Europe and beyond. This particular trajectory of success may suggest that one lesson is to consolidate gains in constituencies amenable to change, before taking the policy gains to the next level, bringing along less active groups. Put differently, in pursuing transformative change, one powerful strategy may be going deep before you go wide”.

Two comparative initiatives by NGOs have taken the cruelty-free cosmetics message and the success of the EU-level lobbying to audiences, industry and governments around the world:

#### *Humane Society International’s (HSI) Be Cruelty-Free campaign:*

“Be Cruelty-Free was born from the recognition that the global nature of the cosmetics industry, coupled with differing regional regulatory requirements, necessitated a coordinated, multinational strategy, if a worldwide end to animal testing for cosmetics was to be achieved. In April 2012, HSI and its affiliates, in partnership with Lush and animal protection groups in

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<sup>13</sup> Communication from the Commission to the European Parliament and the Council on the animal testing and marketing ban and on the state of play in relation to alternative methods in the field of cosmetics. Brussels, 11.3.2013. [http://ec.europa.eu/consumers/sectors/cosmetics/files/pdf/animal\\_testing/com\\_at\\_2013\\_en.pdf](http://ec.europa.eu/consumers/sectors/cosmetics/files/pdf/animal_testing/com_at_2013_en.pdf)

<sup>14</sup> EU Bans Animal-Tested Cosmetics - What Can We Learn from Research? Hans Gutbrod, HRC 30.4.13 <http://www.humanespot.org/content/eu-bans-animal-tested-cosmetics-what-can-we-learn-research>



Australia, Brazil, Canada, India, Korea, New Zealand, Russia and the USA, launched Be Cruelty-Free, with the goal of making cruelty-free cosmetics the global mainstream by replicating the European animal testing and sales bans across all key global cosmetics markets.”<sup>15</sup>

Initiatives have involved:

- Participation in successful ban on cosmetics animal testing in India
- Influencing the revision of national cosmetics safety assessment guidelines in Brazil
- Provided funding for hands-on training to government regulators, and academia and industry scientists in China
- In South Korea, intensive political, regulatory and corporate engagement prompted the Ministry of Food and Drug Safety to announce a significant policy shift to formally recognise non-animal test results for assuring the safety of sunscreens, anti-wrinkle creams and other ‘functional’ cosmetics

*Cruelty Free International, an initiative of the BUAV:*

Also launched in 2012, CFI has partner organisations in 22 countries.

During 2013, CFI have:

- Met with regulatory authorities in China with the aim of gaining acceptance in China for alternatives to testing on animals
- Given a keynote speech at Asia’s premier cosmetics industry event attended by the region’s leading cosmetics industry and regulators Given a keynote speech to the North American Sustainable Cosmetics Summit in New York, highlighting the global trends in ending animal testing for cosmetics
- Presentation to Food and Drug Administration’s hearings on US policy in cosmetics regulation, urging it to follow Europe’s lead
- Funded non-animal alternatives in Vietnam, the only country of the 10 members of the Association of South East Asian Nations to actively test cosmetics on animals. CFI has provided a grant for a detailed scoping study by alternatives experts the Institute for In Vitro Sciences
- Met with Ministry of Health, the Food and Drug Administration and the Cosmetics Association in South Korea

#### 4.1.3 USA

In March 2014, Representative Jim Moran introduced the Humane Cosmetics Act (H.R. 4148) to ban the testing of cosmetics on animals<sup>16</sup>. This aims to not only end animal testing for cosmetics within the United States but also prohibit the sale of products that have been tested elsewhere, bringing the US in line with the European Union.

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<sup>15</sup> Humane Society International’s Global Campaign to End Animal Testing. Troy Seidle. ATLA 41, 453–459, 2013

<sup>16</sup> Cosmetics Regulation Reform in the United States. Physicians Committee for Responsible Medicine. <http://pcrm.org/research/animaltestalt/cosmetics/reform-the-safe-cosmetics-act>. Accessed 24.7.14

The bill would<sup>17</sup>:

- Within one year of enactment, prohibit the testing of cosmetic ingredients and final products on animals in the US
- Prohibit the export and import of animal tested cosmetics within three years of enactment

The Act has been backed by 133 companies and stakeholders in the cosmetics industry and Rep. Moran specifically thanked three NGOs for their “tremendous efforts” in supporting it: the Humane Society of the United States, Cruelty Free International, and the Coalition for Consumer Information on Cosmetics<sup>18</sup>.

The Safe Cosmetics and Personal Care Products Act 2013 was introduced early in March 2013 and is a repeat of attempts to introduce similar legislation in 2010 and 2011. The law, promoted by the Campaign for Safe Cosmetics, would give the Food and Drug Administration authority to ensure that all personal care products are free of harmful ingredients<sup>19</sup>.

Although the legislation is intended to ensure that cosmetic and personal care products are safe, concern has been expressed for some time that would increase animal testing<sup>20</sup>.

Following concerns raised during previous versions of the legislation, the Campaign for Safe Cosmetics has stated that it “supports uses of non-animal testing methods where available and effective, and fully supports initiatives to fund research on alternative, non-animal health and safety testing”<sup>21</sup>.

However, a peer-reviewed paper published in 2014<sup>22</sup> found that if the Safe Cosmetics and Personal Care Products Act was passed:

- Animal testing would surge: One million to 11.5 million animals would be subject to testing in the first 10 years
- Costs to businesses would be tremendous: Under the SCPCPA, cosmetic manufacturers and ingredient suppliers would likely pay \$1.7 - \$9 billion in 10 years to perform animal tests on cosmetic ingredients

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<sup>17</sup> Text of the Humane Cosmetics Act. <https://www.govtrack.us/congress/bills/113/hr4148/text>. Accessed 24.7.14

<sup>18</sup> Cosmetics Industry Leaders Back Moran Bill to End Animal Testing. 27.5.14. <http://moran.house.gov/press-release/cosmetics-industry-leaders-back-moran-bill-end-animal-testing>

<sup>19</sup> Campaign for Safe Cosmetics Press Release, 21.3.13. Toxic Chemicals in Cosmetics, Shampoos, Targeted by Congress

<sup>20</sup> The Leaping Bunny Program Has Serious Concerns about the Safe Cosmetics and Personal Care Products Act. Coalition for Consumer Information on Cosmetics Press Release, 14.5.13. <http://leapingbunny.org/press11.php>

<sup>21</sup> FAQs For Cosmetics Companies About The Safe Cosmetics And Personal Care Products Act Of 2013. <http://safecosmetics.org/article.php?id=695#animal-testing>. Accessed 24.7.14

<sup>22</sup> Knight, J. & Rovidia, C. Safety Evaluations under the Proposed US Safe Cosmetics and Personal Care Products Act of 2013: Animal Use and Cost Estimates. ALTEX. 2014;31(2):177-208

- Regulators would be overwhelmed with implementation: The SCPCPA requires new regulatory functions for the Food and Drug Administration to create priority lists for ingredient testing as well as oversee pre-market evaluation of new ingredients

Co-author of the paper, Jean Knight, states<sup>23</sup>, “In reading the Act, I was surprised to see that it would increase animal testing of cosmetics, since this is counter to the worldwide trend to reduce animal testing. The Act’s language can’t be easily understood unless you have some background in toxicology, so this impact was flying under the radar. Many Leaping Bunny [cruelty-free] certified companies were actually supporting the Act, unaware of the implications for animal testing. The article hopefully brings this information onto the radar so that people can make informed decisions.”

#### 4.1.4 China

China is the world’s fourth largest beauty market, worth an estimated US\$22 billion globally<sup>24</sup>.

Until recently China’s State Food and Drug Administration (SFDA) required animal toxicology test reports to be provided prior to licensing a new cosmetic ingredient<sup>25</sup>. This led to some multi-national cosmetic companies which had not tested on animals for two decades, such as Avon, Estée Lauder and Mary Kay, to animal test again in order to sell in China<sup>26</sup>.

Due to pressure not only from NGOs but also companies which have avoided animal testing for other markets, China began recognising test results that use alternatives to animal testing.

In 2011 the first congress on alternatives to animal testing for cosmetics in China, supported by major cosmetics companies<sup>27</sup>, was held. Scientists from the Institute for In Vitro Sciences continue to offer expertise and guidance in replacing animal-based tests, with financial support from PETA and HSI.

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<sup>23</sup> Study Finds Safe Cosmetics and Personal Care Products Act will result in an increase in animal testing. Coalition for Consumer Information on Cosmetics, 27 January 2014. <http://www.leapingbunny.org/press15.php>

<sup>24</sup> Be Cruelty-Free Campaign to End Cosmetics Animal Testing in China Launches with Pop Singer Wang Feifei, NGOs and Industry. 28.6.13. [http://www.hsi.org/news/press\\_releases/2013/06/bcf\\_china\\_launch\\_062813.html](http://www.hsi.org/news/press_releases/2013/06/bcf_china_launch_062813.html)

<sup>25</sup> Registration of New Cosmetic Ingredient with SFDA in China. Yunbo Shi, March 2012. Chemical Inspection and Regulation Service (CIRS). [http://www.cirs-reach.com/china\\_chemical\\_regulation/SFDA\\_Registration\\_of\\_New\\_Cosmetic\\_Ingredient\\_in\\_China.html](http://www.cirs-reach.com/china_chemical_regulation/SFDA_Registration_of_New_Cosmetic_Ingredient_in_China.html). Accessed 14.8.12

<sup>26</sup> Avon, Mary Kay, Estée Lauder Paying for Tests on Animals. Michelle Kretzer, 16.2.12. <http://www.peta.org/b/thepetafiles/archive/2012/02/16/3-companies-booted-off-cruelty-free-list.aspx>

<sup>27</sup> First congress on alternatives to animal testing in China. 8 March 2011. <http://www.premiumbeautynews.com/en/First-congress-on-alternatives-to-2812?checklang=1>

The BUAV-led Cruelty Free International established the 'China Task Force' with leading companies, the cosmetics industry and regulators to gain acceptance in China for non-animal testing methods.

From 30 June 2014 animal testing for ordinary cosmetics (including make-up, fragrances, skin, hair and nail care products) produced and sold inside China will no longer have to be animal tested. 'Special-use' cosmetics, including hair dyes, deodorants and sunscreens, still require animal testing as do foreign imported ordinary cosmetics<sup>28</sup>.

The next phase in the campaign is to see the rule change applied to foreign imported cosmetics as well.

HSI's Be Cruelty-Free campaign notes that although animal testing has not yet been banned in China, the changes are "very important, because it demonstrates that the Chinese government is receptive to moving away from animal testing. Change in China will inevitably be incremental, rather than sweeping changes. But this is the very first time in more than 20 years that China has made a major change to its cosmetics regulation. Seen within the global context of a general shift away from animal testing, it is important that we acknowledge this as a first step in a multi-step journey towards ending cosmetics cruelty in China"<sup>29</sup>.

#### 4.1.5 India

In May 2014 India becomes South Asia's first country to end cosmetics testing on animals<sup>30</sup>.

Following campaigns by a number of NGOs, the Drug Controller General of India announced in June 2013 that the testing of cosmetics and their ingredients on animals will no longer be permitted. The announcement was made during the Bureau of Indian Standards PCD 19 Cosmetics Sectional Committee meeting, on which PETA India has an official seat.

The test ban was finalised when the Drugs and Cosmetics Rules (Second Amendment) 2014 was notified through Gazette no: 346 (E), following completion of a 45 day public

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<sup>28</sup> China Implements Rule Change in First Step Towards Ending Animal Testing of Cosmetics. Humane Society International, 30 June 2014. [http://www.hsi.org/news/press\\_releases/2014/06/china-implements-rule-change-063014.html](http://www.hsi.org/news/press_releases/2014/06/china-implements-rule-change-063014.html)

<sup>29</sup> Fast Facts on China & Cosmetics Animal Testing. HSI. [www.hsi.org/assets/pdfs/bcf\\_china\\_fast\\_facts.pdf](http://www.hsi.org/assets/pdfs/bcf_china_fast_facts.pdf). Accessed 30.7.14

<sup>30</sup> Historic Milestone Celebrated as India Finalises Cosmetics Animal Testing Ban. Humane Society International, 23 May 2014. <http://www.hsi.org/world/india/news/releases/2014/05/india-bans-cosmetics-animal-testing-052314.html>

consultation<sup>31</sup>. The ban states that no cosmetic which has been tested on animals in the country will be allowed to be sold<sup>32</sup>.

However, the ban will not prevent companies from importing and selling animal-tested cosmetics in India. The Ministry of Health and Family Welfare issued a draft proposal in June 2014 to end the import of cosmetics newly tested on animals abroad<sup>33</sup>. At the time of compiling this report, the proposal was still undergoing public consultation.

More than 30 members of parliament, legislative assemblies and legislative councils backed the HSI Be Cruelty-Free campaign, led by Mrs. Maneka Sanjay Gandhi along with other policy makers and Bollywood celebrities<sup>34</sup>.

PETA India won the 2012 Lobbying Prize for its work on ending animal testing of cosmetics in the country.

#### 4.1.6 Brazil

The Brazilian cosmetics market is the fastest growing in the world<sup>35</sup> but the country's national guidelines still recommends a series of tests on animals for the safety evaluation of new cosmetics products and ingredients. The National Agency for Sanitary Surveillance (ANVISA) continues to rely heavily on toxicity tests using rabbits, guinea pigs and other animals to assess the safety of ingredients and even some finished products<sup>36</sup>.

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<sup>31</sup> Historic Milestone Celebrated as India Finalises Cosmetics Animal Testing Ban. Humane Society International, 23 May 2014. <http://www.hsi.org/world/india/news/releases/2014/05/india-bans-cosmetics-animal-testing-052314.html>

<sup>32</sup> Govt bans animal-tested cosmetics. Rupali Mukherjee. The Times of India, 22 January 2014. <http://timesofindia.indiatimes.com/india/Govt-bans-animal-tested-cosmetics/articleshow/29218436.cms>

<sup>33</sup> More than 70,000 Be Cruelty-Free Petitioners Support India's Proposed Import Ban on Animal Tested Cosmetics. Humane Society International, 18 June 2014. <http://www.hsi.org/world/india/news/releases/2014/06/india-bcf-70k-petition-handover-061814.html>

<sup>34</sup> Historic Milestone Celebrated as India Finalises Cosmetics Animal Testing Ban. Humane Society International, 23 May 2014. <http://www.hsi.org/world/india/news/releases/2014/05/india-bans-cosmetics-animal-testing-052314.html>

<sup>35</sup> HSI asks the Brazilian government ban on animal testing for cosmetics. 11.3.13. [http://www.hsi.org/portuguese/news/press\\_releases/2013/03/enquete\\_cosmeticos\\_portuguese\\_031113.html](http://www.hsi.org/portuguese/news/press_releases/2013/03/enquete_cosmeticos_portuguese_031113.html)

<sup>36</sup> Rabbits and rodents of HSI and ProAnima visit the Ministry of Health to ask that the government put an end to animal testing for cosmetics in Brazil. 13.3.13. [http://www.hsi.org/portuguese/news/press\\_releases/2013/03/bcfw\\_anvisa\\_031313.html](http://www.hsi.org/portuguese/news/press_releases/2013/03/bcfw_anvisa_031313.html)

Humane Society International (HSI) has been active on the issue through its Brazil office, conducting a number of public awareness campaigns involving celebrities<sup>37</sup> and working with scientists to establish non-animal testing methods<sup>38</sup>.

A major boost came in January 2014 when the Governor of the State of São Paulo signed a bill prohibiting cosmetics testing on animals in the state, which hosts more than 700 of the 2,300 cosmetics companies in the country. It is the first state to issue a ban on cosmetics animal testing. It also covers both finished products and ingredients<sup>39</sup>.

In June 2014 a bill was passed which will ban the use of animals in tests for cosmetics where alternatives have already been established. Alternatives which have been approved internationally will be accepted. Animal testing will still be allowed for novel ingredients developed for use in cosmetics, but, according to Cruelty-Free International “even this will be prohibited after an alternative method has been established or in 5 years, whichever happens first”<sup>40</sup>.

Although it seeks to prohibit animal testing of most cosmetic ingredients and products, a compromise agreement means it doesn’t include ‘ingredients with unknown effects’ or prohibit the sale of newly animal-tested cosmetics (meaning companies could still test their cosmetics on animals abroad and sell them back in Brazil).

The Be Cruelty-Free Brazil campaign, led by Humane Society International and supported by ProAnima, ARCA Brasil and the Forum Nacional de Proteção e Defesa Animal, has resulted<sup>41</sup> in:

- More than 150 federal parliamentarians signing the Be Cruelty-Free pledge
- Presenting the Conselho Nacional de Controle de Experimentação Animal with the first ever-technical report proposing a ban on animal testing for cosmetics
- Celebrities Fernanda Tavares, Giselle Itie and Fiorella Mattheis starring in the Be Cruelty-Free video appeal
- Presenting the Ministry of Science, Technology & Innovation with tens of thousands of petition signatures from Brazilian citizens in favour of a ban

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<sup>37</sup> Brazilian Supermodel Fernanda Tavares Says "No" to Cosmetics Animal Testing. 18.12.13. [http://www.hsi.org/news/press\\_releases/2013/12/fernanda-tavares-cruelty-free-121813.html](http://www.hsi.org/news/press_releases/2013/12/fernanda-tavares-cruelty-free-121813.html)

<sup>38</sup> HSI's Work in Brazil to Promote Non-Animal Testing. HSI, 15.12.11. [http://www.hsi.org/news/news/2011/12/brazil\\_cosmetics\\_121511.html](http://www.hsi.org/news/news/2011/12/brazil_cosmetics_121511.html)

<sup>39</sup> São Paulo Bans Cosmetics Animal Testing. 24.1.14. [http://www.hsi.org/news/press\\_releases/2014/01/saopaulo-cosmetics-testing-ban-012414.html](http://www.hsi.org/news/press_releases/2014/01/saopaulo-cosmetics-testing-ban-012414.html)

<sup>40</sup> Breaking News: Brazil bans most animal testing for cosmetics! Cruelty-Free International, 5 June 2014. <http://www.crueltyfreeinternational.org/en/a/Breaking-News-Brazil-bans-most-animal-testing-for-cosmetics>

<sup>41</sup> Be Cruelty-Free Brazil Welcomes Historic Bill to Ban Cosmetics Animal Testing but Warns Urgent Improvements Needed to Close Loopholes. Humane Society International, 5 June 2014. [http://www.hsi.org/news/press\\_releases/2014/06/brazil-bans-animal-cosmetics-testing-060514.html](http://www.hsi.org/news/press_releases/2014/06/brazil-bans-animal-cosmetics-testing-060514.html)

HSI Brazil was shortlisted for the 2013 Lobbying prize for their work which led to the inclusion of animal-free testing methods in national cosmetic safety guidelines.

190,000 Brazilian's signed a Cruelty-Free International petition supporting a testing ban<sup>42</sup>.

#### 4.1.7 Other countries

New Zealand:

HSI and SAFE, working jointly through the Be Cruelty-Free project, have lobbied and raised awareness about animal testing of cosmetics. In March 2014 Green Party MP Mojo Mathers introduced a Supplementary Order Paper in Parliament seeking to ban cosmetics animal testing as part of the Animal Welfare Amendment Bill<sup>43</sup>. However, so far the governing National Party has rejected the amendments on the grounds that "more time" is needed to consider the implications<sup>44</sup>.

The Labour Party has joined the Greens in pledging to ban the marketing of animal tested cosmetics in NZ<sup>45</sup>.

This follows a high-profile two year campaign by Be Cruelty-Free New Zealand, led by SAFE and HSI. A letter to the Prime Minister John Key was signed by 28 cruelty-free cosmetics companies; a nationwide advertising campaign urged Key to 'Hop To It'; a 15,500-strong petition was handed in to Parliament; and there was celebrity support from the likes of Kiwi actress Michelle Langstone<sup>46</sup>.

Australia:

The Labor Party opened a public consultation in May 2014 on animal testing for cosmetics. This follows Labor's pledge during the last election to bring such testing to an end. The Government is currently neutral on the issue<sup>47</sup>.

Vietnam:

The Vietnamese Government announced, in May 2014, that it will ban the use of the cruel Draize rabbit eye test for cosmetics. According to Cruelty-Free International, they negotiated the ban at the conclusion of a training programme they funded at the Institute of Drug

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<sup>42</sup> Breaking News: Brazil bans most animal testing for cosmetics! Cruelty-Free International, 5 June 2014. <http://www.crueltyfreeinternational.org/en/a/Breaking-News-Brazil-bans-most-animal-testing-for-cosmetics>

<sup>43</sup> NZ poised to ban cosmetic testing on animals. SAFE, 20 March 2014. <http://www.scoop.co.nz/stories/PO1403/S00247/nz-poised-to-ban-cosmetic-testing-on-animals.htm>

<sup>44</sup> New Zealand delays progress on animal testing. Cruelty Free International, 27 June 2014. <http://www.crueltyfreeinternational.org/en/a/New-Zealand-delays-progress-on-animal-testing>

<sup>45</sup> Cosmetics tested on animals would be banned under Labour. Isaac Davison. NZ Herald, 16 July 2014. [http://www.nzherald.co.nz/nz/news/article.cfm?c\\_id=1&objectid=11294596](http://www.nzherald.co.nz/nz/news/article.cfm?c_id=1&objectid=11294596)

<sup>46</sup> Be Cruelty-Free New Zealand Welcomes Labour Pledge to Ban Cosmetics Animal Testing. Humane Society International/SAFE. 16 July 2014. [http://www.hsi.org/news/press\\_releases/2014/07/bcf-new-zealand-labour-party-071614.html](http://www.hsi.org/news/press_releases/2014/07/bcf-new-zealand-labour-party-071614.html)

<sup>47</sup> Cruelty Free International backing Australian initiatives. Cruelty Free International, 8 May 2014. <http://www.crueltyfreeinternational.org/en/a/Cruelty-Free-International-backing-Australian-initiatives>

Quality Control in Vietnam. The Department of Drug Administration and the Vietnam Pharmacopeia also agreed to expand cooperation with CFI to move towards official validation of the humane alternative methods<sup>48</sup>.

## 4.2 REACH

REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) is the European Community Regulation on chemicals and their safe use (EC 1907/2006) which entered into force in 2007. Its aim is “to improve the protection of human health and the environment through the better and earlier identification of the intrinsic properties of chemical substances”.<sup>49</sup>

REACH requires manufacturers and importers to collate information on the properties of all chemicals sold in the EU in annual quantities of more than one tonne, and to register the information, along with toxicity data, in a central database run by the European Chemicals Agency (ECHA) by 2018.

Many of the testing methods specified by REACH use animals. Toxicity tests usually involve the poisoning of guinea pigs, rabbits, fish, birds, rats and mice<sup>50</sup>. The total numbers of animals who could be used in testing have been estimated to be as high as 54 million and to cost €9.5 billion<sup>51</sup>.

The ECHA tri-annual report published in June 2014 revealed, although the use of non-animal alternatives has apparently increased since the last report in 2011, the number of new animal tests conducted since 2009 has at least doubled from 1,849 to 4,887<sup>52</sup>. According to the European Coalition to End Animal Experiments (ECEAE)<sup>53</sup>: “As the number of substances registered has nearly doubled since this time, the report in fact shows little change in animal use by the chemical industry.”

The ECEAE state:

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<sup>48</sup> Vietnam agrees to ban cruel rabbit eye tests thanks to Cruelty Free International. 19 May 2014. <http://www.crueltyfreeinternational.org/en/a/Vietnam-agrees-to-ban-cruel-rabbit-eye-tests-thanks-to-Cruelty-Free-International>

<sup>49</sup> REACH. European Commission 6.6.12 (last updated). [http://ec.europa.eu/environment/chemicals/reach/reach\\_intro.htm](http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm) Accessed 15.8.12

<sup>50</sup> REACH. <http://www.eceae.org/en/what-we-do/campaigns/reach>. ECEAE. Accessed 15.8.12

<sup>51</sup> Opinion: Chemical regulators have overreached. Thomas Hartung & Costanza Rovida. Nature 460, 1080-1081. <http://www.nature.com/nature/journal/v460/n7259/full/4601080a.html>

<sup>52</sup> The Use of Alternatives to Testing on Animals for the REACH Regulation. Second report under Article 117(3) of the REACH Regulation. European Chemicals Agency, 2014. [http://www.echa.europa.eu/documents/10162/13639/alternatives\\_test\\_animals\\_2014\\_en.pdf](http://www.echa.europa.eu/documents/10162/13639/alternatives_test_animals_2014_en.pdf)

<sup>53</sup> Animal tests double under REACH - more promotion and use of alternatives urgently needed. BUAV, 6 June 2014. <http://www.buav.org/article/1571/animal-tests-double-under-reach---more-promotion-and-use-of-alternatives-urgently-needed>



- “There has been a doubling of the number of new animal tests done, an increase from 1,849 to 4,887 animal tests, using an estimated minimum of 700,000 animals. There has been a doubling of animal testing in most cases but a trebling (or more) for some of the higher tier animal tests such as reproductive toxicity tests”
- “There is still an unacceptably high number of new animal tests that were done without going through the proper consultation process (the testing proposal process in which both third parties and member states have an opportunity to provide input before a decision on the test is made). ECHA found 293 such new animal tests”
- “Some companies are still conducting new rabbit skin and eye irritation tests. There were 188 new skin irritation tests and 363 new eye irritation tests. Although ECHA report that there has been an increase in the number of registrations including in vitro data, the proportion of dossiers using new animal data has not changed. There are alternatives for these two tests so any new animal test is completely unacceptable”

The BUAV and PETA have both criticised the relatively low number (7%) of skin sensitisation tests that are done using validated in vitro tests<sup>54</sup>. They say that up to 200,000 animals may be used ‘unnecessarily’ because guidance on alternative methods for this endpoint would not be available until 2018.

The ECHA has also come under fire from the UK Chemicals Stakeholder Forum (UKCSF), which has accused the ECHA’s attitude of leading to unnecessary animal testing and called on it to “review its messages and practices on acceptance of alternative methods to ensure it is maintaining a positive stance”<sup>55</sup>.

Revealing the necessity for lobbying efforts to encourage regulatory bodies to greater understand and accept non-animal testing methods, Forum member David Taylor of the Royal Society of Chemistry said: “We still find clients who are very reluctant to undertake alternatives to animal testing when registering a substance simply because of the uncertainty – they don’t know if ECHA will agree with it. However, they know that if they carry out the animal test, ECHA will say yes.”

Dr Katy Taylor of the BUAV, another Forum member, added that the issue was largely due to the volume of substances being registered under REACH. “The problem is the sheer number of chemicals because, for example, in the pharmaceuticals sector you have the opportunity to discuss your approach with the European Medicine Agency, which seems more sensible. Before they do a test they tell the agency [EMA] what tests they’re carrying out and ask for its opinion,” she said.

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<sup>54</sup> REACH sees use of alternative test methods increasing. Leigh Stringer. Chemical Watch, 3 June 2014. <http://chemicalwatch.com/20018/reach-sees-use-of-alternative-test-methods-increasing>

<sup>55</sup> Unnecessary animal testing continuing under REACH, says UK forum. Leigh Stringer. Chemical Watch, 25 July 2014. <http://chemicalwatch.com/20697/unnecessary-animal-testing-continuing-under-reach-says-uk-forum>

NGO focus on REACH has been far more on lobbying that general public awareness and has helped to significantly reduce the number of animals used in testing. Lobbying efforts resulted in a number of changes being made to REACH<sup>56</sup>:

- Mandatory sharing of animal test data: Companies registering the same chemical are obliged to share their data and, if animal testing is required by REACH, the tests will only be done by one of the registrants. Duplicate animal testing should thus be prevented.
- For some chemicals approval must be given by the ECHA before new animal tests can be performed. The public and NGOs have 45 days during which to comment, challenge the need for the tests, or suggest alternatives.
- Alternatives to animal testing are strongly promoted throughout the REACH text which stresses that animal testing must only be undertaken as a last resort.

The European Coalition to End Animal Experiments (ECEAE) is one NGO coalition that has been particularly active on REACH. It has a stakeholder seat, shared with Eurogroup for Animals, at the European Commission's REACH committee, CARACAL. The Competent Authorities for REACH and CLP (CARACAL) committee is an expert group that advises the European Commission and the European Chemicals Agency<sup>57</sup>.

The ECEAE also has a stakeholder seat at the ECHA's (European Chemicals Agency) Biocides Products Committee (BPC), established in 2013, which has an important role in the approval of biocidal products. The ECEAE will attend BPC meetings to verify that animal tests are used only as a last resort and that existing data (where products have already been tested) is shared in order to avoid the need for new animal tests<sup>58</sup>.

The ECEAE's scientific team comment on proposals submitted to REACH in an effort to reduce the number of animals used in chemical testing. Following submissions by the ECEAE, animal tests for substances have been either rejected by the European Chemicals Agency (ECHA) or withdrawn by the company involved, saving thousands of animals<sup>59</sup>.

Although the ECEAE is led by the UK-based BUAV, other members have had a role in moving forward the coalition's campaign on REACH. For example, German NGO Animal 2000 pays the salary for a toxicologist to work for the ECEAE and provide evidence to reduce the number of animals that are used due to the REACH Directive<sup>60</sup>.

In June 2014, the BUAV's Head of Science gave a presentation to ECHA staff on behalf of the ECEAE in which she explained that the ECEAE 'was disappointed with the Agency's

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<sup>56</sup> REACH – the new EU chemicals law: An RSPCA information paper. <http://www.rspca.org.uk/ImageLocator/LocateAsset?asset=document&assetId=1232712121563&mode=prd>. Accessed 15.8.12

<sup>57</sup> ECEAE gains seat at CARACAL, the EU REACH advisory group. 12.11.12  
<http://www.buav.org/article/1132/eceae-gains-seat-at-caracal-the-eu-reach-advisory-group>

<sup>58</sup> BUAV attends first Biocides Products Committee meeting in Helsinki. 31.5.13  
<http://www.buav.org/article/1268/buav-attends-first-biocides-products-committee-meeting-in-helsinki>

<sup>59</sup> REACH. <http://www.eceae.org/en/what-we-do/campaigns/reach> Accessed 7.3.14

<sup>60</sup> REACH - Toxicologist saves lives. Focus, Winter 2011/2012. <http://www.animal2000.de/wp/kampagnen/reach/>

current laissez-faire attitude to animal welfare' and how NGOs had had high expectations that animal testing under REACH would be kept to a minimum by industry and the Agency<sup>61</sup>.

Another coalition working on chemical testing issues is the International Council on Animal Protection in OECD Programmes (ICAPO), comprising of 11 NGOs from North America, Europe and Japan. It has held official status as 'invited experts' at certain OECD programmes since 2002<sup>62</sup>.

ICAPO works to incorporate non-animal testing methods into the activities of the OECD, an economic alliance of the world's industrialised countries. The OECD co-ordinates the development of standardised chemical testing guidelines, which are then adopted by the member countries. It also co-ordinates the development of chemical testing programmes, such as its current programme on endocrine disruptors.

ICAPO has financially supported the attendance of IIVS (the Institute for In Vitro Sciences) and other experts to numerous OECD expert meetings, including those focused on the adoption of in vitro methods for skin irritation, eye irritation, carcinogenicity, genetic toxicity, and for (Q)SAR methods. Their internal experts also attend other expert meetings related to endocrine disruption, inhalation toxicity, and nanomaterials, for example.

ICAPO contributes to a majority of test guidelines and guidance documents, ensuring that those that involve animals use the minimum number of animals and are written to ameliorate some of the most cruel laboratory procedures.

This coalition was the main winner of the lobbying award in the 2013 Lush Prize. The second winner was Forska Utan Djurförsök (the Swedish Fund for Research Without Animal Experiments<sup>63</sup>), for its work with Swedish regulators to replace animal testing and lobbying for Sweden to establish a centre for alternatives to animal testing.

Since January 2013 the Fund has been represented on the Board of Agriculture's National Committee for the protection of animals used in experiments and was appointed by the government as member of the newly formed Central Animal Research Ethical Review Board. The Central board serves as the appeal board in respect to the local ethics committees that approves or rejects applications to use animals in research. It will also be responsible for retrospective assessments of animal experiments, as required in the EU Directive (2010/63/EU) on the protection of animals used for scientific purposes.

### 4.3 Individual species

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<sup>61</sup> BUAV's Dr Katy Taylor presents at European Chemicals Agency on behalf of the European Coalition. BUAV, 13 June 2014. <http://www.buav.org/article/1577/buavs-dr-katy-taylor-presents-at-european-chemicals-agency-on-behalf-of-the-european-coalition>

<sup>62</sup> ICAPO. <http://www.icao.org/> Accessed 7.3.14

<sup>63</sup> [www.forskautandjurforsok.se](http://www.forskautandjurforsok.se)

Whilst several NGOs have highlighted the plight of specific species in labs, usually to gain awareness and support for wider anti-vivisection campaigns, most of these have not had much, or any, lobbying aspects.

Given that dogs and cats are such popular companion animals in many countries, it is no surprise that they are also high profile species for anti-vivisection campaigners.

Across the United States, nearly 65,000 dogs (most of them beagles) are used in labs. The Beagle Freedom Project was founded in 2010 to rehome dogs from labs after they are no longer being used in experiments. They have since rehomed many beagles, cats, rabbits and other animals, with a hugely successful and popular public awareness campaign.

BFP's lobbying work has resulted, in May 2014, Minnesota becoming the first state in the U.S. and first political body in the world to mandate that dogs and cats in labs be adopted when the research is over. "If a dog or cat is used in a tax-payer funded research experiment and is healthy at its end the lab must offer them up to public adoption through a rescue organization like Beagle Freedom Project. No federal or state laws offer any protection to these animals when the research is over and the standard operating procedure for most labs was to summarily euthanize them."<sup>64</sup>

The passing of this legislation took two legislative sessions, thousands of constituent emails, letters, phone calls, and personal visits to the Capitol. "Complimenting this effort was the public ambassador work performed by all the freed beagles living in Minnesota demonstrating they are not test subjects, but wonderful family companions." Public and media awareness events helped to get this law passed.

This legislation is currently being pursued in California and New York and more states in 2015

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<sup>64</sup> The Beagle Freedom LAW! Beagle Freedom Project, 20 May 2014. [http://www.beaglefreedomproject.org/the\\_beagle\\_freedom\\_law](http://www.beaglefreedomproject.org/the_beagle_freedom_law)

## 5 Regulatory acceptance of non-animal tests

### 5.1 Introduction

Validation is a normal procedure in all fields of science, once a test is developed. The validation process is intended to provide confidence in the results and to define where the test may or may not be applied<sup>65</sup>.

Although non-animal tests have been used for some time, regulatory acceptance has sometimes been a problem and animal tests may be used to 'validate' them (despite the accepted problem of species difference). Scientists from the Center for Alternatives to Animal Testing (CAAT) have stated<sup>66</sup>: "One of the arguments is that animal experiments may not be suitable as a gold standard as they do not correlate well enough with human data."

A recent book on 3Rs in toxicity testing provides a useful outline of the regulatory acceptance of non-animal test methods<sup>67</sup>:

- "Validation needed to be followed by a declaration of regulatory acceptance by the relevant government agencies, as a way of encouraging industry to use the validated tests and submit data based on them"
- "Most of the assessments of validation status and regulatory acceptance have occurred since 2000, following the establishment of key alternatives centres and the development of the principles and procedures of validation and regulatory acceptance"
- "The bulk of this effort has been invested in replacement alternatives (full or partial), with acute systemic toxicity and skin sensitization being notable exceptions. This activity has been driven, in part, by the ban on animal testing for cosmetic ingredients, pursuant to the European Cosmetics Directive"
- "Much of what we might term 'toxicological space' has been touched by alternative methods. This is especially true for acute toxicity endpoints, where replacement alternatives have become available for skin penetration, skin corrosion, skin irritation, and phototoxicity. However, the challenge of replacing animal use for chronic endpoints is much more formidable"
- "Validation and regulatory acceptance of new methods do not necessarily ensure full implementation of those methods in all cases, so the degree of implementation and

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<sup>65</sup> Leist, M., Hasiwa, N., Daneshiana M. & Thomas Hartung, T. Validation and quality control of replacement alternatives – current status and future challenges. *Toxicol. Res.*, 2012,1, 8-22

<sup>66</sup> Leist, M., Hasiwa, N., Daneshiana M. & Thomas Hartung, T. Validation and quality control of replacement alternatives – current status and future challenges. *Toxicol. Res.*, 2012,1, 8-22

<sup>67</sup> Stephens, M.L. & Mak, N.S. History of the 3Rs in Toxicity Testing: From Russell and Burch to 21st Century Toxicology. In: *Reducing, Refining and Replacing the Use of Animals in Toxicity Testing* (Ed. Allen, D. & Waters, M.D.) RSC Publishing, 2014

any barriers to implementation would need to be addressed in a more definitive analysis of the impact of alternative methods on toxicology”

According to CAAT<sup>68</sup>: “The field of cosmetics is a good example for progress in establishment and validation of alternative methods: replacement methods for some toxicological domains have been validated. [...] refinement/reduction methods are also available for acute oral toxicity [...]. Many of these tests have been accepted by the OECD, and some have substituted the corresponding animal experiments to a large extent.”

## 5.2 Examples of recent lobbying of regulators

Organisations such as CAAT (Center for Alternatives to Animal Testing) and IIVS (Institute for In Vitro Sciences) conduct lobbying work, persuading regulatory bodies to accept non-animal tests, as part of their scientific outreach around the world.

Examples of recent work include:

### 5.2.1 CAAT<sup>69</sup>

CAAT’s policy program aims:

- to serve as a voice of humane science to policy makers
- to create a legislative and policy culture that values the lives of animals;
- to serve as information hub for policy makers on the availability and feasibility of alternative approaches
- to bring policy makers in contact with scientists that have progressed the field of Tox-21c

Recent achievements:

- Facilitating contact between Members of European Parliament and the corresponding national 3Rs scientists or regulators (e.g. Finland, Greece, Austria, Monaco, Norway and Czech Republic).
- More than 100 face-to-face meetings with officials from the European Parliament since the creation of the policy program (MEPs, policy advisers from the political groups)

### 5.2.2 IIVS<sup>70</sup>

The IIVS International Outreach Program (IOP) provides proactive training of regulators and industry scientists, and works to alleviate barriers associated with the adoption of non-animal methods. IIVS staff meet with scientists, regulators and other key stakeholders within countries to identify obstacles that stand in the way of implementing non-animal methods in safety assessment.

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<sup>68</sup> Leist, M., Hasiwa, N., Daneshiana M. & Thomas Hartung, T. Validation and quality control of replacement alternatives – current status and future challenges. *Toxicol. Res.*, 2012,1, 8-22

<sup>69</sup> *Pers. Corresp.* 23 July 2014

<sup>70</sup> *Pers. Corresp.* 18 July 2014

IVS staff met with law makers in Japan and Taiwan to discuss the current international regulatory status of in vitro methods and how they can be incorporated into a regulatory framework.

## 6 Who is active in the sector? NGOs active in lobbying to end animal testing

The table below lists groups across the world currently active in the area of lobbying against animal testing. The list is certainly not comprehensive. Attempts have been made to include a range of organisations, from grass-roots volunteer-led groups to international, well-funded NGOs. Attention has also been paid to NGOs in ‘emerging’ countries where the demand for consumer products is increasing. This research has been largely web-based and although effort has been put into researching websites in many different languages, we are aware that not all NGOs will have websites, that information available on websites will in some cases be limited and that there will be other effective NGOs which have been missed during our research.

	Organisati on	Campaign	Phone	Email / web
	<b>Australia</b>			
1	Choose Cruelty Free	“An independent, non-profit organisation which actively promotes a cruelty-free lifestyle.” Surveys and accredits companies not testing on animals	+61 39328 1377	<a href="mailto:admin@choosecrueltyfree.org.au">admin@choosecrueltyfree.org.au</a>  <a href="http://www.choosecrueltyfree.org.au">www.choosecrueltyfree.org.au</a>
2	Replace Animals in Australian Testing	Based at University of Wollongong. Aims to "create a network of researchers and other individuals or groups interested in advocating non-animal based research and in strengthening the Australian Government/ NHMRC guidelines and their enforcement"	+61 24221 3387	Dr Denise Russell: <a href="mailto:deniser@uow.edu.au">deniser@uow.edu.au</a>  <a href="http://www.uow.edu.au/arts/research/raat/index.html">www.uow.edu.au/arts/research/raat/index.html</a>
3	Humane Research Australia	“Challenges the use of animals in research and promotes the use of more humane and scientifically-valid non animal methodologies”	+61 38823 5704	<a href="mailto:info@humaneresearch.org.au">info@humaneresearch.org.au</a>  <a href="http://www.humaneresearch.org.au">www.humaneresearch.org.au</a>
	<b>Austria</b>			



	Organisation	Campaign	Phone	Email / web
1	International Bund der Tierversuchsgegner / Ein Recht für Tiere (Rights for Animals)	Animal testing. Long term lobbying on issues such as REACH	+43 1713 08230	<a href="mailto:tierversuchsgegner@chello.at">tierversuchsgegner@chello.at</a>  <a href="http://www.tierversuchsgegner.at">www.tierversuchsgegner.at</a>
	<b>Belgium</b>			
1	Eurogroup for Animals	Various animal protection: animal testing; farmed animals; wildlife; companion animals; EU & animal welfare	+32 2740 08 20	<a href="mailto:info@eurogroupforanimals.org">info@eurogroupforanimals.org</a>  <a href="http://www.eurogroupforanimals.org">www.eurogroupforanimals.org</a>
	<b>Brazil</b>			
1	Humane Society International	Be Cruelty Free campaign	+55 (21) 8342-4163	Helder Constantino: <a href="mailto:hconstantino@hsi.org">hconstantino@hsi.org</a>  <a href="http://www.hsi.org/world/brazil">www.hsi.org/world/brazil</a>
	<b>China</b>			
1	Humane Society International	2013 launched Be Cruelty Free campaign in China with Chinese NGOs and academic scientists. HSI launched an \$80,000 partnership with the Institute for In Vitro Sciences to provide Chinese scientists with hands-on training using advanced non-animal methods.	China mobile: + 86 137189146 49	Peter Li, China Policies Specialist: <a href="mailto:pli@hsi.org">pli@hsi.org</a>
	<b>Europe</b>			

	Organisation	Campaign	Phone	Email / web
1	Stop Vivisection	A Citizens Initiative to end animal experiments. Committee includes scientists, activists and politicians.		<a href="mailto:representative.stopvivisection@gmail.com">representative.stopvivisection@gmail.com</a> <a href="http://www.stopvivisection.eu">www.stopvivisection.eu</a>
2	European Coalition to End Animal Experiments (ECEAE)	A coalition of 19 European NGOs active on all issues relating to animal testing. Particularly campaigning on REACH	+44 (0) 20 7700 4888	<a href="mailto:info@eceae.org">info@eceae.org</a> <a href="http://www.eceae.org/en">www.eceae.org/en</a>
	<b>France</b>			
1	The Anti-Vivisection Coalition France (CAV)	International Toxicology Center switch to non-animal testing; Stop Huntingdon Animal Cruelty; air transport of animals for labs		<a href="mailto:info@cav.asso.fr">info@cav.asso.fr</a> <a href="http://www.cav.asso.fr/en">www.cav.asso.fr/en</a>
	<b>Germany</b>			
1	Deutscher Tierschutzbund e.V. (German Animal Welfare Association)	Various animal protection: animal testing; animal circuses; factory farming; hunting. ECEAE member. Lobbied actively to end animal testing under REACH.		<a href="http://www.tierschutzbund.de">www.tierschutzbund.de</a>
2	Animal2000	Various animal protection: animal testing; rodeos; bullfighting; hunting Pays the salary of a toxicologist who works on behalf of ECEAE to oppose animal testing under REACH.	+49 89-5 46 90 50	<a href="http://www.animal2000.de">www.animal2000.de</a>

	<b>Organisation</b>	<b>Campaign</b>	<b>Phone</b>	<b>Email / web</b>
3	Ärzte gegen Tierversuche e.V. (Doctors Against Animal Experiments)	<p>“We are a charitable organisation of several hundred doctors and scientists who work in the medical field. We support the immediate abolition of all animal experiments on ethical and scientific grounds.”</p> <p>ECEAE member</p> <p>The NGO’s toxicologist works to prevent animal testing under REACH by submitting scientific evidence.</p>	+ 49 89 - 35 99 349	<a href="mailto:info@aerzte-gegen-tierversuche.de">info@aerzte-gegen-tierversuche.de</a>  <a href="http://www.aerzte-gegen-tierversuche.de">www.aerzte-gegen-tierversuche.de</a>
	<b>India</b>			
1	Humane Society International	Be Cruelty-Free campaign for marketing ban on animal-tested cosmetics in India.	+91 9849094113	<p>Alokparna Sengupta:  <a href="mailto:asengupta@hsi.org">asengupta@hsi.org</a>   <a href="http://www.hsi.org/world/india/work/end_animal_testing/be_cruelty_free/be_cruelty_free.html">www.hsi.org/world/india/work/end_animal_testing/be_cruelty_free/be_cruelty_free.html</a> </p>
2	People For Animals	Cruelty Free International partner. PFA members are board members of every Laboratory Ethics Committee.	+91 - 11 - 23357088	<a href="http://www.peopleforanimalsindia.org">www.peopleforanimalsindia.org</a>
3	PETA India	Lobbying and public awareness to help achieve ban on animal testing of cosmetics. Now working to prevent products animal tested elsewhere from being marketed in India.	+91 22-4072 7382	<a href="mailto:Info@petaindia.org">Info@petaindia.org</a>  <a href="http://www.petaindia.com">www.petaindia.com</a>
	<b>Israel</b>			

	<b>Organisation</b>	<b>Campaign</b>	<b>Phone</b>	<b>Email / web</b>
1	Israeli Society for the Abolition of Vivisection Society (ISAV)	General anti-vivisection campaigns. Successfully lobbied against Ministry of Health's ban on cruelty-free products using 'bunny' logo	+972 76-540325 7	<a href="mailto:isav@isav.org.il">isav@isav.org.il</a> <a href="http://www.isav.org.il">www.isav.org.il</a>
	<b>Japan</b>			
1	Japan Anti-Vivisection Association (JAVA)	Lobbying for end of animal testing as Asian representative member of ICAPO (International Council on Animal Protection in OEC programmes); Publishes guide to cruelty-free cosmetics; Campaign partner of Cruelty Free International	+81 (3) 5456-9311	<a href="mailto:java@java-animal.org">java@java-animal.org</a> <a href="http://www.java-animal.org/english">www.java-animal.org/english</a>
	<b>Korea, Republic of</b>			
1	Korean Society for Animal Freedom / Korean Animal Welfare Association	Various animal protection: animal testing; pets; farmed animals; illegal animal slaughter programme; animal use in sports and entertainment. benicetobunnies.org website educates public on animal testing and gathers signatures for their campaign 'No to cosmetics testing on animals'. Signatures will be used in persuading government organisations to ban animal testing and dissuade companies from testing on animals in producing cosmetic products.	+82 2-2292-633 7	<a href="mailto:admin@animals.or.kr">admin@animals.or.kr</a> / <a href="mailto:hjl@animals.or.kr">hjl@animals.or.kr</a> <a href="http://www.animals.or.kr">www.animals.or.kr</a>  Campaign website: <a href="http://www.benicetobunnies.org">www.benicetobunnies.org</a>

	Organisati on	Campaign	Phone	Email / web
	<b>New Zealand</b>			
1	Save Animals From Exploitation (SAFE)	<p>Various animal protection: animal testing; factory farming; rodeos; poisoning.</p> <p>Produces guide to cruelty-free cosmetics; organising Cruelty Free Cosmetics week; is part of the Be Cruelty Free campaign.</p>	+64 3 379 9711	<a href="mailto:info@safe.org.nz">info@safe.org.nz</a> <a href="http://www.safe.org.nz">www.safe.org.nz</a> <a href="http://www.safeshopper.org.nz">www.safeshopper.org.nz</a>
2	NZ Anti-Vivisection Society (NZAVS)	Recent lobbying work includes involvement in campaigns against animal testing of legal highs and cosmetics	+64-3-379-0093	<a href="http://www.nzavs.org.nz">www.nzavs.org.nz</a>
	<b>Spain</b>			
1	Igualdad Animal (Animal Equality)	<p>Various animal protection: animal testing; zoos; animal circuses; fur; bullfighting/ fiestas; veganism.</p> <p>Conducts undercover investigations and animal rescues.</p> <p>June 2013: Animal Equality gave a presentation in the European Parliament on the campaign 'Stop Vivisection'.</p>	+34 915 222 218	<a href="mailto:info@igualdadanimal.org">info@igualdadanimal.org</a> <a href="http://www.igualdadanimal.org">www.igualdadanimal.org</a>
2	Animanaturalis	<p>Various animal protection: animal testing; zoos; animal circuses; fur; bullfighting/ fiestas; vegetarianism.</p> <p>June 2013: Animanaturalis gave a presentation in the European Parliament on the campaign 'Stop Vivisection'.</p>		<a href="http://www.animanaturalis.org/home/es">www.animanaturalis.org/home/es</a>
	<b>Sweden</b>			

	<b>Organisati on</b>	<b>Campaign</b>	<b>Phone</b>	<b>Email / web</b>
1	Forska Utan Djurförsök / The Swedish Fund for Research Without Animal Experiments	Promotes the development and validation of replacement alternatives to animal experiments. Grants are awarded annually to research, validation and information projects.	+46 8749 03 40	<a href="mailto:info@forskautandjurforsok.se">info@forskautandjurforsok.se</a>  <a href="http://www.forskautandjurforsok.se/in-english">www.forskautandjurforsok.se/in-english</a>
	<b>Switzerland</b>			
1	Ligue suisse contre la vivisection (LSCV) (Swiss League Against Vivisection)	Supports development of non-animal testing methods and takes legal action to prevent animal tests. Publishes list of cruelty-free cosmetics.	+41 (0)22 349 73 37	<a href="mailto:admin@lscv.ch">admin@lscv.ch</a>  <a href="http://www.lscv.ch">www.lscv.ch</a>
2	Zurcher Tierschutz Association (Zurich Animal Protection Association)	Various animal protection: animal testing; fur; farm animal welfare. Funds non-animal testing; has a representative on the Zurich Animal Experiments Committee and the Federal Animal Experiments Committee.	+41 44 261 97 14	<a href="mailto:info@zuerchertierschutz.ch">info@zuerchertierschutz.ch</a>  <a href="http://www.zuerchertierschutz.ch">www.zuerchertierschutz.ch</a>
	<b>UK</b>			

	<b>Organisati on</b>	<b>Campaign</b>	<b>Phone</b>	<b>Email / web</b>
1	British Union for the Abolition of Vivisection (BUAV)	Key issues include: primates in research; cruelty-free cosmetics; animal testing of household products in UK; REACH; Freedom of information. Conducts undercover investigations. Co-ordinates the European Coalition to End Animal Experiments and Cruelty Free International (global campaign to end animal testing for cosmetics).	+44(0)20 7700 4888	<a href="mailto:info@buav.org">info@buav.org</a> <a href="http://www.buav.org">www.buav.org</a> <a href="http://www.crueltyfreeinternational.org">www.crueltyfreeinternational.org</a>
2	National Anti-Vivisection Society (NAVS)	Part of Animal Defenders International (ADI). Animals in space research; freedom of information; World Day for Laboratory Animals; Good Charities Guide (charities funding non-animal medical research).	+44 (0)20 7630 3340	<a href="http://www.navs.org.uk">www.navs.org.uk</a>
3	InterNICHE (International Network for Humane Education)	Network of students, teachers and campaigners working for fully humane education and training in medicine, veterinary medicine and biological science. Produced award-winning video on alternatives available in nearly 20 languages; book describing over 500 products designed for progressive life science education; offers a global Alternatives Loan Systems - libraries of products available for free loan, as well as literature, support and advice for teachers and students. Conferences, seminars and training.	+44 (0) 116 210 9652	<a href="mailto:coordinator@interniche.org">coordinator@interniche.org</a> <a href="http://www.interniche.org">www.interniche.org</a>

	Organisati on	Campaign	Phone	Email / web
	<b>USA</b>			
1	Coalition for Consumer Information on Cosmetics (CCIC)	Coalition of 8 national animal protection groups. The CCIC “promotes a single comprehensive standard and an internationally recognised Leaping Bunny Logo”.	+1 888546-CCIC	<a href="mailto:info@LeapingBunny.org">info@LeapingBunny.org</a> <a href="http://www.leapingbunny.org">www.leapingbunny.org</a>
2	The American Anti-Vivisection Society (AAVS)	Key issues include: Ban Pound Seizure; End Animal Cloning; Compassionate Shopping. In 2006, AAVS assumed the leadership role as Chair of the Coalition for Consumer Information on Cosmetics (CCIC). Free phone app with guide to over 200 cruelty-free cosmetics companies.	+1 800-729-2287	<a href="mailto:aavs@aavs.org">aavs@aavs.org</a> <a href="http://www.aavs.org">www.aavs.org</a>
3	Humane Society International (HSI)	Launched ‘Be Cruelty Free’, a global campaign in partnership with NGOs worldwide. Active in key emerging countries such as Brazil, India, China. Lobbying to end animal testing in several countries	+1 202-452-1100	<a href="mailto:info@hsi.org">info@hsi.org</a> <a href="http://www.hsi.org">www.hsi.org</a>
4	Physicians Committee for Responsible Medicine (PCRM)	PCRM is Secretariat of the International Council on Animal Protection at OECD (ICAPO), which was formed to incorporate alternative methods that can replace, reduce, and refine animal use in OECD guidelines and programs.	+1 202-686-2210	<a href="mailto:pcrm@pcrm.org">pcrm@pcrm.org</a> <a href="http://www.pcrm.org">www.pcrm.org</a>



	Organisati on	Campaign	Phone	Email / web
5	Center for Alternative s to Animal Testing (CAAT)	Promote humane science by supporting the creation, development, validation, and use of alternatives to animals in research, product safety testing, and education. Seek to effect change by working with scientists in industry, government, and academia.	+1 410-614-49 90	<a href="mailto:caat@jhsph.edu">caat@jhsph.edu</a> <a href="http://caat.jhsph.edu">http://caat.jhsph.edu</a>
6	Internation al Council on Animal Protection in OECD Programm es (ICAPO)	ICAPO works to incorporate non-animal testing methods into the activities of the Organisation for Economic Co-operation and Development (OECD), an influential international organisation that develops guidelines and programmes for the testing of chemicals.	+1 202-686-22 10	<a href="mailto:icapo@pcrm.org">icapo@pcrm.org</a> <a href="http://www.icapo.org">www.icapo.org</a>
7	Beagle Freedom Project	The Project negotiates with labs to hand over animals for re-homing to suitable private homes. In its lobbying work, BFP put forward the Beagle Freedom Bill in November 2012, to mandate that research facilities that receive tax-dollar support would have to offer dogs and cats to non-profit rescue organisations for public adoption. From January to May 2013 BFP ran this legislative campaign in the State of Minnesota. The bill passed the committee with unanimous support but did not pass into law. For the next legislative session BFP will be advancing this same bill again in Minnesota, California and Michigan.	+ 1818-330-4 040	<a href="mailto:shannon@beaglefreedomproject.org">shannon@beaglefreedomproject.org</a> <a href="http://www.beaglefreedomproject.org">www.beaglefreedomproject.org</a>

## 7 Lobbying Prize winners 2013

Two organisations shared the Public Awareness Prize in 2013:

The International Council on Animal Protection in OECD Programmes (£40,000)

<http://www.icao.org/>

For their successful work with the OECD, now a world leader in the promotion of non-animal methods, approaches and policies.

The Swedish Fund for Research Without Animal Experiments (£10,000)

<http://www.forskautandjurforsok.se>

For their work with Swedish regulators to replace animal testing.

Also shortlisted:

PETA India

[www.petaindia.com](http://www.petaindia.com)

For its major role in the successful campaign to ban the testing of cosmetics on animals in the country.

Center for Alternatives to Animal Testing (CAAT)

<http://caat.jhsph.edu>

For its lobbying for a legal implementation of 21st Century Toxicity in the US and the EU, educating legislators and politicians about the urgent need for regulatory change, and the availability of new methods.

Physicians Committee for Responsible Medicine

<http://pcrm.org>

For lobbying on the Chemical Safety Improvement Act to make it a requirement for the use of non-animal test methods where reasonably and practicably available.

PETA, Laboratory Investigations Department

[www.peta.org](http://www.peta.org)

For its international work to advocate for the creation of policies that require and encourage the replacement of crude animal experiments with modern non-animal teaching, research and testing methods.

Stop Vivisection

[www.stopvivisection.eu](http://www.stopvivisection.eu)

For running a European Citizens Initiative proposing a new Directive aimed at ending animal experiments and making the use of data relevant to humans in biomedical and toxicological research compulsory, in the place of data obtained on animals.

Humane Society International - Brazil

[www.hsi.org/portuguese/issues/cosmetic\\_product\\_testing/libertesedacrueldade/libertesedacrueldade.html](http://www.hsi.org/portuguese/issues/cosmetic_product_testing/libertesedacrueldade/libertesedacrueldade.html)



For its work with the Brazilian authorities and companies to gain acceptance and use of proven non-animal methods and testing strategies and to update regulatory testing requirements to replace or reduce animal testing.