



The challenges of 'cruelty free' access to China's cosmetics market

In this expert article, the Humane Society International's Irene Zhang argues that despite recent updates to China's cosmetics regulations, significant challenges remain for foreign companies seeking to offer a cruelty-free guarantee for their cosmetic products.

In an effort to streamline processes – and partly in response to both international calls for harmonisation and consumer demand for increased transparency regarding cosmetic safety, quality and efficacy – China is updating regulations that have not seen review for many years. In November 2014, for example, China's Food and Drug Administration (CFDA) sought advice from the public on the Regulations on the Cosmetic Administration and Supervision and the Administrative Measures for Cosmetics Labels, and in March 2015, on a further two documents involved in the licensing of cosmetics production.

As part of the review process, China is adopting the model used by other leading markets whereby cosmetics companies assume increasing responsibility for assuring product safety. One of the first significant steps in this transition to increased corporate responsibility came in June 2014 when the CFDA introduced regulatory reform that removed the mandatory requirement for finished product animal testing for ordinary (non-special use) cosmetics manufactured in mainland China.

The Humane Society International (HSI) welcomed the fact that the rule change could allow for a substantial reduction in animal testing and thus reduce trade barriers for Chinese companies through a shift to ingredient-based risk assessments, instead of the previously mandated animal testing of each new product formulation.

The capacity of domestic companies to embrace this opportunity could be limited because the CFDA is yet to provide guidance or a methodology that would allow cosmetics companies to assume more responsibility for assuring product safety. A lack of either formal acceptance or process for adopting OECD, or other internationally recognised non-animal testing methods, could also have an impact.

Increasing the availability, uptake and acceptance of existing and new *in vitro* and computational tools in toxicology remains a significant challenge in China that must be overcome.

While campaigns such as *BeCrueltyFree* (China) offer practical assistance to domestic companies in how to navigate the new liberalised regulatory system, progress could be achieved more quickly if China's various ministries adopted greater harmonisation. For example, while the CFDA has yet to accept any non-animal test methods, Chinese chemical regulators at the Ministry of Environmental Protection (MEP) have adopted virtually every available OECD test guideline including a dozen *in vitro* methods.

As the one-year anniversary of the cosmetics animal testing rule relaxation approaches, there is an urgent need for far greater forward momentum by the CFDA, not least in abandoning its requirement for seemingly redundant validations (in China) for OECD-approved non-animal tests that have already passed scientifically rigorous multi-year validations elsewhere.

China's strict regulations requiring animal testing of cosmetics have traditionally meant that cruelty-free companies have been unable to sell in the lucrative Chinese market. But there are signs that change is coming. While the rule change last year doesn't apply to foreign-imported cosmetics, it does provide foreign companies with a little more wriggle room to enter China without new pre-market animal testing, but it's still too early to say with certainty that animal testing can be avoided altogether in every case.

It is now technically possible for a foreign company to produce its formulations overseas but complete final stage product assembly inside China and thus qualify as 'domestically manufactured'. In doing this it could then remove the pre-market animal testing requirement for finished products that still applies to foreign imports, but only as long as it produces exclusively non-special use cosmetics and only uses cosmetic ingredients already registered on China's Inventory of 'Existing Chemical Substances Produced

or Imported in China' (IECIC). Any foreign company producing special use products such as hair dyes, deodorants or sunscreens, or using ingredients new to China, will fall foul of the CFDA's requirement for ingredients animal testing.

Taking advantage of this opportunity may not be a practical option for most small and medium sized foreign companies, but it does provide the first opportunity for larger cruelty-free companies. However, none of this addresses the potential for post-market animal testing. When the domestic cosmetics animal testing rules were relaxed last year, the CFDA made it clear that post-market surveillance would increase to compensate. The *BeCrueltyFree* campaign has conducted extensive enquiries with the relevant agencies to determine whether or not animal testing forms a regular part of post-market surveillance, but it has proved a challenge to get consistent answers from one agency to another, or indeed from one regional authority to another.

The Chinese regulatory system is not a simple top-down affair with central control, but a rather more fragmented, regionally autonomous system whereby local FDAs are at liberty to determine the nature of the testing they require on a case-by-case basis. While some opt simply for microbiological testing, others have confirmed to HSI that animal testing has occurred. Unlike pre-market testing, companies are not notified if their products are selected for post-market testing, so they could remain entirely unaware if this has taken place.

Gaining cruelty-free company access to the Chinese market is understandably a priority for some, but in the rush to do so it's imperative to keep corporate ethical principles intact. The *BeCrueltyFree* campaign will continue to seek official clarification about post-market animal testing but, in the meantime, there is simply too much conflicting information to offer consumers a guarantee that a cosmetic company can remain cruelty-free in China.

The future of China's cosmetics regulation holds great promise for increased global harmonisation, but that must include a swifter transition away from animal testing in the beauty industry. With test bans in place across the EU, Israel, Norway, India and New Zealand, and bans proposed in Australia, Brazil, Taiwan and the United States, China's animal test-based regulatory system is looking increasingly isolated. In the year ahead HSI hopes that the CFDA will lead from the front, swiftly adopting *in vitro*, *in silico*, read across and AOP test methods, and increasing investment in modern testing infrastructures, so China doesn't just keep pace with scientific progress but actively drives it forward.

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