



Be Cruelty-Free Australia



HUMANE SOCIETY
INTERNATIONAL



humane research australia

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Submitted via email to: cosmetic_testing@health.gov.au

To Whom It May Concern:

Implementing a Ban on Cosmetic Testing on Animals - Consultation Paper March 2017

#BeCrueltyFree Australia, a partnership between Humane Society International (HSI) and Humane Research Australia, welcomes the opportunity to comment on the Department of Health's consultation paper on the proposed implementation of a ban on cosmetic animal testing on animals ("consultation paper").

We thank you for the opportunity to provide these comments.

General Comments on Consultation Paper March 2017

The following five key points should be incorporated within legislation to ban cosmetics animal testing and trade in Australia:

- The cosmetics animal testing ban legislation should prohibit both cosmetics animal testing and the introduction of cosmetics products and ingredients newly tested on animals abroad.
- **The ban should not be limited to chemical ingredients used *exclusively* for cosmetics.** The new industrial chemicals legislation should include provisions to ban the use of new animal test data to support the introduction of all chemicals used as cosmetic ingredients, regardless of their previous, concurrent, or future introduction for use within other industries.
- The new industrial chemicals legislation should ensure that all chemical introductions for use as cosmetic ingredients are captured. All volume thresholds should be subject to the ban and all declarations should include reference to animal testing even if under volume thresholds so no unintended loopholes are created.
- **Repurposing a chemical substance (and any associated animal test data) used initially for a different purpose, for subsequent use in a cosmetic product *should not be allowed.*** Animal test data derived after the enactment of the ban should not be allowed to introduce a chemical for use in cosmetics, nor to assure the safety of an ingredient for cosmetics purposes. If the safety of an ingredient for use in cosmetic or the safety of the cosmetic product cannot be assured without the use of new animal test data, then the introduction (or continued use) of the ingredient should not be allowed for cosmetics purposes.

- The cosmetics animal testing ban *should not* rely on the availability of alternatives.

Comments on the Proposed framework for the implementation of a ban on the testing of cosmetics on animals

Strategy #1:

The new industrial chemicals legislation include provisions to ban the use of new animal test data to support the introduction of chemicals used exclusively as cosmetic ingredients.

Comments: The term “exclusively” should be removed from this strategy.

Only a small minority of substances (10% or less, according to some industry estimates) are used exclusively as cosmetic ingredients. Thus, narrowing the scope of the testing and sales bans to exclude all dual-use ingredients would undermine the spirit of the action, and have little practical impact on preventing new animal testing. Such a narrow scope would not be in harmony with other national bans around the globe and would also break the Coalition’s promise to Australians to end this practice.

NICNAS already requires chemical introducers to specify the intended use of a substance and undergo separate introductions for different uses. Therefore, banning the use of new animal test data to support the introduction of a chemical for cosmetic use would ensure that new animal test data are not used to justify the safety of an ingredient for cosmetic purposes without impacting other regulated industries.

Subsequent legislative language and the ban should be drafted to include any and all chemical introductions for use in a cosmetic ingredient, regardless of whether the chemical is, or may in future also be, used in other industries.

The new industrial chemicals legislation should also ensure that all chemical introductions for use as cosmetic ingredients are captured. All volume thresholds should be subject to the ban and all declarations should include reference to animal testing even if under volume thresholds so no unintended loopholes are created.

Strategy #2:

The National Health and Medical Research Council’s (NHMRC) Australian Code for the care and use of animals for scientific purposes (the Animal Ethics Code) be amended to ban cosmetic testing on animals.

Comments: This strategy would support the implementation of a legal ban on cosmetic animal testing in Australia. However, to ensure a full legal ban on cosmetic animal testing in Australia, Strategy #3 - to adopt the amendment into all state and territory laws - will need to be fulfilled.

Strategy #3:

The NHMRC work with states and territories to ban cosmetic testing on animals by adopting the amended Animal Ethics Code into state and territory laws.

Comments: The NHMRC should work with states and territories to ensure the amendment banning cosmetic testing on animals is incorporated in all state and territorial animal welfare acts as soon as possible. A strategy and legally enforceable deadline for achieving adoption in all states and territories as soon as possible should be developed.

Strategy #4:

The Government work with the cosmetics industry to develop a voluntary code of conduct for industry on animal testing of cosmetic products.

Comments: Any voluntary code of conduct for industry regarding the animal testing of cosmetic products should *not* be used in lieu of legal bans on cosmetic animal testing, the use of new animal test data to prove the safety of a cosmetic or cosmetic ingredient, or the sale or trade of newly animal tested cosmetics or cosmetics containing newly animal tested ingredients. The ban on cosmetic animal testing and the sale or trade of cosmetics containing newly animal tested ingredients must be legally binding and enforceable.

It is our understanding after further consultation with the Department that this voluntary code of conduct is intended to be applied in relation to cosmetic labelling claims. The #BeCrueltyFree campaign does not actively support labelling legislation, as we believe that comprehensive and meaningful legislation banning cosmetic animal testing and trade is a more effective measure for ensuring consumer clarity that new animal testing has not been conducted for the purposes of safety evaluation in the development or manufacture of cosmetics after a fixed cut-off date.

Strategy #5:

An information and communications approach will be developed to provide clarity for consumers and industry around promotional claims that can or cannot be made on cosmetic products.

Comments: A comprehensive and legally enforceable ban on cosmetic animal testing, the use of new animal test data to prove the safety of cosmetics and cosmetic ingredients, and the sale or trade of newly animal tested cosmetics or cosmetics containing newly animal tested ingredients is necessary to comply with consumer expectations and previously communicated election promises by the Coalition Government. Consistency with the Coalition's previous policy announcement to "ban the testing of finished cosmetic products on animals in Australia, the testing of cosmetic ingredients on animals in Australia and the sale of cosmetic products and ingredients that have been tested on animals outside of Australia"¹ should be ensured.

¹ <https://www.liberal.org.au/latest-news/2016/06/03/coalition-will-ban-cosmetic-testing-animals-0>

Exceptions:

Exception 4- repurposing a chemical substance (and any associated animal test data) used initially for a different purpose, for subsequent use in a cosmetic product;

Comments: This exception should be removed from consideration.

This exception would undermine the purpose of a cosmetic animal testing and trade ban and render it all but meaningless. Few chemicals are used exclusively for cosmetics, with most having dual-uses. Use of animal test data derived after the enactment of the ban should not be allowed to introduce a chemical for use in cosmetics, nor to assure the safety of an ingredient for cosmetics purposes. If the safety of an ingredient for use in cosmetic or the safety of the cosmetic product cannot be assured without the use of new animal test data, then the introduction of the ingredient should not be allowed for cosmetics purposes.

Allowing the use of new animal test data, used initially for a different purpose, to be subsequently used for a cosmetic product, would create a loophole so large as to render a ban all but meaningless. Such an exception would not be consistent with the Coalition's policy announcement to implement a ban on cosmetics animal testing and the sale of animal tested cosmetics in Australia.

Additional points:

1. Meaningful legislation that prohibits both cosmetics animal testing and the sale of cosmetics products and ingredients newly tested on animals abroad is necessary.
2. Loopholes which limit the ban to chemical ingredients used exclusively for cosmetics or allow the use of new animal test data used initially for a different purpose to be used in cosmetics products despite the ban are unnecessary and are not consistent with either the Coalition's commitment to a ban, nor global precedent for cosmetics animal testing bans.
3. A cosmetics animal testing ban should not rely on the availability of alternatives, and would in fact promote alternatives production. This approach is taken in the EU, India, and other nations which have implemented similar bans and has been seen to contribute greatly towards the growth of the global in vitro toxicity testing market. "The global in vitro toxicology testing market is expected to reach USD 27.36 Billion by 2021 from USD 14.15 Billion in 2016, at a CAGR of 14.1% from 2016 to 2021"²

² <http://www.marketsandmarkets.com/PressReleases/in-vitro-toxicology-testing.asp>

General Comment

Strategies #2 and #3, to amend the Animal Ethics Code and adopt the amendment(s) into state and local laws, would address a ban on cosmetic animal testing within Australia once fully implemented. As the consultation paper notes, “The initial consultation process conducted by the Department of Health involved State and Territory governments in their roles as regulating the use of animals in research. Through this process jurisdictions advised that no applications were received to test cosmetics and/or their ingredients from 2013 to 2015.” Therefore, such a ban on cosmetic animal testing in Australia should be straightforward and legally codify what is already existing practice.

A strategy to ban the use of new animal test data to support the introduction of chemicals used as cosmetic ingredients would support a ban on cosmetic animal testing within Australia by ensuring that if such ingredients were tested, contrary to the Animal Ethics Code, the resulting test data would be banned from use for the purposes of introducing a chemical for use as a cosmetic ingredient under NICNAS regulations.

Additionally, a strategy to ban the use of new animal test data to support the introduction of chemicals used as cosmetic ingredients would effectively ban the introduction of cosmetics products and ingredients newly tested on animals, both at home and abroad. Under such a strategy, the use of new animal test data would not be allowed to substantiate the safety of cosmetic ingredients under NICNAS regulations. Because the Australian Federal Government does not have the authority to directly regulate the sale of cosmetics, this is an effective way to prevent the introduction of newly animal tested cosmetics and cosmetic ingredients to the Australian market after the effective date of the ban.

In addition to the strategies proposed, it is important to address several additional points made in the Consultation Paper.

- The use of new animal test data in the EU under the Cosmetics Regulation (EC) No 1223/2009

The consultation paper states the following in respect to the EU ban:

“This ban includes an exception to allow animal testing should an alternative non-animal test be unavailable, for example, in order to protect public health, the environment, and/or worker safety.”

“Consistent with the EU approach, the proposed approach would allow for exceptions for animal testing for public health and safety, worker health and safety, and the environment, where no non-animal test method is available and the risk cannot otherwise be adequately assessed.”

The only derogation to the EU ban provided for in the Cosmetics Regulation is as follows:

A derogation shall be granted only where:

- (a) the ingredient is in wide use and cannot be replaced by another ingredient capable of performing a similar function;

(b) the specific human health problem is substantiated and the need to conduct animal tests is justified and is supported by a detailed research protocol proposed as the basis for the evaluation.³

The European Commission and the European Chemicals Agency (ECHA) issued a Joint Statement in 2014 on the possibility to perform, under certain conditions, animal tests for substances used in cosmetics. According to the Joint Statement, the Cosmetics Regulation's animal testing ban does not apply to testing required for (i) environmental endpoints, (ii) exposure of workers and (iii) non-cosmetic uses of substances under the REACH Regulation⁴.

However, it is important to note that this is only one interpretation of the Cosmetics Regulation, and a controversial one at that. A complaint has been filed with the European Ombudsman regarding the Joint Statement, and is currently under investigation. According to the Ombudsman, "the Joint Statement merely provides guidance for cosmetics manufacturers and Member States charged with monitoring compliance with the Cosmetics Regulation. *The Joint Statement thus does not constitute a legally binding interpretation of the Cosmetics and REACH Regulations (emphasis added).* The fact that the Commission and ECHA can issue such guidance does not, however, prejudice the issue of whether the guidance given is correct."⁵

In a 2016 ruling, the Court of Justice of the European Union ruled that the Cosmetic Regulation's animal testing ban "*must be interpreted as meaning that it may prohibit the placing on the European Union market of cosmetic products containing some ingredients that have been tested on animals outside the European Union, in order to market cosmetic products in third countries, if the resulting data is used to prove the safety of those products for the purposes of placing them on the EU market*" [emphasis supplied].

The Advocate General opinion⁶ for the same court case stated that:

"the marketing ban must be understood as preventing reliance on the results of animal testing for the purpose of meeting the requirements of the Cosmetics Regulation (subject to the relevant cut-off dates) . . .

141. It is irrelevant to the application of the marketing ban where the testing was conducted. The testing may have been conducted in the EU (for example, to comply with REACH), or outside the EU (for example, because it is required by relevant foreign legislation).

142. The subjective intent or specific purpose behind the testing is also irrelevant (whether that be the specific purpose of the lab conducting the tests, the entity

³ Article 18, Section 2. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:en:PDF>

⁴ https://echa.europa.eu/view-article/-/journal_content/title/clarity-on-interface-between-reach-and-the-cosmetics-regulation

⁵ https://www.ombudsman.europa.eu/en/cases/correspondence.faces/en/71811/html.bookmark#_fn1

⁶ <http://curia.europa.eu/juris/document/document.jsf?text=&docid=175149&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=745731>

commissioning them or some other entity). In particular, it makes no difference if the exclusive purpose, the main purpose or just one of the multiple purposes was to conduct testing with a view to satisfying the requirements of a given piece of legislation (EU or non-EU).

143. It is equally irrelevant whether that piece of legislation is cosmetics or non-cosmetics related.

144. It is irrelevant whether and at what point in time marketing of cosmetics (in the EU) was foreseen.”

In light of the above, it should be clarified that although a cosmetics ingredient may undergo new animal testing for the purposes of other chemicals legislation, either within the EU or abroad without triggering the marketing ban, these new animal data *cannot* be used to substantiate the safety of cosmetics products for the purposes of placing them on the EU market.

The consultation paper also states: “Through the consultation process to date it is understood that the EU ban does not prevent companies from undertaking this testing however data arising from this testing cannot be used to support the introduction of the cosmetic into the EU.”

Therefore, it should be stressed that such testing is not a permitted exception to the cosmetics ban but is instead testing conducted for other regulatory purposes and which cannot subsequently be used to support the introduction of a cosmetic or cosmetic ingredient.

An Australian ban should likewise ensure that use of new animal test data derived after the enactment of the ban is not permitted as a basis for introducing a chemical for use in cosmetics, nor to assure the safety of an ingredient for cosmetic purposes. Repurposing a chemical introduced initially for a different purpose for subsequent use in a cosmetic product is not a problem in itself; however, reliance on animal test data derived after enactment of the cosmetic animal testing and sales ban *should not* be allowed for cosmetic safety substantiation purposes.

- The cosmetics animal testing ban in New Zealand

The consultation paper states the following: “The ban on ingredients however is limited to those ingredients that are intended exclusively for use in a cosmetic.”

Although this is indeed the case in New Zealand, the language does not reflect global best practice. Other markets such as the EU-28, Norway, Switzerland, India, Israel, Taiwan, and Guatemala have all banned cosmetics animal testing for both finished cosmetic products *and* cosmetic ingredients, regardless of whether or not the ingredient is intended exclusively for use in cosmetics, and this same model is being heeded in similar legislation under discussion in the United States, Canada, Brazil and other major markets.

It should also be noted that the New Zealand language only pertains to domestic cosmetic animal testing and is not applied to the broader scope of introduction of cosmetics chemical ingredients through chemicals legislation or the sale of newly animal tested cosmetics.

- The phase-in period for a ban on cosmetics animal testing and the introduction of cosmetics and cosmetic ingredients

The consultation paper states the following: “The proposed approach would be phased in gradually to allow consumers time to adjust and industry time to comply.”

As it is mostly claimed that no animal testing for cosmetics takes place in Australia, and the consultation has confirmed that “no applications were received to test cosmetics and/or their ingredients from 2013 to 2015,” the Animal Ethics Code should *immediately* be amended to ban cosmetic testing on animals. All effort should be made to ensure adoption of the amendment within state and local law as soon as possible and with immediate effect.

Implementation of a strategy to ban the use of new animal test data to support the introduction of chemicals used as cosmetic ingredients must necessarily fall within the existing timeframe for NICNAS reform; however, *one year* should be sufficient time for compliance with this ban.

- Government Commitment

The Government has publicly committed to “ban the testing of finished cosmetic products on animals in Australia, the testing of cosmetic ingredients on animals in Australia and the sale of cosmetic products and ingredients that have been tested on animals outside of Australia”⁷

This commitment has been widely reported in the media and to the public.

To comply with consumer expectations and previously communicated election promises, a comprehensive and legally enforceable ban on cosmetic animal testing, the use of new animal test data to prove the safety of cosmetics and cosmetic ingredients, and the sale or trade of newly animal tested cosmetics or cosmetics containing newly animal tested ingredients is necessary.

- Public Opinion

A majority of Australians oppose animal testing on cosmetics and support banning the sale of newly animal-tested cosmetics.

A public opinion poll conducted in May 2013 by Nexus Research⁸ on behalf of Humane Research Australia found that the overwhelming majority of Australians (85%) oppose using animals to develop cosmetics and 81% support a national ban on the sale of cosmetics tested on animals. Similarly, a July 2014 opinion poll by Roy Morgan Research⁹ showed that 'Not Tested on Animals' was one of the top 3 features looked for by Australian female consumers when buying cosmetics, ranking higher than anti-ageing benefits and sun protection factor.

⁷ <https://www.liberal.org.au/latest-news/2016/06/03/coalition-will-ban-cosmetic-testing-animals-0>

⁸ <http://www.humaneresearch.org.au/interview/australians-say-no-to-animal-experiments?A=SearchResult&SearchID=31296192&ObjectID=72973&ObjectType=7>

⁹ <http://www.roymorgan.com/findings/5698-is-animal-testing-for-cosmetics-on-way-out-201407240022>

A recent report by Roy Morgan Research¹⁰ states:

“As of July this year, the sale of cosmetics and other personal products tested on animals or containing animal-tested ingredients will be prohibited in Australia, following the introduction of new legislation by the Coalition (with support from the ALP, the Greens and the Animal Justice Party). The latest findings from Roy Morgan confirm that this move reflects growing concern among Aussie women that the make-up and skincare items they buy should be cruelty free.

Last year, 46% of Australian women who use cosmetics nominated ‘Not tested on animals’ as a feature important to them when purchasing make-up, up from 41% in 2012 (a proportional increase of 12%). During this time, it has overtaken ‘Sun Protection Factor’ (stable at 42%) in importance, and is currently just behind ‘Natural look’ (50%, down from 52%). ‘Value for money’ (60%) remains the top priority for consumers, but this has declined from 62% since 2012.

Of the 10 features that matter most to Aussie women when buying cosmetics, ‘Not tested on animals’ has gained the most ground.”

¹⁰ <http://www.roymorgan.com/findings/7167-new-legislation-banning-animal-testing-on-cosmetics-in-line-with-public-201703080937>