



# Be Cruelty-Free Australia



## RECOMMENDED AMENDMENTS TO INDUSTRIAL CHEMICALS BILL 2017 TO FULLY PROHIBIT DATA DERIVED FROM ANIMAL TESTING AFTER JULY 2018 FROM USE IN AUSTRALIAN COSMETICS

Measures specified in the Industrial Chemicals Bill 2017 represent an important step toward the Government's commitment to ending cosmetic animal testing and trade in Australia, but require further augmentation to ensure that no loopholes exist that could allow newly animal tested cosmetic ingredients to be introduced to the Australian market after the ban comes into effect. The #BeCrueltyFree Australia campaign – on behalf of the more than 11 million members of Humane Society International and Humane Research Australia – is calling for amendments to Sections 103 and 168 of the Government bill to ensure that animal test data obtained after July 2018 are *prohibited without exception* from application for *all cosmetic end uses*.

### WHY DOES NEW ANIMAL TESTING OCCUR IN THE BEAUTY SECTOR?

1. Safety assessment of *new* ingredients (usually co-regulated under chemicals law)
2. Re-assessment of *existing* ingredients (e.g. due to a specific safety concern)
3. Safety assessment of *finished* cosmetic products (only in China)

### MOST COSMETIC INGREDIENTS IN USE GLOBALLY ARE *MULTI-USE* CHEMICALS

New ingredients used by cosmetics manufacturers are typically sourced from specialty chemical producers. These upstream suppliers are the ones who normally conduct or commission any new animal testing, in accordance with registration data requirements specified in chemicals legislation. However, new animal testing can also occur after a chemical ingredient is first introduced, e.g. to clarify a reported safety concern, to address an emerging data requirement, etc. This subsequent testing may be carried out or commissioned by the supplier, cosmetic manufacturer, other end user, government, or any other third party.

According to the industry trade body Cosmetics Europe, “on average, around 10% or less of the new ingredients used by large cosmetics manufacturers were new to market (i.e. have not previously been used in other product sectors). The response from [small to medium-sized companies] was similar” (p. 29 of [Cosmetics Europe response](#) to 2013 European Commission impact assessment). In other words, only a small proportion of chemicals are used “solely” as ingredients for cosmetics; the great majority have multiple end uses.

### WHAT IS ACHIEVED BY A BAN ON ANIMAL TEST DATA FOR COSMETICS?

The rationale behind banning the use of new animal test data for use in safety substantiation for cosmetics is to create an economic disincentive for cosmetic manufacturers to create demand for, and purchase, novel ingredients tested on animals from specialty chemical companies. Take away the demand and a major driver for new animal testing also disappears. Further, the ban creates an incentive for innovation in non-animal testing techniques. The EU, India and other nations which have implemented similar bans have been seen to contribute greatly towards the growth of the global [in vitro toxicity testing market](#), which is expected to double in size over the next five years – from US\$14.5 billion in 2016 to \$27.36 billion by 2021.

#### CONTACTS:

Nicola Beynon, HSI Australia Head of Campaigns (in Sydney) t (02) 9973 1728 / 0415 954 600 [nicola@hsi.org.au](mailto:nicola@hsi.org.au)  
Hannah Stuart, #BeCrueltyFree Australia Campaign Coordinator t 0407 193 526 / +44 75 8341 7121 [hannahstuart@humaneresearch.org.au](mailto:hannahstuart@humaneresearch.org.au)  
Troy Seidle, HSI Global Senior Director of Research and Toxicology (in Toronto) t +1 64 7236 3889 [tseidle@hsi.org](mailto:tseidle@hsi.org)

## WHY IS THE GOVERNMENT'S PROPOSED BAN LANGUAGE INSUFFICIENT?

Sections 103 and 168 of the Industrial Chemicals Bill 2017 create a framework for prohibiting the use of animal test data “if an industrial chemical is to be introduced for an end use *solely* in cosmetics.” Conversely, chemicals introduced with *multiple* specified end uses are exempt from the prohibition. According to this two-track system proposed by the Government, the same cosmetic ingredient could be treated completely differently from the standpoint of the animal test data ban depending on the end use(s) specified, with a sole end use in cosmetics (track 1) being subject to the ban, whilst those with multiple end uses (track 2) are not. Thus, a company wishing to circumvent the ban could do so with ease by submitting any or all new chemical registrations as “multi-use,” side-stepping Sections 103 and 168 altogether. This is a glaring and dangerous loophole, which could utterly defeat the Government's stated policy goal for a ban.

## HOW WOULD #BECRUELTYFREE'S AMENDMENTS CLOSE THE LOOPHOLE?

#BeCrueltyFree *strongly* advises removing the qualifier “solely” from Sections 103 and 168, and adjusting the two-track system to group end uses as “cosmetic” (alternate track 1) or “non-cosmetic” (alternate track 2) to ensure that the cosmetics animal testing ban applies to *all* introductions for cosmetic use. Under such a framework (illustrated in Figure 1, overpage), where new animal test data are to be submitted as part of a multi-use introduction, cosmetic end uses of a chemical would be introduced separately from all non-cosmetic end uses, thereby ensuring the animal test data ban is applied in a *consistent* and *comprehensive* manner in the categorisation and regulation of chemicals used as ingredients in cosmetics (as is the case in the EU and other markets). This approach would ensure that an introducer could not use new animal test data for any cosmetic introduction (either sole use or multi-use), without impacting applications for non-cosmetic uses, i.e. an introducer could still use new animal test data for the other non-cosmetic introduction, as per Australian regulation. An introducer could also still submit a single combined multi-use application that includes a cosmetic end use, provided this is done without the use of new animal test data. The Government's proposed language already provides for a separate application process for chemicals with an exclusive end use in cosmetics, so our suggestions would not require any changes to existing regulatory criteria. The only difference is the manner in which chemicals are grouped – and this difference is of the utmost importance for ensuring the integrity of the animal test data use ban.

## WHAT IF NEW ANIMAL TEST DATA PRODUCED AFTER 1 JULY 2018 INDICATE THAT A CHEMICAL IS POTENTIALLY HAZARDOUS TO HUMAN HEALTH OR THE ENVIRONMENT?

Section 100 of the Government's bill creates an overarching “obligation to report information on hazards,” according to which evidence of previously undocumented hazards to human health or the environment must be communicated to the Department of Health. #BeCrueltyFree's suggested amendments to Section 103 include the addition of a reference to Section 100 to clarify that evidence of new hazards of a previously evaluated/registered chemical that could jeopardise human health or the environment may be exempt from the animal test data use ban. Furthermore, proposed rules accompanying the new legislation would provide for limited circumstances where new animal test data may need to be considered to protect human health and the environment.

## WOULD #BECRUELTYFREE AMENDMENTS ALIGN WITH EU REGULATION?

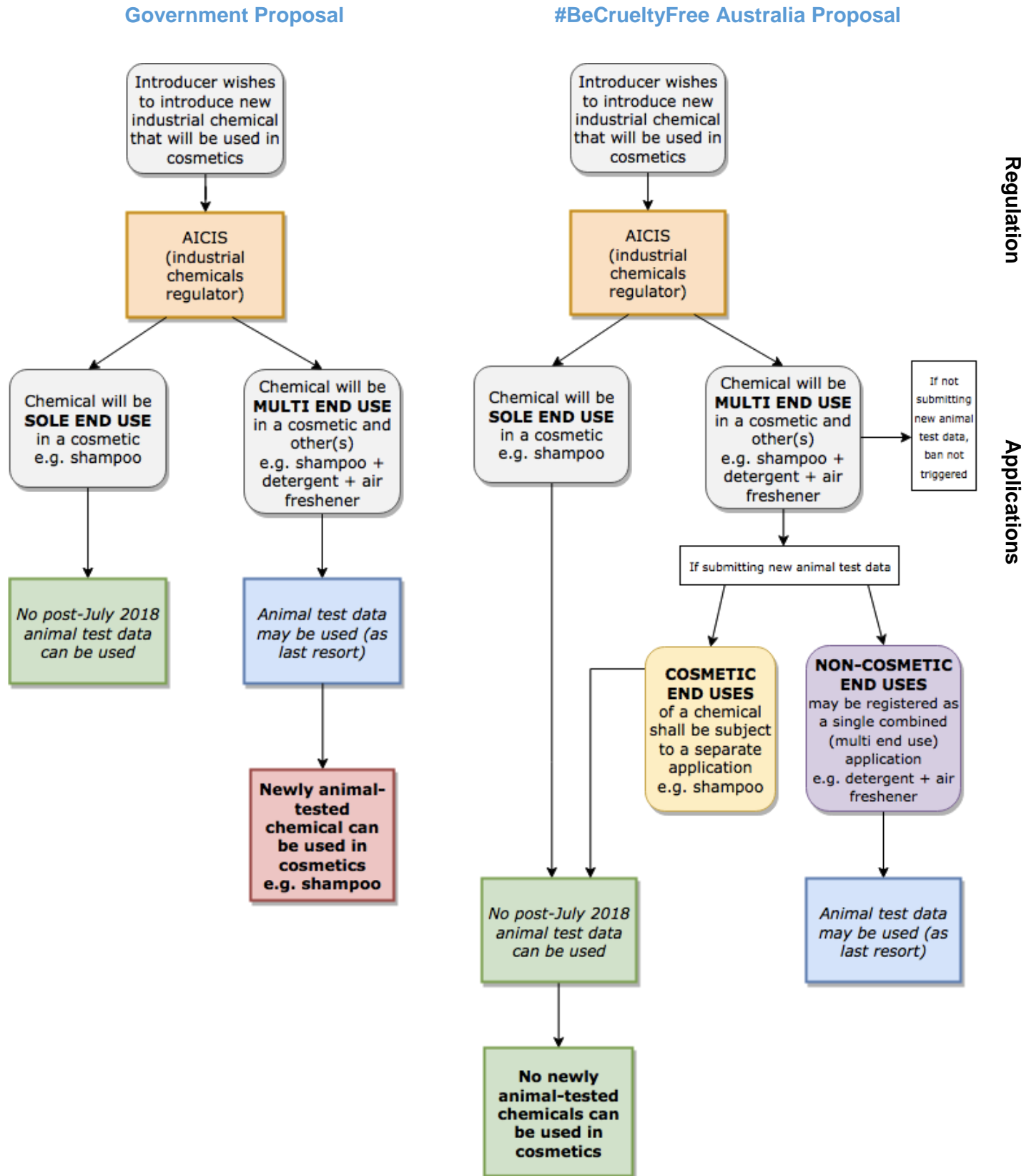
We understand the Government's desire to align Australian regulation as much as possible with that of its major trading partners, particularly the EU, and submit that the amendments proposed by #BeCrueltyFree would better align Australian and European cosmetics regulation than the Government bill as currently worded. EU Regulation 1223/2009 does not discriminate between substances used as ingredients in cosmetics and other end uses in terms of how and when the marketing ban for newly animal-tested cosmetics is applied. The pivotal determining factor, as articulated in the [September 2016 judgment](#) of the European Court of Justice – is “if the resulting data is used to prove the safety of those products for the purposes of placing them on the EU market” (paragraph 45). In other words, reliance upon new animal test data for a cosmetic end use is the defining trigger for the EU ban – *not* whether an ingredient is used solely in the beauty sector. Our suggested amendments remove the overly narrow language of Sections 103 and 168, closing potential loopholes and moving the bill into closer alignment with EU law.

## WOULD #BECRUELTYFREE AMENDMENTS ALIGN WITH INTERNATIONAL BEST PRACTICE?

As currently worded, Sections 103 and 168 fall short of international best practice. The EU-28, Norway, Switzerland, India, Israel, Taiwan and Guatemala have all banned new animal testing for both finished cosmetic products as well as *all* 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. The amendments #BeCrueltyFree proposes below would bring Australia level with international best practice.

**Figure 1: Operation of the ban on new animal test data for cosmetics within the AICIS framework**



# RECOMMENDED AMENDMENTS TO INDUSTRIAL CHEMICALS BILL 2017 TO FULLY PROHIBIT DATA DERIVED FROM ANIMAL TESTING AFTER JULY 2018 FROM USE IN COSMETICS IN AUSTRALIA

Prepared by #BeCrueltyFree Australia campaign on behalf of Humane Society International, Humane Research Australia, and our more than 11 million supporters in Australia and globally

14 June 2017

**Industrial Chemicals Bill 2017**

**#BeCrueltyFree Australia Amendments**

---

## Section 103

### Ban on animal test data for determining category for cosmetics

1. Without limiting paragraph 102(1)(b), if an industrial chemical is to be introduced for an end use solely in cosmetics, rules made for the purposes of that paragraph may include the requirement mentioned in subsection (2).
  2. The requirement is that, when determining the category of introduction for such an industrial chemical, a person must not use animal test data obtained from tests conducted on or after 1 July 2018 in circumstances prescribed by the rules.
1. Without limiting paragraphs 100(2) or 102(1)(b), if an industrial chemical is to be introduced for a cosmetic end use ~~solely in cosmetics~~, rules made for the purposes of that paragraph ~~may include~~ must meet the requirement mentioned in subsection (2).
  2. The requirement is that, when determining the category of introduction for such an industrial chemical, a person must not use animal test data obtained from tests conducted on or after 1 July 2018 in relation to a cosmetic end use in circumstances prescribed by the rules.

## Section 168

### Ban on animal test data for applications for cosmetics

1. Without limiting subsection 167(1), if an industrial chemical is to be introduced for an end use solely in cosmetics, an application under this Act relating to the introduction must meet the requirement in subsection (2).
  2. The requirement is that the application must not include animal test data obtained from tests conducted on or after 1 July 2018 in circumstances prescribed by the rules for the purposes of this subsection.
1. Without limiting subsection 167(1), if an industrial chemical is to be introduced for a cosmetic end use, an application under this Act relating to the introduction must meet the requirement in subsection (2).
  2. The requirement is that ~~the an~~ application for a cosmetic end use must not include animal test data obtained from tests conducted on or after 1 July 2018 in circumstances prescribed by the rules for the purposes of this subsection. For industrial chemicals with one or more non-cosmetic end use for which animal test data obtained from tests conducted on or after 1 July 2018 are required, a separate application shall be made.