SUPPLEMENTARY COMMENTS & ADDITIONAL MATERIALS PROVIDED IN SUPPORT OF #BECRUELTYFREE AUSTRALIA SUBMISSION

Please find below supplementary comments and additional materials, provided in response to questions asked at the Senate Inquiry public hearing (26th July 2017) and in support of our submission to the Senate Inquiry ('*RECOMMENDED AMENDMENTS TO INDUSTRIAL CHEMICALS BILL 2017 TO FULLY PROHIBIT DATA DERIVED FROM ANIMAL TESTING AFTER JULY 2018 FROM USE IN AUSTRALIAN COSMETICS*, 14th June 2017).

SUPPLEMENTARY COMMENTS

In response to questions from Senator Watt, '*What information have you been provided from the department as to why they did not go down the EU path?*' and '*What information has the department provided to you to explain why they have gone down the path of limiting the requirements to chemicals that are used solely in cosmetics?*':

The Department has expressed its desire to align Australian regulations as much as possible with that of major trading partners such as the EU. While we understand the Department's desire to align Australian regulation with EU law, our position is that the proposed wording for the Australian regulation is unnecessary to achieve the stated policy goal and in fact creates legal loopholes which do not exist in EU law or regulation.

During our ongoing communications with the Department in regards to the proposed ban on the use of newly derived animal test data for cosmetics, the Department referenced a 2014 factsheet (produced by the European Chemicals Agency (ECHA); see Attachment A) in support of its proposal to distinguish between chemicals used exclusively in cosmetics vs. those with multiple uses. Crucially, as we outlined during the hearing, and as we have outlined to the Department, we fear that the Department has interpreted this document well beyond its intended purpose or context. Understanding the context under which the ECHA factsheet was developed is vital to its correct interpretation.

ECHA, as the agency responsible for overseeing the registration and evaluation of chemicals in the EU, develops a variety of guidance to assist companies in complying with their obligations under complex and sometimes overlapping legal frameworks. The 2014 factsheet arose in response to questions from companies as to whether the marketing ban contained within the EU cosmetics regulation could be used as a basis for adapting or waiving REACH data requirements for the purpose of avoiding new animal testing. In this specific and narrow context, concerned only with how the REACH Regulation is interpreted and applied in the light of the Cosmetics Regulation and not with the interpretation and application of the Cosmetics Regulation, the question of whether a chemical is used exclusively for cosmetics is indeed appropriate and consequential. The waiver-specific context of this guidance is further reinforced in an accompanying media release (see Attachment B) and Q&As developed by ECHA).

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Furthermore, the specific and narrow context of the fact sheet guidance was reinforced in a recent ruling by the European Ombudsman (Decision in case 1130/2016/JAS concerning the joint statement made by the European Commission and the European Chemicals Agency on the conduct of animal tests for substances used in cosmetics, see Attachment C), which clearly stated that:

> "… *the joint statement is concerned only with how the REACH Regulation is interpreted and applied in the light of the Cosmetics Regulation. The joint statement does not purport to deal with the interpretation and application of the Cosmetics Regulation in the light of the REACH Regulation*."

The Ombudsman's assessment also stated that:

> "*The joint statement does not constitute a legally binding interpretation of the rights and duties of manufacturers or distributors. Furthermore, the fact that the Commission and ECHA may issue such guidance does not prejudge the issue of whether their guidance is correct. It is for the Court of Justice to provide a definitive interpretation of EU law*."

Additionally, in the recent EU court Case C-592/14 (see Attachment D), Advocate General Bobek issued a legal opinion addressing the ECHA opinion, stating that a reading that "*The prohibition [EU ban] would therefore only apply to substances with an actual or potential use exclusively in cosmetics*" would "*have little practical effect*" and for the purposes of Cosmetics Regulation "*reliance on the animal testing results is key. . . they cannot be used to demonstrate the safety of the ingredient*." [emphasis added]

It is therefore crucial to note that:

- Guidance regarding the waiving of potential new animal testing for chemical registration (as outlined in the fact sheet referenced by the Department) is separate and unrelated to the use of post-ban animal test data for safety substantiation of a cosmetic use.
- ECHA is not the regulatory authority for cosmetics in the EU, and as such ECHA guidance is not intended to provide an interpretation of EU cosmetics regulation (see the 11 March 2013 Communication from the European Commission for the definitive interpretation in this regard).

We believe the Department has conflated these two separate and distinct scenarios, and in so doing erred in its interpretation of both the intent and the scope of the ECHA guidance as a basis for its approach to the proposed ban on the use of newly derived animal test data for cosmetics in Australia.

Under the proposed wording for the Australian cosmetic animal testing data ban, loopholes would be written into Australian law that, quite simply, are not written into and cannot be found in EU law.

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.

We therefore reiterate our recommendation to remove the qualifier "solely" and to adjust the two-track system to group end uses as "cosmetic" or "non-cosmetic" to ensure that the cosmetics animal testing ban applies fairly and equally to *all introductions for cosmetic use*. Our suggested amendments remove the overly narrow language of Sections 103 and 168, closing potential loopholes and better aligning the Australian ban with EU law.

In response to the question from Senator Watt, 'Exactly how widespread is the use of industrial chemicals in cosmetics? The fact that the legislation talks about chemicals being 'solely' used in cosmetics means, obviously, it is a fairly widespread occurrence—that industrial chemicals also end up being used in cosmetics.':

In addition to detail included in our submission and our response outlined during the hearing, we would reiterate that most cosmetic ingredients in use globally are multi-use chemicals.

We note that in response to a question from Senator Watt – "*If it is the case that there are very few chemicals that are used solely for cosmetics—I should stop there. Do you accept that that is the case?*", the Department stated that "*We do find for those new chemicals that would be subject to the ban that there are actually quite a large number of chemicals which are currently being introduced solely for that cosmetic use*" (page 33 of proof Hansard transcript).

However, the Department's own submission to this inquiry indicates that, for the 2014-2015 year, **the majority of chemicals introduced that used animal test data were multi-use (79%;** 11 out of 14). The table on page 8 of their submission outlines these figures and is included below.

	Chemicals introduced 2014-15	Number using animal test data (derived post EU ban)
Cosmetic use only	4,269	3
Multiple uses	2,889	11
TOTAL	7,158	14

Profile of Chemicals Introduced under Australian Regulatory Arrangements - National Industrial Chemicals Notification Scheme (NICNAS) using 2014-15 data

We also note the response from Mr Craig Brock, of industry body Accord Australasia, during the hearing: **"***It is rarely the case that our industry, the cosmetic industry, would have just specific ingredients for the specific purpose of being used in a cosmetic*" (page 24 of proof Hansard transcript).

It is also worth noting that, irrespective of what specific proportion of chemicals used in cosmetics each year are multi-use, the ban will not capture the multi-use proportion. We would also reiterate that evidence provided by the Department, industry, and within our own submission, indicates that most cosmetic ingredients in use are multi-use chemicals.

If the ban provisions within the legislation are restricted to ingredients used solely in cosmetics, and chemicals introduced with *multiple* specified end uses are exempt from the prohibition, it would completely defeat the Government's stated policy goal for a ban.

Our recommended amendments to Sections 103 and 168 of the Government bill will ensure that animal test data obtained after July 2018 are *prohibited without exception* from application for *all cosmetic end uses*. Our amendments would thereby ensure the ban captures 100% of cosmetic end uses.

It is also important to note that our amendments would ensure that new animal- test data is banned for any and all chemical introductions for cosmetic use, regardless of whether the chemical is also being introduced for other uses, while still ensuring that animal testing is permitted for multi-use industrial chemicals when introduced for uses other than cosmetics (see Attachment E, our flowchart, and our submission for an outline of this). This would align with the EU approach (which prohibits the use of any data derived from new animal testing for the purposes of cosmetic safety substantiation in the EU).

Our amendments would better align the Australian ban with EU law, bring Australia level with international best practice, and meet the Government's own stated policy goal of banning cosmetics animal testing and trade in Australia.

In response to comments by Mr Brock, regarding ingredient supply, upstream chemical companies, and test data, made in response to Senator Watt's question '*One point you made was that it would be rare for chemicals to be solely used in cosmetics and not used for other purposes. Doesn't that mean that the proposed legislation is pretty meaningless if it is restricted to chemicals that are solely used for cosmetics?*' (page 25 Hansard proof):

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.

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.

ADDITIONAL MATERIALS

Attachment A – a factsheet that was provided to us by the Department on 25th May 2017, within the context of ongoing discussions with the Department on alignment of the EU and Australian bans, and which was referenced during our response to questions during the hearing - https://echa.europa.eu/documents/10162/13628/reach_cosmetics_factsheet_en.pdf/2fbcf6bf-cc78-4a2c-83fa-43ca87cfb314

Attachment B - ECHA and the European Commission media release accompanying the 2014 fact sheet - provides clarification on the specific and narrow context of the 2014 fact sheet guidance - https://echa.europa.eu/-/clarity-on-interface-between-reach-and-the-cosmetics-regulation

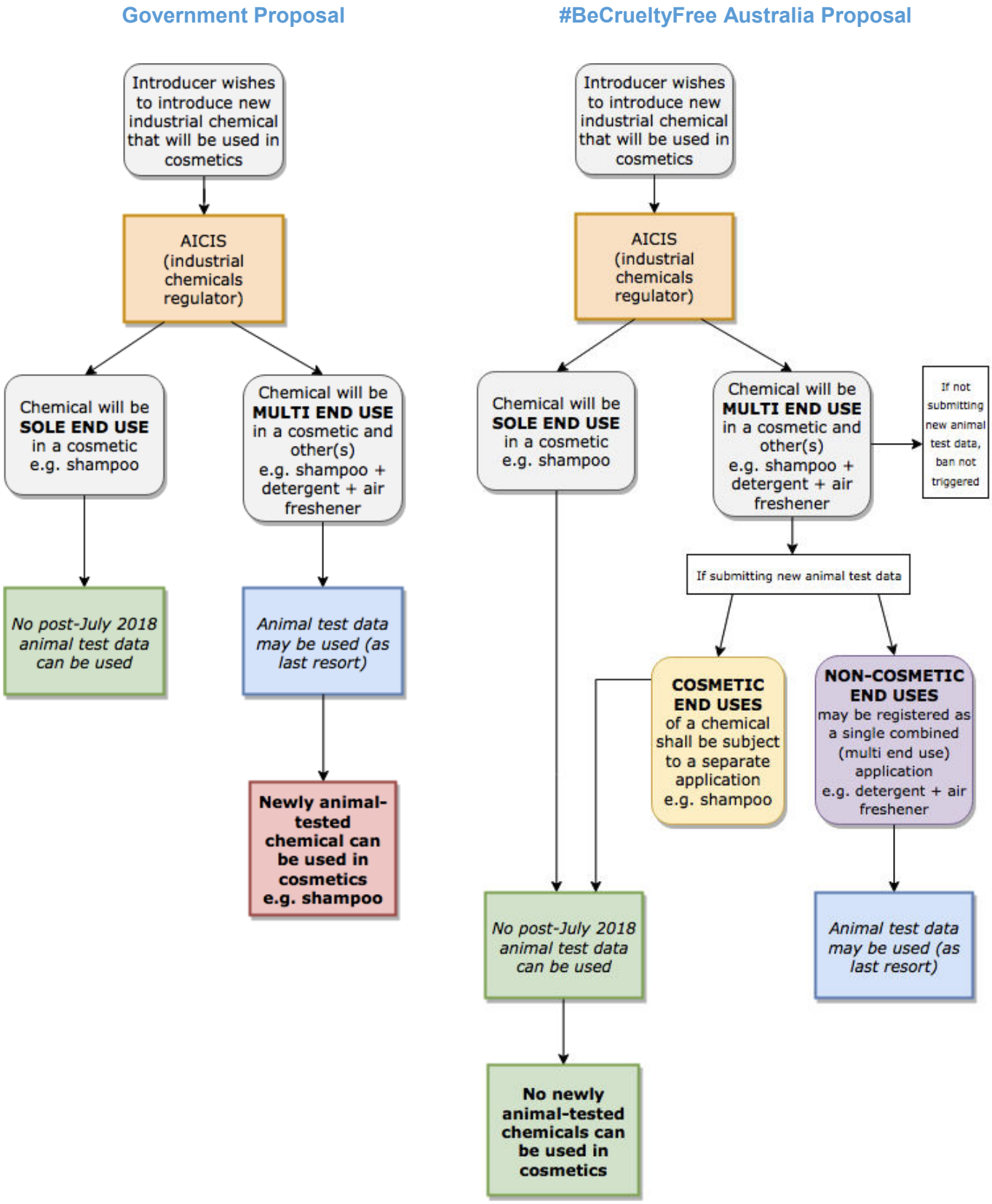
Attachment C – Decision in case 1130/2016/JAS concerning the joint statement made by the European Commission and the European Chemicals Agency on the conduct of animal tests for substances used in cosmetics – provides further clarification on the specific and narrow context of the 2014 fact sheet guidance - https://www.ombudsman.europa.eu/cases/decision.faces/en/81713/html.bookmark#_ftn1

Attachment D – Opinion of Advocate General Bobek, paragraphs 128-133, EU court Case C-592/14 - http://curia.europa.eu/juris/document/document.jsf;jsessionid=9ea7d0f130d55a33b7df38454d55b781c75f71b340f3.e34KaxiLc3eQc40LaxqMbN4PaN0Ne0?text=&docid=175149&pageIndex=0&doclang=en&mode=lst&dir=&occ=first&part=1&cid=530419

Attachment E – Extract from #BeCrueltyFree Australia submission with amendments (see below)

ATTACHMENT E

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



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), where new animal test data are to be submitted as part of a multi-use introduction, cosmetic end uses of a chemical would be assessed 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.

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.