

Be Cruelty-Free Australia



**HUMANE SOCIETY
INTERNATIONAL**



hra

humane research australia

12th July 2017

NICNAS Reforms
GPO Box 58
SYDNEY NSW 2001
[Redacted]

Re: Implementing reforms to the National Industrial
Chemicals Notification and Assessment Scheme
(NICNAS) - Consultation Paper 5

To Whom It May Concern:

#BeCrueltyFree Australia, a partnership between Humane Society International (HSI) and Humane Research Australia (HRA), welcomes the opportunity to comment on the Department of Health's consultation paper 5 on the implementation of reforms to the National Industrial Chemicals Notification and Assessment Scheme (NICNAS).

In the EU, HSI is an accredited stakeholder organisation with the European Chemicals Agency (ECHA) and is an observer at ECHA's Member State Committee as well as the committee of EU Competent Authorities for REACH and Classification and Labelling (CARACAL). We are also members of the Stakeholder Advisory Forum for the European Reference Laboratory for Alternatives (EURL-ECVAM), which monitors the development and uptake of alternative non-animal test methods. Our experts contributed to all of the consultations and stakeholder processes undertaken by the European Commission while REACH was formulated, and we were actively engaged in the relevant political negotiations.

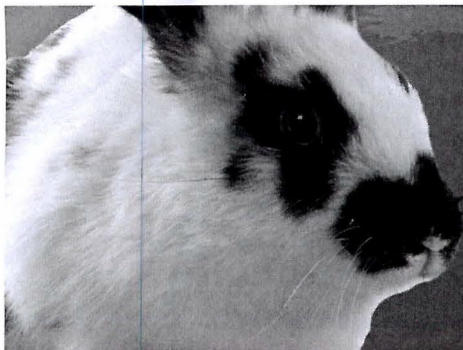
Our scientific staff are central to the growing community of experts working internationally to replace outdated animal tests with more relevant, informative and reliable non-animal methods. We contribute as invited experts to the OECD's Test Guidelines Programme and regularly present at meetings of the ICCR (International Cooperation on Cosmetics Regulation).

We thank NICNAS once again for the opportunity to comment and we also appreciate the continued open and inclusive approach to the consultation process.

Yours sincerely,



Hannah Stuart
Coordinator



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EXCERPT OF RESPONSE TO CONSULTATION PAPER 5 & SUPPORTING MATERIAL PERTAINING TO REFORMS TO THE NATIONAL INDUSTRIAL CHEMICAL NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

12 July 2017

KEY OBJECTIVES

In relation to the ban on animal test data for determining category for cosmetics and for applications for cosmetics, provisions should:

- Ensure that the ban on new animal test data apply equally to all introductions for cosmetic use, and not only to industrial chemicals with a stated end use “solely” in cosmetics;
- Prohibit the repurposing of new animal test data used initially to introduce an industrial chemical for a non-cosmetic use to later support of a cosmetic use;
- Not undercut a company’s obligation to report previously undocumented hazards to human health or the environment to the Department of Health.

Part 9 // Ban on the use of new animal test data for cosmetic ingredients

We have provided the Government with separate, detailed feedback and suggested amendments to the Industrial Chemicals Bill 2017 (see Attachment A, hereto), which shall not be repeated other than to 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.

The Department has expressed its desire to align Australian regulations as much as possible with that of major trading partners such as the EU. For the purpose of the proposed ban on the use of newly derived animal test data for cosmetics, the Department references a 2014 factsheet produced by the European Chemicals Agency (ECHA) in support of its proposal to distinguish between chemicals used exclusively in cosmetics vs. those with multiple uses. However, understanding the context under which the ECHA factsheet was developed is vital to its correct interpretation, and we fear that the Department has interpreted this document well beyond its intended purpose or context.

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 marketing 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, the question of whether a chemical is used exclusively for cosmetics is indeed appropriate and consequential (and the waiver-specific context of this guidance is further reinforced in an accompanying media release and Q&As developed by ECHA).

It is crucial to note, however, that:

- Guidance regarding the waiving of potential new animal testing for chemical registration 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.

To the Department's question, "What are your views on the proposed limited circumstances in which animal test data would be permitted to protect human health and the environment?", we note that 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. Our 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.

In March 2017 the Department released a consultation paper outlining other policy options in regard to implementing the cosmetics animal testing ban. Here we would again reiterate and expand upon previous comments made in response to this consultation paper, now within the context of Consultation Paper 5 (June 2017), which calls for comments on proposed regulatory rules contained within delegated legislation which directly relate to the implementation of the cosmetics animal testing ban.

In particular, point 4 on the list of 'Exceptions' outlined on p. 15 of the March 2017 Consultation Paper, suggests that the design of the ban would allow for "repurposing a chemical substance (and any associated animal test data) used initially for a different purpose, for subsequent use in a cosmetic product". We contend, however, that allowing the use of new animal test data, which was 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 meaningless. Such an exception would not be consistent with the Government's policy announcement to implement a ban on cosmetics animal testing and the sale of animal tested cosmetics in Australia.

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. The proposed 'repurposing' exception is unnecessary and is not consistent with either the Government's commitment nor global precedent for cosmetics animal testing bans. We therefore reiterate our previous recommendation that this exception be removed from consideration.