



Australian Government
Department of Health

**Submission to the Senate Community Affairs Legislation Committee
Inquiry**

Industrial Chemicals Bill 2017 and related Bills

12 June 2017

1. Purpose of this submission

The Department of Health is pleased to provide this submission for consideration by the Senate Community Affairs Legislation Committee.

Through this submission, the Department seeks to highlight the extensive consultations that have occurred to develop and implement reforms to industrial chemicals regulation in Australia.

This submission also includes information about the consultations on the ban on animal test data for cosmetic ingredients, which are regulated as industrial chemicals in Australia.

Stakeholders for industrial chemicals cover a wide range of interest areas, including the industry sector, community, public health and worker safety groups, environmental groups and animal welfare groups.

2. Chemicals regulation

Chemicals in Australia are regulated under a number of schemes. If a chemical is not for a therapeutic, agricultural, veterinary or food use, it is considered an industrial chemical in Australia.

Industrial chemicals play an essential role in everyday life. They are in paints, petrol, plastics, cleaners, dyes, fragrances and cosmetic products. But they can also present risks to human health, worker safety and the environment that require management through fit-for-purpose regulation.

Industrial chemicals are part of a multi-billion dollar global market and are subject to various regulatory arrangements around the world. It is important that Australian regulations align, as far as possible, with our major trading partners.

Industrial chemicals are both imported and manufactured locally, with Australian imports and exports of industrial chemicals combined exceeding approximately \$62 billion in 2015-16.¹ For example, the Australian manufacturing industry for cosmetic products is globally focused, employs some 18,000 people,² with exports worth approximately \$535 million in 2015-16.³

The Commonwealth has regulated industrial chemicals since 1989 under the *Industrial Chemicals (Notification and Assessment) Act 1989*, known as the National

¹ [Key Facts: Australian Chemicals And Plastics Manufacturing Data Card 2017](https://industry.gov.au/industry/IndustrySectors/chemicalsandplastics/Pages/ChemicalsPlasticsManufacturingDataCard.aspx); Department of Industry, Innovation and Science - <https://industry.gov.au/industry/IndustrySectors/chemicalsandplastics/Pages/ChemicalsPlasticsManufacturingDataCard.aspx>

² IBIS World Industry report G4271B1852 Cosmetics and Toiletry Retailing in Australia – May 2016

³ IBIS World Industry report C1852 Cosmetics, Perfume and Toiletries, Manufacturing in Australia – June 2016

Industrial Chemicals Notification and Assessment Scheme (NICNAS). This would be replaced from 1 July 2018 by the Australian Industrial Chemicals Introduction Scheme (AICIS).

3. Overview of the reforms

The Industrial Chemicals Bill 2017 establishes the legislative framework for a new risk-based regulatory scheme for the Commonwealth to continue to regulate the introduction of industrial chemicals in Australia. Please refer to [Attachment A](#) for information on the reforms.

The following key features of the reformed industrial chemicals scheme describe how the legislation achieves a balance between reducing unnecessary regulatory burden for industry and maintaining human health, worker safety and environmental protections against harms from industrial chemicals.

Risk-based approach to regulation

Regulatory touch will be proportionate to the level of risk to human health and safety and the environment. The new scheme rebalances pre- and post-introduction regulatory controls, so that there will be less emphasis on pre-introduction assessment of lower risk new chemicals and a greater focus on post-introduction evaluation and monitoring.

Light touch regulation for the lowest risk chemicals will reduce industry's annual regulatory burden by around \$23 million. This will be achieved through a reduction in the number of chemicals assessed pre-introduction by the regulator by more than 70 per cent, enabling the regulator to focus efforts on higher risk chemicals; and less annual reporting and faster, simpler online processes.

The faster regulatory pathway for lower risk chemicals would promote a more innovative industry by providing an incentive to introduce new, safer chemicals.

Introducers will continue be required to apply for assessment for higher risk chemicals, which will maintain the protection of the Australian people and the environment.

Continuing to maintain Australia's high standards of protection

The protection of human health, worker safety and the environment is paramount.

The legislation includes a new power for the Executive Director to impose conditions on introductions or refuse introduction of an industrial chemical where the health and environmental risks in Australia cannot be managed. The legislation will introduce the ability for the Executive Director to initiate evaluations of both listed (on the Inventory) and unlisted chemicals. The Executive Director will be able to

adopt a flexible approach, allowing any triggers for initiating evaluations to be considered and regulatory effort to focus on areas of potential health or environmental concern.

Improved post-introduction monitoring and compliance powers will provide the safeguards necessary to maintain protections of health and safety of consumers, workers and the environment. These powers and more appropriate compliance tools will allow the Executive Director to apply a proportionate response to non-compliance based on the circumstances. This replaces the current 'feather or brick' approach where the regulator can either work with the introducer to remedy the breach through an (informal) administrative notice or pursue criminal prosecution.

Improved transparency

Greater transparency will be achieved by striking a balance between confidentiality and publicly available information. The public will have access to more information on the risks of an industrial chemical assessed by the regulator through published risk assessment statements that will be linked to the subsequent Inventory listings. This information will assist users of these chemicals to be aware of the risks they pose and controls on their use in order to enable safe use.

There will no longer be a confidential section of the Inventory. Instead, confidentiality of business information will be protected by the use of partially masked names or uses in circumstances where the Executive Director is satisfied that disclosure of the confidential information could reasonably be expected to cause substantial prejudice to commercial interests, that would outweigh the public interest in revealing the information.

Better international alignment

The Department has worked closely with other international regulators, including in the USA, Canada and the European Union, to align definitions and key concepts wherever possible.

Introducers will also be able to make greater use of relevant information on industrial chemicals that are approved overseas.

This supports the Australian industry to become more competitive internationally.

4. Consultations to reform the industrial chemicals regulation

The Department has worked closely with stakeholders over a number of years to deliver the industrial chemicals reforms, including:

- the review of NICNAS by the Department in 2012-2014

- targeted consultations in 2013-2014 to develop the Regulation Impact Statement: Options for reforming industrial chemicals regulation⁴
- four consultation papers and eight public workshops in 2016-17 to develop the implementation details for the legislation
 - 148 written submissions; over 350 stakeholders attended workshops.

A fifth consultation paper was released on 1 June 2017. This focuses on the technical and operational arrangements of the scheme to be in the rules⁵ and guidance materials. The details will be developed through further workshops and consultation over the next six months. As the rules are legislative instruments, they are subject to disallowance by Parliament. It is anticipated they would be tabled early in 2018.

The Department is also planning an education and training program for industry and other interested stakeholders once the rules and guidance materials are available and prior to commencement of the new scheme on 1 July 2018.

All stakeholder views have been considered when developing the reforms. The Regulation Impact Statement identified stakeholder concerns, and the subsequent consultation papers systematically identified stakeholder positions and suggestions and how the Department sought to address them. However, it has not been possible to accommodate all views.

Stakeholder views have remained polarised on some aspects. While most stakeholders support the objectives of the reforms, they do not agree on how to achieve the objectives. Some favour a more restrictive approach to regulation (mostly community stakeholder groups) and others favour a more deregulatory approach. For example, various community and environmental groups sought pre-introduction assessment of a wider range of chemicals whereas some industry stakeholders sought changes to the proposed categorisation such that fewer chemicals are subject to assessment.

The Department has sought to balance the varied stakeholder views by adopting a streamlined, risk-proportionate and transparent approach to industrial chemicals regulation while continuing to maintain Australia's high standards of protections for the public, workers and the environment.

⁴ This document is available on the Office of Best Practice Regulation website: - <http://ris.pmc.gov.au/2015/06/05/industrial-chemicals-assessment-reforms-%E2%80%93-regulation-impact-statement>

⁵ The term *rules* is used to refer to all forms of secondary legislation, such as ministerial determinations and other legislative instruments. Rule-making powers are included in the principles-based legislation in order to enable the primary legislation to remain responsive and flexible as science develops and the international regulatory environment changes over time.

5. Consultations to the ban on animal testing for cosmetic ingredients

The Department has also undertaken extensive consultation between November 2016 and March 2017 on the implementation of the ban on cosmetic testing on animals. This has included:

- [Two consultation papers](#) regarding the development of a ban and this was supported by stakeholder workshops, an online survey, online submissions and consumer market research
 - 80 stakeholders attended workshops; 760 online submissions; 24,591 respondents to the online survey; 2,047 members of the public participated in the market research.

Industry stakeholders indicated that they consider the data ban to be a pragmatic approach which eliminates unnecessary animal testing, aligns Australia's regulatory approach with comparable international bans and ensures that the Australian cosmetics industry can remain competitive globally.

Animal welfare stakeholders are supportive of a ban but they would like the ban to include all chemicals, not just those used solely in a cosmetic product.

The Department's extensive research with consumers, including the survey and targeted workshops, segmenting the Australian population, overall indicated that most participants held the view that, while supporting the ban, safety should not be compromised.

For further information, please refer to the fact sheet at [Attachment B](#).

Industrial Chemicals Reforms

The package of six Bills to reform industrial chemicals regulation includes:

- Industrial Chemicals Bill 2017 – establishes the new regulatory arrangements
- Industrial Chemicals (Consequential Arrangements and Transitional Provisions) Bill 2017 – to transition arrangements on foot under the old scheme to the new
- Industrial Chemicals Charges (General) Bill 2017 – for continued cost-recovery
- Industrial Chemical Charges (Customs) Bill 2017 – for continued cost-recovery
- Industrial Chemicals Charges (Excise) Bill 2017 – for continued cost recovery
- The Industrial Chemicals (Notification and Assessment) Amendment Bill 2017 – to put in place early wins for industry around low risk chemicals.

The main Industrial Chemicals Bill implements the principles-based framework for a new streamlined and risk proportionate industrial chemicals scheme and will establish:

- the Australian Industrial Chemicals Introduction Scheme to replace the National Industrial Chemicals Notification and Assessment Scheme, and a new Inventory
- six categories of introduction that are proportionate to the level of risk to human health and safety or the environment
- increased public transparency while protecting certain confidential business information
- a responsive, flexible and transparent process for the regulator to evaluate any chemical
- a ban on the use of data derived from an animal test from 1 July 2018 to support the introduction of a cosmetic ingredient
- increased international harmonisation and greater use of international assessments from comparable regulators
- continuation of Australia's obligations under certain international agreements.

To enable the new legislation to remain responsive to scientific developments and changes in industry, the technical and operational details for the new scheme will be set out in delegated legislative instruments, which will be disallowable.

How does Industrial chemical regulation work in Australia?

- Chemicals in Australia are regulated under a number of schemes. If a chemical is not for a therapeutic, agricultural, veterinary or food use, it is considered an Industrial chemical under the existing scheme. This will not change for the new scheme.
- When a business wishes to introduce a medium to high risk industrial chemical in Australia they need to provide information, including data, so that the regulator can make an assessment of the risks of that chemical and provide information to promote their safe use. This helps protect the Australian people and the environment.

What impact will the reforms have on industry?

- Light touch regulation for the lowest risk chemicals, through less annual reporting and a faster and simpler introduction process, will reduce industry's annual regulatory burden

by around \$23 million. This would promote a more innovative industry by encouraging the introduction of new, safer chemicals.

- Introducers will only be required to apply for assessment for higher risk chemicals. Overall, assessments are expected to reduce from 3% to approximately 0.3% of all new chemicals introduced.
- Faster online processes will simplify applications and provide for same-day registration for introducers.
- Introducers will be able to make greater use of relevant international risk assessments, provided the risks are no higher than acceptable in the Australian context.

What impact will the reforms have on public and worker health and safety and environment?

- The reforms will continue to maintain Australia's high standards for protecting the community, workers and the environment.
- The Executive Director will be able to impose conditions on new higher risk chemicals, and refuse to allow a chemical to be introduced.
- The Executive Director will also have more flexibility to rapidly respond to risks from new chemicals or chemicals already on the market.
- Modern enforcement tools will be available to ensure compliance and identify non-compliance.

How will transparency be increased?

- More appropriate information will be available to the public on the risks of an industrial chemical through linking of inventory listings to assessment statements.
- Confidentiality will be protected by the use of partially masked name or uses where appropriate. There will no longer be a confidential section of the Inventory.

What will be the impact on existing chemicals in the market?

- Transition arrangements will minimise disruption to introduction by moving all chemicals on the existing Inventory to the new Inventory.
- Similarly, existing assessment certificates or permits will be deemed to be assessment certificates under the new Act, or transitioned to one of the six introduction categories.

Ban on Cosmetic Testing on Animals

What is a cosmetic?

- Cosmetics are used by consumers every day – estimates indicate each consumer uses at least seven different cosmetic products per day and many of us use more:
 - Oral hygiene: mouthwash and toothpaste
 - Soaps and deodorants: antiperspirants, bath gels, body washes, antibacterial hand washes, shampoos and conditioners
 - Make up and beauty: nail polish, mascara, depilatory products, hair dyes and perfumes
 - Skin care: skin cleansing, acne washes, secondary sun protection products (with an SPF of 15 or below), lip care creams, anti-ageing creams, moisturisers and shaving creams, and
 - Some baby care and hygiene products.

How are cosmetics regulated in Australia?

- Cosmetic ingredients are subject to regulation under the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), which is established by the Industrial Chemicals (Notification and Assessment) Act 1989.
- When a business wishes to introduce a medium to high risk industrial chemical in Australia they need to provide information including data so that the regulator can make an assessment of the risks of that chemical and provide information to promote their safe use. This helps protect the Australian people and the environment.
- Cosmetics products are also consumer goods and are subject to the broad provisions of the Australian Consumer Law (ACL) (Schedule 2 of the Competition and Consumer Act 2010) which is regulated by the Australian Competition and Consumer Commission.

What do we know about cosmetic testing on animals?

- There is no cosmetic testing on animals conducted in Australia.
- The use of animal test data is decreasing as cheaper laboratory or computer simulation methods have become increasingly available since the ban in the European Union (EU).
- The following table shows the limited use of animal test data to support cosmetics applications for introduction into Australia.

	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

Consultation with Industry, Animal Welfare stakeholders and the Australian Community

- All stakeholders argued for harmonisation with international approaches to a ban on animal testing
- Consumers wanted a ban that would not unduly impact on the safety of the products they purchase or on Australian industry
- Animal welfare stakeholders considered the introduction of a ban would position Australia as a progressive nation on animal welfare issues.

Budget 2017-18 Announcement

- As part of the 2017-18 budget package, the Government will implement a ban on cosmetic testing on animals by:
 - Introducing legislation to enable a national ban on the use of new animal test data to support the introduction of chemicals used exclusively as cosmetic ingredients;

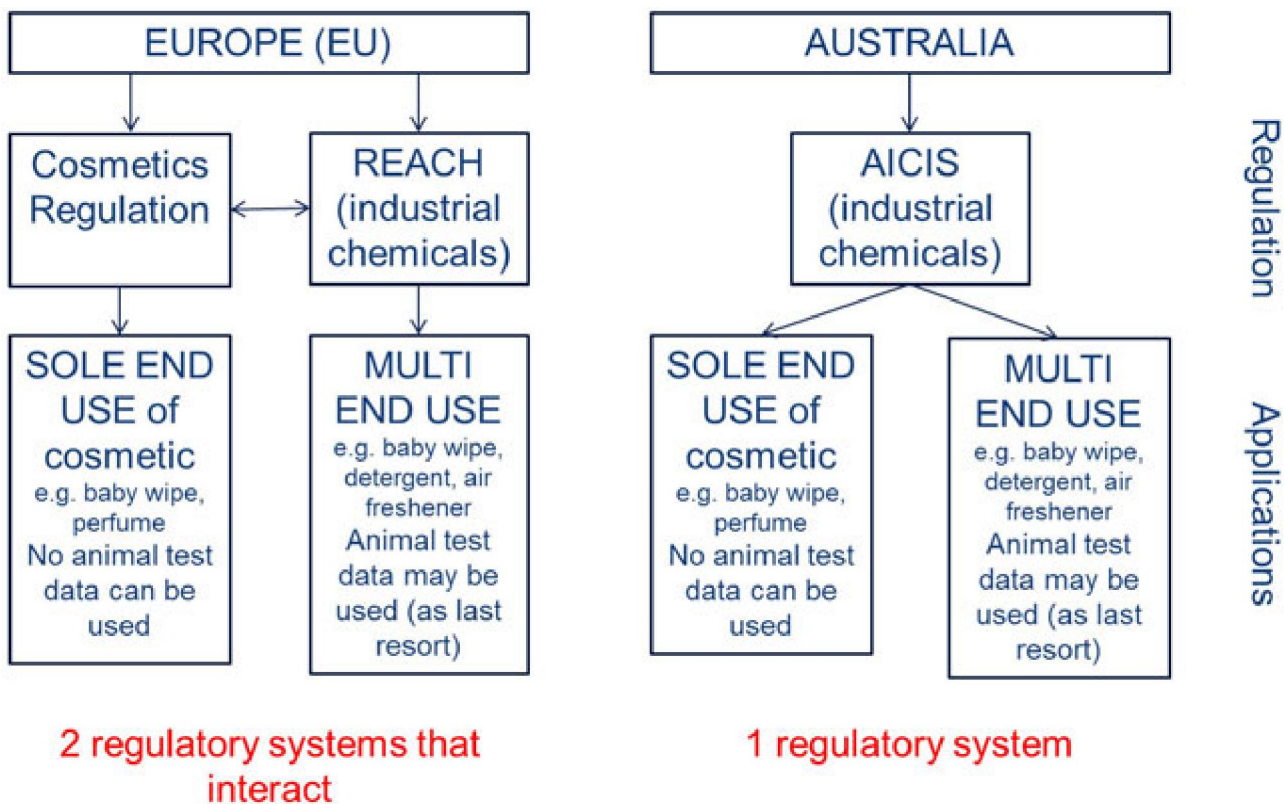
- Working with states and territories to incorporate a testing ban through their respective legislation, triggered by changes to the National Health and Medical Research Council Australian code for the care and use of animals for scientific purposes; and
- Working with the cosmetics industry, in consultation with key animal welfare stakeholders, to develop a voluntary code of practice on the sale of cosmetic products.

Legislation to enable the ban on the use of data from animal testing

- On 1 July 2017, the Assistant Minister for Health introduced legislation into Parliament to reform the regulation of industrial chemicals. This legislation bans the use of data derived from an animal test conducted after 1 July 2018 to support the introduction of a chemical in a cosmetic.
- This will apply a ban on the use of animal testing data for more than 99% of the cosmetics introduced into Australia. The remaining less than 1% are circumstances where these chemicals are also used in other industries and this information is critical to ensure we protect consumers, the public and the environment.

How does the EU ban cosmetic testing on animals?

- The EU prohibits the use of animal test data to support the safety of a cosmetic marketed in the EU, where the data have been generated in order to meet regulatory requirements for the marketing of cosmetics.
- Animal test data on chemicals used solely in cosmetics is permitted to meet EU regulatory obligations for protection of workers and the environment. Animal testing is permitted to meet EU obligations for substances that are used for multiple purposes (i.e. not solely in cosmetics).
- Testing undertaken to meet overseas regulatory regimes (eg China) cannot be used to support marketing approval but such testing does not result in a ban of a product.



Comparison of how the EU and the Australian bans operate within each regulatory system