

## **EXPLANATORY STATEMENT**

### **Select Legislative Instrument No. 9, 2019**

Subject - *Industrial Chemicals (Notification and Assessment) Act 1989*

*Industrial Chemicals (Notification and Assessment) Amendment (Reforms) Regulations 2019*

#### **Authority**

The *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) establishes the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), being a national system of notification and assessment of industrial chemicals for the protection of human health and the environment to deliver the safe and sustainable use of chemicals.

Section 111 of the Act provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing matters required or permitted by the Act to be prescribed, or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

#### **Purpose**

The purpose of the proposed Regulations is to implement components of the 2015-16 Budget measure: Reducing the Burden of the Industrial Chemicals Regulatory Framework to Industry. The proposed Regulations will amend the *Industrial Chemicals (Notification and Assessment) Regulations 1990* (the Regulations) to achieve better international alignment of the criteria for polymers of low concern and remove the requirement to provide Safety Data Sheets and labels for certain new industrial chemicals in cosmetics introduced at low volumes.

#### **Background**

The Act establishes a national system of notification and assessment of industrial chemicals, to provide for registration of certain persons proposing to introduce industrial chemicals, to provide for national standards for cosmetics imported into, or manufactured in, Australia, and for related purposes.

The proposed Regulations form part of a broader package of reforms to NICNAS. These broader reforms were announced by Government in the context of the 2015 Budget and are proposed to commence from 1 July 2020 through a package of six Bills:

- The Industrial Chemicals (Notification and Assessment) Amendment Bill 2017 (the ICNA Amendment Bill)
- Industrial Chemicals Bill 2017 - which will establish the new regulatory scheme
- Industrial Chemicals (Consequential Arrangements and Transitional Provisions) Bill 2017
- Industrial Chemicals Charges (General) Bill 2017

- Industrial Chemical Charges (Customs) Bill 2017
- Industrial Chemicals Charges (Excise) Bill 2017.

There will be certain elements of the reforms package that will be implemented in advance of the broader reforms. These certain elements, otherwise referred to as the ‘early reforms’, will be implemented in 2019 through: the ICNA Amendment Bill and amendments to the Regulations. The early reforms will reduce red tape for lower risk chemicals by: changing definitions and the criteria for polymers of low concern to more closely align with international approaches, as well as exempting them from notification before introduction; removing certain annual reporting obligations that will no longer be required once the broader reforms are implemented; and removing a requirement to provide Safety Data Sheets and labels for certain cosmetics that will also no longer be required once the broader reforms are implemented.

In particular, the new definition of polymer of low concern will achieve better international alignment with comparable jurisdictions, such as the USA and Canada. This would also complement related amendments in the ICNA Amendment Bill which, in effect, expands the number of very low risk polymers that fall within the definition. Polymers are chemicals used in household paints, for example. The proposed Regulations also include amendments to Schedule 4 that draw on the work of the OECD New Chemicals Clearing House to create better international alignment.

### **Details**

Details of the Regulations are set out in the [Attachment](#).

Subsection 5(1)(f) of the Act provides that regulations may prescribe such other characteristics of a polymer of low concern. Regulations 4A to 4I define these other characteristics.

Subsection 21(4)(b)(1) of the Act provides that regulations may prescribe requirements relating to the introduction of a new industrial chemical in a cosmetic not exceeding 100 kilograms in a 12 month period (either by itself or in a mixture with one or more other chemicals). Regulation 6AB(5A) sets out the requirement to give the Director a Safety Data Sheet relevant to the chemical or product containing the chemical and the label attached to the packaging of the chemical or product containing the chemical.

The Act specifies no conditions that need to be satisfied before the power to make the proposed Regulations may be exercised.

### **Documents Incorporated by Reference**

No documents are incorporated by reference.

The Regulations are a legislative instrument for the purposes of the *Legislation Act 2003*.

The Regulations commence on the later of:

- (a) the start of the day after this instrument is registered; and

(b) immediately after the commencement of Schedule 1 to the *Industrial Chemicals (Notification and Assessment) Amendment Act 2019*.

However, the provisions do not commence at all if the event mentioned in (b) above does not occur.

Authority: Section 111 of the *Industrial Chemicals (Notification and Assessment) Act 1989*

## **CONSULTATION**

This package of early reforms is a result of stakeholder input from an extensive consultation process on the industrial chemicals reforms that included: four public consultation papers, eight public forums, approximately 130 written submissions and consultation with the NICNAS Strategic Consultative Committee (the main advisory committee comprising industry and community representatives) and comparable international regulators. In particular, Consultation Paper 3, released in April 2016, expressly sought stakeholder views on matters included in the proposed Regulations. These early reforms are not contentious.

**Details of the proposed *Industrial Chemicals (Notification and Assessment) Amendment (Reforms) Regulations 2019***

**Section 1 - Name**

This section provides that the title of the Regulation is the *Industrial Chemicals (Notification and Assessment) Amendment (Reforms) Regulations 2019*.

**Section 2 - Commencement**

This section provides for the Regulations to commence on the later of:

- (a) the start of the day after this instrument is registered; and
- (b) immediately after the commencement of Schedule 1 to the *Industrial Chemicals (Notification and Assessment) Amendment Act 2019*.

However, the provisions do not commence at all if the event mentioned in paragraph (b) does not occur.

**Section 3 - Authority**

This section provides that the regulations are made under the *Industrial Chemicals (Notification and Assessment) Act 1989*.

**Section 4 - Schedule(s)**

This section provides that each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

**Schedule 1 – Amendments**

**Part 1 – Amendments**

**Item [1] – Amendment to regulation 2**

Regulation 2 provides for definitions. This item inserts three additional definitions: high concern reactive functional group, low concern reactive functional group and moderate concern reactive functional group. These definitions are further defined in the appropriate clauses of Schedule 3 (see item [11]).

**Item [2] – Amendment to regulations 4A, 4B and 4CA**

The existing regulations 4A, 4B and 4CA set out the scientific characteristics related to size and reactivity that define what constitutes a polymer of low concern.

This item would repeal and substitute regulations 4A, 4B and 4CA, with new regulations for 4A and 4B, to better describe these characteristics and to more closely align with other international criteria for polymers of low concern.

**Items [3] - [6] – Amendments to regulation 4I**

Regulation 4I of the Principal Regulations prescribes other characteristics, for the purposes of paragraph (f) of the definition of ‘polymer of low concern’ in section 5(1) of the Act.

**Item [3] – New subregulation 4I(1A)**

To avoid unnecessary repetition and to accommodate the new subsection added to Regulation 4I (see Item [6]), this item inserts a new paragraph that identifies the correct subsection of the Act that refers to the definition other characteristics of a polymer of low concern.

**Item [4] – Amendment to subregulation 4I(1)**

Consistent with the inclusion of item [6], the previous text has been amended to prevent the new subregulation from being contradicted.

**Item [5] – Amendment to subregulations 4I(2) and (3)**

Consistent with the inclusion of item [6], the previous text has been amended to reflect the inclusion of the new text and the new structure of the Regulations.

**Item [6] – New sub-regulation 4I(4)**

The item provides additional information that a polymer would not meet the definition of a polymer of low concern if its integral composition contained (except as an impurity) a chain (whether branched or linear) of fully fluorinated carbon atoms, at least one end of which is terminated by a perfluoromethyl (CF<sub>3</sub>) group. This is to prevent polymers with potentially persistent, bioaccumulative or toxic degradation products from being considered to be polymers of low concern.

**Item [7] – New subregulation 6AB(1C)**

This item sets out, in law, those regulations that apply to a new industrial chemical that is a polymer of low concern, as referenced in a new subparagraph of the amended Act.

**Item [8] – Amendment to subregulation 6AB(5A)**

The repeal of this subregulation provides for a reduction in regulatory burden for introducers of low volume chemicals, introduced in a cosmetic. The subregulation’s repeal means that introducers no longer must provide either Safety Data Sheets or packaging labels of the chemical or product to the Director of NICNAS.

### **Item [9] – Amendment to subparagraph 6AB(7)(a)(i)**

Consistent with the repeal of Item [8], this Item provides for the removal of a reference to this subparagraph. It further provides for an updated inclusion ensuring that the Director of NICNAS is still provided with a notification, in writing, from the introducer of the cosmetic, that the chemical is safe for use, including by high-risk groups (including, for example, infants, elderly persons and atopic persons), consistent with the anticipated pattern of consumer exposure.

### **Item [10] – Amendments to subparagraph 6AB(7)(b)(i)**

In keeping with item [8], this Item removes reference to the repealed subregulation.

### **Item [11] – Amendments to Schedule 3**

The existing Schedule 3 provides, in a single table, the reactive functional groups that were considered to be of low, moderate and high concern. This item repeals the existing table and substitute with updated and restructured tables, which have the effect of removing the following reactive functional groups from the high concern list and adding them to the moderate concern list:

- Acid anhydrides
- Acid halides
- Aldehydes
- Alkoxysilanes (with alkoxy greater than C2 alkoxy silane)
- Allyl ethers
- Cyanates
- Epoxides
- Hemiacetals
- Imines (ketimines and aldimines)
- Methylol amides
- Methylol amines
- Methylol ureas
- Unsubstituted positions ortho and para to phenolic hydroxyl

### **Items [12-30] – Amendments to Schedule 4**

The Regulations contain tables of chemicals of prescribed reactants. These Items add new chemicals, or in the case of Item 26 repeal and substitute a chemical, to the existing tables of chemicals found in the Regulations. Therefore the table format is intended to replicate the presentation of the chemicals in the Regulations, including column headings. The purpose of each table is to present the information in a consolidated way and thereby remove repetition when explaining each Item line.

For each table, the following explanation applies:

- For Item numbers [12-30], Item refers to the Item number in the *Industrial Chemicals (Notification and Assessment) Amendment (Reforms) Regulations 2019*.
- CAS number refers to the Chemical Abstracts Service Registry Number. A CAS number (also known as a CAS RN) is a well-known concept used internationally

to provide a unique identifier for chemical substances. It provides an unambiguous way to identify a chemical substance or molecular structure when there are many possible systematic, generic or proprietary names.

- Table item refers to where the new chemical will be inserted into the existing table of Items in the Regulations. For example, table item 111A would be inserted after table item 111.

### Items [12 - 15] – Amendments to Schedule 4, Part 1

These Items amend the current Schedule 4, Part 1, Di and Tri Basic Acids table, to include:

<b>Di and Tri Basic Acids</b>			
<b>Item</b>	<b>Substance</b>	<b>CAS number</b>	<b>Table item</b>
12	1,4-Cyclohexanedicarboxylic acid	1076-97-7	111A
13	2,5-Furandione, dihydro-	108-30-5	116A
14	5-Isobenzofurancarboxylic acid, 1,3-dihydro-1,3-dioxo-	552-30-7	121A
14	1,3-Isobenzofurandione	85-44-9	121B
15	Unsaturated fatty acids, C <sub>18</sub> , dimers, hydrogenated	68783-41-5	131

### Items [16 - 18] – Amendments to Schedule 4, Part 2

These Items amend the current Schedule 4, Part 2, Modifiers table, to include:

<b>Modifiers</b>			
<b>Item</b>	<b>Substance</b>	<b>CAS number</b>	<b>Table item</b>
16	Ethanol	64-17-5	204A
17	Methanol	67-56-1	206A
18	1-Propanol, 2-methyl-	78-83-1	209A

### Items [19 - 29] – Amendments to Schedule 4, Part 3

These Items amend the current Schedule 4, Part 3, Monobasic Acids and Natural Oils table, to include or substitute, as indicated, the following substances:

<b>Monobasic Acids and Natural Oils</b>			
<b>Item</b>	<b>Substance</b>	<b>CAS number</b>	<b>Table item</b>
19	Castor oil	8001-79-4	302A
19	Castor oil, dehydrated	64147-40-6	302B
19	Castor oil, dehydrated, polymerised	68038-02-8	302C
20	Coconut oil, hydrogenated	84836-98-6	303A
21	Corn-oil fatty acids	68308-50-9	304A
22	Fatty acids, C <sub>8-10</sub>	68937-75-7	312A
22	Fatty acids, C <sub>14-18</sub> and C <sub>16-18</sub> -unsaturated	67701-06-8	312B
23	Fatty acids, olive oil	92044-96-7	317A
24	Fish oil	8016-13-5	324A
25	Hexadecanoic acid	57-10-3	326A

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**Monobasic Acids and Natural Oils**

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Item	Substance	CAS number	Table item
25	9-Hexadecenoic acid, (9Z)-	373-49-9	326B
26	Hexanoic acid, 3,3,5- trimethyl-	23373-12-8	328A
26	Hexanoic acid, 3,5,5-trimethyl-	3302-10-1	328 repealed
27	Linseed oil, polymerised	67746-08-1	330A
28	Octadecanoic acid,	57-11-4	331A
28	9-Octadecenoic acid (9Z)-	112-80-1	331B
28	9,12-Octadecadienoic acid (9Z,12Z)-	60-33-3	331C
29	Olive oil	8001-25-0	335A

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**Item [30] – Amendments to Part 4 of Schedule 4**

These Items amend the current Schedule 4, Part 4, Polyols table, to include the following substance:

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**Polyols**

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Item	Substance	CAS number	Table item
30	1,3-Propanediol	504-63-2	408A

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**Item [31] – Amendment to Schedule 4**

This Item adds an addition part, Part 5, to the schedule, on derivatives. Derivatives are substances that are chemically derived from a specific compound. This table sets out the substances derived from those substances set out in Parts 1 and 3 of Schedule 4:

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**Derivatives**

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Item	Substances
1	A diethyl or triethyl ester of a substance listed in Part 1 of this Schedule
2	A dimethyl or trimethyl ester of a substance listed in Part 1 of this Schedule
3	An anhydride of a substance listed in Part 1 or Part 3 of this Schedule
4	An ethyl ester of a substance listed in Part 1 or Part 3 of this Schedule
5	A methyl ester of a substance listed in Part 1 or Part 3 of this Schedule

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**Item [32] – Application of amendments made by Part 1 of Schedule 1**

This Item adds an addition at the end of Schedule 5 that provides the information on when the amendments made by Part 1 of Schedule 1 to the *Industrial Chemicals (Notification and Assessment) Amendment (Reforms) Regulations 2019* are to be applied. It stipulates that the amending regulations apply to the introduction of new industrial chemicals, immediately on and subsequently to the commencement time. Applications made for permits or assessment certificates made, but not finalised, before the commencement time will not be subject to the new regulations.



The definition of amending regulations is also provided, identifying it as Part 1 of Schedule 1 to the *Industrial Chemicals (Notification and Assessment) Amendment (Reforms) Regulations 2019*. Additionally, commencement time is defined as the time that the amending regulations commence.

**Statement of Compatibility with Human Rights**  
*Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny)  
Act 2011*

**Industrial Chemicals (Notification and Assessment) Amendment (Reforms)  
Regulations 2019**

These Regulations are compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

**Overview of the regulation**

The *Industrial Chemicals (Notification and Assessment) Regulations 1990* (the Regulations) require amendments to update the definition of a polymer of low concern (PLC), to allow for international alignment. The regulations also provide for a reduction in regulatory burden for introducers of certain new industrial chemicals in cosmetics introduced at low volumes. Introducers of industrial chemicals, under this category, will no longer be required to provide Safety Data Sheets or examples of packaging labels to the Director of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS).

**Human rights implications**

These amendments will not make any substantive changes. In relation to PLCs, the regulations propose changes to the PLC criteria to achieve greater international alignment. The other amendments made by this regulation focus on reducing unnecessary regulatory burden. These changes do not reduce health protections, nor do they remove the obligation on introducers of these chemicals to report adverse effects on work health and safety, public health or the environment of which the introducer of the chemical has become aware.

The amendment regulations do not engage any of the applicable rights or freedoms.

**Conclusion**

The amendment regulations are compatible with human rights as they do not raise any human rights issues.

**Senator the Honourable Bridget McKenzie Minister for Regional Services,  
Sport, Local Government and Decentralisation**