

EXPLANATORY STATEMENT

Select Legislative Instrument 2012 No. 86

Industrial Chemicals (Notification and Assessment) Act 1989

Industrial Chemicals (Notification and Assessment) Amendment Regulation 2012 (No. 1)

The Act establishes the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). Under the Act, the Director NICNAS is appointed by the Governor-General to administer functions conferred on him or her by the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act).

Section 111 of the Act provides, in part, 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.

The Act provides for a national system of notification and assessment of industrial chemicals for the purposes of: aiding in the protection of the Australian people and the environment; providing information and making recommendations about industrial chemicals to Commonwealth, state and territory bodies; giving effect to Australia's obligations under international agreements; collecting statistics in relation to these chemicals; setting and enforcing national standards for cosmetics introduced into Australia.

Subsection 110(1) of the Act provides that the regulations may prescribe fees for specified services. Subsections 110(2) to 110(6) set out details for when fees are due, the payment schedules and other arrangements. The fees for services defined in section 110 are prescribed in the *Industrial Chemicals (Notification and Assessment) Regulations 1990*.

The purpose of the regulation is to:

- amend all fees and charges for the NICNAS for 2012-13, in accordance with the NICNAS Cost Recovery Impact Statement (CRIS) for 2012-13 to 2015-16;
- introduce a screening fee for new chemicals applications, in accordance with the CRIS; and
- make consequential amendments arising from the new *Model Work Health and Safety Regulations 2011* (Model Regulations), which were developed by Safe Work Australia and commenced in the Commonwealth on 1 January 2012.

Consistent with the Government's cost recovery policy, NICNAS operates on a fee for service basis for the assessment of New Chemicals. In general, a new industrial chemical is a chemical that is being introduced into Australia for the first time. It is defined as an industrial chemical that is not listed on the Australian Inventory of Chemical Substances (AICS), or it is a listed chemical subject to a condition of use. NICNAS also applies a levy (NICNAS Registration) across the broader base of industry to fund all other programs such as stakeholder outreach, compliance activities and the assessment of existing chemicals.

NICNAS undertook a review of its cost recovery arrangements in accordance with the Australian Government Cost Recovery Guidelines. The review looked at the appropriateness of cost recovery, design of cost recovery charges to minimise any under/over recovery, and adequacy of monitoring arrangements.

The purpose of the CRIS was to transparently demonstrate compliance with the Cost Recovery Guidelines and to outline changes to the existing cost recovery arrangements based on review outcomes. Key changes included better alignment of fees with the costs associated with delivering the services, which includes the introduction of some new fees for service, the reclassification of some existing fees and the abolition of those fees no longer relevant; and amendment of the annual registration charge tier structure to provide a more equitable structure.

This CRIS for 2012-13 to 2015-16 was reviewed by the Department of Finance and Deregulation for compliance with the Cost Recovery Guidelines.

The fee increase was discussed with the NICNAS's Industry Government Consultative Committee and approved by the Parliamentary Secretary for Health.

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

Two rounds of public consultation were conducted during development of the CRIS. Stakeholder consultation was undertaken in accordance with the government's consultation principles, with an emphasis on achieving high quality consultations. A stakeholder engagement strategy was developed and published on the NICNAS website www.nicnas.gov.au. Regular updates were also provided to stakeholders through NICNAS's established consultative mechanisms, e.g. Industry Government Consultative Committee and the Community Engagement Forum.

A discussion paper was released in June 2010 and NICNAS provided a variety of opportunities for stakeholders to contribute to the review through a mix of workshops, one-on-one meetings, an online survey and written submissions. A draft CRIS was then released in October 2011 for public comment and further workshops and stakeholder meetings were held. Further written submissions were received and are published on the NICNAS website. Stakeholder views were taken into account in finalizing the CRIS.

The Model Regulations were developed through extensive consultation by Safe Work Australia. They were developed in accordance with guidelines in the Intergovernmental Agreement for Regulatory and Operational Reform in Occupational Health and Safety. Draft regulations were released for public comment in December 2010 and 1343 written submissions were received. These amendments to the NICNAS regulations are necessary consequential changes arising from the Model Regulations, namely, amendments to the definition of a hazardous chemical and adoption of the Globally Harmonised System of Classification and Labelling of Chemicals. NICNAS stakeholders were consulted on these consequential changes through NICNAS's Industry Engagement Group and the Chemical Gazette. These new Model Regulations are already enacted in work health and safety legislation in the Commonwealth and in most states and territories.

The Act specifies no conditions that need to be met before the power to make the regulation may be exercised.

The regulation is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

The regulation commences on 1 July 2012.

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

DETAILS OF THE *INDUSTRIAL CHEMICALS (NOTIFICATION AND ASSESSMENT) AMENDMENT REGULATION 2012 (No. 1)*

Section 1 – Name of Regulation

Section 1 provides for the regulation to be referred to as the *Industrial Chemicals (Notification and Assessment) Amendment Regulation 2012 (No. 1)*.

Section 2 – Commencement

Section 2 provides for the regulation to commence on 1 July 2012.

Section 3 – Amendment of *Industrial Chemicals (Notification and Assessment) Regulations 1990*

Section 3 provides for Schedule 1 to amend the *Industrial Chemicals (Notification and Assessment) Regulations 1990* (the Principal Regulations).

Schedule 1 - Amendments

Item [1] – Regulation 2

Definition of comparable agency

Reduced fees for new chemicals applications are available if the application is accompanied by an assessment report from a comparable agency. This amendment is an editorial amendment which transfers the list of comparable agencies in subregulation 15(6) to the list of definitions in regulation 2.

Definition of GHS

In the Model Regulations the definition of a hazardous chemical was amended (on 1 January 2012) as the classification and labelling of a hazardous chemical are now based on criteria in the United Nations Globally Harmonised System of Classification and Labelling of Chemicals (GHS). GHS is used in the new definition of a hazardous chemical so it is also defined in this regulation. The GHS system replaces the *Approved Criteria for Classifying Hazardous Substances* (the Approved Criteria).

Definition of limited application

In the notification of a new chemical, limited information is required for some applications, e.g. low volume and some polymer applications. In these applications, the submission of some information requirements in the Schedule to the Act, e.g. detailed toxicology data, is not mandatory. This amendment is an editorial amendment which transfers the scheduled data requirements in regulation 13 to the list of definitions in regulation 2.

Definition of standard application

As distinct from a limited application, the complete list of data requirements in the Schedule to the Act is required for most new chemicals applications – such a notification is described as a standard application. This amendment is an editorial amendment which transfers the scheduled data requirements in regulation 13 to the list of definitions in regulation 2.

Item [2] – Regulation 4AA

In the Model Regulations the definition of a hazardous chemical is amended and commenced in the Commonwealth on 1 January 2012. As a consequential amendment, the definition of a hazardous chemical in the regulation is amended.

Item [3] – Regulation 11AA

This amendment corrects an error in the Principal Regulations.

Item [4] – Regulation 11AB

This amendment is an editorial amendment which places the amounts for registration charge in Schedule 2 to the regulation. Consequently subregulation 11AB is not required.

Item [5] – Regulation 13

This amendment is an editorial amendment which places the fees for new chemicals applications and secondary notifications in Schedule 2 to the regulation. Consequently regulation 13 is amended to note that all fees, charges and penalties are listed in the schedule.

Items [6] and [7] – Subregulations 14(1) and (2)

Previously fees for new chemicals applications could be paid by instalment. This policy ceased some years ago and consequently subregulation 14(2) is omitted and subregulation 14(1) is also amended.

Items [8] and [9] – Subregulations 15(4) to (8) and (9)*Removal of fees for priority existing chemicals (subregulation 15(4))*

Under National Industrial Chemicals and Assessment Scheme (NICNAS) cost recovery arrangements, fees have not applied for the assessment of priority existing chemicals for many years. This fee provision is therefore redundant and the subregulation is omitted.

The Cost Recovery Impact Statement (CRIS) stated that fee rebates be replaced with set fees for certain new chemicals notifications. The fee rebates omitted are:

- removal of rebate for notification using standard template (subregulation 15(5));
- modular assessment using assessment report from another Australian or international authority (comparable agency) (subregulation 15(6));
- modular assessment of the analogue of a chemical previously assessed by NICNAS (subregulation 15(7)); and
- group notification and assessment (subregulation 15(8)).

Removal of rebate for notification using standard template (subregulation 15(5))

The Principal Regulations currently provide for a rebate when a draft assessment report, prepared by the applicant, is submitted with a notification statement about a new chemical. This provision in the regulation was used when an applicant submitted their notification using the electronic template developed by NICNAS. The CRIS proposes that this rebate no longer apply.

Modular assessment using assessment report from another Australian or international authority (comparable agency) (subregulation 15(6))

Under the NICNAS Low Regulatory Concern Chemicals (LRCC) reforms, rebates were introduced for the notification of new chemicals which had been previously assessed by another Australian regulatory authority, e.g. APVMA, or comparable international assessment authority, e.g. an EU member country. The CRIS proposes that the rebate for this new chemicals assessment category be replaced with a set fee. The new set fee is in Schedule 2.

Modular assessment of the analogue of a chemical previously assessed by NICNAS (subregulation 15(7))

Under the LRCC reforms, a rebate was introduced for the notification of a new chemical which was similar to a chemical which had been previously assessed by NICNAS (i.e. an analogue), with a further rebate available if the use of the chemical was similar to the use of the analogue previously assessed. The CRIS proposes that the rebates for this new chemicals assessment category be replaced with a set fee, and that the fee be different for a Standard, Limited or Polymer of Low Concern (PLC) assessment. The new set fees are in Schedule 2.

Group notification and assessment (subregulation 15(8))

Under the LRCC reforms, a rebate was introduced for the joint notification of new chemicals which were similar to each other and had similar uses, e.g. the notification of a group or 'family' of similar chemicals. The CRIS proposes that the rebates for this new chemicals assessment category be replaced with a set fee, and that the fee be different for a Standard assessment compared to a Limited or PLC assessment. The CRIS proposes that this rebate be replaced with a set fee. The new set fees are in Schedule 2.

Introduction of non-refundable screening fee

This amendment is provided for in new subregulations 15(4) and 15(5).

The CRIS proposes that a non-refundable screening fee of 15 per cent of the overall fee be introduced for all new chemicals applications when the Director determines that the application is not complete, e.g. for lack of sufficient data. The prescribed fee minus the screening fee is returned to the applicant in such a case. This policy applies to all new chemical applications for an assessment certificate or a permit and for the secondary notification of a new chemical.

The regulation provides that the Director must advise the applicant in writing of deficiencies in the application and allow the applicant at least 14 days to either provide the information or satisfy the Director that some or all of the information cannot be provided. The timeframe for compliance with the notice is included in the written notice to the applicant. The decision by the Director to return an application is subject to appeal to the Administrative Appeals Tribunal (AAT).

Item [10] – Subregulation 17(1)

Regulation 17 lists decisions by the Director in the Principal Regulations which are subject to appeal to the AAT. The amendment to the regulation provides for an appeal to the AAT when the Director determines, under new subregulation 15(4), that an application is not complete.

Item [11] – Regulation 18

This amendment is an editorial amendment which places late renewal penalties in Schedule 2 to the regulations. Consequently regulation 18 is not required.

Items [12] and [13] – Schedule 1AA, clause 2(a) and clause 3(d)

As the GHS system has replaced the Approved Criteria for the classification of hazardous chemicals, risk phrases which applied under the Approved Criteria in the Principal Regulations are replaced with corresponding hazard classes which apply under the GHS.

Under the Act, new chemicals which meet certain criteria in guidelines are eligible for low volume and early introduction permits. In the regulation Schedule 1AA specifies the low hazard criteria which apply for low volume and early introduction permits. Items [12] and [13] replace the criteria for health effects which applied under the Approved Criteria with corresponding hazard classes which apply under the GHS.

Item [14] – Schedule 1AB, clause 2(2)

This amendment corrects an error in the Principal Regulations.

Item [15] – Schedule 1AB, clause 2(2)(a)

As the GHS system has replaced the Approved Criteria for the classification of hazardous chemicals, risk phrases which applied under the Approved Criteria in the Principal Regulations are replaced with corresponding hazard classes which apply under the GHS.

Under the Act new chemicals which meet certain criteria in guidelines are eligible for controlled use and early introduction permits. In the regulation Schedule 1AB specifies the low risk criteria which apply for controlled use and early introduction permits. Item [15] replaces the criteria for health effects which applied under the Approved Criteria with corresponding hazard classes which apply under the GHS.

Item [16] – Schedule 2

This item lists the amended fees, charges and penalties determined by the CRIS. The Schedule includes fees transferred from regulations 11AB, 13 and 18 and includes new set fees to replace new chemicals rebates previously in regulation 15.

The Schedule contains the following list of new and amended fees, charges and penalties.

Item 1 – application for early non-confidential listing on AICS

Item 2 – application for inclusion of chemical on confidential section of AICS

Item 3 – application to be holder of confidence of a chemical on confidential section of AICS

Item 4 – application to transfer a chemical from non-confidential section of AICS to confidential section of AICS

Item 5 – application to retain listing of chemical on confidential section of AICS

Item 6 – application for commercial evaluation permit and renewal of permit

Item 7 – application for certain information to be exempt from publication

Item 8 - application for low volume permit and renewal of permit

Item 9 - application for controlled use permit and renewal of permit

Item 10 – (a) application for new chemicals assessment certificate, including fees for a standard notification, limited notification and PLC notification

(b) application for assessment certificate under an alternate state or territory law

(c) application for new chemicals assessment certificate under an approved foreign scheme, including fees for a standard notification, limited notification and PLC

(d) application for new chemicals assessment certificate accompanied by an assessment from a comparable agency, including fees for a standard notification, limited notification and PLC notification – this fee replaces a rebate

(e) application for new chemicals assessment certificate for a chemical similar to one previously assessed by NICNAS, including fees for a standard notification, limited notification and PLC notification - this fee replaces a rebate

(f) simultaneous application for new chemicals assessment certificate for a second chemical similar to and with similar use to first chemical notified, including fees for a standard notification, limited notification and PLC notification - this fee replaces a rebate

Item 11 – application for self-assessed new chemicals assessment certificate

Item 12 – application to vary data requirements

Item 13 – application for early introduction of new chemical under section 30 of the Act

Item 14 – application for early introduction of low hazard and low risk new chemical under section 30A of the Act

Item 15 - application to vary assessment report

Item 16 - application to vary public report

Item 17 – application for extension of assessment certificate

Item 18 – nomination of foreign scheme

Item 19 – application for secondary notification of a new chemical

Item 20 – application for registration under section 80F of the Act

Item 21 - application for renewal of registration

Item 22 – registration charge for tier 2

Item 23 - registration charge for tier 3

Item 24 – penalties for late renewal of registration

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 Regulation 2012 (No. 1)

This regulation is 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 National Industrial Chemicals Notification and Assessment Scheme (NICNAS) undertook a review of cost recovery arrangements as recommended by the Australian Government Cost Recovery Guidelines (the Cost Recovery Guidelines). The review looked at the appropriateness of cost recovery, design of cost recovery charges to minimise any under/over recovery, and adequacy of monitoring arrangements.

The purpose of the Cost Recovery Impact Statement (CRIS) was to transparently demonstrate compliance with the Cost Recovery Guidelines and to outline proposed changes to the existing cost recovery arrangements based on review outcomes. Key proposed changes included better alignment of fees with the costs associated with delivering the services and amendment of the annual registration charge tier structure to provide a more equitable structure. Under NICNAS, fees and charges are paid by the manufacturers and importers of industrial chemicals.

In accordance with the CRIS, the following amendments to the *Industrial Chemicals (Notification and Assessment) Regulations 1990* (the Regulation) are required:

- amendments to new chemicals notification fees, inventory-related fees and NICNAS registration fees and charges (including late penalty fees);
- replacement of fee rebates with set fees for certain new chemicals notification categories; and
- introduction of a non-refundable screening fee, as a component of the overall fee, for new chemicals notifications.

Also, new work health and safety laws commenced in the Commonwealth, New South Wales, Queensland, the Australian Capital Territory and the Northern Territory on 1 January 2012, based on the model *Work Health and Safety Regulations 2011* (Model Regulation) developed by Safe Work Australia. With introduction of the Model Regulation, consequential amendments are required to the NICNAS regulation.

Human rights implications

Under the NICNAS cost recovery structure, fees and charges are confined to the introducers of industrial chemicals. The amendments to the regulation may have some impact on costs for some manufacturers and importers. However, there is no impact on the human rights of these introducers or on other persons or organisations.

Under the Act, decisions by the Director NICNAS are subject to appeal to the Administrative Appeals Tribunal. This provision has been maintained in these proposed amendments to the regulation.

Overall, the regulation does not engage any of the applicable human rights or freedoms.

Conclusion

The regulation is compatible with human rights as it does not raise any human rights issues.

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