



INFORMATION, ANALYSIS
AND ADVICE FOR THE PARLIAMENT

INFORMATION AND RESEARCH SERVICES

Bills Digest
No. 167 2002–03

Industrial Chemicals (Notification and Assessment) Amendment Bill 2003

ISSN 1328-8091

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Published by the Department of the Parliamentary Library, 2003

I N F O R M A T I O N A N D R E S E A R C H S E R V I C E S

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Industrial Chemicals (Notification and Assessment)
Amendment Bill 2003

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4 June 2003

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Industrial Chemicals (Notification and Assessment) Amendment Bill 2003

Date Introduced: 28 May 2003

House: House of Representatives

Portfolio: Health and Ageing

Commencement: Royal Assent

Purpose

To amend the *Industrial Chemicals (Notification and Assessment) Act 1989* ('the Act') to:

- allow the introduction of increased volumes of new industrial chemicals to Australia under the commercial evaluation permit system; and
- change the process for registration of companies under the Act.

Background

The Act establishes a system of notification and assessment of industrial chemicals to protect health, safety and the environment and to provide for registration of people or companies proposing to introduce industrial chemicals into Australia.

The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) administers the Act and is located within the Commonwealth Department of Health and Ageing.

Commercial Evaluation Permits

The commercial evaluation permit ('CEP') system was introduced by the Keating Labor Government in 1992. The then Minister for Consumer Affairs, the Hon Jeanette McHugh MP, explained that the new system would:

allow for the introduction¹ of new industrial chemicals for the sole purpose of commercial evaluation. New industrial chemicals introduced for this purpose are to be

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exempt from the assessment provisions of the Act. This means that importers and manufacturers may evaluate the commercial potential of a new industrial chemical without having to invest resources in preparing the detailed notification package covering the chemical's physical and chemical properties and toxicology which is currently required. The Bill enhances innovative product development by significantly reducing regulatory requirements.²

According to a recent Government report:

The amendment established a fast track mechanism to allow for innovation and development of new industrial chemical products and processes, while maintaining adequate health and environmental safeguards.³

The *Explanatory Memorandum* states that NICNAS has issued over 500 commercial evaluation permits to approximately 120 companies since the commencement of the CEP system.⁴

Reform of the CEP system

A need to reform the CEP provisions was identified by NICNAS in 1999 in response to representations by the chemical industry. These included formal representations from industry members of the NICNAS Industry Government Consultative Committee (IGCC) who argued that regulatory barriers were an obstacle to technical innovation within the industry. The IGCC agreed that the reform of the CEP provisions was a priority issue.⁵

NICNAS commissioned a survey of industry practices relevant to commercial evaluation of industrial chemicals. The findings were presented to the IGCC, the chemical industry and representatives from relevant departments in State and Territory Governments.⁶ The survey suggested three main areas for reform:

- chemical volume;
- time periods of permits;⁷ and
- customer agreements.⁸

According to NICNAS:

Resolving the issues with time periods of permits and customer agreements has been estimated to lead to an estimated 8% increase in applications. Resolving the issues with volume would lead to an estimated 28% increase in applications. Overall, a substantial increase in useability of the CEP would be achieved, with the added value of encouraging research, development and the introduction of new technology with industry.⁹

While a change to the Act was required to address the issue of chemical volume, NICNAS believed that time periods and customer agreements could be effectively covered by in-

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house administrative changes and improved guidance for the chemical industry on how to use the CEP category.¹⁰

In December 2001 NICNAS released a public discussion paper canvassing reforms to the CEP system. Three submissions were received.¹¹ The final report prepared by NICNAS in response to the discussion paper (the '*NICNAS Final Report*') is available on the [NICNAS website](#).¹²

The volume issue

The CEP system allows introduction of up to 2000 kg of a new industrial chemical for up to two years, with the Director of NICNAS able to refuse the application if not satisfied the volume applied for is needed for effective commercial evaluation.

Under the current system, companies wishing to introduce more than 2000 kg for commercial evaluation need to submit an application for an 'assessment certificate.' Applications for assessment certificates involve a longer NICNAS assessment time (more than 90 days unless the chemical is of low hazard), a more detailed notification package, including test reports (which may include toxicity and ecotoxicity test reports) and a higher assessment fee (up to \$11,700 for a standard notification).

In comparison, CEP data requirements are minimal, the NICNAS assessment time is 14 days and the assessment fee is \$2,600.

The Bill proposes that the maximum volume for introduction of new industrial chemicals under the CEP scheme be doubled to 4000 kg. The justification for this increase appears to be 'anecdotal evidence (which) suggests that the existing volume limit can be restrictive on industry.'¹³ According to the *Explanatory Memorandum*:

NICNAS internal analysis of current CEP users suggests that the needs of most of the current users are covered by the existing 2000 kg limit....Responses to the Industry Survey revealed that across a range of industry sectors and production processes, the chemical volume required for commercial evaluation ranged from 25-1000kg, with 1000-2000 kg being the most frequent volume needed. Twenty-eight per cent...of responses indicated that the current 2000 kg maximum is too low for effective commercial evaluation, however thirty-eight per cent...of companies rated their reliability to forecast the volumes of chemicals needed as poor. Most respondents did not nominate the volume increase they required and taken as a whole, the responses did not provide clear direction for any specific percentage or volume increase that would satisfy most requirements.¹⁴

NICNAS estimates that with a new maximum volume of 4000 kg, there will be an increase of 99 per cent per year in the quantity of industrial chemicals covered by CEP applications. NICNAS internal analysis suggests that the needs of more than 97 per cent of potential CEP users would be covered with a volume limit of 4000 kg.¹⁵

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Environmental and safety issues

In proposing a greater maximum volume under the CEP system, the Parliamentary Secretary to the Minister for Health and Ageing, Trish Worth MP, stated that 'a strong prerequisite for the reform was that worker and public health and environmental standards were not to be compromised'.¹⁶

According to the *Explanatory Memorandum*:

NICNAS maintains that the risk in allowing introduction to Australia of the higher volume of chemical not supported by a full data package (currently set at 2000 kg under the CEP system), is offset by the capacity under the Act to assign CEP conditions.¹⁷

The Government plans a range of additional regulatory measures to balance any risk arising from increasing the volume of industrial chemicals that can be introduced under the CEP system. In her Second Reading Speech, Ms Worth noted that:

In moving to the higher volume, there are additional responsibilities for NICNAS and industry in maintaining community standards for chemicals introduction. Applicants are to provide a summary of health and environmental effects of the chemicals for NICNAS to use in the risk assessment. NICNAS is to upgrade its guidance on the use of the commercial evaluation permit system. In addition, it is introducing a raft of administrative changes to help ensure that companies understand and comply with permit conditions, including the requirement that they report back to NICNAS on any adverse effects experienced during the commercial evaluation and the success or otherwise of the commercial evaluation process. NICNAS is to compile this information and provide feedback to the public.¹⁸

At present, according to NICNAS:

The CEP is currently the only NICNAS new chemicals assessment category that does not require the applicant to provide some information, however brief, on the health and environmental effects of the chemical.¹⁹

The Government has indicated that this will be remedied. The *Explanatory Memorandum* refers to 'the proposed legislative change...to include a summary of the health and environment effects of the chemical as a data requirement'.²⁰ The NICNAS Final Report suggested that the *Industrial Chemicals (Notification and Assessment) Regulations 1990* ('the Regulations') could be amended to include such a requirement as part of the CEP system.²¹

Company Registration

Industrial chemicals cannot be introduced into Australia without registration under the Act. Under current provisions, a company has to renew its registration 30 days before the registration actually expires. The Second Reading Speech notes that compliance with the

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registration date has been 'persistently low (around 50% each year)' and that 'companies cannot understand a renewal deadline which precedes expiry of registration by a month'.²²

The Bill will align the deadline for renewal of registration with the expiry date. It will also introduce a late renewal penalty.

Registration Fees

Company registration fees and charges are currently prescribed in the Act. As the Second Reading Speech notes:

This is an exception rather than a rule as all other NICNAS fees and charges are placed in regulations. This has resulted in an inflexible fee system which cannot readily respond to cost recovery needs.²³

The Bill removes registration fees and charges from the Act. They will be specified instead in the Regulations and will allow for the application of consumer price indexation.

Main Provisions

Schedule 1 Part 1

Part 1 of Schedule 1 amends **section 21(E) of the Act** by increasing the maximum quantity of a new industrial chemical permitted to be covered in a CEP application from 2000 kg to 4000 kg.

Schedule 1 Part 2

Part 2 of Schedule 1 amends **Part 3A of the Act** by aligning the deadline for renewal of registration under the Act with the expiry date of registration, and by introducing a penalty for late renewals. It also removes references in Part 3A to a specific registration fee, replacing these with provision for the payment of 'the amount prescribed' for the purpose of registration.

Under **new section 80B** of the Act, it will be an offence of 'strict liability' to introduce industrial chemicals without a current registration. Such an offence places the onus on the company to establish a valid reason for not ensuring that its registration was in force when introducing new chemicals.

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Concluding Comments

It may well be the case, as the Parliamentary Secretary said in her Second Reading Speech, that:

The change in maximum chemical volume allowable under the commercial evaluation permit will enable the faster introduction of new and innovative chemicals and technology...²⁴

However, despite the fact that 'NICNAS consulted widely for this reform',²⁵ the justification for the increase appears to rest largely – as the *Explanatory Memorandum* says – on 'anecdotal evidence' from industry that the existing 2000 kg limit is a barrier to timely commercial evaluation. In particular, there is no specific justification cited in the *Explanatory Memorandum* or the *NICNAS Final Report* for doubling the volume of chemicals allowed to bypass the normal approval process.

NICNAS plans to introduce a range of additional environmental and safety measures to compensate for what it describes as 'the risk' in allowing an increased quantity of chemicals to be introduced without a detailed assessment of the chemical's physical and chemical properties and toxicology. It is clearly beneficial for the community that companies will now be required to provide as part of the CEP process a 'summary of the health and environment effects of the chemical'. Even with the objective of encouraging the introduction of new technology in mind, Parliament might be entitled to ask why the CEP system has not required until now even basic information on the potential dangers of new chemicals.

It appears from the *NICNAS Final Report* that some of these additional safety measures will be introduced in regulations.²⁶ However the increase in the allowable quantity of industrial chemicals under the CEP system is not tied to the introduction of new safety measures. There is nothing in the Bill that prevents the introduction of the additional quantities of industrial chemicals before the planned new safety measures are in place.

Endnotes

- 1 'Introduction' includes importing and/or manufacturing.
- 2 House Hansard, 24 June 1992, p. 3844.
- 3 National Industrial Chemicals Notification and Assessment Scheme, [*Reform of the Commercial Evaluation Category \(CEC\) Permit Scheme, Final Report*](#), November 2002 (*'NICNAS Final Report'*), p. 1. (at <http://www.nicnas.gov.au/publications/pdf/cep-reform-jan2003.pdf>)
- 4 *Explanatory Memorandum*, p. 4.

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- 5 *NICNAS Final Report*, p. 1.
- 6 *ibid.*, p. 2.
- 7 According to NICNAS: 'The Director of NICNAS can already specify permit conditions for a period of commercial evaluation that extends beyond the period allowed for the introduction of the chemical, conditional on safe use. To raise industry awareness, NICNAS is to promote to clients that the period of use for a CEP can extend beyond the maximum introduction period allowed in the CEP. This will be included in NICNAS Guidance.' *Ibid*, p. 3.
- 8 The NICNAS Final Report notes that the term "Customer Agreement" has been changed to 'User Agreement' so that all users of the new industrial chemical introduced under the CEP system must provide such agreements. In addition, in order to provide more flexibility in relation to User Agreements, applicants can submit these with CEP Permit applications, obtain a preview copy of the CEP conditions to take to potential users, and submit additional User Agreements after the CEP has been issued. Through such measures, NICNAS anticipates that downstream users will become better informed about the CEP conditions. (*Ibid*, p. 3.)
- 9 *ibid.*, p. 2.
- 10 *Explanatory Memorandum*, p. 9.
- 11 Details of submissions and the Government response are at Attachment A in *NICNAS Final Report*, p. 6 ff.
- 12 <http://www.nicnas.gov.au/publications/pdf/cep-reform-jan2003.pdf>.
- 13 *Explanatory Memorandum*, p. 6.
- 14 *ibid*, p. 6.
- 15 *ibid.*, p. 6.
- 16 *Second Reading Speech*, House Hansard, 28 May 2003, p. 14747.
- 17 *Explanatory Memorandum*, p. 9.
- 18 *Second Reading Speech*, House Hansard, 28 May 2003, p. 14747.
- 19 *NICNAS Final Report*, p. 4.
- 20 *Explanatory Memorandum*, p. 6.
- 21 *NICNAS Final Report*, p. 4.
- 22 *Second Reading Speech*, House Hansard, 28 May 2003, p. 14747. The *Explanatory Memorandum* does not explain the reason for the current renewal procedure.
- 23 *Second Reading Speech*, House Hansard, 28 May 2003, p. 14747.
- 24 *ibid.*
- 25 *Explanatory Memorandum*, p. 9.
- 26 *NICNAS Final Report*, p. 4.

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