

# **Industrial Chemicals (Notification and Assessment) Regulations (Amendment) 1997 No. 419**

## EXPLANATORY STATEMENT

Statutory Rules 1997 No. 419

(Issued by the authority of the Minister for Workplace Relations and Small Business)

*Industrial Chemicals (Notification and Assessment) Act 1989*

Industrial Chemicals (Notification and Assessment) Regulations (Amendment)

Section 111 of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) provides that the Governor-General may make regulations prescribing (inter alia) 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.

Subsection 110(5) of the Act allows regulations to be made prescribing circumstances in which the Director of Chemicals Notification and Assessment may, on behalf of the Commonwealth, wholly or partly waive or remit fees that would otherwise be payable under section 110.

Subsection 4(1) of the *Acts Interpretation Act 1901* provides that where an Act has been enacted but has not come into force, and that Act confers power to make a regulation, such a regulation may be made in anticipation of the commencement of that Act as if the Act had come into force.

The *Industrial Chemicals (Notification and Assessment) Amendment Act 1997* (the Amendment Act) received the Royal Assent on 30 June 1997. Items 3, 4, 5, 9, 10, 46, 52, 53, 86, 94 and 95 commence on 30 December 1997 by reason of subsection 2(3) of the Amendment Act, which provides for commencement of the relevant provisions after 6 months if not proclaimed earlier.

Regulations 3, 4, 6, 7 and 11 are made in anticipation of the commencement of items 9, 46, 52 and 95 of the Amendment Act. The Amendment Act evinces no intention contrary to section 4 of the *Acts Interpretation Act 1901*.

The primary purpose of these regulations is to prescribe a range of matters relating to measures introduced by the Amendment Act, and to provide for remission of part of the fee for notification of introduction of a new chemical if certain prerequisites are met. These regulations:

- \* prescribe criteria to be satisfied before new chemicals may be introduced in cosmetics in quantities not exceeding 10 kilograms per year without the need for an assessment certificate (regulation 6);
- \* prescribe a range of matters related to new section 30A which allows the Director of Chemicals Notification and Assessment (the Director) to grant a permit allowing the introduction of a chemical before it is assessed in accordance with the Act (early introduction):
  - a definition of the term hazardous substance (before a permit may be granted in relation to a chemical the Director must be satisfied that it is not a hazardous substance) (proposed regulation 4);
  - criteria relating to the environmental effect of a new chemical which must be met before the Director may grant a permit allowing early introduction (regulation 7).

- additional matters which the Director must take into account in considering whether early introduction is consistent with the reasonable protection of occupational health and safety, public health and the environment (regulations 3 and 7);
- the fee required to accompany an application for an early introduction permit (regulation 11);
- \* allow the Director to remit 15 percent of the fee payable for assessment of a chemical in circumstances where the applicant submits a satisfactory draft assessment report with their application (regulations 8 and 9); and
- \* correct a number of minor typographical errors (regulations 5 and 10).

The regulations commence on 30 December 1997, to coincide with the commencement of the relevant provisions of the Amendment Act. Details of the regulations are attached.

## ATTACHMENT

### INDUSTRIAL CHEMICALS (NOTIFICATION AND ASSESSMENT) REGULATIONS (AMENDMENT)

#### **Regulation 1**

Sub-regulation 1.1 provides for commencement of these regulations on 30 December 1997.

#### **Regulation 2**

Sub-regulation 2.1 is a formal provision, providing that the Industrial Chemicals (Notification and Assessment) Regulations ('the existing Regulations') are amended as set out by these Regulations.

#### **Regulation 3**

Sub-regulation 3.1 inserts two new definitions in regulation 2 of the existing Regulations:

\* *natural waterway* is defined as including streams (permanent and ephemeral), rivers, lakes, estuaries and coastal waters which are natural and where water is naturally present or may flow through or gather. The notion also encompasses artificial structures such as irrigation channels, dams, reservoirs, impoundments and holding ponds from which water may reach natural waterways directly;

\* *water treatment works* is defined as meaning a sewer or similar structure in which a chemical is diluted, held or treated, prior to discharge to a natural waterway.

These definitions relate to new regulation 7C (inserted by sub-regulation 7.1), which prescribes details relating to the likely release of the chemical as a matter which the Director must take into account in considering whether early introduction is consistent with the reasonable protection of occupational health and safety, public health and the environment. [Further details on regulation 7C are provided in the notes to sub-regulation 7.1, below.]

#### **Regulation 4**

Sub-regulation 4.1 inserts a new regulation 4AA to define the term *hazardous substance* for the purposes of section 5 of the Act.

Section 5 of the Act is an interpretation provision and *contains definitions* of a number of terms. Item 9 of the Amendment Act inserts a definition of *hazardous substance* into section 5 of the Act. The meaning of this term is to be prescribed.

A *hazardous substance* is defined by reference to existing standards, produced by the National Occupational Health and Safety Commission; namely:

- \* the *List of Designated Hazardous Substances* [NOHSC: 10005 (1994)]; and
- \* the *Approved Criteria for Classifying Hazardous Substances* [NOHSC: 1008 (1994)].

These standards are already familiar to introducers of industrial chemicals.

#### **Regulation 5**

Sub-regulation 5.1 makes a minor typographical correction to paragraph 4A(1)(a) of the existing Regulations.

## Regulation 6

Sub-regulation 6.1 inserts a new regulation 6AB. Regulation 6AB prescribes additional criteria for the introduction of low volumes of chemicals in cosmetics for the purposes of paragraph 21(4)(b) of the Act.

Item 46 of the Amendment Act inserts a new subsection 21(4) into the Act. (This item comes into effect on 30 December 1997 by reason of subsection 2(3) of the Amendment Act, which provides for commencement of specified provisions after 6 months if not proclaimed earlier.)

Subsection 21(4) provides an exemption from the notification and assessment requirements of the Act

for the introduction of new industrial chemicals in very small amounts (that is, quantities not exceeding

10 kilograms in any 12 month period). This is consistent with similar requirements in the European

Union.

Subsection 21(4) provides that the general prohibition on introduction without assessment does not prohibit the introduction of a new industrial chemical in very small amounts:

- \* unless the person knows that the chemical poses an unreasonable risk to occupational health or safety, public health or the environment (paragraph 21(4)(a)); and
- \* if the chemical is introduced in a cosmetic - if additional prescribed requirements relating to introduction (such as requirements relating to its use, packaging or labelling) are met (paragraph 21(4)(b)).

The following additional criteria are prescribed in relation to the introduction of low volumes of a chemical in cosmetics for the purposes of paragraph 21(4)(b) of the Act:

- \* the chemical is not used in the cosmetic as a preservative; a colouring agent; or an ultraviolet filter [subregulation (2)];
- chemicals which are preservatives colouring agents, or ultraviolet filters have the potential to be comparably active by nature and present in products in very low concentrations; for this reason such chemicals are required to be subject to the normal assessment requirement under the Act;
- \* the chemical is not prohibited for use as a cosmetic, or for use in cosmetics, in the European Union (in accordance with the 1976 European Council Cosmetic Directive), or the United States of America (in accordance with the *Food, Drugs and Cosmetics Act 1938*) [sub-regulation (3)];
- the presence of a cosmetic on an overseas 'prohibited for use list' indicates that there are sufficient grounds for concern over the use of the chemical to justify full assessment;
- \* compliance with Commonwealth, State and Territory requirements relating to the manufacture or importation of the chemical [sub-regulation (4)];
- these requirements will include, but are not limited to, requirements relating to the use, packaging and labelling of the chemical;

- \* a requirement that, unless the chemical is present in the cosmetic at a concentration of less than 1 percent, the introducer have information available to indicate that the chemical will be safe for use by potentially high risk groups, consistent with the anticipated pattern of consumer exposure [subregulation (5)]
- \* the person introducing the chemical must notify the Director in writing of the introduction [paragraph 6(a)]:
  - additional requirements for the notification are set out in sub-regulation (7);
- \* the person introducing the chemical must keep for five years all information relating to occupational health and safety and public health matters on the chemical contained in the cosmetic as is available to the person [sub-regulation (6)]:
  - information is to be taken to be available to the person if, having regard to the person's abilities, experience, qualifications and other attributes the person ought reasonably to have been aware of the information [sub-regulation (9)];
  - this information must be readily available to the Director upon request [sub-regulation (8)].

## **Regulation 7**

Sub-regulation 7.1 inserts new regulations 7B and 7C. These regulations prescribe a range of environmental criteria relevant to the granting of early introduction permits under new section 30A.

Item 52 of the Amendment Act inserts (among other provisions) a new section 30A into the Act. (This item comes into effect on 30 December 1997 by reason of subsection 2(3) of the Amendment Act, which provides for commencement of specified provisions after 6 months if not proclaimed earlier.)

New section 30A allows the Director to issue a permit allowing the early introduction of a chemical in certain circumstances.

Subsection 30A(3) sets out the matters the Director must be satisfied about before he or she may issue a permit. These include that:

- \* the prescribed criteria relating to the environmental effect of the chemical have been met [these criteria are established by new regulation 7B]; and
- \* that, having regard to a range of factors, the Director is satisfied that the early introduction of the chemical is consistent with the reasonable protection of occupational health and safety, public health and the environment [matters additional to those specified in the Act are prescribed by regulation 7C, as provided for by paragraph 30A(4)(g)].

### *Regulation 7B*

Regulation 7B prescribes criteria which must be met in relation to the environmental effect of a chemical before the Director may grant a permit allowing introduction of the chemical before assessment in accordance with the Act. In relation to:

- \* chemicals for which full notification is required [those to which subsection 23(4) of the Act applies]; and
- \* synthetic polymers with a number-average molecular weight of less than 1,000 [those to which subsection 23(8) of the Act applies]

the following environmental effect criteria are prescribed:

- \* the chemical must meet a certain standard relating to the likelihood of uptake of the chemical by aquatic organisms; the standards set act to restrict the likelihood of uptake of a chemical by such organisms;
- \* the chemical must be readily biodegradable; and
- \* the chemical must have less than a specified level of aquatic toxicity, based on common aquatic toxicity tests.

In relation to:

- \* synthetic polymers with a number-average molecular weight of 1,000 or more [those to which subsection 23(7) of the Act applies]; and
- \* chemicals for which a limited notification is required [those to which subsection 23(9) of the Act applies]

the biodegradability and aquatic toxicity criteria do not apply.

These criteria are not required to be met because:

- \* synthetic polymers with a number-average molecular weight of 1,000 or more [ie, those to which subsection 23(7) applies], are not considered to pass through biological membranes (reducing the chance of bioaccumulation of the chemical in aquatic organisms); and
- \* chemicals requiring limited notification are not required to meet such criteria during assessment; the criteria are therefore inappropriate for early introduction.

However, these matters are relevant matters for the Director to take into account in deciding whether he or she is satisfied that the introduction of the chemical is consistent with reasonable protection of the occupational health and safety, public health and the environment. [The notes on regulation 7C, below, refer.]

In the case of synthetic polymers of low concern [those to which section 24A applies], the regulations require that the Director be satisfied that the largest component of the chemical is carbon or silicon.

### *Regulation 7C*

Regulation 7C prescribes additional matters which the Director must take into account in deciding whether he or she is satisfied that the introduction of the chemical is consistent with reasonable protection of the occupational health and safety, public health and the environment. The Director is required to be so satisfied before he or she may grant an early introduction permit.

The Director is required to have regard to the likelihood of the chemical being released into natural water-ways.

The Director is also required to have regard to the likelihood of the chemical being released into a water treatment works at a rate of more than 10 kilograms per year from an individual source or 50 kilograms in total in circumstances where an applicant for a permit for early introduction of a chemical to which either subsection 23(7) of the Act or 23(9) of the Act applies does not have information to demonstrate that the chemical meets the biodegradability and aquatic toxicity tests outlined above:

that is, in the case of an application for early introduction of a synthetic polymer with a numberaverage molecular weight of 1,000 or more, or a chemical for which a limited notification is required, the introducer does not have information available (as it is not required to be provided for assessments of these chemicals) or, if they do, it does not demonstrate that the biodegradability or aquatic toxicity standards are met.

### **Regulation 8**

Sub-regulation 8.1 amends regulation 15 of the existing Regulations to allow the Director to remit 15 percent of the fee payable for an application for assessment of a chemical under section 23 of the Act. (The level of the fee payable in relation to such an application is dependent upon the nature of the notification, which in turn relates to the complexity of the assessment required to be conducted in relation to the chemical.)

The Director is empowered to remit 15 percent of the application fee if satisfied that the applicant has submitted with the application a draft assessment report that complies with the requirements relating to such reports, which are contained in sections 32 and 33 of the Act.

This reduction in fees reflects the reduction in assessment costs required to be incurred if the applicant provides a draft assessment report.

### **Regulation 9**

Sub-regulation 9.1 makes an amendment to regulation 17 of the existing Regulations consequential upon the insertion of sub-regulation 15(5) [notes on Regulation 8 refer].

This sub-regulation adds the exercise of the Director's power to remit 15 percent of the fee payable for an application for assessment under sub-regulation 15(5) to the list of matters in relation to which an application for review may be made to the Administrative Appeals Tribunal.

### **Regulation 10**

Sub-regulations 10.1 and 10.2 make minor typographical corrections to Form 1A, set out in Schedule 1 to the existing Regulations.

### **Regulation 11**

Sub-regulation 11.1 prescribes a fee of \$500 for an application under section 30A for a permit allowing early introduction of non-hazardous chemicals.

This level of fee has been determined consistent with the full cost-recovery arrangements introduced by the Amendment Act. That is, the fee has been set at a level which reflects the essentially administrative nature of the early introduction permit system.