

**NATIONAL MODEL REGULATIONS
FOR THE CONTROL OF
SCHEDULED CARCINOGENIC SUBSTANCES
[NOHSC:1011(1995)]**

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CITATION

1. These regulations may be cited as the *National Model Regulations for the Control of Workplace Hazardous Substances, Part 2—Scheduled Carcinogenic Substances* [NOHSC:1011(1995)].

OBJECTIVE

2. The objective of these national model regulations is to eliminate or minimise the risk of adverse health effects due to exposure to a scheduled carcinogenic substance in the workplace by:
 - (a) providing for the prohibition of certain uses of carcinogenic substances listed in Schedule 1;
 - (b) requiring employers to ensure that an employee's exposure to a scheduled carcinogenic substance is eliminated or minimised through appropriate assessment, control, monitoring and health surveillance procedures;
 - (c) requiring employers and suppliers to notify their use of a scheduled carcinogenic substance to the relevant public authority;
 - (d) providing information on assessment, control, monitoring and health surveillance procedures appropriate to the notified carcinogenic substance; and
 - (e) requiring suppliers, employers and their employees to comply with these national model regulations.

SCOPE AND APPLICATION

- 3(1) These national model regulations are additional to all other provisions of the *National Model Regulations for the Control of Workplace Hazardous Substances* [NOHSC:1005(1994)]¹.
- (2) These national model regulations shall apply to all workplaces in which a scheduled carcinogenic substance (or any of its salts) is used as a pure substance or in a mixture containing 0.1% or more of that substance, determined as a weight/weight (w/w) concentration for solids and liquids and a volume/volume (v/v) concentration for gases.

INTERPRETATION

4. The interpretations contained in regulation 4 of the *National Model Regulations for the Control of Workplace Hazardous Substances* [NOHSC:1005(1994)] also apply to these national model regulations. In addition, in these national model regulations:

'**Analysis**' means a process used for the purpose of identifying the kind or quantities of ingredients in a substance.

'**Bona fide research**' means systematic investigative or experimental activities which are carried out for the purpose of either:

- (a) acquiring new knowledge (whether or not that knowledge will have a specific practical application); or
- (b) creating new or improved materials, products, devices, processes or services.

'Laboratory' means a building or room equipped for bona fide research or practical teaching, and which is not used for production purposes.

'Scheduled carcinogenic substance' means a carcinogenic substance listed in Schedule 1 or Schedule 2 to these national model regulations.

PROHIBITION OF SCHEDULED CARCINOGENIC SUBSTANCES

- 5(1)** A supplier shall not supply any carcinogenic substance listed in Schedule 1 except:
- (a) for the purpose of bona fide research or analysis, where the purchaser has notified the relevant public authority in respect of that carcinogenic substance in accordance with sub-regulation 6(5); or
 - (b) where an exemption to use the carcinogenic substance has been granted by the relevant public authority.
- (2)** A supplier or an employer shall not use any carcinogenic substance listed in Schedule 1 except:
- (a) for the purpose of bona fide research or analysis, where the supplier or employer has notified the relevant public authority in accordance with sub-regulation 6(5); or
 - (b) where an exemption to use the carcinogenic substance has been granted by the relevant public authority.

NOTIFICATION OF SCHEDULED CARCINOGENIC SUBSTANCES

- 6(1)** An employer or supplier shall not use a scheduled carcinogenic substance unless:
- (a) a suitable and sufficient assessment has been carried out; and
 - (b) the relevant public authority has been notified of the intention to use a Schedule 2 carcinogenic substance; and
 - (c) the conditions have been met for use of a Schedule 2 carcinogenic substance which may have been specified by the relevant public authority under sub-regulation 7(2).
- (2)** A supplier shall not supply any carcinogenic substance listed in Schedule 2 except where the purchaser provides evidence that the relevant public authority has been notified of the intention to use that substance.
- (3)** Notwithstanding regulation 11 of the *National Model Regulations for the Control of Workplace Hazardous Substances* [NOHSC:1005(1994)]¹, a suitable and sufficient assessment shall include:
- (a) a review of the current Material Safety Data Sheets and other relevant supplementary information which is available; and
 - (b) an assessment of the specific work involving potential exposure to any scheduled carcinogenic substance.
- (4)** An employer or supplier shall notify the relevant public authority with the following information in respect of the intended use of a carcinogenic substance listed in Schedule 2:
- (a) the business address of the employer;

- (b) the address of any place where the carcinogenic substance will be used or produced;
 - (c) the name of the carcinogenic substance;
 - (d) the name(s) and address(es) of the supplier(s) of each carcinogenic substance;
 - (e) details of the activity or process using carcinogenic substances and the reasons for the use or production;
 - (f) the quantity of each carcinogenic substance to be used or produced per annum;
 - (g) the number of employees exposed to each carcinogenic substance;
 - (h) the name and business address of the person or organisation carrying out the assessment;
 - (i) justification that elimination and substitution are not practicable and that the controls in place are the best practicable; and
 - (j) a description of the measures taken to prevent or minimise exposure of persons to the carcinogenic substance and to protect the health of persons.
- (5) Notwithstanding sub-regulation 6(4), where any carcinogenic substance listed in Schedule 1 or Schedule 2 is used in a laboratory or laboratories for the purpose of bona fide research or analysis, the employer shall make a Laboratory Notification to the relevant public authority in relation to all such notifications.
- (6) A Laboratory Notification shall be in writing and contain the following information in respect of the intended use of a carcinogenic substance listed in Schedule 1 or Schedule 2:
- (a) the business address of the employer;
 - (b) the address of the location where the carcinogenic substance(s) will be used or produced;
 - (c) the name(s) of the carcinogenic substance(s);
 - (d) the quantity of each carcinogenic substance to be used or produced per laboratory per annum;
 - (e) a statement that the carcinogenic substance(s) will be used for bona fide research or analysis;
 - (f) a justification that elimination and substitution are not practicable and that the controls in place are the best practicable; and
 - (g) a description of the measures taken to prevent or minimise exposure of persons to the carcinogenic substance and to protect the health of persons.

- (7) Notwithstanding sub-regulation 6(6), where one or more Schedule 1 or Schedule 2 carcinogenic substances are to be used in a laboratory or laboratories for the purpose of bona fide research or analysis, the employer may make a single Laboratory Notification for the information required under sub-regulation 6(6) for all such carcinogenic substances.
- (8) Any significant changes to the information provided under sub-regulations 6(6) and 6(7) shall be notified to the relevant public authority.
- (9) A notification under sub-regulation 6(1)(b) shall be revised by the employer:
 - (a) whenever there is evidence to indicate that it is no longer valid;
 - (b) when there has been a significant change in the use of a scheduled carcinogenic substance; or
 - (c) when the assessment is reviewed.

The new information shall be notified to the relevant public authority.

- (10) A new notification under sub-regulations 6(1)(b) or 6(5) shall be submitted at intervals not exceeding five years.

RESPONSE OF THE RELEVANT PUBLIC AUTHORITY

- 7(1) The relevant public authority shall acknowledge a notification received under regulation 6 within 14 days of receiving the notification.
- (2) The relevant public authority may respond to the notification specifying in writing the conditions to be met by the employer or supplier for the use of any scheduled carcinogenic substance. Any such response shall be within 60 days of receipt of the notification.
- (3) The notification shall be regarded as accepted where the relevant public authority does not respond to the notification in accordance with sub-regulation 7(2).

RECORD KEEPING

- 8(1) An employer shall maintain the following information, as a record in a suitable form, for at least 30 years from the date of the last entry in the record:
 - (a) a list of employees whose position has been identified as a result of an assessment as having a likelihood of exposure to a carcinogenic substance listed in Schedule 1 or Schedule 2, including full names, dates of birth and addresses during the period of the persons' employment with the employer;
 - (b) a copy of any notification made to, and any exemption granted by, the relevant public authority; and
 - (c) a copy of the conditions for use of a scheduled carcinogenic substance which may have been specified by the relevant public authority under sub-regulation 7(2).

- (2) A supplier shall retain as a record, for a period of five years, the following information for each scheduled carcinogenic substance they supply:
 - (a) the name of the purchaser; and
 - (b) the name and quantity of each scheduled carcinogenic substance supplied.

ADVICE AND REPORTING

- 9(1) An employer shall provide a report to the relevant public authority, as soon as practicable, whenever:
 - (a) a spill or incident has occurred which has, or is likely to have, resulted or could result in exposure of a person to a scheduled carcinogenic substance; or
 - (b) monitoring or health surveillance results indicate excessive exposure to a scheduled carcinogenic substance.
- (2) Where accidental exposure of any person to a scheduled carcinogenic substance is reasonably thought to have occurred, the employer shall notify that person as soon as practicable.
- (3) An employer shall provide a written statement on termination of employment to an employee to whom sub-regulations 6(4)(g), 9(1) and 9(2) apply, including:
 - (a) the name(s) of the scheduled carcinogenic substance(s) that the employee was potentially exposed to;
 - (b) the period of potential exposure to the scheduled carcinogenic substance(s);
 - (c) details of how and where records can be obtained; and
 - (d) the advisability of having periodical health assessments and the types of tests which are relevant.

PROHIBITED CARCINOGENIC SUBSTANCES

Substance Name [Chemical Abstract Number]

2-Acetylaminofluorene [53-96-3]

Aflatoxins

4-Aminodiphenyl [92-67-1]

Amosite [12172-73-5] (brown asbestos)
— except for removal and disposal purposes
and situations where amosite occurs naturally
and is not used for any new application.

Benzidine [92-87-5] and its salts (including
benzidine dihydrochloride [531-85-1])

bis(Chloromethyl) ether [542-88-1]

Chloromethyl methyl ether [107-30-2] (technical
grade which contains bis(chloromethyl) ether)

Crocidolite [12001-28-4] (blue asbestos)
— except for removal and disposal purposes
and situations where crocidolite occurs naturally
and is not used for any new application.

4-Dimethylaminoazobenzene [60-11-7]

2-Naphthylamine [91-59-8] and its salts

4-Nitrodiphenyl [92-93-3]

SCHEDULE 2

NOTIFIABLE CARCINOGENIC SUBSTANCES

Substance Name [Chemical Abstract Number]

Acrylonitrile [107-13-1]

Benzene [71-43-2] — when used as a feedstock
containing more than 50% of benzene by volume

Chrysotile [12001-29-5] (white asbestos)
— when used for the manufacture of asbestos products.

Cyclophosphamide [50-18-0] (cytotoxic drug) — when
used in preparation for therapeutic use in hospitals
and oncological treatment facilities, and in manufacturing
operations

3,3'-Dichlorobenzidine [91-94-1] and its salts (including
3,3'-Dichlorobenzidine dihydrochloride [612-83-9])

Diethyl sulfate [64-67-5]

Dimethyl sulfate [77-78-1]

Ethylene dibromide [106-93-4] — when used as a fumigant

4,4'-Methylene bis(2-chloroaniline) [101-14-4] — MOCA

2-Propiolactone [57-57-8]

o-Toluidine [95-53-4] and
o-Toluidine hydrochloride [636-21-5]

Vinyl chloride monomer [75-01-4]

EXPLANATORY NOTE ON SUBSTANCES IN SCHEDULE 2 WHICH HAVE THERAPEUTIC USES

Schedule 2 to the *National Model Regulations for the Control of Scheduled Carcinogenic Substances* [NOHSC:1011(1995)] includes some substances that have therapeutic uses. At present, the substances that appear in schedule 2 that have therapeutic uses, or are starting materials for products that have therapeutic uses, include cyclophosphamide (an anti-cancer drug) and acrylonitrile (used to make moulds in dentistry).

Under these national model regulations, employers must notify the relevant public authority of the intention to use a Schedule 2 carcinogenic substance. We accept that the identification of some substances that have therapeutic uses as being carcinogens may cause some concern to those who are receiving these substances and to those who are involved in their use. However, it is important to understand that for these substances that have therapeutic uses, the risks involved with their use have been assessed. Further, the assessments have determined that the benefits achieved from their use greatly outweigh any associated risks and, therefore, they have obtained approval for use.

APPENDIX 1

CRITERIA FOR THE DEVELOPMENT AND REVIEW OF SCHEDULES FOR CARCINOGENS

PREFACE

For the appropriate administration of the *National Model Regulations for the Control of Workplace Hazardous Substances, Part 2 — Scheduled Carcinogenic Substances* [NOHSC:1011(1995)], it is necessary that:

- small numbers of carcinogenic substances should be scheduled; and
- the relevant public authority should also consider relevant industry codes of practice, guidance notes and best practice, in addition to the provisions of the *National Model Regulations for the Control of Workplace Hazardous Substances* [NOHSC:1005(1994)]¹.

INTRODUCTION

These criteria are specifically intended to enable the compilation of schedules of carcinogens for the *National Model Regulations for the Control of Workplace Hazardous Substances, Part 2—Scheduled Carcinogenic Substances* [NOHSC:1011(1995)].

The schedules developed using these criteria are for regulatory purposes only and are not intended to represent an exhaustive list of carcinogenic substances which may be used in Australian workplaces. The absence of a substance from Schedule 1 or Schedule 2 should not be presumed to indicate the absence of a carcinogenic hazard.

Substances on any of the schedules may be listed for certain uses, and exceptions for certain uses may be noted alongside the entry.

There is no hierarchy of importance in the criteria.

A substance will be assessed against each criterion, where applicable.

GENERAL CRITERIA

To be considered for scheduling, the substance shall have been classified as a Category 1 or Category 2 carcinogen in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(1994)]².

Category 1 carcinogens are substances known to be carcinogenic to humans.

Category 2 carcinogens are substances regarded as if they are carcinogenic to humans.

For the purpose of scheduling, consideration will be given to the nature and extent of exposure to the substance which could occur in Australian workplaces.

Consideration will also be given to all available experimental findings, including mechanism of action and dose-response data, to assist in establishing the carcinogenic risk of the substance in question.

Scheduled carcinogens may be subject to a clause of limitation to account for risks associated with the use of particular carcinogens in certain situations. A clause of limitation may apply to substances listed in

Schedule 1 or Schedule 2. It can be used to exempt a carcinogenic substance from the notification requirements under particular circumstances of use, or to include the notification requirements under particular circumstances of use. A carcinogenic substance may appear in both schedules with a clause of limitation in each. Any use outside the clauses of limitation is subject to the requirements of the *National Model Regulations for the Control of Workplace Hazardous Substances* [NOHSC:1005(1994)]¹.

Schedule 1 carcinogens are prohibited substances and are usually Category 1 carcinogens. However, potent carcinogens used only for research or analytical purposes, and having no other known usage, may also be included.

Schedule 2 carcinogens are substances which have specific limitations on their usage.

An unassigned carcinogen is one which has been considered for scheduling and has been assessed as not requiring scheduling, notwithstanding the provisions of the *National Model Regulations for the Control of Workplace Hazardous Substances* [NOHSC:1005(1994)]¹.

SPECIFIC CRITERIA

In addition to the general criteria, if elimination of a carcinogen is not practicable, consideration should be given to the availability of a practicable substitute in reaching a final decision in respect of scheduling.

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| Schedule 1 (Prohibited carcinogenic substances) | — | A reasonably practicable substitute is available. |
| Schedule 2 (Notifiable carcinogenic substances) | — | No reasonably practicable substitute is available; and |
| | — | Absence of other regulatory controls to prevent or minimise exposure to the required standard; and |
| | — | Practicable and purposeful to notify. |

REFERENCED DOCUMENTS

1. National Occupational Health and Safety Commission, 'National Model Regulations for the Control of Workplace Hazardous Substances' [NOHSC:1005(1994)] in *Control of Workplace Hazardous Substances: National Model Regulations and National Code of Practice*, Australian Government Publishing Service, Canberra, 1994.
2. National Occupational Health and Safety Commission, *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(1994)], Australian Government Publishing Service, Canberra, 1994.