



EXISTING CHEMICALS REVIEW

THE EXISTING CHEMICALS PROGRAM

Introduction

The Existing Chemicals Program is a program of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), which was established in 1990 under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act). Funding of the Program is 100% cost recovered through company registration fees.

Priority Existing Chemical (PEC) Assessments

The most well known activity of the Program is the assessment of chemicals known as Priority Existing Chemicals (PECs). PEC assessments are legislated under the Act, and have legislated timeframes and consultation and appeal provisions. Prior to 1997-98, all chemicals declared PECs underwent full risk assessments on occupational health and safety, public health and environmental effects.

Concerns over the length of time required for such assessments and the corresponding small number of chemicals being assessed as PECs were first highlighted in a review of the Program in 1994. This led to legislative changes to the Act in 1997-98 that expanded the range of PEC assessments able to be conducted.

As well as full risk assessments, NICNAS can now conduct more focused 'preliminary' assessments on specified aspects of a chemical, namely, its properties, use or uses, intrinsic adverse effects, and/or the extent to which people or the environment will be exposed to the chemical. Preliminary assessments consider whether a full risk assessment is required for the chemical. The legislative changes in 1997-98 also allowed chemicals to be assessed together as a group.

These reforms to the program have enabled the quicker generation and dissemination to the Australian community of information on priority chemicals of concern. A list of PEC assessments completed as at June 2003 are contained in Attachment 1.

The Nomination, Screening and Selection of PECs

The selection of chemicals to undergo a PEC assessment is based on a process that screens and ranks publicly nominated chemicals of concern. Nominations of chemicals of concern can be made at any time, however to publicise and administratively facilitate nominations NICNAS periodically makes calls for nominations.

A publicity campaign for a call for nomination involves advertisements in national newspapers, notices in the *Chemical Gazette* and *NICNAS Matters*, and mail-outs to a target audience of occupational health and safety groups, relevant government authorities, industry associations, workers' health centres, unions, environmental groups and consumer bodies.

Nominated chemicals are screened to determine whether they are indeed industrial chemicals as defined under the Act, and if so, placed on a 'base list' of chemicals. Each chemical on this list is then screened and ranked against a set of criteria covering issues in public health, occupational health and safety, and the environment.

Each criterion is indicative of a type of potential hazard to people or the environment and the set of criteria therefore give an overview of the types of hazards usually presented to people and the environment when exposure to the chemical occurs. In addition, the criteria include one for national or international concern to facilitate the responsiveness of the PEC program.

The final list of selected and standby chemicals is known as the Candidate List. Reasons for non-selection of chemicals are documented and reported to the nominators of the chemicals and published on the NICNAS website. The Candidate List is used when considering which chemical(s) to recommend for assessment as PECs. Information obtained through the screening and ranking process, as well as information obtained from industry through notices placed in the *Chemical Gazette*, and any other relevant information is taken into consideration when selecting chemicals as PECs.

Outcomes of PEC assessments

PEC assessment reports provide information on risks to human health and the environment. Recommendations on ways to control and reduce the risks are made available to companies introducing chemicals, to people in the workplace, to other government agencies, and the public.

Recommendations contained in PEC assessment reports are generally directed to three groups: peak agencies and regulatory bodies such as the National Occupational Health and Safety Commission (NOHSC) and the National Drugs and Poisons Schedule Committee (NDPSC); state and territory government authorities; and industry. Examples of the types of recommendations that have been made are detailed in Attachment 2.

Post Assessment Activities

A significant number of activities undertaken by the Program relate to the post-assessment follow-up of chemicals that have previously been assessed as PECs.

Safety Info Sheets, containing the main findings and recommendations of a PEC assessment, written in plain English, are now compiled for all PECs, and disseminated widely to industry, unions and labour councils, and state and territory representatives

Chemicals that have been assessed as PECs are subject to secondary notification and assessment should significant new data about the chemical or its uses or exposure in

Australia become available. Literature searches are conducted regularly and any new data analysed as part of normal post-assessment surveillance. Other post-assessment activities include cooperative projects with industry, unions and/or government authorities on such things as communication strategies related to a particular chemical. Uptake of PEC recommendations by regulatory bodies, both Commonwealth and State, are followed up on a regular basis.

A project to measure the uptake of recommendations by industry began in 2001-02. An evaluation tool for assessing the uptake of recommendations in a selected number of PEC reports has been developed and tested. The review of the Program will inform any further activities to be undertaken to measure the uptake of recommendations by industry. It is hoped that the evaluation will assist in identifying factors that may be inhibiting uptake of recommendations, and point the way to strategies to improve the outcomes of the PEC Program.

Other Chemical Information Products

In recent years, the Program has undertaken the production of chemical information products that are more targeted in their focus than PEC assessments and faster to produce. The chemicals selected are of concern for some reason, may or may not be on the PEC candidate list, and have not been declared as PECs.

These chemical information products serve to address the situation where there is a need for data on a chemical, but not necessarily for an in-depth evaluation of the data. Some examples of the products produced to date are contained in Attachment 3.

High Volume Industrial Chemical List (HVICL)

Another output of the Existing Chemicals Program is the compilation of a list of chemicals present in Australia in high volumes, based on information supplied by industry. The initial HVICL was compiled between 1999-2002, and it will be updated regularly. The HVICL contains approximately 300 chemicals that are either imported or manufactured in Australia in quantities ≥ 1000 tonnes.

Its creation was required as part of Australia's obligations under the OECD's High Production Volume Existing Chemicals Program, which decides individual country contributions to the program on the national production of high volume chemicals. The HVICL will also assist to rationalise Australia's input to the OECD Program by allowing us to support or selectively sponsor the international assessment of chemicals of particular importance to the Australian people and environment. It will assist in the screening of chemicals for assessment under the Existing Chemicals Program by providing information on quantities (and therefore potential exposure) of individual chemicals being considered for assessment, and on the pattern of introduction (import and/or manufacture), uses, and industry sectors that it is used in.

Five chemicals were selected from the list in June 2003 as a pilot project to produce easily accessible chemical information sheets. The five chemicals selected were urea, sodium hydroxide, sulfuric acid, ethene, chloro- and copper.

Enquiries

The Program provides a telephone and written information service to people with general queries about existing industrial chemicals as well as queries specific to the Program. The number of enquiries on chemicals has increased in the last few years. One factor in this increase is believed to be the increasing ease of access to overseas chemical information on the internet, leading to more interest in the situation in Australia.

International Harmonisation of the Assessment of Existing Chemicals

There are two international assessment programs for existing chemicals that coordinate international agreement of chemical assessments, based on draft assessments contributed by participating countries. These programs are the OECD's Screening Information Data Set (SIDS) program, and the International Program on Chemical Safety's (IPCS) Concise Chemical Assessment Documents (CICADS) Program.

The SIDS program aims to fill data gaps for existing chemicals produced in high volume in the OECD. CICADS provide summaries of the health and environment effects of a chemical and characterise risk. Australia, via NICNAS, participates in these programs.

Australia has sponsored or co-sponsored five chemicals (glutaraldehyde, NVP, 2-butoxyethanol, 1,4-dioxane, ortho-dichlorobenzene) in the SIDS program. All sponsored chemicals to date have been PECs or candidate PECs, thus rationalising the resources required to participate in the program. In addition, NICNAS actively reviews and provides comments on draft assessments submitted by other countries. Hazard assessments produced under the SIDS program have been used by NICNAS in reviews of chemicals and the production of information sheets on chemicals, as well as in developing risk assessments of PECs. NICNAS representatives participate in the OECD's Existing Chemicals Task Force that policy guidance to the SIDS program.

NICNAS has also contributed to the CICADS program through submission of two documents drawn from PEC assessments on TGIC and HCFC-123.

NICNAS' participation in these programs allows access to existing chemical assessments from many governments for use in the national assessment program, and enables us to contribute to the global effort to assess existing chemicals, including the harmonised development of Australian assessment methodologies with overseas authorities.

Attachment 1

List of Chemicals Assessed as PECs

PEC Assessment Number	Chemical	CAS	Date of publication of report
Full Assessments -			
1	TGIC (Triglycidylisocyanurate)	2451-62-9	April 1994
1a	TGIC Secondary Notification#		
2	Savinase – Proteolytic enzymes in detergents	various	Feb 1993
3	Glutaraldehyde	111-30-8	June 1994
4	HCFC-123	306-83-2	March 1996
4a	HCFC-123 Secondary Notification#		
5	Sodium ethyl xanthate	140-90-9	May 1995
5a	Sodium ethyl xanthate Secondary Notification#		
6	2-butoxyethanol in cleaning products	111-76-2	Oct 1996
7	1,4-dioxane	123-91-1	June 1998
8	Trichloroethylene	79-01-6	March 2000
9	Chrysotile asbestos	12001-29-5	Feb 1999
11	N-vinyl-2-pyrrolidone	88-12-0	April 2000
13	<i>para</i> -dichlorobenzene	106-46-7	Dec 2000
14	<i>ortho</i> -dichlorobenzene	95-50-1	Feb 2001
18	Ammonium, potassium and sodium persulphate in hairdressing	7727-54-0; 7727-21-1; 7775-27-1	June 2001
21	Benzene	71-43-2	Sept 2001
22	Limonene*	5989-27-5; 5989-54-8; 138-86-3	May 2002
NA/405S	Polymer in Reactint Red X64	Not assigned	April 2003
23	Acrylamide	79-06-1	May 2002
24	Methylcyclopentadienyl manganese tricarbonyl (MMT)	12108-13-3	June 2003
25	Alkyl Phosphate Anti-Valve Seat Recession Additive	Exempt information	June 2003
Preliminary Assessments -			
10	Acrylonitrile	107-13-1	Feb 2000
12	Glycolic acid in cosmetics	79-14-1	April 2000
15	Tetrachloroethylene	127-18-4	June 2001
16	Short chain chlorinated paraffins	Various	June 2001
17	Trisphosphates	Various	June 2001
19	Hydrofluoric acid	7664-39-3	June 2001
20	Polybrominated flame retardants	Various	June 2001

* Limonene exists as its isomers, d-limonene (CAS Number 5989-27-5), l-limonene (CAS Number 5989-54-8), and dl-limonene (CAS Number 138-86-3; which replaces the former CAS number 7705-14-8)

Under the Act, a second notification of a chemical that has been assessed as a PEC may be required where an introducer of the chemical becomes aware of any circumstances that may warrant a reassessment of its hazards and risks. Three secondary notification assessments have been conducted to date.

Attachment 3

Other Chemical Information Products

Chemical(s)	Content of assessment	Sources utilised	Reason for assessment
<i>Other Assessments</i>			
Tetrachlorobenzyl toluenes; polychlorinated naphthalenes; polychlorinated diphenyl ethers; polychlorinated styrenes	Identification of quantities imported and manufactured, uses, amounts produced and/or released as by-products of processing and manufacture, and recommendations with regard to the need or not for further assessment.	International assessments; literature searches; data from Australian industry, NGOs, unions, government agencies, specialist overseas agencies.	Potential to persist and bioaccumulate in the environment,
<i>Information sheets</i>			
Sodium laurel sulphate; ammonium laurel sulphate.	Toxicity overview, information on import, manufacture and use, regulatory status; information on use in products.	International assessments; literature search; examination of secondary sources; Australian regulatory publications.	High level of enquiries to NICNAS stimulated by media reports of adverse effects.
Copper, sodium hydroxide, sulfuric acid, urea, ethene, chloro-	Identity, properties, import, manufacture and use, regulatory status, toxicity and health and safety information.	International assessments; Australian regulatory publications	Present in high volume in Australia, have not undergone a hazard assessment by NICNAS
Ortho-phthalaldehyde; calcium hemihydrate	Toxicity overview, information on import, manufacture and uses in Australia, regulatory status, reasons for non-selection as candidate chemicals.	Literature searches, OECD databases; Australian regulatory publications.	Nominated as PECs but not selected.

Attachment 3

PEC Report Recommendation Types

Recommendations directed to peak bodies -

- exposure standards
- hazard classification
- poisons scheduling
- dangerous goods classification
- establishment of biological monitoring guidelines and a biological exposure index
- establishment of formal health surveillance guidelines
- the phase-out of a chemical (chrysotile asbestos)
- better coding of injury statistics

Recommendations directed to state/territory government authorities -

- compliance action to improve industry performance and ensure compliance with standards and codes of practice
- preparation and dissemination of plain English information sheets

Recommendations directed to industry –

- workplace control measures to reduce workplace exposure such as -
 - the use of certain engineering controls and/or personal protective equipment
 - phasing out of certain uses of a chemical (e.g. trichloroethylene in aerosols and in cold cleaning)
- improved hazard communication through -
 - update and review of labelling
 - update and review of information contained in material safety data sheets
 - implementation of training and education
- routine air monitoring
- establishment or updating of industry codes of practice
- safer product formulation
- safer packaging
- establishment of health surveillance program
- safe disposal of waste
- development of emergency plan
- the filling of data gaps about a chemical or safer alternatives to the chemical through further research such as toxicity testing

Occasionally recommendations are made to other organisations. For instance, the PEC assessment of limonene included a recommendation to the Australasian College of Dermatologists that medical practitioners should include oxidised limonene in patch testing of hand eczema patients.