



**Australian Government**  

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**Department of Health and Ageing**  
**NICNAS**

**SELECTION PROCEDURES FOR**

# **PRIORITY EXISTING CHEMICALS**

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## **GLOSSARY**

## PURPOSE

The purpose of this document is to describe the administrative procedures and definitions for the selection of a Base List of chemicals from public nominations. Scientific criteria are then applied to chemicals on the Base List to identify a Candidate List of chemicals from which a chemical is selected for declaration as a Priority Existing Chemical (PEC).

One of the aims of the PEC Program is for the selection process to be open and accountable to the public. This is a reference document that endeavors to satisfy this aim.

This document revises the earlier "Selection Procedures for Priority Existing Chemicals" (October 1991 and December 1998). It addresses amendments to the *Industrial Chemicals (Notification and Assessment) Act, 1989*. The selection criteria have been streamlined into fewer steps to increase the efficiency of the process.

## INTRODUCTION

### WHAT IS NICNAS?

The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is an independent Commonwealth statutory scheme established to aid in the protection of people at work, the public and the environment from the harmful effects of industrial chemicals, through the mandatory notification and assessment of these chemicals.

This is achieved through the assessment of all new industrial chemicals that are entering Australia for the first time, and for industrial chemicals that are already in use in Australia on a priority basis.

NICNAS was established on 17 July 1990 with the enactment of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cmwlth).

### WHAT IS AN INDUSTRIAL CHEMICAL?

NICNAS only applies to industrial chemicals.

Industrial chemicals are defined as substances other than:

- Agricultural chemicals;
- veterinary chemicals;
- human therapeutic substances;
- food and food additives; and
- radioactive substances.

NICNAS considers chemical entities, alone, or as components of mixtures, not the mixtures themselves.

For convenience, industrial chemicals will be referred to as chemicals in this document.

### WHAT IS AN EXISTING CHEMICAL?

Existing chemicals are those industrial chemicals which are listed on the Australian Inventory of Chemical Substances (AICS), and are not notifiable as new chemicals.

## **WHAT ARE PRIORITY EXISTING CHEMICALS?**

There are a large number of chemicals in Australia and limited resources available to gather and assess information on them. NICNAS provides a mechanism for the closer examination and assessment of chemicals that are thought to pose a potential risk to human health and safety or to the environment. These chemicals may be declared priority existing chemicals (PECs).

## **WHICH INDUSTRIAL CHEMICALS CAN BE NOMINATED FOR CONSIDERATION AS PECs?**

Any chemical present in Australia, except new chemicals (see Glossary) which have already been assessed under NICNAS, can be nominated for consideration as a PEC.

## **ENHANCED EXISTING CHEMICALS PROGRAM**

Amendments have been made to the process for declaring PECs. The declaration can be focussed on certain purposes or circumstances. A system for preliminary assessment has been introduced to address concerns without the need for a comprehensive 'full' risk assessment. Preliminary assessments are useful where information on the hazards of the chemical, or exposure (including use), will provide sufficient information for health and environment recommendations to be made. In addition, they are a useful step in determining whether a full risk assessment is needed.

The amendments also allow a group of chemicals to be assessed together if it is more efficient. This can be specified by notice in the *Chemical Gazette*.

These changes enable the purpose and focus of the assessment to be clarified at the outset.

## **WHO IS INVOLVED IN THE PEC PROGRAM?**

There are a number of key players in the PEC program. These players and their roles are described below.

### **Nominators**

Nominators are members of the public, organisations, unions, industries and government bodies who nominate industrial chemicals for consideration as PECs.

### **Minister for Employment, Workplace Relations and Small Business (the Minister)**

The Minister (Commonwealth) is responsible for NICNAS and has the authority to declare PECs.

## **Government Agencies**

The three Commonwealth government agencies that participate in NICNAS and are responsible for the assessment of PECs are:

National Occupational Health and Safety Commission (NOHSC) which administers NICNAS and performs the primary toxicological assessment and the occupational health and safety assessment;

Environment Australia (EA), which performs the environmental hazard assessment; and

Therapeutic Goods Administration (TGA), which performs the public health assessment.

## **Director of Chemicals Notification and Assessment (the Director)**

The Director carries out the day-to-day management of NICNAS.

## **Applicants for the assessment of a PEC**

Applicants will be manufacturers and importers of the chemical who apply for a PEC to be assessed. A person cannot introduce the chemical into Australia while it is a PEC unless the person has applied for assessment of the PEC.

## **Notifiers**

Notifiers are people required by the Director to provide information. The information provided assists in making a recommendation to the Minister to declare a chemical a PEC or in assessing a PEC.

## **ARE THERE OTHER PATHWAYS TO DECLARING PECS?**

While this document deals with the selection of PECs from public nominations, the Director may, on his/her own initiative, also recommend PECs to the Minister.

## OVERVIEW OF THE PEC NOMINATIONS AND SELECTION CYCLE

Industrial chemicals that are of concern to individuals or organisations, because they believe the chemicals present a risk to the public, people at work or the environment, can be nominated for possible selection as a PEC.

NICNAS will periodically call for public nominations and a Base List of chemicals will be selected from these nominated chemicals. The nomination and selection cycle is illustrated in Diagram A.

At the close of the nomination phase, NICNAS carries out an initial screening to exclude ineligible chemicals. The remaining chemicals will then be compiled into a Base List.

For Base List chemicals, data will be gathered on their health and environmental effects, together with information such as use patterns, volume and physical-chemical properties. This data will be drawn from a wide range of sources, such as international databases, journals, reference books and through direct requests for information from industry.

This data will be used to rank the Base List chemicals in relation to their effect on both human health and safety and the environment in order to select Candidate Chemicals. This selection process will be carried out in two stages by the appropriate government agency, that is, NICNAS, TGA or EA.

Initially, the health and environment selection criteria will be applied to the available data. For chemicals selected at this first stage other relevant data such as use patterns, exposure and volumes will then be considered.

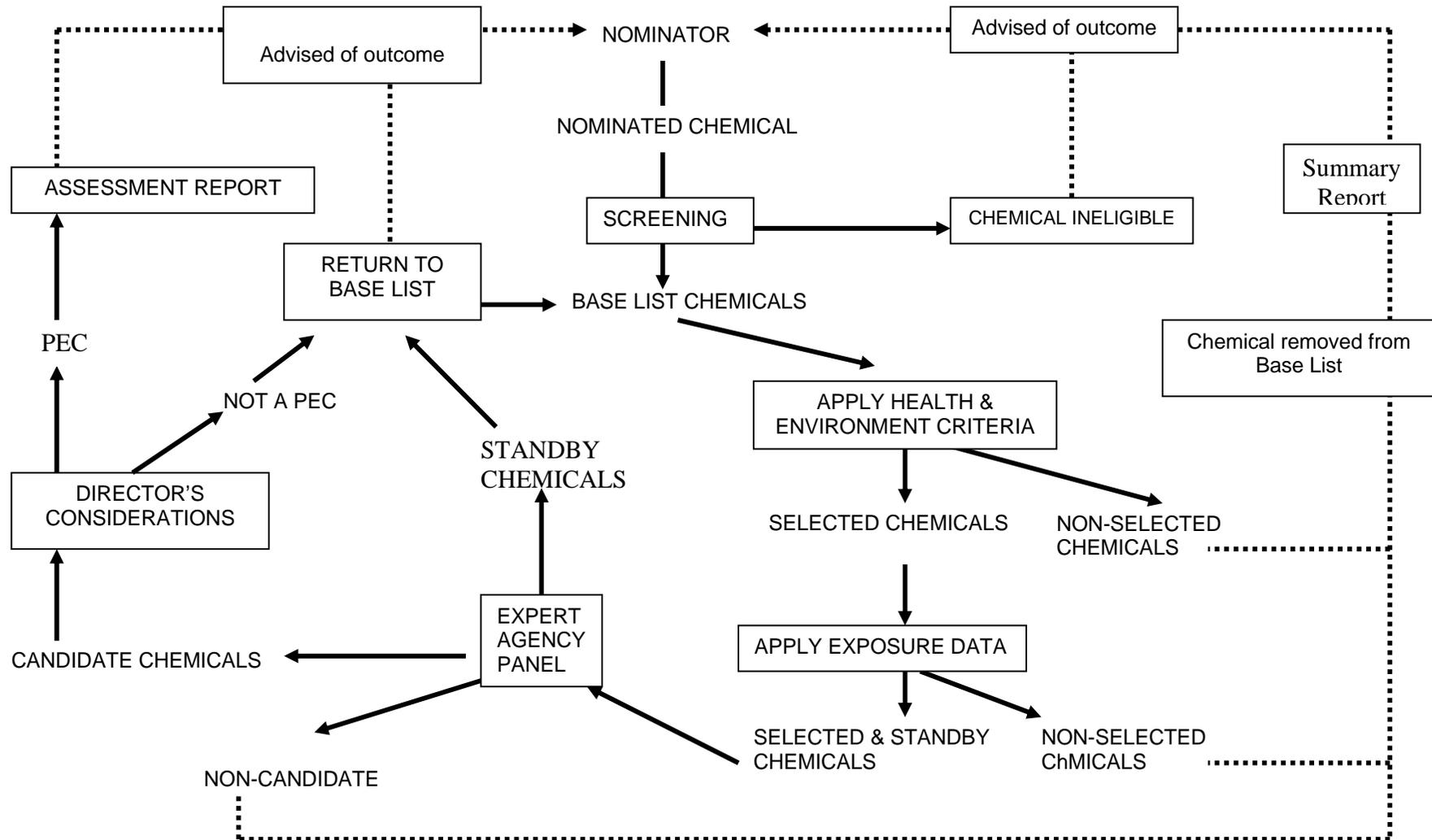
The Expert Agency Panel will consider the data, finalise the ranking and recommend a list of Candidate chemicals to the Director.

The Director will consider the Candidate chemicals, together with supporting data and relevant social and regulatory matters. The Director may recommend some or all of the Candidate chemicals to the Minister for declaration as PECs. This may occur over a period of time. It is expected that the new Candidate List will be replaced after a period of approximately three years, again after a public nomination phase.

The Minister may declare some or all of the recommended chemicals as PECs.

Details of the nomination, screening and selection phases are given in the following pages.

THE PEC NOMINATION AND SELECTION CYCLE



## **SELECTION OF CANDIDATE CHEMICALS**

The process for selecting Candidate chemicals is set out in Diagram B.

### **PURPOSE OF THE SELECTION PROCESS**

The purpose of the selection process is to select chemicals on the basis of the:

- risk of adverse effects;
- degree of concern; and
- benefits to be gained through assessment.

### **NOMINATION PHASE**

Nomination of chemicals to be considered as PECs are called for, with a notice in the *Chemical Gazette* and advertisements (Attachment A) appearing in at least one national newspaper. In addition, letters are sent directly to a target audience. The target audience will include occupational health and safety groups, government authorities, such as State/Territory OHS authorities, industry associations, workers' health centres, unions, environmental groups and consumer bodies.

Additional publicity may be organised for the nomination phase.

A nomination form (Attachment B) and an information pamphlet (Attachment C) are sent to prospective nominators, who are also asked if they are interested in attending a seminar.

If sufficient interest is received, seminars will be held to assist people to make informed nominations and to explain the selection process.

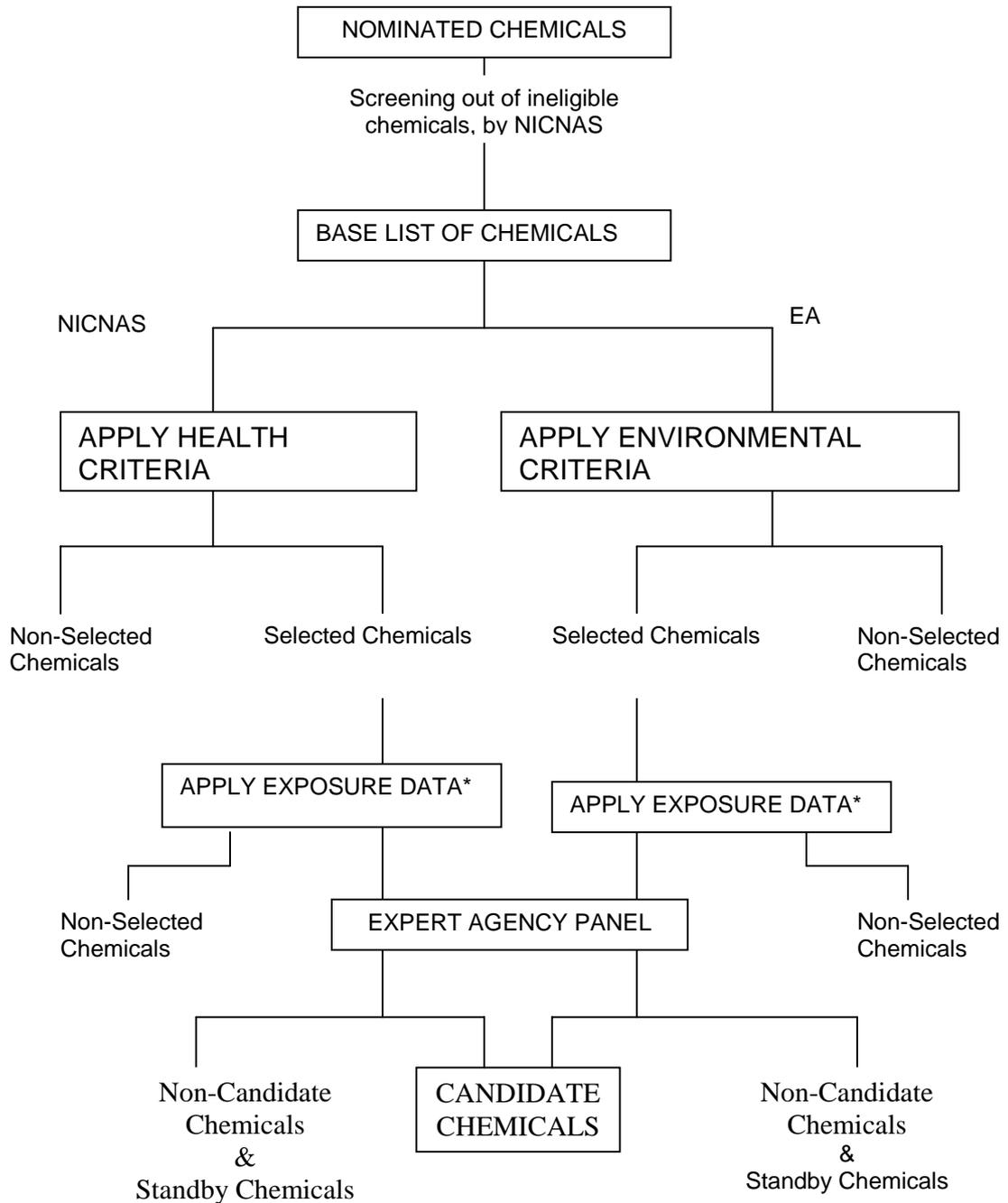
### **SCREENING PHASE**

When a nomination form is received it is assigned a file/folio number and date stamped. The original nomination form is filed and a copy placed in a working folder. All nominated chemicals are entered into the PEC database.

All nominations will be screened for eligibility by NICNAS.

**DIAGRAM B**

**SELECTION OF CANDIDATE CHEMICALS FROM PUBLIC NOMINATIONS**



\* Exposure data will be obtained from industry questionnaires, public nomination forms, State and Territory agencies and unions.

For a chemical to be eligible for declaration as a PEC it:

- must be an 'industrial' chemical, as defined earlier;
- must not be a 'new industrial chemical' (see Glossary), other than:
  - chemicals used solely for the purpose of research, development, and analysis,
  - incidentally-produced chemicals, and
  - chemicals which have been exempted from notification by regulation
- must be a chemical entity (see Glossary)·for example, the chemical cannot be a mixture but may be a UVCB substance (see Glossary); and,
- must not be an article (see Glossary).

For a nomination to be acceptable into the PEC Program:

- the chemical must be eligible, as defined above;
- the chemical must be present in Australia; and
- the first part of the nomination form must be completed.

All nominations will be acknowledged and nominators advised as to whether their chemical has been accepted to the Base List. The Base List consists of those nominated chemicals that are eligible for consideration, in accordance with the *Industrial Chemicals (Notification and Assessment) Act*.

## **SELECTION CRITERIA**

The criteria are those established by the former Expert panel in 1991, which considered nominations under the first NICNAS public nomination cycle. Some of the original steps have been amalgamated to reduce the number of screening steps.

In addition, a criterion of national or international concern has been included, to facilitate responsiveness of the Scheme.

Each criterion is indicative of a type of potential hazard to people or the environment, for example:

the acute oral toxicity test is indicative of the immediate to short term toxicity of a chemical and provides information on a specific toxic effect (death) of a chemical if

swallowed; and

the Bioconcentration Factor (BCF) is a measure of the potential of a chemical to concentrate in an organism.

Hence, the set of criteria give an overview of the types of hazards usually presented to people and the environment when exposure to industrial chemicals occurs.

The criteria chosen are also those for which data is likely to be available. There are other measures of toxicity which could be used, such as neurotoxicity, but this information is not often available.

For a number of the criteria the cut-off values are clearly defined and based on the National Occupational Health and Safety Commission's *Approved Criteria for Classifying Hazardous Substances*, [NOHSC:1008(1994)]. However, for some criteria the cut-off values are not absolute and values will be assigned on a weight of evidence and also take into account the classification system described in the *Approved Criteria*.

## **RANKING OF BASE LIST CHEMICALS**

All Base List chemicals are subjected to the ranking criteria. The Base List will be ranked into groups for health and environmental considerations using the criteria. This ranking process assists in the selection of Candidate Chemicals on health and environmental grounds and excludes those of low hazard. The criteria and scoring system for health and environment are given in tables 1-7.

An indicative list of data sources which are searched in order to fulfil the information requirements for ranking is at Attachment D.

Synopses of the data gathered and the values assigned in the ranking are recorded in the PEC database.

### **Health**

Data searches for health effects are undertaken for all Base List chemicals.

Selection criteria for health are applied, and values assigned (Table 1A and Table 1B). Criteria values for health effects are 'High', 'Medium', or 'Low'. Where there is national or international concern on health grounds a 'High' value is assigned.

Chemicals are divided into two Selection Groups:

- *Selected chemicals*, ie chemicals of high potential hazard or chemicals with insufficient data; and
- *Non-selected chemicals*, ie chemicals of low concern.

When a chemical is assigned a High value for any health effect it is placed in the Selected chemicals group.

Exposure data is obtained from a range of sources including nomination forms, and may also be sought from State/Territory agencies and unions. Exposure data will be sought from industry for those chemicals with insufficient exposure information from other sources and from time to time in order to select chemicals for recommendation to declare as PECs. A questionnaire and covering letter (Attachments E1 and E2) are sent to known manufacturers and importers seeking this information.

An exposure profile for each chemical is then compiled using the information collected from reference materials, the questionnaires and the nomination forms. This information is applied to the health exposure selection criteria (Table 2A) and each criterion given a value. Using these values, each chemical is given an overall score for health exposure (Table 2B).

The health effects, exposure scores and quantities imported/manufactured are then combined (Table 3), to generate three groups:

- *Selected*, ie chemicals of high potential hazard;
- *Non-selected*, ie chemicals of low potential hazard; and
- *Standby*, ie chemicals with insufficient data.

*Non-selected* chemicals are removed from the Base List and the nominators receive a summary report on their nominated chemical(s).

*Selected* and *Standby* chemicals are considered by the Expert Agency Panel for inclusion in the Candidate list of chemicals.

## **Environment**

Data searches are undertaken for all Base List chemicals to determine whether each of the environmental criteria is met. The environmental effects and exposure/fate criteria are applied to the gathered data (Table 4). A value is allocated for each selection criterion. Where there is national or international concern on environmental grounds a 'High' value is assigned.

The chemicals are then divided into two groups according to these environmental criteria values (Table 5):

- *Selected*, ie chemicals of high potential hazard or chemicals with insufficient data; and
- *Non-selected*, ie chemicals of low concern.

*Non-selected* chemicals are removed from the Base List and the nominators receive a summary report on their nominated chemical(s).

Industry is approached for exposure information on *Selected* chemicals with insufficient data. This information is sought by a questionnaire (Attachment E1), at the same time as exposure data is sought for those chemicals identified in the Health ranking.

The environmental rankings are determined from Tables 6A and 6B and then chemicals are selected based on environmental scores of Table 7.

- *Selected*, ie chemicals of high potential hazard;
- *Non-selected*, ie chemicals of low potential hazard; and
- *Standby*, ie chemicals with insufficient data.

*Non-selected* chemicals are removed from the Base List and the nominators receive a summary report on their nominated chemical(s).

*Selected* and *Standby* chemicals are then considered by the Expert Agency Panel.

## **CANDIDATE LIST**

A meeting of the NICNAS Expert Agency Panel is convened to consider ranking of the chemicals. With the aim of selecting a Candidate List of chemicals the *Selected* chemicals are reviewed along with *Standby* chemicals. Special considerations which may be applied for Standby chemicals are considered in the section on “Other Information about the PEC Selection Process”. Other parties who have specialist knowledge may also be consulted. The Candidate List is prepared and the reasons for the decisions are documented. The Candidate List is then passed to the Director for consideration.

Chemicals not placed on the Candidate List are returned to the Base List.

Non-candidate chemicals are removed from the Base List and the nominators receive a summary report on their nominated chemical(s).

This concludes the process for establishing a new Candidate List, which replaces the previous Candidate List. Note that chemicals are not automatically transferred from the old to the new Candidate List. Chemicals on the old List must be re-nominated to be included in the new List, to ensure that the Candidate List reflects current concerns. A copy of the current Candidate List is at Attachment G.

## **CONSIDERATION OF THE CANDIDATE LIST BY THE DIRECTOR**

### **THE PROCESS**

The Director considers the Candidate List together with the supporting documentation. The Director's considerations also take into account information from notifiers and social and regulatory issues relevant to the recommendation of a chemical as a PEC.

### **COLLECTION OF INFORMATION FROM NOTIFIERS**

The Act provides a means for the Director to call for information before making a recommendation to the Minister. This information assists the Director in deciding whether to recommend a chemical as a PEC. To obtain the information, a notice may be placed in the *Chemical Gazette* stating that the Director is considering recommending a chemical as a PEC and calling for information about the chemical. This notice may be a general call for information or be directed to specific people.

### **DIRECTOR'S CONSIDERATIONS**

The basis for the Director's recommendation of a PEC is "reasonable grounds for believing that..... an industrial chemical gives, or may give, rise to a risk of adverse (health or environmental) effects ....".

It is essential for all recommendations of a PEC that the decision is reasonable in the circumstances. Whether a decision is reasonable can only be decided after due consideration is given to all relevant facts pertaining to a matter.

Once it has been established that there maybe a significant risk of an adverse effect from an industrial chemical, the Director takes into consideration social and regulatory matters pertinent to the recommendation of the chemical as a PEC. The matters set out here are not intended as an exhaustive list of considerations but point to a range of matters that may arise in consideration of a particular PEC candidate.

### **International and Other National Regulatory Action and Assessments**

Part of the administration of NICNAS, is to monitor overseas regulatory action and publications. It is important that these regulatory actions be evaluated for their relevance to Australian occupational and environmental exposure conditions. Publicly available overseas health and safety and environmental assessments are considered in relation to their adequacy in covering matters relevant to NICNAS and Australia. Wherever feasible and relevant, NICNAS uses the reports of other national and international bodies, in order to avoid duplication of effort.

### **Australian Regulatory Action**

A number of industrial chemicals are already the subject of specific regulatory attention. This may range from an exposure standard, to a specific standard and code of practice.

Where a regulatory action deals comprehensively with the health hazards associated with use of a workplace substance and recommends a comprehensive control strategy, this may mean that the call for information and subsequent assessment as a PEC has been effectively pre-empted.

In circumstances where regulatory action is underway or where regulations exist, consideration will need to be given to whether the PEC assessment process could add useful information to:

- the development of the regulations; or
- improving application of the regulations.

### **Consideration By Other Mechanisms**

The Director needs to be aware of other mechanisms in which a particular chemical is being considered in relation to health and safety and environmental matters.

Consideration needs to be given as to whether declaration and assessment of a chemical as a PEC would be complementary to the action recommended by other mechanisms.

### **Substances no longer manufactured or imported**

Where an industrial chemical is present in the workplace or the environment by virtue of its persistence, but is no longer manufactured or imported, it will be difficult to collect exposure data. The manufacturers or importers may no longer be in operation or may have inadequate records of past practices. Where a substance has such ubiquity in the workplace or environment, information on exposure would involve intensive surveys. However, the Director may determine that a widespread problem exists and that an assessment of the chemical would be beneficial. The value of declaring a chemical a PEC in these cases will need to be considered.

### **Documenting the Nomination and Selection Process**

In recommending a chemical for declaration as a PEC the Director has to ensure that the matters considered have been documented, so that there is a record of the basis for the decision.

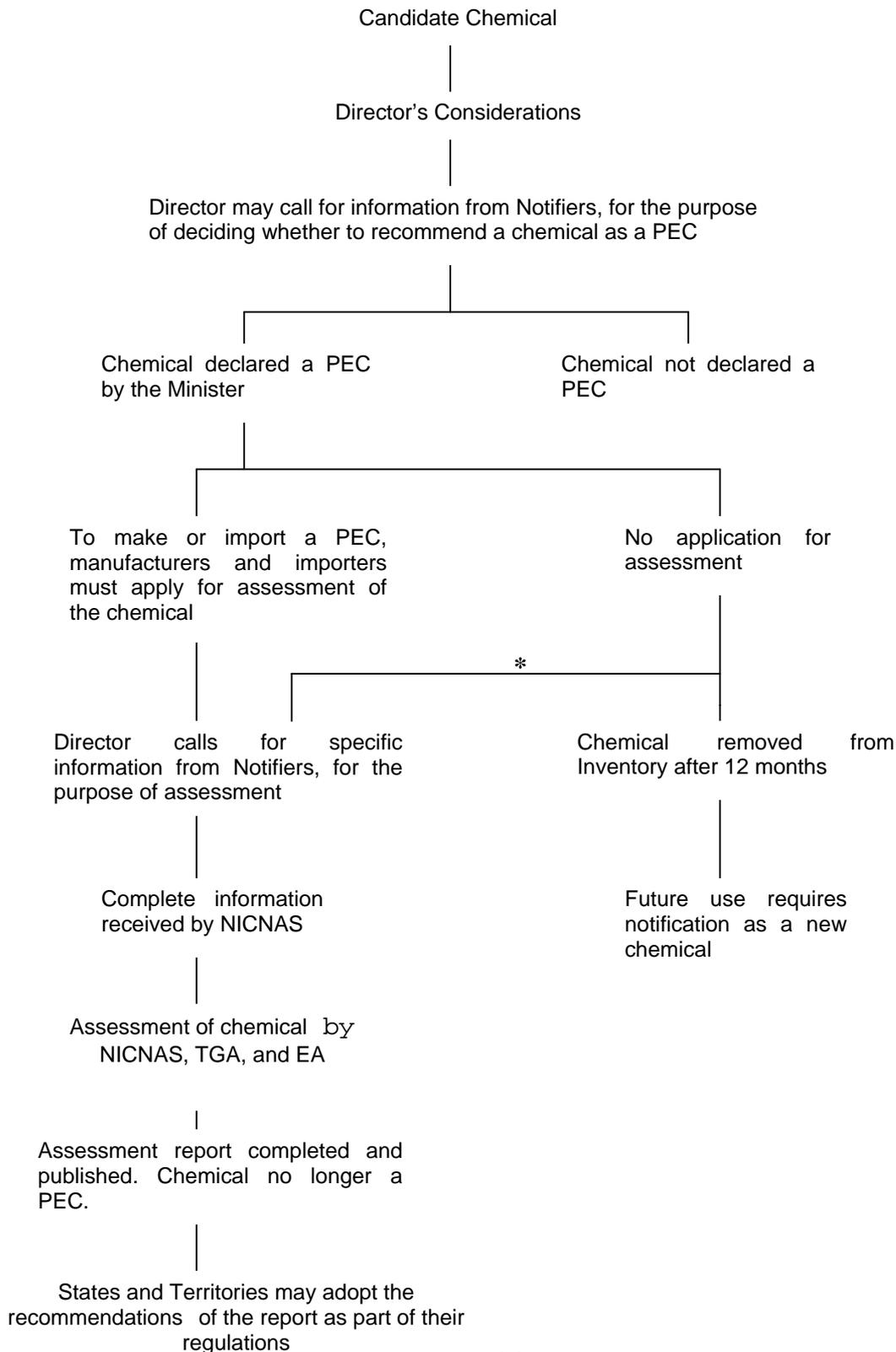
## **RECOMMENDATION OF A CHEMICAL AS A PEC**

As a result of the selection of PECs from public nominations, the Director may recommend to the Minister for Employment, Workplace Relations and Small Business that the chemical be declared a PEC.

The Director may also recommend PECs to the Minister on his or her own initiative.

**DIAGRAM C**

**THE PEC PATHWAY: FROM CANDIDATE CHEMICAL TO PEC**



\* See 'Substances no longer manufactured or imported', earlier in this report

## **DECLARATION AND ASSESSMENT OF PECs**

### **DECLARATION OF A PEC**

The Director uses the information that is obtained through the screening and ranking process, together with any information gained from a section 48 notice, to help decide whether to recommend to the Minister of Employment, Workplace Relations and Small Business, that a chemical be declared as a priority existing chemical.

The Minister for Employment, Workplace Relations and Small Business may decide, on the basis of a recommendation from the Director of NICNAS, to declare a chemical to be a priority existing chemical (PEC). A notice of declaration is published in the *Chemical Gazette*. It provides details of the type of assessment to be undertaken and what information is required to be supplied to NICNAS by applicants (see below).

### **ASSESSMENT OF A PEC**

Once a chemical has been declared a PEC, all importers and manufacturers are required to make an application for assessment within 28 days of the declaration. The application must be accompanied by the information referred to in the declaration notice.

A 'weight of evidence' approach is adopted in the assessment of each chemical, taking into account all available information including published literature, unpublished data, public information, international and overseas national assessments and the data submitted in response to notices placed in the Chemical Gazette.

Full assessments will usually include information on chemical and physical properties, uses, exposure, kinetics and metabolism, effects on experimental animals and in vitro test systems, and human health effects. It will usually include a hazard assessment and classification, a section on risk characterisation, risk management, and recommendations. Full assessments must include an occupational, consumer and/or environmental risk assessment. However they can be targeted at a particular concern, for example a particular use.

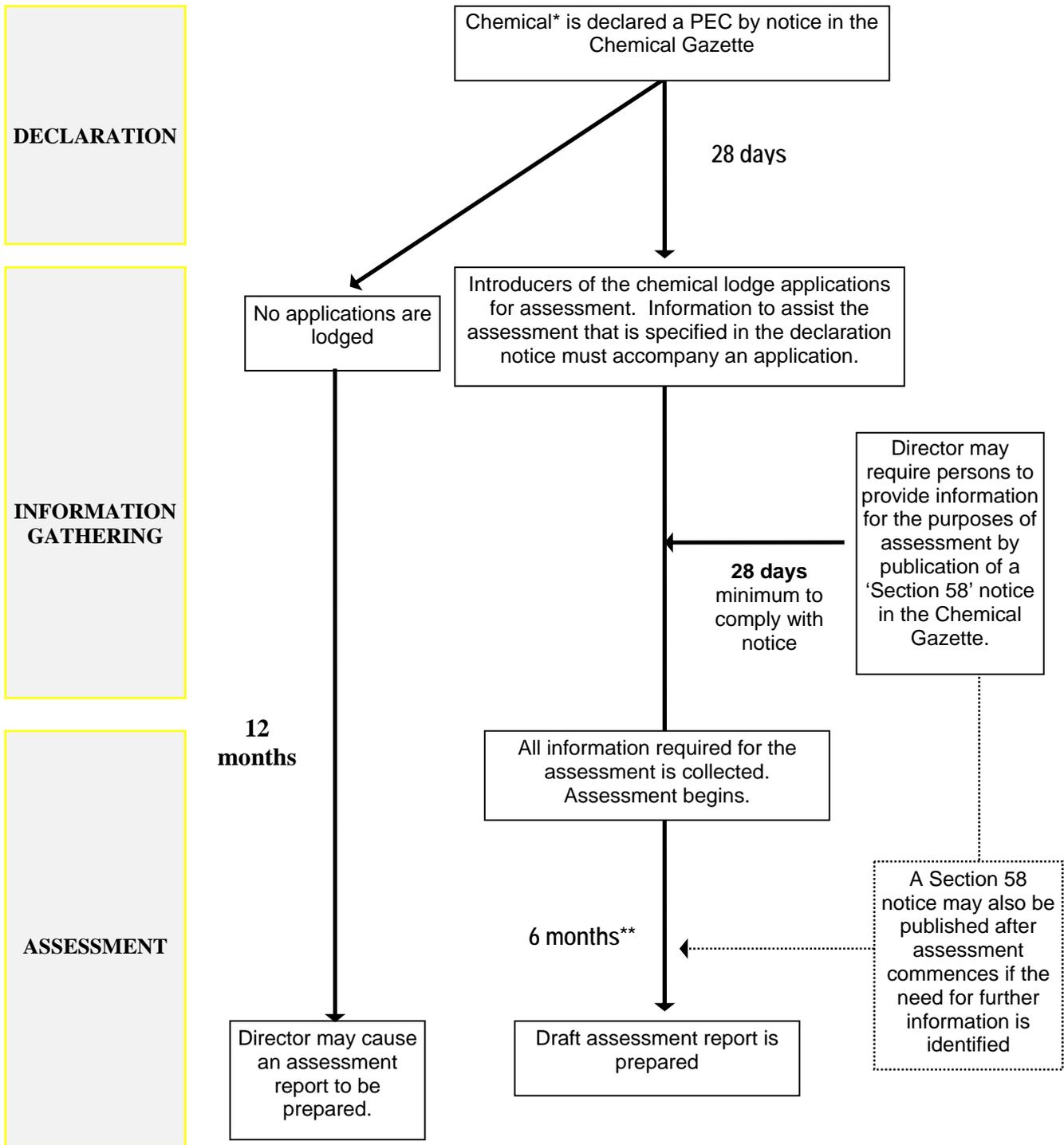
Preliminary assessments are less detailed and are always tailored to the particular aspects that are the focus of the assessment eg hazard or exposure. Preliminary assessments do not include a risk assessment, but an outcome may be a recommendation that a risk assessment is required. .

Sometimes related or similar chemicals are assessed as a group. This flexibility in assessment ensures that NICNAS resources are targeted effectively to priority areas of concern.

NICNAS will coordinate the assessment and perform the occupational health and safety assessment. EA will undertake the environmental hazard assessment, and TGA will carry out a public health assessment.

As the assessment proceeds, NICNAS may request more information from introducers of the chemical or other specified people through placement of a notice in the *Chemical Gazette* under the provisions of section 58 of the Act (a 'section 58 notice').

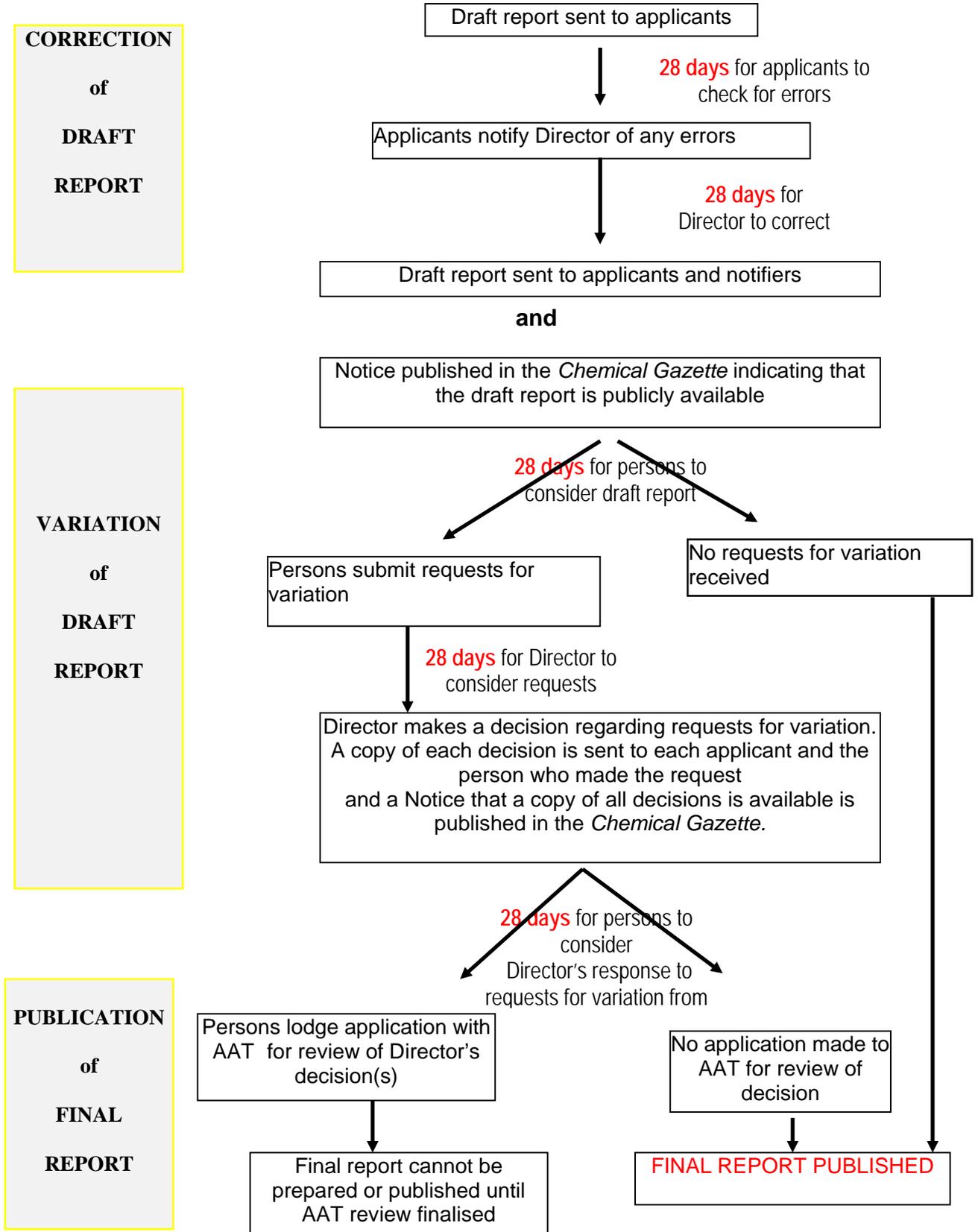
**PROCEDURES FOLLOWING DECLARATION OF A CHEMICAL TO PREPARATION OF DRAFT REPORT**



\* The notice specifies whether the declaration applies to the chemical generally or only when it is used for particular purposes or in particular circumstances. If more than one chemical is declared, the notice will specify if they are to be assessed together.

\*\* Assessment timeframe of 6 months may be extended by the Minister

## PROCEDURES FOR FINALISATION OF PEC ASSESSMENT REPORT



## **PUBLIC COMMENT**

NICNAS is committed to industry and public involvement, and sees consultation with these groups as an essential part of the assessment process.

When the draft report of the assessment is prepared, a copy of the draft report is given to applicants with a notice asking the applicants to notify of any errors in the report. Any errors must be corrected by the Director within 56 days of sending the draft report to applicants.

Corrected draft reports are sent to applicants and anyone who has provided information for the report in response to a section 58 notice ('notifiers'). At the same time, a notice is published in the *Chemical Gazette* describing how copies of the report can be obtained.

Requests for variation to the report may be made by any interested party on the appropriate form within 28 days of publication of the notice. The decisions made by the Director are then made publicly available (a notice is placed in the *Chemical Gazette*). Copies are sent to applicants and those persons requesting variation of the report.

There are provisions for appeal to the Administrative Appeals Tribunal (AAT) if a person does not agree with a decision made by the Director regarding a request for a variation to the draft report. A report cannot be finalised or published until any such appeal is finalised.

## **ASSESSMENT REPORT**

An assessment report includes a summary of health and safety and environmental matters that were considered in the assessment. Full assessment reports include recommendations on:

- the precautions and restrictions to be observed during the importation, manufacture, handling, storage, use or disposal of the chemical to protect persons exposed to the chemical;
- controls to limit emissions of the chemical into the environment;
- the packaging, labelling, handling, transportation or storage of the chemical;
- the measures to be employed in emergencies involving the chemical to minimise hazard to people and damage to the environment;
- the uses of the chemical; and
- the means of disposal of the chemical.

Preliminary assessment reports will include a recommendation on whether a full assessment is required.

These assessment reports are provided to the States and Territories which are encouraged to give effect to the recommendations, possibly through adoption as part of their regulations. This promotes uniform regulation of industrial chemicals throughout Australia.

Summary assessment reports are published in the *Chemical Gazette*. Full assessment reports are published and the Gazette notice advises how to obtain copies.

Once the assessment report is published the chemical is no longer a PEC.

## **OUTCOMES**

Publication of assessment reports are a major outcome of the Existing Chemicals Program. They make available to companies introducing chemicals, to people within the workplace, to other Government agencies, and the public, information on any risks to human health and the environment, and recommendations on ways to control and reduce any risks. This contributes significantly toward making workplaces safer and in protecting human health and the environment.

Recommendations from PEC assessment reports can have an important bearing on regulatory action that may be implemented within Australia in the context of protecting the health of workers and the public, and protecting the environment. For instance, they may impact on national occupational exposure standards, hazard classification, health surveillance guidelines, labelling requirements, and the development of codes of practice.

Another major outcome of the assessment process is the contribution that is made to international chemical assessment program. The quality of the assessments produced by NICNAS is accepted as being high on an international level. As a member country of the OECD, Australia participates in the OECD's High Production Volume Existing Chemicals Program. Australia also contributes reports to the International Program on Chemical Safety (IPCS) Concise International Chemical Assessment Document (CICAD) Program. Assessments produced as part of Australia's Existing Chemicals Program are utilised in these international fora, forming a part of Australia's contribution to the world-wide assessment of existing chemicals. Participation in international assessment programs also assists in the review and development of Australian assessment methodologies.

## **OTHER INFORMATION ABOUT THE PEC SELECTION PROCESS**

### **CHEMICALS**

#### **Standby Chemicals**

Standby chemicals have insufficient data available to assess their potential hazard.

Given the limited resources available the following approach is taken. The list of Standby Chemicals are checked against the Organisation for Economic Cooperation and Development (OECD) High Production Volume (HPV) list. If the chemical is on the HPV list then this indicates that international work is underway, or will be undertaken, to generate a Screening Information Data Set (SIDS). The SIDS data will be generated by industry and will provide information to be used in the PEC selection process. This information will be available to Australia through the OECD program when completed. A summary of the HPV program is provided at Attachment F.

If the Director is concerned about the chemical, then the Director may recommend that the chemical be declared a PEC and require notifiers to provide missing data. Some of the Stand-by chemicals may be declared as PECs for a preliminary assessment.

All standby chemicals not declared PECs and on the Candidate List are reviewed for any new information is reviewed and this is applied in subsequent selection cycles.

#### **Non-Selected Chemicals and Non-Candidate Chemicals**

Non-selected chemicals and non-candidate chemicals are removed from the Base List. Nominators of these chemicals are informed of the outcome of the selection process and provided with a summary report on their nominated chemical(s).

#### **Candidate Chemicals not declared PECs**

Candidate chemicals not chosen as PECs remain on the Candidate List, to be reviewed at the next selection cycle. The nominators are informed and receive a summary report on their nominated chemical(s).

### **AVAILABILITY OF INFORMATION**

A summary of the information collected on all eligible chemicals in the selection process is publicly available. Copies can be viewed on request to the Nominations Officer.

At the completion of the selection process all nominators of Base List chemicals are informed of the outcome of the consideration of their chemical(s) and provided with a summary of the information collected on their chemical(s). Nominators of ineligible

chemicals are informed at the beginning of the selection process that their chemical is ineligible.

A list of current and previous PECs is published annually in the *Chemical Gazette*.

### **REVIEW OF DECISION**

The Industrial Chemicals (Notification and Assessment) Act provides that where a chemical is declared a PEC application may be made to the Administrative Appeals Tribunal for a review of the decision.

### **EVALUATION OF THE PEC SELECTION PROCESS**

An evaluation of the Existing Chemicals Program was undertaken to assess the effectiveness of the program and to address the operation of selection processes used for PECs. A report was published in 1994. The evaluation found that the selection procedures used to identify candidate PECs were acceptable allowing for public participation and creating a basis for ownership of the Program among nominators.

Table 1A: Health Effects Criteria

SELECTION CRITERIA	Low	Medium	High
<b>HEALTH EFFECTS</b>			
Acute toxicity: LD <sub>50</sub> oral, mg/kg LD <sub>50</sub> dermal, mg/kg LC <sub>50</sub> inhalation, mg/L/4hr	LD <sub>50</sub> > 25 LD <sub>50</sub> > 50 LC <sub>50</sub> > 0.5	5 < LD <sub>50</sub> ≤ 25 10 < LD <sub>50</sub> ≤ 50 0.1 < LC <sub>50</sub> ≤ 0.5	LD <sub>50</sub> ≤ 5 LD <sub>50</sub> ≤ 10 LC <sub>50</sub> ≤ 0.1
Irritation	no effect reported	slight/moderate skin or eye irritant	Corrosive, Severe eye damage. Respiratory irritant
Sensitisation	no effect reported	Skin positive	Respiratory positive
Repeat dose General toxicity	no effect reported	Reversible effects	Irreversible effects
Genotoxicity	no effect reported	<i>In vitro</i> positive	<i>In vivo</i> positive
Carcinogenicity	no effect reported	Human case reports/Equivocal animal evidence	Confirmed human evidence/Strong animal evidence
Reproductive damage/ Teratogenicity	no effect reported	Human case reports/Equivocal animal evidence	Confirmed human evidence/Strong animal evidence
<b>SPECIAL CONCERNS</b>			
Demonstrated adverse effects	No reported concern	Concern based on less substantial reports (potential or suspected health effects)	Concern based on substantiated reports of health effects or human studies indicating health effects.
Regulatory action taken overseas on health grounds.	No recorded concern.	Concern based on partial restriction or special review.	Concern based on severe restriction, withdrawal or banning of a chemical

**Table 1B: Scores for Health**

**Health Effects**

- H** at least one High value
- M** at least one medium value
- L** data exist on at least two criteria
- ?** data exist on only one criterion or no data

**Special Concerns**

- H** at least one High value
- M** at least one Medium value
- L** two Low values

**Table 2A: Health Exposure, Quantity**

<b>SELECTION CRITERIA</b>	<b>Low</b>	<b>Medium</b>	<b>High</b>
Production/import quantity (tonne/year)	< 10		≥ 10
Occupational exposure: Number of persons exposed and level of exposure	Low	Medium	High
Public exposure: Number of persons exposed and level of exposure	Low	Medium	High

**Table 2B: Score for health exposure**

- H** at least one High value
- M** at least two medium values
- L** data exist on at least two criteria
- ?** data exist on only one criterion or no data

**Table 3: 2nd Ranking – Health**

SELECTION GROUP	HEALTH SCORES
<b>Selected chemicals</b>	<p><b>H</b> effect or <b>H</b> special concerns</p> <p><b>M</b> effect or <b>M</b> special concerns <i>and</i> <b>H</b> exposure</p> <p><b>M</b> effect or <b>M</b> special concerns <i>and</i> <b>M</b> exposure</p>
<b>Non-selected chemicals</b> (removed from Base List)	<p><b>L</b> effect and <b>L</b> special concerns</p> <p><b>M</b> effect or <b>M</b> special concerns <i>and</i> <b>L</b> exposure</p>
<b>Standby chemicals</b> (insufficient data)	<p>? effect and ? special concern</p> <p><b>M</b> effect or <b>M</b> special concerns <i>and</i> ? exposure</p>

Table 4: Environmental Fate And Effects Criteria

SELECTION CRITERIA	Low	Medium	High
<b>ENVIRONMENTAL FATE</b>			
Biodegradability: BOD <sub>28</sub> or BOD <sub>5</sub> /COD	> 60% ≥ 0.5%	> 20% but ≤ 60%	≤ 20%
Bioaccumulation: LogP <sub>ow</sub> or BCF or Water solubility, ppm or Molecular weight	< 1 < 10 > 25 > 1,000	1 to <3 and >8 10 to < 100	>3 to < 8 ≥ 100
<b>ENVIRONMENTAL EFFECTS</b>			
Acute aquatic toxicity 96h LC <sub>50</sub> fish*, ppm	> 10	> 1 to ≤ 10	≤ 1
Chronic aquatic toxicity NOEC fish**, ppm	> 1	0.1 to ≤ 1	≤ 0.1
<b>SPECIAL CONCERNS</b>			
Demonstrated adverse effects on environment or bioaccumulation or persistence in soil/sediment and/or surface/groundwater.	No recorded concern	Concern based on less substantial reports (potential or alleged environmental incidents).	Concern based on substantiated reports of major wildlife or environmental contamination.
Regulatory action taken overseas on environmental grounds	No recorded concern.	Concern based on partial restriction or special review.	Concern based on severe restriction, withdrawal or banning of a chemical.

\* or 48h EC<sub>50</sub> daphnia, 96h LC<sub>50</sub> shrimp, 72h EC<sub>50</sub> algae [The highest toxicity value out of all the available results is to be used (ie the result obtained for the most sensitive species)].

\*\* or chronic NOEC to Daphnia, shrimp or algae (as above, the highest value is to be used ie the result obtained for the most sensitive species).

**Table 5: 1st Ranking - Environment**

<b>SELECTION GROUP</b>	<b>ENVIRONMENTAL CRITERIA VALUES</b>
<i>Selected</i> chemicals	One or more High values <b>OR</b> At least one Medium value for each category <b>OR</b> No data for aquatic toxicity <b>OR</b> No data for fate
<i>Non-selected</i> chemicals removed from Base List	Do not meet the above criteria

**Table 6A: Ranking for Environmental Exposure/Fate and Effects/Quantity and Use**

<b>SELECTION CRITERIA</b>	<b>Low</b>	<b>Medium</b>	<b>High</b>
<b>ENVIRONMENTAL EXPOSURE / FATE</b>			
Production/import Quantity (tonne year)	< 10		≥ 10
Use:  Where data are available the following can be used: kg/year released from a single point source* kg/year released in total*	Restricted exposure  ≤ 50 ≤ 500	Limited or moderate exposure  > 50 but ≤ 500 > 500 but ≤ 1000	Widespread exposure  > 500 > 1000
Biodegradability: BOD <sub>28</sub> or BOD <sub>5</sub> /COD	> 60 % ≥ 0.5%	> 20% but ≤ 60 %	≤ 20%
Bioaccumulation: LogP <sub>ow</sub> or BCF or Water solubility, ppm or Molecular weight	< 1  <10  > 25  > 1,000	1 to < 3 and >8  10 to < 100	>3 to < 8  ≥ 100
<b>ENVIRONMENTAL EFFECTS</b>			
Acute aquatic toxicity 96h LC50 fish**, ppm	> 10	> 1 to ≤ 10	≤ 1
Chronic aquatic toxicity NOEC fish***, ppm	> 1	0.1 to ≤ 1	≤ 0.1
<b>SPECIAL CONCERNS</b>			
Demonstrated adverse effects on environment or bioaccumulation or persistence in soil/sediment and/or surface/groundwater.	No recorded concern	Concern based on less substantial reports (potential or alleged environmental incidents).	Concern based on substantiated reports of major wildlife or environmental contamination.
Regulatory action taken overseas on environmental grounds	No recorded concern.	Concern based on partial restriction or special review.	Concern based on severe restriction, withdrawal or banning of a chemical.

- \* These figures refer to release through normal use only as opposed to accidental release.
- \*\* or 48h EC<sub>50</sub> daphnia, 96h LC<sub>50</sub> shrimp, 72h EC<sub>50</sub> algae [The highest toxicity value out of all the available results is to be used (ie the result obtained for the most sensitive species)].
- \*\*\* or chronic NOEC to Daphnia, shrimp or algae [as above the highest toxicity value is to be used (ie the result obtained for the most sensitive species)].

**Table 6B: 2nd Scores for Environment**

**Environmental Exposure/Fate**

- H** at least one High value
- M** at least two Medium values
- L** more than two Low values
- ?** data exist on two or less criteria

**Environmental Effects**

- H** at least one High value
- M** at least one Medium value
- L** at least one Low value
- ?** insufficient data

**Special Concerns**

- H** at least one High value
- M** at least one Medium value
- L** two Low values

**Table 7: 2nd Ranking - Environment**

<b>SELECTION GROUP</b>	<b>ENVIRONMENTAL SCORES</b>
<b>Selected chemicals</b>	<p><b>H</b> effects or <b>H</b> special concerns or <b>H</b> exposure</p> <p><b>H</b> effects or <b>H</b> special concerns and <b>M</b> exposure</p> <p><b>M</b> effect or <b>M</b> special concerns <i>and</i> <b>H</b> exposure</p> <p><b>M</b> effect or <b>M</b> special concerns <i>and</i> <b>M</b> exposure</p> <p><b>H</b> effect or <b>H</b> special concern and <b>L</b> exposure</p>
<b>Non-selected chemicals</b> (removed from Base List)	<p><b>M</b> effect or <b>M</b> special concerns <i>and</i> <b>L</b> exposure</p> <p><b>L</b> effect or <b>L</b> special concerns <i>and</i> <b>M</b> exposure</p> <p><b>L</b> effect or <b>L</b> special concerns <i>and</i> <b>L</b> exposure</p> <p><b>L</b> effect or <b>L</b> special concern and <b>H</b> exposure</p>
<b>Standby chemicals</b> (insufficient data)	<p>? effect and ? special concerns</p> <p><b>M</b> effect or <b>M</b> special concerns <i>and</i> ? exposure</p> <p><b>L</b> effect or <b>L</b> special concerns <i>and</i> ? exposure</p>

**ATTACHMENT A**

**ADVERTISEMENT CALLING FOR NOMINATIONS FOR PECS**

The Weekend Australian	-12 December 1998
Daily Commercial News	-15 December 1998

## **PUBLIC NOMINATION BROCHURE AND NOMINATION FORM**

### **Call for Nomination of Industrial Chemicals of Concern for Assessment**

The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is inviting members of the public who have a concern about the public health, occupational health and safety, and/or environmental effects of an industrial chemical in Australia, to nominate that chemical for consideration for declaration and assessment under its Priority Existing Chemicals (PEC) Program.

Nominated chemicals will be screened and ranked, and the resulting list will be used by NICNAS as a basis for selecting chemicals for assessment over the next three years.

A nomination form is enclosed in the back pocket of this pamphlet.

#### **WHAT IS NICNAS?**

NICNAS was established in 1990 under the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act), to aid in the protection of people at work, the public and the environment, from the harmful effects of industrial chemicals. NICNAS assesses industrial chemicals entering Australia for the first time, known as new chemicals, to determine their potential risk to human health and the environment prior to their importation and/or manufacture. NICNAS also identifies and assesses the potential risks from selected industrial chemicals which are already in use in Australia, known as existing chemicals. In its assessment reports, NICNAS makes recommendations on appropriate control measures to be observed while using, handling, storing, and disposing of the chemical. Recommendations may also be made to regulatory authorities.

NICNAS forms an integral part of the Commonwealth's regulatory framework for chemicals. Other national chemical regulatory organisations include the National Registration Authority (NRA) for agricultural and veterinary chemicals, and the Therapeutic Goods Administration (TGA), which covers therapeutic drugs.

The availability of NICNAS assessment reports to State/Territory regulatory agencies, companies introducing chemicals, people in the workplace, other government agencies, and the public has contributed significantly to making workplaces safer and in protecting human health and the environment from hazardous chemicals.

## **WHAT IS AN EXISTING INDUSTRIAL CHEMICAL?**

Under the Act, industrial chemicals are defined as substances other than those used exclusively as agricultural and veterinary chemicals, human therapeutic substances, food or food additives and radioactive substances.

Examples of chemicals that fall under the definition of an industrial chemical are dyes, solvents, plastics, and photographic chemicals, and chemicals used in an industrial process, as well as some chemicals used in the home, such as paints, cleaning agents and cosmetics. The chemical may be used on its own, or be part of a mixture (an ingredient).

Existing industrial chemicals are those industrial chemicals which are listed on the Australian Inventory of Chemicals Substances (AICS), and are not notifiable as new chemicals. AICS lists chemicals that were in use in Australia over the period 1977 to 1990, and is updated annually to include the names of chemicals which were assessed as new chemicals five or more years previously.

Nominated chemicals will be screened to ensure that they fall within the legal definition of an existing industrial chemical.

## **WHAT IS THE PRIORITY EXISTING CHEMICALS PROGRAM?**

Under the PEC Program, NICNAS performs assessments of existing industrial chemicals in Australia. There are over 40,000 chemicals listed on AICS, and so assessment of existing chemicals is undertaken on a priority basis, in response to concerns over health and environmental effects.

The legal mechanism by which a chemical is assessed is through its declaration as a Priority Existing Chemical (PEC) by the Minister for Employment, Workplace Relations and Small Business, following recommendation by the Director of NICNAS. Declaration occurs if there are reasonable grounds for believing that the manufacture, handling, storage, use or disposal of a chemical gives rise, or may give rise, to a risk of adverse health effects or adverse environmental effects.

Chemicals can be nominated for declaration as PECs at any time by direct application to the Director of NICNAS. Calls for nominations from the public, such as the current one, are periodically made by NICNAS, in order to update its knowledge of chemical concerns in the wider community and to publicise its activities. The last public nomination phase occurred in 1991.

## **WHAT IS AN ASSESSMENT?**

Changes in 1997 to the Act have enabled the PEC Program to undertake a wider range of PEC assessments than previously. In addition to full assessments, less detailed assessments known as 'preliminary assessments' may be undertaken. Furthermore, chemicals can now be assessed as a

group if this is considered appropriate. Assessments can be limited to particular uses of a chemical, or its use in specified circumstances.

*Full assessments* will usually include information on chemical and physical properties, uses, exposure, kinetics and metabolism, effects on experimental animals and in vitro test systems, and human health effects. They will usually include a hazard assessment and classification, a section on risk characterisation, risk management, and recommendations. Full assessments include an occupational, consumer and/or environmental risk assessment.

*Preliminary assessments* aim to provide information on particular aspects of a chemical, such as its properties, uses to which it is put, any adverse effects on persons or the environment which the chemical has the intrinsic capacity to cause, or the extent to which persons or the environment are or will be exposed to the chemical. Risk assessments are not included in preliminary assessments, however a conclusion of a preliminary assessment may be that a full assessment is needed.

The assessment process involves desk-based research and evaluation, supplemented by site visits. Information is collected from manufacturers, importers and users of the chemical, and from searches of published international scientific literature, and other relevant sources. The Director can require persons believed to possess relevant information to disclose this information to NICNAS, through publication of a notice in the *Commonwealth Chemical Gazette*.

Once all relevant information has been collected, a draft assessment report is prepared. Depending on the type of assessment undertaken, the draft report can include environmental assessments prepared by Environment Australia and public health assessments prepared by the Department of Health and Aged Care. The draft report is peer reviewed by NICNAS and experts external to NICNAS, after which a final draft report is prepared.

Final draft reports go through a public comment phase which allows for interested parties to request a variation. Final reports may be purchased from NICNAS, and are also held for viewing at the library of the National Occupational Health and Safety Commission, at 92 Parramatta Rd, Camperdown, NSW 2050. Summary reports of assessments, which give notice that an assessment has been completed, are published in the *Commonwealth Chemical Gazette*.

## **THE PUBLIC NOMINATION PROCESS**

### ***Who can nominate?***

Any person or organisation with a concern about the public health, occupational health and safety, and/or environmental effects of an industrial chemical may nominate the chemical for assessment.

Nominators may include members of the public, workers, unions, industry groups, public interest groups, and State, Territory and Commonwealth government agencies.

### ***How do I nominate a chemical?***

Nominations must be in writing, and be mailed or faxed to the Director of NICNAS. During the current public nomination process, in order to assist processing of nominations, it is requested that people use the enclosed nomination form, and address it to the contact officer shown on the form.

Nomination forms are also available on request from NICNAS, and can be downloaded from the NICNAS Web site at <http://www.nicnas.gov.au/forms/files/PECNom.doc>

### ***How do I know if a chemical I am thinking of nominating has already been through the PEC Program?***

Check tables A and B below. Completed assessment reports for PECs 1 to 21, listed in table A, can be ordered from NICNAS and are also available electronically at :  
<http://www.nicnas.gov.au/publications/car/pec/pecindex.htm>.

Safety information sheets have been compiled from information contained in Priority Existing Chemical (PEC) assessment reports and are available at:  
<http://www.nicnas.gov.au/publications/>.

### ***What is the closing date for nominations?***

The current public nomination phase will close on Friday 26 March 1999.

Nominations received after the closing date will be considered in future selection cycles. Such nominations may be made by writing a letter, or sending the enclosed form to the Director of NICNAS.

### ***What happens after nominations are received?***

Nominated chemicals will first be screened to determine if they are eligible for inclusion in the PEC program. A chemical cannot be accepted into the program if it is not an existing industrial chemical under the definitions of the legislation.

Chemicals will be considered by a committee comprising NICNAS and its expert advisory agencies, that is, Environment Australia and the Department of Health and Aged Care. Representatives on the committee will be experts in the field of toxicology, public and occupational health, and the environment. The committee will:

- Assess the chemicals against a set of criteria covering issues in public health, occupational health, and the environment;
- Decide whether the concerns relating to health and the environment are sufficient to merit further consideration;
- Rank the chemicals on the basis of the perceived severity of the threat posed to human health or the environment.

In the ranking of chemicals these factors may be considered:

- whether it has been recently reviewed by another government agency within Australia;
- whether it is under review in another country, and NICNAS is awaiting the outcome of such a study;
- whether an assessment report from another country is available.

Chemicals that are ranked with a high priority may not only include those which rank highly in all areas of concern, but could also cover those which may have a very strong concern in one key area.

Further details of the screening and ranking process, including details of the criteria to be used, is available from NICNAS.

## **OUTCOMES OF THE PUBLIC NOMINATION PROCESS**

The outcome of this process is a ranked list of chemicals that will be considered for recommendation for assessment as PECs by the Director of NICNAS. This list is known as the Candidate List. In deciding to recommend any chemicals from this list as PECs, the Director may find it necessary to call for further information through means of a notice in the *Commonwealth Chemical Gazette*.

Chemicals that were nominated during the first public call for nominations in 1991, and which have not been assessed, underwent a call for further information and a screening process in October 1997. These chemicals must be re-nominated to be considered for the new Candidate List. This will ensure that chemicals which are no longer of concern are no longer on the list. A list of these chemicals is available on request from the Nominations Officer.

NICNAS will write to nominators to inform them of the outcome of their nomination.

**TABLE A***Chemicals Already Assessed as PECs*

<b>Chemical</b>	<b>PEC No.</b>	<b>CAS No.</b>	<b>Published</b>
TGIC – Triglycidylisocyanurate	1	2451-62-9	April 94
Savinase - Proteolytic enzymes in detergents	2	various	Feb 93
Glutaraldehyde	3	111-30-8	June 94
HCFC-123	4	306-83-2	March 96
Sodium ethylxanthate	5	140-90-9	May 95
2-Butoxyethanol in cleaning products	6	111-76-2	Oct 96
1,4-Dioxane	7	123-91-1	June 98
Trichloroethylene	8	79-01-6	March 2000
Chrysotile	9	12001-29-5	February 1999
Acrylonitrile	10	107-13-1	February 2000
HCFC-123 (Secondary Notification)	4S	306-83-2	July 1999
N-Vinyl-2-Pyrrolidone	11	88-12-0	April 2000
Sodium Ethyl Xanthate (Secondary Notification)	5S	140-90-9	February 2000
Glycolic Acid in cosmetics	12	79-14-1	April 2000
<i>Para</i> -Dichlorobenzene	13	106-46-7	December 2000
<i>Ortho</i> -Dichlorobenzene	14	95-50-1	February 2001
Tetrachloroethylene	15	127-18-4	June 2001
Short Chain Chlorinated Paraffins (SCCPs)	16	Various	June 2001
Trisphosphates	17	Various	June 2001
Ammonium Persulfate in hair dressing	18	7727-54-0	June 2001
Potassium Persulfate in hair dressing		7727-21-1	
Sodium Persulfate in hair dressing		7775-27-1	
Hydrofluoric Acid (HF)	19	7664-39-3	June 2001
Polybrominated Flame Retardants (PBFRs)	20	Various	June 2001
Benzene	21	71-43-2	September 2001

## TABLE B

### *PECs in Progress*

Chemical	PEC NO.	CAS No.
<i>Full Assessments:</i>		
Limonene		
<i>d</i> -limonene		5989-27-5
<i>l</i> -limonene		5989-54-8
<i>dl</i> -limonene		138-86-3
Acrylamide		79-06-01

### FURTHER INFORMATION

For further information on NICNAS and the PEC Program, see the NICNAS home page on the internet at <http://www.nicnas.gov.au>

Pamphlets and information papers available from this site and also from NICNAS include:

- *National Industrial Chemicals Notification and Assessment Scheme (NICNAS)*
- *Enhanced Assessment Program of Existing Chemicals*
- *The NICNAS Existing Chemicals Assessment Process and Program*
- *NICNAS Company Registration*

The following publication is available from NICNAS:

- *Procedures for Public Nomination and Selection of Priority Existing Chemicals 1998*

For any of these publications, and to obtain further information on the nomination process, contact:

Nominations Officer  
Existing Chemicals Team  
NICNAS  
GPO Box 58  
Sydney 2001  
Phone: (02) 8577 8800.  
Fax: (02) 8577 8888  
Email: [info@nicnas.gov.au](mailto:info@nicnas.gov.au)





## **PRIORITY EXISTING CHEMICALS NOMINATION FORM**

### **Purpose Of This Form**

The National Industrial Chemicals Notification and Assessment Scheme (NICNAS), has issued an invitation to the public to participate in its review of existing industrial chemicals by nominating chemicals to be considered for assessment as Priority Existing Chemicals. Anyone who believes that the manufacture, handling, storage, use or disposal of an industrial chemical gives rise, or may give rise, to a risk of adverse health effects or adverse environmental effects, may nominate it for consideration.

This form is designed to assist you in making a nomination.

### **How To Fill Out The Form**

A separate nomination form should be completed for each chemical, except where you think that a group of chemicals should be assessed together, for instance, because the chemicals are closely associated by their properties, and/or are commonly known by a single name.

Please ensure that your nomination form is complete.

### **Confidentiality**

**The identity and address of individuals nominating a chemical on their own behalf, or on behalf of an organisation will be kept confidential. Where an individual is nominating on behalf of an organisation, the name of the organisation will NOT be kept confidential unless this is specifically requested.**

### **Due Date**

Nominations should reach NICNAS by **Friday 26 March 1999**.

### **Help Available**

If you require assistance in completing this form, please contact the officer below.

### **Returning your Form**

A reply paid envelope is enclosed in a pocket at the back of this pamphlet. Otherwise, the form may be mailed or faxed to the address shown below:

Nominations Officer,  
Existing Chemicals Team  
NICNAS  
GPO Box 58

Sydney 2001  
Telephone: (02) 8577 8800 Fax: (02) 8577 8888

# PRIORITY EXISTING CHEMICALS NOMINATION FORM

## 1. Details of Nominator

**This section is to provide NICNAS with contact names and addresses to acknowledgement of your nomination, request clarification of any matters, and notify you of the outcome of your nomination.**

Name: \_\_\_\_\_

Phone number: \_\_\_\_\_

Fax Number: \_\_\_\_\_

E-mail address: \_\_\_\_\_

Address: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Are you making this nomination on behalf of an organisation?

No

Yes  ⇒ Please fill out the information below

Name of organisation: \_\_\_\_\_  
\_\_\_\_\_

Address of organisation: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

## 2. Details of chemical nominated

This section enables NICNAS to clearly identify the chemical or chemicals being nominated. You should use one nomination form for one chemical nomination. However, if you are nominating a group of chemicals that you think should be assessed together, you may list the chemicals on one form.

Chemical Name(s): \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Product or Trade Name(s): \_\_\_\_\_



How is the chemical used?

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---

Who uses the chemical (e.g. householder, welder, builder), and in what quantity?

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---

Where can the chemical be obtained? (e.g. retail outlet, employer's premises, etc)

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---

---

Is this chemical available to members of the public?

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---

---

---

How many people use the chemical?

---

---

---

---

Describe what you know about the effect this chemical has on people

---

---

---

---

If possible, provide information on how, where and in what quantity the chemical is released into the environment

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---

Describe what you know about the effect this chemical has on the environment\_\_\_\_\_

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\_\_\_\_\_Do you have a Material Safety Data Sheet (MSDS) for this chemical or for a product containing this chemical?

No

Yes  ⇒ Please attach a copy/copies

Do you have a label for this chemical or a product containing this chemical?

No

Yes  ⇒ Please attach label(s)

**5. PLEASE SIGN HERE**

Signature:\_\_\_\_\_

Date:\_\_\_\_\_

**Thank you for completing this form. Please return to :**  
Nominations Officer, Existing Chemicals Team, NICNAS,  
GPO Box 58, Sydney NSW 2001  
Telephone: (02) 8577 8800; Fax: (02) 8577 8888

**INFORMATION PAPER**

**THE NICNAS EXISTING  
CHEMICALS  
ASSESSMENT  
PROCESS  
AND  
PROGRAM**

**NATIONAL INDUSTRIAL CHEMICALS  
NOTIFICATION AND ASSESSMENT SCHEME**



February 1998

### *Object of this document*

This document outlines the Existing Chemicals Program that operates within NICNAS. The purpose of this paper is to explain the Program and the steps involved in the assessment of existing chemicals.

### *What is NICNAS?*

The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is an independent Commonwealth statutory scheme established to aid in the protection of people at work, the public and the environment from the harmful effects of industrial chemicals, through the mandatory notification and assessment of these chemicals.

This is achieved through the assessment of all new industrial chemicals that are entering Australia for the first time, and for industrial chemicals that are already in use in Australia on a priority basis.

NICNAS was established on 17 July 1990 with the enactment of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cmwlth).

### *What is an Industrial Chemical?*

Under NICNAS, industrial chemicals are defined as substances other than agricultural and veterinary chemicals, human therapeutic substances, food or food additives and radioactive substances.

### *What is an Existing Chemical?*

Existing chemicals are those industrial chemicals in use in Australia. They include all the chemicals which are listed on the Australian Inventory of Chemical Substances (AICS).

### *The Existing Chemicals Program*

Due to the large number (over 40,000) of existing chemicals in use in Australia, NICNAS assesses these chemicals on a priority basis in response to concerns about their health and/or environmental effects. Such chemicals are referred to as Priority Existing Chemicals (PECs).

Assessment allows recommendations for protecting the Australian people and the environment to be made.

### *What is an assessment?*

A full PEC assessment aims to find out the risks (if any) to workers, members of the public, or the environment of importing, manufacturing, using, storing, handling or disposing of a chemical, or a group of chemicals. It will recommend ways to reduce any risks. Assessments may take into account all uses of the chemical, or only specified uses.

Less detailed assessments known as ‘preliminary assessments’ aim to provide information on particular aspects of a chemical, such as its properties, uses to which it is put, any adverse effects on persons or the environment which the chemical has the intrinsic capacity to cause, or the extent to which persons or the environment are or will be exposed to the chemical.

The publication of assessment reports provides a basis for informed and scientifically based regulatory and other action on the chemicals that have been subject to assessment.

## A Six Step Review Process

There are six steps involved in the process of existing chemicals assessment. These are outlined as follows:

- Step 1: Nomination
- Step 2: Screening and Information Gathering
- Step 3: Declaration
- Step 4: Assessment
- Step 5: Public Comment
- Step 6: Outcomes

### Step 1 - Nomination

Nomination of chemicals to be assessed as a PEC is an open process. Any person or organisation with a concern about the public health, occupational health and safety, or environmental effects of an industrial chemical may nominate it for assessment.

Nominators may include members of the public, workers, unions, industry groups, public interest groups, and State, Territory and Commonwealth government agencies.

The chemicals nominated can be chemicals used on their own, or chemicals that form part of a product (an ingredient) or industrial process.

The Director of NICNAS periodically makes a public call for nominations, through notices in the Chemical Gazette, relevant industry journals, and national newspapers. Nominations should be

made on the appropriate form, available from NICNAS. Nominations for chemicals may also be accepted by the Director at any time, not only when there is a public nomination phase.

## Step 2 - Screening and Information Gathering

Once nominated, chemicals are screened to determine if they are eligible for inclusion in the program.

A chemical may not be accepted into the program if it is not an industrial chemical under the definitions of the legislation.

Each nominated chemical is then assessed against a set of criteria covering issues in public health, occupational health and safety, and the environment.

By consulting a number of standard sources of chemical information, a decision is made on whether the concerns relating to health and environment are sufficient to merit further consideration.

The chemicals are then ranked on the basis of the perceived severity of the threat posed to human health or the environment.

Additionally, in the ranking of chemicals these factors may be considered:

- whether it has been recently reviewed by another government agency within Australia,
- whether it is under review in another country, and NICNAS is awaiting the outcome of such a study.

Chemicals that are ranked with a high priority may not only include those which rank highly in all areas of concern, but could also cover those which may have a very strong concern in one key area (eg carcinogenicity).

The outcome of the screening and ranking process is a candidate list of chemicals.

The Director of NICNAS may decide that more information is needed in relation to particular chemicals on the candidate list. To seek this information, the Director may publish a notice in the Chemical Gazette under the provisions of section 48 of the Act (known as a 'section 48 notice').

A section 48 notice is directed to persons who have imported or manufactured the chemical(s) in the 12 months prior to the publication of the notice, and/or to anyone who the Director believes has relevant information concerning the chemical(s).

The notice can require the provision of various types of information, such as amounts imported or manufactured, known uses of the chemical in Australia, information on health effects or environmental effects, or information on occupational exposure.

A summary of the information obtained from a section 48 notice is prepared within 90 days of the date the last information was received. The summary is published in the *Chemical Gazette*, or a notice giving details of how to obtain a copy is published.

### Step 3 - Declaration

The Director uses the information that is obtained through the screening and ranking process, together with any information gained from a section 48 notice, to help decide whether to recommend to the Minister of Workplace Relations and Small Business, that a chemical be declared as a priority existing chemical.

The Minister of Workplace Relations and Small Business may decide, on the basis of a recommendation from the Director of NICNAS, to declare a chemical to be a priority existing chemical (PEC). A notice of declaration is published in the *Chemical Gazette*. It provides details of the type of assessment to be undertaken and what information is required to be supplied to NICNAS by applicants (see below).

### Step 4 - Assessment

Once a chemical has been declared a PEC, all importers and manufacturers are required to make an application for assessment within 28 days of the declaration. The application must be accompanied by the information referred to in the declaration notice.

A 'weight of evidence' approach is adopted in the assessment of each chemical, taking into account all available information including published literature, unpublished data, public information, international assessments and the data submitted in response to notices placed in the *Chemical Gazette*.

Full assessments will usually include information on chemical and physical properties, uses, exposure, kinetics and metabolism, effects on experimental animals and in vitro test systems, and human health effects. It will usually include a hazard assessment and classification, a section on risk characterisation, risk management, and recommendations. Full assessments include an occupational, consumer and/or environmental risk assessment.

Preliminary assessments are less detailed, tailored to the particular aspects that are the focus of the assessment. Preliminary assessments do not include a risk assessment.

Sometimes related or similar chemicals are assessed as a group. This flexibility in assessment ensures that NICNAS resources are targeted effectively to priority areas of concern.

As the assessment proceeds, NICNAS may request more information from introducers of the chemical or other specified people through placement of a notice in the *Chemical Gazette* under the provisions of section 58 of the Act (a 'section 58 notice').

## Step 5 - Public Comment

NICNAS is committed to industry and public involvement, and sees consultation with these groups as an essential part of the assessment process.

When the draft report of the assessment is prepared, a copy of the draft report is given to applicants with a notice asking the applicants to notify of any errors in the report. Any errors must be corrected by the Director within 56 days of sending the draft report to applicants.

Corrected draft reports are sent to applicants and anyone who has provided information for the report in response to a section 58 notice ('notifiers'). At the same time, a notice is published in the *Chemical Gazette* describing how copies of the report can be obtained.

Requests for variation to the report may be made by any interested party on the appropriate form within 28 days of publication of the notice. A copy of the decision made by the Director in relation to requests for variation is sent to each applicant and the person who made the request.

There are provisions for appeal to the Administrative Appeals Tribunal (AAT) if a person does not agree with a decision made by the Director regarding a request for a variation to the draft report. A report cannot be finalised or published until any such appeal is finalised.

## Step 6 - Outcomes

The publication of assessment reports are a major outcome of the Existing Chemicals Program. They make available to companies introducing chemicals, to people within the workplace, to other Government agencies, and the public, information on any risks to human health and the environment, and recommendations on ways to control and reduce any risks. This contributes significantly toward making workplaces safer and in protecting human health and the environment.

PEC assessment reports are available from NICNAS. Summary reports are also available, and are published in the *Chemical Gazette*. These are useful in providing a shorter summary of the main findings of a full assessment.

Recommendations from PEC assessment reports can have an important bearing on regulatory action that may be implemented within Australia in the context of protecting the health of workers and the public, and protecting the environment. For instance, they may impact on national occupational exposure standards, hazard classification, health surveillance guidelines, labelling requirements, and the development of codes of practice.

Another major outcome of the assessment process is the contribution that is made to international chemical assessment program. The quality of the assessments produced by NICNAS is accepted as being high on an international level. As a member country of the OECD, Australia participates in the OECD's High Production Volume Existing Chemicals Program. Assessments

produced as part of Australia's Existing Chemicals Program are utilised in this international forum, forming a part of Australia's contribution to the world-wide assessment of existing chemicals. Participation in international assessment programs also assists in the review and development of Australian Assessment methodologies.

For more information on the Existing Chemicals Program and the assessment process please contact the Team Leaders, Existing Chemicals Team, on (02) 8577 8890 or (02) 8577 8880 (phone) or (02) 8577 8888 (fax).

## DATA SOURCES FOR SELECTION CRITERIA

Data for each criterion is sought from the primary reference set. If the information is not found in this set then the secondary reference set is searched.

### DATA SOURCES FOR HEALTH EXPOSURE AND EFFECTS

#### Primary References

##### Databases

TOMES Plus            RTECS, Registry of Toxic Effects of Chemical Substances

                              HSDB, Hazardous Substances Data Bank

                              REPROTEXT - use; reproductive risks; methods of detection and analysis

CCRIS, Chemical Carcinogenesis Research Information System

GENETOX, Genetic Toxicology (EPA)

EXICHEM    OECD database of International Regulatory Action

SciFinder 2000

##### Journals

Major toxicology journals  
Major epidemiology journals

##### Reference Texts

Australian Inventory of Chemical Substances (AICS)  
European Inventory (EINECS)  
US Inventory - compiled under the Toxic Substance Control Act Merck Index  
Patty's Industrial Hygiene and Toxicology  
International Programme on Chemical Safety (IPCS) -Environmental Health Criteria documents  
NTP (National Toxicology Programme)  
ECETOC (European Chemical Industry Ecology and Toxicology Centre)  
ASTDR (US Agency for Toxic Substances and Disease Registry)  
OECD High Production Volume Programme  
International Agency for Research on Cancer (IARC) monographs

Exposure Standards for Atmospheric Contaminants in the Occupational Environment  
[NOHSC:1003(1991)] and  
[NOHSC:3008(1991)]

## Secondary References

### Abstract Databases

- OSHRM - HSELINE  
- NIOSHTIC  
- CISDOC } bibliographic databases containing  
references to workplace health  
and safety literature.
- CCINFO - MSDS, Material Safety Data Sheets  
- Chemical Information  
- Occupational Health and Safety Information
- TOXLINE - CIS, toxicology-related material from the CIS  
abstracts of the ILO  
- TOXBIB, toxicology references from SDILINE, the  
most recent month of MEDLINE
- TOXNET - DART, Developmental and Reproductive Toxicology

## DATA SOURCES FOR ENVIRONMENTAL EXPOSURE AND EFFECTS

### Primary References

#### Factual Databases

- STN - Registry  
- Phytomed
- DIALOG - Chemintell  
- Federal Register Abstracts  
- Heilbron  
- Kirk-Othmer online  
- Polymer online  
- Oceanographic abstracts  
- Pollution abstracts
- ECDIN
- TOXNET - Hazardous Substances Databank  
- Toxic Release Inventory
- OECD - Exichem

## Journals

Aquatic Toxicology  
Archives of Environmental Contamination and Toxicology  
Bulletin of Environmental Contamination and Toxicology  
Chemical Regulation Reporter  
Chemosphere  
Chemistry and Industry  
Chemistry in Britain  
Ecotoxicology and Environmental Safety  
Environmental Pollution Series A  
Environmental Pollution Series B  
Environmental Science and Technology  
Environmental Toxicology and Chemistry  
Federal Register  
Groundwater (US publication)  
Groundwater (BMR publication)

## Reference Texts

Chemyclopedia 90, American Chemical Society, 1989  
Chemical Regulation Reporter  
Handbook of Environmental fate and Exposure Data for Organic  
Chemicals, p H Howard, Lewis publishers, 1989  
Environmental Health Criteria Documents  
International Programme on Chemical Safety (IPCS) -  
Environmental Health Criteria documents  
Environmental properties of chemicals, E Nikunen, R Leinonen and A Kultamaa, Ministry of the  
Environment, Finland, 1990.

## **Secondary References**

### Abstract Databases

ORBIT        – Aqualine  
DIALOG      – Aquatic sciences and fisheries abstracts  
              - Biosis  
  
              – CA Search  
STN        – Enviroline  
              – Compendex  
              - C S Chem

## SOME INTERNET DATA SOURCES

### 1. Australian Chemical Sites

- Chemicals in Australia  
<http://www.vianet.net.au:81/~acted>
- Royal Australian Chemical Institute  
<http://www.chem.csiro.au/vraci/>

### 2. Australian Chemical and Chemical Equipment Companies

1. Hurst Australia Pty Ltd <http://www.hurst.com.au/>
2. Tiger Chemical Company <http://www.tigerchem.com/>
3. MSA Safety Products <http://www.msa-aust.com.au/>
4. Drager safety division <http://www.drager.co.nz/>

### 3. Australian Government Sites

1. EnviroNET Australia  
<http://www.environment.gov.au/epg/environet/environet.html>
2. National Pollutant Inventory  
<http://www.environment.gov.au/epg/np/np/home.html>
3. Environment Protection Group  
<http://environment.gov.au/epg/epg.html>
4. Australian Government Index of Publications (AGIP)

### 5. Legal sites

5. Australian Attorney Generals Dept's Legal Database  
<http://scaleplus.law.gov.au/>
6. Australasian Legal Information Institute (Austlii)  
<http://www.austlii.edu.au/index.html>
7. National Drugs and Poisons Schedule Committee (TGA)  
<http://www.health.gov.au/tga/docs/html/ndpsc/ndpsc.htm>
8. Government Online Directory (Federal Gov)  
<http://gold.directory.gov.au/tmpl/s.html>
9. Air Toxics site (EA)  
<http://www.environment.gov.au/airtoxics>

### 6. Australian OH&S Sites

1. Worksafe Australia <http://www.worksafe.gov.au/>
2. Safety Line (Worksafe WA) <http://www.safetyline.wa.gov.au/>
3. Standards Australia <http://www.standards.com.au/>

4. Safety Institute of Australia Inc. <http://www.sia.org.au/>
5. Industrial Foundation for Accident Protection <http://www.ifap.asn.au/index.asp>
6. ACEL Information <http://www.ancel.net.au/>
7. CCH Occupational Health and Safety Law <http://www.cch.com.au>
8. Australian Safety News bulletin <http://www.safetynews.com/>

## 7. Overseas Chemical Sites

1. The Carcinogenic Potency Project <http://potency.berkeley.edu/cpdb.html>
2. Chemical Economics Handbook (CEH) <http://piglet.sri.com/>
3. The Chemical Industry <http://www.neis.com/>
4. Chemical Industry Institute of Toxicology (CIIT) <http://www.ciit.org/>
5. Cosmetic, Toiletry & Fragrance Assoc <http://www.ctfa.org/>
6. Extension Toxicology Network <http://ace.orst.edu/info/extoxnet/ghindex.html>
7. American Chemical Society  
<http://www.lib.uchicago.edu/~atbrooks/CINF/cinfhome.html>
8. IUPAC <http://chem.qmw.ac.uk/iupac/>
9. Chemical Patents Plus <http://casweb.cas.org/chempatplus/>
10. The Chlorine Institute Inc <http://www.c12.com/>
11. Institute for Scientific Information <http://www.isinet.com/>
12. MDL <http://www.mdli.com/>
13. ChemExpo <http://www.chemexpo.com/>
14. ChemCenter <http://www.chemcenter.org/>
15. ChemFinder Searching  
<http://chemfinder.camsoft.com/>
16. ChemExper <http://www.chemexper.com/main>
17. ECDIN  
<http://ulisse.ei.jrc.it/Ecdin/Ecdin.html>
18. American Assoc. Advancement of Science <http://www.aaas.org/> - anchor505898
19. EurekAlert! <http://www.eurekalert.org/>
20. Science Online <http://www.sciencemag.org/>
21. Science News Online <http://www.sciencenews.org/>
22. SRI International  
<http://piglet.sri.com/Welcome.html>
23. Chemical Marketing Reporter
24. TERA - risk assessment info + useful links <http://www.tera.org/>
25. Toxicology and Pharmacology – useful site <http://www.santel.lu/SANTEL/toxico/>

## 8. Overseas Chemical Companies

1. ICN Pharmaceuticals <http://www.icnpharm.com/>
2. ARCO Chemical Company <http://www.arcochem.com/>
3. National Starch and Chemical Company  
<http://www.nationalstarch.com/>

4. (Large list of companies available from:)  
[http://www.neis.com/chemical\\_companies.html](http://www.neis.com/chemical_companies.html)

### 9. Overseas Government Sites

1. U.S. EPA <http://www.epa.gov/>
2. FIZ Chemie <http://www.fiz-chemie.de/en/>
3. NIST Chemistry WebBook <http://webbook.nist.gov/chemistry/>
4. U.S. Government Printing Office <http://www.access.gpo.gov/>
5. ATSDR <http://www.atsdr.cdc.gov/toxpro2.html>
6. JISHA Home Page (Japan) [http://www.jisha.or.jp/index\\_e.html](http://www.jisha.or.jp/index_e.html)
7. European Commission <http://europa.eu.int/index-en.htm>
8. U.S. FDA <http://www.fda.gov/>
9. European Environment Agency <http://www.eea.eu.int/>
10. NIOSH (US) <http://www.cdc.gov/niosh/homepage.html>
11. OSHA (US) <http://www.osha.gov/comp-links.html>
12. US EPA sector notebook reports (profiles of particular industries)  
<http://es.epa.gov/oeca/sector/index.html>
13. Swedish Chemicals Inspectorate (KEMI) <http://www.kemi.se/>
14. US Dept of Energy Gray Literature site <http://www.osti.gov/graylit/>  
(includes hard to find lit from US EPA)
15. US Chemical Safety and Hazard Investigation Board <http://www.chemsafety.gov/>  
(includes details of chemical accidents)
16. Congressional Research Service -Environmental Protection Policy and Law –  
<http://www.cnire.org/nle/info-9.html>  
(a list of US & international sites) also gov reports if backtrack from this address
17. Canadian gov site <http://www.ec.gc.ca/>
18. European Chemicals Bureau, Ispra Italy <http://ecb.ei.jrc.it/>
19. National Institute of Technology & Evaluation (Japan) <http://www.nite.go.jp/>
20. Drug Information: guide to 9,000 prescription & OTC drugs  
<http://www.nlm.nih.gov/medline/druginformation.html>
21. US EPA industry sector notebooks (profiles of industries)  
<http://es.epa.gov/oeca/sector/index.html>
22. Dutch Environmental Protection Agency (chemicals)  
<http://www.minvrom.nl/minvrom/>
23. Danish Environmental Protection Agency  
<http://www.mst.dk/homepage/>

### 10. Overseas OH&S Sites

1. Vermont SIRI (+good links MSDS) <http://hazard.com/>
2. Environmental Health at Uni of Edinburgh <http://www.med.ed.ac.uk/hew>
3. ACGIH <http://www.acgih.org/>
4. Syracuse Research Corp Environmental Science website <http://esc.syrres.com/>  
(contains a physical properties database and Environmental Fate database)

## 11. International Organisation Sites

1. OECD Chemicals Programme  
<http://www.oecd.org/ehs/chem2.htm>
2. World Health Organisation (WHO) <http://www.who.int/>
3. IPCS <http://www.who.int/pcs/index.htm>
4. IARC <http://www.iarc.fr/>
5. UNEP Chemicals (IRPTC) & WHO – GEENET  
(=IRPTC+GEENET+PRTR+PIC+POPS+IRB) <http://irptc.unep.ch/>
6. International Council of Chemical Associations  
<http://www.cefic.org/activities/hse/mgt/hpvinit.htm>  
(contains list of HPV chemical initiative)

## 10. Useful internet search engines and indexes for chemical and OHS related info

1. Safety Search (Aust and int. gov and ohs sites)  
<http://www.ohs.com.au/search.htm>
2. Cheminfo <http://www.indiana.edu/~cheminfo/>
3. OSHWEB <http://oshweb.me.tut.fi/oshwebdata/>
4. Chemfinder Webserver (Article on it to be found at  
<http://chemfinder.camsoft.com/chimia.html>  
See article by ACS mentioned above under General Chemical Information)
5. Over 15,000 urls of chemistry web sites  
<http://www.chemindustry.com/>
6. Sites on chemical health and safety info incl msds  
<http://pubs.acs.org/hotartcl/chemtech/99/nov/DeAngelo.html>  
(American Chemical Society publication)
7. List of free journals and databases in science & technology  
<http://www.library.ucsb.edu/istl/01-winter/internet.html>
8. Pharmacology & Toxicology sites  
<http://santel.lu/SANTEL/toxico/toxico.html>
9. Chemicals industry sites  
<http://www.competia.com/express/index.html>

**INDUSTRY QUESTIONNAIRE**

**PRIORITY EXISTING CHEMICAL PROGRAM - NICNAS QUESTIONNAIRE**

**CHEMICAL:**

**SYNONYMS:**

**CAS NUMBER:**

**COMPANY:**

**ADDRESS:**

**POST CODE:**

**CONTACT NAME:**

**PHONE NUMBER:**

**EMAIL ADDRESS:**

**FAX:**

1. Do you manufacture the above chemical? Y / N

If yes, please provide an estimate of the quantity you manufacture (tonnes/year)

\_\_\_\_\_

2. Do you import this chemical? Y / N

If yes, please provide an estimate of the quantity you import (tonnes/year)

\_\_\_\_\_

3. Does the chemical have a trade name? Y / N

If yes, please state

\_\_\_\_\_

4. Please estimate the category and number of workers likely to be exposed to the chemical from the manufacturing process or importation onwards. Also, please estimate the maximum duration of exposure for each category.

Category	No. Workers	Hours/day	Days/yr
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

5. What control measures do you have in place for the prevention of worker exposure (eg ventilation systems, protective clothing)?

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

6. Is the chemical released into the environment through manufacturing, use or disposal?  
Y / N

If yes, please identify how it is released (eg in air, water, sewerage, landfill) and the quantity and concentration of each release (eg concentration in the waste stream, together with frequency and length of the discharge period).

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7. Who are the downstream users of the chemical (eg trades, industry categories, consumers) and what do they use the chemical for?

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8. Please provide any unpublished health and environmental test data on the chemical which may assist us.

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Please return to:  
Existing Chemicals Team  
Chemical Safety Group  
NICNAS  
PO Box 58  
Sydney 2001 NSW

or FAX: (02) 8577 8888

Page 2 of 2

**QUESTIONNAIRE COVERING LETTER**

«(address »

Dear «name»

**PRIORITY EXISTING CHEMICALS PROGRAM**

Recently NICNAS sought public nomination of industrial chemicals for consideration as priority existing chemicals (PEC) under the National Industrial Chemicals Notification Scheme (NICNAS). NICNAS provides for closer examination of PECs in order to assess the risk they present to human health and the environment. Nominations have already been screened for their eligibility as industrial chemicals.

Information on exposure will be used in determining if a chemical should be declared as a PEC. Accordingly, we are seeking exposure data from industry to enable proper consideration of nominations.

Attached is a questionnaire on ....., a nominated chemical, which we believe you manufacture/import. This notice is being sent to you in accordance with s48 (6) of the Industrial Chemical Notification and Assessment Act.

It would be appreciated if you would complete the questionnaire to the best of your knowledge. Please fax or mail the form back to the Nominations Officer, Existing Chemicals Team, NICNAS, GPO Box 58, Sydney 2001 by (date). Please supply us with any other information on the chemical which may assist us in determining whether to declare the chemical a PEC.

Thank you for your cooperation.

If you have any questions relating to this request please telephone on (02) 8577 8800, or send a fax on (02) 8577 8888.

Yours sincerely

**SUMMARY OF THE OECD CO-OPERATIVE INVESTIGATION OF  
HIGH PRODUCTION VOLUME CHEMICALS**

Through an OECD Council Decision, Member countries have decided to undertake the investigation of high production volume (HPV) chemicals in a cooperative way. These HPV chemicals include all chemicals reported to be produced or imported at levels greater than 1000 tonnes per year in at least one Member country. The Decision means that they will co-operatively:

- select the chemicals to be investigated;
- collect effects and exposure information from government and industry files;
- complete the agreed upon Screening Information Data Set, (SIDS), by testing;
- make an initial assessment of the potential hazard of each chemical.

The co-operative work is carried out by allocating HPV chemicals over the various Member countries, which would undertake to make the results available to the other Member countries. Member countries agree together on any follow-up actions. When complete dossiers have been prepared the results will be made available worldwide through UN-bodies, with which close cooperation is maintained to this effect.

Collection of information on chemicals is undertaken in a harmonised effort with the European Communities.

After complete SIDS are available an initial assessment of this information will be undertaken and those chemicals of no current concern will be set aside. In addition a number of chemicals may be identified for which further testing or gathering of exposure information is needed to clarify specific issues. Cooperation will also be sought in undertaking this work and in carrying out, for chemicals which are considered to be of concern, more in-depth systematic assessments and risk reduction activities.

The chemical industry fully supports the OECD HPV work because it avoids duplication of efforts among chemical companies and of testing to fulfil requirements of various countries.

The co-operative OECD work will therefore lead to considerable benefits for many parties because:

- environmental protection and human health are improved as existing chemicals are investigated more effectively;
- the financial costs involved in the testing will be substantially reduced as a

result of increased efficiency in undertaking the work;

- the mutual understanding of national procedures for initial assessment of chemicals will be increased, and possibly these procedures can be harmonized;
- the use of animals in testing will be reduced as much duplicative testing will be avoided.

**ATTACHMENT G****CANDIDATE LIST AS OF 1 FEBRUARY 2000**

<b>Chemical</b>	<b>CAS No</b>
Various Azo dyes	
1,3 butadiene	106-99-0
2-hydroxy 2',4,4'-trichlorodiphenyl ether	3380-34-5
Bismuth oxychloride	7787-59-9
t-butyl alcohol	75-65-0
Chlorinated styrenes including octachlorostyrene	29082-74-4
Chromium (VI) compounds	
Lead chromate	7758-97-6
Lead sulphochromate	1344-37-2
Zinc chromate	13530-65-9
N,N Dimethylformamide	68-12-2
Epichlorohydrin	106-89-8
Ethylene oxide	75-21-8
Formaldehyde	50-00-0
Hydroquinone	123-31-9
Isocyanates including:	
2,4 TDI	584-84-9
2,4'-MDI	5873-54-1
2,6-TDI	91-08-7
4,4'-MDI	101-68-8
Polymethylene polyphenylene isocyanate	9016-87-9
Isopropyl alcohol, isopropanol	67-63-0
Mercury compounds	
Methyl ethyl ketone peroxide	1338-23-4
Methyl ethyl ketone	78-93-3
Methyl tert butyl ether	1634-04-4
Methylene chloride	75-09-2

Naphthalene polychlorinated	70776-03-3
Peracetic acid	79-21-0
Phenolphthalein	77-09-8
Polychlorinated biphenyl ethers	
Sodium cyanide	143-33-9
Sodium hydroxide	1310-73-2
Sodium hypochlorite	7681-52-9
Styrene	100-42-5
Tetrachlorobenzyltoluenes including:	
- dichloro [(dichlorophenyl)methyl] methyl benzene (Ugilec 141)	76253-60-6
(chlorophenyl)(chlorotolyl) methane, mixed isomers (Ugilec 121)	No CAS Number
1,1,1,2-tetrafluoroethane	811-97-2
Tetrafluoroethylene	116-14-3
Toluene	108-88-3
Triethanolamine	102-71-6
Xylene – mixed	1330-20-7
o-xylene	95-47-6
p-xylene	106-42-3
m-xylene	108-38-3

## Table 2: Standby Section of Candidate List

Chemicals contained in the standby section of the Candidate List were reviewed in June 2001

Chemical	CAS No
Alkyl phenol ethoxylates including	
Nonyl phenol ethoxylate	9016-45-9
Nonyl phenol ethoxylate blend	63496-57-1
Octylphenoethoxylate	9036-19-5
Carbon disulphide	75-15-0
N-methyl pyrrolidone	872-50-4

Methyl methacrylate	80-62-6
Mobil jet oil:	
1-Naphthalenamine	134-32-7
1-Naphthalenamine, N-phenyl	90-30-2
2-Naphthalenamine	91-59-8
2-Naphthalenamine, N-phenyl	135-88-6
Tricresol phosphate	1330-78-5
Naphthalene	91-20-3
Nickel	7440-02-0
Nickel oxide	1313-99-1
Nickel sulfate	7786-81-4
Phthalates including:	
diethylhexyl phthalate (DEHP)	117-81-7
Diethylphthalate (DEP)	84-66-2
Dibutylphthalate	84-74-2
di isodecyl phthalate (DIDP)	26761-40-0
di isononyl phthalate (DINP)	28553-12-0
butylbenzyl phthalate (BBP)	85-68-7
dimethyl phthalate (DMP)	131-11-3
dicyclohexyl phthalate	84-61-7
di-n-hexyl phthalate	84-75-3
di-n-pentyl phthalate	131-18-0
di-n-propyl phthalate	131-16-8
di(2-ethylhexyl) adipate	103-23-1
1,1,2,2-tetrabromoethane	79-27-6
Triethyl tetramine	112-24-3

## GLOSSARY

### Article

This means an item which is formed to a specific shape, surface or design during manufacture, has an end use function dependent in whole or in part upon its shape or design, and which undergoes no change of chemical composition during end use except as an intrinsic aspect of that end use. Fluids and particles are not considered articles regardless of shape or design.

### Australian Inventory of Chemical Substances

The Australian Inventory of Chemical Substances (the Inventory) is the listing of existing chemical substances established and kept by the former DASETT before the commencement of NICNAS, and kept by the Director after the commencement of NICNAS.

### BCF

Bioconcentration Factor (BCF) is the quotient of the test substance concentration in the test organism to the concentration in the test water at steady state. (OECD Test Guideline 305 A to 305 E or equivalent.)

### BOD<sub>28</sub>

Biochemical Oxygen Demand is a standard measure of the dissolved oxygen consumed by microbial life while assimilating and oxidising the organic matter present in the test container. BOD<sub>28</sub> refers to the Biochemical Oxygen Demand after 28 days at 20°C.

### BOD<sub>5</sub>

Biochemical Oxygen Demand after 5 days at 20°C.

### Chemical entity

Chemical entities include discrete chemical elements, compounds and complexes which may exist as a pure or technical grade or as components in a physical mixture of chemicals. Hence, a mixture itself is not eligible for declaration as a priority existing chemical but the components in the mixture are.

### EC<sub>50</sub>

Effective concentration: the concentration which affects 50% of a test population after a specified exposure time. EC<sub>50</sub> usually relates to effects other than lethality (eg immobilisation, growth rate) in the test organisms.

### LC<sub>50</sub> aquatic

The concentration of a test substance that is lethal to 50% of the test organisms over the total duration of the test (eg 96h LC<sub>50</sub> refers to a 96 hour test).

#### LC<sub>50</sub> inhalation

The concentration of a test substance in air that produces death in 50% of an experimental animal population.

#### LD<sub>50</sub>

A dose of a test substance that produces death in 50% of a population of experimental animals. LD<sub>50</sub>s may be estimated after swallowing, by injection or after application to the skin. It is usually expressed as mg/kg of body weight.

#### LOEC

The lowest concentration that, within the testing period, induces a specified and statistically significant adverse effect on the exposed organisms as compared with the controls (eg 96h LOEC refers to a result from a 96 hour test).

#### New industrial chemical

A new industrial chemical is an industrial chemical that:

- (a) is not listed on the Australian Inventory of Chemical Substances; and
- (b) in the case of a synthetic polymer - is a new synthetic polymer.

Manufacturers and importers of a new industrial chemical must apply for an assessment certificate before introducing the chemical into Australia. A notification statement, including information on health and environmental effects and exposure, must be submitted. The information is assessed by NICNAS, including advice from TGA and EA and an assessment report published.

#### P<sub>ow</sub>

The octanol-water partition coefficient is the equilibrium ratio of the molar concentrations of a chemical in octanol and water, in dilute solution. (OECD Test Guideline 107 or equivalent.)

#### Ready biodegradability

This is the ability of a chemical to break down under stringent test conditions which provide only limited opportunity for biodegradation and acclimatisation to occur. (OECD Test Guideline 301A to 301E or equivalent.)

## UVCB substance

UVCBs are poorly-defined substances which cannot be represented by a complete chemical structure and specific molecular formula. These are typically of unknown or variable composition, complex reaction products or biological materials.