National Standard for Environmental Risk Management of Industrial Chemicals
Discussion Paper

March 2016
© Copyright Commonwealth of Australia, 2016.

National Standard for Environmental Risk Management of Industrial Chemicals Discussion Paper is licensed by the Commonwealth of Australia for use under a Creative Commons Attribution 4.0 International licence with the exception of the Coat of Arms of the Commonwealth of Australia, the logo of the agency responsible for publishing the report, content supplied by third parties, and any images depicting people. For licence conditions see: https://creativecommons.org/licenses/by/4.0/

This report should be attributed as ‘National Standard for Environmental Risk Management of Industrial Chemicals Discussion Paper, Commonwealth of Australia 2016’.

The Commonwealth of Australia has made all reasonable efforts to identify content supplied by third parties using the following format © Copyright, [name of third party].

Disclaimer

The views and opinions expressed in this publication are those of the authors and do not necessarily reflect those of the Australian Government or the Minister for the Environment.

While reasonable efforts have been made to ensure that the contents of this publication are factually correct, the Commonwealth does not accept responsibility for the accuracy or completeness of the contents, and shall not be liable for any loss or damage that may be occasioned directly or indirectly through the use of, or reliance on, the contents of this publication.
Executive summary

In 2006, the Council of Australian Governments (COAG) identified chemicals and plastics as a ‘regulatory hotspot’ and requested that the Productivity Commission review Australia’s system of regulating chemicals and plastics across all sectors. The Productivity Commission’s 2008 *Research Report on Chemicals and Plastics Regulation* highlighted that management of environmental risks from industrial chemicals across jurisdictions was fragmented and inefficient, and less effective than other chemical risk management regimes.

Following the recommendations made in the 2008 Productivity Commission Research Report, the Australian Government and state and territory environment ministers have agreed to establish a National Standard to enable a nationally consistent approach to environmental risk management of industrial chemicals across Australia.

The proposed approach for the National Standard is consistent with the objectives of the Strategic Approach to International Chemicals Management (SAICM) and similar to approaches to environmental risk management of industrial chemicals adopted in other advanced economies. In particular, the National Standard aims to prioritise pollution prevention and minimise chemical risks to the environment while providing a transparent, efficient and effective approach to environmental risk management of industrial chemicals.

Industrial chemicals have a range of uses. They are used in every workplace and household in the country. Industrial chemicals are any chemical that is not used in medicines (human and animal), pesticides, foods and food additives, or chemicals used for therapeutic reasons (as defined under the Commonwealth *Industrial Chemicals (Notification and Assessment) Act 1989* (ICNA Act)). Most industrial chemicals are not harmful to the environment or human health. However, there are some chemicals that can result in significant harm if not managed appropriately.

The National Standard will enable a nationally consistent approach to managing the risks that industrial chemicals may pose to the environment. The objectives of implementing the Standard are to meet the overarching objectives of the Productivity Commission and commitment across jurisdictions and:

- Achieve better protection of the environment through improved management of the environmental risks posed by industrial chemicals.
- Provide a nationally consistent, transparent, predictable and streamlined approach to environmental risk management of industrial chemicals for governments, industry and the community.
- Categorise or classify chemicals based on their level of concern to the environment, taking into consideration environmental risks, inherent hazard characteristics and relevant socio-economic aspects.
- Provide a framework that will allow agencies to regulate industrial chemicals more efficiently and effectively.
- Implement an outcomes-based risk management approach to encourage continued innovation in environmental protection and also enable industry to keep costs related to risk management as low as possible.

The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) aids in the protection of the Australian people and the environment by assessing industrial chemicals to

---

identify any risks they may pose to the environment and human health. The NICNAS is a statutory scheme administered by the Australian Government Department of Health. Consistent with their current role, NICNAS will continue to undertake the role of the risk assessor for the purposes of the National Standard. The risk assessor will undertake environmental risk assessments of industrial chemicals and provide recommendations for appropriate risk management.

With the introduction of the National Standard, the risk management recommendation from the risk assessor will take into consideration National Standard scheduling criteria and environmental risk management measures. The National Standard will outline a national decision on the management of risks that chemicals pose to the environment. This Discussion Paper outlines the design and operation of the National Standard, including scheduling and decision-making under the National Standard.

As outlined in the Decision RIS, the National Standard will include three general categories for industrial chemicals – High, Intermediate and Low Concern. Determining the level of concern that a chemical poses to the environment involves consideration of:

- the harm that the chemical could cause to the environment (hazards),
- the probability the chemical will cause harm from its assessed use and volume of use (risk)

A set of schedules will be indicative of the industrial chemical's level of concern in the environment and will be coupled with proportionate risk management measures to prevent harm to the environment. In the National Standard, the general categories for industrial chemicals will be further broken into a total of eight specified categories known as Schedules:

- Schedule 1 to 2 – Low Concern
- Schedule 3 to 6 – Intermediate Concern
- Schedule 7 to 8 – High Concern

The schedule to which the industrial chemical is to be assigned under the National Standard will be based on its scope of assessment. The scope of assessment is the assessed use, and volume of use. This means that each time NICNAS assesses a chemical against a different scope of assessment, it may be scheduled in a different Schedule under the National Standard. This approach is consistent with a risk-based, proportionate approach. It takes into consideration the likely release of a substance into the environment and takes into account that different uses of substances result in different releases to the environment.

In the context of the number of chemicals used in Australia, it is expected that the majority of chemicals will be scheduled as Low Concern chemicals with very few being considered High Concern.

Under the National Standard, each Schedule will have a set of defined risk management measures. Risk management measures refer to the directive controls that will be relevant to the scheduled chemical under the National Standard. As the Schedules increase, the concern a substance poses to the environment increases. The greater the concern to the environment, the more stringent the risk management measures need to be to prevent harm to the environment.

Risk management measures will be developed in consultation with governments, industry and the community over the coming months. Development of risk management measures needs to take into consideration the need for those requirements to be achievable and implementable by users and ensure they are measurable and enforceable in each jurisdiction.
It is the responsibility of each jurisdiction, whether it is the Australian Government, or states and territories, to determine the appropriate compliance and enforcement activities that are best suited to the jurisdictions’ current regulatory frameworks and resources.

This Discussion Paper provides a foundation for the National Standard, its Schedules, criteria for scheduling industrial chemicals, decision-making and scheduling processes, and risk management conditions. The final Standard will be considered by Australia’s environment ministers, which is anticipated to occur in late 2016.

This paper includes the following information:

- A detailed National Standard including Schedules, criteria for categorisation into Schedules, scheduling and decision-making processes and any other associated aspects
- Principles for the development of risk management measures
- A discussion on outcomes-based regulation and how risk management measures under the National Standard are intended to be outcomes-based
- An outline of the forward process for finalising the National Standard and risk management measures.

Feedback is sought on the current measures being implemented for chemicals in use. This information will be used to more clearly define the risk management measures for inclusion in the draft of the National Standard, which will be released for public consultation later this year.

This paper serves as a basis for engagement with stakeholders business, industry and community representatives on the development of the Standard. The Department of the Environment and the states and territories welcome your input.
Table of contents

1. Purpose .............................................................................................................................................. 1
2. Overview of the Reforms ...................................................................................................................... 2
   2.1 Objectives of the Reforms .............................................................................................................. 2
   2.2 Previous Consultation .................................................................................................................... 3
   2.3 Overview of Timeline for Implementation ..................................................................................... 4
3. Industrial Chemicals .............................................................................................................................. 7
   3.1 Current arrangements for managing industrial chemicals ........................................................... 8
   3.2 Industrial Chemical Reforms ......................................................................................................... 9
4. The National Standard .......................................................................................................................... 12
   4.1 The National Standard roles, functions and general processes .................................................. 14
   4.2 Proposed National Standard scheduling criteria .......................................................................... 19
5. Risk management measures ............................................................................................................... 31
   5.1 Principles for developing risk management measures .................................................................. 31
   5.2 Risk Management Measures under the National Standard ......................................................... 35

Table index

Table 1: Explanation and definitions of roles, functions and processes .................................................. 16
Table 2: Scheduling criteria .................................................................................................................... 20
Table 3: National PBT criteria ............................................................................................................... 50
Table 4: GHS Hazard Statements for classification of long lasting environmental hazards .............. 51
Table 5: GHS Hazard Statements for classification of acute environmental hazards ....................... 52

Figure index

Figure 1: Timeline for the Reforms ......................................................................................................... 4
Figure 2: Examples where industrial chemicals are used in Australia ................................................. 7
Figure 3: Chemical lifecycle and exposure ............................................................................................. 8
Figure 4: The National Standard concern categories and schedules .................................................. 13
Figure 5: Roles, functions and general processes .................................................................................. 15
Figure 6: National Standard scheduling criteria decision trees ............................................................ 27
Figure 7: Hierarchy of Control ............................................................................................................... 34
Appendices

Appendix A – National Standard Scheduling and Decisions Process
Appendix B - Guidance on the Scheduling Criteria
## Acronyms and Abbreviations

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AICS</td>
<td>Australian Inventory of Chemical Substances</td>
</tr>
<tr>
<td>BAF</td>
<td>Bioaccumulation factor</td>
</tr>
<tr>
<td>BCF</td>
<td>Bioconcentration factor</td>
</tr>
<tr>
<td>BMF</td>
<td>Biomagnification factor</td>
</tr>
<tr>
<td>COAG</td>
<td>Council of Australian Governments</td>
</tr>
<tr>
<td>ICNA Act</td>
<td>Commonwealth Industrial Chemicals (Notification and Assessment) Act 1989</td>
</tr>
<tr>
<td>NICNAS</td>
<td>National Industrial Chemicals Notification and Assessment Scheme</td>
</tr>
<tr>
<td>OBPR</td>
<td>Office of Best Practice Regulation</td>
</tr>
<tr>
<td>OECD</td>
<td>Organisation for Economic Cooperation and Development</td>
</tr>
<tr>
<td>PEC</td>
<td>Predicted Environmental Concentration</td>
</tr>
<tr>
<td>PNEC</td>
<td>Predicted No-Effect Concentration</td>
</tr>
<tr>
<td>RIS</td>
<td>Regulation Impact Statement</td>
</tr>
<tr>
<td>SAICM</td>
<td>Strategic Approach to International Chemicals Management</td>
</tr>
</tbody>
</table>

## Glossary of terms

**Advisory Committee**

The Advisory Committee will be comprised of experts from a range of scientific and policy fields related to management of industrial chemicals. The Committee will review risk management recommendations made by the risk assessor for all High Concern chemicals, and Intermediate and Low Concern chemicals for which a review is requested and deemed valid by the Decision Maker. Only the Advisory Committee will be able to review socio-economic considerations related to risk management that are outside of the scheduling criteria.

**Chemical substance**

For the purposes of this paper, a chemical substance describes a:

- chemical element, including a chemical element contained in a mixture, or
- compound, polymer or complex of a chemical element, including such a compound, polymer or complex contained in a mixture, or
- substance of unknown or variable composition, complex reaction products or biological materials (UVCB), or
- naturally-occurring chemical

but does not include:

- an article, or
- a radioactive chemical, or
- a mixture.

The use of ‘Chemical’, ‘Chemical Substance’ or ‘Substance’ in the context of the paper refers to those with industrial uses (see Industrial chemical).

**Concern**

Concern is a measure of the potential consequences of a chemical
Potential consequences of a chemical substance’s use could be positive or negative. They include considerations of the risk defined by the risk assessment, the inherent hazard characteristics of a chemical substance or its degradation products, and any relevant social and economic impacts related to a chemical’s use.

Chemicals are proposed to be categorised in High (schedules 7 and 8), Intermediate (schedules 3 to 6) and Low (schedules 1 and 2) Concern schedules.

**Decision Maker**

The Decision Maker is the person with responsibility for scheduling or listing decisions made under the National Standard and the risk management conditions assigned to an assessed industrial chemical. The Decision Maker is the Minister responsible for the federal Environment portfolio or their delegate.

**The Department**

Australian Government Department of the Environment

**Environment ministers**

Ministers responsible for the environment portfolios in their respective jurisdictions

**Environmental harm**

Environmental harm for the purposes of the National Standard is the consequence of a chemical having an adverse effect on organisms or other aspects of the environment, such as waterways or the ozone layer.

**Exposure (environmental)**

Exposure is the amount of chemical released to the environment and the route by which it is released. Environmental exposure assessments in risk assessments characterise either the extent to which organisms may be exposed to a chemical stressor, or the concentration of a chemical in various environmental compartments (e.g. water, soil, air), which may then have the potential to affect organisms. The three main steps to an exposure assessment are:

- Release estimation
- Consideration of the environmental fate and partitioning behaviour
- Derivation of a predicted environmental concentration.

Additional information on environmental exposure assessment is presented in the Environmental Risk Assessment Guidance Manual for Industrial Chemicals.

**Hazard (environment)**

The environmental hazards of a chemical are those characteristics of a substance, whether they be measured, observed or calculated, that have the potential to cause harm to an organism, or any other aspect of the environment, for example, the ozone layer. A chemical’s properties, and therefore hazards, are characteristics that generally do not change, although new information on them may become available.

**Industrial chemical**

Under the Industrial Chemicals (Notification and Assessment) Act 1989 (Cth), an industrial chemical is any chemical that has an industrial use (s 7(1)). The term ‘industrial use’ is defined to mean a use other than an excluded use (s 7(2)). The term ‘excluded use’ is defined in s 7(2). Therefore, an industrial chemical is any chemical that is not:

- An agricultural chemical or a constituent of an agricultural chemical; or
- A veterinary chemical or a constituent of a veterinary chemical; or

---

<table>
<thead>
<tr>
<th>Jurisdictions</th>
<th>The Australian Government and State and Territory governments</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Standard</td>
<td>The National Standard is the term used to describe the schedules with standard set of risk management measures for industrial chemicals according to a chemical’s level of concern to the environment. The National Standard will outline the standard risk management measures, scheduling criteria, scheduling processes and scheduling decisions.</td>
</tr>
<tr>
<td>Risk (environmental)</td>
<td>Risk is the probability of adverse effects caused under specified circumstances by an agent in an organism, a population, or an ecological system. It is based on the hazard of a chemical and its level of exposure for a specific use and location. Risk is analysed during the risk assessment process and can be represented simplistically as: Risk = function (Hazard × Exposure)</td>
</tr>
<tr>
<td>Risk assessment</td>
<td>Risk assessment is the systematic scientific evaluation of potential adverse effects resulting from exposure to a hazardous agent or situation. Risk assessment requires the integration of both quantitative as well as qualitative scientific information. Risk assessments that inform scheduling decisions under the National Standard will be undertaken by the Risk Assessor under the National Industrial Chemicals Notification and Assessment Scheme (NICNAS).</td>
</tr>
<tr>
<td>Risk assessor</td>
<td>The risk assessor for the purposes of the National Standard is the Australian Government under the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). The risk assessor will complete risk assessments and make risk management recommendations to the National Standard.</td>
</tr>
<tr>
<td>Risk management</td>
<td>Risk management is the process by which policy actions are chosen and implemented to control risks identified in the risk assessment. Risk management involves consideration of the scientific evidence and risk assessment and, if needed, any social or economic factors. For the purposes of the National Standard, risk management involves the scheduling decisions (including decisions on risk management measures), implementation of decisions by jurisdictions, and relevant compliance and enforcement activities.</td>
</tr>
<tr>
<td>Risk management advice</td>
<td>Risk management advice is prepared by the Advisory Committee for consideration by the Decision Maker. Risk management advice outlines the considered risk management recommendation and any socio-economic implications for a scheduling decision.</td>
</tr>
<tr>
<td>Risk management measure</td>
<td>Risk management measures are outcomes-based requirements that apply to chemicals scheduled under the National Standard. They will outline the outcome that must be achieved for chemicals in order to prevent harm to the environment.</td>
</tr>
<tr>
<td>Risk management recommendation</td>
<td>Risk management recommendations are prepared by the risk assessor following scientific evaluations of the risks posed to the environment. Risk management recommendations are included in the risk assessment and take into consideration the scheduling criteria under the National Standard.</td>
</tr>
<tr>
<td>Scope of assessment</td>
<td>The scope of assessment describes the assessed use of an industrial chemical as defined in a NICNAS risk assessment report. This will be the assessed use of the substance and the circumstances in which it is used (volume, concentration in products, etc.)</td>
</tr>
<tr>
<td><strong>Scheduling criteria</strong></td>
<td>Scheduling criteria are developed upfront and outline the hazards and risks taken into consideration by the risk assessor when developing a risk management recommendation.</td>
</tr>
<tr>
<td>------------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Scheduling decision</strong></td>
<td>Scheduling decisions are made by the Decision Maker. They will outline the Schedule to which a chemical is assigned based on its scope of assessment and the risk management measures that are appropriate for the chemical. Scheduling decisions will be enforceable and be publicly available.</td>
</tr>
</tbody>
</table>
1. **Purpose**

The Australian Government and state and territory environment ministers have agreed to establish a National Standard to enable a nationally consistent approach to environmental risk management of industrial chemicals across Australia. The Council of Australian Governments (COAG) agreed to progress these reforms to the chemicals management framework following recommendations made in a 2008 Productivity Commission Research Report on Chemicals and Plastics Regulation.

The primary purpose of this Discussion Paper is to outline the design and operation of the National Standard, including scheduling and decision-making under the National Standard. These proposals align with the policy intent set out in the Decision Regulation Impact Statement, which was considered and agreed by ministers.

This Discussion Paper provides an overview of the Schedules for industrial chemicals and how risk management conditions may be applied for the Schedules under the National Standard. It also informs engagement with business, industry and community representatives on the development of the Standard.

This paper serves as a basis for engagement with stakeholders in a series of targeted forums. Further information on how to provide written feedback and participate in the forums are provided in Section 2.3.

This paper includes the following information:

- A detailed National Standard including Schedules, criteria for categorisation into Schedules, scheduling and decision-making processes and any other associated aspects
- Principles for the development of risk management measures
- A discussion on outcomes-based regulation and how risk management measures under the National Standard are intended to be outcomes-based
- An outline of the forward process for finalising the National Standard and risk management measures.

Matters that are out of scope for this Discussion Paper are:

- Chemicals that are not defined as industrial chemicals
- Risk assessments and associated processes for industrial chemicals (including the reforms to the National Industrial Chemicals Notification and Assessment Scheme)
- Implementation mechanisms in jurisdictions
- Compliance and enforcement activities to be undertaken by jurisdictions
- Assurance, monitoring and reporting activities
2. **Overview of the Reforms**

2.1 **Objectives of the Reforms**

The reforms are being driven by two overarching objectives:

- To achieve better protection of the environment through improved management of the environmental risks posed by industrial chemicals.
- To provide a nationally consistent, transparent, predictable and streamlined approach to environmental risk management of industrial chemicals for governments, industry and the community.

The benefits of establishing a nationally consistent approach include:

- giving Australians greater confidence that potentially harmful, high risk chemicals are subject to appropriate and consistent environmental measures across the nation;
- making it simpler and more cost-effective for industry to fulfil its obligations for managing the environmental implications of chemicals by streamlining current systems, reducing fragmentation, and improving transparency, simplicity and consistency;
- increasing information about, and understanding of chemicals and the environment so that governments, industry and the community can make informed choices about chemicals and help identify areas needing greater attention so that resources can be allocated strategically to deliver improved outcomes; and
- helping Australia meet its international obligations for sound management of chemicals, for example under the Stockholm Convention on Persistent Organic Pollutants.

2.1.1 **A Brief History of the Reforms**

In 2006, the Council of Australian Governments (COAG) identified chemicals and plastics as a ‘regulatory hotspot’ and requested that the Productivity Commission review Australia’s system of regulating chemicals and plastics across all sectors. The Productivity Commission’s 2008 *Research Report on Chemicals and Plastics Regulation*[^1] highlighted that management of environmental risks from industrial chemicals across jurisdictions was fragmented and inefficient, and less effective than other chemical risk management regimes. Other chemical risk management regimes include health, transport and occupational health and safety that have established frameworks for managing the risks associated with industrial chemicals.

The Productivity Commission also recognised that existing national regulatory arrangements for industrial chemicals were not sufficient to provide adequate environmental protection.

In November 2008, COAG agreed to the recommendations made and tasked environment ministers with implementing the reforms relating to environmental risk management. Two Regulation Impact Statements (RIS) - a Consultation RIS, and later, a Decision RIS - were prepared to support the policy. The RISs considered approaches to manage the risks posed to the environment from industrial chemical use. The Consultation RIS was publicly released in 2013. Feedback on the Consultation RIS informed the development of the Decision RIS. The Decision RIS presented options for consideration by environment ministers.

Environment ministers from the Australian Government and all states and territories met in July 2015 and agreed to establish a National Standard for environmental risk management of industrial chemicals.

In accordance with the preferred option outlined in the Decision RIS (Option 2), the Standard will be established under Commonwealth legislation and implemented by each state and territory.

The preferred option in the Decision RIS sets out the parameters for the reforms agreed to by ministers and enabled the Australian Government and state and territory environment agencies to commence work on the detailed design and implementation of the reforms, allowing for consultation and engagement with industry and community representatives as part of this phase. For more detailed information on the context and parameters of the reforms agreed to by ministers, please refer to the Decision RIS\(^4\).

### 2.2 Previous Consultation

The reform of Australia’s approach to environmental risk management of industrial chemicals has been developed in consultation with a wide range of stakeholders including governments, industry and the community, over several years.

#### 2.2.1 Consultation Regulation Impact Statement

A Consultation RIS was released in April 2013. PricewaterhouseCoopers facilitated public consultation. This consultation included public forums, focus groups, one-on-one meetings and written submissions. Feedback from the Consultation RIS resulted in the proposal to develop a National Standard, canvassed in detail in the Decision RIS. Stakeholders agreed that there is benefit in government reform to protect the environment and improve the effectiveness and efficiency of risk management actions for industrial chemicals that have the potential to cause environmental harm.

Feedback received favoured an approach that harmonises implementation of national decisions, is economical and integrated with the proposed changes arising from the review of NICNAS and existing risk management frameworks implemented by states and territories.

#### 2.2.2 Decision Regulation Impact Statement

The Decision RIS was developed in cooperation with states and territories and with ongoing engagement with industry. There is no requirement for formal public consultation for finalisation of a Decision RIS supported by a Consultation RIS.

The Decision RIS outlined the concept of a National Standard for the environmental risk management of industrial chemicals and three options for its implementation. Option 2 was deemed as being the preferred option for implementation and agreed by Environment ministers. Option 2 is a cooperative approach where the National Standard and decision-making powers would be established under Commonwealth legislation, with automatic adoption under jurisdictional legislation for implementation and compliance.

#### 2.2.3 The National Standard Information Paper

The Information Paper on the pathway for design and implementation of the National Standard was released in December 2015. The primary purpose of the information paper was to outline the key steps involved in the implementation of the National Standard, including opportunities for consultation and input into the detailed design and intended operation of the National Standard.

The paper recapped the context of the reforms, including the reform parameters agreed to by Australia’s Environment ministers. The paper also provided an overview of the proposed design and scheduling and decision-making processes under the National Standard, in accordance with the policy intent set out in the Decision RIS.

\(^4\) The Decision RIS is available on the Office of Best Practice Regulation website.
As part of this, the paper invited preliminary feedback from industry and community representatives in response to a small number of questions posed which will help inform subsequent stages of the detailed design of the Standard, noting that further and more substantive consultation will be undertaken during 2016.

Five responses were received on the information paper. Responses were generally supportive of the establishment of the National Standard and noted that more details would be useful to understand the design and processes of the National Standard and the risk management measures. Questions throughout this paper addressed some specific concerns or questions that were raised in submissions on the Information Paper.

2.3 Overview of Timeline for Implementation

This Discussion Paper provides a foundation for the National Standard, its Schedules, criteria for scheduling industrial chemicals, decision-making and scheduling processes, and risk management measures. The final Standard will be considered by Australia’s environment ministers, which is anticipated to occur in late 2016.

The Australian Government and states and territories are actively seeking feedback and input on the design and proposed functioning of the Standard to ensure it is fit-for-purpose and to ensure the objectives of the reforms are met.

Figure 1 provides an overview of the key steps involved in the implementation of the National Standard. The shaded box in the diagram highlights where the Department of the Environment is currently in the process, and summarises the key opportunities for public engagement on the detailed design of the Standard over the coming months.

Figure 1: Timeline for the Reforms
2.3.1 Next Steps

The Department of the Environment and states and territories are seeking feedback on the design and processes of the National Standard, and approach to developing the risk management measures outlined in this Discussion Paper. GHD has been engaged to assist with defining the risk management measures that may be applicable for the chemicals within each schedule.

The content on which GHD, the Department and States and Territories are particularly seeking feedback and engagement has been identified with the light bulb image (as left).

Stakeholders are also invited to:

- Attend a series of public forums that are being held in Adelaide, Perth, Sydney, Melbourne and Brisbane. These forums will provide stakeholders with an opportunity to ask questions or provide feedback on the Discussion Paper.
- Request one-on-one meetings in case stakeholders wanted the opportunity to ask questions or provide feedback in a confidential setting.
- Lodge a written submission on the Discussion Paper. Details for making written submissions are on the Department of the Environment website.

Details for the workshops and registration details are outlined below.

2.3.2 Discussion Paper Workshops

Industry and the community are invited to attend workshops to be held in Adelaide, Perth, Sydney, Melbourne and Brisbane. Representatives from GHD, supported by the Department of the Environment and State and Territory representatives, will attend the workshops.

If you would like to register to attend any of the workshops, please email Chemicals.Management@environment.gov.au.

**Adelaide**
Friday 1 April 2016 10:00 am – 12:00 pm
GHD Adelaide Office
Level 4, 211 Victoria Square Adelaide SA

**Perth**
Monday 4 April 2016 10:00 am – 12:00 pm
GHD Perth Office
999 Hay St, Perth WA

**Sydney**
Thursday 7 April 2016 10:00 am – 12:00 pm
GHD Sydney Office
Level 15, 133 Castlereagh St Sydney NSW
Melbourne
Monday 11 April 2016 10:00 am – 12:00 pm
GHD Melbourne Office
Level 8, 180 Lonsdale St Melbourne VIC

Brisbane
Friday 15 April 2016 10:00 am – 12:00 pm
GHD Brisbane Office
145 Ann St Brisbane QLD
3. **Industrial Chemicals**

Industrial chemicals have a range of uses. They are used in every workplace and household in the country. Industrial chemicals are any chemical that is not used in medicines (human and animal), pesticides, foods and food additives, or chemicals used for therapeutic reasons (as defined under the Commonwealth *Industrial Chemicals (Notification and Assessment) Act* 1989 (ICNA Act)). Industrial chemicals are used in everything from mining and manufacturing processes, to domestic and cosmetic products. The diagram below (Figure 2) outlines industrial chemical uses in Australia.

**Figure 2: Examples where industrial chemicals are used in Australia**

Most industrial chemicals are not harmful to the environment. However, there are some chemicals that can result in significant harm if not managed appropriately. In Australia there are examples where industrial chemicals have contaminated the environment. For example, trichloroethylene contamination concerns in the air, soil and groundwater resulted in the need to evacuate homes in Adelaide’s suburbs.

In general, contamination occurs when chemicals are not properly managed. It may also be the case that people using the chemicals are unaware of their possible adverse effects on the environment.

Removing chemicals from the environment and cleaning contaminated sites can cost hundreds of millions of dollars. For example, in the Botany Bay area, pumping up and remediating groundwater contaminated with chlorinated hydrocarbons has involved building a treatment plant at a cost of $167 million.\(^5\)

Chemicals can enter the environment at any stage during their lifecycle. The lifecycle of a chemical includes all stages of a chemical’s useful life, from manufacture to disposal. The lifecycle is outlined in Figure 3.

---

\(^5\) National Water Commission (2012), *Groundwater Essentials*  
The extensive use and distribution of industrial chemicals in Australia means that chemicals are being released to the environment from many locations across the nation every day. Chemicals are released from industrial, commercial and domestic sources. Without appropriate management, industrial chemicals end up in our waterways, the air we breathe or our drinking water and food we eat. This can be harmful to the environment and everything living in it, including people.

3.1 Current arrangements for managing industrial chemicals

All levels of government share responsibility for managing industrial chemical safety in Australia. The Australian Government is responsible for undertaking national risk assessments of chemicals and setting management standards. States, territories and local governments are responsible for on the ground management of chemicals at locations such as industrial sites, sewage treatment plants and landfills.

The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) aids in the protection of the Australian people and the environment by assessing industrial chemicals to identify any risks they may pose to the environment and human health. The NICNAS is a statutory scheme administered by the Australian Government Department of Health.

Following risk assessment, recommendations may be made as to the most appropriate way to manage chemicals. These recommendations are made to government agencies responsible for managing the risks. Risk management agencies (the risk managers) are responsible for reviewing and implementing management recommendations. In reviewing recommendations and choosing options for risk management, risk managers consider the scientific evidence, as well as engineering, economic, social and political factors. Risk managers are also responsible for compliance and enforcement activities.
3.1.1 Problems with the current arrangements

The current Australian framework for managing risks to the environment from industrial chemicals is fragmented and inconsistent. The framework is generally ineffective for consistently managing hazardous chemicals. It is inefficient for businesses, difficult for the community to engage with and duplicative.

Under the current arrangements, each jurisdiction implements risk management recommendations for the environment in different ways. Some jurisdictions, for different reasons, may also choose not to manage certain chemicals. In other jurisdictions, risk management recommendations are only partially addressed. When jurisdictions decide to manage a chemical, there are often differences in their approaches. This inconsistency can be confusing and costly for businesses that operate across borders. These businesses have to abide by different rules and regulations in each jurisdiction.

The current system may also not be able to effectively protect the environment into the future. Up to 45 industrial chemicals that are newly introduced into Australia each year may have the potential to harm the environment if they are not properly managed. There are also approximately 38 000 industrial chemicals on the Australian Inventory of Chemical Substances (AICS) that are allowed to be used in Australia and have not been assessed for their risks to the environment or human health. NICNAS is leading work to review chemicals that are on the AICS. It is expected that a portion of these chemicals may require some level of management to protect the environment.

For more information on these issues, please refer to the Decision RIS.

3.2 Industrial Chemical Reforms

There are several reforms to the Australian industrial chemicals framework in progress. These reforms stem from recommendations made in the 2008 Productivity Commission Research Report on Chemicals and Plastics Regulation.

The two agreed reforms being undertaken to the industrial chemicals framework are:

- The Council of Australian Governments (COAG) Chemical Reforms to establish a National Standard for Environmental Risk Management of Industrial Chemicals (see The Department of the Environment website)
- The reforms to the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) (see the NICNAS website)

These address separate recommendations made in the 2008 Productivity Commission report and different parts of the Australian industrial chemicals framework. The National Standard and the reforms to NICNAS address risk management approaches and risk assessment processes, respectively.

The Australian Government Department of Industry, Innovation and Science, on behalf of COAG, has also appointed a consultant to review Commonwealth chemicals assessment functions. This work includes analysing the costs and benefits of structural change to Commonwealth assessment functions while taking into consideration ongoing work and agreed reforms. Once completed, the final report on options will guide future decision-making. Further information is available on the Department of Industry, Innovation and Science website.
What was the decision made in terms of establishing the National Standard for environmental risk management of industrial chemicals?

In November 2008, COAG agreed to the recommendations made in the 2008 Productivity Commission research report and tasked environment ministers with implementing the reforms relating to environmental risk management.

Environment Ministers from the Australian Government and all states and territories met in July 2015 and have agreed to establish the National Standard for Environmental Risk Management of Industrial Chemicals. In accordance with the preferred option outlined in the Decision RIS (Option 2), the Standard will be established under Commonwealth legislation and implemented by each state and territory. Full implementation of the National Standard is expected by 2018.

The COAG Decision RIS that supported the decision of all Australian governments is available on the Office of Best Practice Regulation (OBPR) website.

What was the decision in relation to reforming the National Industrial Chemicals Notification and Assessment Scheme?

As part of the 2015–16 Budget, the Australian Government Assistant Minister for Health announced changes to the National Industrial Chemical Notification and Assessment Scheme (NICNAS) on 26 May 2015. The changes will introduce a more proportionate risk-based framework and make greater use of information from overseas regulatory agencies.

The reforms are intended to maintain current health and environmental protections, while addressing industry concerns regarding regulatory costs and delays associated with pre-market assessments for new chemicals. The primary objective of the NICNAS reforms is to focus regulatory effort for the assessment of industrial chemicals on higher risk chemicals.

A RIS analysed options for reform of the regulations and recommended a more targeted combination of pre- and post-market regulatory controls for new chemicals, and post-market regulatory controls for existing chemicals, with the assessment requirements informed by hazard and exposure. The changes are anticipated to streamline the process for introducing new lower-risk chemicals, without compromising current health and environmental protections.

The RIS that supported the decision of the Australian Government for these reforms is also available on the OBPR website.

What is different about the aspect of the chemicals framework the National Standard is addressing and the work undertaken by NICNAS?

NICNAS and the National Standard for environmental risk management of industrial chemicals address different parts of the Australian chemicals framework – risk assessment (NICNAS) and risk management (National Standard).

Risk assessment is the systematic scientific evaluation of potential adverse effects resulting from exposure to a hazardous agent or situation. Risk assessment requires the integration of both quantitative as well as qualitative scientific information. Risk assessment of industrial chemicals is currently undertaken according to the Commonwealth Industrial Chemicals (Notification and Assessment) Act 1989 (ICNA Act). The reforms to NICNAS will introduce a more proportionate risk-based framework for risk assessment and make greater use of information from overseas regulatory agencies in assessments.

Risk management refers to the process by which policy actions are chosen to control hazards identified in the risk assessment stage. Risk management takes into consideration the scientific evidence and risk estimates – as well as engineering, economic, social and political factors – in
evaluating options for risk management measures and choosing one of those options. Currently there are no nationally agreed risk management measures for industrial chemicals. The National Standard aims to address this gap. For the purposes of the National Standard, these options aim to be developed up front and, where possible, standardised to ensure a transparent, predictable, national approach to risk management.

**How will the National Standard and the risk assessments undertaken by NiCNAS align?**

How will the reforms to NiCNAS affect the National Standard reforms?

A national environmental risk assessment is currently completed by NiCNAS according to the ICNA Act. Consistent with their current role, NiCNAS will continue to undertake environmental risk assessments of industrial chemicals and provide recommendations for appropriate risk management. With the introduction of the National Standard, the risk management recommendation will now take into consideration National Standard scheduling criteria and environmental risk management measures. Chemicals that do not have a risk management recommendation stemming from a risk assessment completed by NiCNAS will not have a formal scheduling decision under the National Standard.

While the processes for risk assessment and risk management are standalone, the National Standard is being developed to ensure the risk assessment and risk management processes are streamlined to limit time taken for scheduling under the National Standard. It is proposed that the risk management recommendation consultation periods are integrated with the consultation periods in place/proposed for NiCNAS risk assessments.

The National Standard will also have scheduling criteria that are developed up front. These criteria have been developed in consideration of the information that is proposed to be available to undertake a risk assessment and consideration of the expert advice that can be provided by risk assessors. The risk assessors will use the scheduling criteria and scientific assessment in the formulation of a risk management recommendation. The scheduling criteria are also considered internationally to be information needed to undertake a best-practice assessment of environmental risk and are consistent with the information requirements and assessment processes outlined in the [Environmental Risk Assessment Guidance Manual for industrial chemicals](#).

The Australian Government Department of the Environment is working closely with NiCNAS to ensure that industrial chemicals of environmental concern are assessed so that national risk management recommendations can be made for the purposes of the National Standard.

It should also be noted that the risk assessment will only make recommendations for environmental risk management. A Decision Maker will be responsible for final scheduling decisions for industrial chemicals. More information is provided in the National Standard Scheduling and Decision Making Process (Appendix A) and in Section 4.
4. The National Standard

This section outlines the proposed design of the National Standard and associated processes, consistent with the information and policy intent set out in the Decision RIS agreed to by environment ministers. Initial feedback was sought in the National Standard Information Paper and suggested changes by respondents have been incorporated into the design.

The National Standard will enable a nationally consistent approach to managing the risks that industrial chemicals may pose to the environment. The National Standard will address the problems with the current framework to manage chemical risks. The National Standard will outline a national decision on the management of risks that chemicals pose to the environment.

The objectives of implementing the Standard are to:

- Meet the overarching objectives of the reforms
  - achieve better protection of the environment through improved management of the environmental risks posed by industrial chemicals.
  - provide a nationally consistent, transparent, predictable and streamlined approach to environmental risk management of industrial chemicals for governments, industry and the community.
- Categorise or classify chemicals based on their level of concern to the environment, taking into consideration environmental risks, inherent hazard characteristics and relevant socio-economic aspects.
- Provide a framework that will allow agencies to regulate industrial chemicals more efficiently and effectively.
- Implement an outcomes-based risk management approach to encourage continued innovation in environmental protection and also enable industry to keep costs related to risk management as low as possible.

As outlined in the Decision RIS, the National Standard will include three general categories for industrial chemicals – High, Intermediate and Low Concern. It is proposed that these general categories are further broken into a total of eight specified categories known as Schedules as in Figure 4 below.

Substances of lowest concern to the environment will be in Schedule 1 and substances of highest concern to the environment will be in Schedule 8.
Figure 4: The National Standard concern categories and schedules

What are the design features of the National Standard?

As outlined in the Decision RIS, some of the design features of the National Standard include:

- Uniformity across Australia of environmental risk management outcomes for industrial chemicals for ease of implementation and increased environmental protection
- Upfront development of the Standard to ensure greater transparency, predictability, certainty and consistency for industry and the community
- Alignment with international standards where appropriate, to inform the development of the National Standard
- A streamlined mechanism to address the increased number of existing chemicals that are likely to undergo risk assessments
- Alignment of processes for environmental scheduling to integrate with existing timeframes for risk assessments, where possible, or follows seamlessly without imposing lengthy time burdens on industry
- An outcomes-based risk management approach to encourage continued innovation in environmental protection and also enable industry to keep costs related to risk management as low as possible
- Ensuring that scheduled decisions are easily accessible and searchable to enable businesses to make informed decisions
- Enabling the accelerated scheduling of low concern chemicals to ensure that an expert body and Decisions Maker’s time is used more efficiently, focusing on chemicals of higher concern to the environment
Why does Australia need its own management Standard and why can’t we just adopt risk management approaches from other countries?

In October 2014, COAG agreed to explore adopting, as a general principle, trusted international standards or risk assessment processes for systems, services and products, unless it can be demonstrated that there is good reason not to. The Decision RIS outlined the reasons for establishing a National Standard for environmental risk management of industrial chemicals.

Risk management of chemicals relies on a risk assessment of a chemical being completed in the Australian context. Simply adopting international risk management determinations, without consideration of Australian uses and exposures or the Australian risk management framework is not likely to result in the required level of mitigation. Significant constraints and risks are associated with acceptance of overseas risk management determinations. Risk assessment recommendations specific for the Australian context will inform the risk management decisions, which will also be tailored to ensure states and territories and businesses have the capability and infrastructure available for appropriate protection of the environment.

How does the National Standard approach align internationally?

The proposed approach for the National Standard is consistent with the objectives of the Strategic Approach to International Chemicals Management (SAICM) and similar to approaches to environmental risk management of industrial chemicals adopted in other advanced economies. In particular, the National Standard aims to prioritise pollution prevention and minimise chemical risks to the environment while providing a transparent, efficient and effective approach to environmental risk management of industrial chemicals.

Many advanced economies have worked towards achieving the objectives of SAICM. Canada, the European Union, the United States of America and Japan have approaches to environmental risk management of industrial chemicals that mirror the objectives of SAICM and some, along with Australia, contribute to the United Nations Environment Programme (UNEP) and SAICM.

4.1 The National Standard roles, functions and general processes

Figure 5 and Table 1 outline the overarching roles and functions under the National Standard. The figure and table detail:

- the roles and responsibilities of the Risk Assessor, the Advisory Committee and the Decision Maker
- the development of risk management recommendations and risk management advice to inform decision-making
- the processes for consultation and review of risk management recommendation and published decisions
- matters within scope of this paper and supporting matters outside the scope of this paper.

More details on the processes under the National Standard are presented in Appendix A.
Figure 5: Roles, functions and general processes

New or Existing Industrial Chemical

Risk Assessment Processes

RISK ASSESSOR

Risk Assessment
Risk Management Recommendation

Consultation 1

Recommended High Concern Chemicals (Schedules 7 and 8)

Recommended Low and Intermediate Concern Chemicals (Schedules 1 to 6)

Consultation 2

Was a review of recommendation requested during Consultation 1 and deemed valid by the DECISION MAKER?

YES

ADVISORY COMMITTEE

Risk Management Advice

DECISION MAKER

Scheduling Decision

Schedule 1 Schedule 2 Schedule 3 Schedule 4 Schedule 5 Schedule 6 Schedule 7 Schedule 8

Scheduling Decision published

Implementation by Jurisdictions

Note: Yellow shading highlights aspects that are within scope of the Discussion Paper
Table 1: Explanation and definitions of roles, functions and processes

More details on the processes are provided in Appendix A.

Bold text in the table indicates definitions are presented elsewhere in the document.

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>The National Standard</td>
<td>The National Standard will outline scheduling criteria, scheduling processes and scheduling decisions for industrial chemicals for which a risk assessment has been completed by the Risk Assessor. The National Standard includes a set of schedules that indicate an industrial chemical’s level of concern pertaining to the environment and outline proportionate risk management measures to prevent harm to the environment.</td>
</tr>
</tbody>
</table>

**Designated Persons**

The Risk Assessor for the purpose of the National Standard includes those people working for the Australian Government that undertake scientific evaluations of the risk an industrial chemical poses to the environment. These scientific evaluations take into consideration the chemical’s hazards and likelihood of exposure to the environment in accordance with the Industrial Chemicals (Notification and Assessment) Act 1989 under the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). The Risk Assessor prepares risk assessments, and risk management recommendations that will take into consideration of the National Standard scheduling criteria.

The role of the risk assessor is outside the scope of this paper and the development of the National Standard.

The Advisory Committee will be comprised of experts from a range of scientific and policy fields related to management of industrial chemicals. The Advisory Committee will review risk management recommendations for all chemicals identified by the Risk Assessor to meet the criteria for High Concern chemicals, and any other chemicals assessed by the Risk Assessor for which a valid request for review is received. The Advisory Committee may choose to consult with government agencies, industry and the broader community in order to inform their review of the recommendation. The Advisory Committee may take into consideration the scientific analysis presented in the risk assessment and any socio-economic considerations that may affect how a chemical is scheduled or managed. Only the Advisory Committee will review chemicals in terms of socio-economic impacts. The Advisory Committee will prepare risk.
<table>
<thead>
<tr>
<th>DECISION MAKER</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Decision Maker will be the Minister responsible for the federal environment portfolio or their delegate. They will make the final <strong>scheduling decision</strong> for industrial chemicals under the National Standard based on their scope of assessment. The Decision Maker must consider the <strong>risk management recommendation</strong> made by the <strong>Risk Assessor</strong> and, if any, the <strong>risk management advice</strong> prepared by the <strong>Advisory Committee</strong>. The Decision Maker may ask the <strong>Advisory Committee</strong> to review any recommendation or advice received. The Decision Maker will also be responsible for ensuring requests for reviews of risk management recommendations are valid.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Recommendation, Advice and Decision Documentation</th>
</tr>
</thead>
</table>
| Risk assessments are completed by the **Risk Assessor**. A risk assessment is a systematic scientific evaluation of potential adverse effects resulting from exposure to a hazardous agent or situation. It takes into consideration hazard information on a chemical as well as the routes and likelihood of exposure of the chemical to the environment. Risk assessments require the integration of both quantitative and qualitative scientific information. The risk assessment does not take into consideration socio-economic impacts of a chemical’s use.  

The risk assessment includes the formulation of a risk management recommendation. Following implementation of the National Standard, the risk management recommendation will be made with consideration of the **National Standard scheduling criteria**. The risk management recommendation will include recommendation of an appropriate Schedule and appropriate risk management measures. **Consultation** is undertaken when finalising risk assessments and risk management recommendations.  

The risk assessment and associated processes are outside the scope of this paper. |

<table>
<thead>
<tr>
<th>Risk Management Advice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk management advice is prepared by the <strong>Advisory Committee</strong> to provide the <strong>Decision Maker</strong> with the information needed to make a <strong>scheduling decision</strong>. The Risk management advice includes consideration of the <strong>risk management recommendation</strong> that was made by the <strong>Risk Assessor</strong>, as well as any socio-economic implication for a chemical’s use. The risk management advice will include scheduling and risk management measure recommendations.</td>
</tr>
</tbody>
</table>
### Scheduling Decision

The scheduling decision made by the **Decision Maker** outlines the schedule to which the chemical will be assigned based on its scope of assessment and the risk management measures that will be required. Scheduling decisions will be reviewable.

### Published Decision

After the scheduling decision is made enforceable, the decision will be made publicly available. This may take the form of an online database searchable, for example, by chemical identifier, schedule, date of decision, etc. Published decisions will be disseminated to all jurisdictions for their information.

### Data

The National Standard scheduling criteria will be used by the **Risk Assessor** in the formulation of a **risk management recommendation** for inclusion in the **risk assessment**. The scheduling criteria outline the hazard and risk information that will inform the assignment of a chemical to a schedule. The scheduling criteria will be publicly available.

### Processes

Risk assessment processes for new and existing industrial chemicals are undertaken in accordance with the *Industrial Chemicals (Notification and Assessment) Act* 1989. The risk assessment processes are outside the scope of this paper.

Consultation 1 is undertaken during the finalisation of the risk assessment and risk management recommendation. Consultation 1 will be undertaken in accordance with the processes outlined in the *Industrial Chemicals (Notification and Assessment) Act* 1989. Consultation in relation to the scientific analysis in the risk assessment should be referred to the **Risk Assessor**. Following finalisation of the science in the risk assessment, a request for review of the risk management recommendation may be made at this stage in accordance with criteria for requesting a review.

Requests for review of risk management recommendations may be made during Consultation 1. Requests for review may be made on scientific, societal or economic grounds in accordance with designated criteria. The **Decision Maker** will be responsible for determining if the request to review the risk management recommendation is valid. If valid, the risk management recommendation will be reviewed by the **Advisory Committee**.
Consultation 2 may be undertaken by the Advisory Committee at any time during the review of the risk management recommendation or a published decision. The Advisory Committee may choose to consult government agencies, industry or the broader community in order to inform their review.

Following publication of a decision, jurisdictions will be responsible for implementing the decisions in accordance with their legislation. Implementation of scheduling decisions is outside the scope of this paper.

4.2 Proposed National Standard scheduling criteria

Consistent with a risk-based, proportionate approach, chemicals will be scheduled under the Standard based on their concern to the environment for a particular scope of assessment (assessed use and volume of use). Determining the level of concern that a chemical poses to the environment involves consideration of:

- the harm that the chemical could cause to the environment (hazards)
- the probability the chemical will cause harm from its assessed use and volume of use (risk).

The scheduling criteria were developed for transparency and ease of categorisation of chemicals under the National Standard. They were developed based on information considered by and available to environmental risk assessors working under the NICNAS.

The criteria are based on internationally accepted information requirements for managing the risk chemicals pose to the environment. Broadly speaking, the criteria are based on a determination of the persistence, bioaccumulation and toxicity potential of the chemicals and also incorporate other characteristics for chemicals that are known to cause harm to the environment.

Who is intended to use the scheduling criteria?

The scheduling criteria are primarily intended to be used by the risk assessor undertaking an environmental risk assessment. However, they are being developed upfront and published publicly to assist businesses and the community in making informed decisions about the chemicals they use.

Developing the criteria up front provides clarity for stakeholders on the processes and potential outcomes of chemicals being scheduled under the National Standard.

Will the changes to NICNAS affect the scheduling criteria?

No. The scheduling criteria have been developed with the changes to NICNAS risk assessment processes and information requirements in mind. The risk assessment will identify areas of concern that need to be taken into consideration while assessing the risk. Risk assessors will use expert judgement and the scheduling criteria to make appropriate risk management recommendations.
How is the Globally Harmonised System for Classification and Labelling of Chemicals (GHS) integrated into the National Standard?

GHS classifications are used as hazard thresholds in both environmental risk assessments and preparation of risk management recommendations for the National Standard. For chemicals with GHS classifications, these classifications can be used in the for hazard categorisation.

Risk management recommendations are based on a chemical’s level of concern to the environment which is a risk-based, proportionate approach that takes into consideration a chemical’s hazards and exposure to the environment. This is to ensure that regulatory effort is proportionate to the risk a chemical poses to the environment, not just the hazards identified in the GHS classification. It should be noted, however, that product labelling is not considered at this stage of the reforms process but may be considered more broadly following implementation of the National Standard.

4.2.1 Proposed scheduling criteria

Table 2 below outlines the characteristics of substances in each Schedule. These characteristics are supported by the Decision Trees in Section 4.2.2 below.

**Table 2: Scheduling criteria**

<table>
<thead>
<tr>
<th>Concern Category</th>
<th>Schedule</th>
<th>Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Concern</td>
<td><strong>Schedule 8</strong></td>
<td>Prohibited</td>
</tr>
<tr>
<td></td>
<td>Substances:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• are persistent, bioaccumulative and toxic (PBT) OR</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• have degradation products that are PBT OR</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• are other substances of significant environmental concern</td>
<td></td>
</tr>
</tbody>
</table>

Note: The Advisory Committee will review all substances categorised into Schedule 8. Substances that have viable alternatives, do not have an essential use in Australia and do not present a net benefit to the community will be prohibited substances under the National Standard. The Advisory Committee will ensure this decision is not in contradiction to other laws in Australia.

<table>
<thead>
<tr>
<th>High Concern</th>
<th><strong>Schedule 7</strong></th>
<th>Restricted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Substances:</td>
<td>• are persistent, bioaccumulative and toxic (PBT) OR</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• have degradation products that are PBT OR</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• are other substances of significant environmental concern</td>
<td></td>
</tr>
</tbody>
</table>

Note: The Advisory Committee will review all substances categorised into Schedule 7. These substances will need to have an essential use in Australia, have no viable alternatives and have a net benefit to the community from their use. In their recommendation, the Advisory Committee will consider detailing all circumstances under which the substance may be used in Australia.

<table>
<thead>
<tr>
<th>Intermediate Concern</th>
<th><strong>Schedule 6</strong></th>
<th>Substances</th>
</tr>
</thead>
<tbody>
<tr>
<td>Substances must not meet the criteria for Schedule 7 or Schedule 8.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concern Category</td>
<td>Schedule</td>
<td>Characteristics</td>
</tr>
<tr>
<td>------------------</td>
<td>----------</td>
<td>-----------------</td>
</tr>
<tr>
<td>with a potentially significant and long lasting impact on the environment</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Substances:**
- are at least harmful to any aspect of the environment

**AND**
- substances are predicted to cause harm to any aspect of the environment following exposure to the environment resulting from the defined scope of assessment\(^6\). This includes:
  - the predicted concentration in the environment that is greater than or equal to the concentration predicted to cause harm to the environment for the specified use and volume - $\text{PEC} \geq \text{PNEC}$
  - the substance is very toxic to the environment with long lasting effects

**AND**
- are perfluorinated AND/OR
- are persistent OR
- are bioaccumulative

<table>
<thead>
<tr>
<th>Intermediate Concern</th>
<th>Schedule 5</th>
<th>Substances must not meet the criteria for Schedule 6 to Schedule 8.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Substances with a potentially significant impact on the environment</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Substances:**
- are at least harmful to any aspect of the environment

**AND**
- are predicted to cause harm to any aspect of the environment following exposure to the environment resulting from the defined scope of assessment. This includes:
  - the predicted concentration in the environment that is greater than or equal to the concentration predicted to cause harm to the environment for the specified use and volume - $\text{PEC} \geq \text{PNEC}$ AND/OR
  - the substance is very toxic to the environment

\(^6\) Note: The scope of assessment will be as defined by NICNAS. It will be the volume of substance introduced, the use of the substance, and the emission of the substance based on reviewed and agreed emission scenarios (OECD or industry developed scenarios). Additional controls noted by introducers in their notification for assessment will not be considered for categorisation of the chemical, but may be taken into consideration in applying risk management conditions.
<table>
<thead>
<tr>
<th>Concern Category</th>
<th>Schedule</th>
<th>Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>with long lasting effects</td>
</tr>
</tbody>
</table>

**OR Substances:**
- are at least harmful to any aspect of the environment

**AND**
- are perfluorinated AND/OR
- are persistent OR
- are bioaccumulative

**AND**
- are not very toxic with long lasting effects AND
- are predicted to result in a concentration in the environment that is less than the concentration predicted to cause harm to the environment for the specified use and volume – that is PEC < PNEC

**OR Substances:**
- are bioaccumulative

**AND**
- are perfluorinated AND/OR
- are persistent OR
- are endocrine disruptors or potential endocrine disruptors

<table>
<thead>
<tr>
<th>Intermediate Concern</th>
<th>Schedule 4</th>
<th>Substances must not meet the criteria for Schedule 5 to Schedule 8.</th>
</tr>
</thead>
</table>
|                      | Hazardous, higher risk substances | **Substances:**
- are at least harmful to any aspect of the environment

**AND**
- are not predicted to harm the environment any aspect of the environment following exposure to the environment resulting from the defined scope of assessment, but may cause harm if the circumstances change. This includes:
  - the predicted concentration in the environment that is less than the concentration predicted to cause harm to the
<table>
<thead>
<tr>
<th>Concern Category</th>
<th>Schedule</th>
<th>Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>environment for the specified use and volume – PEC/PNEC &lt; 1; AND</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- the predicted concentration in the environment that is greater than 10% of the concentration predicted to cause harm to the environment for the specified use and volume – PEC/PNEC ≥ 0.1; AND/OR</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- are toxic to the environment with long lasting effects</td>
</tr>
<tr>
<td></td>
<td></td>
<td>OR Substances:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- are bioaccumulative</td>
</tr>
<tr>
<td></td>
<td></td>
<td>OR Substances:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- are perfluorinated</td>
</tr>
<tr>
<td></td>
<td></td>
<td>OR Substances:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- are endocrine disruptors or potential endocrine disruptors</td>
</tr>
<tr>
<td>Intermediate</td>
<td>Schedule 3</td>
<td>Substances must not meet the criteria for Schedule 4 to Schedule 8.</td>
</tr>
<tr>
<td></td>
<td>Hazardous, moderate risk substances</td>
<td>Substances:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- are at least harmful to any aspect of the environment</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AND</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- are not predicted to harm the environment any aspect of the environment following exposure to the environment resulting from the defined scope of assessment, but may cause harm if the circumstances change significantly. This includes:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- the predicted concentration in the environment that is less than 10% of the concentration predicted to cause harm to the environment for the specified use and volume – PEC/PNEC &lt; 0.1; AND</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- the predicted concentration in the environment that is greater than or equal to</td>
</tr>
<tr>
<td>Concern Category</td>
<td>Schedule</td>
<td>Characteristics</td>
</tr>
<tr>
<td>------------------</td>
<td>----------</td>
<td>-----------------</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1% of the concentration predicted to cause harm to the environment for the specified use and volume – PEC/PNEC $\geq 0.01$; AND/OR - are harmful to the environment with long-lasting effects OR Substances: • have other characteristics that may result in adverse short or long term effects on the environment&lt;sup&gt;7&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

| Low Concern      | **Schedule 2** Hazardous, low risk substances | Substances must not meet the criteria for Schedule 3 to Schedule 8. **Substances:** • are at least harmful to any aspect of the environment **AND** • are not predicted to harm the environment any aspect of the environment following exposure to the environment resulting from the defined scope of assessment, and are not likely to harm the environment if the circumstances change significantly. This includes: - the predicted concentration in the environment that is less than 1% of the concentration predicted to cause harm to the environment for the specified use and volume – PEC/PNEC $< 0.01$ |

| Low Concern      | **Schedule 1** Not hazardous and low hazard substances | Substances that are low hazard or not hazardous to the environment and do not meet the criteria for Schedule 2 to Schedule 8. |

<sup>7</sup> e.g. nanomaterials, persistent substances that may have adverse effects on the environment as they accumulate.
**How many chemicals will be in each Schedule?**

In the context of the number of chemicals used in Australia, it is expected that the majority of chemicals will be scheduled as Low Concern chemicals with very few being considered High Concern. Exact numbers of chemicals in each schedule will depend on the assessed risk of a chemical. Also, the scheduling criteria are still in draft form and won't be finalised until environment ministers have considered the final National Standard.

**Will chemicals of low concern to the environment be scheduled?**

Although Low Concern chemicals will require minimal (or no) risk management, it is intended that they will still be scheduled under the National Standard. This will improve transparency and allow businesses and the community to identify chemicals that have been determined to be Low Concern. This information will support businesses and the community in making informed decisions about the chemicals and products they use and buy.

It is noted that the reforms to NICNAS will result in very few new industrial chemicals of low concern having a risk assessment completed. Therefore, they would not have a risk management recommendation for consideration under the National Standard. However, the Low Concern categories may be populated following the completion of risk assessments for existing chemicals.

**How can I get a new Low Concern chemical on the National Standard?**

There are some circumstances under which introducers of new industrial chemicals may wish to have their chemical scheduled under the National Standard where a risk assessment may not be completed without a request being made (chemicals that are categorised as ‘Exempt’ or ‘Reported’ according to the proposed NICNAS criteria for assessment).

For a chemical to be scheduled, it will need a completed environmental risk assessment and risk management recommendation from the risk assessor. NICNAS are proposing to assess any chemical if requested by the introducer for a fee. The resulting risk management recommendation made in the risk assessment will allow scheduling of any chemical under the National Standard.
4.2.2 Scheduling Criteria Decision Trees

Below are two decision trees to support categorisation of a substance based on its scope of assessment into one of eight Schedules under the National Standard. The categorisation will be supported by an environmental risk assessment completed by the risk assessor. Guidance on responding to questions in the decision trees has been included in Appendix B.

Characterisation of High Concern chemicals and chemicals in Schedule 1 is based on their identified hazards. Schedules 2 to 6 include consideration of a chemical’s likely exposure and risk through normal use. The categorisation of these schedules will be based on the scope of assessment presented to NICNAS.

Risks to the environment for High Concern chemicals are generally not quantifiable and can be considered unknown because of their inherent bioaccumulative and persistent characteristics. Therefore, if a chemical is identified PBT or is otherwise of significant environmental concern, it will automatically be High Concern.

How is a substance categorised into a schedule?

Risk management recommendations are made based the scheduling criteria outlined above and answering the questions posed in the two flowcharts. Guidance on answering the questions is provided in Appendix B.

There are two flowcharts to support categorisation for the purposes of preparing a risk management recommendation (Figure 6). The first step using Chart 1 is to categorise the type of hazard based on the hazard characteristics of a substance. The second step using Chart 2 is to use the assessed risk to the environment based on use and volume of use to determine an appropriate schedule to include in the risk management recommendation.

Determining an appropriate schedule follows a top down approach. A top down approach is used to ensure substances are scheduled based on their highest, most serious hazards and concern to the environment and the substance is recommended for scheduling appropriately.
Figure 6: National Standard scheduling criteria decision trees

Chart 1: Hazard Categorisation

START

Q1. Is the substance Persistent, Bioaccumulative and Toxic (PBT) or otherwise of significant environmental concern?

NO

Q2. Are any PBT substances reasonably expected to form as degradation or transformation products during use or after disposal?

NO

Q3. Is the substance or could the substance harm the environment with long lasting effects in line with the GHS criteria?

NO

Q4. Is the substance acutely harmful, toxic or very toxic to aquatic organisms in line with the GHS criteria?

NO

Q5. Is there evidence to suggest the substance is hazardous to organisms other than aquatic organisms?

NO

Q6. Is the substance bioaccumulative?

NO

Q7. Does the substance contain any perfluorinated functionality?

NO

Q8. Is there evidence to suggest the substance is an endocrine disruptor?

NO

Q9. Is there evidence to suggest that the substance has other characteristics that may result in adverse short or long term effects on the environment?

NO

Q10. Is the substance reasonably expected to form degradation or transformation products during use or after disposal that are moderately hazardous to the environment?

NO

YES

High Concern Chemicals

The Advisory Committee will review all substances that are High Concern and categorise them into either Schedule 7 or 8 depending on whether their introduction into or use in Australia have a net benefit to the community and there are no viable alternatives.

Schedule 7 Restricted Substances

Schedule 8 Prohibited Substances

Moderate Hazard Chemical

Go to Chart 2

Low Hazard Chemical

Schedule 1
Chart 2: Schedule Assignment for Moderate Hazard Chemicals

PEC = Predicted Environmental Concentration (the concentration of a substance likely to be in a particular part of the environment – air, water, soil)
PNEC = Predicted No Effect Concentration (the concentration of a substance not likely to cause harm to an organism in a particular part of the environment)

Q11. Is the substance perfluorinated AND/OR persistent OR bioaccumulative?

Q12. Is the PEC ≥ PNEC AND/OR the substance very toxic with long lasting effects?

Q13. Is the PEC ≥ PNEC AND/OR the chemical very toxic with long lasting effects?

Q14. Is the PEC/PNEC ≥ 0.1 AND/OR the chemical toxic with long lasting effects?

Q15. Is the substance an endocrine disruptor?

Q16. Is the PEC/PNEC ≥ 0.01 AND/OR the chemical harmful with long lasting effects?

Q17. Is the substance also perfluorinated AND/OR persistent OR is it an endocrine disruptor?

Q18. Is the substance also an endocrine disruptor?

Recommended for Schedule 6

Recommended for Schedule 5

Recommended for Schedule 4

Recommended for Schedule 3

Recommended for Schedule 2

Moderate Hazard chemical according to Chart 1

Harmful, toxic or very toxic to aquatic organisms in line with the GHS (acute and/or chronic)

At least harmful to organisms other than aquatic organisms

Bioaccumulative

Perfluorinated functionality

Endocrine Disruptor

Other characteristics that may have adverse short or long term effects on the environment
If the risk management recommendation is based on concern to the environment, does that mean different uses could have different scheduling decisions?

Yes, for Scheduled 3 to 6. Substances will be scheduled according to their scope of assessment. The scope of assessment is the assessed use, and volume of use.

This is in line with the proposed approach being undertaken by NICNAS for listing chemicals on the AICS against a scope of assessment and reassessing chemicals where use falls outside that scope of assessment, when required. Therefore, each time NICNAS assesses a chemical against a different scope of assessment, it may be scheduled in a different Schedule under the National Standard.

This approach is consistent with a risk-based, proportionate approach. It takes into consideration the likely release of a substance into the environment and takes into account that different uses of substances result in different releases to the environment. Risk management under the National Standard is intended to target substances that are of concern to the environment which means targeting substances used in situations likely to result in exposure to the environment that could cause harm to any aspect of the environment.

What information will be published in regards to a scheduling decision?

To help businesses and the general public engage with the Standard, the following information will be published in a database online:

- The chemical name/identifier as published in the risk assessment summary
- The assigned Schedule
- The risk management measures applicable for the chemical’s use
- The defined scope of assessment as published in the risk assessment summary
- The chemical hazards, if any, as published in the risk assessment summary
- The date of the scheduling decision
- Any other relevant information that led to the decision.

Businesses and the public will be able to use this information to better understand the risks to the environment posed by the use and the management of chemicals in Australia. Businesses will also be able to use the information to make informed judgements about chemicals they use and possible scheduling results based on the scheduling of similar chemicals.

How long will the scheduling process take?

The scheduling process for the National Standard is proposed to be streamlined. This is achieved through the development and publication of the National Standard and scheduling criteria up front.

In general, the majority of chemicals may be scheduled within 45 days receipt of the risk management recommendation by the Decision Maker. However, chemicals that need to or have been requested to go to the Advisory Committee may take longer schedule.

For most Low and Intermediate Concern chemicals, the Decision Maker will consider chemicals for scheduling once per month. Detailed information on scheduling processes is outlined in Appendix A.
Are there any specific requirements businesses or introducers need to undertake in the scheduling process?

There are no specific additional requirements that must be undertaken by businesses or introducers for the scheduling processes under the National Standard. Chemical introducers must adhere to the requirements under the ICNA Act for notification and assessment of industrial chemicals. The environmental risk assessment will be completed by the risk assessor and a risk management recommendation made to the Decision Maker under the National Standard. Scheduling processes under the National Standard will be completed by the Australian Government.

However, there may be circumstances under which businesses or introducers choose to engage in the scheduling process, such as requesting that risk management recommendations be reviewed by the Advisory Committee. Details of requesting reviews of risk management recommendations are outlined in Appendix A.
5. Risk management measures

Each Schedule under the National Standard will have a set of defined risk management measures. Risk management measures refer to the directive controls that will be scheduled under the National Standard. States and territories will automatically adopt scheduling decisions under the National Standard.

As the Schedules increase, the concern a substance poses to the environment increases. The greater the concern to the environment, the more stringent the risk management measures need to be to prevent harm to the environment.

Risk management measures will be developed in consultation with governments, industry and the community over the coming months. A proposal for developing the risk management measures, including examples of risk management measures and appropriate measures for each Schedule, is outlined below.

Feedback is sought on the current measures being implemented for chemicals in use. This information will be used to more clearly define the risk management measures for inclusion in the draft of the National Standard.

5.1 Principles for developing risk management measures

The Decision RIS outlined that risk management measures under the National Standard would be outcomes-based to encourage continued innovation in environmental protection and also enable industry to keep costs related to risk management as low as possible.

Other principles that are being proposed for development of the risk management measures are outlined below.

- Risk management measures should aim to prevent harm to the environment.
- Risk management measures should be implementable – chemical users should be able to identify appropriate actions to undertake to work towards meeting the risk management measure.
- Risk management measures should be achievable – chemical users should be able to successfully meet risk management measures with the available tools or actions.
- Risk management measures should be enforceable – compliance and enforcement undertakings should be capable of identifying if a measure has not been appropriately met and identify the responsible party.
- Risk management measures should be appropriate – measures should be capable of being targeted to mitigate the risk identified in the risk assessment and be targeted at the point in the supply chain where harm to the environment is most likely to be prevented.
- Risk management measures should be proportionate – measures should be aligned with the identified hazards and risks of a chemical and be commensurate to those hazards and risks.
- Risk management generally should not result in negative side effects outside the intended use and resulting exposure of a chemical – for example, users attempting to reduce chemical concentrations in water outflows through excessive dilution, causing operational burden on sewage treatment plants that may result in overflow and direct release of chemicals into the environment.
- Risk management measures will aim to complement existing controls undertaken by businesses, where appropriate.
What are outcomes-based risk management measures?

Outcomes-based risk management involves applying the controls necessary to prevent adverse environmental impacts and ensure adequate protection of the environment. Specifying the necessary outcome, such as the maximum allowable concentration in water or air that must not be exceeded, and requiring users to apply appropriate risk-based controls but not mandating a particular set of controls, allows businesses to determine how best to meet the required environmental outcome for a particular chemical.

This approach encourages innovation and allows businesses to make the best decisions for their situation. This is in contrast to prescriptive risk management that details the actions or specific controls, for example, that a person or business must put in place. Setting prescriptive measures has the potential to deter innovation and prevent potential changes to performance of processes. Businesses could also only undertake the prescriptive measure to ensure compliance, even when the intent of risk management, in this case, environmental protection, is not necessarily effectively or efficiently achieved.

Risk management measures under the National Standard will be outcomes-based. What chemical users need to achieve to prevent harm to the environment will be outlined. Some broad examples of outcomes-based measures include:

- setting limits on concentrations that must not be exceeded when material is released to the environment
- preventing release to the environment
- preventing wildlife exposure to chemicals.

The way in which each measure is achieved will be the decision of each business in each different operating environment.

Are outcomes-based measures enforceable?

Development of risk management measures needs to take into consideration the need for those measures to be achievable and implementable by users and ensure they are measurable and enforceable in each jurisdiction. For this to be possible, risk management measures will need to strike a balance between the extremes of describing detailed, prescriptive approaches; or describing broad objectives that provide no direction to users or compliance and enforcement officers.

It is the responsibility of each jurisdiction, whether it is the Australian Government, or states and territories, to determine the appropriate compliance and enforcement activities that are best suited to the jurisdictions’ current regulatory frameworks and resources. A person conducting or undertaking an activity with industrial chemicals should also have the primary duty to ensure, so far as is reasonably practicable, that the environment is not adversely impacted by the conduct. It will generally be the responsibility of each chemical user to demonstrate that the actions taken to meet the outcome are achieving the appropriate level of protection to the environment outlined in the risk management measure.

As the National Standard is seeking to harmonise management arrangements at a national level, it is intended that state and territory governments do not need to impose specific conditions or risk management measures beyond those in the scheduling decision. States and territories are assisting in the preparation of the standard outcomes based measures for the National Standard. For High Concern chemicals that require more specific risk management measures, the Advisory Committee may consult government agencies before provide risk management advice to the Decision Maker.
**Which chemical users will be expected to adhere to the risk management measures?**

Anyone who uses chemicals industrially, commercially or domestically should work towards using chemicals in a way that prevents harm to the environment. The National Standard will outline the measures that need to be undertaken to prevent harm. However, it will be the responsibility of jurisdictions to determine where compliance and enforcement efforts will be targeted. A risk-based, proportionate compliance and enforcement effort may include targeting parties using chemicals in industrial settings, parties using high volumes of chemicals, or parties using chemicals assigned to certain Schedules, for example, Schedules 5, 6 and 7.

Risk management measures will also attempt to prevent harm to the environment at the point in the supply chain where the measure will be most effective. In most cases, this is not likely to be during widespread, consumer use, but with facilities that are capable of implementing the measures. A positive outcome of implementing the National Standard is that greater awareness of the potential impacts chemicals can have on the environment may encourage companies to use safer, greener chemicals in consumer products. These conscious decisions will also help prevent harm to the environment.

**How will the risk management measures be proportionate to the risk?**

A key aspect of the National Standard is to seek to ensure that risks to the environment as identified in the risk assessment are appropriately controlled by setting risk management measures that are proportionate to the potential impact of the chemical on the environment.

Risk management measures listed for each Schedule for consideration, are based on the level of concern posed to the environment by a chemical substance. This provides an overarching approach to mitigation of environmental risks. The measures that are applied for consideration in managing risk to the environment become more restrictive as the environmental concern increases.

As the chemical moves into higher concern Schedules, additional or more protective controls will be required to reduce the potential for environmental impact. The higher Schedules contain industrial chemicals that can have significant, adverse effects on the environment, such as industrial chemicals that are persistent, bioaccumulative and/or toxic. Measures for higher concern chemicals will need to be applied to reduce the potential for release to the environment in quantities that can give rise to concentrations of the chemical in the environment that are likely to harm the environment. Measures may also be needed to prevent any release of a particular chemical to the environment.

Measures need to provide for an adequate level of protection of the environment. That is, the controls must ensure that releases and exposure will not occur at levels of concern. Some control measures are more effective than others. Risk management measures under the National Standard will ensure that chemicals in higher Schedules get the highest level of protection. This ranking is known as the hierarchy of control. The hierarchy of control will first consider the highest level of protection for chemicals in a particular Schedule, and subsequent controls that may be applicable from lower Schedules. The hierarchy is outlined in Figure 7. Control methods at the top of the list are generally more effective and protective than those at the bottom. By following the hierarchy, implementation of more effective control of discharge to the environment should be achieved.
Industrial chemicals with low environmental exposure and limited environmental hazards will have fewer and less stringent controls. For example, a chemical that is in Schedule 2 and is Low Concern can be managed effectively with only a simple set of risk management measures to prevent excessive release to the environment.

With so many different types of industrial chemicals and uses, how will users know which risk management measures are appropriate for the chemical?

Risk management measures need to be appropriate for protection of the environment from chemicals that are captured in each Schedule. It is recognised that the chemicals in each Schedule may be different in:

- nature and characteristic
- the use pattern
- volumes of usage and release
- exposure pathways for environmental impact
- impacts to air, water and/or land.

Therefore, not all risk management measures defined under each Schedule will be appropriate for every chemical in the Schedule. For example, the proposed Schedules encompass a range of industrial chemicals that impact various environmental compartments, including air, surface and ground water, sediment and soil. Controls relevant for gases (a risk to the air compartment)
may not be directly applicable to industrial chemicals that are soluble and pose a risk to the water compartment.

An environmental risk assessment will include a risk management recommendation identifying appropriate risk management measures as identified in the risk assessment. Following a scheduling decision, the published decision will include the scope of assessment and the appropriate risk management measures.

What stages of a chemical lifecycle will risk management measures under the National Standard target?

Risk management measures under the National Standard may target all stages of a chemical’s lifecycle. As noted above, risk management measures will be targeted at the stage of the lifecycle that is likely to prevent harm to the environment in the most efficient and effective way.

Some industrial chemicals are subject to controls through other codes, such as the Dangerous Goods Code and codes relating to occupational health and safety. These have requirements particularly relating to protecting users of chemicals, including packaging, labelling, placarding and warnings, and requirements relating to transport. The National Standard does not intend to duplicate these requirements and assumes that the requirements of other applicable codes and standards will apply. Instead, the National Standard will focus on requirements relating to protection of the environment arising from storage, handling, manufacturing activities, and disposal.

Risk management measures will be targeted at preventing harm to the environment from the normal, intended use of the chemical. Measures to prevent accidental release of a chemical will not be specifically covered under the National Standard but may broadly be covered in measures for limiting or preventing release. As a baseline, reasonable attempts should be made to prevent unnecessary release of any chemical substance into the environment.

5.2 Risk Management Measures under the National Standard

The National Standard aims to achieve better protection of the environment through improved management of the risks posed to the environment by the use of industrial chemicals. Therefore, all measures under the National Standard should aim to prevent harm to the environment. The risk management measures that may be appropriate for each Schedule are outlined below.

Will there be guidance for businesses to help them develop approaches to meeting risk management measures?

Yes. Guidance may be developed by governments or industry to support businesses in understanding the requirements and in developing and implementing appropriate risk management measures.
5.2.1  General use measures

All industrial chemicals used in Australia should be used in a way that does not result in adverse effects on the environment. Therefore, the following general measures are proposed for all industrial chemicals and implementation of risk management measures under the National Standard. These are objectives that chemical users should try to achieve for all chemicals.

- Take reasonable measures to avoid unnecessary intentional release of a chemical substance directly to the environment.
  - This measure aims to ensure chemical substances are not disposed of in bulk quantities (e.g. barrel loads) directly into waterways or landfills, even if that chemical is in Schedule 1. For example, significant quantities of sodium chloride (table salt) in fresh water systems can have serious adverse effects on the surrounding environment. This measure also aims to avoid unnecessary release during use, for example providing packaging and use systems that avoid wastage and residuals that will released to the environment.

- In industrial settings, ensure good housekeeping measures are undertaken to prevent release of chemicals into the environment.
  - Good housekeeping includes processes for cleaning equipment and collecting and preventing spills, proper disposal of wastes and proper and safe storage of chemical substances.

- Avoid implementing measures that will result in adverse effects on the environment that are not directly related to the identified hazards of a chemical substance.
  - This includes ensuring that the treatment of chemical substances does not result in creation of a more harmful substance or and its release to the environment at concentrations of concern; and preferring treatment methods that fully destruct or minimise the quantity of the chemical that is released to the environment as waste.

5.2.2  Schedule 1 – Low Concern

No additional risk management measures beyond the general use measures will apply to chemical substances in Schedule 1.

Schedule 1 industrial chemicals are those for which it is determined there is low Concern and they are not hazardous or are substances with low hazard characteristics. Chemicals in Schedule 1 can be, for example, innocuous chemicals or ‘pantry’ chemicals that someone could expect to find in their homes alongside food items (sodium chloride or acetic acid, for example). Many cosmetic and domestic chemicals are expected to be assigned to Schedule 1.

5.2.3  Schedule 2 – Low Concern

Schedule 2 chemical substances are chemicals that are hazardous to the environment, but are used in volumes and in a way that the concentration in the environment will be much less than the concentration likely to cause harm to the environment. As with Schedule 1 substances, the general use measures may be sufficient to prevent harm to the environment. However, as these chemicals have identified hazards, some additional risk management measures may be required.

Many industrial chemicals that can be found in domestic situations will be in Schedule 2. This includes sodium hydroxide, glutaraldehyde and some chemicals used in detergents. It is expected that hazardous organic chemicals in Schedule 2 are likely to degrade before causing harm to the environment.
Proposed risk management measures include:

- Neutralise chemical substance prior to release to the environment
- Neutralise chemical substance prior to disposal to the sewer
- Release chemical substance to the sewerage system that includes a sewage treatment facility
  - Note: Releases through the sewerage system will be acceptable in most major cities and towns. In industrial settings, this may be subject to trade waste agreements that are outside the scope of the National Standard.
- Dispose residues of the chemical substance in containers through a recycling facility
  - Note: Advice on disposal of large quantities of any chemical should be sought from local and state governments and will not be covered by the National Standard
- Dispose waste with residues of the chemical substance to landfill
- Do not release the chemical substance directly to the environment at a concentration greater than \[x\] concentration.  
  - Note: The threshold will be determined in the environmental risk assessment and recommended by NICNAS, and will relate to the environmental media (land, water, air) that is relevant and the assessed use in terms of the concentration and volume and discharge and the resulting concentration in the media. A numerical value and units will be scheduled following decision.

5.2.4 Schedule 3 – Intermediate Concern

Schedule 3 chemical substances are chemicals that are hazardous to the environment, but are used in volumes and in a way that the concentration in the environment will be less than the concentration likely to cause harm to the environment, but are more likely than Schedule 2 substances to cause harm to the environment if the circumstances regarding use change. Schedule 3 chemical substances may also have unknown effects arising from characteristics such as being a nanomaterial or persistent with potential but unknown long term effects, but do not have other identified hazards.

The risk management measures that are outlined under the National Standard for Schedule 2 chemicals may apply to Schedule 3 chemicals, as appropriate.

Proposed additional risk management measures include:

- Do not allow releases of the chemical substance to surface water with a concentration greater than \[x\] concentration
  - Note: The threshold will be determined in the environmental risk assessment and recommended by the risk assessor and will relate to the environmental media (land, water, air) that is relevant and the assessed use in terms of the concentration and volume and discharge and the resulting concentration in the media. A numerical value and units will be scheduled following decision.
- Do not allow releases of the chemical substance to air with a concentration greater than \[x\] concentration
- Do not allow releases of the chemical substance to soil with a concentration greater than \[x\] concentration
- Do not allow releases of the chemical substance to groundwater with a concentration greater than that allowed for discharge to surface water.
– Note: This measure may include ensuring underground pipelines have leak prevention systems, chemicals are not stored in underground tanks, or all reasonable efforts are taken to ensure the chemical does not leach into groundwater during the intended use

• Do not allow wildlife to access the chemical substance above [x concentration]

– Note: This may be prevented by avoiding storing chemical substances in open tanks or ponds that are easily accessible by and may be attractive to birds or animals.

• Recycle empty storage containers and drums through a licensed recycling facility

• Do not allow releases of the chemical to the sewerage system other than under the terms of a trade waste agreement with the sewerage authority.

– Note, generally sewerage authorities will require industries to enter into a trade waste agreement that allows certain compounds and groups of compounds to be discharged safely to the sewerage system.

• Do not dispose of wastes containing the chemical substance to landfill other than under the terms of an agreement with a licenced landfill operator.

– Note, generally landfill operators will not accept wastes containing industrial chemicals other than under an agreement; this requirement has the intent of ensuring that the acceptance complies with the licence requirements of the landfill and is appropriate for the class of landfill.

5.2.5 Schedule 4 to 6 – Intermediate Concern

Schedule 4 to 6 chemical substances have an increased level of concern to the environment compared to Schedule 3. Schedules 4 to 6 include chemicals for which the quantity released to the environment has the potential to give rise to adverse effects, or for which risk is not quantified but the chemicals are perfluorinated or bioaccumulative or have endocrine disrupting potential and for which a precautionary approach should be adopted to minimise release to the environment.

While Schedule 3 risk management measures may be applied, the risk management measures for Schedule 4 to 6 substances require either prevention of direct, untreated release to the environment at any concentration up to prevention of release to the environment.

Stakeholder feedback is sought on the most appropriate presentation of risk management measures for Schedule 4 to 6 chemical substances.

Proposed additional risk management measures for Schedules 4 to 6 include:

• Dispose chemical to licensed hazardous waste contractor

• Do not allow release of the chemical substance to groundwater

• Do not allow release of the chemical substance to surface water

• Do not allow release of the chemical substance to soil

• Do not allow release of the chemical substance to air.

– Note: The above controls may be met by ensuring that the storage and handling of chemicals utilises systems and controls that provide a high degree of security that planned or uncontrolled releases will not occur and that uses of the chemical are avoided which involve release of the chemical.
The following risk management measures are an additional control. They will prevent release of chemicals substances through waste facilities such as sewage treatment plants and landfills where the release to the environment though these processes is too high and unable to be mitigated further. Chemical substances with these risk management measures may also not be able to be used outside industrial settings.

- Do not allow release of the chemical substance to the sewer other than under the terms of a trade waste agreement in which the concentration of the chemical is specifically recognised
  - Note, the intent of this requirement is to specifically recognise the presence of the chemical to ensure that the sewerage authority properly considers the chemical and its hazard characteristics, rather than allowing the chemical to enter as a member of a group of such chemicals.
- Do not allow release of the chemical substance to landfill other than under the terms of an agreement with a licensed landfill operator in which the concentration of the chemical is specifically recognised.
  - Note, the intent of this requirement is to specifically recognise the presence of the chemical to ensure that the landfill operator properly considers the chemical and its hazard characteristics, rather than allowing the chemical to enter as a member of a group of such chemicals.
- Destroy wastes containing residues of the chemical substance in accordance with best available technology.
  - Note: the selection of best available technology will require that hazardous byproducts or residues are not discharged to the environment, and effective pollution control systems are installed.

5.2.6 Schedule 7 and Schedule 8 – High Concern

Risk management measures for High Concern chemicals are, very generally, that the chemicals are “Prohibited” for Schedule 8 chemicals and “Restricted” for Schedule 7 chemicals. All chemicals that are determined to be High Concern to the environment will be reviewed by the Advisory Committee who will advise the Decision Maker on the appropriate Schedule for the chemical and, if in Schedule 7, the restrictions applied to the use of the chemical.

If a chemical is a Prohibited substance, it is not to be imported, manufactured or used in Australia and export of the substance may be controlled. Restricted use means that a chemical may only be use for specified purposes such as only in identified applications. Additional risk management measures for Schedule 7 substances will focus on ensuring that a chemical substance is never released to the environment in a hazardous state and all precautions are taken to prevent that release.
This report: has been prepared by GHD for Department of the Environment and may only be used and relied on by Department of the Environment for the purpose agreed between GHD and the Department of the Environment as set out Section 1 of this report.

GHD otherwise disclaims responsibility to any person other than Department of the Environment arising in connection with this report. GHD also excludes implied warranties and conditions, to the extent legally permissible.

The services undertaken by GHD in connection with preparing this report were limited to those specifically detailed in the report and are subject to the scope limitations set out in the report.

The opinions, conclusions and any recommendations in this report are based on conditions encountered and information reviewed at the date of preparation of the report. GHD has no responsibility or obligation to update this report to account for events or changes occurring subsequent to the date that the report was prepared.

The opinions, conclusions and any recommendations in this report are based on assumptions made by GHD described in this report. GHD disclaims liability arising from any of the assumptions being incorrect.

GHD has prepared this report on the basis of information provided by Department of the Environment and others who provided information to GHD (including Government authorities), which GHD has not independently verified or checked beyond the agreed scope of work. GHD does not accept liability in connection with such unverified information, including errors and omissions in the report which were caused by errors or omissions in that information.
Appendix A – National Standard Scheduling and Decisions Process
The proposed scheduling and decision-making processes under the National Standard are outlined in Table 1. Details of the processes are below.

**Risk Assessment**

Risk assessments of industrial chemicals of concern will continue to be conducted by the Australian Government Risk Assessor under the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). As part of the risk assessment, a risk management recommendation will be made to the Decision Maker for the National Standard as to the appropriate Schedule for the chemical, taking into consideration its scope of assessment (assessed use and volume of use in Australia) and the scheduling criteria.

The risk management recommendation will also outline appropriate risk management measures selected from a list of standardised, publicly available conditions that are outlined for each Schedule. Recommendations for risk management measures will need to take into consideration the chemical’s properties and potential route of release to the environment to ensure the risk management measures are appropriate for the chemical.

The risk assessment framework for industrial chemicals is currently undergoing reform. One of the main objectives of the reform is to prioritise the assessment of chemicals that are of concern to the environment and allow use of lower concern chemicals without premarket assessment. For new chemicals, this may mean that very few Low Concern chemicals will be scheduled under the National Standard as they will not be assessed for their risk. Existing chemicals on the Australian Inventory of Chemical Substances (AICS) may be scheduled as Low Concern chemicals. Chemical introducers wishing to have new chemicals that are Low Concern scheduled under the National Standard will need to request that Risk Assessor (NICNAS) conduct an environmental risk assessment.

**Risk Management Recommendation Consultation**

The consultation period for risk management recommendations made in a risk assessment will integrate with consultation processes under the ICNA Act to ensure that chemicals are scheduled under the National Standard in a timely and efficient manner. The consultation periods for industrial chemical risk assessments are currently the subject of public consultation as part of the reforms to NICNAS.

Risk management recommendations could be considered by governments and the introducer during the consultation period. If further consideration of the risk management recommendation is required, a request for the recommendation to be reviewed by the Advisory Committee can be made during the consultation period and after the scientific analysis is finalised. Requests for review by the Advisory Committee may be made on scientific, societal or economic grounds. Only the Advisory Committee will review how socio-economic considerations may impact scheduling decisions. The following criteria must be met in order to qualify for a review by the Advisory Committee:

- The categorisation of the chemical into a certain Schedule is not appropriate based on an error in scientific analysis
- The chemical’s characteristics are not consistent with criteria for chemical categorisation under the allocated Schedule
- The risk management conditions are not appropriate for the chemical or the way in which it is used. Inappropriate risk management conditions in this context refer to conditions where the requestor of the review is able to justify, based on scientific or economic grounds, that the conditions cannot be met. In this case, the Advisory Committee may also recommend that new risk management conditions are included under the National Standard.
The Decision Maker will determine if the request for review of the risk management recommendation is valid in accordance with the criteria above.

**Advisory Committee**

The Advisory Committee will only meet and review chemicals under certain circumstances:

1. The risk management recommendation is that the chemical is High Concern. All High Concern chemicals will be reviewed by the Advisory Committee and appropriate scheduling and risk management measures recommended by the Advisory Committee to the Decision Maker as risk management advice.

2. A risk management recommendation for Intermediate or Low Concern chemicals has been requested to be reviewed by industry, governments or the community. The Advisory Committee will only review chemicals if the request for review is deemed valid by the Decision Maker. If no review is requested for Intermediate and Low Concern chemicals, their risk management recommendations from the risk assessment will be forwarded straight to the Decision Maker.

3. The Decision Maker requests that a risk management recommendation be reviewed.

**Role of the Advisory Committee**

The role of the Advisory Committee is to:

- review the risk assessment for all High Concern chemicals and recommend appropriate scheduling and risk management measures to the Decision Maker in their risk management advice based on scientific and socio-economic considerations
- review all Intermediate or Low Concern chemicals where a valid request for review has been made and provide risk management advice to the Decision Maker, taking into consideration the risk management recommendation and any socio-economic factors
- review any risk management recommendation where a request for review has been made by the Decision Maker and provide risk management advice to the Decision Maker, taking into consideration the risk management recommendation and any socio-economic factors
- provide advice that new risk management measures are included under the National Standard.
- review published decisions of chemicals as requested by the Decision Maker as per the requirements under Review of Published Decisions outlined below.
- consult, as required, with government agencies, industry or the broader community to inform their reviews of risk management recommendations or scheduled decisions.

**Meetings**

The Advisory Committee will meet four times per year, but may be convened more or less frequently as required. Meetings may be held face-to-face or via teleconference. Meetings will be scheduled to take place in the middle of each quarter of the year.

An agenda, chemicals for discussion, decisions for review, and risk assessments and risk management recommendations will be forwarded to the Advisory Committee two weeks before the scheduled date for each meeting. Where possible, risk management advice for the Decision Maker should be finalised at the meeting and forwarded to the Decision Maker with supporting reasons for the advice.
Membership

The Advisory Committee will have five to six expert members, covering the areas of industrial chemistry, ecotoxicology, environmental risk management, policy/socio-economics, ecology and regulatory risk management practices. Parties may become members of the Advisory Committee by invitation or nomination. Parties may be selected from government or the broader community as long as their position is consistent with the expertise outlined. The Minister for the federal environment portfolio (the Minister) may invite parties to become members of the Advisory Committee in consultation with all jurisdictions.

The Minister will appoint members to the Advisory Committee in writing. Appointed members will be whoever the Minister believes to be appropriately qualified based on advice from the Department and in consultation with state and territory governments. Members are appointed on the basis of expertise rather than to represent a particular jurisdiction or interest group.

A member may be appointed for a term stated in the member’s appointment but must not be longer than three years. Such members can be appointed for a further term of up to three years but may not serve more than three consecutive terms (nine years in total).

Confidentiality and Conflict of Interest

All members are required to sign a confidentiality agreement and declare any interests of the kind that a member may need to disclose.

Members should declare both pecuniary (which may include professional) interests and non-pecuniary interests. Members should take into account the nature of the Advisory Committee’s role, functions and responsibilities when determining whether to declare a particular interest.

Members will need to make the following declarations:

- A declaration of interest to support the application/expression of interest in relation to the Advisory Committee membership
- A declaration at the time of appointment to the Advisory Committee
- An annual declaration
- A disclosure of interests declaration prior to meetings
- Notification of new or additional interests as soon as practicable after they arise or become apparent.

All relevant conflicts of interest will be disclosed to the public when a member of the Advisory Committee is appointed. The duration and dates of their membership will be noted against the disclosure, as well as the period over which the disclosure is representative of the conflict. The disclosure is to ensure decisions under the National Standard are transparent and defensible.

Disclosure of interests may extend to declaration by a member of holding strong personal, philosophical or religious beliefs or convictions, or personal circumstances, family or other relationships.

The disclosure must be recorded in the minutes of the meeting and the member must not, unless the Committee otherwise determines, either be present during any deliberation of the Committee about the matter or take part in any decision of the Committee about the matter.

When the Committee is making a determination about a member who has made a disclosure, the member, and any other member who has a direct or indirect material personal interest (whether pecuniary or not) in the matter to which the disclosure relates, must not be present during any deliberation of the Committee and must not take part in making that determination.
**Appointment of Chair**

The chair of the Advisory Committee is appointed by the Minister or delegate from within the existing Advisory Committee membership. The Chair holds that office for the term stated in the appointment and may be appointed for further terms, but not for periods longer than the term of their membership. An Acting Chair may also be appointed by the Minister, to assume the role and responsibilities of the Chair when he or she is unable to perform his or her duties.

**Resignation**

Appointed members may resign from the Advisory Committee by signed notice to the Minister. The Chair may resign as Chair and/or as an Advisory Committee member by signed notice to the Minister.

**Remuneration**

The remuneration of the Advisory Committee would be based on the fees determined by the Remuneration Tribunal established under the Remuneration Tribunal Act 1973.

**Non-unanimous Outcomes**

All risk management advice provided by the Advisory Committee should be made by consensus. In the exceptional circumstance where it is not possible to reach consensus, members will be able to vote on the final risk management advice for the Decision Maker.

All members of the Advisory Committee will have equal voting rights. The risk management advice is agreed at an Advisory Committee meeting by a majority of the votes of the members present and voting. Committee members will have the opportunity to outline their reasons for their vote. The Chair at the Advisory Committee meeting will abstain from the voting round. If the vote is tied, the Chair has the casting vote. The quorum is two thirds of the Advisory Committee members.

**Decision Maker**

The Decision Maker for the National Standard will be the Minister for the federal Environment portfolio. The decision-making responsibility can be delegated to a member of the Department of the Environment’s staff.

The Decision Maker makes the final scheduling decision for all chemicals. The scheduling decision must consider the risk management recommendation or advice. The Decision Maker will also have the power to request that risk management recommendations are reviewed by the Advisory Committee prior to making a scheduling decision. The Decision Maker will also have the power to request that the Advisory Committee review published decisions under the National Standard and any risk management measures or scheduling criteria.

All chemicals with an environmental risk assessment will be scheduled under the National Standard. Chemicals will be forwarded to the Decision Maker following:

- finalisation of the risk assessment by the Director of NICNAS
- review by the Advisory Committee, if required.

In the majority of cases, chemicals will be forwarded straight to the Decision Maker after finalisation of the risk assessment.

The Decision Maker will consider chemicals for making a scheduling decision once per month. All chemicals for which a risk assessment is finalised after the previous scheduling decision cut-off will be considered for scheduling. In general, it is expected that the total number of days between the risk assessment being finalised and scheduled scheduling decision being made is
between 14 and 45 days, unless the risk management recommendation is requested to be reviewed by the Advisory Committee.

All risk management recommendations for High Concern chemicals, and Intermediate and Low Concern chemicals for which a valid request is made, will be reviewed by the Advisory Committee. The Advisory Committee will meet four times per year. Therefore, chemicals reviewed by the Advisory Committee may take up to four months to reach a scheduling decision under the National Standard.

Following a scheduling decision by the Decision Maker, the chemical will be included on the National Standard and the decision will be enforceable. All scheduling decisions will be reviewable.

**Administration**

The National Standard Secretariat will be located within the Australian Government Department of the Environment. The Secretariat will be responsible for:

- coordinating communication between external parties and the Advisory Committee or Decision Maker
- compiling a list of chemicals for scheduling and their recommended risk management conditions for the Decision Maker
- notifying the public of decisions made under the National Standard including updating website material as required
- organising information for dissemination to the Advisory Committee
- coordinating and facilitating the meetings of the Advisory Committee
- preparing the Department's recommendation on appointment to the Advisory Committee with appropriate consultation.
Appendix B - Guidance on the Scheduling Criteria
The purpose of this appendix is to support the questions in the decision trees (Section 4.2.2) and provide guidance for stakeholders on the reasons why the questions are posed and how they can be answered.

NICNAS will make scheduling recommendations for the National Standard. They will be the primary users of the scheduling criteria. The criteria will be published online and will be accessible to all stakeholders. This is to ensure scheduling decisions under the National Standard are transparent and predictable. Publication of the criteria will also assist interested stakeholders in determining how a substance may be scheduled under the National Standard and what their potential risk management measures may be. This is to support stakeholders in making informed decisions about the chemicals they use and their potential environmental impact.

The following questions were posed in the decision trees (Figure 6). The information under each question will support the determination of the appropriate response. More information on properties and assessment of industrial chemicals can be found in the Environmental Risk Assessment Guidance Manual for Industrial Chemicals.

**CHART 1**
**Question 1 - Is the substance Persistent, Bioaccumulative and Toxic (PBT) or otherwise of significant environmental concern?**

For the substance to be considered persistent, bioaccumulative and toxic (PBT), it must meet all three hazard characteristics (P and B and T) of the National PBT Criteria. These criteria are outlined in Table 3. More details on persistence, bioaccumulation and toxicity including general guidance on determining these characteristics are outlined at the end of this Appendix.

Persistent, bioaccumulative and toxic (PBT) chemicals are of particular concern to the environment. PBT chemicals persist for long periods, accumulate in biota and can give rise to toxic effects after a greater time and at a greater distance from the source than chemicals without PBT properties. Also concerning is that a cessation of emissions of these chemicals will not necessarily result in a reduction in concentration in the environment.

It is difficult to quantitatively or even qualitatively assess the risk of such chemicals. The additional concerns that may not be adequately addressed by traditional risk assessment methodologies include:

- concern that such substances may accumulate in parts of the environment and that:
  - the effects of such accumulation are unpredictable in the long-term
  - such accumulation would be practically difficult to reverse
  - Determining where a PBT chemical is likely to accumulate is difficult to estimate as they can travel long distances from the source.
- Concern that remote areas of the oceans should remain untouched by hazardous substances resulting from human activity, and that the intrinsic value of pristine environments should be protected.

Because exposure to PBT chemicals is long-term, effects may not be identified in the short-term, or even over a generation. Therefore, a ‘safe’ concentration may be impossible to determine.

Substances that are otherwise of significant environmental concern are those that are highly hazardous to the environment and are often subject to restrictions or bans internationally. These include substances that deplete the ozone layer and inorganic compounds such as toxic metals.

---
that are known to be extremely hazardous to the environment. Of course, where Commonwealth legislation already exists for managing these chemicals in Australia, the Advisory Committee will take this into consideration when developing risk management recommendations. Guidance documents on and lists of particular chemicals that meet these characteristics will be provided.

If the answer to this question is yes, the chemical is High Concern to the environment and prioritised for management under the National Standard. The import, manufacture or use of these substances in Australia is not recommended. However, there are circumstances where their use has a net benefit to the community, usually in terms of protecting public and worker health and safety. All substances identified to be PBT in the risk assessment will be in Schedule 7 (Restricted Substances) or Schedule 8 (Prohibited Substances). An expert Advisory Committee will review all PBT substances and develop appropriate management controls.

**Table 3: National PBT criteria**

<table>
<thead>
<tr>
<th>Hazard characteristic</th>
<th>Environmental medium (or compartment or trophic level)</th>
<th>Indicators and numerical thresholds for positive hazard categorisation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Persistence</strong></td>
<td>Air</td>
<td>Half-life in air (T_{1/2}) ≥ 2 days</td>
</tr>
<tr>
<td></td>
<td>Water</td>
<td>Half-life in water (T_{1/2}) ≥ 60 days</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>Half-life in soil (T_{1/2}) ≥ 6 months</td>
</tr>
<tr>
<td></td>
<td>Sediment</td>
<td>Half-life in sediment (T_{1/2}) ≥ 6 months</td>
</tr>
<tr>
<td><strong>Bioaccumulation</strong></td>
<td>Aquatic</td>
<td>BAF ≥ 2000 or BCF ≥ 2000 or log (K_{ow}) ≥ 4.2 (if BAF and BCF are not available)</td>
</tr>
<tr>
<td></td>
<td>Terrestrial</td>
<td>log (K_{oa}) &gt; 6 and log (K_{ow}) ≥ 2</td>
</tr>
<tr>
<td></td>
<td>Food-chain bioaccumulation potential</td>
<td>BMF &gt; 1</td>
</tr>
<tr>
<td><strong>Toxicity</strong></td>
<td><strong>Aquatic - Acute</strong></td>
<td>96 h LC50 ≤ 1 mg/L and/or 48 h EC50 ≤ 1 mg/L and/or 72 or 96 h ER50 ≤ 1 mg/L</td>
</tr>
<tr>
<td></td>
<td>Fish</td>
<td>96 h LC50 ≤ 1 mg/L and/or 48 h EC50 ≤ 1 mg/L and/or 72 or 96 h ER50 ≤ 1 mg/L</td>
</tr>
<tr>
<td></td>
<td>Invertebrates</td>
<td>96 h LC50, 1 mg/L and/or 48 h EC50, 1 mg/L and/or 72 or 96 h ER50, 1 mg/L</td>
</tr>
<tr>
<td></td>
<td>Algae or other aquatic plants</td>
<td>Chronic NOEC or ECx ≤ 0.1 mg/L and/or Chronic NOEC or ECx ≤ 0.1 mg/L and/or Chronic NOEC or ECx ≤ 0.1 mg/L</td>
</tr>
<tr>
<td></td>
<td><strong>Aquatic - Chronic</strong></td>
<td>Chronic NOEC or ECx ≤ 0.1 mg/L and/or Chronic NOEC or ECx ≤ 0.1 mg/L and/or Chronic NOEC or ECx ≤ 0.1 mg/L</td>
</tr>
<tr>
<td></td>
<td>Fish</td>
<td>Chronic NOEC or ECx ≤ 0.1 mg/L and/or Chronic NOEC or ECx ≤ 0.1 mg/L and/or Chronic NOEC or ECx ≤ 0.1 mg/L</td>
</tr>
<tr>
<td></td>
<td>Invertebrates</td>
<td>Chronic NOEC or ECx ≤ 0.1 mg/L and/or Chronic NOEC or ECx ≤ 0.1 mg/L and/or Chronic NOEC or ECx ≤ 0.1 mg/L</td>
</tr>
<tr>
<td></td>
<td>Algae or other aquatic plants</td>
<td>Chronic NOEC or ECx ≤ 0.1 mg/L and/or Chronic NOEC or ECx ≤ 0.1 mg/L and/or Chronic NOEC or ECx ≤ 0.1 mg/L</td>
</tr>
</tbody>
</table>

BCF = bioconcentration factor; BAF = bioaccumulation factor; \(K_{ow}\) = n-octanol/water partition coefficient; \(K_{oa}\) = octanol/air partition coefficient; BMF = biomagnification factor; LC50 = concentration lethal to 50% of the population; EC50(x) = concentration that has adverse effects to 50% of the population (or growth rate for algae); NOEC = No Observable Effect Level.

Note: These are the general criteria and may not be directly applicable to difficult to test substances such as some surfactants. The risk assessment will identify and justify the PBT characteristics of the chemical.

**Question 2 - Are any PBT substances reasonably expected to form as degradation products during use or after disposal?**
While a substance itself may not be persistent, bioaccumulative or toxic, it may degrade to form a PBT substance during use or upon release to the environment.

Some degradable substances may not degrade completely in the environment and may only undergo primary degradation (the substance loses its original structure and properties). These substances have the potential to form persistent degradation products that may need consideration for categorisation of the parent substance. As degradation products may have different physico-chemical properties to their parent, they should also be considered separately. The potential for a degradation product to persist in the environment is a particularly important consideration when the degradation product fulfils the criteria for categorisation as a PBT substance.

If the answer to this question is yes, the substance is High Concern to the environment and prioritised for management under the National Standard. The import, manufacture or use of PBT substances in Australia is not recommended. All PBT substances will be in Schedule 7 (Restricted Substances) or Schedule 8 (Prohibited Substances). An expert Advisory Committee will review all PBT substances and develop appropriate management controls.

**Question 3 – Is the substance or could the substance harm the environment with long lasting effects in line with the GHS criteria?**

The GHS classification for long lasting environmental hazard consists of four toxicity classification categories and one category for the potential for depletion of the ozone layer. The criteria for classification of a substance into the chronic categories follow a tiered approach where the first step is to identify if available information merits a long-term hazard classification. Classification can be done using available toxicity data. If chronic toxicity data is not available, acute toxicity data and environmental fate data are used for classification.

The GHS hazard statements for effects on the environment are outlined in Table 2. More information on classification of substances under the GHS and guidance for classification of substances can be found in Part 4: Environmental Hazards of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd Revised Edition⁹.

**Table 4: GHS Hazard Statements for classification of long lasting environmental hazards**

<table>
<thead>
<tr>
<th>Hazard Number</th>
<th>Hazard Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>H410</td>
<td>Very toxic to aquatic life with long lasting effects</td>
</tr>
<tr>
<td>H411</td>
<td>Toxic to aquatic life with long lasting effects</td>
</tr>
<tr>
<td>H412</td>
<td>Harmful to aquatic life with long lasting effects</td>
</tr>
<tr>
<td>H413</td>
<td>May cause long lasting harmful effects to aquatic life</td>
</tr>
<tr>
<td>H420</td>
<td>Harms public health and the environment by destroying the ozone in the upper atmosphere</td>
</tr>
</tbody>
</table>

⁹ Available at: https://www.unece.org/fileadmin/DAM/trans/danger/publi/ghs/ghs_rev04/English/ST-SG-AC10-30-Rev4e.pdf
Question 4 - Is the substance acutely harmful, toxic or very toxic to aquatic organisms in line with the GHS criteria?

The GHS classification for acute environmental hazard consists of three classification categories. The criteria for classification of a substance in the acute categories are defined on the basis of acute toxicity data only.

The GHS hazard statements for effects on the environment are outlined in Table 3. More information on classification of substances under the GHS and guidance for classification of substances can be found in Part 4: Environmental Hazards of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd Revised Edition\textsuperscript{10}.

Table 5: GHS Hazard Statements for classification of acute environmental hazards

<table>
<thead>
<tr>
<th>Hazard Number</th>
<th>Hazard Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>H400</td>
<td>Very toxic to aquatic life</td>
</tr>
<tr>
<td>H401</td>
<td>Toxic to aquatic life</td>
</tr>
<tr>
<td>H402</td>
<td>Harmful to aquatic life</td>
</tr>
</tbody>
</table>

Question 5 - Is there evidence to suggest the substance is hazardous to organisms other than aquatic organisms?

The effects to aquatic organisms are considered to best represent the toxicity of an industrial substance in the environment. This is because the primary exposure pathway for most industrial substances is generally the sewer. Surface waters are also thought to be the most likely sink for chemicals released into other compartments in the environment, whether it be through leaching from soils or becoming associated with water or particles in the atmosphere and returning to earth in rain.

Aquatic organisms are also generally considered to receive a higher relative dose of a chemical than terrestrial organisms. They live in the contaminated medium and can be quite sensitive to changes, including changes in water temperature, pH, dissolved oxygen, turbidity and dissolved organic carbon, to name a few.

However, in some cases, substances can be harmful to other organisms if those organisms are exposed to them. The answer to this question is yes if there is sound evidence (studies, test data, observations) that a substance may harm any organism in the environment other than aquatic organisms.

Question 6 - Is the substance bioaccumulative?

Bioaccumulation is the general term that is used to describe substances that are accumulated by organisms either directly from the surrounding media, respiration or through the consumption of food containing the substance. Bioaccumulation of a substance in an organism is not a hazard, but may result in a body burden which can lead to toxic effects.

A substance is bioaccumulative if it meets the following criteria for bioaccumulation (consistent with the PBT criteria in Question 1).

\textsuperscript{10} Available at: https://www.unece.org/fileadmin/DAM/trans/danger/publi/ghs/ghs_rev04/English/ST-SG-AC10-30-Rev4e.pdf
Aquatic bioaccumulation | BAF ≥ 2000 or BCF ≥ 2000 or 
| log $K_{ow} ≥ 4.2$ (if BAF or BCF are not available)
Terrestrial bioaccumulation | log $K_{oa} > 6$ and log $K_{ow} ≥ 2$
Food-chain bioaccumulation potential | BMF > 1

**Question 7 - Does the substance contain any perfluorinated functionality?**

Perfluorinated functionality in a substance can be identified structurally. Carbons that are fully fluorinated, that is, all bonds that are not C-C bonds are C-F bonds, are perfluorinated substances.

Perfluorinated substances are a diverse group of compounds resistant to heat, water, and oil. Perfluorinated substances are very persistent and resist degradation in the environment. The carbon-fluorine bond is one of the strongest and most difficult bonds to break, generally requiring very high temperatures to break the molecule apart. Perfluorinated substances can also bioaccumulate which means their concentration increases over time, particularly in blood and organs of organisms. Because of their unique characteristics and historic release to the environment, surface waters are regularly found to be contaminated with perfluorinated substances, even significant distances from their sources.

Polymers containing perfluorinated functional groups may also be of concern. Even for polymers that are considered to be persistent, it is likely that the last remaining part of a polymer after years of breaking down will be the perfluorinated functional group. Therefore, polymers that contain perfluorinated functional groups but otherwise appear to be not hazardous, may contribute to the total environmental load of perfluorinated substances in the environment over time.

Because of their properties, it is difficult to quantitatively or qualitatively assess the risk of perfluorinated substances. Therefore, these substances are targeted for management to prevent excessive release to the environment.

**Question 8 - Is there any evidence to suggest the substance is an endocrine disruptor?**

An endocrine disruptor is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or populations. Endocrine disruptors interfere in some way with hormone action and in so doing can alter endocrine function such that it leads to adverse effects on the health of organisms in the environment. Of particular concern is the potential for these substances to be active at very low concentrations and cause infertility or reduced fertility in organisms, or irreversible developmental abnormalities. These changes can have serious impacts on ecosystems and cause serious damage to populations in the environment.

Evidence to suggest that a substance is an endocrine disruptor or potential endocrine disruptor includes relevant studies, test data or observations that a substance may possess endocrine-disrupting activity. It may also be possible to determine if a substance may be a potential

---

endocrine-disrupting substance by reviewing its structure. If the substance has structural similarities to other known endocrine-disrupting substances, then it may itself possess endocrine-disrupting activity.

**Question 9 - Is there evidence to suggest that the substance has other characteristics that may result in adverse short or long term effects on the environment?**

In some circumstances, substances may not be hazardous through toxicity or bioaccumulation, but may have other characteristics that may result in short or long term effects on the environment. These substances currently have unquantifiable risks, but there is evidence to suggest their presence in the environment may have possible adverse effects.

This category currently includes nanomaterials and substances that are persistent with the potential to have adverse effects on the environment as they accumulate. These characteristics will be identified in the risk assessment.

Substances in this category that are otherwise not identified as hazardous (at least harmful, bioaccumulative, perfluorinated or endocrine-disrupting) will be recommended for inclusion in Schedule 3. This will enable release to the environment to be managed appropriately. This category will also have the potential to be reviewed to include substances with emerging but yet unquantifiable risks to the environment.

**Question 10 - Is the substance reasonably expected to form degradation or transformation products during use or after disposal that are moderately hazardous to the environment?**

For the purpose of categorisation under the National Standard, substances are moderately hazardous to the environment if the answer to any of questions 3 to 9 is yes. That is, the substance:

- could harm the environment with long lasting effects
- is acutely harmful, toxic or very toxic to aquatic organisms
- is at least harmful to organisms other than aquatic organisms
- is bioaccumulative
- contains perfluorinated functionality
- is an endocrine disruptor or potential endocrine disruptor
- has other characteristics that may result in adverse short or long term effects on the environment

While a substance itself may not be moderately hazardous to the environment, it may degrade to form a substance that is moderately hazardous during use or upon release to the environment.

Some degradable substances may not degrade completely in the environment and may only undergo primary degradation. These substances have the potential to form persistent degradation products that may need consideration for categorisation of the parent substance. As degradation products may have different physico-chemical properties to their parent, they should also be considered separately. The potential for a degradation product to persist in the environment is a particularly important consideration when the degradation product fulfils the criteria for categorisation as a moderately hazardous substance.
If the answer to this question is yes, the substance should be categorised under the National Standard according to the hazard of the degradation product. For example, if the degradation product contains perfluorinated functionality and is toxic to aquatic organisms, the parent substance should be categorised into the appropriate Schedule for the degradation product.

CHART 2

**Question 11 - Is the substance perfluorinated AND/OR persistent OR bioaccumulative?**

For substances identified as at least harmful to organisms, it is important to determine if they also meet the criteria to be considered persistent or bioaccumulative. Substances for which the answer is ‘yes’ to this question have the following characteristics:

- At least harmful to organisms in the environment AND contain perfluorinated functionality
- At least harmful to organisms in the environment AND persistent
- At least harmful to organisms in the environment AND bioaccumulative

**Question 12 - Is the PEC \(\geq\) PNEC AND/OR the substance very toxic with long lasting effects?**

Question 12 asks for identification of the level of risk substances meeting the characteristics in Question 11 pose to the environment. Substances that meet these characteristics will be either Schedule 5 or Schedule 6.

- **Schedule 6:** The answer to Question 12 is ‘yes’
  - Substances that meet the characteristics as outlined in Question 11 AND the assessed concentration of the substance in the environment without additional controls (Predicted Environmental Concentration; PEC) is greater than or equal to the concentration predicted to cause harm to the environment (Predicted No Effect Concentration; PNEC)
- **Schedule 5:** The answer to Question 12 is ‘no’
  - Substances that meet the characteristics as outlined in Question 11 AND the assessed concentration of the substance in the environment without additional controls (Predicted Environmental Concentration; PEC) is less than the concentration predicted to cause harm to the environment (Predicted No Effect Concentration; PNEC)
  - Substances that meet the characteristics as outlined in Question 11 and do not meet the criteria to be classified as very toxic with long lasting effects.

Persistent and at least harmful, or bioaccumulative and at least harmful substances could have adverse long term effects on the environment, even if not recognised immediately. These substances require management to ensure that they do not harm the environment now or into the future.

**Question 13 - Is the PEC \(\geq\) PNEC AND/OR the substance very toxic with long lasting effects?**
Question 13 is the same as Question 12. However it is specifically for substances that do not meet the characteristics outlined in Question 11 but are at least harmful to the environment. That is, these substances are at least harmful, but not perfluorinated, persistent or bioaccumulative.

If the answer to Question 13 is ‘yes’, then the assessed concentration of the substance in the environment without additional controls (PEC) is greater than or equal to the concentration predicted to cause harm to the environment (PNEC) and/or the substance is very toxic with long lasting effects. The substance will be recommended for Schedule 5. This is reflective that these substances are of lower concern to the environment than those that are also perfluorinated, persistent or bioaccumulative.

**Question 14 - Is the PEC/PNEC ≥ 0.1 AND/OR the substance toxic with long lasting effects?**

Question 14 is the result of answering ‘no’ to Question 13, that is, the assessed concentration of the substance in the environment without additional controls (PEC) is less than the concentration predicted to cause harm to the environment (PNEC).

If the answer to Question 14 is ‘yes’, then the substance is classified as toxic to the environment with long lasting effects and/or the assessed concentration of the substance in the environment without additional controls (PEC) is greater than or equal to 10% of the concentration predicted to cause harm to the environment (PNEC).

$$1 > \frac{\text{PEC}}{\text{PNEC}} \geq 0.1$$

This means that the substance is not likely to harm the environment at the current level of exposure to the environment, but if the circumstances were to change slightly, release of the substance may cause harm to the environment. This may occur in the following circumstances, for example:

- the release volume increases 10 fold, either due to an increase in introduction volume (or introducers) or changes in business practices.
- the daily effluent volume in a sewage treatment plant is lower than assessed. This may occur because the substance is now used in the same way but in a location with a smaller population or there is a seasonal variation in the effluent volume.
- the volume of water in the receiving environment decreases, such as in times of drought.

These are just a few examples of where small changes may result in increased risk to the environment.

If the answer to this question is ‘yes’, then the substance is recommended for Schedule 4. Substances with these characteristics should be managed to prevent excessive releases to the environment and ensure the PEC doesn’t change if the circumstances change.

**Question 15 - Is the substance an endocrine disruptor?**

Question 15 is the result of answering ‘no’ to Question 14. Question 15 is asked of substances that are at least harmful to the environment but not perfluorinated, persistent or bioaccumulative and generally lower risk to the environment (PEC/PNEC < 0.1).

If the answer to this question is ‘yes’, then the substance is recommended for Schedule 4. Endocrine-disrupting substances should be managed to prevent excessive releases to the environment. These substances can be active at very low concentrations. They can have serious impacts on ecosystems and cause serious damage to populations in the environment.
Question 16 - Is the PEC/PNEC $\geq 0.01$ AND/OR the substance harmful with long lasting effects?

Question 16 is the result of answering ‘no’ to Question 15, that is, the assessed concentration of the substance in the environment without additional controls (PEC) is less than 10% of the concentration predicted to cause harm to the environment (PNEC).

If the answer to Question 15 is ‘yes’, then the substance is classified as harmful to the environment with long lasting effects and/or the assessed concentration of the substance in the environment without additional controls (PEC) is greater than or equal to 1% of the concentration predicted to cause harm to the environment (PNEC).

$$0.1 > \frac{\text{PEC}}{\text{PNEC}} \geq 0.01$$

This means that the substance is not likely to harm the environment at the current level of exposure to the environment. However, as with Question 14, if the circumstances were to change moderately, release of the substance may cause harm to the environment.

If the answer to this question is ‘yes’, then the substance is recommended for Schedule 3. Substances with these characteristics should have some mitigating measures to prevent excessive exposure, but not as stringent as those to mitigate the potential risks of Schedule 4 substances.

If the answer is ‘no’, the substance will be recommended for Schedule 2.

Question 17 - Is the substance perfluorinated AND/OR persistent OR is it an endocrine disruptor?

Substances that are bioaccumulative and have other characteristics could result in additional adverse effects on organisms in the environment, beyond the effects of bioaccumulative substances.

A substance will be in Schedule 5 if the answer to this question is ‘yes’. These substances will have the following characteristics:

- Bioaccumulative AND perfluorinated
- Bioaccumulative AND persistent
- Bioaccumulative AND evidence indicating its potential to be an endocrine-disrupting substance
- Bioaccumulative AND other characteristics that mean adverse effects on the environment (such as nanomaterials)

If the answer to this question is ‘no’, the substance is Schedule 4.

Question 18 - Is the substance also an endocrine disruptor?

Substances that are perfluorinated and endocrine disrupting are likely to have additional burden on organisms, especially due to the very persistent nature of most perfluorinated substances.

A substance will be in Schedule 5 if the answer to this question is ‘yes’. If the answer is ‘no’, the substance will be Schedule 4.
GHD
Level 2, 45 Brougham Street
Geelong, Victoria 3220
T: (03) 5273 1800  F: (03) 5273 1801  E: gexmail@ghd.com.au

Document Status

<table>
<thead>
<tr>
<th>Rev No.</th>
<th>Author</th>
<th>Reviewer</th>
<th>Approved for Issue</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>P Nadebaum</td>
<td>D Kovacs</td>
<td></td>
</tr>
<tr>
<td></td>
<td>J Gorski</td>
<td>D Kovacs</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>24/03/16</td>
</tr>
</tbody>
</table>