

EXISTING CHEMICALS REVIEW

SUMMARY OF THE REQUIREMENTS OF THE *INDUSTRIAL CHEMICALS (NOTIFICATION AND ASSESSMENT) ACT 1989* WITH REGARD TO THE EXISTING CHEMICALS PROGRAM

1. Introduction

The following is a summary of the provisions within the Industrial Chemicals (Notification and Assessment) Act 1989 (Cwlth) amended (the Act) as they relate to the Existing Chemicals Program (the Program) and describes the:

- objectives of the Act;
- process for the declaration of Priority Existing Chemicals (PECs);
- process for secondary notification assessments;
- current restrictions and penalties as they relate to non-compliance with existing chemicals provisions and secondary notification requirements;
- enforcement provisions under the Act; and
- exempt information and confidential information under the Act.

The summary is prepared to assist in the review of the Existing Chemicals Program (the Program).

With regard to the Program's present assessment activities, the Act is specific only for that of PECs. The Act allows a flexible approach to the types of assessments that may be undertaken - whereby a variety of matters can be addressed.

A full risk assessment (which can be occupational, and / or public and / or environmental) to more focused 'preliminary assessments' (that focus on particular issues of the chemical but not include a risk assessment) may be undertaken (s 51).

A major but not exclusive activity of the Program involves the full risk assessment of PECs – so declared and assessed in accordance with the Act; with legislated timeframes and consultation and appeal provisions (Figure 1).

The remainder of the Program's activities relates to additional assessments and assessment related scheme support (such as nominations, screening and ranking of candidate chemicals). The assessments produced from these activities are illustrated in Figure 2, although all are not prescribed in the Act.

The current Program's activities include:

- PEC assessments (57% of activities);
- assessment related scheme support (29% of activities);
- participation in international assessments (9% of activities);
- PEC administration (4% of activities); and
- responding to public inquiries about existing chemicals (1% of activities).

General information about the Program's current activities, including details about how the nomination, screening and selection of PECs are undertaken is described in the review background paper *Overview of the Current Program*.

While this PEC activity is not detailed in the Act, administrative procedures have been established by NICNAS to prioritise chemicals for selection as PECs.

The focus on the PEC procedures in this summary is not intended to limit consideration of other ways the Program may undertake assessments or activities. Rather it only provides an overview of the Act as it currently applies.

The Act also describes other NICNAS actions relevant to the Program. These include secondary notifications, confidentiality provisions, appeal procedures, compliance / enforcement activities and administrative procedures such as procedures relating to exempt information.

A copy of the Act can be accessed through the Australian Government Attorney-General's Department Internet site at:

<http://scaleplus.law.gov.au/html/pasteact/0/440/pdf/IndCheNotAss89.pdf>

2. Objectives of the Act

The activities of the Program are premised on the objectives of the Act (Part 1 Preliminary section 3), which is to provide for a national system of notification and assessment of industrial chemicals for the purposes of:

- aiding in the protection of the Australian people and the environment by finding out the risks to occupational health and safety, to public health and to the environment that could be associated with the importation, manufacture or use of the chemicals; and
- providing information, and making recommendations, about the chemicals to Commonwealth, State and Territory bodies with responsibilities for the regulation of industrial chemicals; and
- giving effect to Australia's obligations under international agreements relating to the regulation of chemicals; and
- collecting statistics in relation to the chemicals; being a system under which information about the properties and effects of the chemicals is obtained from importers and manufacturers of the chemicals.

Environmental and health effects as they relate to an industrial chemical are defined in the Act (Part 1 Preliminary section 5). Environmental effects are defined as effects 'on the environment of the importation, manufacture, handling, storage, use or disposal of the chemical'.

Health effects are defined as effects 'on occupational health and safety or on public health of the importation, manufacture, handling, storage, use or disposal, of the chemical'.

The Act is in addition to (and is not a substitution for) the requirements of any other law of the Commonwealth – with the Criminal Code applying to all offences against the Act.

The penalties specified under the Act can be applied to natural persons or corporations for offences committed under the Act. The *Crimes Act 1914* provides that where a corporation is convicted of an offence against a law of the Commonwealth, the court may impose a penalty of up to 5 times the amount of the maximum penalty that could be imposed by the court on a natural person convicted of the same offence.

The Australian Inventory of Chemical Substances (AICS) is the legal device that distinguishes new industrial chemicals from existing industrial chemicals in Australia. All chemicals on the AICS are defined as existing chemicals, while industrial chemicals not included in the AICS are defined as new industrial chemicals and must be notified and/or assessed by NICNAS before they can be introduced, unless exempt under the Act. Naturally occurring chemicals are regarded as included on the AICS (section 12 (5)).

Currently, new industrial chemicals are listed on the AICS five years after a certificate is issued by NICNAS. Details about how chemicals are listed on the AICS is given in Section 8.3.

3. Priority Existing Chemicals

The Director (NICNAS) is required under section 54 of the Act to maintain a list of declared PECs.

An existing chemical may be declared a PEC by the Minister (Health and Ageing) under section 51(1) of the Act; subsequent to the recommendation of the Director.

3.1 Declaration of a PEC

To declare an existing chemical a PEC, specific procedures must be undertaken in accordance with the Act.

The collection of information used in the consideration of a PEC declaration occurs under section 48(1) of the Act. The Director may place a notice in the *Chemical Gazette* calling for information about an existing chemical that is being considered for declaration as a PEC.

The *Chemical Gazette* notice will include details of the persons who are required to provide the information and the period in which the information is to be provided (the time frame specified must be at least 28 days).

Relevant available information on the human health and environmental effects of the chemical is consequently collected, together with data on quantity, human and environmental exposure and control measures. A summary of information provided from the Director's call for information is published by NICNAS in the *Chemical Gazette*. Under 50(A) of the Act this occurs within 90 days after the day on which the last information is required.

After consideration of the information received from this call for information, the Director may recommend to the Minister that an existing chemical be declared a PEC. If the recommendation is accepted, the Minister declares the existing industrial chemical a PEC by a notice in the *Chemical Gazette*.

3.2 Assessment of a PEC

The PEC declaration in the Chemical Gazette describes the matters that are to be taken into account in the assessment of the PEC. For example, the assessment may be of a single PEC or a group of PECs (section 51 2 e); or the assessment may be either a full or a preliminary assessment (section 51 2 b).

A full PEC assessment addresses the hazards and risks of the chemical(s). The matters that need to be taken into account in preparing a full PEC assessment are described in section 51 5 of the Act.

A preliminary PEC assessment is less detailed as it is tailored to particular aspects of the chemical and does not include a risk assessment. This type of assessment may be for a specified use(s) or apply to the PEC only when it is manufactured, handled, stored or used in a specified geographical area or in specified circumstances (section 51 2).

A preliminary assessment may be a health or environmental. A description of the matters that may be taken into account in preparing a preliminary assessment is described in section 51 paragraphs (3)(a) to (d) of the Act.

A PEC declaration creates obligations for those importing or manufacturing the chemical to apply for assessment (within 28 days of the declaration) and provide information. Once a PEC is declared, section 55 of the Act requires all those who wish to continue to manufacture or import the chemical while it is a PEC, to apply for assessment of the chemical.

Under section 58 of the Act, the Director then calls for the information required for the PEC assessment. If a need for further information is identified, a further notice may also be published after a PEC assessment commences.

If the Minister has reasonable grounds to believe that an activity involving a PEC gives rise to an unacceptable risk of adverse health effects or adverse environmental effects, the Minister must prohibit the particular activity (while it is a PEC) by a notice in the *Chemical Gazette*.

To finalise a PEC assessment, specified procedures and time frames are set out in the Act (Figure1). Once these are met, publication of the final PEC assessment report revokes the declaration of the chemical as a PEC.

A PEC may be removed from the AICS by the Director under section 68 of the Act. This may occur where:

- a chemical has been a PEC for at least 12 months; and
- an application for the assessment of the chemical has not been received; and
- the Director has not caused the chemical to be assessed.

4. Appeal Provisions

There are a number of appeal provisions within the Act that pertain to the Program. These provisions allow for interested parties to appeal decisions made by the Director (NICNAS) to the Administrative Appeals Tribunal (AAT).

The AAT provides independent review of a wide range of administrative decisions made by the Australian Government (and some non-government bodies). It decides

whether the correct decision has been made in accordance with the applicable law and will affirm, vary or set aside the original decision.

As regards the Program, applications may be made to the AAT for the review of:

- the declaration of PECs: section 51(1);
- extending the period for assessment and report by up to 6 months if it is not reasonably practicable for the assessment to be carried out thoroughly, and the report completed, within the period: section 57(6) for PEC assessments and section 68A(6) for assessment of PECs of which secondary notification is required; and
- prohibition of a priority existing chemical until assessment complete: section 61(2) for PEC assessments and section 67(1)(b) for assessment of PECs of which secondary notification is required.

In addition, an application may be made to the AAT for review of a decision by the Director for the purposes of:

- obtaining information for a PEC assessment: section 58(3);
- variation of a draft PEC assessment report: section 60E(5);
- requiring a secondary notification: section 65(1) or section 65(2); and
- disclosure of exempt information: section 79(a).

Information about the AAT, how to apply to the AAT, and legislation and jurisdiction of the AAT is accessed through the AAT Internet site at: <http://www.aat.gov.au/>

5. Secondary Notification

All chemicals that have been assessed by NICNAS (both new and existing chemicals) are subject to secondary notification. Once a chemical is assessed, the assessment report will recommend the secondary notification of the chemical in certain circumstances specified in the report.

If a person becomes aware of these particular circumstances, or any of the other circumstances that are specified in section 64(2) of the Act (listed below), that person will be required to notify the Director within 28 days of becoming aware of these circumstances.

Section 64(2) of the Act sets out the following circumstances requiring notifying the Director in writing within 28 days:

- s64 (2) (a) the function or use of the chemical has changed, or is likely to change, significantly;
- s64 (2) (b) the amount of the chemical being introduced has increased, or is likely to increase, significantly;
- s64 (2) (c) in the case of a chemical not manufactured, or proposed to be manufactured, in Australia at the time of the assessment—it has begun to be manufactured in Australia;
- s64 (2) (d) the method of manufacture of the chemical in Australia has changed, or is likely to change, in a way that may result in an increased risk of adverse health effects or adverse environmental effects;

s64 (2) (e) additional information has become available to the person as to the adverse health effects or adverse environmental effects of the chemical;

s64 (2) (f) a prescribed event has happened.

Once any of these circumstances are notified to the Director, the Director may decide to require the secondary notification of the chemical. The Director will do so by notice in the Chemical Gazette, which must specify the information about the chemical that is to be given by way of secondary notification.

6. Compliance Issues Relevant to Existing Chemicals

6.1 Compliance & PECs

Contravention of a call by the Director for information to provide certain relevant information about an existing chemical, which is being considered for declaration as a PEC attracts a penalty of up to \$6,600 for individuals or \$33,000 for corporations under s48(7) of the Act.

Those who fail to comply with a call for information about a chemical that has been declared a PEC face the same penalties under s58(8).

Section 56 of the Act provides that it is an offence for introducing a PEC without applying for assessment. This attracts a penalty of up to \$33,000 for individuals and \$165,000 for corporations.

If an importer or a manufacturer fails to comply with a notice prohibiting a particular activity¹ while a chemical remains a PEC they will be liable for fines of up to \$33,000 for an individual or \$165,000 for a corporation. If the same offence is committed by a person other than an importer or manufacturer, fines of up to \$26,400 will apply to an individual or \$132,000 to a corporation.

6.2 Compliance & Secondary Notifications

A person must notify the Director within 28 days of certain specified circumstances occurring, which give rise to the obligation of secondary notification. Failure to do so attracts a penalty of \$13,200 for individuals and \$66,000 for corporations.

If a person fails to provide information to the Director regarding the secondary notification of a new or an existing chemical, in contravention of a notice in the Gazette to do so a penalty of \$3,300 applies for individuals and \$165,000 for corporations.

Failure to give secondary notification about a chemical where required will result in the following:

- in the case of a new industrial chemical the Minister may give written notice to a person suspending the assessment certificate or introduction permit held by that person for that chemical AND an individual will be fined up to \$13,200 and a corporation will be fined up to \$66,000;

¹ s61 provides that “activity”, in relation to a PEC includes the importation, manufacture, use, handling or storage of the chemical.

- in any other case (including PECs) an individual will be fined up to \$13,200 and a corporation will be fined up to \$66,000 and the Minister may prohibit the importation and manufacture of the chemical by that person.

Where a person complies with the requirements for secondary notification after receiving such a notice, the Minister will revoke the notice as soon as is reasonable practicable.

A table summarising Offences and Penalties under the Act as they relate to the Existing Chemicals Program is given in Appendix 1.

7. Enforcement of requirements under the Act

7.1 Inspectors Powers

NICNAS inspectors may enter any premises, with the consent of the occupier, for the purposes of monitoring compliance with the Act. If the occupier of the premises does not give his/her consent to NICNAS inspectors to enter the premises, a warrant may be obtained to do so. To the extent that it is reasonably necessary to monitor compliance with the Act an inspector may:

- search the premises;
- take photographs, or make sketches, of the premises or any substance or thing at the premises;
- take and keep samples of any substance at the premises;
- inspect any record or document kept at the premises; or
- remove, or make copies of, any such record or document.

Where an inspector has reasonable grounds for suspecting that, on a premises there may be evidence of an offence having been committed under the Act, the inspector may:

- with the consent of the occupier of the premises; or
- under a warrant

enter the premises and search the premises for the particular evidence. If the inspector finds the evidence on or in the premises the Act also authorises the inspector to seize the evidence.

7.2 Injunctions

Where a person has contravened or is proposing to contravene the Act, an application can be made to the Federal Court for an injunction restraining the person from engaging in the particular conduct or requiring the person to do a particular act or thing. An application for an injunction can be made by any person (including the Minister). The Court will grant the injunction where it believes that it is desirable to do so.

8. 'Exempt Information' and 'Confidential Information' under the Act

Under the Act, certain information provided by industry to NICNAS can be protected by confidentiality provisions under the legislation. To be protected by these

confidentiality provisions, the information must be considered “Exempt Information” or it must be included in the confidential section of the AICS.

8.1 Exempt Information

Applications can be made to the Director for certain information (e.g. providing information about a PEC, in relation to a secondary notification, or information provided in response to a call for information (S48) to be treated as ‘Exempt Information’.

If the Director is satisfied that:

- publication of the information specified in the application could reasonably be expected to prejudice substantially the commercial interests of the applicant; and
- the prejudice outweighs the public interest in the publication of the information

the information will be treated as exempt information for the purposes of the Act.

8.2 Treatment of exempt information

NICNAS officers who have access to exempt information must not make a record of, or disclose any of the information except:

- in the course of carrying out functions and duties under the Act; or
- by order of a Court; or
- with the consent of the person who gave the exempt information.

Section 79 of the Act also sets out certain circumstances where exempt information can, and in fact *must*, be disclosed if requested by an inquirer. These circumstances arise where the Director:

- is satisfied that the inquiry is to get information for the protection of occupational health and safety, public health or the environment; and
- is satisfied that the public interest in disclosure outweighs any commercial interest of the person because of whose application the information is exempt information; and
- has consulted the person/authority/foreign scheme that gave the exempt information.

The Director must also disclose exempt information if the Director is satisfied of the matters referred to in dot point one and two above and believes that delaying the disclosure to hold the consultation(s) could result in danger to a person's health or safety or to the environment.

8.3 Confidential Section of Inventory

Under the Act, chemicals are listed on the AICS 5 years after an assessment certificate is issued. The Director writes to each holder of an assessment certificate at least 28 days before the chemical is listed on the AICS, informing them of the proposed inclusion and informing them of their right to make an application to the

Director for inclusion of the chemical in the confidential section. If the Director is satisfied that:

- the publication of some or all of the chemical's particulars could reasonably be expected to prejudice substantially the commercial interests of the applicant; and
- the prejudice outweighs the public interest in the publication of those particulars

the Director must include the chemical in the confidential section of the AICS.

An industrial chemical in the confidential section must be transferred to the non-confidential section on the fifth anniversary of its inclusion date, unless a successful application is made to the Director for the inclusion of the chemical in the confidential section to continue. The above criteria must be met for an application to be successful.

8.4 Treatment of chemicals that are listed in the confidential section of the AICS

NICNAS officers must not publish or disclose any of the particulars recorded in the confidential section of the AICS in relation to a chemical except:

- in the course of carrying out functions and duties under the Act; or
- by order of a Court; or
- with the consent of the holders of a confidence about the chemical.

Further, where a person makes a written inquiry to the Director about whether a particular industrial chemical that is not included in the non-confidential section of the AICS is included in the confidential section, and the Director is satisfied that the person intends to introduce the chemical, the Director may answer the inquiry.

8.5 Disclosure of Exempt Information to the States and Territories

As discussed above, exempt information can be disclosed by NICNAS officers for the purposes of carrying out functions and duties under the Act, such as carrying out compliance/enforcement activities. In terms of providing information to Commonwealth, State and Territory authorities for their own enforcement purposes, this is specifically covered under the Act and can be provided as long as there are arrangements in place under which the authority is not to disclose any exempt information in the report except:

- in the course of carrying out functions and duties under a law of the Commonwealth, the State or the Territory relating to industrial chemicals; or
- by order of a court; or
- with the consent of the person who gave the exempt information.

Appendix 1

Offences and Penalties under the Act as they relate to the Existing Chemicals Program

Section	Offence	Maximum penalty for an individual	Maximum penalty for a corporation
s48(7)	Contravening a notice requesting information about potential PECs	\$6,600	\$33,000
s56	Introducing a PEC (without applying for assessment under s55)	\$33,000	\$165,000
s58(8)	Contravention of a call for information about a PEC	\$6,600	\$33,000
s61(4)	Failure of an importer or manufacturer to comply with a notice prohibiting an activity while the chemical remains a PEC	\$33,000	\$165,000
s61(5)	Failure of a person other than an importer or manufacturer to comply with a notice prohibiting an activity while the chemical remains a PEC	\$26,400	\$132,000
s64(1)(2)	Failure to notify the Director within 28 days of certain specified circumstances occurring giving rise to the obligation of secondary notification	\$13,200	\$66,000
s67	Failure to comply with secondary notification requirements <ul style="list-style-type: none"> • in the case of a new industrial chemical • in any other case 	Minister may suspend any assessment certificate or introduction permit held by the person for that chemical AND \$13,200 Minister may prohibit the importation and manufacture of the chemical by that person. AND \$13,200	Minister may suspend any assessment certificate or introduction permit held by the person for that chemical AND \$66,000 Minister may prohibit the importation and manufacture of the chemical by that person. AND \$66,000

Section	Offence	Maximum penalty for an individual	Maximum penalty for a corporation
s67(2)	Introduction of a chemical in contravention of a notice by the Minister prohibiting importation and manufacture of the chemical	\$13,200	\$66,000
s69	Contravention of a notice by Director in the Gazette requiring information re secondary notification of new or existing chemicals	\$6,600	\$33,000
s106(5)	Introduction or export of chemical in contravention of a Regulation made under s106 (i.e. a Regulation that bans or restricts a chemical that is the subject of an international agreement)	\$33,000	\$165,000

Figure 1 Procedures for the finalisation of Priority Existing Chemical Assessment Reports

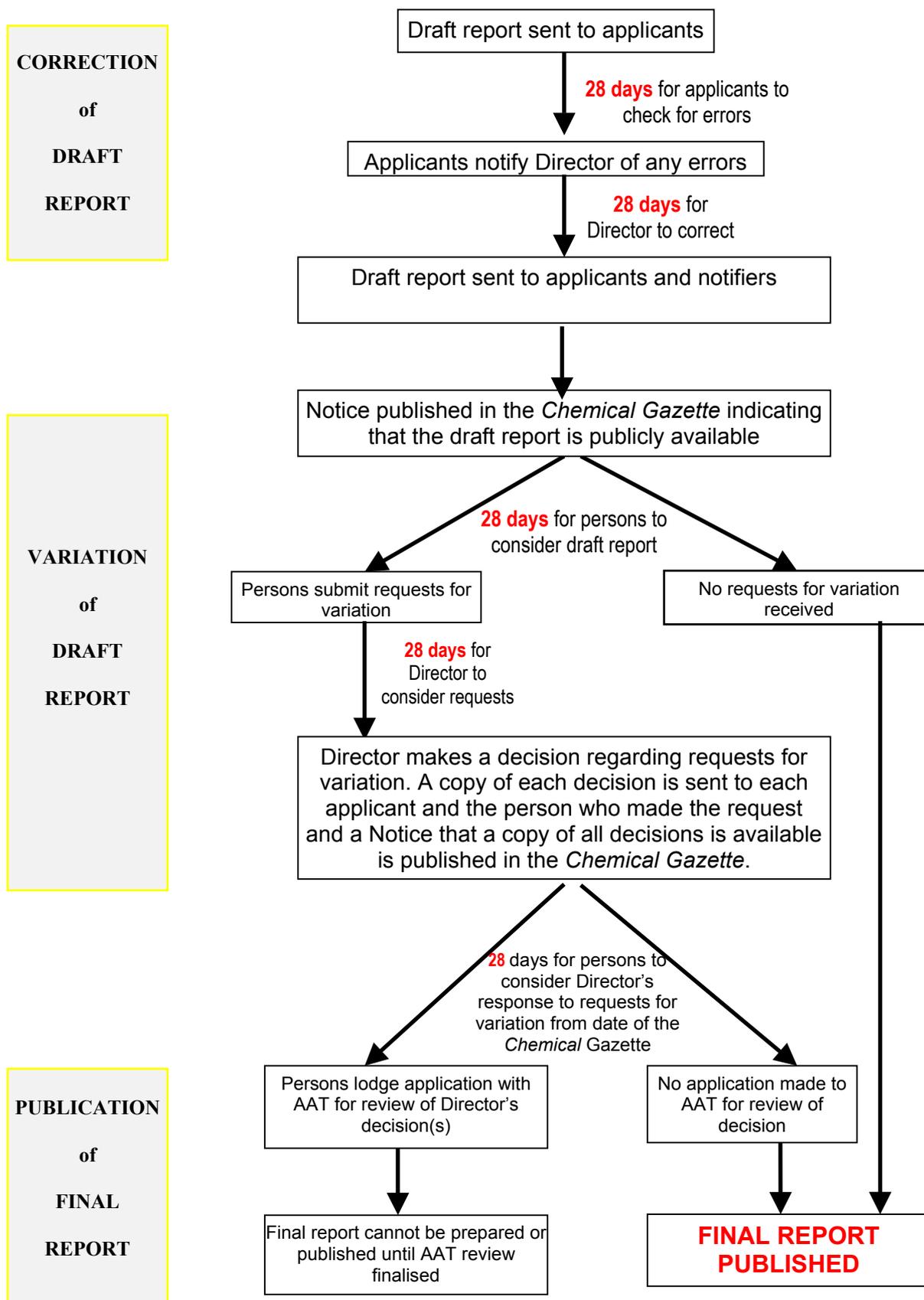


Figure 2 The range of assessments produced by the Program

