



Australian Government
Department of Health and Ageing
NICNAS

ANNUAL REPORTING OF EXEMPTION CATEGORY CHEMICALS

Proposed Model of Implementation

PUBLIC COMMENT PAPER

Purpose

This document outlines NICNAS' proposed model for implementation of annual reporting requirements, introduced under subsections 21(4) and 21(6) of the Industrial Chemicals (Notification and Assessment) Act 1989 (the Act). NICNAS has identified certain issues associated with the reporting where consultation with stakeholders would assist in implementing a model that meets the objective of the reporting requirements without placing an unnecessary burden on reporting parties.

Scope

This document relates only to the annual reporting requirements associated with chemicals introduced under exemptions outlined in section 21 of the Act, the reporting requirements outlined in section 21AA, and the publication requirements under section 21AB. This document does not address the reporting requirements for permits and certificates required under section 40N of the Act. An online facility for the electronic lodgement of annual reports under section 40N is expected to be available from early September.

Background

Amendments to the Act in 2004 introduced a range of exemptions that allows importers and manufacturers of industrial chemicals that pose a low risk to human health and the environment to be introduced without notification to NICNAS. These exemptions, for low-risk chemicals introduced at a quantity not exceeding 100 kg/year/introducer, or less

than 1% in cosmetics, are outlined in subsections 21(4) and 21(6) of the Act. To ensure the ongoing health, safety, and environmental protection from the use of these chemicals, the requirement for introducers to report these new chemicals and their quantity every 12 months for the previous registration year (1 September – 31 August) was introduced.

The annual reporting requirement has for the first time imposed NICNAS obligations on small volume research and educational users of chemicals such as Universities. The new reporting requirements are also expected to impact on certain industry sectors, such as the cosmetics industry, which already utilise the exemption provisions of the Act.

The reporting requirements are outlined in Section 21AA of the Act. The Director is required to maintain and publish a list of these chemicals and their volumes during the following registration year. This requirement is outlined in Section 21AB of the Act. Sections 21 to 21AB are reproduced in Attachment 1.

Work to Date

Independent Impact Assessment

NICNAS engaged the services of Professor Ian Rae of Melbourne University Private Ltd, to consult with the research and education sector. The aim of the consultancy was to assess the magnitude of the impact of the annual reporting requirements and the main reporting issues of concern to this group of stakeholders. The research and education sector has been identified as one of the groups where a special reporting arrangement may need to be implemented due to potentially high numbers of experimental chemicals being developed for research but not for commercial use. The consultant's report (the Rae report) highlights aspects of the reporting requirements which may require special consideration, in particular:

- the need to establish a lower reporting threshold; and
- confidentiality issues associated with the publication of chemical names in the *Chemical Gazette*; and
- the semi-autonomous nature of multi-divisional organisations and the requirement for independent reporting by each division.

Relevant extracts from this report are reproduced in italics throughout the discussion paper.

Stakeholder Consultation

With the recommendations of the Rae report addressed and incorporated into a model for implementation, NICNAS sought initial comments from its Technical Advisory Group. The Technical Advisory Group is comprised of independent members recognised for their expertise and knowledge of chemicals and regulation and aspects of public interest and commercial interest issues.

NICNAS has also consulted with representatives from industry on the proposed model and continues to work with industry representatives to provide a means of reporting which will provide NICNAS with valuable statistics on low volume chemical use in Australia.

Proposal

NICNAS is proposing a web based method of reporting where organisations/companies can log into a portal via the NICNAS website and either enter reporting data or upload report files from the user's PC. The annual reporting module is expected to be the first of a number of electronic transaction modules NICNAS plans to introduce in forthcoming years with further modules being on-line registration renewal, High Volume Industrial Chemical Reporting and 10-100kg cosmetic and non-cosmetic notifications. It is envisaged that the aggregation of these online functions will be accessed via a common Business Entry Point in the future, however, due to the approaching due date for annual reporting prescribed in the legislation, it is expected that annual reporting will be the sole module available through the business entry point in the first instance. NICNAS is currently working in partnership with software development consultants to build the necessary web framework, security architecture and additions and modifications to the current NICNAS database to enable the compilation, storage and validation of this data, and the generation of reports.

Reporting Threshold

The upper reporting threshold of 100 kg per year is stipulated in the legislation; however no lower threshold is stipulated. Consultation with major research and education facilities confirms the large number of research chemicals developed and/or imported at minute quantities.

“Most new industrial chemicals, as many as 6000 a year, are prepared in research laboratories, mainly in universities. The scale of production is small, mostly less

than 1 gram. In addition, these laboratories import an unknown (but possibly large) number of new chemicals every year.”

Professor Rae’s report indicates that requiring reporting of every chemical “introduced” by universities (i.e. no lower threshold) would place a very large burden on the universities and other affected organisations, and would overtax the resources of NICNAS, which is responsible for the administration of the system, in the compilation of data in the initial years.

“It is suggested that NICNAS might establish minimum reporting requirements that would avoid over-regulation and also flooding of the agency with unimportant data, since industrial, community and environmental health are not threatened by the small quantities involved in most research and development. The Australian Pesticides and Veterinary Medicines Authority, for example, maintains reporting limits of 10 kg for agricultural chemicals and 3 kg for veterinary chemicals.”¹

“The concept of reporting levels based on minimum quantities is thus well established and in some form should be adopted by NICNAS as it implements its new responsibilities.”

The additional benefit to NICNAS and stakeholders from annual exemption reporting diminishes for minimal quantities. The risk to workers, the environment, and public health is expected to be very low for chemicals used in the small quantities involved in research and development, as the chemicals used in the laboratory are managed by highly trained professionals in a controlled environment, and is not released for wide dispersive use.

“...one should keep in mind that a major function of the NICNAS is to protect health and safety in the workforce, in the community and in the environment. New chemicals are produced in small quantities, for the most part less than one gram, in research laboratories are never released to the community or the environment and are managed by highly skilled researchers for whom the occupational risks are low.”

The establishment of a lower reporting threshold would align NICNAS with other regulatory agencies such as the APVMA. Additionally, even with the introduction of the 100g threshold, NICNAS maintains a greater level of control over chemicals introduced under an exemption than is required by other new chemicals notification schemes (Table 1.)

1. While reporting is not required, it should be noted that detailed record keeping, including the name and quantity of the chemical, is required by APVMA.

Based on data and recommendations provided by Professor Rae, NICNAS proposes to introduce a lower reporting limit of 100 g in the first instance for chemicals which are introduced for research² or development³. This threshold may, however, be reviewed in forthcoming years. The lower reporting threshold will not apply to chemicals introduced for commercial purposes such as those introduced in cosmetic formulations or for industrial use.

Country	Legislation	Notification Threshold	Reporting Threshold
US	Toxic Substances Control Act	Research & Development: No quantity restriction but company must notify persons involved with R&D of any known health risks. Low Volume <10 000 kg: User is required to submit notice of intent to manufacture Low Release and Exposure (LoREX) Exemption: Independent of volume	Record keeping requirements only above 100 kg. Record keeping requirements only. Record keeping requirements only.
Canada	Canadian Environment Protection Act, 1999	Low Volume Exemption: <100 kg	Research and Development: Reporting required >1000 kg. Requires certain data.
EU	Proposed Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)	Low Volume Exemption: <1000 kg R & D Exemption: 5 years (no volume) – extendable to 10 years. Certain information required.	None. None.

Table 1. Notification and reporting thresholds under foreign chemical notification schemes.

Data Requirements

The legislation prescribes the name of the chemical and quantity as minimum requirements for annual reporting of exemptions. CAS Numbers will also be requested by NICNAS as this will assist in the validation of the data. To increase the utility of the data for both NICNAS and the community, a description of the use category and use setting (industrial, domestic or both) of the chemicals will also be required in order to develop and maintain an awareness of the fate and mode of use of these chemicals.

2. Research, under the Act, does not include research for the purpose of determining market acceptance or consumer preferences.

3. Development, under the Act, does not include tests that relate solely to the commercial evaluation of a product or process.

Industry Sector

The industry sector of the organisation may also be used to group chemicals for publication purposes. For NICNAS registered companies, their primary industry sector will be automatically retrieved from their registration details. At present non-profit R&D and educational institutes are not required to be registered with NICNAS but are expected to establish their identity with NICNAS prior to initial reporting.

Reporting Quantity

Certain groups have raised concern about the administration required to track the exact quantity of a chemical introduced under an exemption. In addition to reporting exact quantities in kilograms of the chemical, it is suggested that NICNAS provides the option of reporting the quantity in bands, that is, ≤ 10 kg or $>10-100$ kg. While this will reduce the administration associated with reporting the quantity of the chemical, it should be pointed out that use of these bands will result in an overestimate of aggregated quantities. Those cosmetic chemicals introduced at less than 1% but greater than 100 kg will need report exact quantities in kilograms.

NICNAS is therefore **seeking comments** from affected sectors as to the usefulness of:

1. Reporting quantity by exact kilogram quantities; or
2. Providing the option of reporting quantity in bands of ≤ 10 kg or $>10-100$ kg.

Registration for use of the module

As mentioned above, non-profit R&D and educational organisations are not required to be registered with NICNAS. In order to access the annual reporting module it is proposed to make use of information already held in the NICNAS database for user ID verification (for example, NICNAS registration number, email address, ABN). It is proposed that non-profit R&D and education organisations provide their details to NICNAS (at no cost to the organisation) in order to receive a NICNAS identification number and have their details recorded on the NICNAS database.

To obtain a NICNAS Organisation Number, a user first accesses the 'sign-in' page via a link from the NICNAS home page. An example of a 'sign-in' page is presented in Figure 1.

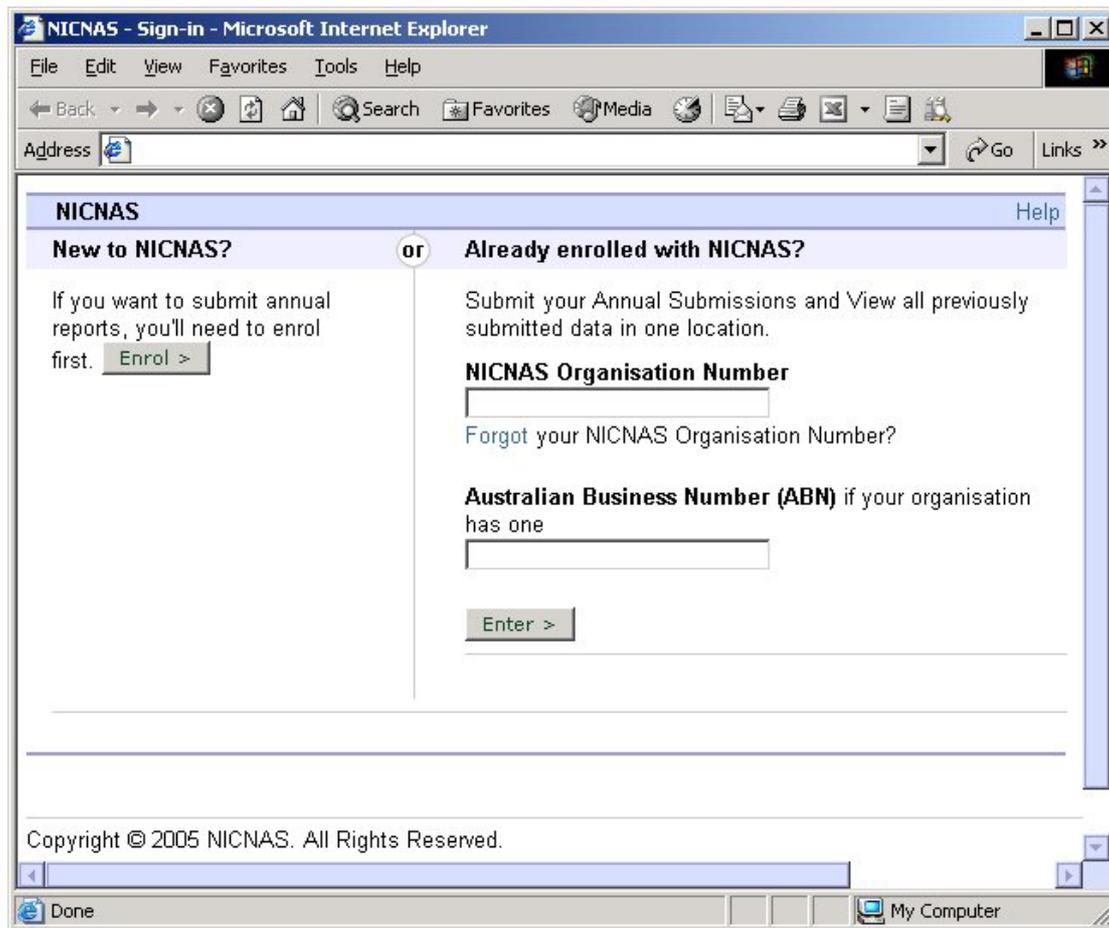


Figure 1. Sign-in page (CSA, 2005)

At the 'sign-in' page the user clicks on the 'Enrol >' button. The user is presented with a 'Enrolment' page that requires the user to enter data. An example of an 'Enrolment' page is presented in Figure 2.

On submission of the Enrolment form, the system sends an e-mail to the entered e-mail address. The user is expected to acknowledge receipt of that e-mail which will confirm that the e-mail address is a genuine one. On acknowledgement of receipt of the e-mail, the NICNAS Organisation Number is generated and the user is notified. The reporter will use the NICNAS Organisation Number when they wish to gain access to view historical Annual Report submissions or submit a new Annual Report.

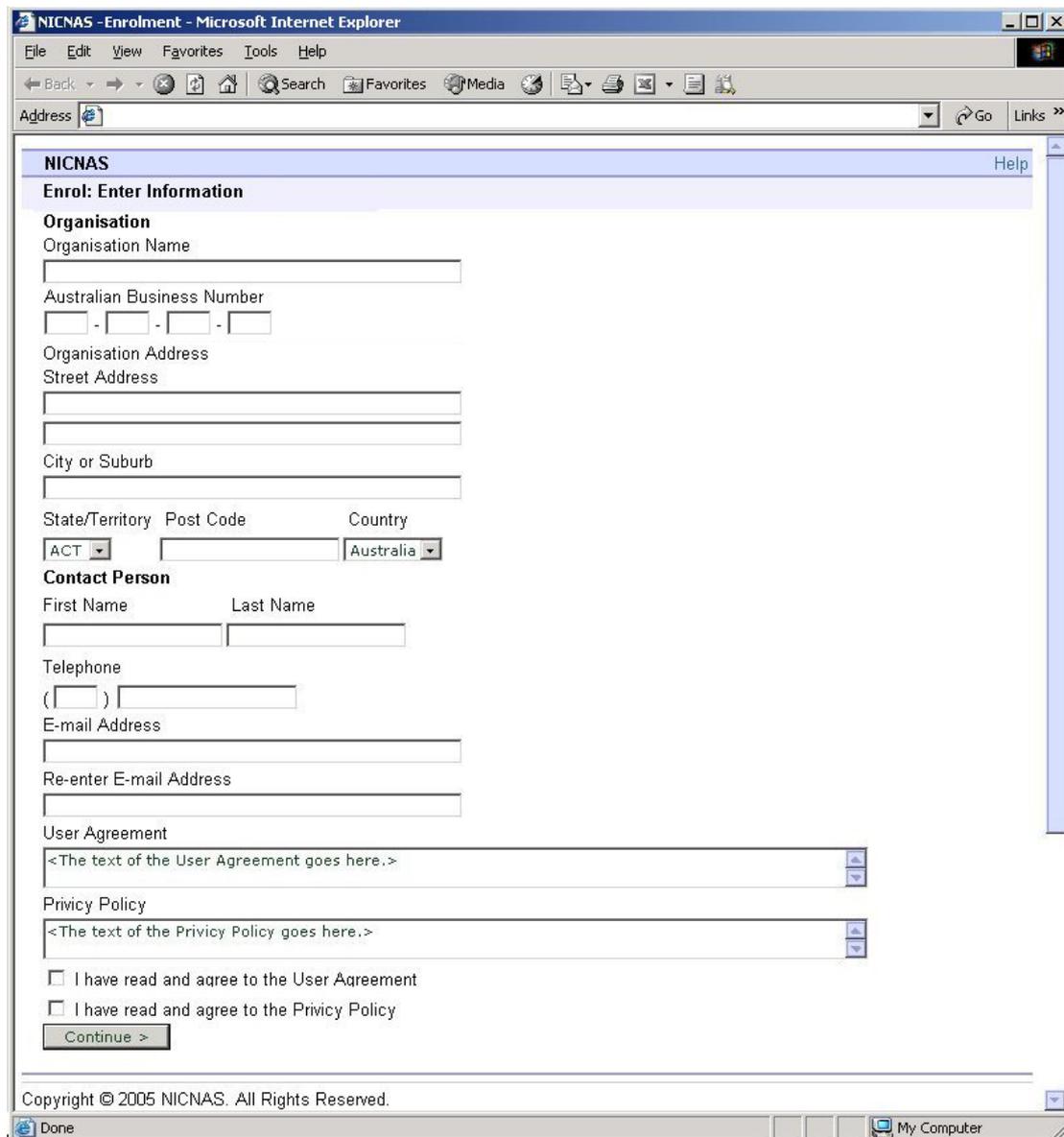


Figure 2. Enrolment Page (CSA, 2005)

Security

The security controls applied to the registration and data access processes have been chosen to reflect the determined level of risk whilst bearing in mind the need to make the facilities afforded by this website as accessible to industry participants as possible.

The registration and data access processes have modest security controls applied. Supply of an ABN and a NICNAS Organisation Number will grant a user access to a Divisional Annual Report Access page. Access from there to a division's data is protected by a single dedicated password which will be set by the user.

NICNAS has not deemed it necessary, at this stage, to require Industry Participants to avail themselves of a Digital Certificate in order to provide NICNAS with trustworthy authentication of remote parties. In subsequent years a higher degree of security may be implemented to ensure the confidentiality of data from previous reporting years between the reporter and NICNAS. This higher level of security will also be required for other business entry point features such as online registration renewal.

Third-Party Information

NICNAS is aware that some introducers are not privy to the exact chemical details of their chemicals or products, and rely on overseas parents or other suppliers to provide NICNAS with technical data. In these cases provision will be made to allow the supplying companies to provide the details to NICNAS in strict confidence.

The reporting page will allow users to elect nominate chemicals for which confidential data is retained by their supplier. Nomination of these chemicals triggers the generation of a form for the reporter to forward to their supplier for completion and return to NICNAS. The details provided to NICNAS by the supplier will not become part of the report provided back to the user in later years. It will be the responsibility of the reporting company to ensure that third-party data are provided.

Reporting by different divisions of the one organisation

NICNAS is aware of organisations consisting of several separate departments/divisions. The degree to which these divisions are able, or do, communicate and coordinate regulatory and other requirements may vary widely. In the case of the annual reporting requirements, several of those departments may be subject to the requirements with little or no knowledge of other departments' reporting requirements.

“The reporting function would need to take account of the semi-autonomous nature of much university research, and to require each researcher to report would be to run the risk that through oversight and lack of infrastructure support at research group level there would be no report. To require aggregation at faculty level (through the office of the Dean) or university level (through the office of the Deputy Vice-Chancellor (Research)) would place an onerous burden on the organisations at either level”

This is expected to be also relevant for the Government research sector, for example, CSIRO who have several independent research divisions sharing a single ABN. NICNAS is therefore **seeking guidance** from affected sectors as to the practicality of:

1. Restriction to one registered user per organisation able to login to the annual reporting module. Submissions of all departments/divisions would need to be coordinated by a single person or section; as opposed to
2. Registered users in each department/division would independently lodge annual reports for their section as required.

The proposed method for multi-divisional reporting by an organisation involves the reporting party entering via the 'Sign-in' page where they are required to submit a NICNAS Organisation Number and an Australian Business Number (ABN) (if applicable). If the entered NICNAS Organisation Number is invalid or does not correspond to the entered ABN then the Sign-in page is redisplayed, annotated with an appropriate failure message. The user is granted the opportunity to enter an alternative NICNAS Organisation Number and ABN (if applicable).

If the entered NICNAS Organisation Number and ABN (if applicable) are valid then the user is presented with the Divisional Annual Report Access Page for the organisation. An example is presented in Figure 3.

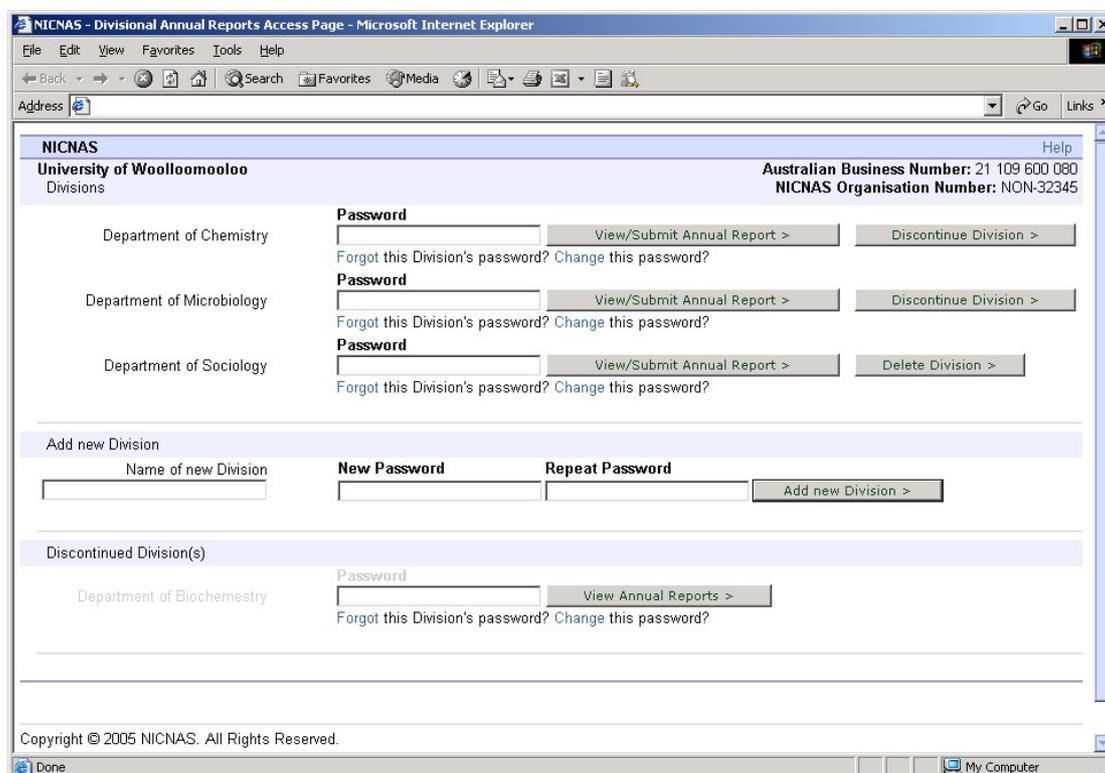


Figure 3. Divisional Annual Report Access Page (CSA, 2005).

In the top section of the Divisional Annual Report Access Page a list of all known divisions for the organisation is displayed. Initially this list will be empty. Against the name of each division appears a password box, a submit button, a 'change password' link, a 'can't remember' link and a 'discontinue' or 'delete' button. On entry of a valid password and clicking the appropriate submit button the user is taken to a page from which historical Annual Reports may be viewed and new reports may be submitted based on the previously reported chemicals. In the middle section is a facility to add a new division.

Provision will also exist to "retire" divisions for which no further submissions are expected. An organisation that has restructured or for which a division no longer exists will be able to use the 'Discontinue Division' button to retire the division. Thereafter historical reports for that division will be accessible via the entry in this bottom section. It will not be possible to submit new annual reports for that division. Discontinued divisions may not be resurrected.

Publication of the List

Section 21AB of the Act (Attachment 1) outlines the requirement for the publication of the list of chemicals provided in reports under section 21 AA. At present there is no provision for information reported under these exemptions to be treated as exempt information in accordance with section 75 of the Act. The Rae report discusses concerns associated with publication of chemical names in the *Chemical Gazette*.

"Confidentiality will be a serious issue for that portion of university and CSIRO research which is industry linked and for organisations like CRCs (Cooperative Research Centres) and small innovative companies. For these groups, the chemicals produced in small-to-medium quantities through pilot scale operations or produced in laboratories that provide material for evaluation are precisely those that the potential notifiers might not wish to see publicly reported."

"Full disclosure of the nature and quantity of a low volume chemical introduced in a particular year, even if this information is not linked to particular companies, would be held by the introducer to be detrimental to business. This conclusion is based on other cases known to the reviewer where arguments have been put forward that, with only a small number of suppliers in a particular field, even the disclosure of the name of a chemical could provide advantage to competitors who would be so-informed of new developments."

In addition to issues of confidentiality, NICNAS believes greater value would be obtained from the list by publication of aggregated quantities grouped by use categories and industry sectors rather than an exhaustive list of chemical names. Publication of such a list would, in many cases, represent a duplication of information readily available from the product catalogues of commercial specialty chemical suppliers.

Additionally, as this is the first exercise in collection of the names of research and development chemicals (these chemicals were not required to be nominated at the inception of the AICS), data entry by reporters will be subject to typographical error and erroneous or inconsistent nomenclature; there will be a large amount of validation (by NICNAS) of this initial data required before a list can be aggregated and published. This validation is expected to be an ongoing exercise that would delay the publication of the list if chemical name were to be the attribute used to aggregate the data.

While the above measures will protect the commercial interests of companies introducing unique chemicals in small quantities, NICNAS suggests publishing the names of some chemicals for which there are lower confidentiality issues. The criteria for publication would therefore be introduction at an aggregated quantity above a certain level (eg >1000 Kg), introduction above a certain percentile of aggregated volume (eg top 5% by quantity) or aggregated number of users (eg. top 5% by number of users of the chemical). Such chemicals will need to be widely used in order to meet any of the above criteria and therefore the issues of confidentiality to any individual reporter are not expected to apply. The names of the organisations reporting these chemicals will not be published.

This proposed approach to publication of the exemptions is therefore designed to protect legitimate commercial interests of organisations reporting small quantities of proprietary chemicals while providing transparency for those chemicals whose aggregated quantities may be of interest from an environmental, OHS, or public health perspective.

Summary of the Reporting Procedure

At this stage of development, with some issues still to be addressed, the process for annual reporting of exemptions can be represented in Figure 4. Once organisations are registered or otherwise verified with NICNAS, access to the annual reporting can be gained via the NICNAS website. In the first year of reporting users will be preliminarily verified using certain fields from their organisation's details stored on the NICNAS database such as their NICNAS registration/organisation number and matching ABN. The user will then be asked to enter their division name or login on behalf of the whole organisation, and nominate a password for subsequent use. The user may then access a

web page where the exemption reporting fields can be populated. A method of uploading data via a specifically formatted spreadsheet is also being considered for organisations reporting on numerous chemicals. NICNAS **seeks comment** from industry as to the need for such a provision.

In subsequent years users can log on to the annual reporting module, report quantities against previously reported chemical names, add new chemicals, and delete any chemicals they are not expecting to report on in the future. This will be essential to maintaining validation of data particularly where approaches to third parties are required. Third-party data will not under any circumstances be divulged to the user.

Timing

While the online system for reporting of permits is expected to be ready for use by 1 September 2005, the reporting of exemptions will be phased in from September/October. In order to meet legislative obligations to report by 28 September 2005, NICNAS will soon be providing the means for a company to register its intention to submit their exemption report at a later date. Registration for exemption reporting will involve providing basic data such as estimates of the number of chemicals expected to be reported and committing to report by a later agreed date. Registration will therefore fulfil reporting obligations (provided later reporting is completed) and will provide NICNAS with information to assist in the phasing in of the reporting.

Feedback

NICNAS is seeking feedback on the proposed model for annual exemption reporting with specific reference to:

- Introduction of a 100g lower reporting threshold for chemicals introduced for non-commercial purposes;
- Proposed data requirements specifically provision of use information and optional banding of quantities;
- Method for registration of non-profit R&D and educational organisations;
- Proposed level of security with respect to online reporting;
- Single Vs Multiple reporting by organisations consisting of several divisions;
- Proposal for handling third party information;
- Proposal to publish aggregated quantities by use category rather than a list of chemical names.
- Proposed timeframe for implementation.

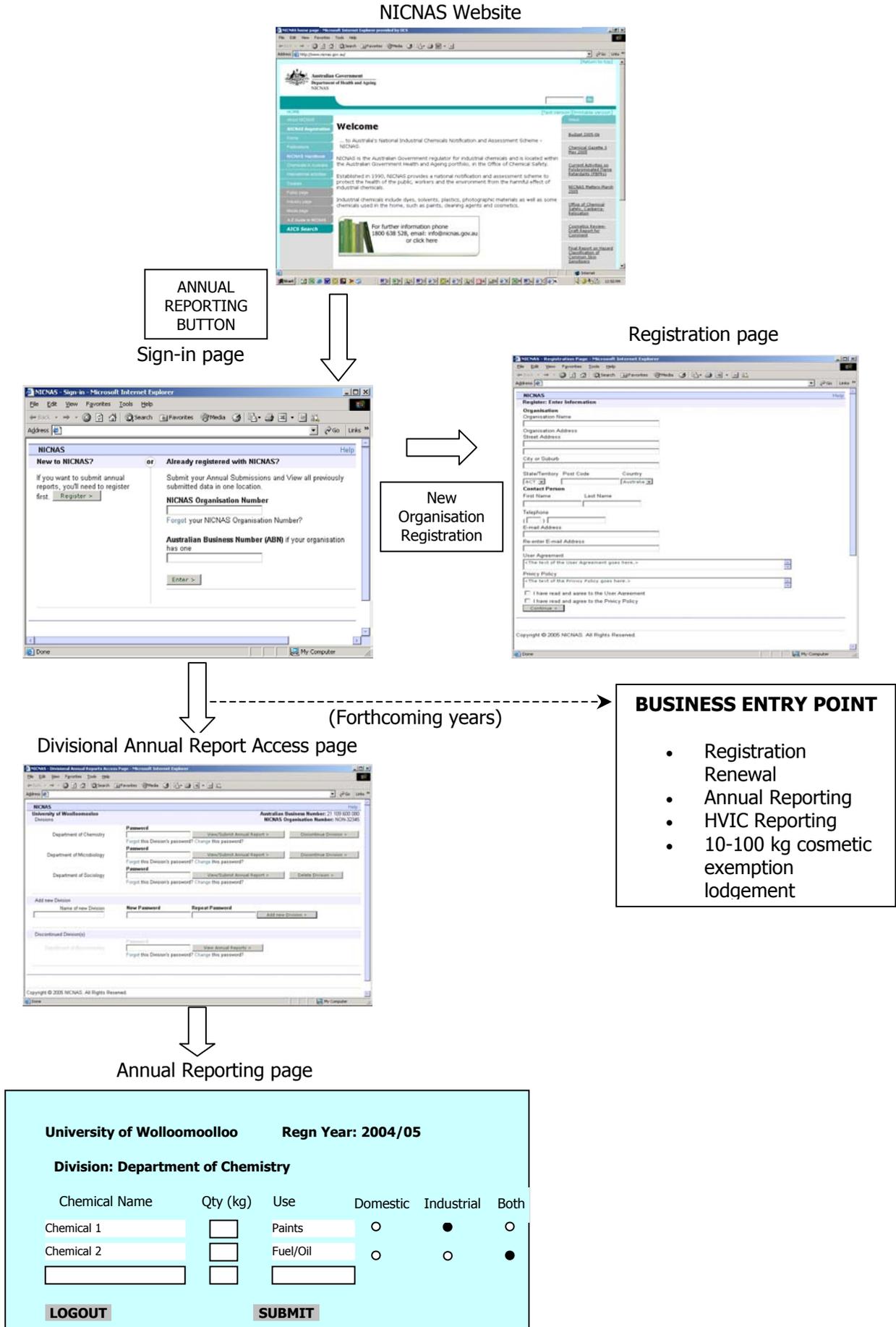
Written comments can be provided to:

Lewis Norman
Team Leader
Data Analysis and Information
NICNAS

Fax: 02 8577 8854
email: lewis.norman@nicnas.gov.au

Submissions should be received by 12 August 2005.

Figure 4. Summary of Reporting Process



References

Computer Systems Australia. 2005. NICNAS – D@N Annual Reporting Module. Discussion Paper Draft 0.1. 17 May 2005.

21 Introduction of new industrial chemicals

- (1) A person must not introduce a new industrial chemical.

Penalty: 300 penalty units.

- (1A) Subsection (1) does not apply if the person holds an assessment certificate in force in relation to the chemical.

Note: A defendant bears an evidential burden in relation to the matter in subsection (1A) (see subsection 13.3(3) of the Criminal Code).

- (2) Subsection (1) does not prohibit the introduction of a new industrial chemical in accordance with:

- (a) a commercial evaluation permit; or
- (b) a low volume permit; or
- (c) a controlled use permit; or
- (d) an introduction permit.

Note: A defendant bears an evidential burden in relation to the matters in subsection (2) (see subsection 13.3(3) of the Criminal Code).

- (3) Subsection (1) does not prohibit the introduction of:

- (a) a new industrial chemical imported solely for an excluded use within the meaning of section 7; or
- (b) a new industrial chemical manufactured in Australia:
 - (i) in an apparatus that is a fixture designed for producing one or more chemicals; and
 - (ii) in the course of a program of research, development or analysis; and
 - (iii) by a person who, before manufacturing the chemical, gave the Director information about the type and location of the apparatus, and a general description of the program and the type of chemical to be manufactured in the apparatus, and a description of all procedures for the safe disposal of the chemical and any hazardous degradation products derived from the chemical; or
- (e) a new industrial chemical that may be introduced under regulations referred to in paragraph 111(c).

Note: A defendant bears an evidential burden in relation to the matters in subsection (3) (see subsection 13.3(3) of the Criminal Code).

- (4) Subsection (1) does not prohibit the introduction by a person of an amount of new industrial chemical not exceeding 100 kilograms in a period of 12 months (either by itself or in a mixture with one or more other chemicals):
- (a) unless the person knows that the chemical poses an unreasonable risk to occupational health and safety, public health or the environment; and
 - (b) either:
 - (i) if the chemical is introduced in a cosmetic—if requirements (if any), prescribed in regulations made for the purpose of this subparagraph, relating to its introduction are met (including requirements relating to its use, packaging or labelling); or
 - (ii) otherwise—if requirements (if any), prescribed in regulations made for the purpose of this subparagraph, relating to its introduction are met (including requirements relating to its use, packaging or labelling).

Note: A defendant bears an evidential burden in relation to the matters in subsection (4) (see subsection 13.3(3) of the Criminal Code).

- (5) For the purposes of subparagraph (4)(b)(i) or (ii), different requirements may be prescribed in respect of different volumes of a particular chemical.
- (6) Subsection (1) does not prohibit the introduction of the following:
- (a) a new industrial chemical introduced by a person:
 - (i) solely for the purpose of research, development or analysis; and
 - (ii) in a quantity of not more than 100 kilograms in any 12 month period;
 - (b) a new industrial chemical:
 - (i) that is introduced by a person at a port or airport in Australia; and
 - (ii) that remains subject to the control of Customs (within the meaning of the Customs Act 1901) at the port or airport at all times before leaving Australia; and
 - (iii) that leaves Australia less than 30 days after the day of introduction;
 - (c) a new industrial chemical:
 - (i) that is a non-hazardous chemical; and
 - (ii) that is introduced in a cosmetic; and
 - (iii) whose concentration in the cosmetic is 1% or less; and
 - (iv) whose introduction meets any requirements, prescribed in regulations for the purposes of this subparagraph, relating to its introduction.

Note 1: A defendant bears an evidential burden in relation to the matters in subsection (6) (see subsection 13.3(3) of the Criminal Code).

Note 2: A person who introduces a new industrial chemical under subsection (6) is required to provide an annual report (see section 21AA).

21AA Annual reporting obligations for introductions under section 21

- (1) A person who introduces a new industrial chemical in a registration year under subsection 21(4) or (6) must provide a report to the Director stating:
 - (a) the name of the chemical that was introduced in the year; and
 - (b) the volume of the chemical that was introduced in the year.
- (2) The report must be provided before or on 28 September of the following registration year.
- (3) The report must be provided in the approved form.
- (4) A person commits an offence if:
 - (a) the person is required to provide a report in accordance with subsections (1) and (2); and
 - (b) the person fails to do so.

Penalty: 10 penalty units.

Note 1: A person does not commit an offence if the person fails to provide the report in the approved form.

Note 2: If a person does not provide the report in accordance with subsection (1) before or on 28 September, the obligation to do so continues after that date, with daily offences being committed until the obligation is complied with (see section 4K of the Crimes Act 1914).

- (5) Subsection 4K(2) of the Crimes Act 1914 ceases to apply in relation to an offence against subsection (4) of this section at the end of the 12th day after 28 September (being 10 October).

Note: Because of this subsection, 120 penalty units is the maximum penalty that can be imposed for offences against subsection (4).

21AB List of chemicals exempt under subsections 21(4) and (6)

- (1) The Director must maintain a list of:
 - (a) the names of the chemicals provided in each report under section 21AA for a registration year; and
 - (b) the volume of such chemicals.
- (2) At least once during the next registration year, the Director must publish the list in the Chemical Gazette.