

## 8 Reduced Fee Notifications

Under the circumstances listed below NICNAS may remit a part of the notification fees for **non-self assessed** Standard, Limited and Polymer of Low Concern applications:

- the notified chemical/polymer is similar<sup>1</sup> to a chemical/polymer which has been previously assessed by NICNAS; or
- the notified chemical/polymer is being notified at the same time as a chemical/polymer which is similar<sup>1</sup>; or
- an assessment of the notified chemical/polymer by Environment Canada and Health Canada under the *New Substances Notification Regulations (Chemicals and Polymers)* of the *Canadian Environmental Protection Act, 1999* is available; or
- an assessment of the notified chemical/polymer by a chemicals notification and assessment scheme operating in a member country of the European Union (EU) or the Organisation for Economic Co-operation and Development (OECD) is available; or
- an assessment of the notified chemical by the Therapeutic Goods Administration (TGA) of the chemical under the *Therapeutic Goods Act 1989* is available; or
- an assessment of the notified chemical by the Australian Pesticides and Veterinary Medicines Authority (APVMA) under the *Agricultural and Veterinary Chemicals Code Act 1994* is available; or
- an assessment of the notified chemical by Food Standards Australia New Zealand (FSANZ) under the *Food Standards Australia New Zealand Act 1991* is available; or
- The application is submitted using the appropriate and current version of the NICNAS electronic template.

Note: In the event that multiple circumstances apply, the reduced fee will not be additive. For example, if an application for a chemical that is similar<sup>1</sup> to a chemical which has been previously assessed by NICNAS, is submitted using the electronic template, a remittance in fees due to use of the electronic template will not apply.

### ***General application requirements***

An application may be made by completing “Attachment 1” of Form STD-1, LTD-1 and PLC-1, as appropriate. This attachment relates solely to the application for a reduced fees. Completion of this attachment does not fulfil the requirements of the notification itself.

In all cases, NICNAS must have consent from the notifier/holder of the data for the original assessment to use the assessment report for the purposes of the NICNAS assessment.

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<sup>1</sup> The term similar is defined by specific criteria in sections 8.1.3 and 8.1.4 below.

All NICNAS Schedule of data requirements must be addressed for the relevant assessment category. Except in the case where the chemical has been previously assessed by NICNAS, copies of all available toxicity data (including that which has been previously assessed) in English, must be provided to NICNAS.

### **8.1 Chemical/polymer similar<sup>1</sup> to chemical which has previously been assessed by NICNAS.**

The Director may remit up to 40% of the fee paid for an application for a non-self assessed certificate where the chemical/polymer being notified is similar<sup>1</sup> to a chemical/polymer that has been previously assessed by NICNAS. The Director may remit a further 20% of the fee paid if the chemical/polymer being notified also has the same, or similar, use to the similar chemical/polymer that has been previously assessed. The fee saving will be dependent on the scope of the original assessment. A reduction in fees does not apply where the original assessment was a self-assessment.

The criteria for similar chemical/polymer are detailed in sections 8.1.3 and 8.1.4 below.

#### ***8.1.1 Notification requirements***

The normal notification procedures (with the exception of payment) for a STD, LTD or PLC notification should be followed (see chapter 5). All NICNAS schedule of data requirements must be addressed for the relevant assessment category. Where a variation of schedule requirements was accepted for particular endpoint(s) in the original notification, an application for a variation of schedule of data requirements for the same endpoint(s) is not be required.

All available data on the notified chemical/polymer must be included as part of the submission. Information in the original assessment report can be used to address particular NICNAS Schedule of data requirements. The following data/information for the notified chemical/polymer itself is required to demonstrate that the criteria for similar chemical/polymer and similar use are met and for risk assessment purposes:

- The identity and composition of the chemical/polymer.
- Introduction and use concentrations
- Use information
- Estimated manufacture and import volume
- Matters affecting occupational health and safety, environmental impact and public health.
- Label and MSDS for the chemical/polymer in the form that it is introduced
- Melting (or boiling) point, particle size, and partition coefficient in the case of chemicals
- Particle size and water solubility in the case of polymers
- Acute oral toxicity (typically for Standard notifications)

- Acute aquatic toxicity for the most sensitive organism (typically for STD notifications).

More detail on the type of information required can be found in [Appendix 12](#) and in the appropriate NICNAS electronic notification template.

Please note: as there will always be a level of uncertainty associated with any chemical/polymer for which a complete suite of (eco)toxicological tests have not been performed, a conservative approach to the assessment is necessary to minimise the potential risks. Thus where new chemical/polymers are of particular or known concern, for example, because of toxicity profile, persistence, or significantly different use patterns which may increase environmental and/or public exposure, additional data for the notified chemical/polymer may be required.

Please also note: although preferred, acute aquatic toxicity data may not be required in circumstances where the predicted environmental concentration (PEC) for the notified chemical is the same as that in the original assessment i.e. volume and use is the same and where the Risk Quotient ( $Q = \text{PEC}/\text{PNEC}$ ) in the original assessment is  $\leq 0.1$ .

The application for reduced fees should consist of:

- A completed “Attachment 1” of Form STD-1, LTD-1, PLC-1, as appropriate.
- the assessment reference e.g. STD/XXXX for the chemical/polymer that has been previously assessed (included in “Attachment 1”).
- a justification of why the chemical/polymer meets the criteria for similar chemical/polymer (included in “Attachment 1”). Where the original notification used read across data the suitability of the read across data for the notified chemical should also demonstrated.
- a statement as to whether an application for reduced fees is being made due the notified chemical/polymer having a similar use (included in “Attachment 1”).
- A list of any other available information (for example, toxicity or environmental test data) about the previously assessed chemical/polymer that was not provided for the original NICNAS assessment (included in “Attachment 1”). **A copy of this data must also be provided as part of the notification.**
- Consent on company letterhead from the notifier/holder of the data for the original assessment (if required).

The notification must be accompanied by payment of the relevant ‘Entry Fee’ (reduced upfront fee). This is approximately 60% of the appropriate notification fee. See [http://www.nicnas.gov.au/Industry/New\\_Chemicals/Fees\\_and\\_Charges.asp](http://www.nicnas.gov.au/Industry/New_Chemicals/Fees_and_Charges.asp) for the current ‘Entry Fee’.

### ***8.1.2 Assessment processes***

During screening NICNAS will verify that the chemical/polymer meets the criteria for similar chemical/polymer and/or similar use and will advise of the outcome in the

screening letter. The appropriate fee will be determined based on the information that is included in the original NICNAS assessment and the amount of work required by NICNAS for the hazard and exposure assessment. The appropriate fee will be advised in the screening letter.

The 90-day statutory assessment timeframe applies for the STD, LTD and PLC applications. However, if the chemical/polymer being notified also has the same, or similar, use to the similar chemical/polymer that has been previously assessed, the process will normally be completed in 28 days.

### ***8.1.3 Criteria for similar chemical***

For a chemical (polymers are considered separately below) to be regarded by NICNAS as similar to another chemical for the purposes of an application for reduced fees, the chemical must be prima facie structurally identical or similar (see below for criteria) and must have been assessed in the same or higher level (i.e. STD) notification category. An exception to this may occur where the full scheduled suite of (eco)toxicity and environmental fate data was assessed in the original lower level (i.e. LTD) notification.

The following identity and physicochemical criteria for the chemical in comparison with the other chemical must be met:

- contains identical substructure(s) that may play a critical functional role, such as those listed in Appendix 15 of the Handbook for notifiers; and
- has the same or similar molecular weight; and
- has the same or expected to be the same molecular properties e.g. lipophilicity, electronic or steric parameters; and
- octanol-water partition coefficient ( $K_{ow}$  not  $\log K_{ow}$ ) within the range of 50% to 200% of the previously assessed chemical

In addition, the differences in identity must not be known to affect the toxicity profile of the chemical. This can be typically demonstrated where the chemical meets the following criteria in comparison with other chemical (although a comparison of other toxicity endpoints may be warranted in certain cases):

- acute oral toxicity: LD50 within the range of 50-200%; and
- aquatic toxicity: LC50 or EC50 within the range of 50-200%.

The chemicals should have the same classification in accordance with the *Approved Criteria for Classifying Hazardous Substances* (<http://www.safeworkaustralia.gov.au/NR/rdonlyres/6AA1E55D-D444-4909-B18B-812688B49A7F/0/MSDSCodeNOHSC20112003.pdf>.)

#### ***8.1.3.1 Examples***

The following examples are types of chemicals that may meet the criteria for similar chemical:

##### *Salts*

Salts often demonstrate a similar pattern of activity when the active chemical form is independent of the counterion found in the preparation (i.e. where the counterion

toxicity is equivalent), and consequently identical *in vivo*. Therefore, salts formed when the hydrogen of an acid is replaced by an alkali metal or a cation of equivalent solubility (e.g.  $\text{NH}_4^+$ ) may be suitable. Thus the  $\text{Na}^+$  salt is reasonably expected to be closely similar in activity to that of the  $\text{K}^+$  salt but quite different in activity to the  $\text{Pb}^+$  salt. Amine salts will be assessed on a case by case basis.

#### *Positional isomers*

An isomer has the same number and kind of atoms and hence the same molecular weight, but differs in respect to the arrangement or configuration of the atoms. Positional isomers have the same empirical formula and unchanged chemical functional groups but have at least a single variation to the branch point of a hydrocarbon chain, for example; normal-, iso- and anteiso- isomeric forms, or a change to the aromatic ring substitution position. However, in heterocyclic ring systems, both the ring size and the number and ring position of heteroatoms should not change. The change in branching or substitution position should not be known to affect the toxicity profile of a chemical e.g. 2-ethyl hexanoic acid is classified with the risk phrase 'possible risk of harm to the unborn child (R63)' whereas octanoic acid isn't and the position of substitution of aromatic amines is known to effect the genotoxicity profile.

#### *Stereoisomers*

A stereoisomer has identical chemical constitution, but differs in respect to the arrangement of the atoms or groups in space e.g. optical and geometric isomers. Stereoisomers may meet the criteria for similar chemical however the change in stereochemistry should not be known to affect the toxicity profile of the chemical, for example, where *in vivo* interconversion occurs.

#### *Bio-isosterism*

Chemicals related by a simple recognised change between two known groups with similar physical or chemical properties that impart similar biological properties to a chemical, for example, chlorine -Cl group replaced by a trifluoromethyl - $\text{CF}_3$  group or cyano - $\text{C}\equiv\text{N}$  group, may meet the criteria for similar chemical.

#### *Essential Oils*

Often essential oils from plants of the same species may be regarded as different chemicals (with different CAS numbers) if separation has resulted in slightly different chemical profiles. Often these differences may have little or no impact on the (eco)toxicological activity of the chemical.

#### *Fatty Acid Resins*

In many cases for chemicals that have a fatty acid chain such as alkyd resins, the fatty acid is not a determinant of chemical properties. Where the saturation profiles are similar (for example in the case of sunflower oil and soybean oil, or tung oil and linseed oil) one fatty acid may be substituted for another without significantly changing the properties of the chemical.

#### *Animal/Plant Derived Fatty Acids*

Fatty acid saturation profiles derived from animals and plants differ slightly; in cases where the saturation profile of the fatty acid has little impact on the pattern of activity, either type may meet the criteria as a similar chemical for the other.

#### ***8.1.4 Criteria for similar polymer***

For a polymer to be regarded by NICNAS as similar to another polymer, the polymer must be assessed in the same notification category. The change in polymer identity must not be known to affect the toxicity profile of the polymer, for example, toxicity to algae is known to be highest for polyanionic polymers when the acid is on alternating carbons of the polymer backbone.

For a polymer to be regarded by NICNAS as similar to the originally assessed polymer/primary polymer, the following identity and physicochemical criteria must be met:

- contain the same linkages and functional groups; and
- water solubility within the range of 50% to 200% .

In addition, the notified polymer must be covered by one of the following situations:

- the notified polymer contains one polymer constituent less than the originally assessed polymer/primary polymer or
- the notified polymer contains a polymer constituent which is similar to a polymer constituent in the originally assessed polymer/primary polymer with all other polymer constituents must be the same (see below for more details) or
- the notified polymer is structurally identical to the originally assessed polymer/primary polymer (see below for more details)

Differences in molecular weight, low molecular weight species and functional group equivalent weight will be taken into account when determining the appropriate reduction in fees.

*Polymer contains a polymer constituent which is similar to a polymer constituent in the originally assessed polymer/primary polymer*

In this case all but one of the polymer constituents should be the same. Where there is a difference in polymer constituent the substituted polymer constituent must meet the criteria for similar chemical. Data on the original polymer constituent and substituted polymer constituent should be provided to demonstrate this.

*Polymer structurally identical to assessed polymer/primary polymer*

In some cases, a polymer may be manufactured by different reaction pathways and, in some cases, using different reactants. This can lead to the identification and naming of a particular polymer in more than one way, with different CAS registry numbers, although the polymers may be structurally identical i.e. contain the same linkages and functional groups. Information to support this should be provided.

### **8.1.5 Criteria for similar use**

*Overall:*

- a similar use is a use that does not require a change to the original exposure assessment and assessment conclusions and recommendations; and
- where the original assessment report states specific secondary notification circumstances of which the Director must be notified (subsection 64(1) of the Act), the new use would not be considered similar whereby these circumstances would be met.

*Specifically the following must be the same:*

- the industry sector in which the chemical is used; and
- the routes of human exposure; and
- the types of workers exposed and to the extent to which these workers are exposed; and
- the routes of environmental release; and
- the potential for public exposure; and
- the volume must be in the same volume range. These volume ranges are < 1 tonne, 1-3 tonnes, 3-10 tonnes, 10-30 tonnes, 30-60 tonnes, 60-100 tonnes. (Note: a use would not be considered similar whereby the increase volume would lead to a change in the original risk assessment); and
- the mode of introduction e.g. importation or manufacture.

### **8.2 Chemical/polymer notified at the same time as a chemical/polymer which is similar and has a similar use (including notification of inseparable mixtures).**

If two or more chemical/polymers which meet the criteria for both similar chemical/polymer and similar use (see above) are notified for a non-self assessed certificate **at the same time**, then a reduction in fees is applicable. In this circumstance the applicant pays the full fee for one application and an administrative fee (See [http://www.nicnas.gov.au/Industry/New\\_Chemicals/Fees\\_and\\_Charges.asp](http://www.nicnas.gov.au/Industry/New_Chemicals/Fees_and_Charges.asp) for the current administrative fee.) for the other notifications.

#### **8.2.1 Application requirements (except in the case of inseparable mixtures)**

The normal notification procedures for a STD, LTD or PLC notification should be followed for one chemical/polymer (considered to be the primary chemical/polymer) (see chapter 5). “Attachment 1” of Form STD-1, LTD-1, PLC-1 should **not** be completed for this chemical/polymer. For the additional chemical/polymers (considered to be secondary chemical/polymers) a Form 1 with “Attachment 1” completed must be submitted.

All available data on the primary and secondary chemicals/polymers must be included as part of the submissions. All NICNAS schedule data requirements must be addressed for the relevant assessment category. If the schedule data requirements are fulfilled from data on the primary and secondary chemicals/polymers, an application

for variation of schedule requirements is not required. If an application for variation of schedule data requirements is needed, one application (and hence one fee) is sufficient to cover all notifications.

If an application for exempt information is required, typically one application (and hence one fee) is sufficient to cover all notifications.

The following data/information for the secondary chemical/polymer itself is required to demonstrate that the criteria for similar chemical/polymer and similar use are met and for risk assessment purposes as follows:

- Information on the identity and composition of the chemical/polymer
- Information on use
- Information on introduction and use concentrations
- Estimated manufacture and import volume
- Matters affecting occupational health and safety, environmental impact and public health.
- Label and MSDS for the chemical/polymer in the form that it is introduced
- Melting (or boiling) point, particle size, and partition coefficient in the case of chemicals
- Particle size and water solubility in the case of polymers
- Acute oral toxicity (typically for Standard notifications)
- Acute aquatic toxicity for the most sensitive organism (typically for STD notifications).

More detail on the type of information required can be found in [Appendix 12](#) and in the appropriate NICNAS electronic notification template.

Please note: as there will always be a level of uncertainty associated with any chemical/polymer for which a complete suite of (eco)toxicological tests have not been performed, a conservative approach to assessment is necessary to minimise risks. Thus where new chemical/polymers are of particular or known concern, for example, because of toxicity profile, persistence, or significantly different use patterns which may increase environmental as well as public exposure, additional data for the notified chemical/polymer may be required.

Please also note: although preferred, acute aquatic toxicity data may not be required in circumstances where the Risk Quotient ( $Q = \text{PEC/PNEC}$ ) for the primary chemical is  $\leq 0.1$ .

The application for reduced fees for the secondary chemical/polymers should consist of:

- A completed “Attachment 1” of Form STD-1, LTD-1, PLC-1, as appropriate.
- A justification of why the chemical/polymer meets the criteria for similar chemical/polymer (included in “Attachment 1”)

The notification for the secondary chemical/polymer must be accompanied by payment of the relevant ‘Administrative Fee’ See “Attachment 1” of Form STD-1,

LTD-1, PLC-1 for the current 'Entry Fee'. Note: A reduced fee is not applicable for the primary chemical/polymer and normal fees apply.

### **8.2.2 Application requirements (inseparable mixtures of similar chemical/polymers)**

In the case of inseparable mixtures, a reduction in fees is applicable where the components meet the criteria for similar polymer (with the exception of the water solubility criteria) or the following criteria for chemicals:

- contains an identical substructure or substructures that may play a critical functional role, such as those listed in Appendix 15 of the Handbook for notifiers (the difference in structure/substructure must not be known to effect the toxicity profile of the chemical); and
- has the same or similar molecular weight e.g. minor variation in chain length; and
- has the same or expected to be the same molecular properties e.g. lipophilicity, electronic or steric parameters

A separate Form 1 is required for all components. "Attachment 1" of Form-1 should **not** be completed for the chemical/polymer of highest concentration (considered to be the primary chemical/polymer) however must be completed for each of the other components (considered to be the secondary chemical/polymers).

Each notification package for the primary and secondary chemical/polymers must contain the following:

- Information on the identity and composition of the chemical/polymer
- Information on use
- Information on introduction and use concentrations
- Estimated manufacture and import volume
- Matters affecting occupational health and safety, environmental impact and public health

Required physico-chemical and eco(toxicological) data in accordance with the Schedule of Data Requirements on the inseparable mixture and the Label and MSDS for the chemical/polymer in the form that it is introduced must be included as part of the notification package for the primary chemical/polymer. This information need not be included in the notification package for the secondary chemical/polymers.

All NICNAS schedule data requirements must be addressed for the relevant assessment category. If the schedule data requirements are fulfilled from data on the inseparable mixture, an application for variation of schedule requirements is not required. If an application for variation of schedule requirements is required, one application (and hence one fee) is sufficient to cover all notifications.

If an application for exempt information is required, typically one application (and hence one fee) is sufficient to cover all notifications.

The application for reduced fees for the secondary chemical/polymers should consist of:

- A completed "Attachment 1" of Form STD-1, LTD-1, PLC-1, as appropriate.

- A justification of why the chemical/polymer meets the criteria for similar chemical/polymer (included in “Attachment 1”)

The notification for the secondary chemical/polymer must be accompanied by payment of the relevant ‘Administrative Fee’. See [http://www.nicnas.gov.au/Industry/New\\_Chemicals/Fees\\_and\\_Charges.asp](http://www.nicnas.gov.au/Industry/New_Chemicals/Fees_and_Charges.asp) for the current ‘Entry Fee’.

Note: A reduction in fees is not applicable for the primary chemical/polymer and normal fees apply.

### **8.2.3 Assessment processes (including inseparable mixtures)**

During screening NICNAS will verify that the chemical/polymer meets the criteria for similar chemical/polymer and/or similar use and will advise of the outcome in the screening letter.

A combined assessment report for the primary and secondary chemical/polymers will be produced. The normal statutory assessment timeframes apply.

### **8.3 An assessment of the notified chemical/polymer by Environment Canada and Health Canada under the New Substances Notification Regulations (Chemicals and Polymers) of the Canadian Environmental Protection Act, 1999 is available.**

The latest information on the approved foreign scheme provisions and reduction in fees based on the availability of a Canadian assessment report can be found in the December 2008 *Chemical Gazette* ([http://www.nicnas.gov.au/Publications/Chemical\\_Gazette/pdf/2008dec\\_whole.pdf#page=18](http://www.nicnas.gov.au/Publications/Chemical_Gazette/pdf/2008dec_whole.pdf#page=18)).

### **8.4. An assessment of the notified chemical/polymer by the APVMA/TGA/FSANZ is available.**

The Director may remit up to 40% of the fee paid for an application for a non-self assessed certificate where an assessment report by the APVMA, FSANZ or TGA is available. The fee saving will be dependent on the scope of the original assessment.

#### **8.4.1 Notification requirements**

The normal notification procedures (with the exception of payment) for a STD, LTD or PLC notification should be followed (see chapter 5). All NICNAS schedule data requirements must be addressed for the relevant assessment category. All available data on the notified chemical/polymer must be included as part of the submission.

NICNAS is currently working with the APVMA, FSANZ, and TGA to develop mechanisms to facilitate the provision of APVMA, FSANZ, and TGA assessment reports to NICNAS. Please contact NICNAS if you are wishing to utilise this option.

## **8.5 An assessment report by a chemicals notification and assessment scheme operating in a member country of the European Union or the Organisation for Economic Co-operation and Development (other than Canada) is available.**

The Director may remit up to 40% of the fee paid for an application for a non-self assessed certificate where an assessment report by a chemicals notification and assessment scheme operating in a member country of the European Union or the Organisation for Economic Co-operation and Development (other than Canada) is available. The fee saving will be dependent on the scope of the original assessment.

### **8.5.1 Notification requirements**

The normal notification procedures (with the exception of payment) for a STD, LTD or PLC notification should be followed (see chapter 5). All NICNAS schedule data requirements must be addressed for the relevant assessment category. All available data on the notified chemical/polymer must be included as part of the submission.

The application for reduction in fees should consist of:

- A completed “Attachment 1” of Form STD-1, LTD-1, PLC-1, as appropriate.
- Details of the overseas authority, that is, when and where notified (included in “Attachment 1”).
- A list of any available information (for example, toxicity or environmental test data) about the notified chemical/polymer that was not provided for the overseas authority assessment (included in “Attachment 1”). **A copy of this data must also be provided as part of the notification.**
- A copy of the overseas assessment report.
- Consent on company letterhead from the notifier/holder of the data for the original assessment (if required).

The notification must be accompanied by payment of the relevant ‘Entry Fee’ (reduced upfront fee). This is approximately 60% of the appropriate notification fee. See [http://www.nicnas.gov.au/Industry/New\\_Chemicals/Fees\\_and\\_Charges.asp](http://www.nicnas.gov.au/Industry/New_Chemicals/Fees_and_Charges.asp) for the current ‘Entry Fee’.

### **8.5.2 Criteria for an Acceptable Assessment Report**

The assessment report must:

- date from post-1994. Preferably, the report should be in English, however, authorised translations are acceptable. Electronic reports are also preferable;
- originate from the national authority of an OECD Member country, preferably any European Union Member State;
- include confidential information, for example, chemical identity. Sanitised documents are not acceptable;
- include a summary and assessment of physicochemical properties;
- include a summary and assessment of toxicological and environmental effects data, as appropriate;
- include a health and environmental risk assessment; and

- be accompanied by a letter of validation from the overseas authority that the report is the full and final report issued for that chemical.

### **8.5.3 Assessment processes**

Acceptance of an assessment report is subject to approval by the Director. The acceptance of the report and the appropriate fee will be advised in the screening letter. The appropriate fee will be determined based on the information that is included in the overseas assessment report and the amount of work required by NICNAS for the hazard assessment.

NICNAS statutory timeframes for assessment remain unchanged.

### **8.6 The application is submitted using the appropriate and current version of the NICNAS electronic template.**

The Director may remit up to 15% of the fee paid for an application for a non-self assessed certificate where an electronic copy of the notification submission prepared using the approved NICNAS electronic template for a Standard or Limited notification category is provided.

#### **8.6.1 Notification requirements**

The notification must be submitted on the approved NICNAS electronic template. The template comprises six documents: (i) the notification form for electronic submission (ii) Schedule Part A - Summary of Notification (iii) Schedule Part B - Identity, Properties and Uses (iv) Schedule Part C1 - Toxicology Information (v) Schedule Part C2 - Environment (vi) Schedule Part D - Polymer Information. If data which is outside the required Schedule parts for the notification category is available to you, the appropriate Schedule Attachment should also be completed to the extent required to cover this data; for example, if mammalian toxicology or genotoxicity data is available for a notification submitted as a Limited notification, the appropriate sections of Schedule Attachment C1 should be completed. For toxicology, ecotoxicology and physico-chemical properties data, there are additional sections that correspond to test data, which is not on the schedule but may be available to you. These additional tests sections should be filled out to the extent required to cover all of the data available to you.

Sufficient information is required to enable the assessment to be made from an occupational, public health and environmental perspective. This includes details of tests performed and where toxicity data are available a summary of the data is required with supporting study reports. Although provision of toxicity data is not a scheduled requirement for Limited notifications, the Act does stipulate that if these data are available to the applicant they should be provided with the submission. Guidance to help with the completion of the approved NICNAS electronic template and an example submission are available.

The templates, guidance documents and example submission can be downloaded from the NICNAS website ([http://www.nicnas.gov.au/Forms/New\\_Chemicals/STD.asp](http://www.nicnas.gov.au/Forms/New_Chemicals/STD.asp))

The notification must be accompanied by payment of the full notification fee (see [http://www.nicnas.gov.au/Industry/New\\_Chemicals/Fees\\_and\\_Charges.asp](http://www.nicnas.gov.au/Industry/New_Chemicals/Fees_and_Charges.asp)).

#### ***8.6.2. Assessment process***

The amount of rebate will be advised at the end of the assessment process. The rebate will be based on the level of detail and completeness of the template submission.