SECTION IV - Continuing Notification and Assessment Methodologies

11. Secondary Notifications

This chapter provides information on your obligations to NICNAS after a new chemical has been assessed and given approval to be introduced by manufacture or import. The chapter also outlines the relevant changes in circumstances associated with a chemical that has been previously assessed, which may lead to a secondary notification.

11.1 Introduction of an Assessed Chemical

For chemicals introduced under a commercial evaluation category and early introduction permit category, the permit holder must notify the Director at the end of the period for which the commercial evaluation or the early introduction permit is issued, any health effects reported, the amount of chemical used and the means of disposal of any surplus.

For chemicals introduced under a low volume chemical category, the permit holder must notify the Director in writing within 28 days of becoming aware of any of the following circumstances: (a) the function or use of the chemical has changed or is likely to change significantly; (b) the amount of the chemical being introduced has exceeded or is likely to exceed the limit allowed to be introduced per annum; (c) the chemical has begun to be manufactured in Australia; and (d) the permit holder has become aware of additional information relating to adverse effects of the chemical.

11.2 Secondary Notifications

Where a chemical has been assessed by NICNAS, there may be changes in circumstances that would necessitate a reassessment of particular aspects of the chemical, that is, a secondary notification and assessment.

Secondary notification may be required, for example, when:

- circumstances foreshadowed in the final assessment report have occurred, for example, a new use of the chemical;
- significant new information about the health or environmental effects of the chemical become available; or
- the Director becomes aware of a significant change in circumstances, for example, a significant increase in the number of people exposed to the chemical.

If it has been less than 5 years since the original assessment certificate was granted, the secondary notification is assessed as a New Chemical and a fee of up to $7,057 applies.

If it has been longer than 5 years since the original assessment certificate was granted, the secondary notification is assessed as an Existing Chemical and no fee applies.

When the Director is notified that NICNAS has received a secondary notification, the decision regarding whether or not to proceed with the assessment rests on the Directors discretion.

11.3 Reporting Obligations

The Introducer Becomes Aware of a Significant Change in Circumstances

When there is a change of circumstances associated with a chemical that has been previously assessed, the onus is on the importer or manufacturer to inform the Director of Chemicals Notification and Assessment (the Director) within 28 days of becoming aware that circumstances have changed.

Relevant circumstances requiring a secondary notification are those which may result in an increased occupational health and safety, public health or environmental risk. These being:

- A significant new use of the chemical which may:
  i. increase the potential for human exposure,
  ii. increase the environmental exposure, or
  iii. change the type of exposure, for example, from dermal exposure to inhalation.

  For example, a chemical initially used as a catalyst in a chemical reaction may later be used as a metal cleaning agent.
- A significant increase in the quantity of chemical imported or manufactured. For example, a tonnage increase from 1 to 10 tonnes per year or from 50 to 500 tonnes per year. Apart from the potentially increased exposure, a significant increase in quantity may lead to a change in the type of exposure; for example, the means of disposing of large quantities may be different from the methods used to dispose of small quantities.
- Production in Australia may have begun for a chemical initially assessed as an imported chemical.
- A change from less than 1 tonne to more than 1 tonne for a chemical originally notified as Limited Notification Polymer of Low Concern.
- A change in the method of manufacture which may lead to an increased risk by:
  i. changing from a closed process to an open system,
  ii. using different raw materials,
  iii. using different processing conditions,
  iv. increasing the number of workers required,
  v. changing the type of exposure,

vi. changing the method of waste disposal, or

vii. increasing the environmental exposure.

- New information on potentially hazardous properties of the chemical may have been identified since the initial assessment. For example, it may become known at a later stage that the chemical is carcinogenic.

The Director Becomes Aware of a Significant Change in Circumstances

If the Director becomes aware, for example, from a third party, of changes or likely changes in circumstances, and has not been informed by the manufacturer or importer, then he or she has the right to call for a secondary notification independently. Based on the type of information available, the Director will decide whether or not secondary notification of the chemical is required.

11.4 Gazetted Secondary Notification

Where the Director has decided that secondary notification of a chemical is required, a notice will be placed in the *Chemical Gazette* and will be addressed to a specific notifier or to all persons who import or manufacture the chemical.

The Director may also contact persons who may hold information that may assist in the secondary assessment. In these cases, the Director will give notice in the *Chemical Gazette* to other selected importers and manufacturers of the chemical to submit information relevant to the change in circumstances that prompted the secondary notification.

By taking into account the change in circumstances and the impact that the change will have on occupational health, public health and the environment, the notice will specify those data items in the Schedule where information must be provided. For example, a significant new use of the chemical may lead to revised occupational health and safety information and revised emergency procedures. Another example, where information on occupational exposure may be specified in the case of a significant increase in the number of workers exposed has prompted a secondary notification.

For further information about the Schedule of data requirements and assessment methodologies, refer to Chapters 11 and 12 in Section IV of this handbook.

11.5 Application for Secondary Notification

An application for a secondary notification should be made on Form 1-SN in Appendix 1. Secondary notification statements must include all available information according to those specified in the notice by the Director in the *Chemical Gazette*. All documents sent to the Director in support of a secondary notification must be in English. The notifier may request that certain items of information remain exempt from publication, with justification of each claim to be included in the notification. Further guidance on confidentiality is detailed in Appendix 6 - Confidentiality.

11.6 Assessment Process and Reports

In normal circumstances, a secondary notification assessment is completed within 90 days from the date of acceptance of an application for a secondary notification assessment, that is, the date of receipt of the complete notification package.

Following the assessment of a notified chemical under a Secondary Notification category, the original assessment report is modified within 90 days. The following reports are prepared and sent to the applicant:

- assessment report (the version containing exempt information);
- full public report (assessment report without the exempt information); and
- summary report.

11.7 Penalties

There may be penalties for failing to notify the Director of a change in circumstances. When deciding whether a notifier should have been aware of a change in circumstances, the Director will take into account the notifier's knowledge, skills and experience as well as the nature of the change in circumstances - for example, the impact of the change on the health and safety of workers, the public at large and the environment. Manufacturers and importers in doubt as to whether a secondary notification is required should contact the Director for advice.

For new chemicals where a failure to make a secondary notification has occurred, the Minister may suspend any assessment certificate or permit which the notifier may have for that chemical. If the chemical is already imported or manufactured in Australia, non-compliance may lead to importation and/or manufacture being prohibited.

12. Assessment Methodologies

This Chapter outlines in detail how the various aspects of a chemical's toxicology, and its effects on occupational health and safety, public health and the environment, are considered in the processing of assessing a new or existing chemical. The material should be used as further guidance when you are compiling your application.

12.1 About NICNAS Assessments

NICNAS officers within the Office of Chemical Safety (OCS) of the Therapeutic Goods Administration carry out toxicological, public health and occupational health and safety assessments. The Risk Assessment and Policy Section of Environment Australia conduct the environmental assessment for NICNAS under a service agreement. The type and degree of assessment varies depending on the type of notification. For example, a quantitative risk assessment may be conducted for a priority existing chemical, whereas a qualitative assessment usually occurs for a new chemical. The risk assessment entails some or all of the following elements:

- hazard identification;
- hazard assessment, incorporating the dose-response relationship;
- exposure assessment; and
- risk characterisation, where the hazard and exposure assessments are integrated.

For some priority existing chemicals, the assessment may be limited to a hazard and/or exposure assessment only.

Assessments are conducted on a case-by-case basis and will be based on a weight of evidence approach, taking into account scientific judgment, knowledge of the mechanism of action of effects, and recognition of the inherent uncertainty in extrapolating animal data to humans. From the risk assessment, recommendations are formulated to manage the risk, taking into account existing risk management strategies.

12.2 Toxicological Assessment

The toxicological assessment establishes the toxicity of the chemical and identifies the set of inherent properties that make it capable of causing adverse effects. For chemicals with unknown toxicity, for example, new chemicals, this would involve a series of animal studies, which investigate the major biological systems. These would include studies for acute toxicity, reproductive toxicity, genotoxicity and perhaps other specific endpoints such as neurotoxicity. For existing chemicals, human health effects data may be available.

Both human and experimental animal data are assessed in accordance with international guidelines to identify the critical health effects of the chemical and to determine the dose-response relationship, with no observed adverse effect levels

(NOAELs) established wherever possible. Good quality human data is given preference for the risk assessment. The health hazards of the chemical are classified in accordance with the NOHSC Approved Criteria for Classifying Hazardous Substances.

The toxicological database may consist of studies that have been performed with a structural analogue of the notified chemical, or with a formulation.

Adequacy and applicability of the data will be taken into account when performing the assessment. Where data gaps exist, or the notification does not require toxicology data, as with some classes of polymer, the evaluator may be able to predict the toxicological hazard from the chemical's physical properties or the characteristics of structurally related chemicals, given that factors such as volatility, solubility and molecular weight can indicate the likely extent of absorption across biological membranes.

Whole animal studies are the mainstay of toxicological testing. However, laboratories are being encouraged worldwide to develop alternative in vitro test systems that will be predictive of toxicity in vivo.

12.2.1 Quality of Data

To ensure that data is of sufficient quality for use in risk assessment, all new testing should be conducted according to internationally recognised methods, for example, the OECD's Test Guidelines, and Good Laboratory Practice (GLP) standards. For many existing chemicals, the data available will have been generated prior to GLP and OECD standard methodology. This data can still be used for the assessment if valid conclusions can be drawn. The evaluation requires the use of expert judgment, with the determination of validity to be both justified and transparent. In determining the quality and validity of data, matters such as completeness and scientific detail in the test report need to be considered.

12.2.2 Relevance of Data

The relevance of test data is considered in the assessment. For example, it is necessary to judge whether the appropriate route of exposure has been used, whether the most suitable species has been studied, and whether the substance tested is representative of the chemical being assessed.

The relevance of animal and in vitro test data for humans is also considered. The evaluation is aided by use of toxicokinetic and metabolism data for the chemical, in both animal and humans if possible. Generally, effects observed in animals are assumed to occur in humans unless there is clear well-documented evidence for a species-specific effect to justify a conclusion that the effect either could not occur in humans or is of little relevance. In vitro data alone are generally not directly predictive for effects on humans.

However, highly electrophilic substances, which give positive results in genotoxicity studies in vitro, may be of concern regarding their potential to be mutagenic in humans at the initial site of contact, for example, the skin or respiratory tract.

12.2.3 Evaluation of Human Data

The evaluation of human data generally requires a more critical appraisal of the validity of the data than animal data. The main types of human data are epidemiological studies, controlled studies in volunteers and case reports.

The strength of epidemiological evidence for specific health effects depends on matters such as the type of analysis and the magnitude and specificity of the response. Confidence in the findings is increased when comparable results are obtained in at least two independent studies on populations exposed to the same chemical under different conditions. Criteria for assessing the adequacy of epidemiological studies include the proper selection and characterisation of the exposed and control groups, adequate characterisation of effect and exposure, sufficient length of follow-up for disease occurrence, and proper statistical analysis.

Controlled human studies are often useful in determining exposure levels associated with acute effects such as skin irritation. Human patch tests for skin sensitising effects can also be conducted. Criteria for a well-designed study include the use of a double-blind study design, inclusion of a matched control group and a sufficient number of subjects to detect an effect. Epidemiological studies with negative results cannot prove the absence of a particular toxic effect of the chemical in humans, but good quality controlled human studies which are negative may be useful in the risk assessment.

12.2.4 Evaluation of Animal and In Vitro Data

Most of the health effects information required for the risk assessment will be derived from controlled studies in experimental animals and in vitro test systems.

The assessor needs to identify the adverse effects of the chemical in the study, and make a judgment about how well the study identifies that particular effect.

Generally, the assessor needs to judge whether the study establishes a dose or exposure level at which the critical effect is not observed. For repeated dose studies, a NOAEL should be established or, where this is not possible, a LOAEL stated.

For each study, it is important to evaluate the study design and how the study was carried out. Matters such as the frequency and duration of exposure, appropriateness of the species and strain of animals used, and the choice of doses need to be considered. Matters that need to be considered in the evaluation of data in each study include the assessment of effects on control animals, causes of mortality, clinical observations during the exposure period, organ and body weight changes and biochemical changes.

12.2.5 Dose Response Assessment

It is generally agreed that there is a threshold dose or concentration for many of the adverse health effects caused by chemicals. The threshold dose may vary considerably for various routes of exposure and for different species because of differences in toxicokinetics and possibly also mechanisms of action. The observed threshold dose

in a toxicity test will be influenced by the sensitivity of the test system, that is, it will depend on the exposure concentrations used in the study.

Unless a threshold mechanism is demonstrated, it is generally taken that thresholds cannot be identified in mutagenicity in vivo and genotoxicity, although a dose-response relationship may be demonstrated under experimental conditions.

When a reliable dose-response relationship has been identified, then the slope of the curve is taken into account. For a steep curve, the NOAEL is more reliable, as the greater the slope, the greater the reduction in response to reduced doses.

For a shallow curve, the uncertainty in the NOAEL may be higher and must be allowed for in the risk characterisation.

12.3 Occupational Health and Safety Assessment

In general, the aim is to determine the potential risk to the health and safety of workers. This is achieved by assessing the health and physico-chemical effects of the chemical, estimating the exposure to workers, and then characterising the risk. However, in some cases, a hazard assessment only is conducted. For new industrial chemicals, the occupational health and safety assessment is normally a hazard assessment as exposure data is limited. For some types of priority existing chemical assessments (preliminary assessments), a characterisation of use or an assessment of exposure only may be required. Where possible, peer-reviewed international reviews are utilised in the assessment.

12.3.1 Exposure Assessment

The exposure assessment is conducted by establishing the use pattern of the chemical and identifying the sources of occupational exposure. Exposure is then estimated by taking into account the routes of exposure, the frequency and duration of exposure, and measured worker data, for example, atmospheric and/or biological monitoring results. Information is needed for each of the scenarios where workers are potentially exposed to the chemical. The reliability of the measured data, and its ability to be representative, are considered in the assessment. If insufficient measured data are available, then model calculations are used to estimate typical and 'reasonable worst-case' exposure levels. Where necessary, default values are used for certain input parameters in the model calculations, for example, inhalation rate, body weight and skin surface area.

Internationally accepted methods are used in the assessment, for example, a modification of the United Kingdom EASE (Estimation and Assessment of Substance Exposure) model is used for estimating exposure. Where exposure levels have been determined from both measured and modelled data, preference is usually given to measured data provided it is both reliable and representative of the scenarios being considered in the assessment.

For new chemicals, the occupational exposure assessment is usually qualitative, as measured data is unlikely to be available and there is insufficient information available to predict reliable quantitative estimates.

12.3.2 Risk Characterisation

The health risk to workers is characterised by integrating the exposure and effects assessments. For brief or short-term exposures, human data and information from acute toxicity studies in animals are taken into account to determine the risk of adverse health effects, such as acute respiratory effects and skin irritation.

For longer term and repeated exposures, the health risk to workers is characterised by firstly comparing exposure estimates with NOAELs to give a margin of exposure (MOE), and then deciding whether there is cause for concern.

Matters taken into account when characterising the risk include the uncertainty arising from the variability in the experimental data and inter- and intra-species variation, the nature and severity of the health effect and its relevance to humans, and the reliability of the exposure database.

Where an exposure estimate is higher than or equal to the NOAEL, the chemical is of concern with regard to the exposure of the human population considered. Where the exposure estimate is lower than the NOAEL, matters such as those mentioned above are taken into account before deciding whether the chemical is of concern. For example, the MOE may be based on a human NOAEL, leading to greater certainty in the characterisation of risk. Conversely, if a LOAEL is used in the absence of a NOAEL, the degree of uncertainty would be higher and a higher MOE would be required. Expert judgment is required to weigh these individual parameters on a case-by-case basis, with the approach to be both transparent and justifiable.

Where it is not possible to determine a NOAEL or LOAEL - for example, where there is a lack of suitable data - the risk is evaluated on the basis of qualitative or quantitative exposure relevant to the human population under consideration.

For certain types of health effects, for example, developmental toxicity, the risk to sensitive sub-populations, for example, pregnant women, is taken into account.

For new chemicals, a more qualitative characterisation takes place as exposures are often unknown or more difficult to predict.

12.3.3 Risk Management

In the assessment, current risk-reduction strategies are appraised and, if the risk characterisation has shown that there is cause for concern, then further control measures are recommended where necessary. Both regulatory and non-regulatory controls may be recommended.

The hierarchy of controls is used to formulate measures, which can be applied directly to the workplace to reduce the risk of adverse health effects. Where regulatory controls may be required, current controls, for example, exposure standards, are appraised for adequacy.

The standard of hazard communication is often addressed when considering risk management strategies. MSDS and labels are assessed against the respective codes of

practice, and programs for the training and education of workers may be recommended.

12.4 Public Health Assessment

In broad terms, the assessment aims to establish whether there is any potential for the chemical to adversely affect the health of members of the public. This will be influenced by two main factors: the nature and extent of any public exposure to the chemical; and the toxicological properties of the chemical.

12.4.1 Exposure Assessment

When performing an assessment, the evaluator will begin by identifying the chemical, together with its estimated production or import volume and proposed use, examine the entire life history of the chemical and consider the potential for the public to become exposed at each phase of its lifecycle. This would begin with importation or synthesis and transport within the country, proceed through to reformulation or use in industrial processes and possible use in consumer or industrial goods, and finish with the eventual disposal of the chemical (or products containing it).

Public exposure to notified chemicals most often occurs when they are sold in consumer products, or when products containing them enter the public domain.

The extent of public exposure will depend on the concentration of the chemical in products, the sales volume and use pattern of the products, and other factors including the physical state of the notified chemical. The evaluator will differentiate between the number of people likely to be exposed and the likely dose (amount of chemical exposure) to each individual resulting from the product's intended use. Most members of the public will be exposed to a chemical constituent of a widely used product, for example, an additive to motor oil, but the amount of exposure may be minimised by a brief duration and/or low frequency of contact. Conversely, small numbers of people, for example, users of a photo-developing solution, may be exposed to comparatively greater amounts of a chemical, with exposure being increased by prolonged or frequent contact.

Some products, such as ink cartridges, will be packaged so as to reduce the opportunity for contact with the notified chemical during normal handling.

Other products may come into contact with members of the public without causing exposure to the notified chemical. For example, polymers or dyes used in plastic or fibre may enter the public domain in an encapsulated, bonded or cured state from which they cannot be absorbed or otherwise become bioavailable. Here, even extensive or prolonged contact would lead to negligible exposure.

The evaluator must take into account the possibility of public exposure arising from release into the environment during transport, manufacturing or end-use.

Among the most important factors here will be the amount of chemical which may be released, the location of possible discharges or spills, and the chemical's physical state when it enters the environment. These will influence the probability of public contact

with the chemical at the release site, or the chemical exhibiting mobility in the air, soil or water, which will in turn determine whether it may be inhaled or enter the potable water supply or food chain. Emergency containment, cleanup and disposal procedures given in the MSDS could play a significant part in mitigating the effects of an accidental release, and will be noted. Similarly, the notified chemical may enter the environment following its disposal, or disposal of products containing it, and the assessment report will include consideration of the likelihood of public exposure arising from this means.

12.4.2 Assessment of Toxicological Assessment

Where toxicology data have been provided, the evaluator will consult the toxicology assessment to determine the nature and severity of any hazards posed by the chemical. Irrespective of the class of notification, the identity and concentration of hazardous impurities or residual monomers will be examined, and the evaluator will comment on their likely toxicological significance at the levels present in products entering the public domain.

12.4.3 Implications for Public Health

Utilising the above information, the evaluator will then assess whether the chemical is likely to pose any significant risks to the public. The use, concentration and physical state of the chemical when it reaches the public domain will have an important bearing on this part of the assessment. Many notified chemicals will have no adverse effect on public health, due to low potential for exposure and/or low toxicological hazard at the levels present in products. However, where frequent or prolonged public exposure to the chemical is anticipated due to its presence in consumer goods, for example, take away food containers, laundry detergents and personal care products, the evaluator may make a quantitative estimate of the user's exposure/intake of the chemical. Some notifiers may supply this information but, alternatively, the evaluator may apply an algorithm based on those described in the European Commission's Risk Assessment of Existing Substances - Technical Guidance Document (1994). The exposure estimate is then related to the results of toxicological studies to determine the margin of exposure between the anticipated consumer exposure/intake and doses causing toxicologically significant effects in animals. Finally, the evaluator will recommend whether any special conditions are required to protect public health, such as warning statements to appear on the label or an upper limit to the concentration at which the notified chemical may be used in certain product types.

12.4.4 Priority Existing Chemicals

Public health assessment methods for priority existing chemicals (PECs) are similar to those for new chemical notifications, although the size and complexity of the assessment report may be increased, depending on the amount of information available on use, and the extent of animal and human toxicological data. If a survey of the PEC's use in industrial and consumer products has been performed, its results will be incorporated into the assessment. Where a PEC has been subjected to Poisons Scheduling, consumer product labels will be examined to verify compliance with the requirements of the Poisons Schedule with regard to signal headings, first aid

instructions and safety directions. Otherwise, the evaluator will comment on the general suitability of label directions for use and other statements.

If there is any indication of potentially significant public exposure to the PEC, either from environmental sources or its use in, or contamination of, consumer products, the evaluator will assess the level of risk to the public. The approach taken will vary with the extent of data on exposure levels and toxicology, and with the nature of any hazard posed by the chemical. As with new chemicals, the evaluator may calculate a margin of exposure. Alternatively, the level of risk to the public may be inferred from the extent of public exposure and epidemiological evidence of health effects in persons exposed occupationally.

Whenever there appears to be significant risk to public health, recommendations are made with a view to reducing public exposure to the PEC. Where public exposure arises from environmental contamination, the evaluator may recommend that measures be taken to reduce emissions of the PEC. If the primary source of public exposure is from consumer products, the evaluator may recommend review of the poisons scheduling status of the PEC, or revision of label instructions for use, first aid instructions and/or safety directions. In cases where the nature of the hazard or the level of risk require it, the evaluator may recommend an upper limit to the concentration of the PEC in consumer products, or even that use of the PEC in consumer products should cease. Where there are grounds for concern based on toxicological findings, but there is insufficient information upon which to base realistic estimates of public exposure and risk, the evaluator may also recommend that further data be obtained to enable an adequate assessment of the implications for public health.

12.5 Environmental Assessment

In conducting an environmental assessment, Environment Australia estimates the extent of the potential environmental exposure based on information supplied by the notifier along with local and literature sources. The environmental effects of the chemical are also measured by the degree of toxicity to aquatic organisms.

The potential hazard of the chemical to the environment and its fate are then evaluated. Schedule information required for an assessment of the potential environmental impact includes chemical identification data (paragraph 1 of Section B of the Schedule), certain physical and chemical data (paragraph 9 of Section B of the Schedule, including water solubility, hydrolysis, partition coefficient, dissociation and adsorption/desorption), volume of import and/or manufacture (paragraph 5 of Section B of the Schedule), environmental release (paragraph 7 of Part B of the Schedule), environmental fate (biodegradability and bioaccumulation potential (paragraphs (q) and (r) of Part C of the Schedule), and the toxicity to aquatic organisms (paragraphs (m) to (p) of Part C of the Schedule). Note that the fate and toxicity information are only required for Standard Notifications, though these should be provided if available for the other categories.

12.5.1 New Chemicals

Exposure

To determine environmental exposure, a cradle-to-grave approach is adopted. Information on all stages of the life cycle of the notified chemical while in Australia is required to determine the amount of chemical released to the environment. This includes releases (if relevant) of the chemical during the manufacture, processing, distribution, application, use and disposal stages (paragraph 7 of Part B of the Schedule). It is emphasised that much, if not all, of this information should be obtained locally, rather than from overseas sources. If low environmental exposure can be demonstrated, consideration to waiving certain elements of the environmental fate and toxicity data requirements for Standard Notifications can be given.

Fate

The fate of the chemical in all of the environmental compartments, including wastewater treatment systems and landfills, is established based on the physical and chemical properties of the chemical. For standard notifications, stability in water (hydrolysis), biodegradation and bioaccumulation are Schedule requirements. However, additional data may be considered if relevant, for example, stability in air, ozone depletion and atmospheric half-life if volatile, transport and distribution between environmental compartments. The level of detail will vary between assessments depending on the available data and the type of assessment, for example, Standard Notifications, Limited Notifications or Polymers of Low Concern Notifications. Monitoring data and levels in the environmental media may also be considered, although this is more common for existing chemical assessments.

Effects

The environmental effects are determined based on ecotoxicological data as outlined in paragraphs (m) to (p) of Part C of the Schedule. Aquatic organisms are used as an indication of the environmental effects as industrial chemicals are often directly released to the aquatic compartment as waste products in effluent.

Tests on three different aquatic species at increasing trophic levels, that is algae, aquatic invertebrates and fish, are essential to gain a sound indication of the ecotoxicological profile, given the potential differences in toxicity to these organisms. The provision of ecotoxicological data is only required for Standard Notifications.

However, data should be provided if available for other classes (Limited Notifications or Polymers of Low Concern Notifications), particularly where the use pattern would result in release to the aquatic compartment and if the substance belongs to a class known to exhibit aquatic toxicity.

Hazard

The exposure, fate and effects data are used to determine the potential environmental hazard. Likely and worst-case exposure patterns are compared to the chemical's ecotoxicological profile to ascertain which living organisms, if any, are likely to be affected by the chemical's proposed use (as detailed in points 2 and 3 of the hazard section for PECs immediately below). If the hazard is unacceptably high, measures will be recommended to reduce the environmental exposure or mitigate the environmental effects.

It is usually difficult to perform a formal hazard assessment for Limited Notifications and Polymers of Low Concern Notifications, as fate and effects data are not Schedule requirements. In these cases, attention is focused on the extent of environmental exposure, particularly to the aquatic compartment, taking into account available ecotoxicity information.

12.5.2 Priority Existing Chemcials (PEC's)

Exposure

Priority existing chemicals often require more in-depth analysis of releases to the environment, as these chemicals are usually high-production volume or high-use substances, so are widespread in use around the country. Surveys are usually conducted by NICNAS to determine import quantities, manufacturers, formulators and end-users. Environment Australia uses this information to predict highest exposures.

Fate

For PECs, the fate of the chemical in all of the environmental compartments is also established, based on the physical and chemical properties of the chemical.

Specifically considered are stability in soil, water (hydrolysis) and air (photolysis and photodegradation), transport and distribution between environmental compartments, including predicted environmental concentrations and distribution pathways, mode of degradation in actual use, biodegradation and bioaccumulation. Additionally, for PEC assessments, monitoring data and levels in the environmental media may also be considered.

Effects

In a similar manner to new chemicals, the environmental effects are determined based on ecotoxicological data as outlined in sections (m) to (p) of Part C of the Schedule. However, as a result of their wider exposure, the toxicity to terrestrial organisms, soil dwelling organisms, terrestrial plants and birds may also be considered during a PEC assessment. The type of organisms that are considered is dependent on the expected/predicted exposure patterns. For example, for chemicals released to soil, the toxicity to soil dwelling organisms may be necessary to determine the potential hazard to these organisms during the calculation of the environmental hazard.

Hazard

The environmental hazard in existing chemical assessments is determined using the following procedures:

1. An estimate of the concentration in respective media (water, soil and air) is made based on release estimates determined above, assuming worst-case conditions. Often, as is the case for new chemicals, the aquatic compartment is the main focus.

2. This estimated environmental concentration is compared to the known environmental effects levels. In order to determine the potential hazard, the lowest toxic effect for the environmental compartment, for example, the LC50 result for Daphnia, is considered. The ratio of the estimated environmental concentration to this toxic effect result is determined.
3. If test results are limited, for example, one acute test for two trophic levels, then a ratio of less than 0.001 indicates the potential environmental hazard is low. If there is a large range of tests, for example, several acute and some chronic for all trophic levels, then a ratio of 0.01 or 0.1 may be justified in determining the potential environmental hazard. Where ratios are larger than acceptable, there is an indication that restrictions on use need to be implemented to reduce the environmental hazard.

12.6 Risk Assessment of Chemicals: Assessment of Exposure from All Sources

A key objective of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) (Section 3) is to provide 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.

Thus, NICNAS is a risk based regulatory system.

NICNAS assesses the risks to occupational health and safety, public health and the environment using well established, internationally accepted methodology (International Programme on Chemical Safety, 1999; European Commission, 2003). Risk assessment, when applied to chemicals generally, is the overall process of decision making, taking into account:

- Hazard assessment (including hazard classification and establishment of dose-response relationships);
- Exposure assessment;
- Risk characterisation; and
- Risk management.

Chemical Risk Assessment: Our Approach

12.6.1 Hazard Assessment

Hazard assessment establishes the toxicity of a chemical and identifies the set of inherent properties that makes it capable of causing adverse effects. Thus, the hazard assessment step identifies the type of hazard that might occur given the appropriate circumstances.

12.6.2 Exposure Assessment

The other major variable in the risk characterisation equation is the estimate of exposure. The purpose of exposure evaluation is to identify the magnitude of exposure to a particular chemical and to determine the frequency and duration of that exposure and all the routes by which exposure occurs over the chemical life cycle.

For the majority of chemicals, exposure assessment is probably the most variable aspect of the risk assessment paradigm. This reflects a variety of contributing factors such as differing and/or unique exposure and use patterns of chemicals across a range of industrial uses, the unique nature of ecosystems, fauna and flora, together with differing methodologies for exposure assessment as well as differences in dose-response extrapolation methodology.

The exposure assessment is a critical element of the risk assessment and can comprise both direct exposure (ie. workers carrying out manufacture; consumer use of household products etc.) as well as indirect exposure via the environment.

The assessment of both direct and indirect exposures via the environment are important considerations for the risk assessment, particularly for the public health and environmental assessments where exposure to a chemical may arise from several sources such as contact with the raw chemical itself, a preparation or mixture, finished goods containing the chemical (eg. treated fabrics and carpet) or via contamination of the environment (eg. lead and other chemicals in household dust and ambient air).

Where exposure of the population to a chemical is likely or suspected (ie. through biomonitoring data or known chemical properties such as leaching) the risk assessment consideration is extended to include all the sources of the exposure. The release of chemicals into the environment, for example, from articles via leaching, exudation and/or surface abrasion, may occur at any time in the life cycle of the article, including during use, handling, disposal or storage. Hence, NICNAS's risk assessment, whilst focussing on regulating chemical use, may also need to consider the use of a chemical in the production of and release from a finished article. Therefore, information about the possible release of a chemical from an article may be required as part of the exposure information to facilitate the risk assessment of an industrial chemical.

12.6.3 Risk Characterisation

The risk characterisation process involves integrating hazard identification, hazard characterisation and exposure assessment outcomes.

The process of interpreting and integrating the information on hazard and exposure to provide a practical estimate of risk is complex and may involve determining what is an acceptable risk and how risk should be managed.

12.6.4 Risk Management

Risk characterisation is only part of the risk analysis process. The second major aspect of risk analysis is risk management. Risk management involves risk evaluation, which addresses the fundamental socio-economic problem of determining the optimal level of risk in society based on a trade off between risk, cost and benefit.

The economic and social benefits of any risk reduction action(s) must be balanced with the economic, political and social costs of implementing the risk reduction strategy(ies). Risk management also involves monitoring, evaluating and reviewing the strategies implemented.

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