FURTHER CONSULTATION ON PROPOSED AMENDMENTS TO THE SCHEDULE TO THE ACT AND THE REQUIREMENT TO PREPARE AND PUBLISH SUMMARY REPORTS

In the April 2010 issue of the *Chemical Gazette*, NICNAS sought comment on two proposed amendments to the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), namely:

- a proposal to remove the requirement to prepare and publish summary reports for both new and existing chemicals: and
- proposed amendments to the Schedule to the Act.

Five responses were received, in light of which NICNAS has refined some proposed amendments to the Schedule and the requirement to prepare and publish summary reports. NICNAS is now seeking further comment on the proposed amendments. Due to the timing constraints of the legislative process, please provide comment on these proposals to NICNAS by 16 August 2010. For any queries regarding this proposal, please contact Dr Matthew Gredley on 02 8577 8873 or at matthew.gredley@nicnas.gov.au.

The following sections provide an overview of comments received and NICNAS's response by way of the refined proposal.

SUMMARY REPORTS

Original proposal

In the April 2010 issue of the *Chemical Gazette*, NICNAS proposed the removal of the requirement to prepare and publish summary reports for both new and existing chemicals assessments. For some years, NICNAS has published the *Chemical Gazette* (including summary reports) and all full public reports on its website and therefore both reports for any given assessment are readily available to the public at no cost. Currently two copies of the summary report, including the copy in the *Chemical Gazette*, and one copy of the full public report are published on the NICNAS website for each assessment. The summary report is an extract from the full public report. Summary reports and full public reports do not contain exempt information.

To ensure that the public is aware that the full public report for an assessed chemical has become available on the NICNAS website, it was also proposed in the April 2010 issue of the *Chemical Gazette* that a notice be placed in the *Chemical Gazette* to this effect stating, for example, assessment number, chemical and/or trade name (subject to exempt information requirements) etc.

Comment received

Three submissions included comment on the proposal to remove the requirement to prepare and publish summary reports for all NICNAS assessments. Two submissions supported the proposal, including one submission which suggested that some key details, other than chemical identity, be included in the *Chemical Gazette* notice. However, in the third submission, there was some concern that the proposed changes may be less efficient for those wishing to review summary information on assessed chemicals on the NICNAS website.

Refined proposal

In light of comments received, NICNAS still proposes to remove the requirement to prepare and publish summary reports. However, it is now also proposed that the notice in the *Chemical Gazette* include the following key information about the assessed chemical:

- assessment number,
- chemical name or trade name,
- notifier details,
- use,
- volume, and
- hazard classification,

and that there be a link to the full public report. It is also proposed that the current sections of the full public report which constitute the summary report be moved to the beginning of the new full public report in order to provide more ready access to a summary of the assessment.

SCHEDULE TO THE ACT

In the April 2010 issue of the *Chemical Gazette*, NICNAS sought comment on the proposed amendments to the Schedule to the Act which were intended to cater for the following notification-related matters:

- the assessment of new active ingredients (UV filters) in secondary sunscreens, which were previously regulated by the Therapeutic Goods Administration (TGA) prior to the cosmetic reform amendments to the Act in September 2007;

- the screening assessment of all new industrial chemicals for their potential to be persistent, bioaccumulative and toxic (PBT), in accordance with Australia's obligations under the Stockholm Convention on Persistent Organic Pollutants (POPS); and

- other amendments in accordance with international best practice, including a more specific requirement on public exposure to the chemical and revision of some physical and chemical properties.

All five submissions included comment on the proposed amendments to the Schedule; these are detailed below. In light of comments received, the proposed amendments have been refined and additional remarks added for clarity. The refined Schedule to the Act is attached to this notice.

Assessment of new active ingredients (UV filters) in secondary sunscreens

Original proposal
Under the NICNAS cosmetic reforms, it was agreed that the data requirements for UV filters in secondary sunscreens previously regulated by TGA would remain the same when regulated by NICNAS. This was announced by special notice in the January 2007 and October 2008 issues of the *Chemical Gazette* and confirmed more recently by the NICNAS Cosmetic Advisory Group. The proposed amendments to the Schedule for UV filters formalise those arrangements. A number of the specific data requirements for UV filters are already listed in Part C (health and environmental effects requirements) of the NICNAS Schedule to the Act, however, to accommodate those not listed in Part C, it was proposed in the April 2010 issue of the *Chemical Gazette* that the additional data requirements listed by TGA be incorporated into a new Part E of the Schedule to the Act (data items listed in amended Schedule attached).

Comments received
The only submission on this item supported the proposal and noted that the proposed data requirements were consistent with current TGA requirements for UV filters in sunscreens.

Refined proposal
Although comment was favourable, two of the items in the new Part E for ultra-violet filters have been reworded to be more specific and therefore assist notifiers.

Screening of all new industrial chemicals for their potential to be persistent, bioaccumulative and toxic (PBT)

Original proposal
Australia is a signatory to the Stockholm Convention on Persistent Organic Pollutants (POPS). The objective of the Convention is to protect human health and the environment from the effects of POPS, which are toxic, persistent in the environment and accumulate in the food chain. The Convention sets out a range of control measures to reduce and eliminate POPS releases; Article 3 requires parties to the Convention to take into account POPS characteristics when conducting assessments on new and existing chemicals. The POPS characteristics are persistence, bioaccumulation, potential for long-range environmental transport and adverse effects on human health and the environment. Accordingly, NICNAS announced by special notice in the January 2004 *Chemical Gazette* that it would undertake the screening assessment of new industrial chemicals to identify potential POPS chemicals and additional data requirements for chemicals which were potentially persistent, bioaccumulative and toxic (PBT) were listed in the notice.

In the April 2010 issue of the *Chemical Gazette*, NICNAS proposed that the Schedule to the Act be modified to reflect the assessment of the POPS characteristics by:

- transferring the requirement to provide information on the potential of the chemical to bioaccumulate in both aquatic and land environments from Part C (health and environmental effects) to Part B (physical and chemical properties and exposure information) of the Schedule; and

- adding a requirement in Part B to provide a description of how the chemical compares with the Australian criteria for persistence, bioaccumulation and toxicity.

It was noted that these amendments will assist NICNAS in conducting an adequate PBT assessment of new chemicals notified in the Standard and Limited Notification categories.

Comments received
Two of the five submissions contained comment on this proposal. One was a question regarding the Australian criteria for PBT, which have been developed by the Environment Protection and Heritage Council and can be found on their website www.ephc.gov.au.

The other submission questioned whether this proposal was consistent with government policy, in particular, recommendations in the Productivity Commission's Research Report on Chemicals and Plastics Regulation (July 2008) (PC Report) whereby NICNAS should become an assessment-only body. In fact, the proposed amendments are to satisfy NICNAS's requirement to assess industrial chemicals for their persistence, bioaccumulation and toxicity.

Refined proposal
No change to this part of the proposal has been made.

Other amendments

Original proposal
In the April 2010 issue of the *Chemical Gazette*, NICNAS proposed other amendments to the Schedule, include the following:

- clarification of information requirements on ways in which the public at large may be exposed to the chemical;

- clarification of requirements for some physical and chemical properties, including flammability;

- addition of requirement to provide information about the reaction scheme used to manufacture a polymer, and

- removal of the option to provide the International Union of Pure and Applied Chemistry (IUPAC) chemical name as part of the chemical's identity.

Comments received
Three submissions included specific comment on the other proposed amendments to the Schedule. Two submissions opposed the proposal to remove the option to provide the IUPAC chemical name for the notified chemical and two questioned the reasoning behind the proposal to include the reaction scheme for polymers as a data requirement. One submission provided comment on the proposal for more specific information on public exposure (in Part B), amendments for physical and chemical properties (in Part B) and removal of the tonnage range for introduction volume (in Part B). In general, greater clarity of the purpose of the proposed amendments was advocated.

Refined proposal
Regarding the proposals to remove the option to provide the IUPAC chemical name for the notified chemical and the proposal to include the reaction scheme for polymers, both proposals were intended to assist NICNAS to definitively identify the notified chemical or polymer and determine unambiguously whether the chemical is a new or existing chemical by reference to chemicals already listed on the Australian Inventory of Chemical Substances (AICS). It is noted that the Chemical Abstracts (CAS) chemical name is required, under regulation 5, for the chemical to be added to the AICS.

In light of comment on these two matters, NICNAS now proposes to retain the current option to provide the IUPAC chemical name. It is also proposed that information on the reaction scheme be provided for polymers and other complex substances at Part B.1(a) of the Schedule, which deals with data to establish chemical identity, to assist with identification of the notified chemical.

Regarding comment on the expansion of the data requirements for public exposure (Part B.8), this amendment was designed to assist notifiers in providing relevant information to NICNAS and to assist in carrying out an adequate risk assessment. The amendment as originally proposed is retained. There will be occasions where the data required under this item will be minimal.

Regarding comment on amendments for some physical and chemical properties (Part B.9), the data requirements currently in the Schedule were included prior to the international classification of chemicals as hazardous substances or dangerous goods. Over time, the list of properties in the Schedule has become inconsistent with these classification systems and therefore inconsistent with current test protocols, e.g. OECD and EU. Therefore the revision of these data requirements for some properties is designed to make NICNAS requirements more consistent with hazard classification requirements and international test protocols. The amendment as originally proposed is retained.

Regarding comment on the proposal to remove the tonnage range for introduction volume (Part B.5), the amendment as originally proposed is retained. However, it is recognised that some notifiers may only be able to estimate the volume as a range, for example, 10-100 tonnes, and this will be reflected in the guidance in the NICNAS Handbook for Notifiers.

Additional explanatory remarks are included in the refined proposal in this notice for your consideration to provide greater clarity on the rationale for the proposed amendments.

Schedule—Matters to be dealt with in notification statement about chemical

Part A

1. Identification of notification category. *[specific sections of Act deleted as they were not consistent with previous amendments to the Act]*
2. Summary of the chemical's health effects and environmental effects.
3. Summary of how the chemical meets the definition of hazardous chemical.
4. Details of any notification made in relation to the chemical in a country other than Australia.
5. Bibliography of the publications referred to in the statement.

Part B

1. The following matters identifying the chemical, and, in the case of a synthetic polymer, each other chemical that is one of its constituent monomers:
   (a) the chemical name of the chemical, that is to say:
      (i) in the case of a pure chemical—the name for it to be used in the Australian Inventory of Chemical Substances, that is the chemical abstracts (CA) preferred Index Name, or, if such a name is not available, the name for it to be used by the International Union for Pure and Applied Chemistry; or
      (ii) in any other case—as complete a description of the chemical as is practicable;

   including, in the case of a biopolymer, a description of the biological source of the biopolymer; and

   in the case of a polymer or complex chemical, information about the reaction scheme used to manufacture the chemical.

[NICNAS has frequently experienced difficulty in determining the chemical identity of polymers notified as new chemicals. This new data requirement is proposed to assist NICNAS in unambiguously identifying the notified polymer (or other complex chemical) where there is uncertainty.]

   (b) the name or names by which the chemical is known or identified in the scientific or technical literature;
   (c) the name under which the chemical has been, or will be, marketed;
   (d) the number assigned to the chemical by the service known as the Chemical Abstract Service;
   (e) the chemical's molecular formula and structural formula;
   (f) the chemical's gram-molecular weight;
   (g) copies of spectra which have been measured to confirm the chemical's structural formula.

2. The following matters showing the composition of the chemical:
   (a) the degree of purity of the chemical, that is to say the weight-percentage of a sample of the chemical that is not an impurity;

(b) the weight-percentage of a sample of the chemical that is a known or reasonably anticipated impurity, including an isomer or a by-product, of a hazardous or toxic nature and details of the toxic properties and hazardous properties of the impurities;

(c) the weight-percentage of a sample of the chemical that is a non-hazardous impurity of not less than 1% by weight of the sample;

(d) the weight percentage of a sample of the chemical that is an additive or adjuvant and the identity of the additives or adjuvants.

3. The proposed uses of the chemical in descending order of importance and the approximate percentage of the quantity of the chemical to be introduced by the notifier that is to have each use.

4. The physical state and appearance, being the colour and form, of the chemical at 20° celsius and 101.3 kPa and a description of the odour (including the odour threshold) and volatility of the chemical. *[The physical state of the chemical is helpful in estimating exposure and therefore the risk to health, safety and the environment.]*

5. The quantity, in tonnes per year, of the chemical proposed to be imported into Australia by the notifier in each of the next 5 years and the quantity of it proposed to be manufactured in Australia by the notifier in each of those years. *[The tonnage range has been deleted, however, some notifiers may only be able to estimate the volume as a range, for example, 10-100 tonnes.]*

6. The following matters affecting occupational health and safety:
   (a) data about occupational exposure factors, that is to say:
      (i) the categories of workers to be involved in working with the chemical; and *[The requirement to provide the number of workers potentially exposed to a chemical has been deleted as it was often difficult for notifiers to estimate the exact numbers of workers for a chemical yet to be introduced.]*
      (ii) the nature of the work to be done by them; and
      (iii) the safety procedures to be observed when handling the chemical; and
      (iv) a brief description of the training and education in safe working practices to be given to those workers; and
      (v) data about the occurrence of work related injuries and diseases affecting workers dealing with the chemical; and
      (vi) any other data relating to occupational hazard associated with the chemical; and
   (b) a list of health conditions (if any) which indicate that the notified chemical should not be used; and
   (c) particulars of procedures for the atmospheric monitoring and biological monitoring of the effects of the chemical; and
   (d) information held, or reasonably obtainable, by the notifier about studies and observations of health problems or adverse symptoms occurring in humans exposed to the substance.

7. The following matters affecting the impact of the chemical on the environment:
   (a) where the chemical is to be manufactured or reformulated in Australia:
      (i) the site of the manufacture or reformulation; and
      (ii) the processes to be carried out at that site; and

(iii) information about the release of chemicals into the environment likely to occur at that site;

(b) in respect of each use of the chemical, information about the situations in which the chemical will be released into the environment and the quantity and concentration of the release;

(c) the requirements for the safe storage of the chemical;

(d) a description of all procedures for the disposal of the chemical and the identity and hazards of any degradation products resulting from the disposal.

8. A description of any ways in which the public at large may be exposed to the chemical, including:

(a) data about public exposure factors, that is to say:

(i) the human populations who may be exposed to the chemical; and

(ii) the activities of the human populations and the duration and frequency of exposure to the chemical; and

(iii) the relevant route(s) of exposure; and

(b) information about ways in which the public may be indirectly exposed to the chemical via the environment.

[The amendment of item B.8 is not a new requirement but simply an expansion of the data requirements for public exposure to assist notifiers in providing relevant and specific information to NICNAS and to assist in carrying out an adequate risk assessment. There will be occasions where the data required under this requirement will be minimal.]

9. The following physical and chemical data about the chemical:

(a) the chemical's melting point and/or freezing point in °C;

(aa) the chemical's boiling point in °C; *[separated melting/freezing point and boiling point]*

(b) the chemical's density in kg/m^3, and:

(i) in the case of a gas—its specific gravity where air = 1; and

(ii) in the case of a liquid—its liquid density and vapour density;

(c) the chemical's vapour pressure in kilopascals at 25°C;

(d) the chemical's water solubility in g/L at 20°C;

(e) in the case of a chemical whose water solubility exceeds 10^{-6} g/L—the degrees of hydrolysis at 25°C at pH values of 4-9 and 1-2

(f) in the case of a chemical that dissolves in water without dissociation or association and which is not surface-active—the partition coefficient (n-octanol/water) at 20°C expressed as log P_{ow};

(g) information about the adsorption and desorption of the chemical to and from standard soils;

(h) in the case of a chemical that dissociates in water—the dissociation constant expressed as pKa determined by a specified manner;

(j) (i) in the case of a chemical that is a solid—the mean particle size and size range including the respirable fraction (1-10 microns); or

(ii) in the case of a chemical that is fibrous—fibre length and length range;

[The physical and chemical properties presently in the Schedule were included prior to the international classification of chemicals as hazardous substances or dangerous goods. Over time, some of the properties listed in the Schedule (below) have become inconsistent with these classification systems and therefore inconsistent with current test protocols, e.g. OECD and EU. The revision of these data requirements for some physical and chemical properties is intended to make NICNAS requirements more consistent with hazard classification requirements and international test protocols.]

(k) the chemical's flash point in °C; *[simplified]*

(m) other information about the chemical's flammability, including:

(i) <u>for gases and vapours</u>, the upper and lower limits of flammability in air;

(ii) <u>for solids, the ability to propagate combustion</u>; and *[added to enhance specificity]*

(iii) details of the nature and identity of toxic and hazardous products of the chemical's combustion;

(n) the chemical's auto-ignition temperature;

(p) <u>the chemical's explosive properties</u>, including the chemical's potential (if any) to detonate as the result of heat, shock or friction;

(q) information about the stability and reactivity of the chemical, including:

(i) <u>the chemical's oxidising properties</u>; *[added to enhance specificity]*

(ii) particulars of conditions constituting the chemical's instability; and

(iii) information about the products of the chemical's decomposition and their hazards

being data obtained from tests:

(r) of samples of the chemical of a specified purity as described in paragraph 2(a); and

(s) by a specified authority or organisation; and

(t) conducted under specified conditions; and

(u) conducted in accordance with the principles of good laboratory practice.

10. Identification of the analytical methods for the detection and determination of the chemical.

11. Particulars of the labels in the presented form to be fixed to products consisting of or containing the chemical.

12. Particulars of the proposed Material Safety Data Sheet in the prescribed form for the chemical and for all commercially available products, or substances used in the workplace, containing the chemical.

13. (a) a full description of procedures for making the chemical harmless in an emergency in the workplace; and

(b) a full description of procedures for making the chemical harmless in an emergency outside the workplace.

[The following two items in Part B have been transferred from Part C (item 14) or added (item 15) to enable NICNAS to screen new industrial chemicals for their potential to be persistent, bioaccumulative and toxic (PBT), in accordance with Australia's obligations under the Stockholm Convention for Persistent Organic Pollutants (POPS). The amendments are simply formalising arrangements

announced in the January 2004 issue of the Chemical Gazette, when NICNAS began the screening of new chemicals to identify potential POPS chemicals.]

14. the potential of the chemical to bioaccumulate in both aquatic and land environments.

15. a description of how the chemical compares with the criteria for persistence, bioaccumulation and toxicity (PBT).

Part C

The following data about the effects of the chemical:

1. the chemical's acute toxic effects by the oral route;
2. the chemical's acute toxic effects by the dermal route;
3. the chemical's acute toxic effects by inhalation;
4. in the case of a chemical that does not have predictable corrosive properties—the extent of dermal irritation caused by the chemical;
5. in the case of a chemical that does not have predictable corrosive properties—the extent of eye irritation caused by the chemical;
6. any sensitising potential of the chemical;
7. the toxic effects of the chemical on administration for a period of 28 days; *[amend 10-14 days to 28 days for consistency with international test protocols]*
8. any induction by the chemical of point mutations in microbial test systems;
9. any production by the chemical of chromosome damage in mammalian cells grown *in vitro*;
10. any production by the chemical of genotoxic damage in a suitable *in vivo* test; *[amended for consistency with other international notification and assessment requirements for industrial chemicals]*
11. the toxicity of the chemical to fish after their continuous exposure for 4 days to a series of concentrations of the chemical in water assessed by the test known as the Fish Acute Toxicity Test;
12. the toxicity of the chemical to aquatic invertebrates shown by the effects of the chemical on daphnids exposed to a series of concentrations of the chemical in water assessed by the test known as *Daphnia* sp, Acute Immobilisation Test and Reproduction Test;
13. the effects of the chemical on algae exposed for at least 3 days to a series of concentrations of the chemical in water assessed by the test known as Algal Growth Inhibition Test;
14. the tendency of the chemical to degrade assessed using the test known as a Ready Biodegradability Test;

being data obtained:

(i) by specified methods; and

(ii) from specified raw data.

Part D

1. The weight-percentage of the total ingredients for the polymer that is represented by each ingredient.
2. The number-average molecular weight of the polymer or, where polymers of more than one molecular weight composition are to be introduced, the lowest number-average molecular weight.
3. The weight-percentage of low molecular weight species of the polymer on its introduction represented by each residual monomer.
4. The maximum weight percentage of low molecular weight species of the polymer below 500 daltons and below 1000 daltons *[add 500 as it is used in the risk assessment]*.
5. Information about all products resulting from the degradation, decomposition or depolymerisation of the polymer.
6. Information on the natural loss of monomers, additives and impurities from the polymer.

Part E

[Additional new data requirements for secondary sunscreen active ingredients(UV filters) - in accordance with NICNAS cosmetic reforms for the transfer of eligible cosmetic ingredients from TGA.]

1. The photostability of the chemical.
2. Information about the phototoxicity of the chemical.
3. Information about the photosensitisation of the chemical.
4. Information about the bioavailability via the oral and dermal routes *[amended to make more specific]*.
5. The toxic effects of the chemical on administration for a period of 3 to 6 months, by the oral and dermal routes.
6. Information about the photomutagenicity of the chemical.
7. The toxic effects of the chemical to reproduction, including toxicity to male fertility
8. The carcinogenic potential of the chemical, including photocarcinogenicity.
9. The potential of the chemical to interact with other sunscreening agents *[amended to make more specific]*.