Proposed amendments to the Schedule to the Act and the requirement to prepare and publish summary reports, April 2010 - proposal.

Amendments are proposed to the Schedule to the Industrial Chemicals (Notification and Assessment) Act 1989 (the Act) to cater for the following matters:

- the cosmetic reform amendments to the Act in September 2007;
- the ratification by Australia of the Stockholm Convention on Persistent Organic Pollutants (POPS); and
- minor amendments in accordance with international best practice.
- requirement to prepare and publish summary reports

Cosmetic ingredients

In the amendments to the Act in September 2007, cosmetic ingredients in some cosmetic products previously regulated by the Therapeutic Goods Administration (TGA) became industrial chemicals within the scope of NICNAS. Among these were new active ingredients (UV filters) in secondary sunscreens, which had specific data requirements when regulated by the TGA. During the reform process, it was agreed that the data requirements for UV filters would be maintained under NICNAS and that the Schedule to the Act would be amended when appropriate. The revised arrangements were foreshadowed in special notices in the January 2007 and October 2008 issues of the Chemical Gazette and confirmed more recently by the NICNAS Cosmetic Advisory Group. 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 is proposed that the additional data requirements listed by the TGA be incorporated into a new Part E of the Schedule to the Act (data items listed in draft amended Schedule below) to apply to UV filters used in cosmetics and personal care products only.

Persistence and bioaccumulation

The objective of the Stockholm Convention on Persistent Organic Pollutants (POPS) 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, including emissions of by-product POPS, and to ensure the sound management of stockpiles and wastes containing POPS. Article 3 of the Stockholm Convention 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 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.

It is now proposed that the Schedule to the Act be modified to reflect these obligations, by:

- transferring the requirement to provide information on the potential of the chemical to bioaccumulate in both aquatic and land environments from Part C 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.

These amendments will assist NICNAS in conducting an adequate PBT assessment of new chemicals notified in the Standard and Limited Notification categories.

Minor amendments

Other minor amendments are proposed, in accordance with international best practice. These include the following:

- enhanced requirement on information to be provided 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; and

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

The proposed Schedule to the Act, with amendments indicated follows.

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

Part A

1. Identification of notification category. *[specific sections of Act deleted]*
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 *[delete IUPAC]*

(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;

(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.

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. *[tonnage range deleted]*

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 *[delete number of workers]*

(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: *[make more specific]*

(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.

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;

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

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

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

(ii) for solids, the ability to propagate combustion; 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) the chemical's explosive properties, 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) the chemical's oxidising properties; [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.

14. the potential of the chemical to bioaccumulate in both aquatic and land environments. *[transferred from Part C in accordance with Australia's responsibilities under the Stockholm Convention for Persistent Organic Pollutants]*

15. a description of how the chemical compares with the criteria for persistence, bioaccumulation and toxicity (PBT). *[added in accordance with Australia's responsibilities under the Stockholm Convention for Persistent Organic Pollutants]*

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]*;
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]*
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. *[delete (r)]*

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]*.
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.
7. Information about the reaction scheme used to manufacture the polymer. *[new data requirement]*

Part E

[additional new data requirements for secondary sunscreen active ingredients(UV filters) - in accordance with NICNAS cosmetic reforms]

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 toxicokinetics of the chemical.
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 interaction potential of the chemical.

Removal of the requirement to prepare and publish a summary report for each assessment.

Background

For both new chemicals and existing chemicals, there is a requirement under the Act that a full public report and a summary report be prepared for each assessment and that the summary report be published in the *Chemical Gazette*. This requirement to publish a summary report has been included in the Act since its commencement in 1989, at a time when the full public report was available in hard copy only for a fee. The summary report consists of information extracted from the full public report and does not include any exempt information.

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. Accordingly, the need for a separate summary report has become obsolete.

For existing chemicals, NICNAS is proposing to amend the Act to implement the recommendations of the NICNAS Existing Chemicals review, one being a new range of assessment types to better suit the need and intended outcome from the assessment process. Shorter reports for existing chemicals will therefore be adequately catered for under proposed legislative amendments.

Proposal

Firstly, it is proposed that amendments be made to the Act to remove the requirement to prepare and publish summary reports for both new and existing chemicals.

To ensure that the public is aware that the full public report for an assessed chemical has become available on the NICNAS website, it is proposed 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.