Position paper regarding data requirements for notification of new chemical substances containing a perfluorinated carbon chain

Action plan for assessment and management of chemicals which may degrade to perfluorinated carboxylic acids (PFCAs), perfluoroalkylsulfonates (PFASs), and similar chemicals

1. Purpose

This position paper outlines the NICNAS default position for assessing potential health and environmental hazards for notification of new chemical substances containing a perfluorinated carbon chain, and additional data requirements, particularly for cases where a notifier believes that the default position should not apply for a specific chemical.

2. Background

Perfluorinated chemicals are present in a variety of industrial, commercial and consumer products in Australia. The widespread occurrence of certain perfluorinated substances in the environment, in certain animal species and in humans has attracted regulatory concern and/or action globally. This is because perfluorinated substances are known to be persistent. Some of them are bioaccumulating, in particular those with long carbon chains, and some have been reported to cause toxic effects in laboratory animals, for which the relevance to human health cannot be dismissed.

One of this group of chemicals, perfluorooctane sulfonate (PFOS), has been subject to phase out on a global basis. PFOS is a fully fluorinated organic compound and is a member of a large family of perfluoroalkyl sulfonate (PFAS) based chemicals. The term PFAS refers to a general category of perfluorinated sulfonate compounds and includes compounds of carbon chain lengths greater than four; and the term PFOS refers to a subcategory of PFAS compounds that have an eight-carbon chain length.

3. Regulatory Actions

a) PFOS

Australia has issued two NICNAS alerts on PFOS, available at http://www.nicnas.gov.au/Publications/NICNAS_Alerts.asp. These recommended that PFOS- and related PFAS-based chemicals be restricted to only essential uses, for which no suitable and less hazardous alternatives are available such as certain Class B fire fighting foams, and that, further, these foams not be used for training purposes in order to minimise dispersal into the Australian environment.

Since 2000, the U.S. EPA has imposed a ban of PFOS, with exemptions for special uses in the aviation, photography and microelectronics industries. In June 2005, Sweden proposed a global ban on PFOS and its related substances under the Stockholm Convention on Persistent Organic Pollutants. Previously, both Sweden

and Britain filed for national bans on PFOS to the European Commission (EC), and urged the EC to pursue an EU-wide ban. In December 2005, the EC issued a proposal for a Directive to restrict the use of PFOS in carpets, textiles, clothing and other items and this is currently under consideration by the Council.

b) PFOA

From July 2000, the OECD has been leading an international collaboration on the scientific assessment and surveys on perfluorinated chemicals, and NICNAS has been actively involved in these OECD activities. The details can be found at the NICNAS website and in the NICNAS Alert 1, 2 and 4. In Australia, following co-regulatory activity with NICNAS and Industry the imports of polymers containing PFOA has virtually ceased dropping from 27.5 tonnes in 2003 to approximately 20 kg in 2004, of which only 25 g has been used in the local manufacture of non-stick cookware. PFOA is not manufactured in Australia or imported as the base chemical.

Article 3 of the Stockholm Convention, which Australia ratified on 20 May 2004, 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. A notice in the Chemical Gazette of January 2004 indicated that additional data in accordance with the Information Requirements and Screening Criteria of Annex D of the Convention may be requested by NICNAS, in particular, information relating to persistence, bioaccumulation and toxicity (PBT).

In December 2005, Health Canada and Environment Canada proposed temporary prohibitions on the introduction of four new polymers containing fluorinated carbon chains based on the toxicological effects of their breakdown products, perfluorocarboxylic acids (PFCAs). In February 2006, Environment Canada and Health Canada also published a position paper "Perfluorinated carboxylic acid (PFCAs) and precursors: A proposed action plan for assessment and management". A Canada Gazette notice was published in June 2006.

In January 2006, the US EPA launched a global PFOA (perfluorooctanoic acid) stewardship program. The eight major companies that use or manufacture PFOA have committed to reduce facility emissions and product content of PFOA and related chemicals by 95 percent by no later than 2010, and to work toward eliminating emissions and product content by 2015. The term PFOA and its related substances includes PFOA, PFOA precursors and related higher homologue chemicals. The precursors refer to chemicals that can break down to form another chemical, in this case, PFOA. The US EPA, in March 2006, also proposed amendment of polymer exemption rule of Premanufacture Notification (PMN) to exclude from eligibility polymers containing as an integral part of their composition certain perfluoroalkyl moieties consisting of a CF_3- or longer chain length.

4. What perfluorinated chemicals are covered by this position paper?

A perfluorinated carbon chain refers to the structure of F-$(CF_2)_n$— in a chemical substance. The perfluorinated carbon chain could be a portion of the chemical or

polymer. The perfluorinated carbon chain in polymers may be incorporated in the structures of monomers.

In molecules such as PFOS and PFOA, the perfluorinated carbon chain length (n) is eight and seven, respectively. However, chemicals with shorter perfluorinated carbon chains (n = 4, 5 or 6) are being introduced into commerce increasingly as new chemicals, as Industry seek to shift their technologies away from PFOS and PFOA. The US EPA PMN exemption rule has a cut-off of n=2 for fluorotelomers and n=1 for other perfluoroalkyl moieties in polymers. The US EPA also proposed significant new use rule on PFAS substances with a fluorinated chain equal and greater than five carbons. Environment Canada proposed restrictions on four chemicals with n≥4 perfluorinated carbon chains.

Based on the scientific evidence and overseas regulatory agency actions, NICNAS has determined that the additional data requirements, in Australia, apply to new chemical substances with a perfluorinated carbon chain length (n) equal to or greater than four carbons, whether linear or branched. An upper limit of a perfluorinated carbon chain length will be set on practical grounds, and where the perfluorinated chain length is greater than 24 carbons, these will no longer be considered to be covered by this action plan for assessment and management of PFCAs and PFASs.

NICNAS has determined that, for new chemical notifications, the additional data requirements apply to:

1. Perfluorinated chemicals and polymers listed in the "Preliminary lists of PFOS, PFAS, PFOA and related substances" (consisting of approximately 600 chemicals), where these are being introduced to Australia for the first time. (http://www.nicnas.gov.au/Publications/NICNAS_Alerts.asp)
2. Chemicals and polymers other than those on this list where these include a perfluorinated carbon chain of length (n) equal to or greater than four carbons, whether linear or branched, other than those in the categories listed below.

Importantly, the additional data requirements will **not** apply for:

- Chlorofluorocarbons (CFCs), hydrochlorofluorocarbons (HCFCs), hydrofluorocarbons (HFCs), perfluorocarbons (PFCs), hydrofluoroethers (HFEs), perfluoroethers (PFEs) and polymers with fluorinated backbone structures, except where these have side chains meeting the above description which are separated from the backbone by non-fluorinated segments.

In specific cases where it is not clear to a notifier whether these requirements apply, NICNAS will assist the notifier in reviewing the chemistry and advise of data requirements for notification.

5. What does this mean for a Notification?

A. Default data

i) Schedule Data Requirements:
The normal set of Schedule Data Requirements (see NICNAS Handbook for Notifiers) for the notification category will be required for the chemical itself.

- The repeated dose study where required by the Schedule must address data on hepatotoxicity since the liver is the target organ for most perfluorinated compounds.
- The requirement for information on impurities and/or residual monomers is important for these chemicals and polymers, and analytical reports must be provided.
- Impurities and residual monomers containing perfluorinated chains will need to be characterised at ≥0.01%, except where the chemical or polymer is proposed to be used in a food contact application, in which case these impurities should be characterised at ≥1 ppm, due to the possibility of migration of the impurities into food.

Additional requirements beyond the Schedule may be requested by NICNAS where the chemical itself is predicted to be highly persistent, or to produce persistent breakdown products other than those discussed below. These are addressed in later Sections of this paper.

ii) Degradation Products:

The perfluorinated sections of chemicals or polymers containing perfluorinated carbon chains are resistant to degradation. By the combined effects of hydrolysis and biodegradation, the perfluorinated chains are considered to produce a group of simpler perfluorinated chemicals, including perfluoroalkyl sulfonates (PFAS) and perfluoroalkyl carboxylic acids (PFCAs). Even comparatively slow degradation will result in increasing concentrations of these chemicals in the environment, due to their persistence.

NICNAS will, as a default, assume that:

- Perfluorinated chains terminated with a sulfonyl group (eg sulfonamide) will degrade to PFAS of the same chain length.
- Perfluorinated chains terminated with a hydrolysable group such as iodide or a silane will degrade to a PFCA containing one less perfluorinated carbon atom,
- Perfluorinated chains terminated with an alkyl or aryl group will degrade to form a mix of PFCAs with both the original chain length and one less perfluorinated carbon atom.

These assumptions will be used for assessment purposes except where the notifier can provide experimental information to indicate that these are not relevant.

iii) Toxicity Information on Degradation Products:

Toxicity information relating to a limited set of degradation products is currently available to NICNAS.

- For perfluorooctane sulfonic acid (PFOS) and its derivatives, the OECD hazard assessment report will be used as a default toxicity data source. http://www.oecd.org/dataoecd/23/18/2382880.pdf
- For perfluorooctanoic acid (PFOA) and its derivatives, the US EPA preliminary risk assessment will be used as a default source http://www.nicnas.gov.au/Publications/NICNAS_Alerts/PFOs_Preliminary_Risk_Assessment_PDF.pdf
- For perfluorobutane sulfonic acid (PFBS) and its derivatives, the NICNAS hazard assessment for potassium perfluorobutane sulfonate will be used as a default source.

http://www.nicnas.gov.au/Publications/CAR/Other/Potassium_Perfluorobutane_Sulfonate_PDF.pdf

Default data sources may be subject to change as new toxicity data becomes available to NICNAS.

For degradation products other than those listed above, the PFOA hazard information will be used to estimate the hazard for PFCAs. For PFAS degradation products apart from PFBS, the PFOS hazard information will be used to estimate the hazard.

Notifiers should familiarise themselves with the relevant hazard information for the assumed breakdown products, as this will be used for assessment purposes except insofar as the notifier can provide experimental information to indicate that these are not relevant, as specified in Section B below.

The toxicity of impurities and residual monomers will also be considered using the default toxicity information unless additional relevant information is provided by the notifier.

iv) Persistence and Bioaccumulation Characterisation:

For perfluorooctane sulfonic acid (PFOS) and its derivatives, the OECD hazard assessment report will be used as a default data source. For perfluorooctanoic acid (PFOA) and its derivatives, the US EPA preliminary risk assessment will be used as a default source, while for perfluorobutane sulfonic acid (PFBS) and its derivatives, the NICNAS hazard assessment will be used as a default source. Default data sources may be subject to change as new data becomes available to NICNAS.

For degradation products other than those listed above, the PFOA hazard information will be used to estimate the persistence and bioaccumulation for PFCAs, subject to the assumption that bioaccumulation will be greater for PFCAs of more than eight carbon atoms. For PFAS degradation products apart from PFBS, the PFOS hazard information will be used to estimate the persistence and bioaccumulation, again subject to the assumption of greater bioaccumulation for PFAS of more than eight carbon atoms.

v) Confidentiality:

No claims of exempt information for the identities of the breakdown products will be accepted.

vi) Assessment Outcomes:

Based on the hazard information for PFOA and PFOS, chemicals and polymers which produce PFCA and PFAS breakdown products apart from PFBS will be subject to the policy outlined in NICNAS PFOS Alert Number 2 (http://www.nicnas.gov.au/Publications/NICNAS_Alerts.asp), which sets out that these chemicals should be restricted to only essential uses, for which no suitable and less hazardous alternatives are available. Justification should be provided as to why a use should be considered essential and why no substitutes are available.

Lack of degradation of a polymer and/or lower toxicity than shown by the default data sets for the critical effects of hepatotoxicity, developmental toxicity and

carcinogenicity must be demonstrated prior to a certificate being issued for uses which are outside this policy.

B. Provision of Alternative Data by Notifier

i) Degradation Products:
In lieu of the default degradation assumptions, the notifier should provide information on the degradation pathways of the new chemical or polymer and the likely degradation products containing the perfluorinated carbon chain. In doing this a higher-tiered test such as an inherent biodegradability test report is required, as there is a greater possibility of degradation occurring in the presence of other nutrients than under the conditions of a ready biodegradability test, where only the test substance is present. This test should include characterisation of the degradation products and their rate of formation.

If the notifier claims that no degradation of the new chemical or polymer containing a perfluorinated carbon chain occurs, a report on analysis and characterisation of degradation products under relevant degradation conditions must be provided, as an inherent biodegradability test does not by itself give information on other degradation modes such as hydrolysis, or on formation of stable degradation products by a mechanism which does not involve mineralisation of a substantial proportion of the chemical or polymer, such as side chain cleavage.

If literature sources relating to surrogate data other than the default information used by NICNAS is provided, the notifier has to provide scientific justification on the applicability of the above studies to the notified chemical. NICNAS will determine if the surrogate data is applicable. An application for Variation of Schedule Requirements should be submitted under these circumstances.

ii) Toxicological Data:
The repeated dose study needs to address data on hepatotoxicity since the liver is the target organ for most perfluorinated compounds. In addition, the notifier is required to provide reproduction/developmental toxicity study and carcinogenicity studies for the degradation products, or for representative degradation products in the case where a number of different products are predicted. The carcinogenicity test can be performed separately or combined with a chronic toxicity study. All these tests should be performed according to the OECD Guidelines for Testing of Chemicals. It is recognised that typically perfluorinated chemicals have not been reported to have genotoxicity potential and hence these tests are not required to be submitted. However, genotoxicity studies if available should be provided.

These data are required to be submitted for the chemical itself if this is predicted to be persistent, rather than being degraded or metabolised to PFAS or PFCA, or for persistent degradation products which are not in the PFAS or PFCA categories. The data requirements apply regardless of the notification category, except that these data are not required for the chemical itself in the case of notifications of polymers with Number Average Molecular Weight (NAMW) >1000.

If literature sources relating to surrogate data other than the default information used by NICNAS is provided, the notifier has to provide scientific justification on the

applicability of the above studies to the notified chemical. NICNAS will determine if the surrogate data is applicable. An application for Variation of Schedule Requirements should be submitted under these circumstances.

6. Refinement of NICNAS Defaults

It is proposed that NICNAS will approach companies that are likely to hold relevant toxicity data for chemicals other than PFOS, PFOA or PFBS to form a NICNAS Technical Working Group. This Working Group will facilitate provision of the data on the above toxicity endpoints to NICNAS. NICNAS will then prepare and publish a hazard assessment report for any well characterised PFAS or PFCA chemical and this can be used as a default toxicology data set for one or more of the PFAS or PFCA breakdown products in future notifications of new perfluorinated chemicals. This would ensure that NICNAS decisions will be based on the same data set, avoids duplication of assessment, avoids consideration of data of differing quality, and reduces the burden on industry to provide the same/similar data for all notifications.

7. What are the notification options for notifiers?

A. Permit Applications

If insufficient toxicity data is available on the new chemical and there is no direct public exposure to the chemical, introduction of small volumes of the chemical may be allowed under Low Volume Chemical or Controlled Use Permits for a limited time period. Control of release of breakdown products into the environment will have to be addressed.

B. Polymer of Low Concern Applications

A polymer containing a perfluorinated group will NOT be considered under the Polymer of Low Concern (PLC) category, due to the potential health and/or environmental risks posed by the persistent breakdown products.

C. Assessment Certificate Applications

If the importation period or quantity for a permit is likely to be exceeded, the chemical or polymer may be notified in the Standard or Limited Certificate categories, subject to the above data requirements. Self Assessment options are NOT available for chemicals or polymers covered by this paper.

8. Existing Chemicals Assessments

All information on perfluorinated compounds currently in use in Australia and those occurring as breakdown products is monitored by NICNAS and Existing Chemicals activity will be undertaken as necessary.