

Availability of Assessment Reports for Four (4) Fluorotelomer Based Substances Currently Prohibited under the New Substances Program

Introduction: Following the assessment of four fluorotelomer based substances under the New Substances provisions of the *Canadian Environmental Protection Act, 1999* (CEPA 1999), these substances were suspected by Health Canada and Environment Canada of being “toxic” according to section 64 of CEPA (1999), and subjected to a prohibition under section 84(1)(b). The notice of the Minister’s decisions appeared in the *Canada Gazette* on July 17, 2004: Vol. 138, No. 29 and on Feb. 5, 2005: Vol. 139, No. 6. Assessment reports leading to these decisions are now available upon request.

These prohibitions are temporary in nature, and will expire after two years (June 23, 2006 for three of the substances, and January 17, 2007 for the fourth) unless a regulation is introduced to manage these substances, in which case the prohibitions will expire when the regulations come into force.

The New Substances Program: The CEPA (1999) approach to the control of new substances is both proactive and preventative, employing a pre-import or pre-manufacture notification and assessment process. When this process identifies a new substance that may pose a risk to health or the environment, the Act empowers the Minister of the Environment to intervene prior to or during the earliest stages of its introduction to Canada. This ability to act early makes the New Substances Program a unique and essential component of the federal management of toxic substances. Substances suspected of being “toxic” or capable of becoming “toxic”, may be controlled as necessary, including prohibiting their import or manufacture.

Scope of Decisions: The New Substances Notification Regulations (Chemicals and Polymers) [NSNR (Chemicals and Polymers)] are applicable only to substances new to Canada. For the purposes of the CEPA (1999), the Domestic Substances List (DSL) defines through exclusion substances which are considered new to Canada. Those substances that are on the DSL therefore do not require notification to the New Substances Program.

The decision by the Minister to prohibit these specific fluorotelomer based substances does not extend to substances listed on the DSL. As a consequence, the decisions do not impede or restrict the import or manufacture of any existing fluorotelomer based substance. These decisions do not represent a final conclusion on fluorotelomer based substances.

Assessment of these New Substances: The assessment conclusions are based upon information indicating the substances that were prohibited would ultimately be a source of perfluorocarboxylic acids (PFCAs) with a range of fluorocarbon chain lengths. Particular concern exists in the cases of PFCAs with longer chain lengths as these have shown a greater potential for bioaccumulation. Members of this class are known to be persistent and suspected to be bioaccumulative, subject to long-range transport (via a precursor), widespread throughout Arctic biota and associated with adverse effects in laboratory animals. Preliminary evidence shows a trend of increasing concentrations in Arctic mammals.

The Minister based his decision upon data available at the time of the assessment. Much of the data used in arriving at an assessment conclusion had been recently published and had not been reproduced by other laboratories. Certain details on the environmental fate of the substances, including reaction rates and mechanisms have not been definitively described. The toxicological conclusions pertaining to PFCA breakdown products are based on data from one of these acids (perfluorooctanoic acid), which in the absence of further information, has been applied to PFCAs of other chain lengths.

The assessments do not attribute the environmental presence of PFCAs solely to the new substances, nor do they preclude contribution from other substances or international sources.

While uncertainties are present in the understanding of the toxicology, environmental fate and exposure routes to humans and the environment, the decision to prohibit the new substances is a precautionary and preventative measure. This recent decision allows Environment Canada and Health Canada time to develop an approach to furthering the understanding of this class of substance while temporarily halting the introduction of these four fluorotelomer based substances in Canada.

Acquiring Additional Information: Research efforts by Government, Academia and Industry are underway to better understand the fate, toxicity and exposure of PFCAs from fluorotelomer based sources. For example, a workshop on the Environmental Fate of Fluorotelomer Based Polymers (CEMN, 2004) was held in September, 2004 with the aim of better understanding the environmental behaviour of these substances. Some of the key research areas identified in this meeting include defining all sources of PFCAs in the environment, determining the extent of fluorotelomer alcohol release due to residual monomers and due to polymer degradation, determining degradation rates of fluorotelomer based polymers, increasing understanding of bioaccumulation mechanisms, continued monitoring for a variety of fluorochemicals in various media, furthering development of analytical standards, performing analytical methods comparison, developing environmental partition coefficients, and determining the relative importance of airborne transport.

To further the understanding of these and related substances, Environment Canada and Health Canada intend to:

1. Determine the scope of further risk assessment activities. (To this end, an interdepartmental meeting and an international workshop on the Environmental Fate of Fluorotelomer Based Polymers (CEMN, 2004) were held to examine the knowledge base of fluorinated chemicals relevant to environmental risk assessment. A report on the workshop is available at <http://www.trentu.ca/cemn/NewsReports/CEMNReport200401.pdf>)

2. Engage international partners on the global dimensions of the issues, and
3. Participate in the development of scientific information to inform risk assessment and risk management.

Conclusion:

The assessment of the new fluorotelomer based substances concluded that they could be sources of PFCAs. The Minister of the Environment prohibited these substances as a precautionary and preventative measure. The prohibition is temporary in nature, allowing additional time to consider new scientific data and the longer term risk management actions which may be necessary to apply to these and other related substances. Scientific work is already in progress to gather these data. The Minister's decision to prohibit applies solely to the four identified new substances and does not impact any similar substances already listed on the DSL. It does not represent a final conclusion on this class of chemicals.

Reference:

CEMN (Canadian Environmental Modelling Network). 2004. *Proceedings of a Workshop on the Environmental Fate of Fluorotelomer-Based Polymers*. Toronto, Canada, September 12 – 14, 2004. CEMN Report No. 200401

For additional information on the New Substances Notification Regulations (Chemicals and Polymers), please visit the new substances website at <http://www.ec.gc.ca/substances>. For copies of the assessment reports (edited for the presence of confidential business information), please provide a request, including your name, affiliation and e-mail address to:

The New Substances Notification Information Line
Notification and Client Services Section
New Substances Division
Science and Risk Assessment Directorate
Environment Canada
Place Vincent Massey, 14th Floor
Gatineau QC K1A 0H3

Telephone: 1-800-567-1999 (toll-free in Canada)
1-819-953-7156 (outside Canada)
Facsimile: 1-819-953-7155
E-mail: nsn-infoline@ec.gc.ca

November 24, 2005