

RISK MANAGEMENT STRATEGY

FOR NEW FLUOROTELOMER BASED SUBSTANCES PROHIBITED UNDER SECTION 84 OF CEPA 1999

1. ISSUE

A scientific assessment was undertaken by Environment Canada and Health Canada on four fluorotelomer based substances subsequent to notifications under the *New Substances Notification Regulations* of the *Canadian Environmental Protection Act, 1999* (CEPA 1999). The assessment indicated that the four notified substances are ultimately a source of long-chain perfluorinated carboxylic acids (PFCAs). Residual fluorinated starting materials and intermediates present in the notified substances, as well as degradation products, are released from the notified substances and further degrade to PFCAs.

PFCAs with longer chain lengths 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 animals. Preliminary evidence shows a trend of increasing PFCA concentrations in Arctic mammals.

Based on the results of the assessment, three Notices of Ministerial Prohibitions were published in Part I of the *Canada Gazette* on July 17, 2004 under the authority of subsection 84(5) of CEPA 1999 and a fourth one on February 5, 2005. The Notices prohibit the importation or manufacture of the four substances under paragraph 84(1)(b) of CEPA 1999. The prohibitions will expire after two years, on June 23, 2006 and January 17, 2007, respectively, unless proposed regulations in respect of these substances are published before the expiry of the two years.

The decision to prohibit the new substances is a precautionary and preventative measure. These four fluorotelomer based substances are considered to meet the criteria set out in section 64 of CEPA 1999 as they may enter the environment in a quantity or concentration or under conditions that

- have or may have an immediate or long-term harmful effect on the environment or its biological diversity; and
- that constitute or may constitute a danger in Canada to human life or health.

There are currently substances of the same chemical class already in commerce in Canada. A proposed Action Plan has been prepared to address all PFCAs and their precursors. This Action Plan covers:

- substances currently prohibited under the New Substances provisions of CEPA 1999,
- the approach by the New Substances Program in addressing such substances in the future,
- the approach for members of this class already in commerce, including early risk management action;
- engagement of the research community and international regulators in contributing to assessment and management issues.

This Risk Management Strategy addresses the first item of the Action Plan. It presents an approach to maintain the prohibitions for these four substances beyond the expiry of the Notices of Ministerial Prohibitions, to protect the environment and human health in Canada.

2. BACKGROUND

2.1 Substances

The substances addressed by this risk management strategy are four fluorotelomer based substances. Fluorotelomer based substances belong to the larger class of fluorochemicals referred to as polyfluorinated alkyl (PFA) compounds. Polyfluorinated chemicals contain carbons that are primarily saturated by fluorine. It is the strength of the carbon-fluorine bonds that contributes to the extreme stability and unique properties of these substances. The larger class of PFAs includes the more familiar substances, perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA) which are currently being assessed by Environment Canada and Health Canada and other international regulators.

For the purposes of this document, these four substances will be referred to as "fluorotelomer based substances". The identity of each of the four fluorotelomer based substances is presented in Table 1.

Table 1 – Substance Identity

NSN # ¹	Chemical Name
12763	Hexane, 1,6-diisocyanato-, homopolymer, reaction products with alpha-fluoro-omega-2-hydroxyethylpoly(difluoromethylene), alkylbranched alcohols and 1-alkanol
12798	2-propenoic acid, 2-methyl-, hexadecyl ester, polymers with 2-hydroxyethyl methacrylate, gamma-omega-perfluoro-C10-16-alkyl acrylate and stearyl methacrylate
12863	2-propenoic acid, 2-methyl-, 2-methylpropyl ester, polymer with butyl 2-propenoate and unsaturated anhydride, perfluoroalkyl esters, <i>tert</i> -Bu benzenecarboperoxoate-initiated
13211 and 13395	Perfluoroalkylhydroxyaminoazetidinium polymer

¹ New Substances Notification identification number used for evaluation purposes

2.2 Production, Import and Use

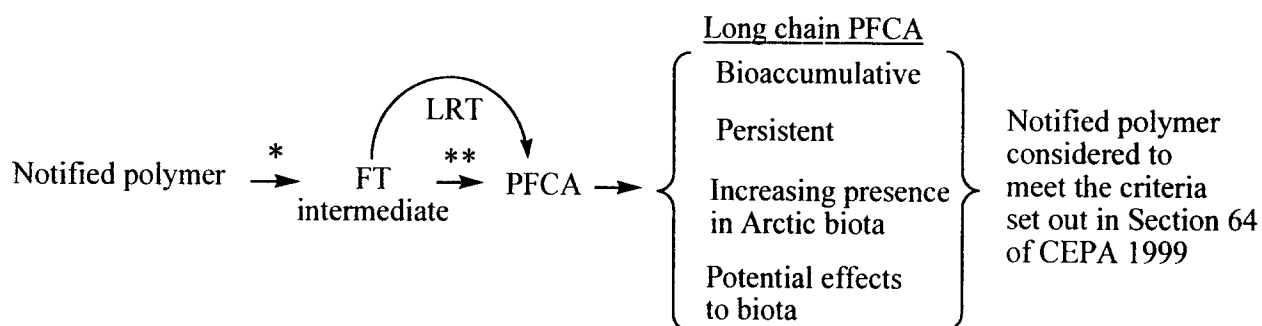
The four fluorotelomer based polymers are not manufactured in Canada but they are imported as raw chemicals for incorporation into formulations for use in application to manufactured materials. The primary uses of these substances are applications involving water, oil, soil and grease repellents for paper, fabric, leather, packaging, rugs and carpets and tiles and grouts, and as a levelling agent in coatings.

In addition, manufactured items on which these substances have been applied might be imported into Canada.

3. WHY WE NEED ACTION

Based on the weight of the available scientific evidence, Environment Canada and Health Canada conclude that these four substances are considered to meet the criteria set out in section 64 of CEPA 1999. See figure 1 below summarizing conclusions.

The conclusions for the four substances is based on the finding that through degradation and due to residual unreacted monomers, three of the substances have the potential to release fluorotelomer alcohols (FTOHs) that subsequently transform to long chain PFCAs. The fourth substance is a source of PFCAs through non-FTOH intermediates.



* Abiotic and/or biotic degradation, and residual release

** Abiotic and/or biotic degradation

LRT: Long-range transport

FT: Fluorotelomer

PFCa: Perfluorinated carboxylic acid

Figure 1: Summary of the Line of Evidence Leading to the Conclusion

Evidence indicates FTOHs have the ability to undergo long range transport and undergo transformation to PFCAs. It is suggested that longer chain PFCAs exhibit properties of persistent organic pollutants (POPs) as there is evidence they are persistent, bioaccumulative, and based on data for PFOA, associated with adverse effects in laboratory animals. PFCAs are found to be widespread throughout Arctic biota and concentrations in wildlife are increasing over time.

4. EXPOSURE SOURCES

There are no known natural sources of these fluorotelomer based substances or their degradation compounds, such as FTOHs and PFCAs, in the environment.

Fluorotelomer substances such as FTOHs and fluorotelomer epoxides, present as residuals, can be released to the environment during the application of the four fluorotelomer based substances to materials and surfaces. Further losses may occur through degradation of the polymer during the lifetime and disposal of products and materials that contain these polymers. Once released to the environment, fluorotelomer based substances can further degrade to PFCAs and therefore are also considered exposure sources of PFCAs.

Through use, disposal, and degradation the fluorotelomer substances from the notified polymers may enter the environment through municipal/industrial wastewater discharge, direct discharge to the environment and landfilling.

4.1 Application on material

Fluorotelomer based substances can potentially be released during the application of these four substances contained in paints and coatings and in repellents applied to materials such as carpets, paper, packaging and textiles.¹

Paints and Coatings

Commercial application of the fluorotelomer based substances contained in paints and coatings can potentially result in some release to the environment due to losses from equipment and spillage. Equipment losses, estimated at 1% daily (New Substances assessment report and EPA standard assumptions for pre-manufacturing notification assessments), occur from wash water residues from material left in shipping cylinders. Spillage, estimated at 0.5% daily (New Substances assessment report and EPA standard assumptions for pre-manufacturing notification assessments), occurs from equipment cleaning and

¹ Unless otherwise indicated, the information on exposure sources provided in this document is based on that contained in the new substances evaluation reports written by Environment Canada and Health Canada.

losses during application by brush, roller or spray. Releases are primarily as liquid discharge to process wastewaters.

Manufacturing Application of Repellents

Manufacturing application refers to operations in which the fluorotelomer based substances are used as product aids to produce industrial, commercial and consumer materials. This includes use as product aids in tanneries, textile mills, carpet manufacturers and by packaging producers to treat surfaces for water, oil, soil and grease repellency. Releases of the polymers from these sources occur primarily from the discharge to process wastewaters from industrial or manufacturing processes.

Consumer Application of Repellents

It is possible that the fluorotelomer based substances are packaged for use in consumer spray applications. Releases of the polymers could occur from overspray during application to personal items such as carpets, garments and other textiles. Consumer overspray of fluoropolymer products onto personal items has been estimated at 34% by volume. Releases from consumer overspray are primarily to air and to wastewater from washing the treated textiles.

4.2 Material Lifetime

The day-to-day use of materials that have been treated for repellency with the fluorotelomer based substances may contribute to fluorotelomer based substances being released to the environment. Potential emissions have been identified from residuals, the washing of fabrics, the general use and cleaning of carpets, and from paints and coatings.

Residuals

Two of the four polymers (NSN# 12763 and NSN# 12798) are reported to contain residuals of up to 2% (data submitted by the notifier), some of which may be unreacted FTOH. No residuals were reported in the polymer NSN# 12863, however based on similar polymers some residual unreacted FTOH is probable. Release of all of this residual FTOH from the polymers is expected to occur over a relatively short period of time following application. For the substances notified under NSN# 13211 and 13395, the residual fluorinated starting materials, and intermediates and by-products are on the order of 3000 ppm (total) on a dry weight basis of polymer.

Carpets

Releases of up to 95% of fluorochemicals used in carpet treatments have been reported over an average carpet lifetime of 9 years. Attributable losses are estimated at 50% from general traffic and vacuuming of the carpet, and 45% from steam cleaning. Releases of fluorotelomer based substances from these sources are to air and wastewater.

Textiles

Washing of textiles treated with the fluorotelomer based substances is expected to result in releases of fluorotelomer based substances to wastewater. It has been reported that 73% of fluorochemicals applied to a personal garment may be lost from washing the treated textiles during the garment's lifetime.

Paints and Coatings

Releases of fluorotelomer based substances from paints and coatings are expected to occur during the lifetime of the coated material. When the coating is applied, the fluorinated portion of the polymer is exposed to the surface (DuPont 2004a) and is therefore susceptible to degradation from the polymer and subsequent release to the environment. The release of fluorotelomer based substances from this source is potentially to air, wastewater and landfill.

Other

Other potential applications of the four fluorotelomer based substances include surface protection of stone, tile, and paper, and use in fire fighting foams, inks, polymers, adhesives, waxes and polishes and caulks. Although these uses are not suspected to be widespread, it is assumed that all applications of the four polymers will eventually result in the degradation and release of fluorotelomer based substances to the environment.

4.3 Material Disposal

Materials refer to items, goods or merchandise in which the fluorotelomer based substances have been applied as coatings or repellents. This includes rugs and carpets, furniture, fabrics, leather articles, paper packaging and construction waste. When materials are disposed of in a landfill, or recycling facility, it is expected that over a period of time, the fluorotelomer based substances will be released to soil, surface water and/or groundwater. Air can be considered a significant pathway of concern during material disposal due to the potentially high volatile nature of the fluorotelomer based substances. Release from domestic waste incineration is not considered significant as incineration represents only a small proportion (3%) of solid waste disposal in Canada.

Additionally, consumer spray products that may contain these polymer substances are a potential source of fluorotelomer based substance emissions upon disposal. It has been reported that approximately 12.5% of a spray can's volume may remain in the can, which may be diverted to landfills (3M, 2000).

4.4 Long Range Transport

An additional source of fluorotelomer based substances and PFCAs to the Canadian environment is long range transport from releases outside of Canada. Given the vapour pressure and the estimated atmospheric lifetime, fluorotelomer based substances such as FTOH, have the potential to undergo long range

atmospheric transport to remote regions. This long range transport potential to remote regions is supported by the presence of the degradation products of FTOHs, PFCAs, in the Canadian Arctic. Therefore, releases of fluorotelomer monomers such as FTOH from outside of Canada have the potential to be transported to the Canadian environment.

5. CONSIDERATIONS

5.1 Context for Risk Management

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.

Substances of the same chemical class already in commerce will be addressed under the proposed Action Plan for assessment and management of PFCAs and precursors.

5.2 Existing Controls of Fluorotelomer based substances

Other than the recent Ministerial Prohibitions by Environment Canada, there are no known existing controls in Canada or internationally on fluorotelomer based substances, fluorotelomer substances (intermediates) or PFCAs. However, there is considerable international activity underway and interest is high in many jurisdictions

5.3 Alternatives

Given that the four fluorotelomer based substances are new substances under the *New Substances Notification Regulations*, their use in Canada has been very limited; as such, the availability of alternatives is not a consideration of risk management activities. However, it is expected that alternatives to the four fluorotelomer based substances are available and that these are comparable in cost and effectiveness. Alternatives include various other fluorinated compounds as well as hydrocarbon-based and silicone-based polymers.

6. PROPOSED OBJECTIVES

6.1 Environmental Objective

The ultimate degradation products of the notified fluorotelomer based substances are PFCAs of varying carbon chain lengths. Given the persistent and bioaccumulative properties of the long-chain PFCAs, and that levels in biota are found to be increasing over time, and may ultimately induce long-term toxic effects in biota, the longer chain PFCAs ($\geq C_9$) are considered to meet the criteria established under the Stockholm Convention on Persistent Organic Pollutants (POPs).

The short term environmental objective for fluorotelomer based substances, fluorotelomer substances (intermediates) and PFCAs is to prevent to the extent possible further increases in levels of PFCAs in the environment. The ultimate long term environmental objective will be a part of a strategic approach for all PFA substances. This strategic approach is currently being developed jointly by Health Canada and Environment Canada as the environmental and health risks of the PFA substances are assessed.

6.2 Short-Term Risk Management Objective

In order to eliminate a potential new source of long chain PFCAs to the environment, the proposed short-term risk management objective for the four fluorotelomer based substances is to prohibit their importation and manufacture. This translates into maintaining the Ministerial prohibitions established under the New Substances Program for these substances.

7. PROPOSED RISK MANAGEMENT APPROACH

7.1 Manufacture and Import

It is proposed to develop a regulation to prohibit the importation and manufacture of the four notified fluorotelomer based substances. A regulation will permit Environment Canada to enable a complete prohibition whereas a voluntary agreement, such as an Environmental Performance Agreement (EPA), would allow other companies not party to the agreement to import below the New Substance Notification regulations threshold for the substances.

The proposed path forward for developing a regulation is to amend the existing *Prohibition of Certain Toxic Substances Regulations* in order to list the four notified fluorotelomer based substances in a Schedule to the Regulations.

7.2 Manufactured Items

The Ministerial prohibition on the four fluorotelomer based substances does not extend to the import of manufactured items (as defined under CEPA 1999) containing or treated with these polymers. Since the short term risk management objective is to maintain the existing prohibition, it is not considered at this time to include manufactured items under the scope of a regulation prohibiting the importation and manufacture of these fluorotelomer based substances.

Internationally coordinated actions are needed to address the import of manufactured items containing these four fluorotelomer based substances and other PFCAs and precursors.

8. IMPLEMENTATION OF THE STRATEGY AND INSTRUMENT

The objective is to publish the proposed regulations by June 23, 2006 in order to maintain the current prohibition for the four fluorotelomer based substances.

A compliance strategy, which includes compliance promotion and enforcement, will be important for the success of the implementation of the regulation. A compliance promotion plan for this instrument will be developed. The risk manager and regional counterparts will work together to provide information to the target community in order to promote compliance with this instrument. An enforcement strategy will also be developed by Environment Canada to verify compliance to the regulations.

9. PROPOSED CONSULTATION APPROACH

9.1 General Approach

Consultation with provinces and territories will be done through the CEPA National Advisory Committee. A multi-stakeholder consultation will also be held in early 2006. This consultation will include the proposed risk management approach and the proposed Action Plan for dealing with future new substances notifications and the PFCAs and precursors currently in commerce. As well, these documents will be posted on Environment Canada website for comments.

An official 60 day consultation period will also follow publication of the proposed regulations in the *Canada Gazette*.

9.2 Stakeholders

Stakeholders include but may not be limited to:

- Canadian importers of the four fluorotelomer based substances;
- Canadian users of the four fluorotelomer based substances;
- Various industry associations;

- Environmental/Health non-government organizations (ENGOS).

10. NEXT STEPS / TIMELINES

Action	Target Completion Date
Approval of Risk Management Strategy	November 2005
Publication of Assessment Reports	November 2005
Stakeholder Consultations	February 2006
Publication of proposed regulation in <i>Canada Gazette</i> , Part 1	June 2006