Binational Summary Report: Nonylphenol and its Ethoxylates

1. Overview:

Annex 3 - Chemicals of Mutual Concern commits the Parties to identify and designate, on an on-going basis, Chemicals of Mutual Concern (CMCs) in the Great Lakes which originate from anthropogenic sources and that are agreed to by both Parties as being potentially harmful to the environment or human health.

As such, the Annex 3 Subcommittee (C3) has charged an Identification Task Team with reviewing and critically evaluating relevant existing data and information, in accordance with the Binational *Considerations* developed by the C3, in order to determine which of a suite of seven candidate chemicals / classes should be recommended as CMCs.

This *Binational Summary Report* documents the application of the *Binational Considerations* to the candidate CMC nonyl phenol and nonyl phenol ethoxylates (NP/NPEs). This report was developed with input and review of the entire ITT and the recommendations were reached by a vote of the full ITT.

With respect to NP/NPE, the ITT has concluded that there is insufficient data and/or information available to effectively apply the *Binational Considerations*. Therefore, **the ITT has recommended that NP/NPE be identified as insufficient information on which to base a determination.** With respect to NP / NPEs, the recommendation was reached by a 2/3 majority vote of the ITT.

The ITT concluded that while there are a few exceedances of some benchmarks for NP/NPE in surface water, and sediments in the great lakes, these data are limited and may not fully reflect the impact of recent reductions in the use of NP/NPE. Moreover, new data with which to more fully assess NP/NPE in the Great Lakes environment are anticipated within the next few years. For example, in 2015, NP/NPEs were added to the Canadian Great Lakes Fish Monitoring and Surveillance program analyte list, and also to the US Toxics Release Inventory (TRI). Results from those programs will not be available before 2016. Therefore, at this time, the ITT cannot determine whether NP/NPEs presently pose a threat to the environment or human health of the Great Lakes basin.

While a determination for NP/NPE could not be reached, a number of needs and opportunities for additional activities were identified, many which could provide information necessary to reach a determination, for example:

- Initiate and/or continue surface water, wastewater effluent, sediment and top-predator fish monitoring on the Canadian and US sides of the Great Lakes, in order to establish long-term trends and to provide a measure of the performance of federal management actions;
- Need for updated use and release information, for remaining unmanaged sources in Canada and more broadly in the US, in order to better understand the present magnitude of the issue;
- Evaluate forthcoming data (e.g. Minnesota Pollution Control waste water treatment effluent concentrations, collected in 2014 and US EPA Great Lakes Fish Monitoring and Surveillance data);

2. Chemical background:

Nonylphenol ethoxylates (NPEs) are surfactants that have been in commerce for over 50 years and until recently were considered high production volume chemicals. As a result, NPEs have been used in many industrial sectors, including: cleaning products, degreasers, detergents for institutional and domestic use; textile processing; pulp and paper processing; paints, resins and protective coatings; oil and gas recovery; steel manufacturing; pest control products; and power generation (EC 2004a).

Nonylphenol (NP) is primarily used as a raw material in the manufacture of NPEs and also has some use in the production of plastics, resins and their stabilizers. NP is also an intermediate that can occur during the biodegradation of NPEs in the environment (US EPA 2010).

The use of NP and NPEs in cleaning products and detergents for institutional and consumer use was at one time their predominant use; however, these uses have declined significantly in recent years due to federal risk management measures implemented under the Canadian Environmental Protection Act, 1999 (CEPA 1999), the US EPA Design for Environment (DfE) initiatives and also market pressures in North America generally, that have been underway since 2005.

NP and NPEs are subject to regulatory attention in Canada, the US and internationally, primarily because of their toxicity to aquatic organisms in waters receiving treated and untreated effluents containing NP and NPEs. Discharges from textile wet processing and paper and pulp processing have been identified as sources of concern and were subject to control in Canada, which was successful in significantly reducing Canadian releases of NP / NPEs from these sources.

Substances:

- Nonylphenol (NP)
- Nonylphenol ethoxylates (NPEs)

NP is a term used to refer to a group of isomeric compounds each consisting of a nine-carbon alkyl chain attached to a phenol ring, with a chemical formula of $C_{15}H_{24}O$ (CCME 2002). The various isomers can differ both in the degree of alkyl chain branching and in the position on the phenol ring at which the alkyl chain is attached. Most NP produced commercially is in the form 4-nonylphenol, with varied alkyl chain branching (CCME 2002).

NPEs are a major derivative of NPs, which consist of a phenol group attached to both a nine-carbon alkyl chain and an ethoxylate chain and a general formula of C_9H_{19}-$C_6H_4O(CH_2CH_2O)_nH$ (CCME 2002). While the number of ethoxylate groups (n) may range from 1 to 100, most commercially produced NPEs containing between 6 and 12 (CCME 2002).

Environmental Fate:

NP and NPEs are not expected to readily volatize into air and are expected to degrade rapidly in the atmosphere (EC and HC 2001).

Although there are some conflicting reports in the literature, in general NP and NPEs are not readily biodegradable in water using standard test methods. However, substantial biodegradation will occur after a period of acclimation and therefore NP and NPEs are inherently biodegradable in water. The NPE biodegradation mechanism involves the stepwise loss of ethoxy groups to lower NPE congeners followed by production of NP (EC and HC 2001). As such, through their degradation in wastewater treatment plants and in the environment, NPEs can act as a significant source of NP and low mole NPEs (e.g. NPE1 and NPE2). While NP and NPEs can be effectively removed in wastewater treatment plants (WWTPs), with removal rates commonly greater than 90%, low levels of NP/NPE degradation metabolites have been reported in effluent and receiving surface waters (Melcer 2007).

Noting that data available are limited, the CEPA 1999 assessment concludes that NP/NPEs do not meet the criteria for persistence in air ($t^{1/2} \geq 2$ days), water ($t^{1/2} \geq 182$ days), soil ($t^{1/2} \geq 182$ days) or sediment ($t^{1/2} \geq 365$ days) as defined by the *Persistence and Bioaccumulation Regulations*, under CEPA 1999 (EC and HC 2001).

The CEPA 1999 assessment of NP and NPEs found that the available literature suggests that the bioaccumulation of NPEs in aquatic biota is low to moderate. Bioconcentration factors (BCF) and bioaccumulation factors (BAF) in biota (including algae, plants, invertebrates and fish) range from 0.9 to 3400 (for NPE) and 4120 (for NP), which is below the criteria for bioaccumulation (BAF/BCF > 5,000) as defined by the *Persistence and Bioaccumulation Regulations*, under CEPA 1999 (EC and HC 2001).

Status in Canada:

NP and NPEs were determined to be Toxic under CEPA 1999 Section 64(a) because they "may have an immediate or long-term harmful effect on the environment or its biological diversity" (EC and HC 2001)

As a result NP/NPEs were subject to risk management activities under CEPA 1999, including pollution prevention planning notifications for their use in wet textile processing, paper pulp processing as well as in products for soap and cleaning, textile wet processing and pulp and paper processing aids (EC 2004a). See Section 4 for additional details.

Status in the United States:

NP/NPEs were listed under the US EPA Chemical Action Plan program and an Action Plan document was published. (US EPA 2010)

- In 2010, EPA announced an Action Plan for NP and NPE.   The Action Plan did not itself constitute a final Agency determination or other final Agency action. The Action Plan was based on EPA's initial review of readily available use, exposure, and hazard information on NP and NPEs. It proposed the following course of action under the Toxic Substances Control Act (TSCA) and the Emergency Planning and Community Right-To-Know Act (EPCRA) as well as voluntary actions under the US EPA Design for Environment (DfE) Program. See Section 4 for further details.

NP/NPEs were recently added to the TSCA Work Plan for Chemical Assessments: 2014 Update (US EPA 2014)

EPA intends to use the TSCA Work Plan for Chemical Assessments to focus and direct the activities of the Existing Chemicals Program over the next several years. EPA notes that identification of a chemical on the TSCA Work Plan for Chemical Assessments does not itself constitute a finding by the Agency that the chemical presents a risk to human health or the environment. Rather, identification of a chemical on the TSCA Work Plan for Chemical Assessments indicates only that the Agency intends to consider it for assessment. The Agency believes that identifying these chemicals early in the review process would afford all interested parties the opportunity to bring additional relevant information on those chemicals to the Agency's attention to further inform the assessment.

Canadian Risk Assessment:

NP and NPEs were risk assessed under CEPA, 1999 (EC and HC 2001). The CEPA 1999 risk assessment reached the following conclusions:

- CEPA 1999 64(a): Based on the available data, it is concluded that NP and NPEs are entering 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. Therefore, NP and NPEs are considered to be "toxic" as defined in CEPA 1999 Section 64(a).

- CEPA 1999 64(b): Based on the available data, it is concluded that NP and NPEs are not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger to the environment on which life depends. Therefore, NP and NPEs are not considered to be "toxic" as defined in CEPA 1999 Section 64(b).

- CEPA 1999 64(c): On the basis of consideration of the margin of exposure between effect levels and reasonable worst-case estimates of intake from environmental media, NP and NPEs are not considered to be “toxic” as defined under CEPA 1999 Section 64(c) and are therefore not a priority for investigation of options to reduce public exposure through control of sources that are addressed under CEPA 1999. However, given the relatively low margin of exposure estimated for some products indicates that there is a potential need for refinement of the human health risk assessment, in order to determine the potential need for measures to reduce public exposure to NP/NPEs in products.

NP/NPEs therefore were only concluded to be toxic as per CEPA 1999 Section 64(a). This was primarily because, in 2001 NP and NPEs from untreated or partially treated textile mills that discharge directly to the aquatic environment occur at levels that are likely to cause harm to aquatic organisms and 2001 discharges of NP and NPEs from a select number of wastewater treatment plants (WWTPs) and pulp and paper mills also occur at levels of concern.

Other relevant findings regarding the potential to cause ecological harm identified in the CEPA 1999 risk assessment for NP/NPEs included:

- Noting that data available were extremely limited, the final assessment concluded that NP/NPEs are not likely to meet the criteria for persistence in air, water, soil or sediment nor are they likely to meet the criteria for bioaccumulation, as defined under the *Persistence and Bioaccumulation Regulations*, under CEPA 1999.

- The major route of entry of NP/NPEs into the Canadian environment at the time of the assessment was through the discharge of wastewater and industrial effluents, the composition / mixture of which can differ considerably depending on the source and the degree and type of treatment;

- There were a large number of ecotoxicological studies available to conduct the risk assessment reporting acute and chronic effects of NP/NPEs in aquatic biota, inducing number of estrogenic responses;

Relevant findings of the risk assessment with regards to the potential risks of NP and NPES to human health include:

- Monitoring data for those media most relevant to human exposure (e.g. indirect exposure from a wide range of industrial activities and direct exposure from consumer products etc.) are extremely limited;
  - Based on reasonable worst-case estimates, indirect exposure to NP and NPEs is estimated to result principally from the consumption of food (0.017 mg/kg-bw per day);
  - Potential intakes from subsistence populations from the consumption of local fish and game from environments receiving large quantities of NP and NPEs are expected to be similar (0.014 mg/kg-bw per day);

- Based on a available data for NP and NPEs, a lowest observable effect level of 12 – 18 mg/kg-bw per day was used assess risk to human health:, and;

  - Resulted in margin of exposure for intake of NP and NPEs via food of approximately 700;

  - Margin of exposure using reasonable worst-case exposures for some consumer products are considerably less (e.g. 0.5 for skin moisturizer, 43 for deodorant, 8 for fragrances and 21 for household cleaners);

- The estrogenic potential of NP and NPEs has been identified in a number of studies; however, these compounds were between 3 and 5 orders of magnitude less active in this regard than estradiol and were only estrogenic at relatively high dose levels,

  - For example, other effects (e.g. renal histopathology) were observed at doses of NP three times lower than those in estrogen responsive tissues (i.e. 12 vs. 50 mg/kw-bw per day);

For further information, please refer to the Priority Substances List Assessment Report for Nonylphenol and its Ethoxylates (EC and HC 2001)

United States Risk Assessment:

NPEs were assessed by US EPA for use as inert ingredients in pesticide products under the Food Quality Protection Act (US EPA 2006). This human health risk assessment, which also considered data on NP, was conducted as part of a reassessment of all inert ingredients as mandated by Food Quality Protection Act (FQPA). It concluded there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to NPEs when used as an inert ingredient considering dietary and non-occupational exposures. This EPA assessment also found no concern for increased sensitivity to infants and children from NPEs. It also concluded NP and NPE are not carcinogenic.

NP was assessed for hazards under the US EPA High Production Volume (HPV) Challenge Program in 2009. Under the HPV Challenge Program, companies were "challenged" to make health and environmental effects data publicly available on chemicals produced or imported in the United States in the greatest quantities. HPV chemicals are classified as those chemicals produced or imported in the United States in quantities of 1 million pounds or more per year. Each submission contains data on a checklist of 18 specific tests

EPA has published a Screening level hazard characterization for NP under the category of Alkylphenols (US EPA 2009). The US EPA Chemical Action Plan document (US EPA, 2010) presents a hazard characterization summary and an exposure characterization summary.

US EPA categorizes the NP/NPE Action Plan document as a "screening level review," along with the caveat that it is based on "EPA's initial review of readily available use, exposure, and hazard information". The US EPA Action Plan Document for NP/NPE states that on a national basis "Some of the measured surface water concentrations particularly those near industrial discharges exceed the water quality criteria for freshwater species living in the water column. NP and NPEs in the freshwater and saltwater ecosystems have the potential for ecological effects on all trophic levels of aquatic species exposed to them." It also expresses concern for exposure to women and children due "to the presence of NP and NPEs in detergents, cleaners, agricultural and indoor pesticides, food packaging and cosmetics".

The TSCA Work Plan for Chemical Assessments: 2014 Update includes (US EPA, 2014b) includes hazard and exposure characterizations. The updated 2014 TSCA Work Plan Document includes a table of hazard and exposure characteristics and rankings for NP/NPE; however supporting data or references are not provided.

The Work Plan table states NP/NPE meet the criteria for prioritization for risk assessment based on potential for reproductive toxicity, developmental toxicity, aquatic toxicity, moderate environmental persistence and moderate bioaccumulation. However, the recent proposed NP/NPE Significant New Use Rule (SNUR) referred to NP and NPEs as "persistent and low-to-moderately bioaccumulative.

The TSCA Workplan characterizes the use of NP/NPE as "commercial and industrial". It states that NP/NPE meet the exposure criteria for prioritization for risk assessment due to their use in "industrial detergents as well as other cleaners, degreasers (some for consumer use), and dry cleaning". It states industrial uses include "petroleum dispersants, emulsifiers, wetting agents, adhesives, paper and textile processing formulations, prewash spotters, metalworking fluids, some paints and coatings, and dust control agents." For these reasons, NP and NPE were added to the TSCA Work Plan for further risk assessment. (US EPA 2014b)

3. Review of existing scientific data and a qualitative evaluation of their significance:

Globally, NP and NPEs have been identified in industrial waste water from the pulp and paper industry, paint industry (production of paints), production (and use) of detergents and cleaning agents, metal working industry, textile and leather industry, the photographic industry, the civil and mechanical engineering industry, air transport (anti-icing use), agriculture (pesticide use), WWTPs, landfills and storm water at least from waste sorting sites. (Baltic Marine Environmental Protection Commission 2013)

The use of alkylphenol ethoxylates, which is considered to be primarily (>85%) NPE, in North America (including the U.S., Canada and Mexico) dropped by 44.8% between 2004 (232,000 tons) and 2013 (128,000 tons) (Colin A. Houston & Associates, Inc. 2006, 2007, 2013). This is thought to be due in part to regulatory requirements in Canada for pollution prevention plans in high consumption and high emission product areas (cleaning products, wet textile processing and paper and pulp processing). The drop was also influenced by voluntary initiatives under the U.S. EPA Design for Environment Program and market pressures due a policy announcement by Wal-Mart in 2006 to restrict the use of NPEs in cleaning and laundry products that it sells.

Canadian Source, Use and Release Information:

Sources:

Based on reports from facilities on preparation and implementation of pollution prevention plans, by December 2013, both manufacturing and importation of products containing NP and NPEs decreased significantly. The annual use of NP and NPEs in product manufacturing decreased to 86 tonnes and import decreased to 27 tonnes, compared with 2100 and 850 tonnes respectively in the baseline year of 1998. This represents an overall reduction of 96% in NP and NPEs used to manufacture products and imported products (EC 2014a).

In addition, the NP and NPEs used in textile mills reported under the pollution prevention plans decreased from 207069 kg in 1998 to 20.2 kg in the final year of the plan, representing a 99.9% reduction (EC 2012b).

Uses:

NPEs and NPE-containing products have many industrial, commercial, institutional and household uses in Canada, including lubrication, defoaming, assisting in dyeing, as emulsifiers, controlling deposits and cleaning machinery and materials, scouring fibres, as wetting and de-wetting agents and in product finishing (EC and HC 2001).

NP and NPE-containing products are used in many sectors in Canada, including, textile production, pulp and paper manufacturing, metal processing, petroleum refining, oil and gas recovery, power generation, food and beverage processing, plastics manufacture, and the building and construction industry, as well as in soap and cleaning product, paint, resin and protective coatings formulation. (EC and HC 2001) However, since risk management was initiated in Canada in 2004, their use in soaps and cleaning products, textile mills and pulp and paper manufacturing products has been significantly reduced (EC 2012b, 2014a).

As of 2001, NP/NPEs were identified in approximately 200 pesticides currently registered for use in Canada, with 40% containing less than 1% NP/NPE, 85% containing less than 10% NP/NPE and 95% containing less than 20% NP/NPE (EC and HC 2001).

Releases:

In Canada NP and NPEs are listed in Canada's National Pollutant Release Inventory (EC 2015a).

Based on 1998 and 1999 averages and prior to the implementation of Pollution Prevention Planning under CEPA 1999, the use of soap and cleaning products was the largest source of releases of NP and NPEs followed by the use of textile processing aids, agricultural products, and pulp and paper processing aids (EC 2004a).

Based on these averages, soap and cleaning products, textiles production products and pulp and paper manufacturing products alone were responsible for nearly 80% of the use and estimated releases of NP and NPEs in Canada (EC 2004a).

The following table summarizes the estimated releases of NP and NPEs due to each sector and products as percentages of the total estimated annual release on NPEs (values are rounded to the nearest percentage) (EC 2004a).

Sectors and products	**Total Release (%)**
Soap and Cleaning Products	56
Textile Production Products	18
Agricultural Products – Pesticides	8
Pulp and Paper Manufacturing Products	5
Other Products	4
Formulators/Distributors of Products	4
Plastic, Resins, Polymers Manufacturing Products	3
NP/NPEs Producers	1
Paints & Varnish	1
Toilet Preparations	<1
TOTAL	**100**

Table 1: Canadian releases of NP/NPEs (1998-1999) prior to implementation of risk management actions. (EC 2004a)

Under the NPRI, Facilities are required to report to the NPRI if NP and NPEs were manufactured, processed or otherwise used at the facility in a quantity of 10,000 kg or more and employees worked 20,000 hours or more in a calendar year. Releases of NP / NPEs to air and water since 2000, as reported to the NPRI, are presented in Figures 1 and 2 below. In 2014, Environment Canada reduced the NPRI mass threshold for NP and NPEs from 10 tonnes (10,000kg) to 1 tonne (1,000kg). Pollution prevention planning requirements have decreased the use of these substances to below the previous NPRI 10 tonne threshold and the threshold was decreased to 1 tonne in response to these lower quantities (EC 2014b).

The trend for facilities meeting the reporting criteria has declined between 2003 and 2012 (Table 2). Since risk management was initiated in Canada in 2004, their releases from soaps and cleaning products, textile mills and pulp and paper manufacturing products have been reduced by more than 95%.

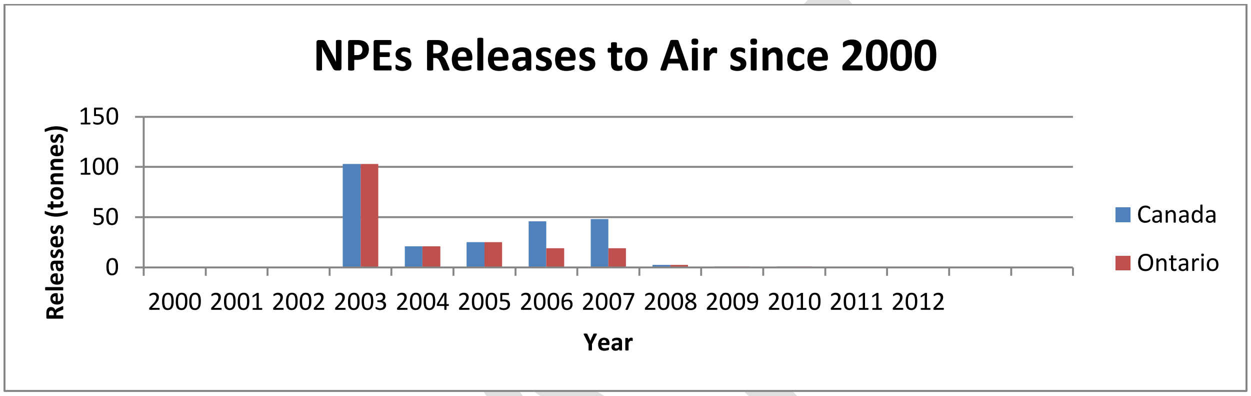

Figure 1: Releases of NPEs to air in Ontario and for all of Canada, since 2000, as reported to the National Pollutant Release Inventory. (EC 2015a)

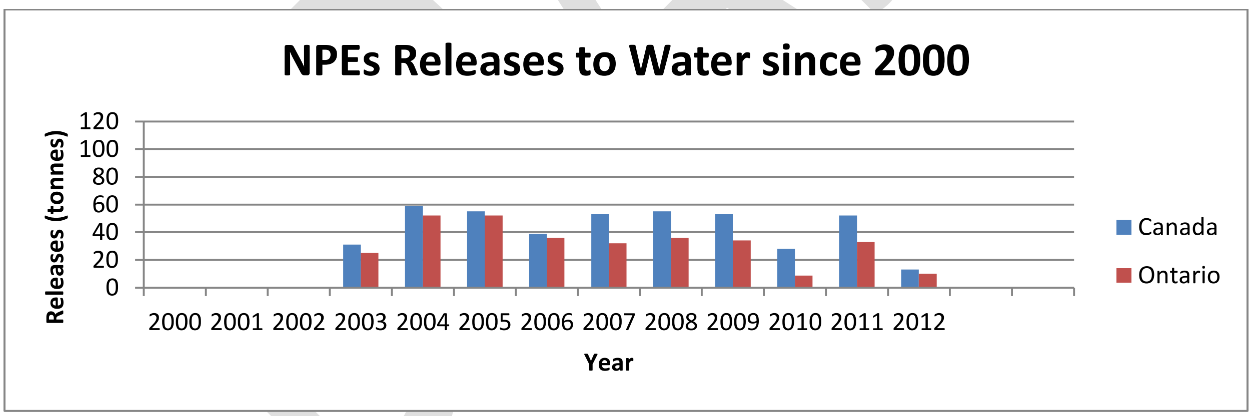

Figure 2: Releases of NPEs to air in Ontario and for all of Canada, since 2000, as reported to the National Pollutant Release Inventory. (EC 2015a)

Year	Number of facilities meeting the NPE trigger criteria	Total number of facilities that reported releases to water	Number of WWTPs that reported releases to water	Total reported quantity to water (tonnes)
2003	75	7	4	31
2004	74	10	7	59
2005	69	7	7	55
2006	64	5	5	39
2007	52	6	6	53
2008	49	6	6	55
2009	47	6	5	53
2010	43	3	3	28
2011	43	7	5	52
2012	37	4	3	13

Table 2: Breakdown of Canadian facilities reporting NPE releases to water to the National Pollutant Release Inventory. (EC 2015a)

United States Source, Use and Release Information:

The US EPA Chemical Data Reporting (CDR) requires that chemical manufacturers periodically update production information for compounds listed in the TSCA Chemical Substance Inventory. For the 17 total NPs/NPEs (four NPs + 13 NPEs) on the TSCA Inventory, chemical companies reported production volume for the following four NPs/NPEs to the most recent (2012) CDR: Branched NP CASRN 84852-15-3 at 100-500 million lbs., branched NP CASRN 91672-41-2 at 1-10 million lbs., linear NPE CASRN 9016-45-9 at 10-50 million lbs., and branched NPE CASRN 127087-87-0 at 1-10 million lbs (US EPA 2014). Overall, reported NP/NPE production volumes decreased from the previous reporting period (2006) to the 2012 reporting period.

Uses:

NP's main use is in the manufacture of NPEs and is also used as epoxy cure catalysts. NPEs are nonionic surfactants that are used in a wide variety of industrial applications and consumer products. (EPA 2010) NPEs can be found in consumer products related generally to home care, personal hygiene, automotive, and lawn care. Specifically, NPEs are used in: Laundry detergents, engine and battery cleaners, all-purpose cleaners, paints, metal polishers, stain pretreatment, sealants, paint/varnish strippers, wallpaper removers, hand cleaners, floor strippers, disinfectant/mold inhibitors, concrete cleaners, tile/grout cleaners, degreasers, brush cleaners, tile adhesives, and wood finishes (US EPA 2014c; NIH, 2014; CPID 2014; US EPA 2010; US EPA 2009).

Releases:

In the US, NP was recently added to the TRI (US EPA 2014); however, emission date will not be available until 2016.

Environmental Quality Guidelines:

<u>Canada:</u>

The Canadian Council of Ministers of the Environment has developed Canadian sediment and surface water quality guidelines for NP and NPEs, for the protection of aquatic life (CCME, 2002a,b).

Surface Water and Sediment	
	Freshwater
Water Quality Guidelines (WQGs) for Protection of Aquatic Life for NP/NPEs	1.0 µg/L [(1)]
Interim sediment quality guidelines (ISQGs) for NP/NPEs	1.4 mg/kg, dry weight [(2)(3)]

(1) Expressed on a Toxic Equivalent Q (TEQ) basis using Toxic Equivalency Factors (TEFs) relative to NP
(3) Expressed on a TEQ basis using NP TEFs; assumes 1% TOC.
(4) Provisional; use of equilibrium partitioning approach.

Table 3: Canadian Council of Ministers of the Environment (2002) Canadian Environmental Quality Guidelines. (CCME 2002a,b)

Compound	**TEF relative to NP**
NP	1
NP*n*EO (1 < *n* < 8)	0.5
NP*n*EO (*n* > 9)	0.005
NP1EC	0.005
NP2EC	0.005

$$\text{Total TEQ} = \sum_{i=1}^{n} (C_i \times TEF_i)$$

TEQ = concentration of the mixture of NP compounds expressed as toxic equivalent of NP where:

n = number of NP compounds

i = 1, 2, 3, …, n

Ci = concentration of compound i

TEFi = toxic equivalency factor for the compound I (unitless).

Table 4: TEFs for NP, NPEs, NPECs (relative to NP). (Servos 2000 and CCME 2002)

<u>United States:</u>

US EPA finalized ambient Water Quality Criteria for NP in 2006 – see table below (US EPA 2005; US EPA 2006). The EPA WQC provides guidelines to states for the development of state Water Quality Standards under the Clean Water Act. When monitoring indicates an exceedance of state WQS, regulatory mechanisms exist under the National Pollutant Discharge Elimination System (NPDES) to enact controls. The NP WQC document notes “the ability of NP to induce estrogenic effects has seldom been reported at concentrations below the freshwater final chronic value”, which is 6.6 µg/L.

Freshwater (µg/L)	
Acute	Chronic
28	6.6

Table 5: U.S. EPA Aquatic Life Ambient Water Quality Criteria for Nonylphenol (US EPA 2005: US EPA 2006).

Monitoring Data and Other Considerations:

<u>Wastewater:</u>

Through the Monitoring and Surveillance Program in the Chemicals Management Plan (CMP), Environment Canada monitored NP and NPEs at 12 WWTPs across Canada between 2010 and 2012. This monitoring work includes sampling of raw influent, final effluent and biosolids, where present at each location. It also included sampling in winter and summer months and a sampled across a range of wastewater treatment systems (Shah and Smyth 2013).

The results of monitoring in Canadian wastewater and biosolids, conducted in 2010-2011, suggest that the risk management measures for NP and NPEs in products have been effective in reducing their levels in wastewater effluents and biosolids. These results also provide information about the range of removals of these compounds in typical wastewater treatment systems employed in Canada. The table below provides median concentrations of NP compounds in Canadian wastewater influents and effluents and also provides an estimate of WTTP removal efficiencies (Shah and Smyth, 2013). Comparison with Canadian WWTP effluent concentrations from a 1995 study show an overall reduction of approximately 53% in NP and a 98% reduction in similar WWTPs (i.e. similar treatment processes and size etc.) (Smyth 2014).

Regardless, these monitoring results indicate that many wastewater treatment processes have effluents that meet the Canadian environmental objective for NP and NPEs. Furthermore, wastewater is diluted to the environment according to proscribed discharged ratios. However, it would still be beneficial to follow up with surface water testing to confirm these results.

Influent	**NP**	**NP1EO**	**NP2EO**
Detection Frequency	80/84	59/84	80/84
Median of all values (ng/L)	2,540	2,300	1,300
Effluent	**NP**	**NP1EO**	**NP2EO**
Detection Frequency	75/84	55/84	71/84
Median of all values (ng/L)	203	124	< 330
Removal Efficiency	**~ 92%**	**~ 95%**	**~ 75%**

Notes:
NP = 4-nonylphenol (toxic equivalency factor =1)
NP1EO = 4-nonylphenol monoethoxylate (toxic equivalency factor =0.5)
NP2EO = 4-nonylphenol diethoxylate (toxic equivalency factor =0.5)
Total concentration = ∑(Cx x toxic equivalency factor)

Table 6: Detection frequency, and median concentrations (ng/L) in Canadian WWTP influent and effluent, sampled in 2010 and 2011 (Shah and Smyth 2013)

Barber et al (2011) conducted a study in the North Shore Channel (NSC) and effluent from the Northside WWTP along with control samples from the Outer Chicago Harbor to examine effects of biologically-active chemical mixtures on fish in a wastewater-impacted urban stream. Sampling was conducted in 2006 and 2007 and NP, NP1-4EO were among the analytes. NPEC1-4 was the most frequently detected; however these compounds are 200-fold less toxic than NP according to the Canadian TEFs for these compounds. From box plots presented in the paper: WRP effluent contained NP at approximately 1 µg/L and NP1-4EO at approximately 1 to 5 µg/L with one sample at 9 ug/L. NSC water: contained NP/NP1-4EO at approximately 1 to 5 ug/L. The study also cites Rameriz et al. (2009) for concentrations in largemouth bass from the same locations, in which NP was not detected in fish fillet or liver at MDL (9.7 ng/g).

Barber et al (2011) also measured greater than 100 biologically active compounds. Twenty three compounds were detected in all samples, including estrogens (17β-estradiol and estrone) and androgens (testosterone and 4-androstene-3,17-dione and cis-androsterone). The majority of male fish collected in the North Shore Channel during both sampling events had detectable plasma vitellogenin concentrations albeit at lower values than female conspecifics at the same site. All mature fish from both sites (North Shore Channel and control Outer Chicago Harbor) were gametogenic with males actively producing spermatozoa and females producing vitellogenic oocytes. No histopathological changes (ovatestis, atretic testis, oratretic ovaries) were observed in reproductive tissues in fish from both sites. The authors concluded that 80% of the 17β-estradiol equivalence quotient (EEQ) in the North Shore Channel was attributed to 17-estradiol, estrone and estriol**.**

Recent data collected by the Minnesota Pollution Control Agency (Streets 2015) have indicated that concentrations of NP and NPEs in wastewater influents and effluents have remained steady despite deselection by industrial laundries, to which a possible link to household consumer product use (laundry detergents) is being investigated. Seven of the twelve large industrial laundries which eliminated NPE discharge are in the Metro Twin Cities Main wastewater treatment plant sewershed, and MPCA estimates their total annual reduction at 179 tons. This apparently-large reduction is what led MPCA staff to expect to see some reduction in Main Plant influent concentrations. However, analysis in fall of 2014 of 24-hour composite samples of that influent showed little change versus baseline data from influent sampling done in 2012 and 2013. About 70% of wastewater volume entering the Metro Plant is domestic. MPCA has therefore decided to work with Twin Cities Metro Plant staff to analyze samples taken on branches of their system which are dominated by domestic discharge. That work will take place in spring of 2015.

Biosolids:

Lee et al (2004) conducted a study in Toronto WWTPs to establish the baseline levels of the EDCS in the sewage samples collected in Toronto. Concentrations in influent for NP were 2.8 to 16.7 ug/L; for effluent for NP were 0.5 to 9.1 ug/L. ; for raw sludge were for NP were 15 to 311; NP1-3EO: 57 to 497 ug/g-dw for digested biosolids for NP were 85 to 514; NP1-3EO: 18 to 342 ug/g-dw. The sampling for this study was done prior to risk management in Canada. The authors concluded that future research on the fate of endocrine disrupting chemicals (including NP and NPEs) in biosolids amended soils is recommended for the better understanding of their dissipation and transportation in the environment. See discussion under Staples, 2013 and 2014 below on biosolids amended terrestrial risk assessments.

Shah and Smyth (2013) also looked at NP, OP, NP1EO and NP2EO measured in Canadian Municipal Wastewater and Biosolids between 2010 and 2011. Biosolids median values (µg/g) were: NP (62.9), NP1EO (4.390) and NP2EO (1.240), with max values (µg/g) of: NP (163.0), NP1EO (116.0) and NP2EO (21.4).

The Shah and Smythe (2013) measured biosolids concentrations translated into reductions of 72, 99, 78, and 93% for NP, OP, NP1EO and NP2EO respectively in biosolids, when their results were compared to those of a 2002.

Staples et al (2013) estimated the risks to terrestrial macro-invertebrates and plants from exposure to para-NP in biosolids-amended soil. BOSOLIDS concentration from samples analyzed for NP taken in the US between 2001 and 2013 from 4 studies ranged between 5.4 and 1380 mg/kg-dw with a median concentration of 91 mg/kg-dw. Based on this median value in biosolids the median calculated concentration of p-NP of 0.13 mg/kg-dw in biosolids-amended soil (based on median NP in biosolids 91 mg/kg) is well below the Chronic Toxicity value of 2.3 mg/kg-dw used in the study (HQ = 0.05). The maximum calculated concentration of p-NP of 2.03 mg/kg-dw in soil (based on maxNP in biosolids of 1380 mg/kg) is slightly below the Chronic Toxicity value (HQ = 0.88); In the probabilistic risk assessment, none of the soil concentrations of p-NP overlap with any of the toxicity values (NOEC or EC10). Most of the distribution of soil concentrations were one or more orders of magnitude below the toxicity values; Based on this assessment concentrations of p-NP in biosolids in the US do not appear to pose a risk to macro-invertebrates, plants, and microbes that dwell at the bottom of the terrestrial food webs from the land application of biosolids to agricultural fields. Note: This assessment only considered lower tiered taxa. Future assessments could assess secondary exposure pathways (e.g., mammals, birds).

Staples, C. et al (2014) estimated risks to small mammals from exposure to p-NP in biosolids-amended soil. Measured concentrations of p-NP within biosolids from North American WWTPs were used to calculate soil concentrations and dose rates, assuming that 100% of the p-NP within the biosolids was bioavailable. The distribution of soil concentrations of p-NP did not overlap with the distribution of toxicity values (NOEC or EC10) for organisms (invertebrates, plants, microbes) at the base of the terrestrial food-web. Toxicity to small mammals was represented by a multi-generation test with rats that yielded the lowest NOAEL among several studies (13 mg/kg-bw/day).The lowest NOAEL were based on adult systemic toxicity, reproductive toxicity and offspring toxicity. Dose rates were calculated for the short-tailed shrew, a representative small mammal that lives in fields and consumes small invertebrates and plants. The short-tailed shrew was assumed to live its entire life within the biosolids-amended fields and consume only food from the fields. All dose rates were below the point-of-departure value of 13 mg/kg-bw/day. Based on this assessment, concentrations of p-NP in biosolids that are applied to soil do not appear to pose a risk to macro-invertebrates, plants, and microbes that dwell at the bottom of the terrestrial food webs or to small mammals that consume them.

Canadian CCME soil quality guidelines for NP/NPEs, for the protection of environmental and humane health are all greater than the Chronic Toxicity (soil) value used in the Staples 2013 and 2014 assessments. The calculated biosolids amended soil concentrations in Staples 2013 and 2014 are all below the CCME soil EQGs of 5.7 mg/kg (agricultural and residential) and 14 mg/kg (commercial and industrial) (CCME 2002b).

<u>Water:</u>

According to the risk assessment report for NP and NPEs, based on data published between 1997 and 1998, Canadian fresh water contained concentrations of NP that ranged from <0.02 µg/L to 4.25 µg/L. These concentrations were also observed in rivers across Canada. NPEs were found in rivers, lakes and harbours in Canada at concentrations of 2.30 µg/L, 5.07 µg/L and 10.3 µg/L, respectively (EC&HC 2001).

Bodies of fresh and surface water in Canada have not been actively monitored for NP and NPEs since the publication of the risk management strategy and risk management instruments. Surface water testing in Quebec has demonstrated a decrease of NP and NPEs between 89% and 99% at seven test sites between 2000-2003 and 2009-2010 (Gauthier 2013). Over the same time period, the resulting median concentrations dropped from 8.14 µg/L to 0.59 µg/L. The seven sites were selected due to their proximity to textile facilities.

On a US national level, Klecka et al (2007) conducted an assessment of surface water and/or sediment monitoring studies available in the published or publicly available literature to develop a statistical understanding of exposures to alkylphenol ethoxylates (APE), including NPE and its metabolites in US surface waters. A literature search was conducted to identify environmental monitoring studies published during the 15 year period between 1990 and 2005, which contained information on surface water and/or sediment concentrations of APE and its metabolites in US waters. Nineteen reliable monitoring studies, most of which were conducted by the US Geological Survey (USGS), were reviewed and the highest concentrations of all NPE metabolites were generally observed for rivers in heavily urbanized or industrialized locations with average concentrations of 1.7 µg/L, 1.2 µg/L, 2.3 µg/L, and 8.1 µg/L for NP, NPE1, NPE>1, and nonylphenol ethoxycarboxylate (NPEC) respectively reported. Klecka et al. (2007) reported NPE>1 as a group because the US Geological Survey (USGS), which provided much of the data analyzed in this paper, frequently reported in this manner. However, a review of the database that catalogued all of the raw data analyzed by Klecka et al. (2007) confirmed that the majority (87%) of the data points categorized as NPE>1 do in fact represent concentrations of NPE2 (Klecka, G.M. (2009, August).

Klecka et al. (2007) conducted an assessment of the aggregate exposure to APE and its metabolites measured in US surface waters. The authors relied on the US EPA WQC for NP to establish the benchmark for environmental safety in US waters and the TEFs developed by Environment Canada (2002) to calculate the relative contribution of NPE metabolites and the aggregate toxicity of NP and other NPE degradation intermediates. The authors also assumed that the toxicity interaction between the various NPE metabolites was additive. Their conservative evaluation of aggregate exposure to all APE degradation metabolites - not just NPE degradants - concluded that 97% of the samples contained aggregate NP-equivalent concentrations which were below the EPA chronic freshwater WQC of 6.6 ug/L and suggested that on a nationwide basis, the likelihood of surface water concentrations exceeding the chronic EPA WQC for NP is low.

Klecka et al. (2007) also used the available data to examine changes in reported concentrations of NPE metabolites in surface water in the U.S. generally over a 15 year sampling period from 1990 through 2005. While noting that the data were drawn from a diverse set of studies with different sampling strategies and analytical methods, the authors found that maximum concentrations varied widely; however, the mean and 90^{th} percentiles for concentrations of NPE and its metabolites remained relatively constant during this time period. Therefore, it was assumed that any apparent shifts in maximum concentrations represented a bias in sampling locations toward effluent-dominated streams. These findings together with market information regarding the declining volume use of NPE in consumer cleaning products and laundry detergents, textile and paper pulp manufacturing make it likely that concentrations of NPE metabolites in US surface waters have not increased since 2005 and likely have decreased.

<u>Sediment:</u>

Hull et al. (2014) compared maximum reported NP TEQ concentrations from US and Canadian sites in the Great Lakes (64,050 µg/kg and 110,000 µg/kg, respectively, as identified in Klecka et al. 2007) and compared to established no-observed effect concentration (1400 µg/kg) to establish worst-case scenario hazard quotients of 46 and 79 for US and Canadian Great Lakes sediments, respectively.

<u>Fish Biomonitoring:</u>

Lazano et al. (2012) conducted a study on the concentration of organic contaminants in fish and their biological effects in a wastewater-dominated urban stream in Chicago. Samples were collected in 2006-2007. Stream average concentrations in the fall (µg/L) were: NP (0.55), NP1EO (1.16), NP2EO (1.73) and NP3EO (ND), which corresponds to an NP equivalent based total of 2 µg/L. Stream average concentrations in the spring (µg/L) were: NP (1.01), NP1EO (5.08), NP2EO (2.92) and NP3EO (1.73), which corresponds to an NP equivalent based total of 4.9 µg/L. The average NP/NPEO concentrations are below US EPA chronic WQC of 6.6 µg/L for freshwater, even on an NP TEQ basis.

The authors also found biological endpoints for endocrine effects measured in the same fish showed that there was an apparent positive correlation for physiological effects based on increased vitellogenin levels in males versus concentration of NPEs. However, there were no observable histological differences in fall versus spring fish samples and that no meaningful statistical analysis based on either size or sex of the collected fish was possible due to limited sample size for fish. No fish population decline was observed. Concentrations of NP/NPEO in fish filet were 4.8 times lower than those in whole fish concentrations.

Human Biomonitoring:

No Great Lakes specific human biomonitoring is available for NP. However, a paper (Osimitz et al 2015) critically reviewed and assessed all relevant full-text publications related to human exposure to NP in various regions based on a variety of data quality attributes. The authors concluded reasonable certainty of no harm for source-specific and aggregate (based on biomonitoring) exposures to NP. Also, the US EPA stated that NP has been detected in human breast milk, blood, and urine and is associated with reproductive and developmental effects in rodents (Ademollo et al, 2008; Chen et al, 2008; Calafat et al, 2008; and US EPA 2010).

Conclusions:

Media	Summary
Air	There are currently no air data nor benchmarks with which to assess NP/NPE in the great lakes environment.
Water	Great lakes specific data was not available to sufficiently assess current concentrations or to establish spatial or temporal trends. 97% of US surface water samples collected between 1990 and 2005 fall below the US water Quality Criteria for NP. Trends are inconclusive.
Wastewater	Canadian WWTP monitoring in 2010-2011 indicates that median concentrations of NP/NPEs in Canadian WWTP effluents have decreased significantly since the mid-1990's and at present, removal efficiencies for NP/NPEs can be as high as 95%. WWTP effluent data from the Minnesota Pollution Control Agency are under review and not available for this evaluation.
Sediment	A single study (Hull et. al 2014) reported maximum observed NP TEQ concentrations from a US and Canadian site in the Great Lakes (64,050 µg/kg and 110,000 µg/kg, respectively) and compared these to an established no-observed effect concentration of 1400 µg/kg, in order to estimate worst-case scenario hazard quotients of 46 and 79 for US and Canadian Great Lakes sediments, respectively.
Wildlife	A single study (Lazano et. al 2012) looked at fish samples collected in 2006-2007 in Chicago provide NP equivalent based total of 4.9 µg/L, which is below US EPA chronic WQC of 6.6 µg/L for freshwater. Biological endpoints for endocrine effects measured in the same fish showed that there was an apparent (non-significant) positive correlation

Media	Summary
	for physiological effects based on increased vitellogenin levels in males versus concentration of NPEs.
Biomonitoring	No Great Lakes specific human biomonitoring is available for NP.

While the availability of Great Lakes specific monitoring data is generally limited, recently reported concentrations of effluents discharged from Canadian WWTPS to the Great Lakes receiving waters have generally been below conservative levels of concern to aquatic organisms.

4. Review of past, present and/ or planned science and risk management actions:

Canadian Risk Management Actions:

Environment Canada held consultations with stakeholders in 2002 to discuss the risk management approach being considered. Following these consultations, the final risk management strategy: *Risk Management Strategy for Nonylphenol and its Ethoxylates under CEPA (1999)* was published in September 2004 (EC 2004a,b).

The environmental objective of all risk management actions is to achieve ambient concentrations in Canadian waters that do not exceed the Canadian Council of Ministers of the Environment *Canadian Water Quality Guidelines for the Protection of Aquatic Life* (CWQG) for NP and NPEs, established in 2002, of 1.0µg/L and 0.7µg/L expressed in toxic equivalency units for NP (NP TEQ) for freshwater and marine waters, respectively (EC 2004a,b).

The risk management strategy recommended the development of a Pollution Prevention (P2) Planning Notices to require facilities that meet specific criteria to develop a P2 plan that takes into account the risk management objective of reducing NPEs in two phases within specified timelines (EC 2004a,b).

As such two P2 Planning Notices were published in 2004:

1. *Notice Requiring the Preparation and Implementation of Pollution Prevention Plans in Respect of Nonylphenol and its Ethoxylates Contained in Products*.

The P2 Planning Notice applied to importation and on-site manufacturing of NP and NPEs in soap and cleaning products, processing aids used in textile wet processing and pulp paper processing aids as well as raw NP and NPEs above 2,000 kg.

A person whose facility or facilities met the criteria listed in the P2 Planning Notice between January 1, 2003, and December 31, 2012 was required to prepare a P2 plan taking into consideration the risk management targets of 50% and 95% in 2 phases. This P2 planning notice has now expired (EC 2004c).

2. *Notice Requiring the Preparation and Implementation of Pollution Prevention Plans in Respect of Effluents from Textile Mills that Use Wet Processing (TMEs) and Nonylphenol (NP) and its Ethoxylates (NPEs).*

The P2 Planning Notice applied to persons who owned or operated a textile mill that was involved in wet processing activities that used NP and NPEs and met specific effluent discharge criteria. Persons who met the criteria in the P2 Planning Notice between 1999 and 2003 had to prepare a P2 plan that took into consideration the risk management objective of reducing NP and NPEs relative to the base year (typically 1998) by 97% by 2009 (EC 2004d). This P2 Planning notice has expired.

Also in 2004, Environment Canada worked with the Canadian pulp and paper industry, through the Forest Products Association of Canada, to obtain a voluntary phase-out commitment for NP and NPE use with the pulp and paper processing industry (EC 2004b).

In February 2003, Health Canada's Pest Management Regulatory Agency (PMRA) sent letters to manufacturers of pesticide products containing more than 1% by weight of NP and NPEs. In these letters, PMRA requested manufacturers of these products to address the potential adverse effects of these substances on the aquatic environment by substitution of NP and NPEs with less harmful alternatives. PMRA also requested the manufacturers of these products to submit a plan and commit to the substitution of NP and NPEs (EC 2004b).

Sectors and products	**Total Release (%)** (Based on 1999 data)	**Risk Management Option proposed in the Risk Management Strategy**	**Risk Management Tool Used**
Soap and Cleaning Products	56	A 95% reduction of NP and NPEs used or imported from base year levels (typically 1998 level) by December 31, 2010.	Pollution Prevention (P2) Planning Notice
Textile Production Products	18	A 97% reduction in NPEs use in textile mills	Pollution Prevention (P2) Planning Notice
Agricultural Products – Pesticides	8	Risk Management Plan established by the Pest Management Regulatory Agency (PMRA)	In 2003, PMRA distributed letters to registrants of products identified as containing >1% NPEs, asking that they develop and submit a plan and commitment for substitution for NP and NPEs.
Pulp and Paper Manufacturing Products	5	>99% reduction	Voluntary industry implementation
Other Categories	13	No action	n/a

Table 7: Summary of CEPA 1999 risk management actions and objectives. (EC 2004a,b)

Other Canadian actions that may reduce NPE emissions include:

Wastewater Systems Effluent Regulations, 2012:

On June 29, 2012, the Government of Canada put in place the *Wastewater Systems Effluents Regulations* (WSER) under the *Fisheries Act* (EC 2012c). The objective of the Regulations is to reduce the threats to fish, fish habitat and human health from fish consumption by decreasing the level of deleterious substances deposited to Canadian surface water from wastewater effluent. To achieve the objective, the Regulations set national effluent quality standards that require secondary wastewater treatment or equivalent in wastewater systems across Canada. The WSER will improve the overall level of wastewater treatment, which is expected to further reduce NP and NPEs and other pollutants in wastewater effluent. (EC 2012c)

Alternatives Assessment:

In 2002, Environment Canada assessed the environmental impact of alternatives to NPEs that were available at the time for consideration as alternatives in formulations in Canada. The report titled *Alternatives to Nonylphenol Ethoxylates: Review of Toxicity, Biodegradation, & Technical Aspects* (EC 2002) was released to formulators of NPE-containing products.

Canadian Risk Management Progress:

A Final Evaluation Report for the P2 Planning for NP and NPEs in products was published in December, 2014 (EC 2014a). Based on reports from facilities on preparation and implementation of P2 plans, by December 2013, both manufacturing and importation of products containing NP and NPEs decreased significantly. The annual use of NP and NPEs in product manufacturing decreased to 86 tonnes and import decreased to 27 tonnes, compared with 2100 and 850 tonnes respectively in the baseline year of 1998. This represents an overall reduction of 96% in NP and NPEs used to manufacture products and imported products (**Figure 3**) (EC 2014a). Therefore, the risk management objective for the P2 Planning Notice for NP and NPEs in products can be considered to be achieved (EC 2014a).

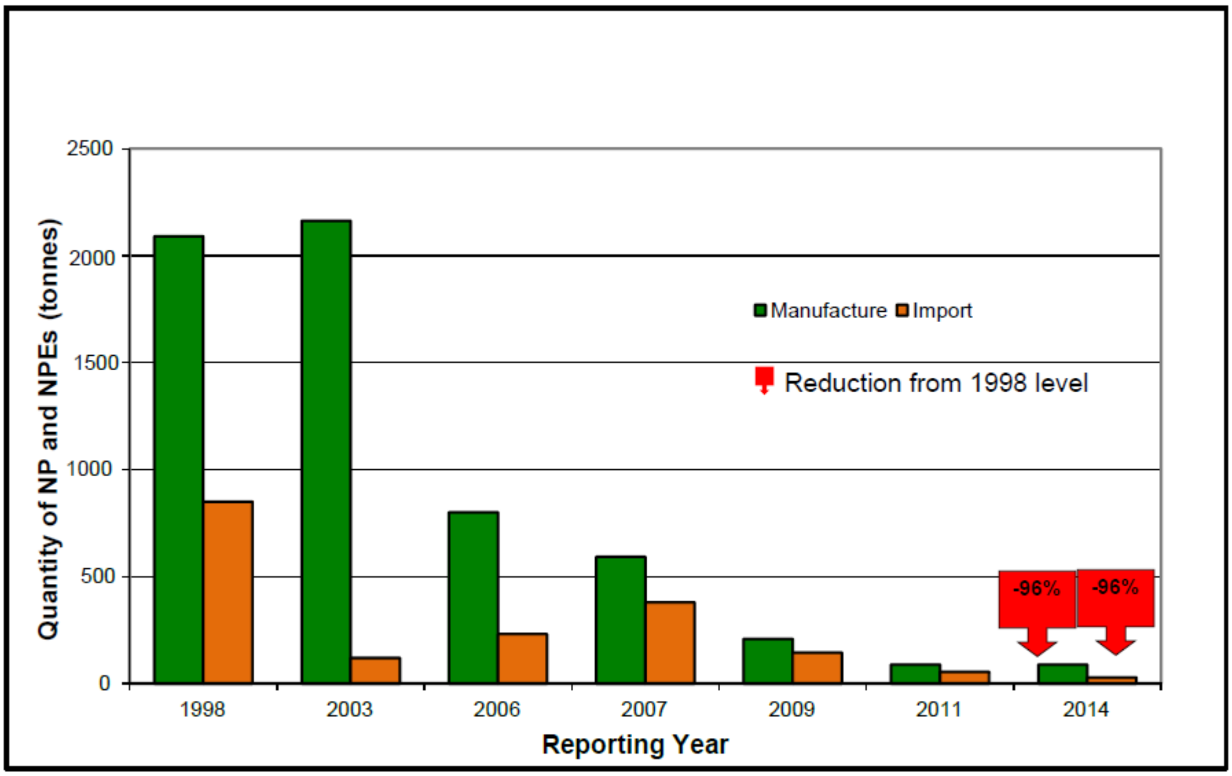

Figure 3: Reported annual use of NP and NPEs in products manufactured or imported for all facilities subject to the P2 Planning Notice for NP and NPEs in Products (EC, 2014a)

A final summary report for the P2 Planning and Effluents from Textile Mills that use Wet Processing of NP and NPEs was published in July, 2012 (EC 2012b). The NP and NPE reduction target of 97% from base year has been surpassed. NP and NPE use was reduced by 99.99% from the base year (1998 for most mills) to the implementation year (2009 for most mills). The amount of NP and NPEs used declined from over 207 tonnes (207 069 kg) in the base year to 20 kg in the implementation year, as can be seen in Figure 4 below (EC 2012b).

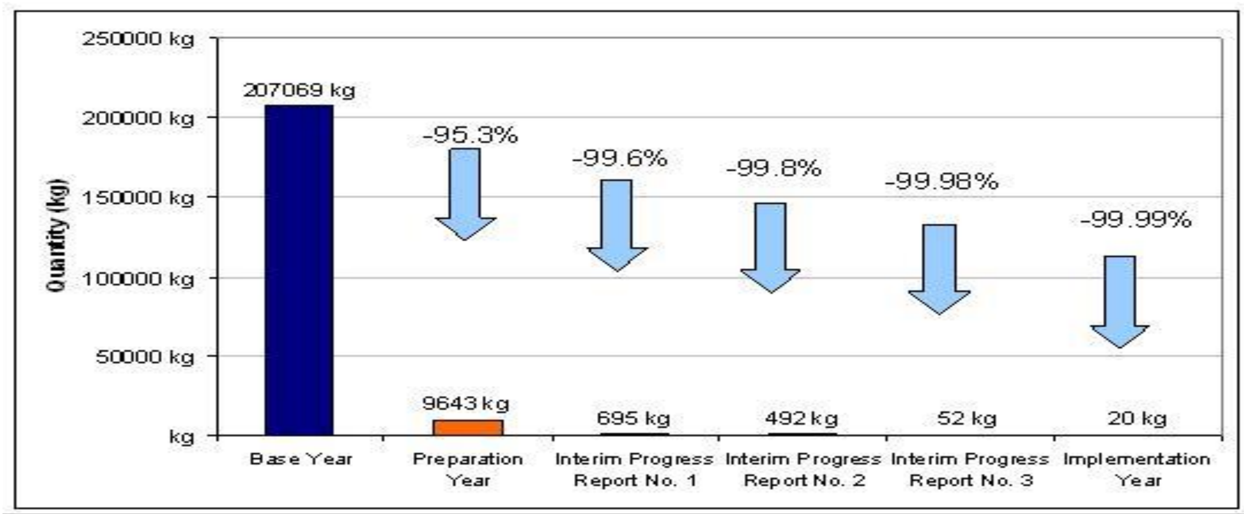

Figure 4: Quantities of NP and NPEs used by textile mills subject to the P2 Planning Notice for effluents of Textile Mills that use Wet Processing and NP and NPEs (EC 2012b)

Mills subject to the notice were required to reduce the toxicity of their effluents to a level equivalent to or greater than an IC_{50} of 13% (EC 2012b). A minimum of four toxicity tests were to be performed throughout the year in order to determine if this objective was met (EC 2012b). According to Environment Canada's analysis of active mills, the majority (61%) were considered to have met the objective and a further 31% demonstrated that they passed some, but not all, of their toxicity tests (EC, 2012b). Therefore, 92% of active mills were considered to have met or partially met the requirements and the four mills that did not submit any toxicity results are now closed (EC 2012b).

With regards to the voluntary phase-out of NP and NPEs in pulp and paper processing, voluntary reductions of 99.8% were forecasted to have been completed by 2003 according to a 2001 survey done by FPAC, in conjunction with Environment Canada. According to this survey, five pulp and paper mills alone used 600,000 kg of the total 643,000 kg of NP and NPEs used in 2001 by the mills who responded to the survey, which is 92% of the total NP and NPEs used by this sector (EC 2015b).

Further communication with FPAC in 2010 confirmed the voluntary reductions of the 2001 survey. While there is the potential that NPE products could be reintroduced by the pulp and paper industry, this does not seem very likely. The existence of viable alternatives to NPEs in products and their proven toxicity would make it unlikely that a mill would return to their use (EC 2015b).

With regards to NP and NPEs in pesticide products, a number of responses were received in response to PMRA's request for substitution from various registrants on their planned approaches and PMRA also reviewed numerous applications to reformulate the pesticide products. As a result, manufacturers of these products forecasted a greater than 99% reduction in NP and NPEs use in their products (EC 2015b).

The overall risk management strategy for NP and NPEs has been successful, as the individual risk management instruments have effectively reduced NP and NPEs use in the targeted sectors: P2 Planning Notices for NP and NPEs in products and textile mill effluents and voluntary measures have greatly reduced the use of NP and NPEs in Canada (EC 2012b, 2014a, 2015b).

Environmental monitoring at WWTPs, the primary pathway for NP and NPEs to enter the environment, also suggests that the risk management strategy has been effective. The reduction of NP and NPEs resulting from the risk management actions combined with the results of the CMP wastewater monitoring provide an indication that environmental objectives of the Canadian Risk Management Strategy are being met.

However, periodic monitoring of wastewater effluents and ambient water surveillance should be considered and compared to relevant guidelines where applicable, to validate that the environmental objectives are being met.

United States Risk Management:

US EPA has undertaken regulatory actions and promoted voluntary actions to manage potential risks from NP and NPEs.

US EPA Regulatory Actions

2006 - NPEs were assessed and approved by US EPA for use as inert ingredients in pesticide products under the Food Quality Protection Act (US EPA 2006)

2010 - US EPA published a Nonylphenol and Nonylphenol Ethoxylates Action Plan:

- Initiating Significant New Use Rules (SNUR) for NP/NPE under TSCA Section 5. A Proposed Rule for a SNUR on certain NP and NPEs has been issued, with the public comment period closing on January 15th, 2015 (US EPA 2014).
- Initiating a Test Rule under TSCA Section 4 to determine information necessary to determine effects that NP and NPEs may have on human health and the environment. EPA already issued an advance notice of proposed rulemaking (ANPRM). (US EPA, 2009, June 9) However, EPA intends to evaluate how releases and exposures are mitigated through on-going phase outs and would finalize any proposed testing accordingly.
- Develop an alternatives analysis and encourage elimination of NPE use in laundry and other industries that discharge NPEs to water, such as the pulp and paper processing industries. An alternatives analysis was completed by EPA DfE (US EPA, 2012, May 9)
- Initiate rulemaking to add NP and NPE to the Toxics Release Inventory (TRI) under Section 313 of EPCRA. A Final Rule adding NP to the TRI was published on Sept. 30, 2014. (US. EPA, 2014, Sept). EPA plans to begin the process of adding a category of NPEs to TRI in early 2015.
- Consider initiating rulemaking under TSCA Section 5(b)(4) to add NP and NPE to the list of chemicals that present or may present an unreasonable risk of injury to health or the environment.

2014, September – US EPA issued a Final Rule to add NP to the Toxics Release Inventory (TRI) under Section 313 of EPCRA. Reporting will be available until 2016 (US EPA 2014).

2014, October - US EPA issued a Proposed Rule to remove certain inert ingredients, including NP, from the approved chemical substance list for pesticide products because there are no registrations that contain them (US EPA 2014).

2014, October - US EPA published notification of a Proposed Rule to issue Significant New Use Rules (SNUR) for Certain NP and NPE under TSCA Section 5, which was made available for public comment (US EPA 2014).

US EPA Design for Environment Voluntary Programs

March 2007 - US EPA Office of Pollution Prevention and Toxics (EPA, OPPT), Design for the Environment Program (DfE) Formulators Program is launched. The EPA DfE Formulator Program is a voluntary program in which EPA partners with cleaning product manufacturers and others in the design of products with a more positive health and environmental profile. Under the Formulators Program, DfE assesses the potential health and environmental effects of each ingredient in the approved formulations. NPEs are not allowed for use in products approved by the DfE Formulators Program.

2007 - For detergent uses, US EPA DfE sponsored the CleanGredients database, which offers a source of ready alternatives that are functionally equivalent to NPEs based on performance characteristics and safer because they meet the DfE criteria for safer surfactants.

2008 - EPA OPPT, DfE Formulators Program Safer Detergent Stewardship Initiative (SDSI) - Building on its Formulator work, DfE launched SDSI, a high-level recognition program for companies (manufacturers, formulations, end users, and sellers) who commit to switch completely to “safer surfactants”. NPEs are provided as an example of a surfactant class that does not meet the SDSI definition of a safer surfactant.

2010 - EPA DfE reached an agreement with the Textile Rental Services Association of America (TRSA) to expedite a phase-out of NPEs in industrial laundry detergents, one of the major remaining down-the-drain uses of NPEs. The phase out is being coordinated through the DfE SDSI program and would end the use of NPEs by TRSA members in industrial laundry detergents by 2013 for liquid detergents and 2014 for powder detergents. Between 2010 and 2014, TRSA members’ use of NPEs in liquid and powder industrial laundry detergents decreased, and they are still trying to completely eliminate the use of NPEs in both liquid and powder industrial laundry detergents.

2012- Through its Design for the Environment program, US EPA released a final Alternatives Assessment for NPEs identifying eight safer alternatives (US EPA, 2012).

Ongoing – In the Action Plan for NP/NPEs, US EPA stated that it intends to encourage the manufacturers of all NPE-containing direct-release products (e.g., firefighting gels and foams, dust-control agents and de-icers) to move to NPE-free formulations and encourage the elimination of NPE in other industries that discharge NPEs to water, such as the pulp and paper processing and textile processing sectors, where safer alternatives may be available. DfE also intends to expand the scope of SDSI, and encourage those industries to make commitments under SDSI. Other

Market-Based Risk Management Initiatives:

2006 - Wal-Mart announced at a Molecule-to-Molecule meeting hosted by its Chemical Intensive Products Network that it would promote the de-selection of NPEs in detergent and cleaning products sold at its stores (Wal-Mart, 2006).

IDENTIFICATION OF GAPS IN MANAGEMENT AND/OR SCIENCE:

1.) Are environmental levels below applicable benchmarks?

Based on the limited environmental data available, levels of NP/NPEs in the Canadian nearshore environment of the Great Lakes Basin are generally below applicable benchmarks in all environmental media and are expected to continue to decline based on the significant and ongoing reduction in uses and releases in Canada, primarily in the three areas (cleaning/laundry products, wet textile processing and paper and pulp processing) which were determined to contribute most significantly to environmental emissions in the Canadian CEPA 1999 risk assessment.

Minimal monitoring data are available for NP/NPE in the Great Lakes Basin on the US side. However, more recent data available since the market influence of the Canadian regulations, US EPA DfE initiatives and market trends since the Wal-Mart action on NPEs in 2006 indicate compliance with the US. EPA WQC for NP, even on a TEQ basis. A U.S. national study of NP/NPE in US surface waters conducted in the 15 years prior to the declining use of NP/NPEs found on a nationwide basis that the likelihood of surface water concentrations exceeding the chronic EPA WQC for NP was low, even on an aggregate TEQ basis. Most exceedances in that study were found in the arid southwest of the United States.

2.) Is Great Lakes Basin Human Health being adequately addressed?

The CEPA Assessment of NP/NPE which was conducted in 2002 when volumes of these compounds were at their peak concluded that NP and NPEs were not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger to the environment on which life depends and were not considered a priority for investigation of options to reduce public exposure through control of sources that are addressed under CEPA 1999. No water quality guidelines or benchmarks have been promulgated for the protection of human health.

3.) Are objectives for substances being met?

See question 1 above. In general, objectives are being met on the Canadian side. Since implementing federal risk management actions, Canadian release volumes and WWTP effluent concentrations of NP/NPEs have declined significantly. .

4.) If not, what else can be done?

While the limited available Great Lakes and other (e.g. Canadian) environmental and WWTP concentrations data for NP/NPEs do not indicate an environmental concern at this time, monitoring and surveillance data in the Great Lakes could be considered a data gap , as it would complement and possibly validate the broader Canadian and US wastewater monitoring data that is available.

As such initiating and/or continuing periodic surface water, WTTP influent/effluent, sediment and top-predator fish monitoring on the Canadian and US sides of the Great Lakes would be beneficial in order to establish long-term trends and to provide a measure of past, present and forthcoming federal management actions on both sides.

5.) Are there gaps in risk management and/or science activities?

From a Canadian perspective, no gaps in or needs / opportunities identified at this time for additional risk management activities for NP and NPEs which would significantly benefit the Great Lakes basin. Canadian federal risk management actions (e.g. P2 Planning) have been successful in greatly reducing releases of NP/NPEs to the Canadian environment; however, some actions have now expired.

Regulatory activities and voluntary market shifts in the North American market have almost halved the quantity of NPEs consumed in North America, and likely in the US.

The US EPA just recently initiated regulatory actions on NP/NPE that have yet to take effect and the EPA DfE program continues to promote alternatives to NPE is applications with high emissions to the aquatic environment. Therefore, as in Canada, additional risk management actions for these compounds in the US do not appear warranted in the Great Lakes Basin.

As mentioned above, with regards to science activities, initiating and/or continuing periodic surface water, WTTP influent/effluent, sediment and top-predator fish monitoring on the Canadian and US sides of the Great Lakes would be beneficial in order to establish long-term trends and to provide a measure of past, present and forthcoming federal management actions on both sides.

Additionally, alternative assessments completed to date may not sufficiently address the potential ecological or human health effects of alternative surfactants and other ingredients which attempt to match the function and performance of NPEs.

Conclusions:

The ITT concluded that while there is evidence of exceedances of some benchmarks for NP/NPE, there is limited data available from the Great Lakes, specifically in the US nearshore environments, to adequately conclude whether NP/NPEs pose a threat to the Great Lakes environment. Moreover, new data with which to fully assess NP/NPEs in the Great Lakes environment are anticipated within the next few years. For example, in 2015, NP/NPEs were added to the Great Lakes Fish Monitoring and Surveillance program analyte list, and also to the Toxics release Inventory (TRI). Results from these programs will not be available before 2016.

5. Final Recommendation:

With respect to NP/NPE, the ITT has concluded that there is insufficient data and/or information available to effectively apply the *Binational Considerations*. Therefore, **the ITT has, by 2/3 majority, recommended that NP/NPE be identified as insufficient information on which to base a determination.**

While consensus was reached NP/NPE there were dissenting views. Given the information available and considering existing management actions:

- Some members felt that NP/NPE should be designated as a Chemical of Mutual Concern, while others felt that they should be designated as Not a Chemical of Mutual Concern.

6. References:

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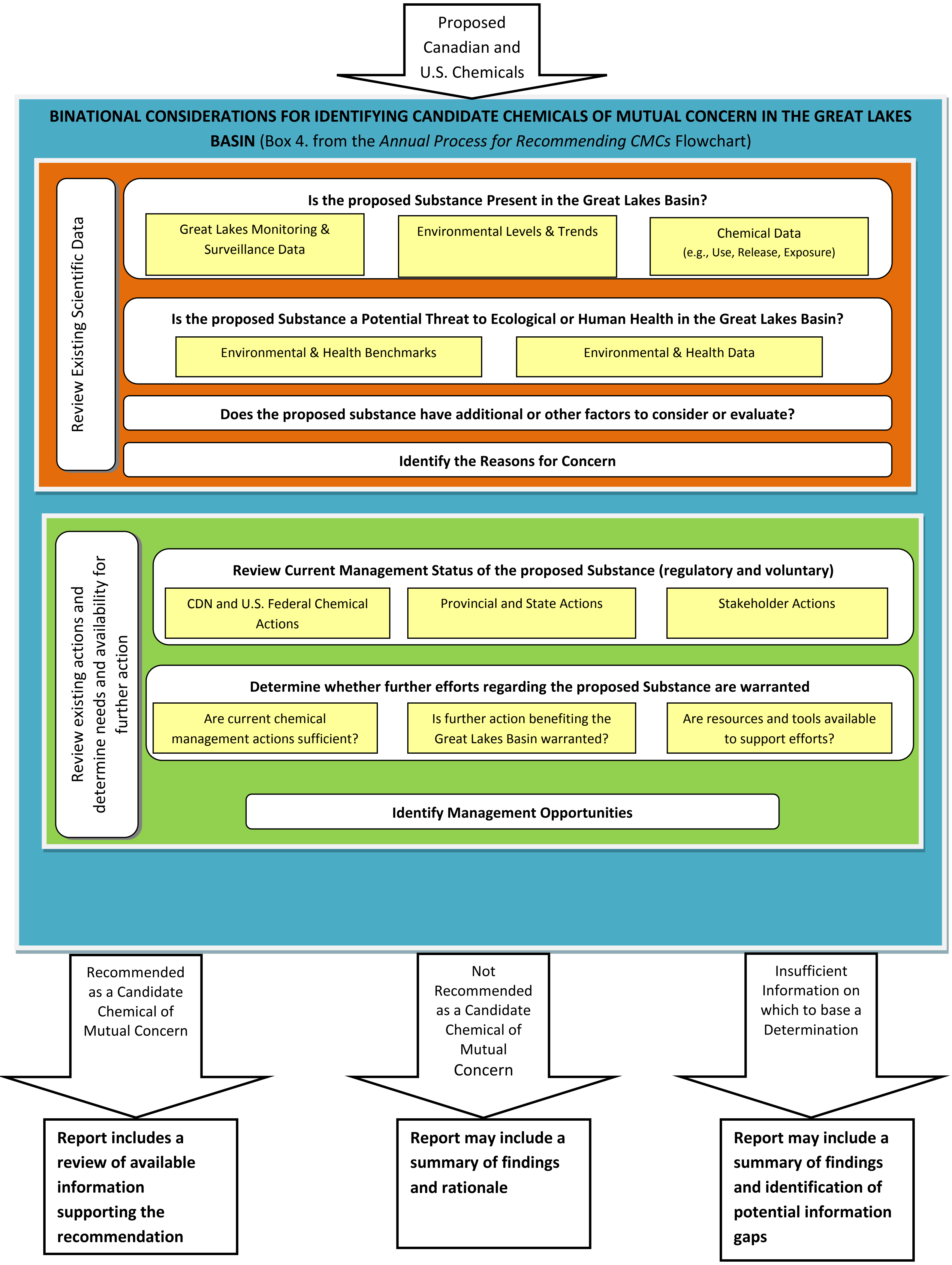
Appendix A:

Binational Considerations When Evaluating Candidate Chemicals of Mutual Concern


Proposed Canadian and U.S. Chemicals
BINATIONAL CONSIDERATIONS FOR IDENTIFYING CANDIDATE CHEMICALS OF MUTUAL CONCERN IN THE GREAT LAKES BASIN (Box 4. from the Annual Process for Recommending CMCs Flowchart)
Review Existing Scientific Data
Is the proposed Substance Present in the Great Lakes Basin?
Great Lakes Monitoring & Surveillance Data
Environmental Levels & Trends
Chemical Data (e.g., Use, Release, Exposure)
Is the proposed Substance a Potential Threat to Ecological or Human Health in the Great Lakes Basin?
Environmental & Health Benchmarks
Environmental & Health Data
Does the proposed substance have additional or other factors to consider or evaluate?
Identify the Reasons for Concern
Review existing actions and determine needs and availability for further action
Review Current Management Status of the proposed Substance (regulatory and voluntary)
CDN and U.S. Federal Chemical Actions
Provincial and State Actions
Stakeholder Actions
Determine whether further efforts regarding the proposed Substance are warranted
Are current chemical management actions sufficient?
Is further action benefiting the Great Lakes Basin warranted?
Are resources and tools available to support efforts?
Identify Management Opportunities
Recommended as a Candidate Chemical of Mutual Concern
Not Recommended as a Candidate Chemical of Mutual Concern
Insufficient Information on which to base a Determination
Report includes a review of available information supporting the recommendation
Report may include a summary of findings and rationale
Report may include a summary of findings and identification of potential information gaps

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