Performance Measurement Evaluation for Risk Management of 1,3-Butadiene, 2-methyl-, (Isoprene)

1 – About Performance Measurement

The Government of Canada is conducting performance measurement (PM) on the risk management of toxic substances to ascertain whether actions taken to help protect Canadians and their environment are meaningful and effective over time. Performance measurement will help determine how well the risk management actions have reduced or eliminated the risk associated with each toxic substance. Adjustments may be required when risk management tools are not achieving the desired outcome.

The Government of Canada establishes goals in order to help protect Canadians and their environment from risks posed by toxic substances. The Government attempts to achieve these goals by setting human health, environmental and risk management objectives, and then developing a strategy to meet those objectives. Performance measurement assesses how risk management actions contribute to protecting Canadians from toxic substances and identifies any areas of improvement that should be addressed moving forward.

2 – Background

1,3-Butadiene, 2-methyl- (CAS RN:78-79-5), also known as isoprene, is a clear, colourless liquid at room temperature and is highly reactive and capable of polymerizing explosively when heated. Isoprene is produced naturally by various plant and tree species. Isoprene is also produced by humans as it is present in exhaled breath. It is also the basic structural unit in many natural products such as terpenes and vitamins A and K (IARC 1994; Canada 2008).

Isoprene is also an industrial chemical, and at the time of assessment, it was principally used as a monomer in the production of polyisoprene, butyl rubber and styrene-isoprene-styrene (SIS) rubber. Polyisoprene was used in the production of vehicle tires and a wide variety of products including paint resins, footwear, adhesives, molded goods as well as cosmetic products. Butyl rubber was primarily used in the manufacture of inner tubes, while SIS rubber was used in pressure sensitive adhesives (Canada 2008).

The Government of Canada identified isoprene as a priority for assessment based on its classification by an international organization as a substance which was found to cause cancer, as well as genetic effects in some research studies with laboratory animals. It

was also believed there was potential for exposure of isoprene to Canadians based on its known uses in products available to consumers. Accordingly, the substance was assessed by the Government of Canada to determine if there was a risk to human health or to the environment posed by the substance.

The principal route of exposure to the substance was found to be through inhalation of indoor air (95%), followed by ambient air (< 5%) (Canada 2008). Exposure to isoprene via inhalation induced a variety of non-cancer effects in experimental animals. In addition, hyperplasia occurred at sites at which tumours were also observed (lungs, forestomach, kidneys and testis). In a rodent model, the lowest-observed-effect-concentration (LOEC) for exposure to isoprene was 11 000 µg/m³ (Mamedov 1979).

Smoking is expected to be the primary source of isoprene in the indoor air of homes. Canadian indoor air studies performed in 2012-2013 measured significantly higher levels of isoprene in homes where smoking occurs every day or almost every day, compared to non-smoking homes (Li 2019). Data reported to Health Canada under the *Tobacco Reporting Regulations* on the emissions of Canadian cigarettes between 2005-2015 shows that the average isoprene levels in mainstream smoke is 240 ± 89.9 µg per cigarette and 653 ± 154.9 µg per cigarette under International Organization for Standardization and modified smoking conditions (e.g., using larger puff volumes and puff frequencies), respectively.

Isoprene was selected for performance measurement evaluation because key indicator data is available and risk management tools have been in place for a sufficient amount of time to measure impact. In addition, this performance measurement evaluation also aligns with the evaluation of the “Pollution Prevention Planning Notice for the Synthetic Rubber Manufacturing Sector in Respect of Isoprene” by Environment and Climate Change Canada (ECCC).

3 – Risk Assessment and Risk Management Approaches

The risk assessment under the Chemicals Management Plan in 2008 concluded that isoprene may have been entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health. It was established that isoprene met the criterion in paragraph 64(c) of the *Canadian Environmental Protection Act, 1999* (CEPA). Subsequently, isoprene was added to CEPA Schedule 1 by Order in the *Canada Gazette* on February 3rd, 2011 (Canada 2011).

A risk management approach was published which set out objectives to be achieved to prevent or control the risks posed by exposure to isoprene. The human health objective was to minimize exposure to isoprene, and hence the risk to human health associated with this substance to the extent practicable (Canada 2009). Concordantly, the risk

management objective for this substance was to reduce exposure to isoprene from industrial emissions to the extent practicable.

3.1 Pollution Prevention Planning Notice for the Synthetic Rubber Manufacturing Sector in Respect of Isoprene (2012)

A Pollution Prevention (P2) Planning Notice, or P2 Notice, is an instrument that requires the preparation and implementation of pollution prevention plans so that organizations can improve their environmental performance by reducing or eliminating pollution before it is generated (Canada 2019c). The risk management objective for the P2 Notice for the synthetic rubber manufacturing sector was to reduce human exposure to isoprene through the reduction of industrial emissions of isoprene to the environment by 80% relative to the base year using best available technology economically achievable. The P2 Notice was developed by Environment and Climate Change Canada and applies to the specific sector in order to manage their isoprene emissions. The goal of the P2 Notice was to reduce potential for human exposure to isoprene near a facility releasing isoprene into the air.

Only one company in Canada imports pure isoprene for use in rubber applications (Canada 2007). One of this company's facilities located in Sarnia, Ontario (ON) releases the large majority of all industrial isoprene emissions in Canada. The P2 Notice focused on decreasing emissions from the company that was the single largest emitter in Canada. In 2012, the company expressed its commitment to implement the P2 plan and to reduce isoprene emissions by 80% relative to the 2009 baseline year (Canada 2012).

3.2 Health Canada's Cosmetic Ingredient Hotlist (the Hotlist)

The Government of Canada took action to help prevent deliberate use of isoprene in cosmetic products by describing the substance as a prohibited ingredient on Health Canada's Cosmetic Ingredient Hotlist. Using this administrative tool, Health Canada informed manufacturers and others that a cosmetic containing isoprene may contravene section 16 of the *Food and Drugs Act* (FDA). Compliance with FDA section 16 is monitored, in part, through the mandatory notification provisions of section 30 of the *Cosmetic Regulations*, which requires that all manufacturers and importers provide a list of the cosmetic's ingredients to Health Canada (Canada 2019a).

Health Canada's decision to describe the substance as a prohibited ingredient on the Hotlist aligns with actions taken in the European Union, where isoprene is present on the "List of Substances which must not form part of the composition of cosmetic products"(EU, 2016).

4 – Performance Measurement Indicators

The following sections identify the programs and activities that provide key indicator data for the performance measurement of isoprene.

4.1 Environmental Releases – National Pollutant Release Inventory (NPRI)

The NPRI is Canada's legislated, publicly accessible inventory of pollutant releases (to air, water, and land), disposals and transfers (Canada 2019b). The inventory data provides a Canada-wide and facility-specific emissions perspective. Environmental releases of isoprene have been collected by the NPRI since 1999. From 1999 to 2013, the threshold for facilities to report isoprene to the NPRI was 10,000 kg per year, manufactured, processed or otherwise used. From 2014 onwards, the reporting threshold was reduced to 100 kg per year, manufactured, processed or otherwise used, to increase the coverage of reporting for isoprene. The NPRI data is suitable to help evaluate the effectiveness of the P2 Notice for the Synthetic Rubber Manufacturing Sector. Furthermore, the P2 Notice requires that facilities measure emissions of isoprene to air before and after implementing pollution prevention plans.

4.2 Ambient Air – National Air Pollution Surveillance (NAPS)

The NAPS program uses standardized methods to collect air quality data from outdoor monitoring stations across Canada. Ambient air levels of isoprene have been measured by the NAPS network since 1989. Data collected, compiled and analyzed by this program provides the Government and Canadians with information about isoprene levels in ambient air within several urban, suburban and rural locations in the country (Canada 2016). Isoprene levels fluctuate seasonally in ambient air. For example, isoprene is naturally emitted to the atmosphere from various plant and tree species in the spring and summer and from combustion processes such as wood-burning stoves and fireplaces in the winter.

4.3 Indoor Air –Air Quality Studies and Canadian Health Measures Survey

Health Canada has conducted a number of indoor air research studies, collecting indoor air samples of various pollutants from residences across Canada. These studies provide information on exposures to several volatile organic compounds (VOCs), including isoprene, found indoors and outdoors. Four studies have measured the levels of isoprene in indoor air: Windsor (2005), Regina (2007), Halifax (2009) and Edmonton (2010).

A component of the Canadian Health Measures Survey (CHMS) measured the concentration of 88 VOCs in air for a representative sample of Canadian households.

Isoprene was measured in three of the CHMS cycles: Cycle 2 (2010 – 2011), Cycle 3 (2012 – 2013) and Cycle 4 (2014 – 2015). The data obtained through the studies and surveys are important indicators, as indoor air accounts for approximately 95% of human exposure to isoprene (Canada 2008).

4.4 Market Information - Mandatory information gathering under CEPA

Several sections of CEPA, such as section 71, allow the Government of Canada to collect information from industry and other individuals regarding their activities with substances. The Government of Canada has used these authorities under CEPA, along with broader approaches and stakeholder engagement, to collect information on the commercial status of substances. In May 2007, a notice was published in the *Canada Gazette*, Part I: Vol. 141, No. 19 - May 12, 2007 under section 71 of CEPA to gather basic market information on isoprene. This market information includes manufacturing and import information, product types, and quantities of industrial releases containing the substance (Canada 2007).

5 – Key Performance Indicator Data

Performance indicator data has been collected and analyzed to evaluate the effectiveness of risk management tools that have been put into place. The performance measurement baseline was formed by data obtained from industry through NPRI submissions and using mandatory information gathering under section 71 of CEPA. Data reported to the NPRI provided industrial release data over time and data submitted in response to the section 71 Notice provided historical market information. Data submitted through the *Cosmetic Regulations* provided information on the presence of isoprene in cosmetic products.

5.1 NPRI and P2 Notice Findings

In the years leading up to the implementation of the P2 Notice, Canada-wide isoprene emissions to air reported to the NPRI largely fluctuated between 10 000 and 20 000 kg/year. The Sarnia, Ontario (ON) facility most significantly involved with the substance began reporting isoprene releases to the NPRI in 2004, and at that time, accounted for approximately 92% of all reported releases in Canada. By 2009, isoprene air emissions from that facility nearly doubled compared to 2004 (9 000 kg in 2004 versus 17 401 kg in 2009), accounting for approximately 99% of all reported releases in Canada. In 2017, that facility accounted for approximately 77% of all releases in Canada reported to NPRI, with 15 other facilities reporting smaller quantities of isoprene releases.

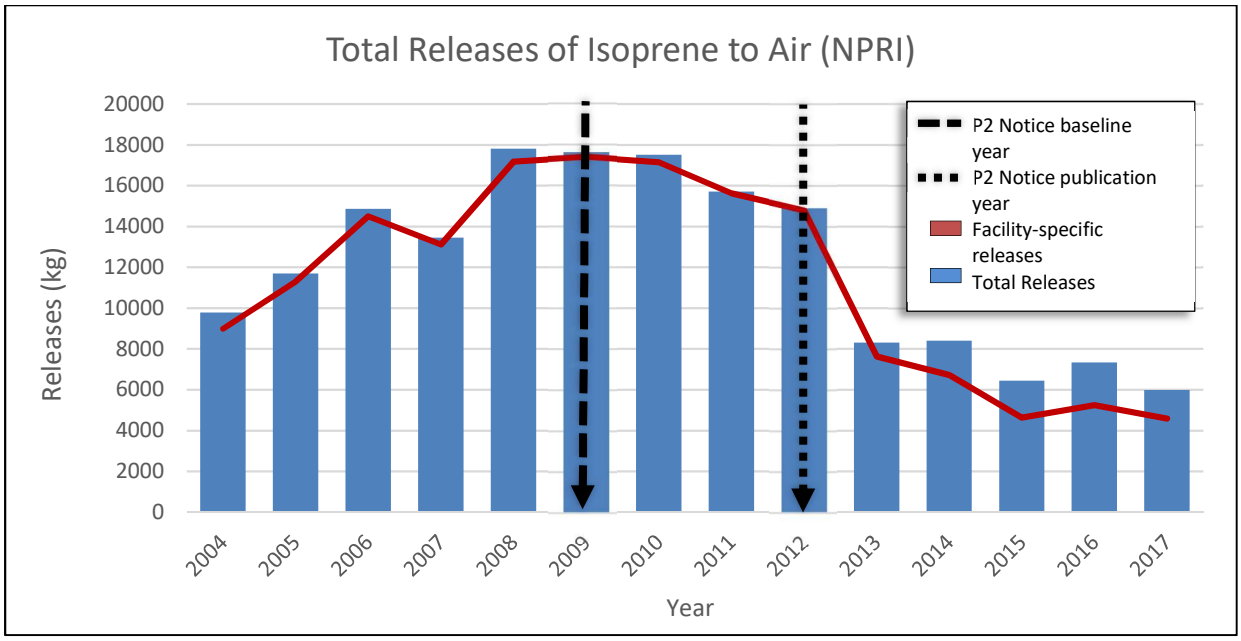

Figure 1. Total of all reported isoprene emissions to air, in kilograms from all facilities across Canada in the NPRI datasets (2004 - 2017), and the facility subject to the P2 Notice.

The P2 Notice baseline (2009) and publication year (2012) are indicated. *NPRI Disclaimer: variability in levels from year to year can occur for a variety of reasons, including but not limited to, calculation differences and facility reporting requirements*.

Overall, there has been an 86% reduction in reported Canada-wide isoprene releases since reporting began in 1999 to 2017, the latest year for which reviewed NPRI data is available. According to the 2018 P2 Notice submission, isoprene releases reported by the company have decreased by 78% relative to the 2009 baseline year.

5.2 Ambient Air Data

As the major source of industrial isoprene emissions to air was located in Sarnia, ON, data was gathered to compare average isoprene concentrations in ambient air from monitoring stations in Sarnia, ON, with data gathered from across Canada.

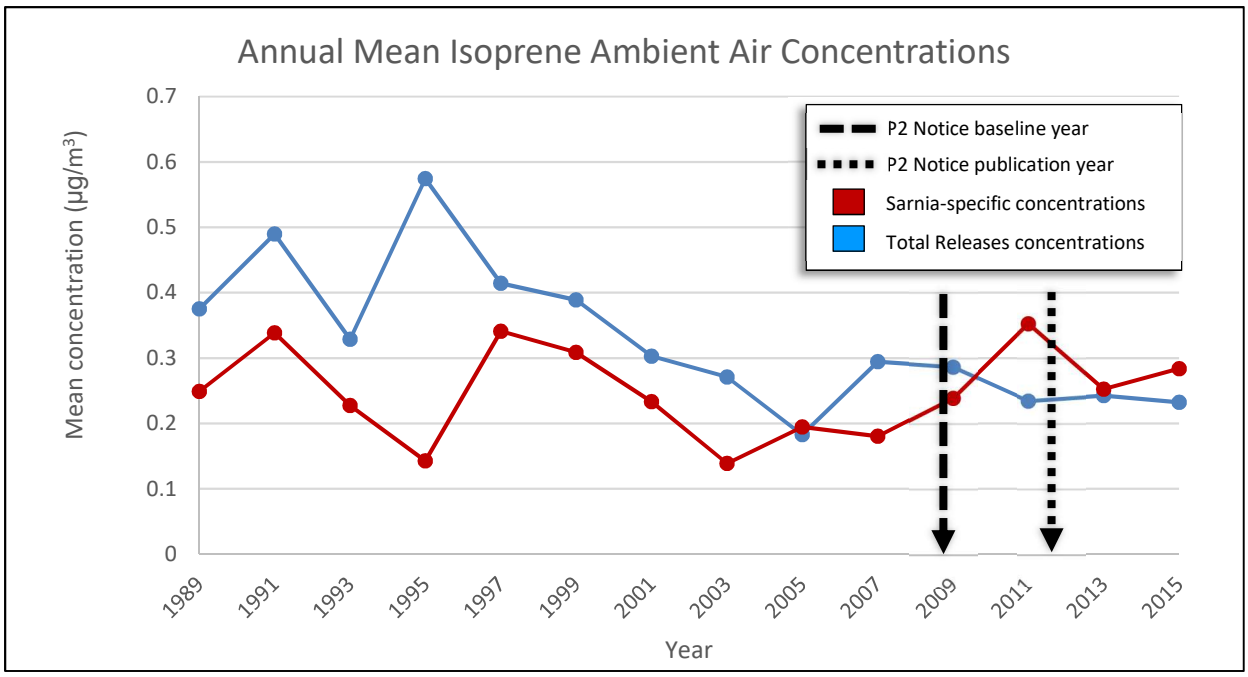

Figure 2: Annual mean ambient outdoor air concentrations of isoprene measured by the NAPS program from 1989 to 2015.

Each point represents the annual mean isoprene levels in ambient air across Canada and Sarnia, ON. The baseline year (2009) and year of publication (2012) for the P2 Notice are indicated.

As illustrated in Figure 2, average isoprene levels in ambient air across Canada fluctuate between 0.1 and 0.6 µg/m³. Annual mean ambient air concentrations of isoprene in Sarnia, ON appear to be comparable to the mean concentrations compiled from across Canada.

While the levels show variation, the average level of isoprene in ambient air remains significantly below the conservatively selected lowest identified inhalation effect level of 11 000 µg/m³ considered in the risk assessment of the substance (Canada 2008).

5.3 Indoor Air

Data presented in four Health Canada studies show that the indoor air concentrations of isoprene from individual Canadian cities are similar to the concentrations found Canada-wide through the CHMS. It is difficult to directly compare these data because the studies vary in geographical location (targeted vs. national). The general observation is that while isoprene concentrations in indoor air are variable, they remain significantly lower than the conservatively selected lowest identified inhalation effect level of 11 000 µg/m³ considered in the risk assessment of the substance (Canada 2008).

Table 1: Mean concentrations of isoprene in indoor air samples from four Canadian studies of residential homes from 2005 to 2010 (Health Canada 2005-2010).

	Windsor (2005)		Regina (2007)		Halifax (2009)		Edmonton (2010)	
Season	Summer	Winter	Summer	Winter	Summer	Winter	Summer	Winter
Geometric Mean (µg/m³)	6.685	2.852	3.958	0.577	2.112	2.31	3.253	4.049
95th Percentile (µg/m³)	17.83	6.567	15.595	2.162	7.44	7.703	8.813	10.37

Table 2: Mean concentrations of isoprene in indoor air samples from CHMS Cycle 2 (2010 – 2011), Cycle 3 (2012 – 2013) and Cycle 4 (2014 – 2015). Detection frequency represents the percent of samples for which isoprene was detected.

	Cycle 2 (2010 – 2011)[E]	Cycle 3 (2012 – 2013)[F]	Cycle 4 (2014 – 2015)[G]
Geometric Mean (µg/m³)	3.06	3.14	3.17
95th percentile (µg/m³)	23.4	22.8	23.4
Detection Frequency (%)	99.92	99.91	99.84

[E] Zhu J et al. 2013 [F] Li Y et al. 2019

Tobacco smoke was expected to be the primary source of isoprene in the indoor air of homes and other environments where smokers are present. For example, there is a four-fold increase in levels of isoprene in environments where smoking occurs compared to environments without smoking (Heavner et al. 1996). CHMS Data from Cycle 2, Cycle 3 and Cycle 4 surveys identified whether smoking occurred in the home, with data summarized in Table 3. The data is consistent with the findings that smoking results in higher concentrations of isoprene in indoor air.

Table 3: Mean concentrations of isoprene in indoor air samples from the CHMS cycles 2 (2010 – 2011), 3 (2012 – 2013) and 4 (2014 – 2015). Data presented from non-smoking homes and from homes where someone smoked inside the home.

	Cycle 2 (2010 – 2011)		Cycle 3 (2012 – 2013)		Cycle 4 (2014 - 2015)	
Smoke in home?	YES	NO	YES	NO	YES	NO
Geometric Mean (µg/m3)	12.57	2.42	8.85	2.47	9.48	2.75
95th percentile (µg/m3)	62.8	9.5	44.5	8.7	68.6[G]	[H]

[G] Use data with caution.
[H] Data is too unreliable to be published.

5.4 Section 71 Market Data

Reported uses for isoprene in the 2006 calendar year obtained from the mandatory information gathering initiative under section 71 of CEPA, included use as a monomer in the production of polyisoprene (cis-1,4-polyisoprene), butyl rubber (isobutene-isoprene copolymer), thermoplastic and elastomeric co-block polymers (e.g., styrene-isoprene-styrene rubber). Polyisoprene was used mostly in the production of vehicle tires and manufacturing a range of products available to consumers, including cosmetics.

The section 71 market data shows the total quantity of isoprene manufactured in Canada in 2006 exceeded 10 000 tonnes, and the total quantity imported was between 1 000 and 10 000 tonnes. In addition, a single facility also reported using 3 424 tonnes for butyl-rubber manufacturing. No cosmetic products were reported to specifically contain isoprene. (Canada 2007).

6 – Performance Measurement Evaluation

6.1 Impacts of Interventions

The Government of Canada took action to reduce exposure to isoprene from industrial air emissions using a P2 Notice. There is a reduction in isoprene air releases from the company subject to the P2 Notice. The facility requested an extension in 2016 to meet their 80% emission-reduction target, and received an extension until the end of December 2018. According to data reported to the NPRI, the facility has reached 78% reduction in isoprene emissions to air from the baseline year in 2009 (17 401 kg in 2009 versus 3 862 kg in 2018), while increasing production. Refer to the Pollution prevention

(P2) planning notice for the synthetic rubber manufacturing sector (isoprene) Final Performance report for more details on the findings. Overall, there has been an 86% reduction in Canada-wide isoprene releases since reporting began in 1999. Mean ambient air concentrations of isoprene recorded at monitoring stations located Canada-wide and those located near the facility in Sarnia, ON remain significantly lower than the LOEC of 11 000 µg/m³ (Mamedov 1979).

The Government's decision to describe isoprene as a prohibited ingredient on the Cosmetic Ingredient Hotlist has helped to prevent the deliberate use of isoprene in cosmetics. At the time of this performance evaluation, no notifications have been received for the use of isoprene in cosmetics (Canada 2019d).

6.2 Objective Outcomes

The risk management objective for this substance was to reduce exposure to isoprene from industrial emissions to the extent practicable. The objective has been partially met as the largest source of industrial emissions has been reduced by 78%.

The human health objective was to minimize exposure to isoprene to the extent practicable. There is no exposure of concern to isoprene through use of cosmetics, and isoprene levels in indoor air remain significantly below the lowest identified inhalation effect level.

Smoking remains a concern for exposure to toxic substances, including isoprene. Continued messaging related to the harms of smoking may further Canadians and their families from exposure to second- and third-hand smoke, thereby contributing toward the human health objective.

It is therefore concluded that the Government of Canada has achieved its objectives set out to protect Canadians from the risks posed by this substance.

7 – Conclusion

The Government of Canada took action to help prevent exposure to isoprene by using Health Canada's Cosmetic Ingredient Hotlist to describe the substance as a prohibited ingredient in cosmetics under section 16 of the *Food and Drugs Act* and introducing a P2 Notice for the synthetic rubber-manufacturing sector to reduce air emissions. Based on the data presented in this report, it is concluded that the risk management actions taken have achieved their desired results by protecting the health of Canadians from concerns that were identified in the final screening assessment, published in 2009.

While any exposure is a concern, isoprene is produced naturally by various plant and tree species. Industrial air emissions have been reduced to the extent practicable, but humans do have increased exposure to isoprene in environments were smoking occurs.

This validates the ongoing need to promote the negative health outcomes related to smoking.

Based on the above findings, the risk management approach put in place is performing as intended and has met the set objectives effectively. Moving forward, NPRI data will be used to track isoprene emissions from industrial sources over time. In addition, the Cosmetic Ingredient Hotlist continues to be an effective risk management instrument for preventing intentional use of isoprene in cosmetics. Moreover, although it is unlikely that new exposures should arise, the Identification of Risk Assessment Priorities process is in place to identify and evaluate newly available information to determine if further assessment may be warranted (Canada 2017).

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Annex to Performance Measurement Evaluation for Risk Management of 1,3-Butadiene, 2-methyl-, (Isoprene)

Plain text wording to accompany figures for web accessibility

Figure 1

This figure consists of a bar chart.

This blue bar chart shows the total of all reported isoprene emissions to air, in kilograms, from facilities across Canada collected by the National Pollutant Release Inventory from 2004 to 2017. The chart also shows the reported emissions for the specific facility located in Sarnia, Ontario, subject to the Pollution Prevention (P2) Notice as a red line across the blue bars. There is an upward trend in isoprene emissions to air from 2004 to 2008, which remain stable until 2010, and then emissions begin to decrease steadily from 2010 to 2017. This trend shows both Canada-wide and Sarnia emissions as the Sarnia facility accounts for the majority of releases across Canada.

This bar chart also identifies the P2 Notice baseline year of 2009 with a yellow dashed line and P2 Notice publication year in 2012 with a green dashed line.

Year	Total reported emissions of isoprene in kilograms by all facilities across Canada	Total reported emissions of isoprene in kilograms from the facility located in Sarnia, Ontario
2004	9782	9000
2005	11698	11300
2006	14865	14500
2007	13447	13121
2008	17807	17176
2009	17401	17620
2010	17148	17505
2011	15698	15630
2012	14907	14791
2013	8298.50	7635
2014	8400.72	6727
2015	6434.59	4633
2016	7330.77	5251
2017	5984.86	4591

Figure 2

This figure consists of a line graph.

This graph shows annual mean isoprene ambient air concentrations across Canada from 1989 until 2015 with a blue line, and shows data points of the annual mean isoprene ambient air concentrations in Sarnia, Ontario, with a red line. Data was gathered by the National Air Pollution Surveillance program. The data demonstrates that mean isoprene ambient air concentrations between 1989 and 2015 were measured between 0.1 and 0.6 micrograms per cubic metre across Canada and in Sarnia, Ontario.

This bar chart also identifies the P2 Notice baseline year of 2009 with a yellow dashed line and P2 Notice publication year in 2012 with a green dashed line.

Year	Annual mean isoprene levels in ambient air across Canada (micrograms per cubic metre)	Annual mean isoprene levels in ambient air in Sarnia, Ontario (micrograms per cubic metre)
1989	0.3753	0.2488
1991	0.4899	0.3384
1993	0.3287	0.2275
1995	0.5744	0.1430
1997	0.4142	0.3410
1999	0.3892	0.3087
2001	0.3031	0.2333
2003	0.2711	0.1388
2005	0.1827	0.1948
2007	0.2944	0.1802
2009	0.2865	0.2394
2011	0.2350	0.3530
2013	0.2428	0.2525
2015	0.2322	0.2837