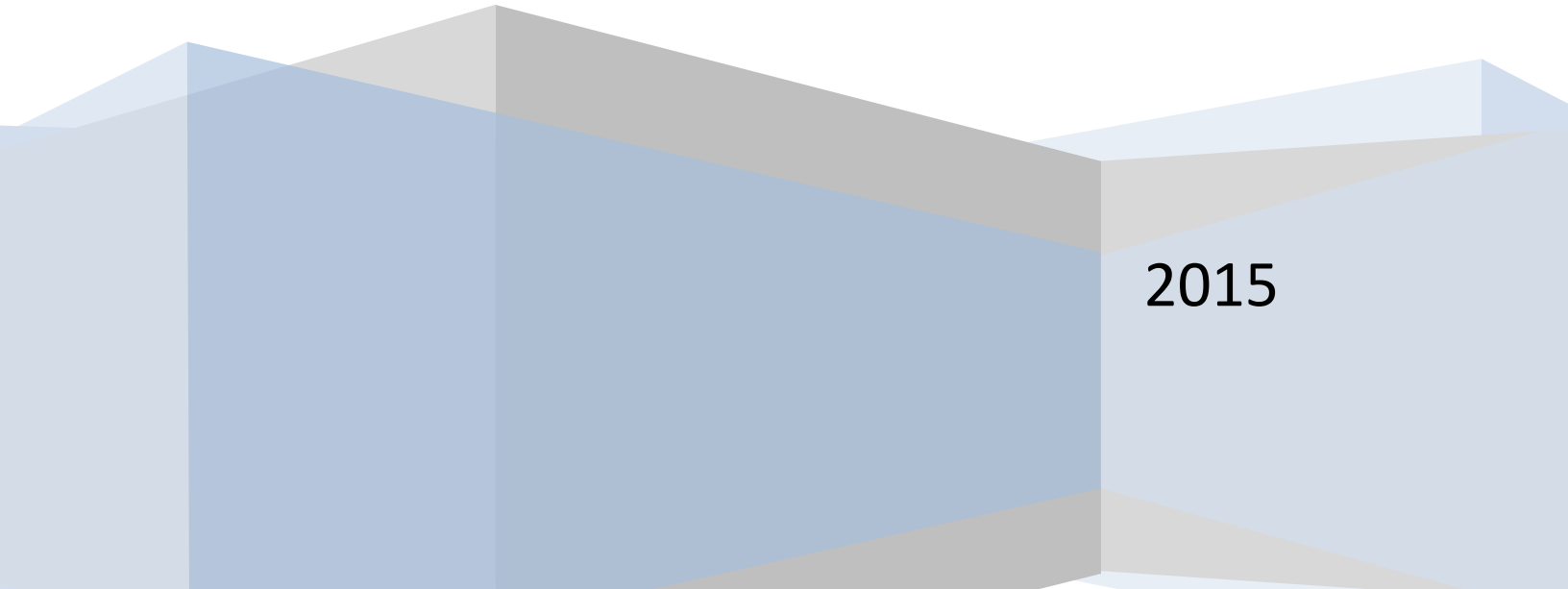
Environment and Climate Change Canada
Health Canada

Identification of Risk Assessment Priorities:

Results of the 2015 Review



2015

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Background

Under Canada's Chemical Management Plan (CMP), Environment and Climate Change Canada (ECCC) and Health Canada (HC), in addition to addressing substances already identified as priorities for assessment have continued to develop approaches to incorporate new scientific knowledge and increase collaboration with other regulatory and international agencies. One of the formal approaches developed by ECCC and HC is an annual process by which both departments compile new information on substances, evaluate this information, and then subsequently determine if further action on the substance(s) may be warranted. This approach is described in the document titled "Approach for identification of chemicals and polymers as risk assessment priorities under Part 5 of the Canadian Environmental Protection Act, 1999 (CEPA 1999)" (Environment Canada, Health Canada 2014), hereinafter referred to as the Approach for Identification of Risk Assessment Priorities ("The Approach"). This initiative supports ongoing priority setting by identifying additional potential priorities for risk assessment in a transparent manner. In the Approach document, the process for identifying additional priorities was described in three steps: Acquisition, Evaluation, and Action. These three steps are briefly described below.

- **Acquisition** refers to the active and passive collection of information relevant to the potential health and ecological risks of substances.
- **Evaluation** refers to the triage of substances for which new information has been received. This evaluation requires expert judgment, and consideration of the different types of information that may be available for any given substance.
- **Action** refers to the type of activity that will be undertaken on the substances identified as candidates for further work. These actions could include assessment, additional risk management, data collection, research and monitoring, generation of new data, etc.

This report describes the manner in which the Approach was applied in the 2015 review, and the results.

Scope of 2015 Review

At the outset of the 2015 review, the scope of the initiative was established to determine which substances to recommend for inclusion, and by extension, exclusion, from consideration. The scope is anticipated to change with future iterations of review.

The scope of the review for the 2015 review was primarily focused on identifying new hazard and/or exposure information for substances that are on Canada's Domestic Substances List (DSL) which were not recently, currently, or already scheduled to be assessed under the CMP. In some situations, information on substances that were not within the pre-defined scope (i.e. substances not on the DSL) may have been considered; particularly in situations where new information was brought forward by CMP program staff.

The process developed for this review focused on identifying sources of new information that would constitute indicators of hazard and/or exposure. Focusing on these sources of new information supported efficient decision-making, while still being comprehensive and scientifically sound.

Acquisition

While not an exhaustive list of the sources of information consulted, the following are illustrative of sources utilized in the 2015 review:

- Hazard classifications from agencies such as;
    - International Agency for Research on Cancer (IARC)
    - National Toxicology Program (NTP)
    - United States Environmental Protections Agency (US EPA)
    - European Chemicals Agency (ECHA)
- Classifications from the Global Harmonised System (GHS) obtained, for example, from ECHA's Harmonised Classification and Labelling information
- International lists of restricted and/or prohibited substances, or other lists of international priorities, such as;
    - Substances of Very High Concern (SVHC) and Authorization list from ECHA
    - US EPA Action Plans and US EPA Toxic Substances Control Act (TSCA) work plan
    - Community Rolling Action Plan (CoRAP) from ECHA
- Data obtained under S.71 of CEPA (e.g. Inventory Update surveys)
- Data submitted under S.70 of CEPA
- Substances identified as potentially requiring review pursuant to S.75 requirements
- Notifications to Health Canada concerning substances used in cosmetics
- Canadian and international Material Safety Data Sheets (MSDS)/Substance Data Sheets (SDS)
- US EPA Chemical and Product Categories (CPCat)
- Non-confidential data reported under the US EPA Chemical Data Reporting (CDR) Rule
- Available Canadian and international biomonitoring, environmental monitoring and surveillance data

After reviewing the pertinent sources of information, the process identified approximately 2600 substances that had one or more types of information representing potential indicators (i.e. hazard/exposure indicators). The 2600 substances do not represent a list of substances that are potential future priorities, but rather substances with information that required further evaluation under the Approach.

Evaluation

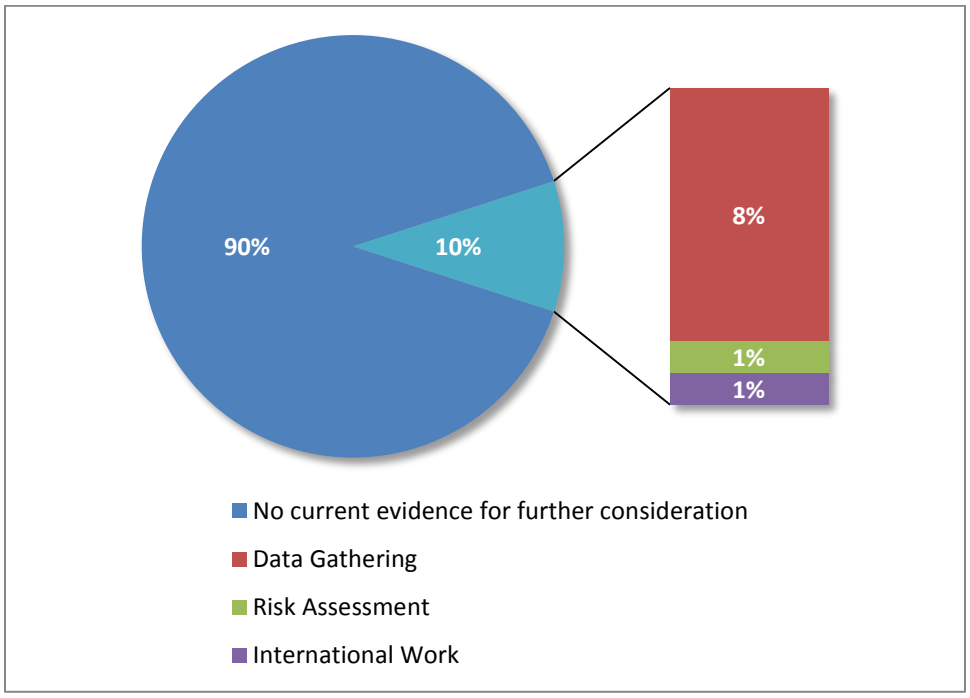
The guiding principles and considerations involved in the evaluation process are described in the Approach (Environment Canada, Health Canada 2014).

The process applied under this Approach supported a triaging of the approximately 2600 substances to separate those which are unlikely to require further work based on information available at this time, from those which represent potential new priorities for assessment, or which require further information and data to determine this. The outcomes of this exercise are discussed in the following section.

Results and Action

Approximately 10% of the 2600 substances were identified as meriting further activity, including: i) additional data gathering; ii) prioritization for risk assessment iii) monitoring of ongoing international activity. These outcomes, and the relative proportions of evaluated substances that fall within each, are shown in Figure 1.

Figure 1: Outcomes of the 2015 Review



As Figure 1 illustrates, for the majority of substances (90%) evaluated within the 2015 review, it was determined that there was no basis for prioritization for assessment or further information gathering at this time. This group also includes substances where a hazard may have been identified, but the uses and exposures that were identified were not relevant in the Canadian context. These substances will continue to be part of future review cycles.

Approximately 10% of substances were identified as candidates for further work. A further breakdown of the specific outcomes for these substances, and a description of what actions these outcomes represent, is provided below.

A total of 28 substances (1%) were identified as candidates for risk assessment via this process. In these instances, there was a strong indicator of both hazard and exposure and, hence, a basis for further prioritization for risk assessment. These substances have been recommended for addition to existing CMP risk assessment plans, and in most cases, would augment groups of substances that were already identified as priorities under the third phase of the CMP. These substances are listed in Appendix A, along with the rationale for their recommended addition to the CMP risk assessment plan. Scheduling of assessments in the third Phase of CMP (including substances added through this Approach) will be communicated to stakeholders separately.

The need for additional data gathering was identified as an outcome for 194 (8%) of substances examined (list of substances available upon request). These substances were seen as having relevant hazard and exposure indicators, but require further data gathering to determine whether they are priorities for risk assessment. The most common scenario under this outcome was when there was an indicator of hazard, yet the commercial status in Canada was uncertain. There are a number of options available to address the data needs including, but not limited to, their addition to future S.71 surveys such as Inventory Updates or targeted surveys, and research or monitoring plans.

Lastly, 27 substances (1%) were identified as currently being subject to international activities. This outcome captures substances that have been prioritized internationally by other organizations, for which assessment work and/or data gathering is ongoing or planned. Outcomes of these activities will inform what actions, if any, are suitable in future review cycles. It should be noted that some substances were identified as candidates for risk assessment, even though they have been identified internationally for further work. For these substances, international work will continue to inform the risk assessment of these substances (i.e. as international data gathering activities conclude), but existing information, relevant to Canada, was considered sufficient to prioritize these substances for assessment at this time.

Appendix A. Substances Identified as Priorities for Risk Assessment

CAS RN	Substance Name	Ecological or Human Health Trigger	Rationale
75-28-5	Propane, 2-methyl-	Ecological & Human Health	The screening assessment of butane and isobutane in the presence of 1,3-butadiene indicated that screening assessment of butane and isobutane, in the absence of 1,3-butadiene, will be conducted with the group of substances that are remaining priorities for assessment as a result of categorization (Environment Canada, Health Canada 2009).
94-13-3	Benzoic acid, 4-hydroxy-, propyl ester	Human Health	Listed on the ECHA CORAP. Suspected reproductive toxicant, potential for endocrine-related effects, wide dispersive use (ECHA 2015a). Considered for addition to a parabens grouping.
94-18-8	Benzoic acid, 4-hydroxy-, phenylmethyl ester	Human Health	Available data indicate potential for endocrine-related effects and some parabens identified in biomonitoring studies (e.g. NHANES in USA). Considered for addition to a parabens grouping.
94-26-8	Benzoic acid, 4-hydroxy-, butyl ester	Human Health	Available data indicate potential for endocrine-related effects and some parabens identified in biomonitoring studies (e.g. NHANES in USA). Considered for addition to a parabens grouping.
95-31-8	2-Benzothiazolesulfenamide, N-(1,1-dimethylethyl)-	Ecological	Identified as Very Persistent (vP) and Toxic (T) in ECHA Dossier (ECHA c2007-2015). This substance had only met the inherent toxicity criteria in categorization (Environment Canada, Health Canada 2007). Study summaries on persistence indicate no ready biodegradation (ECHA c2007-2015). Quantities reported under the US CDR indicate 8.5 million lbs in commerce in the US in 2011 (US EPA 2012). This substance has not been surveyed in Canada. Considered for addition to the planned CMP3 benzotriazole and benzothiazole group (Canada 2016).
95-33-0	2-Benzothiazolesulfenamide, N-cyclohexyl-	Ecological	Identified as Very Persistent (vP) and Toxic (T) in ECHA Dossier (ECHA c2007-2015). This substance had not met any of the ecological categorization criteria (Environment Canada, Health Canada 2007). Quantities reported under the US CDR indicate 11 million lbs in commerce in the US in 2011 (US EPA 2012). This substance has not been surveyed in Canada. The European Union

			Risk Assessment Report indicates that this substance rapidly degrades to MBT (CAS RN 149-30-4) and MBTS (CAS RN 120-78-5), which are remaining priorities in the planned CMP3 benzothiazoles and benzothiazole group (ECB 2008, Canada 2016). Considered for addition to the CMP3 benzotriazole and benzothiazole group.
99-76-3	Benzoic acid, 4-hydroxy-, methyl ester	Human Health	Listed on the ECHA CoRAP due to potential for endocrine-related effects, CMR, wide dispersive use (ECHA 2015a). Methylparaben is in commerce (Phase 2 DSL Inventory Update), and has been detected in biomonitoring studies (e.g. NHANES in USA). Considered for addition to a parabens grouping.
106-97-8	Butane	Ecological & Human Health	The screening assessment of butane and isobutane in the presence of 1,3-butadiene indicated that screening assessment of butane and isobutane, in the absence of 1,3-butadiene, will be conducted with the group of substances that are remaining priorities for assessment as a result of categorization (Environment Canada, Health Canada 2009).
107-18-6	2-Propen-1-ol	Human Health	Listed on the ECHA CORAP. Suspected CMR (ECHA 2015a). Phase 2 DSL Inventory Update indicates substance in commerce (Environment Canada 2012).
115-86-6	Phosphoric acid, triphenyl ester	Ecological & Human Health	Triphenyl phosphate (TPP) is on the ECHA CORAP for human health and endocrine-related effects (ECHA 2015a). Data reported in response to the Phase 2 DSL Inventory Update indicate that in 2011, TPP was imported in quantities greater than 100,000 kg in flame retardants, lubricants and plasticizers (Environment Canada 2012). Considered for addition to the planned CMP3 flame retardant group (Canada 2016). Next steps will be informed by ongoing work with the US under the RCC. (http://www.ec.gc.ca/international/default.asp?lang=en&n=7C5E4437-1).
120-47-8	Benzoic acid, 4-hydroxy-, ethyl ester	Human Health	Available data indicate potential for endocrine-related effects and some parabens identified in biomonitoring studies (e.g. NHANES in USA). Considered for addition to a parabens grouping.
140-66-9	Phenol, 4-(1,1,3,3-tetramethylbutyl)-	Ecological &	Potentially identified for a review via analysis of notifications

		Human Health	received under the proposed subsection 75(2) procedure based on NFRA reported in the PIC Circulars. Identified as high hazard based on presence on the Candidate List of Substances of Very High Concern (SVHC) for endocrine disruption in the environment (ECHA 2015b) and based on presence on the US TSCA Work Plan due to its high aquatic toxicity score and high persistence score (US EPA 2014). Data reported in response to the Phase 2 DSL Inventory Update indicate that in 2011, greater than 100,000 kg were in commerce (Environment Canada 2012). Releases have been reported to the National Pollutant Release Inventory in 2002 (total of 0.01 tonnes to all media) (NPRI 1993-2014). Considered for addition to CMP3. Next steps will be informed by ongoing work with the US under the Regulatory Cooperation Council
156-60-5	Ethene, 1,2-dichloro-, (E)-	Human Health	Substance reported to Phase 2 DSL Inventory Update in high (>100,000 kg) quantities (Environment Canada 2012). On the TSCA workplan (US EPA 2014). Suggest risk assessment be considered based on the relatively low RfD (0.02 mg/kg) and the relatively large volume in commerce.
2687-91-4	2-Pyrrolidinone, 1-ethyl-	Human Health	This substance, NEP, is close analog of a substance already in CMP3, 2-Pyrrolidinone, 1-ethyl- (NMP) and is in commerce based on responses to Phase 2 DSL Inventory Update (Environment Canada 2012). Evidence of reproductive toxicity (GHS Category 1b). NMP is classified as reproductive toxicant as well [ESIS].
4191-73-5	Benzoic acid, 4-hydroxy-, 1-methylethyl ester	Human Health	Available data indicate potential for endocrine-related effects and some parabens identified in biomonitoring studies (e.g. NHANES in USA). Considered for addition to parabens grouping.
4221-80-1	Benzoic acid, 3,5-bis(1,1-dimethylethyl)-4-hydroxy-, 2,4-bis(1,1-dimethylethyl)phenyl ester	Ecological	The inherent toxicity of this substance was uncertain at the time of categorization (Environment Canada, Health Canada 2007). Data reported in response to the Phase 1 DSL Inventory Update indicate that in 2008, this substance was in commerce at greater than 100,000 kg (Environment Canada 2009). No new aquatic toxicity data is available; however toxicity is expected to be similar to that of remaining priorities in the planned CMP3

			Hindered phenol group (Canada 2016). Considered for addition to the CMP3 Hindered phenol group.
4247-02-3	Benzoic acid, 4-hydroxy-, 2-methylpropyl ester	Human Health	Available data indicate potential for endocrine–related effects and some parabens identified in biomonitoring studies (e.g. NHANES in USA). Considered for addition to a parabens grouping.
18472-51-0	D-Gluconic acid, compd. with N,N''-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediimidamide (2:1)	Ecological & Human Health	Initially flagged due to human health hazard indicator (Developmental toxicant- ECHA dossier), but further investigation shows potential eco-concern. Chlorhexidine acetate was assessed in Batch 12 of the CMP Challenge with a draft conclusion that it met 64a criteria (Environment Canada, Health Canada 2013). Data for the parent compound chlorhexidine and its other salts (e.g., gluconate) were considered in the assessment in characterizing the hazard of chlorhexidine acetate. Chlorhexidine gluconate has reported quantities in commerce in excess of 10,000 kg in response to the Phase 2 DSL Inventory Update (Environment Canada 2012), which is higher than what was reported for chlorhexidine acetate in 2005/2006. The chlorhexidine acetate assessment is being updated to include chlorhexidine gluconate.
25167-32-2	Benzenesulfonic acid, oxybis[dodecyl-, disodium salt	Ecological	The inherent toxicity of this substance was uncertain at the time of categorization (Environment Canada, Health Canada 2007). Data reported in response to the Phase 1 DSL Inventory Update indicate that in 2008, in commerce between 10,000 and 100,000 kg (Environment Canada 2009). No new aquatic toxicity data available, however toxicity is expected to be similar to that of CAS RN 70146-13-3, a remaining priority in the planned CMP3 Alkyl aryl sulfonates/LABS and derivatives group (Canada 2016). Considered for addition to the CMP3 Alkyl aryl sulfonates/LABS and derivatives group.
25322-17-2	Naphthalenesulfonic acid, dinonyl-	Ecological	The inherent toxicity of this substance was uncertain at the time of categorization (Environment Canada, Health Canada 2007). Data reported in response to the Phase 1 DSL Inventory Update indicate that in 2008, in commerce between 10,000 and 100,000 kg (Environment Canada 2009). No new aquatic toxicity data are

			available, however toxicity is expected to be similar to that of remaining priorities in the planned CMP3 Naphthalene sulfonic acids and salts group (Canada 2016). Considered for addition to the CMP3 Naphthalene sulfonic acids and salts group.
25619-56-1	Naphthalenesulfonic acid, dinonyl-, barium salt	Ecological	The inherent toxicity of this substance was uncertain at the time of categorization (Environment Canada, Health Canada 2007). Data reported in response to the Phase 1 DSL Inventory Update indicate that in 2008, in commerce between 10,000 and 100,000 kg (Environment Canada 2009). No new aquatic toxicity data are available, however toxicity is expected to be similar to that of remaining priorities in the planned CMP3 Naphthalene sulfonic acids and salts (Canada 2016). Considered for addition to the CMP3 Naphthalene sulfonic acids and salts group.
28777-98-2	2,5-Furandione, dihydro-3-(octadecenyl)-	Ecological	The inherent toxicity of this substance was uncertain at the time of categorization (Environment Canada, Health Canada 2007). Data reported in response to the Phase 1 DSL Inventory Update indicate that in 2008, in commerce at quantities greater than 1,000,000 kg (Environment Canada 2009). No new aquatic toxicity data, however toxicity is expected to be similar to that of remaining priorities in the planned CMP3 Carboxylic acid anhydrides group (Canada 2016). Considered for addition to the CMP3 Carboxylic acid anhydride group
36443-68-2	Benzenepropanoic acid, 3-(1,1-dimethylethyl)-4-hydroxy-5-methyl-, 1,2-ethanediylbis(oxy-2,1-ethanediyl) ester	Ecological	The inherent toxicity of this substance was uncertain at the time of categorization (Environment Canada, Health Canada 2007). Data reported in response to the Phase 1 DSL Inventory Update indicate that in 2008, in commerce at quantities between 10,000 kg and 100,000 kg (Environment Canada 2009). No new aquatic toxicity data available, however toxicity is expected to be similar to that of remaining priorities in the planned CMP3 hindered phenols group (Canada 2016). Considered for addition to the CMP3 Hindered phenols group.
58965-66-5	Benzene, 1,2,4,5-tetrabromo-3,6-bis(pentabromophenoxy)-	Ecological & Human Health	The inherent toxicity of this substance was uncertain at the time of categorization (Environment Canada, Health Canada 2007). A New Substances Notification was received on a similar 3-ring

			brominated flame retardant, with data indicating that this substance may be toxic to daphnia in chronic exposure and has potential effects in mammals (adrenal glands, testes). Data reported in response to the Phase 1 DSL Inventory Update indicate that in 2008, in commerce at quantities between 1,000 kg and 10,000 kg (Environment Canada 2009), and reported in quantities ranging from 1 million to 10 million lbs in the US in 2002 (US EPA 2012). A similar, less brominated substance, and potential degradation product, has been found in herring gull eggs around the Great Lakes (Chen et al. 2011). Considered for addition to the planned CMP3 Flame Retardants group (Canada 2016).
60223-95-2	Naphthalenedisulfonic acid, dinonyl-	Ecological	The inherent toxicity of this substance was uncertain at the time of categorization (Environment Canada, Health Canada 2007). Data reported in response to the Phase 1 DSL Inventory Update indicate that in 2008, in commerce at quantities between 10,000 kg and 100,000 kg (Environment Canada 2009). No new aquatic toxicity data available, however toxicity is expected to be similar to that of remaining priorities in the planned CMP3 Naphthalene sulfonic acids and salts group (Canada 2016). Considered for addition to the CMP3 Naphthalene sulfonic acids and salts group.
65652-41-7	Phosphoric acid, bis[(1,1-dimethylethyl)phenyl] phenyl ester	Ecological	The inherent toxicity of this substance was uncertain at the time of categorization (Environment Canada, Health Canada 2007). Data reported in response to the Phase 1 DSL Inventory Update indicate that in 2008, in commerce at quantities between 10,000 kg and 100,000 kg (Environment Canada 2009). No new aquatic toxicity data available, however it is related to other remaining priorities in the planned CMP3 flame retardants (Canada 2016). Considered for addition to the CMP3 Flame Retardant group.
3846-71-7	Phenol, 2-(2H-benzotriazol-2-yl)-4,6-bis(1,1-dimethylethyl)-	Ecological & Human Health	Potentially identified for a review via analysis of notifications received under the proposed subsection 75(2) procedure based on NFRA reported in the PIC Circulars. Identified as high hazard based on presence on the Candidate List of Substances of Very High Concern (SVHC) for PBT and vPvB properties (ECHA 2015b).

			This substance has not been surveyed in Canada. Considered for addition to the planned CMP3 benzotriazole and benzothiazole group and will require further data gathering to inform the exposure assessment (Canada 2016).
85204-21-3	2-Butenoic acid, 4-[(2-ethylhexyl)amino]-4-oxo-, (2Z)-, compd. with 2,2',2''-nitrilotris[ethanol] (1:1)	Ecological & Human Health	Potentially identified for a review via analysis of notifications received under the proposed subsection 75(2) procedure based on TSCA actions from the United States. Considered for addition to CMP3.

Abbreviations: ECHA = European Chemicals Agency; CORAP = COmmunity Rolling Action Plan; CMP3 = Third Phase of CMP; US CDR = United States Chemical Data Reporting; NFRA = Notifications of Final Regulatory Action; PIC = Prior Informed Consent; RCC = Regulatory Cooperation Council

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