



Pilot Phase of the Confidential Substance Identity Claim Review Project

Purpose

The purpose of this document is to outline the results and lessons learned from the implementation of the pilot phase of the <u>confidential substance identity claim review project</u>.

Annex 1 provides a summary of the public comments received on the <u>Notice of Intent</u> for the pilot phase and their associated government responses.

Context

In October 2018, the <u>Approach to disclose confidential information and promote transparency</u> <u>in chemicals management</u> (the Approach) was published. This policy document sets out several measures to help improve the transparency of the Chemicals Management Plan (CMP), including the introduction of a review of confidentiality claims for substance identity after a period of ten years. To implement this part of the Approach, a process to review confidentiality claims on substance identity that are older than ten years for substances on the Domestic Substances List (DSL) was developed, starting with a pilot phase to address 23 substances in the third phase of the CMP. The number of substances in the pilot phase increased to 24 due to the receipt of a voluntary request by a notifier to rescind the confidentiality claim on the identity of another substance. The pilot phase consisted of the substances listed in Annex 2 and Annex 3.

Results

Table 1 provides a summary of the number of substances in the pilot phase, whether they are owned by Canadian nominators, notifiers or foreign suppliers, as well as the responses received in regards to the disclosure of the substance identities.





		Responses (per substance)		
	Number of	Willing to	No	Justification submitted
Owner of masked name	substances	disclose	response	to retain confidentiality
Canadian nominator or				
notifier	13	12	1	0
Foreign supplier	11	6	1	4
Total	24	18	2	4

Table 1. Owners of masked substances in the pilot phase and their responses

Table 2 provides an overview of the outcomes of the pilot phase. Three substances from the pilot phase were deleted from the confidential portion of the DSL and added to the non-confidential portion of the DSL by their Chemical Abstracts Service Registry Number (CAS RN) and descriptive chemical names (see Annex 2). The masked name of four substances were amended on the confidential portion of the DSL in accordance with the *Masked Name Regulations*. The disclosure of 17 substances were put on hold, as either no responses regarding the confidentiality claims were received or there are operational challenges with the administration of the DSL. The Government of Canada will consider alternative solutions to disclose the identities of substances for which no responses were received. One substance that consists of two main components remains on the confidential portion of the DSL, but its identity will be disclosed in relevant documents to allow for a transparent risk assessment.

Final Outcome	Number of substances
Disclose to substance name and CAS RN	3
Maintain confidentiality claim; update masked name on DSL listing	4
Disclosure on hold	17*
Total	24

Table 2. Number of substances associated with each final outcome of the pilot phase

*One substance (Confidential Accession Number (CAN) 11105-8) has two components, only one of which has a CAS RN.

Lessons Learned and Next Steps

Environment and Climate Change Canada deliberately used a more extensive process for the pilot phase in order to test multiple aspects of the project. Based on the results of the pilot phase, the process for future phases will be streamlined to increase efficiency.

For example, during the targeted communication step of the pilot phase, nominators, notifiers, foreign suppliers and other companies known to have involvement with a substance were sent one letter for each substance with which they were involved. As such, certain companies received several copies of the letter, each addressing a different substance. In the future, only

one letter identifying all relevant substances under review could be sent to each company during the targeted communication step rather than sending one letter per substance.

In addition, during the broad communication step of the pilot phase, a Notice of Intent (NOI) was published to inform the public of the government's intent to disclose the identities of several substances. The substances included on the NOI were those for which the nominator, notifier or foreign supplier did not respond or indicated that the confidentiality claim was no longer necessary during the targeted communication step. In the future, the NOI may include only the substances for which no response is received from the original nominator, notifier or foreign supplier, rather than all the substances which Environment and Climate Change Canada intends to publically identify.

Updates to the text of the <u>Approach</u> and the <u>process flowchart</u> have been made in order to reflect a more streamlined process.

Annex 1: Public Comments and Responses

On November 30, 2019, ECCC published a *Notice of intent to amend the* Domestic Substances List *to disclose the identity of certain substances currently identified by a masked name* in the *Canada Gazette*, Part I. Comments received in response to this Notice of Intent were considered.

Comment summary	Response		
A stakeholder requested that the government clearly define what constitutes "a reasonable attempt" on ECCC's part to contact the nominator, notifier or foreign supplier. They expressed that in the case of imported substances, the foreign suppliers should be contacted and given the opportunity to substantiate the confidentiality claim.	This was taken into account in the pilot phase. The Government contacted nominators, foreign suppliers and other organizations known to be involved with the substances to provide them with the opportunity to substantiate the confidentiality claim on the substance identity or to provide comments. The Government plans on continuing this practice in future phases of the project.		
A stakeholder expressed concern that the lack of response from a nominator, notifier or foreign supplier at the beginning of the process could lead to disclosure of confidential information without prior knowledge of one or more affected companies who may rely on the confidential identity.	This was taken into account in the pilot phase. One of the purposes of the Notice of Intent was to announce the intention to disclose certain substances and to allow affected companies to submit comments or justifications to maintain confidential identity claims. The Government plans on continuing this practice in future phases of the project.		
A stakeholder requested that the government contact both the foreign supplier and nominator of a confidential substance before disclosing the substance identity in order to ensure that severe adverse impacts on foreign suppliers is avoided.	This was taken into account in the pilot phase. At least 24 hours prior to disclosing any information, the nominators and foreign suppliers will be given notice of the disclosure of the substance identity.		

Annex 2: Substance identifiers for substances in the pilot phase before and after DSL amendment

Before DSL amendment After DSL amendment				endment
CAN	Masked Name	Outcome	CAS RN	Substance Name
11145-3	Alkylamine salt of complex phosphate ester	Disclose	91745-46-9	Amines, C12-14-alkyl, reaction products with hexanol, phosphorus oxide (P2O5), phosphorus sulfide (P2S5) and propylene oxide
12208-4	Silica gel, reaction product with chromic acid, bis(triphenylsilyl) ester and metal alkalkoxide	Disclose	221455-10-3	Silica gel, reaction products with chromic acid (H2CrO4) bis(triphenylsilyl) ester and ethoxydiethylaluminum
17922-3	1,4- Benzenedicarboxylic acid, 1,4-dimethyl ester, polymer with 1,4- cyclohexanedimethanol and cycloalkane diol	Disclose	261716-94-3	1,4-Benzenedicarboxylic acid, 1,4-dimethyl ester, polymer with 1,4- cyclohexanedimethanol and 2,2,4,4-Tetramethyl- 1,3-cyclobutanediol
CAN	Masked Name	Status	CAN	Masked Name
11053-1	Fatty acids compounded with ethylenediamine	Maintain confidentiality claim	11053-1	Reaction products of alkyl carboxylic acid and hydrogenated castor oil fatty acid with alkyl diamine
11555-8	Fatty acids, reaction products with maleic anhydride and triethanolamine	Maintain confidentiality claim	11555-8	Amides, tall-oil fatty, tall- oil, (iminopolyalkanediyl)poly -, phosphates
11556-0	Fatty acids, reaction products with maleic anhydride	Maintain confidentiality claim	11556-0	Fatty acids, unsatd., maleated
11557-1	Fatty acids, reaction products with maleic anhydride and oleylamine	Maintain confidentiality claim	11557-1	Fatty acids, unsatd., maleated, reaction products with alkenamine

Annex 3: List of substances for which disclosure is on hold

CAN	Masked Name		
10001-2	Borated reaction product of polybutenyl succinic anhydride with ethylene diamine- piperazine polymer		
10015-7	Derivative of amines, polyethylenepoly-compounds with (polybutenyl) succinic anhydride		
10024-7	Metal alkyldithiophosphates		
10026-0	Alkenylsuccinic anhydride, product with polyethylenepolyamines and inorganic acid		
10680-6	Alkenylsuccinimide, sulfurized		
10685-2	Substituted dimercaptodithiazole		
10703-2	Substituted alkylphenol, calcium salt		
11105-8	Phosphorothioic acid, dialkyl ester, alkylamine salt		
11167-7	Alkyl ester of styrene-maleic acid polymer, product with substituted heteromonocycle		
11200-4	Substituted acrylate of a dimethyl, alkyl, substituted carbomonocycle, ammonium chloride derivative		
11482-7	Formaldehyde, reaction product with phenol, polybutene derivs., polyethylene polyamines with alkenoic acid		
11483-8	Formaldehyde, reaction product with phenol, polybutene derivs., polyethylene polyamines, alkenoic acid and metallo acid		
11487-3	Fatty acids, tall-oil, reaction products with monomethyl maleate and a polyethylenepolyamine		
11496-3	N,N' 2-Tris(6-isocyanatohexyl)imidodicarbonic diamide, α-fluoro-ω-(2- hydroxyethyl)poly(difluoromethylene), heteromonocycle-methanol and 1- octadecanol adduct		
11497-4	α-Fluoro-ω-[2-[(1-oxo-2-propenyl)oxy]ethyl]poly(difluromethylene), polymer with 2- methyl-2-propenoic acid phenylmethyl ester, (Z)-2-butenedioic acid bis(2- ethylhexyl) ester and 2-methyl-2-propenoic acid 2-(heteromonocycle) ethyl ester		
11498-5	α-Fluoro-ω-[2-[(2-methyl-1-oxo-2-propenyl)oxy]ethyl]poly(difluoromethylene), polymer with 2-methyl-2-propenoic acid octadecyl ester and 2-methyl-2-propenoic acid 2-(heteromonocycle)ethyl ester		
11504-2	α-Fluoro-ω-[2-[(2-methyl-1-oxo-2-propenyl)oxy]ethyl]poly(difluoro-methylene), polymer with 2-methyl-2-propenoic acid 1,1-dimethylethyl ester and 2-methyl-2- propenoic acid 2-(heteromonocycle)ethyl ester		