

New Substances Notification Advisory Note 01-99

Renewal of the Agreement for Sharing of Information Between the U. S. Environmental Protection Agency (USEPA), and Environment Canada (EC) and Health Canada (HC) (Four Corners Agreement)

This note is intended to inform companies about the renewal of the Four Corners Agreement and the potential benefits that may result for new substances notifications in Canada.

On July 1, 1994, the New Substances Notification (NSN) Regulations of the *Canadian Environmental Protection Act* (CEPA) came into force. Under these Regulations, chemicals and polymers that are new to Canada require notification and submission of information sufficient to make an initial assessment of risk to human health and the environment, prior to manufacture or importation into Canada. Any substance not listed on the CEPA Domestic Substances List (DSL) is considered "new" to Canada and subject to notification.

Substances that appear on the US EPA Toxic Substances Control Act (TSCA) Inventory of 1985 but not on the DSL, form the basis for a second list, the Non-domestic Substances List (NDSL). Substances that appear on the NDSL have reduced information requirements for notifications in Canada. Since 1995, the NDSL has been undergoing annual revisions which add or delete all substances incorporated into, or removed from the TSCA Inventory five or more years before the date of the NDSL revision. By way of example, the 1994 additions to the TSCA inventory were eligible for inclusion, and were added to the NDSL in January 1999. The 5-year interval is significant because during this time, it can be reasonably expected that information based on actual use of the chemical in the U.S. will have accumulated that might assist with the substance's assessment in Canada. Furthermore, companies required to notify substances that are not on the NDSL are subject to full notification and associated testing costs even though relevant information may already be available from U.S. authorities.

For this reason, Canadian and American chemical industries have explored with both governments, ways in which the interval can be reduced, and benefits of reduced information requirements can be achieved. One way to do so is to facilitate sharing of information used by the U.S. EPA's New Chemicals Program with their counterparts in Canada, and vice versa.

The result of these consultations has been an information sharing pilot project and associated agreement between the governments of the United States (U.S. Environmental Protection Agency) and Canada (Environment Canada and Health Canada), the Industry Coordinating Group for CEPA, and the U.S. Chemical Manufacturers Association (the “4 Corners” parties). The procedures laid out in the agreement have encouraged voluntary sharing of information between countries while protecting the confidentiality of any information and providing industry with opportunities to reduce testing costs, assessment fees and time to market.

The pilot began in 1996 and lasted until 1998. In September 1998, the “4 Corners” parties met and generally agreed that there were enough positive outcomes to shift from a pilot project to an on-going program, and to renew the agreement with a number of constructive modifications. These include establishing target timelines for completing the review of industry submissions by Environment Canada and Health Canada, and calling for a biennial review of the program, its costs and benefits and improvements. The renewed agreement took effect June 23, 1999 and will continue indefinitely unless modified or terminated.

Embodied in the new agreement is a recognition that while having a substance added to the NDSL is the greatest benefit, it is not the only one. Due to the significant and rising costs of testing, individual companies that make Four Corners submissions may also benefit by obtaining waivers for some of the additional information requirements that they would face for substances not yet appearing on the NDSL.

The Four Corners Agreement will be of greatest benefit to companies having a genuine intent to manufacture or import substances in such quantities and within timelines where there will be a clear advantage over waiting 5 years for the routine updates based on the TSCA Inventory. Where this is not the case, government agencies are not encouraging submissions since the effort required to respond represents a significant resource burden with consequences for other aspects of their programs.

A number of documents are available that will facilitate completion of Four Corners submissions including:

- Administrative Procedures for Data Sharing;
- US and Canadian application forms;
- US and Canadian "Limited Permission to Disclose" forms; and
- Guidelines for Canadian Importers and Manufacturers for Implementation of EPA/EC Information Exchange Agreement.

Based on consultations that have been taking place in Canada on cost recovery fees for government services under the CEPA New Substances Program, the government will be proposing a fee of \$2000 for all Four Corners Agreement submissions.



These fees will be required once *New Substances Notification Cost Recovery Regulations* are proposed and promulgated. This fee for service will facilitate completion of the reviews within the target timelines described in the agreement thus affording industry the greatest opportunity to benefit.

If you are interested in making a submission, or you have any questions or comments about the agreement, procedures or the proposed fees for this service in Canada, please contact us by mail at:

Four Corners Agreement,
New Substances Branch,
Environment Canada,
14th Floor, Place Vincent Massey,
351 St. Joseph Blvd., Hull, Quebec, K1A 0H3

You can also reach us by facsimile at (819) 953-7155 or through the New Substances Notification Information Line at (800) 567-1999 (in Canada) or at 819 953-7156 (outside Canada).

Sincerely,

Original signed by Jim Armstrong for

J.A. Buccini
Director
Commercial Chemicals Evaluation Branch
Toxics Pollution Prevention Directorate



PROPOSED ADMINISTRATIVE PROCEDURE FOR DATA SHARING UNDER THE “4 CORNERS” AGREEMENT

- STEP 1: The CEPA notifier, (an agent for the US PMN filer) makes an application to Environment Canada for addition of a substance to the Non Domestic Substance List (NDSL).
- The application must include:
- a. The original TSCA PMN and PMN number
 - b. The US TSCA Notice of Commencement (NOC), if applicable
 - c. Any TSCA 5(e) or 8(e) compliance documentation
 - d. Any US generated Letters of Concern (LOCs)
 - e. A copy of, or reference to, a New Substance Notification (as per CEPA Schedules I or II (chemicals) or Schedules VI or VII (polymers) for the substance. The notification will include all information and test data in respect of the substance that are relevant to identifying hazards to human health and the environment and that are in the notifier’s possession or to which the notifier ought reasonably to have access. This includes all new data generated on the substance since the original PMN was filed.
 - f. CEPA notifier and US PMN filer provide authorization allowing Environment Canada and Health Canada to discuss submissions fully with US EPA and exchange information as warranted with US EPA.
- STEP 2. Environment Canada acknowledges receipt of the request and identifies the information submitted. Environment Canada copies THE US EPA and the US PMN filer (identified in #1).
- STEP 3. The CEPA notifier requests the US PMN filer to authorize the US EPA to send Environment Canada the US EPA Review Notes.
- STEP 4. The US PMN filer:
- a. Requests the US EPA to send Review Notes to Environment Canada
 - b. Provides authorization for the US EPA to direct reviews to Environment Canada and discuss reviews of particular PMN submissions with Environment Canada staff.



- c. Includes acknowledgment letter from Environment Canada (STEP 2.) and additional information generated since the filing of the PMN (STEP 1.e.new data) with the request package.

STEP 5. US EPA sends Review Notes to Environment Canada.

STEP 6. Environment Canada and Health Canada make one of two decisions regarding addition to NDSL. In instances where the decision is 1) to add the chemical to the NDSL, Environment Canada and Health Canada will advise the notifier of the addition, and 2) in instances where a chemical will not be added to the NDSL, Environment Canada and Health Canada will identify elements for which testing will not be required of the notifier.

STEP 7. Environment Canada informs CEPA notifier and the US EPA of decision. In addition, Environment Canada provides the US EPA with the Environment Canada/Health Canada assessment.

STEP 8. Environment Canada sends the US EPA all subsequent health and safety data generated after the receipt of the CEPA application referenced in STEP 1.

CONDITIONS:

1. This is a case by case procedure. Either party may, without restriction, determine that particular PMN submissions are not appropriate for this procedure.
2. The TSCA PMN# is the main reference identifier for all requests, files and correspondence. Environment Canada will also assign a CE identifier number to the application received from the CEPA notifier.
3. Resource requirements cannot be estimated until the process is functional. Excessive resource requirements may result in re-examination of the process.
4. Frequent refusal by any party to abide by the informal agreement would result in a re-examination of the process.
5. Confidential Business Information in EPA PMNs submitted to Environment Canada and Health Canada through this agreement would be protected under Canadian law.
6. This informal agreement between EPA, Environment Canada and Health Canada will be operational for a 2-year period which will include a review of the program annually. Industry input will also be sought at this time.



7. EPA will send Environment Canada and Health Canada all pertinent reports that have been generated during a PMN review which may include a chemistry report, a SAT report, a fate report, an engineering report, an exposure assessment report, a Focus report, and other reports generated during more detailed reviews, as well as test data reviews on the PMN. To the extent possible, data on analogue/surrogate substances used in EPA assessments will also be included in these packages as long as that information has not been claimed confidential by non-Four Corners submitters of 8(e) chemicals and other similar PMN chemicals with test data.
8. Environment Canada and Health Canada will commit to respond to the notifier within 90 days of receipt of the complete package which includes the information to be received from the EPA. The response will inform the notifier of the outcome of the review, indicating either, acceptance of the substance onto the NDSL or specifying any reduced information provision requirements in cases where NDSL listing is not granted. It may also inform the notifier that further time is needed to complete the review process and provide an explanation as to why more time is necessary.
9. In an effort to make this process even more timely for PMN submitters who may want to manufacture/import chemicals in Canada, the EPA and Canada are willing to commit to the following for 1)chemicals notified in the US but which have not yet completed review or for 2)chemicals which have undergone US review but have not yet been commercialized in the US: in the first instance a PMN submitter should inform EPA that they want to participate in the "Four Corners Agreement" as "bonafide participants" by putting this request in the cover letter to the PMN submission and insert the bolded statement, "**4 Corners**" **Candidate**, on page 4 of the PMN form under the Chemical Identity Information Section B.1(e). Then EPA would be willing to give these reports greater consideration and release them to Canada once the assessment is complete. This could occur before the 90-day review period is over and before the substance is commercialized in the US. In the second instance, PMN submitters could request "4 Corners" participation even after the US 90-day review period is over and before a substance is commercialized in the US.
10. US regulated new chemicals are candidates for the "Four Corners" program and potentially could become eligible for the NDSL.



ACTION ITEM DIAGRAM

CEPA NOTIFIER		US PMN FILER	ENVIRONMENT CANADA	US EPA
Step 1.	Submits Application to Environment Canada (see address below)	Cosigns Authorization with CEPA Notifier		
Step 2.			Sends acknowledgement letter to CEPA Notifier with CE# -cc to US PMN Filer -cc to US EPA (see address below)	Opens docket
Step 3.	Requests US PMN Filer to Authorize US EPA to send review notes to Environment Canada			
Step 4.		-Authorize US EPA to send Review Notes to Environment Canada -Submit any New Data to US EPA		
Step 5.				US EPA sends Review Notes to Environment Canada
Step 6.			Makes Decision re Addition to NDSL	
Step 7.			Informs CEPA Notifier & US EPA of Decision	
Step 8.			Subsequent New Data Sent to US EPA	

Addresses:

Environment Canada:
 New Substances Branch, TPPD
 Environment Canada
 14th Floor, Place Vincent Massey
 Ottawa, ON K1A 0H3

US EPA :
 Document Control
 Office of Pollution Prevention and Toxics,
 Attn: Anna Coutlakis
 US EPA East - Mail Code 7405M
 1200 Pennsylvania Avenue, N.W.
 Washington, DC 20460



"FOUR CORNERS" AGREEMENT **Limited Permission to Disclose (NSN Notifier)**

_____, requests that the substance _____
[name of CEPA notifier] [substance name or NSN # if available]

submitted pursuant to the New Substances Notification (NSN) Regulations of the *Canadian Environmental Protection Act* (CEPA) be considered for review in the manner specified by the "FOUR CORNERS" AGREEMENT. _____,
[Name of CEPA notifier]

hereby gives permission to Environment Canada and Health Canada to disclose all or any part of the content of the NSN dossier, including assessment reports, and Confidential Business Information (CBI) as defined by Canadian law, to the U. S. EPA under the following terms:

1. This permission is a limited one. It is made to permit U. S. EPA to receive all test data provided within the NSN dossier as well as the Environment Canada and Health Canada assessment reports as contemplated under the bilateral agreement titled "Agreement for sharing of Information Between the U. S. Environmental Protection Agency (USEPA) and Environment Canada (EC) and Health Canada (HC) Administrative Procedures", signed June 9, 1999, effective June 23, 1999.
2. This permission is not, therefore, a general waiver of either substantive or procedural CBI protections provided by Canadian law.
3. _____, recognizes that Environment Canada makes no
[Name of CEPA notifier]
representation as to the level of security that information claimed as CBI might be afforded once the information is disclosed to U. S. EPA.
4. Environment Canada will, however, inform U. S. EPA of the existence of any CBI claims under Canadian law known to Environment Canada at the time of disclosure by Environment Canada.
5. _____, furthermore, makes this permission to disclose with
[Name of CEPA notifier]
the understanding and belief that U. S. EPA will give this information, claimed as CBI under Canadian law, all protections to which it is entitled under applicable American law.



I have the authority to sign this Limited Permission to Disclose on behalf of

_____.
[Name of company]

Signature: _____

Name Typed: _____

Title: _____

Date: _____



"FOUR CORNERS" AGREEMENT Limited Permission to Disclose (TSCA PMN Filer)

_____ a company that has previously submitted to U.S. EPA a pre-manufacture notice (PMN) contest confidential business information (CBI) as defined by American law, hereby gives permission to U.S. EPA to disclose the entire contents of a U.S. EPA PMN file, including CBI, denominated as PMN _____ to Environment Canada and Health Canada under the following terms:

1. This permission is a limited one. It is made to facilitate the review of this PMN file by the two named Canadian federal agencies as contemplated under the bilateral agreement titled "Agreement for Sharing of Information Between the U.S. Environmental Protection Agency (USEPA) and Environment Canada (EC) and Health Canada (HC) Administrative Procedures," signed June 9, 1999, effective June 23, 1999.

2. This permission is not, therefore, a general waiver of either substantive or procedural CBI protections provided by American law.

3. _____ recognizes that U.S. EPA makes no representation as to the level of security that information claimed as CBI might be afforded once the information is disclosed to Environment Canada or Health Canada.

4. U.S. EPA will, however, inform Environment Canada and Health Canada of the existence of any CBI claims under American law known to U.S. EPA at the time of disclosure.

5. _____ furthermore, makes this limited disclosure with the understanding and belief that Environment Canada and Health Canada will give this information claimed as CBI under American law, all protections to which it is entitled under applicable Canadian law,

I have the authority to sign this Limited Permission to Disclose on behalf of

[name of company]

Signature: _____

Name Typed: _____

Title: _____

Date: _____



Sharing New Chemicals information Between the United States and Canada

Dear Sir/Madam:

Below is the documentation/and or data being sent to the US EPA **by the PMN filer** as part of a project in shared hazard data and risk assessment between the United States and Canada:

Signature and Title of Authorized Official _____

Company name _____

Company Address _____

Date _____

Subject chemical substance identifier	CE # PMN #
Items included :	
1. PMN Filer's Authorization letter allowing US EPA to send/discuss CBI re PMN Submission with EC	
2. Copy of EC Acknowledgement letter	
3. Data Generated Since PMN Submission	
4. Other	



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Signature and Title of Authorized Official _____

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Subject chemical substance identifier:	PMN #
Items included :	
1. US TSCA PMN	
2. US TSCA Notice of Commencement (NOC)	
3. Any TSCA 5(e) or §8(e) Compliance documentation	
4. Any US Generated Letters of Concern (LOCs)	
5. All New Data on the Chemical Generated since the Original PMN was Filed	
6. Authorization by both CEPA Notifier and US PMN Filer allowing Environment Canada and Health Canada to Discuss Submissions and Exchange information with US EPA	