Four Corners Arrangement

Appendix 1

International Context

Sharing information about substance assessments is a priority issue arising from the UN Conference on Environment and Development (UNCED) (June 1992, Rio de Janeiro). Better use of existing information and mechanisms for information exchange is a vital part of Agenda 21, Chapter 19, which provides the blueprint for action to ensure the environmentally sound management of substances. The Organization for Economic Co-operation and Development (OECD) initiated efforts in the mid-1990s to encourage information and work sharing among member and other countries as well as the mutual acceptance of notifications (MAN).

In 1999, an OECD Task Force (OECD TF) on New Chemicals was established to develop and implement a program of work that, among other things, promotes bi/multi-lateral arrangements to formalize cooperation. Some of the activities in which the Task Force is engaging include the development of a standard notification form to simplify reporting and facilitate data sharing and the development of a standard reporting or documentation format for assessment of new substances. By the same token, the OECD TF is working toward greater alignment of regulatory schemes for certain special categories (i.e. site-limited, export only, research and development), in order to provide greater similarities for these classes and to reduce the resources needed to manage new substance programs without compromising the protection of the environment and human health. This Arrangement between Canada and the U.S. contributes to this goal, as well as provide other direct benefits to the countries.

Compatibility in regulations is particularly important because of the high level of trade and the economic interdependence of the chemical industries of the US and Canada. Total trade in chemicals exceeded \$27 billion in 2002. Moreover, a major portion of that trade represents within-company transactions made in order to rationalize North American production as efficiently as possible.

Historical Context

New Substances Notification Regulations

On July 1, 1994 the New Substances Notification Regulations of the Canadian Environmental Protection Act (CEPA, since amended in 1999) came into force. Under these regulations, the manufacture or import into Canada of chemicals and polymers that are new to Canada require notification and submission of information sufficient to make an initial assessment of risks to environmental and human health. Any substance not listed on the CEPA Domestic Substances List (DSL) is considered new to Canada. Substances that appear on the US EPA *Toxic Substances Control Act* (TSCA) Inventory of 1985, but are not on the DSL form the basis of a second list, the Non Domestic Substance List (NDSL), for

which there are reduced information requirements. The NDSL is administered under CEPA. This is currently done yearly by including the annual additions to the TSCA Inventory, but with a 5-year interval to permit the accumulation of information based on actual use of the substance. Thus, the 1994 additions to TSCA were eligible for inclusion on the NDSL in 1999.

Four Corners Pilot Project

Canadian and American chemical industries expressed their belief that the 5-year waiting period is too restrictive and wished to explore ways by which additions to the TSCA Inventory could be moved onto the NDSL in less than 5 years. It was proposed that, if the information used by the U.S EPA's New Chemicals Program to make a decision regarding a substance was made available to decision makers in charge of Canada's New Substances Program, the process for adding that substance to the NDSL could be expedited.

Consultations between the U.S. Environmental Protection Agency, the Government of Canada (Environment Canada and Health Canada), the Canadian Chemical Producers' Association, and the Chemical Manufacturing Association (the "4 Corners" participants) resulted in a Pilot Project. A process was established for sharing the information about the assessment of new substances, including confidential data between the U.S. and Canadian governments.

The pilot began in 1996 and lasted until 1998. The aims of the pilot were to encourage voluntary sharing of information, protect the confidentiality of any business information exchanged between the two governments, and provide industry with opportunities to reduce testing costs, and time to market. In addition the US and Canadian governments would gain significant insight into each other's program and competencies.

First Four Corners Agreement

In September 1998, the "4 Corners" participants 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 the completion of the review by Environment Canada and Health Canada, and calling for a biannual review of the program, its costs and benefits and improvements. The renewed agreement took effect June 23, 1999 and was to continue indefinitely unless modified or terminated.

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

Modernizing the Four Corners Agreement/Arrangement

Until now, the Four Corners Agreement focused on providing a mechanism to expedite the movement of substances newly added to the US TSCA Inventory onto Canada's NDSL, before the required 5 year waiting period elapsed, or to identify Canadian data requirements that could be waived based on US assessment of the same new substance.

However, one of the recommendations of the recent New Substances Notification (NSN) Regulations multi-stakeholder consultations would reduce the waiting period for the addition of new TSCA listings to the NDSL from 5 years to 1 year along with changes to the information requirements set out in the notification schedules. Consequently, this change could significantly alter the perceived value and use of the Four Corners Agreement by industry.

The Signatories and Supporting Partners agreed that it was necessary to change the Agreement into an Arrangement which has a broader scope and provides greater benefits. Meetings were held in Wakefield, Quebec, Canada in July 2002, Washington D.C., January, 2003 and Wakefield September, 2003 to discuss modernizing the Four Corners Arrangement. The revised Four Corners Arrangement was finalized and signed in November, 2003.

Appendix 2

Key Considerations for Confidential Business Information

There are a number of key considerations that will guide the actions of the Signatories concerning the exchange of Confidential Business Information (CBI) under their respective laws. Signatories agree not to release such information to persons outside their respective government Departments, except with the agreement of the owner of the information.

 Addressing the issue of CBI and how the exchange of information can proceed between the Signatories without compromising the safeguards within the two systems

In both countries (US and Canada), national legislation provides protection of information submitted by Industry; failing to protect this information could adversely affect markets and investments that Industry make to develop new substances. The federal laws are as follows:

- Relevant US legislation protecting information provided in Section 14 of the Toxic Substances Control Act.
- Relevant Canadian legislation protecting the confidentiality of information is found in sections 313 to 321 of the Canadian Environmental Protection Act, 1999 (CEPA 1999) and also the Access to Information Act and Privacy Act.

Procedures for Exchanging Information

The confidential business information (CBI) submitted by Industry in relation to a specific notification will be exchanged between Signatories by a secure mechanism (e.g., encrypted e-mail, etc) according to the national laws in regard to CBI of each country, unless the Signatories receive permission from Industry to use other transmittal methods. Other information that is not confidential may be shared by phone, fax, e-mail, surface or air-mail.