Cooperative Arrangement Between the Environmental Protection Agency (EPA) of the United States and Environment Canada (EC) and Health Canada (HC) on the Subject of New Substances (a.k.a. The Four Corners Arrangement (4CA))

A Brief History

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 importation into Canada of chemicals and polymers that are "new to Canada" require notification and submission of information sufficient to make an initial assessment of any risk posed to the environment or human health. Any substance not listed on the CEPA Domestic Substances List (DSL) is considered new to Canada.

Another CEPA list, the Non Domestic Substances List (NDSL), contains those substances that while new to Canada, are not new to the U.S. (i.e., they appear on the U.S. EPA *Toxic Substances Control Act* (TSCA) Inventory of 1985). NDSL substances, while still subject to notification requirements, face less onerous information requirements than substances new to both Canada and the U.S.

The NDSL is updated annually by adding those substances that were introduced to the U.S. TSCA five years prior (e.g., substances added to the TSCA in 1990 were added to the NDSL in 1995). Thus, the 1994 additions to TSCA were eligible for inclusion on the NDSL in 1999.

At the time, Canadian and American chemical industries felt that the five-year waiting period was too restrictive and sought to explore ways by which additions to the TSCA could be moved onto the NDSL sooner. They proposed that the information used by the U.S EPA's New Chemicals Program be made available to Canada's New Substances Program so that the process for adding that substance to the NDSL could be shortened.

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 "Four 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.

In September 1998, the "Four 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. The renewed agreement took effect June 23, 1999 and was to continue indefinitely unless modified or terminated.

Until now, the Four Corners Agreement focused on providing a mechanism to expedite the movement of substances from the US TSCA Inventory to Canada's NDSL before the five-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 from the recent *New Substances Notification Regulations* (NSNR) multi-stakeholder consultations was to reduce the waiting period for the addition of new TSCA listings to the NDSL from five years to one and to make changes to the information requirements set out in the notification schedules. If implemented, 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 a less formal "Arrangement" that could have a broader, more global scope and provide greater benefits. As such, regular meetings and teleconferences on how the Four Corners Agreement could be modernized have resulted in a revised Four Corners Arrangement that will be signed in November 2003. The Arrangement aims to achieve efficiencies of resources for all parties with respect to the introduction of new substances to the North American marketplace, while continuing to protect human health and the environment.

The Objectives of the new Arrangement are:

- Increasing cooperation and understanding between US and Canadian governments involved in new substances, notably with respect to each others' risk assessment and risk management policies and practices;
- Identifying possible strategies for overcoming regulatory, administrative and other barriers to greater cooperation and alignment and taking appropriate actions; and
- Identifying and taking appropriate actions to ensure progress toward the long term goal of greater co-operation and alignment of Canadian and US new substance regulatory schemes, for example the mutual acceptance of notifications (MAN).

Benefits to Government:

- Use resources more efficiently by making greater use of work carried out by the other jurisdiction, without compromising the sovereign right of each government to make sound decisions associated with the assessment and management of new substances; and
- Allow greater exchange of scientific, policy and regulatory expertise;

Benefits to Industry:

- Reducing expenses associated with data generation, and preparing and submitting new substances notifications;
- Alleviating further testing on well-defined categories of substances;
- Improvement in risk assessment through the use of best available scientific methods (e.g. appropriate use of Structural Activity Relationship (SAR)) to address data requirements);
- Reducing time to introduce or market new substances;
- Improving the basis to allow governments to share information in new substance notifications;
- Strengthening access to foreign markets in the global commercialization of new substances;
- Creating an information sharing process that is dependable and predictable; and
- Improving the model that could be used in bi-lateral or multi-lateral arrangements with other jurisdictions, as envisioned by the Organization for Economic Co-operation and Development (OECD) program.