

**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))**

**Revised, Fall 2003**

## Definitions:

For the purposes of this Arrangement, the following definitions apply:

“*Parties*” refer to the following ‘Four Corners Arrangement’ participants:

- in the case of the United States, to the Office of Pollution Prevention and Toxics, US Environmental Protection Agency (EPA);
- in the case of Canada, to the New Substances Branch of Environment Canada (EC) and New Substances Assessment and Control Bureau of Health Canada (HC);
- in the case of US industry, the American Chemistry Council (ACC); and
- in the case of Canadian industry, the Industry Coordinating Group (ICG) for the *Canadian Environmental Protection Act (CEPA)*.

“*Signatories*” refer to the Governments which sign this Arrangement, in the case of the United States, to the Office of Pollution Prevention and Toxics, US Environmental Protection Agency (EPA), and in the case of Canada, to the New Substances Branch of Environment Canada (EC) and New Substances Assessment and Control Bureau of Health Canada (HC).

“*Supporting Partners*” refer to those associations and companies of both Canadian and US Industry dealing with the notification of new substances that are involved in this Arrangement. They include, in the case of US industry, the American Chemistry Council (ACC) and in the case of Canadian industry, the Industry Coordinating Group (ICG).

## Scope:

The scope of this Arrangement, between the Parties, includes, but is not limited to, exchanging information on our new chemical regimes, working cooperatively through projects of mutual benefit, sharing of assessment and management related resources and adopting, when desirable and where possible, consistent practices and regulatory approaches.

### <sup>1</sup> Note:

1. Under the Revised Four Corners Arrangement both the US and Canadian companies continue to invoke the Four Corners process when notifying new substances to either government as per the procedures described in the Advisory note and accompanying documents found on Environment Canada’s New Substances website at [www.ec.gc.ca/substances](http://www.ec.gc.ca/substances), under “Links”, International Programs.
2. The following additional information on the Four Corners Arrangement can be found on Environment Canada’s New Substances website:
  - Appendix 1 - International Context and Historical Context,
  - Appendix 2 - Key Considerations for Confidential Business Information and Procedures for Exchanging Information and,
  - The Work-Plan Under the Four Corners Arrangement.

## **Objective:**

The overall objective of this Arrangement is to work toward achieving efficiencies of resources, for all Parties, for the introduction of new substances to the North American marketplace, while continuing to protect human health and the environment. This includes, but is not limited to:

- 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).

## **Specific Potential Benefits:**

The potential benefits sought by the Signatories and Supporting Partners include, but are not limited to, the following:

### Signatories:

By expanding national perspectives on new substance notification, assessment and risk management the government will potentially:

- 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 risk assessment and management of new substances;
- Improve risk assessment methodologies, processes and practices and,
- Allow greater exchange of scientific, policy and regulatory expertise.

The Signatories recognize the similarities and differences of the Chemical Industry in their respective countries, and in the notification, assessment and risk management schemes in place. They also note the large number of substances being introduced annually and the level of effort they must make to complete assessments as required by their national laws under strict regulatory frameworks. The efficiencies and potential cost reductions that would result from enhanced information and work sharing between the Canadian and the US notification, assessment and risk management schemes are viewed to be significant.

### Supporting Partners:

- 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 on new substance notifications;
- Strengthening access to foreign markets in the global commercialization of new substances;
- Creating an information sharing process on the new chemical regimes 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.

### **Roles and Responsibilities:**

#### All Parties to this Arrangement will:

- Work co-operatively to fulfill the objectives of the Arrangement;
- Identify strategies that foster co-operative problem solving;
- Support consensus recommendations to ensure relevant actions in the Work Plan are identified and carried out;
- Participate in regular meetings/teleconferences;
- Remain flexible and open to new ideas; and
- Respect and recognize differing views.

Detailed roles and responsibilities for specific actions are outlined in the Work Plan; found on Environment Canada's New Substances website.

### **Specific Areas of Cooperation:**

Subject to meeting the requirements of paragraphs 1 and 2 in the Special Issues section, implementation of this Arrangement will be achieved through a cooperative work program that will be adopted on an annual basis. The cooperative work program (found in the Work Plan), is organized into seven specific areas of cooperation as outlined below.

1. Overcoming Regulatory, Administrative and Other Barriers – involves identifying strategies and actions, by all Parties, to overcome barriers to greater information sharing, co-operation and alignment of new substances schemes.
2. Expanding Knowledge & Information Sharing- involves increasing knowledge and building confidence in each country's scientific, regulatory and policy approaches.

3. Scientific, Policy and Regulatory Consultative Services - enables Signatory experts to consult each other on scientific, policy and regulatory aspects of notifications submitted to either or both countries.
4. Work Sharing on Co-notifications - enables Signatories and Supporting Partners to negotiate sharing of tasks associated with notifications submitted simultaneously in both countries by one or more companies.
5. Advancing Scientific Tools - concerns the mutually beneficial development of models, databases, risk assessment and management methods and other scientific resources.
6. Staff Development - includes staff exchanges and joint training programs.
7. Special Projects - includes joint projects that support mutually beneficial initiatives.

### **Special Issues:**

1. *Maintaining Equivalent Protection of Confidential Business Information (CBI) Canada (EC/HC) and the US EPA will continue maintaining CBI protection of each other's information as they have done since the Four Corners Agreement pilot began in 1996. Companies participating in the Program must submit their consent in writing to both Signatories (US and Canada) prior to allowing for the exchange of information that they have claimed confidential in their notifications. The consent form is on Environment Canada's New Substances website at [www.ec.gc.ca/substances](http://www.ec.gc.ca/substances).*
2. *Exchanging Information* - Strict procedures for exchanging information between the Signatories are necessary to ensure that the safeguards identified above within the two systems are not compromised; the details are included in the New Substances website.

### **Duration and Administrative Conditions:**

This Arrangement will come into effect two (2) weeks following the signature of Signatories and will be in place for a period of two (2) years.

Either Signatory may cancel this Arrangement by providing 45 days notice in writing to the other Signatory.

In addition, the Signatories and Supporting Partners will review this Arrangement on a regular basis with a view to ensuring that the objectives are being met in a mutually satisfactory way.

The Signatories and Supporting Partners will communicate on a regular basis concerning each area of co-operation.

By mutual written consent this Arrangement may be amended or extended on the basis of the recommendations made by the Signatories and Supporting Partners following the regular review of the document.

Done in duplicate in each of the English and French languages.

Signatories:

*For Environment Canada:*

***Original signed by:***

***November 6, 2003***

---

Barry Stemshorn  
Assistant Deputy Minister  
Environmental Protection Service  
Environment Canada

---

Date

*For Health Canada:*

***Original signed by:***

***November 21, 2003***

---

Hélène Goulet  
Acting Assistant Deputy Minister  
Healthy Environments and Consumer Safety Branch  
Health Canada

---

Date

*For the Office of Pollution Prevention and Toxics, Environmental Protection Agency (EPA) of the United States:*

***Original signed by:***

***January 8, 2004***

---

Charles M. Auer, Director  
Office of Pollution Prevention and Toxics  
Environmental Protection Agency  
United States of America

---

Date

Supporting Partners:

*For Canadian Industry:*

***Original signed by:***

***December 8, 2003***

---

Jack Soule  
Chair, Industry Co-ordinating Group, for CEPA

---

Date

*For American Industry:*

***Original signed by:***

***January 6, 2004***

---

Kathleen Ambrose  
Vice President, International Affairs  
American Chemistry Council

---

Date