

Cooperative Arrangement Between the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) of Australia and Environment Canada (EC) and Health Canada (HC), on the subject of Sharing Information on New Industrial Chemicals

Introduction

Sharing information about chemical 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 are vital parts of Agenda 21, Chapter 19, which provides the blueprint for action to ensure the environmentally sound management of chemicals. 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.

More recently, an OECD Task Force (OECD TF) on New Chemicals was established to develop and implement a two year program of work that, among other things, promotes bi/multi-lateral arrangements to formalize cooperation. Some of the activities the Task Force is engaging in include the development of a standard notification form to simplify reporting and facilitate data sharing and the development of a standard format for assessment of new chemicals. By the same token, the OECD TF is working toward the harmonization of data requirements for certain special categories (i.e. site-limited, export only, research and development), in order to provide greater transparency of such requirements and to reduce the resources needed to manage new industrial chemical programs without compromising the protection of the environment and human health.

This Arrangement is in keeping with wider OECD effort aimed at learning from each other, enhancing information and work sharing, and harmonizing national new industrial chemicals schemes. The demonstration of international leadership in this regard will ultimately serve to leverage government resources in both countries through similar Arrangements with other countries. The benefits associated with such a bilateral Arrangement would be to increase the efficiency of new industrial chemical notification and assessment schemes by providing greater transparency in assessments. It can also lead to a possible reduction in animal testing, a reduction in resources needed for new industrial chemicals work in governments and industry, and speed up of product introduction for some chemicals.

This Arrangement between Australia and Canada (the Participants) and the activities undertaken pursuant thereto, will provide a model for the cooperation envisaged with other OECD countries and will be consistent with the initiatives undertaken by the OECD TF on New Chemicals. Through this work, a wealth of

experience will be gained regarding new industrial chemicals notification and assessment schemes between the Participants.

Definitions:

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

"*Industry*" refers to those sectors and companies of both Australian and Canadian Industry that are involved in the notification of new industrial chemicals. For the purposes of this Arrangement, an Advisory Group, representing industry from both countries, has been established to provide ongoing, co-ordinated industry input; (*industrie*)

"Participants" refer in the case of Australia, to the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) 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), which will undertake the activities. (*participants*)

Objective:

The key objective of this Arrangement is to achieve meaningful economies of time and cost as well as other benefits for the Participants and for the Industry notifying relevant authorities in either country.

Specific Benefits:

The benefits sought with respect to the Participants and the Industry include, but are not limited to, the following:

The Participants :

- Saving government scientific resources associated with the assessment of new industrial chemicals;
- Providing greater access to external scientific expertise;
- Expanding national perspectives on new industrial chemical notification, assessment and risk management.

The Participants recognize the similarity of the chemical Industry in their respective countries, and in the notification, assessment and risk management schemes in place. They also note the increasing numbers of industrial chemicals being introduced annually and the additional level of effort required by the Participants to complete assessments as required by their national laws under strict regulatory frameworks. The efficiencies and potential cost reduction that would result from enhanced information and work sharing between programs are viewed to be significant.

The Industry:

- Reducing expenses associated with data generation, and preparing and submitting new industrial chemical notifications;
- Reducing time to introduce or market new industrial chemicals;
- Reducing data submitted for assessment and risk management decision-making;
- Access to incentives as determined for NICNAS assessments (Australia);
- Establishing a potential basis for legislative reform in new industrial chemical notifications (Australia);
- Strengthening access to foreign markets in the global commercialization of new industrial chemicals
- A process which is dependable and predictable.

In the case of Australia, government and industry have long been seeking the means to apply the “foreign schemes provisions” in the *Industrial Chemicals (Notification and Assessment) Act 1989* (IC(NA)A) that could emerge from this Arrangement with Canada.

Scope:

The scope of this Arrangement between the Participants includes, but is not limited to, exchanging information, providing (when possible) financial resources through jointly funded projects of mutual benefit, and sharing of assessment-related resources.

Specific Areas of Cooperation:

Implementation of this Arrangement will be achieved through a cooperative work program that will be adopted on an annual basis. The cooperative work program for the period **1 April, 2002 to 31 March, 2003** appears in Appendix I and is organized into six specific areas of cooperation as outlined below.

1. Expanding Knowledge & Information Sharing- involves increasing knowledge and building confidence in each country’s assessment programs, by exchange of assessment reports, summaries of underlying test data, model results, program guidelines, policies and related information. In some cases it might result in existing systems being modified to be more conducive to such exchanges.
2. Scientific and Regulatory Consultative Services - enables Participants experts to consult on scientific and regulatory aspects of notifications submitted to either or both countries, including industrial chemical identity, listing of industrial chemicals on domestic inventories, interpretation and validation of test and predicted data, and risk management options.

3. Work Sharing on Co-notifications - enables Participants to negotiate sharing of tasks associated with the assessment of notifications submitted simultaneously in both countries by one or more Industry.
4. Advancing Scientific Tools - concerns the development of models, databases and other scientific resources in support of effective and valid assessments.
5. Staff Development - includes staff exchanges and joint training programs, where appropriate and achievable.
6. Special Projects - includes jointly funded projects that support meaningful initiatives such as those emerging under the OECD TF on New Chemicals.

In addition, the Participants will communicate on a regular basis, in the form of reports, electronic mail, teleconferences or meetings concerning each area of Co-operation. Such communications will occur at least every three months for the duration of the Arrangement.

Special Issues:

Maintaining Equivalent Protection of Confidential Business Information (CBI) - In both countries, national legislation provides protection of information submitted by Industry on a commercial-in-confidence basis; failing to protect this information could adversely affect markets and investments that Industry make to develop new industrial chemicals; Appendix II outlines the key considerations that guide this facet of the Arrangement and the declarations of both countries.

Exchanging Information - Strict procedures for exchanging information between the Participants are necessary to ensure that the safeguards identified above within the two systems are not compromised; Appendix III outlines these procedures including the involvement of Industry where the information pertains to a specific notification.

Reporting to Industry - Participants are aware of the significant role that the Industry broadly will play in the success of this Arrangement, particularly when the results are promoted internationally. The Participants will endeavour to consult regularly with Industry, through the joint Industry advisory groups representing both countries. The purpose of *such consultation* will be to offer regular advice concerning the Arrangement, and the work conducted under it; Appendix IV provides additional information about the Advisory Group.

Duration and Administrative Conditions:

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

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

In addition, this Arrangement will be reviewed annually by the Participants and Industry (for this first Arrangement, prior to March 31, 2003) with a view to ensuring that the objectives are being met in a mutually satisfactory way.

By mutual written consent of each Participant, this Arrangement may be amended or extended on the basis of the annual review.

DONE in duplicate at Ottawa, this 1st day of May, 2002, in each of the English and French languages; should discrepancy be found between the two versions, the English one will take precedence.

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