

**Cooperative Arrangement between the Commonwealth of Australia,
as represented by the Director,
National Industrial Chemicals Notification and Assessment Scheme
(NICNAS) of Australia and the
Department of the Environment of Canada and the
Department of Health of Canada, on the
Subject of Sharing Information on New Industrial Chemicals**

Introduction

This Cooperative Arrangement between the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) of Australia and the Department of Environment of Canada (“EC”) and the Department of Health of Canada (“HC”) (“the Arrangement”) is in keeping with many international efforts aimed at learning from each other’s expertise. The Arrangement focuses on enhancing information and work sharing as well as working towards greater cooperation and alignment with national new industrial chemicals schemes.

The Canada/Australia Arrangement first signed in 2002 and renewed in 2007 is of benefit to industry and both countries. It is recognized that a bilateral Arrangement can increase the efficiency of new industrial chemical notification and assessment schemes by providing greater transparency in assessments, a possible reduction in animal testing and a reduction in resources needed for new industrial chemicals work by governments. Industry can benefit by shorter product to market times and in efficiencies of resources. This Arrangement is in keeping with the aims of both governments to provide the utmost in protection to human health and the environment. Appendix V sets out in more detail the international and historical context of the Arrangement.

This Arrangement includes exchanging information on both Canadian and Australian new chemical schemes, 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.

This Arrangement is not intended to be legally binding upon the Participants.

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1. Definitions:

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

"Industry" refers to the sector and those companies in both Australia and Canada involved or likely to be involved in the notification of new industrial chemicals.

"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 Division of EC and the New Substances Assessment and Control Bureau of HC, which will carry out the activities.

2. Objective:

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

3. Scope:

The scope of this Arrangement 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.

Canadian and Australian companies continue to invoke the Arrangement's processes when notifying new substances to either government.

The Arrangement and Appendices can be found on the NICNAS and Environment Canada websites.

Additional information on the Arrangement can be found in the following Appendices:

- Appendix I –The Annual Workplan for the Arrangement
- Appendix II– Key Considerations for Confidential Business Information
- Appendix III – Procedures for Exchanging Information
- Appendix IV – Communication with Industry
- Appendix V – International Context and Historical Context,

- Appendix VI Archived Projects – Completed Under the Workplan

4. Specific Benefits:

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

For the Participants:

- Saving government scientific resources associated with the assessment and notification 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.

For 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 are working towards applying the “foreign schemes provisions” in the *Industrial Chemicals (Notification and Assessment) Act 1989* (IC(NA)Act), as amended, and that could emerge from this Arrangement with Canada.

5. Roles and Responsibilities:

Participants to this Arrangement agree to:

- Work co-operatively to fulfil the objectives of this Arrangement;
- Identify strategies that foster co-operative problem solving;
- Perform their respective roles and responsibilities in accordance with the Work Plan attached at Appendix I to this Arrangement, as amended from time to time. The Work Plan is described in general in the Arrangement under the heading “Specific Areas of Cooperation”;
- Communicate on a regular basis, including through reports, electronic email, regular meetings and teleconferences, in relation to this Arrangement generally and in relation to each area of cooperation set out in the Work Plan at Appendix I;
- Remain flexible and open to new ideas; and
- Respect and recognize one another’s differing views.

Detailed roles and responsibilities for specific actions are outlined in the Work Plan (Appendix I).

6. 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 appears in Appendix I as the Workplan and addresses six specific areas of cooperation as outlined below.

- a) Expanding Knowledge and 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;
- b) Scientific and Regulatory Consultative Services – enables Participant’s 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;
- c) 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;
- d) Advancing Scientific Tools – concerns the development of models, databases and other scientific resources in support of effective and valid assessments;

- e) Staff Development – includes staff exchanges and joint training programs, where appropriate and achievable.

- f) Special Projects – includes projects that support meaningful initiatives such as those emerging under the Organisation for Economic Cooperation and Development (OECD) Task Force 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.

7. Special Issues:

Maintaining Equivalent Protection of Confidential Business Information (CBI) - In both countries, 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 industrial chemicals. Appendix II outlines the key considerations that guide this facet of this Arrangement and the agreement of the Participants in relation to the protection of CBI.

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 Industry will play in the success of this Arrangement, particularly when the results are promoted internationally. The Participants agree to regularly consult and inform Industry as appropriate, through the Industry organizations and groups, in both countries or by other appropriate means. The purpose of reporting to industry will be to seek advice concerning this Arrangement as needed, and to keep industry apprised of the work conducted under it. Appendix IV provides additional information about communication with industry. Appendix VI will contain one page reports on each project as the projects are completed or terminated.

8. Administration:

The Participants agree that:

This Arrangement will commence two (2) weeks after the signature of the last Participants and remains in place (unless cancelled or extended) for five years from the date of its commencement.

Appendix I constitutes the Workplan and each project under the Workplan will be completed and/or removed from the Workplan as needed and will be archived in Appendix VI. The Workplan will be reviewed annually.

Each Participant will be responsible for their own resourcing and/or financial contributions to any work carried out under this Arrangement unless other arrangements are specifically agreed upon between the Participants.

The Arrangement will be reviewed every four years by the Participants and Industry will be informed of the review, 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 review.

Either Participant may cancel this Arrangement by providing 6 months notice, in writing, to the other Participant.

Signed in quintuplicate at Gatineau, Quebec, Canada; Ottawa, Ontario, Canada; and Marrickville, New South Wales, Australia, in each of the English and French languages, each version being equally valid.

Signatories

For the commonwealth of Australia, as represented by the Director, National Industrial Chemicals Notification and Assessment Scheme (NICNAS):

Roshini Jayewardene
Acting Director
NICNAS

Date

For the Department of Environment of Canada:

Brian T. Gray
Assistant Deputy Minister
Science and Technology Branch

Date

For the Department of Health of Canada:

Susan Fletcher
Assistant Deputy Minister
Healthy Environments and Consumer Safety Branch

Date