

Appendix I

Full Projects Reports will be provided in a template format and listed in Appendix VI as the projects are completed and/or terminated.

Work-Plan 2007/08	
<i>Administrative and Regulatory Matters</i>	
Project Listing	Description
Assessments Reports	Australia to draft document on value of EC/HC reports exchanged to date and to provide feedback on assessment reports received from Canada
Annual Reporting	Australia to provide information on Annual Reporting structure and reports
Performance Indicators	Australia to provide information on service standards and performance indicators used in the annual reporting system as well as for increasing efficiency in service delivery
Standard Operating Procedures (SOP)	<p>Development of a strategy to promote and engage industry on co-notifications (as per Work Item A sub-group)</p> <p>Jointly develop criteria for selection of substances for co-notification process</p> <p>Share internal SOP developed for information sharing of Canadian assessment reports with Australia</p>
<i>Joint-Scientific Endeavours</i>	
Project Listing	Description
Foreign Scheme Provision	<p>Australia working on formally declaring and recognizing Canada as a Competent Authority under the Foreign Schemes Provision of The Australian <i>Industrial Chemicals (Notification and Assessment) Act 1989</i></p> <ul style="list-style-type: none"> • Australia to develop criteria for acceptance
Developing Guidance on Hazard Assessments	<p>Guidance to be developed in various areas including:</p> <ul style="list-style-type: none"> • Selection of the critical study • Selection of the critical endpoint • Use of assessment factors
Green Sheets	<p>Work on format for Robust Study summary output and finalize</p> <p>Engage Australia to test green sheets as part of a pilot project</p>
Pink Sheets	Work on format for Robust Study summary output and finalize

Format of Hazard Assessments	Environment Canada and Health Canada to provide the format for hazard assessments and method for reporting data <ul style="list-style-type: none"> Coordinate with OECD New Chemicals Task Force Work
Co-notification of Substances	Similar to work being conducted under Pilot Process (OECD) (comment – Australia – except that the assessment work would be shared for co-notification)
Persistence, Bioaccumulation, Toxicity (PBT) Assessments	Information sharing on specific classes of chemicals (Brominated Flame Retardants (BFRs), Perfluorooctanoic acids (PFOAs) Perfluoroalkylcarboxylates (PFCAs)) <ul style="list-style-type: none"> Australian suggestion – Conduct workshop on PFOS, PFOA – possible video conference Approaches Schedule requirements for these chemicals Robust Study summary – output and finalize
Project Listing	Description
QSAR Models	Staff Exchange– Australia to Canada – evaluator to visit Canada to develop QSAR expertise <ul style="list-style-type: none"> QSARs for PBT QSARs for ERA Mass-balance bioaccumulation models
Exposure Assessments Expose A Working Group – EC/HC	Sharing of information on exposure assessments <ul style="list-style-type: none"> Health Canada to share information on calculating indirect exposure through drinking water Australia to share experience regarding direct exposure resulting from cosmetics <p>Joint endeavour – standardizing default release scenarios and assumptions</p> <ul style="list-style-type: none"> Estuary Study: Examine how estuaries are considered as receiving environments in Australia to compare methods and models used in exposure assessments by both Canada and Australia
Exchange of Information on Polymer Related Issues <ul style="list-style-type: none"> Technical Guidance Document Polymer Working Group (POLYWOG) 	Joint endeavour – need for guidance material to be developed on what are considered degradable polymers Information Exchange: Low Concern Polymer (LCP)

	<p>Water Availability Reaction Scheme Outcome of POLYWOG Workshops</p>
Fate Assessments	<p>Integration of predictive tools used in Canadian fate assessments – Australia building in-house tools</p> <p>Engage Australia in biodegradation validation work (yellow sheets)</p>
Chemical Class Waivers	<p>Build on work conducted to date for chemical class waivers</p> <p>Identify and draft proposals for chemical classes which may be eligible for reduced data requirements</p> <p>Australia has developed criteria for low hazard/low risk substances – use this work to identify whether links can be made with chemical class waivers.</p> <p>Australia to share information on Low Regulatory Concern Chemicals (LRCC)</p>
Analogues (surrogate data)	Exchange of information on acceptability of analogue (surrogate) data
Standardize Assessment Templates <ul style="list-style-type: none"> Hazard assessment 	Work with Australia to standardize assessment templates
Project Listing	Description
Peer Review of Assessments	<ul style="list-style-type: none"> Ad-hoc consultations to resolve scientific issues Peer Review of complete risks on an as needed basis
Ongoing Work	<ul style="list-style-type: none"> Information Sharing Requests Request for Technical Advice

Appendix II – Key Considerations for Confidential Business Information

There are a number of key considerations that will guide the actions of the Participants concerning the exchange of Confidential Business Information (CBI) under their respective laws. The issue of CBI and how the exchange of information can proceed between the Participants without compromising the safeguards within the two systems is as follows:

- Participants will agree to protect CBI provided by Companies. Participants agree not to release such information to persons outside the respective work groups, except with the agreement of the owner of the information.
- Relevant Australian legislation protecting CBI provided for NICNAS assessment includes the exempt information provisions in Sections 75–80 of the *Industrial Chemicals (Notification and Assessment) Act* 1989.
- Relevant Australian legislation protecting the confidentiality of information provided by another Government is found in section 33 and subsection 45(1) of the *Freedom of Information Act* 1982.
- 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 the *Access to Information Act* and *Privacy Act*, as amended. Canada exchanges confidential information protected by article 313 of the *Canadian Environmental Protection Act* (1999), as amended, only in conformity with this and other applicable Canadian legislation.

Appendix III – Procedures for Exchanging Information

The Participants agree to exchange confidential business information (CBI) submitted by industry in relation to a specific notification between Participants only by international courier, unless the Participants receive permission from industry to use other transmittal methods. Other government information which is not confidential will be shared by phone, fax, email, surface mail or airmail.

Appendix IV – Communication with Industry

Inform industry organizations and companies of this Arrangement in both Canada and Australia through updates to the appropriate industry groups.

Ensure industry awareness of the simultaneous notifications and/or sharing of assessment information between authorities as authorized under Canadian and Australian legislation (Appendix II).

Apprise industry groups and organizations of visits by other Governments or industry groups in Australia and/or Canada as appropriate.

Discuss transparency issues, including sharing assessment reports with Companies, as authorized under the *Canadian Environmental Protection Act*, 1999 and the *Access to Information Act* and the *Privacy Act*, as amended.

Report on activities to the Organization for Economic Co-operation and Development (OECD) New Chemicals Task Force.

Appendix V – International and Historical Context of the Arrangement

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.

Australian legislation recognizes Canada (New Substances Program) as a competent authority under the "Foreign Schemes Provisions" in the "*Industrial Chemicals (Notification and Assessment) Act*" 1989 (IC(NA)Act), as amended. The New Substances Program foresees an increase in notifications from Australian Industry as a result of Canada being recognized in the IC(NA)Act.

This Arrangement between Australia and Canada (the "Participants") and the activities undertaken 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.