

Cooperative Arrangement between the Office of Pollution Prevention and Toxics (OPPT) of the Environmental Protection Agency (EPA) of the United States and the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) of the Australian Government Department of Health and Ageing on the Subject of Risk Assessment and Management of Chemicals

Objective

The objective of this Cooperative Arrangement is to achieve efficiencies of resources in the review and management of new and existing chemicals, and enhance the respective abilities of EPA/OPPT and NICNAS (“the Participants”) to protect human health and the environment. The Participants intend to achieve this objective through the following specific activities:

- Increasing knowledge and understanding in new and existing chemical reviews with respect to each Participant’s risk assessment and management approaches and practices;
- Identifying possible strategies for overcoming regulatory, administrative and other barriers to achieve greater cooperation; and
- Implement, as appropriate, actions to ensure progress toward the long term goal of greater cooperation of Australia’s and the United States’ new and existing chemicals regulatory schemes, for example, new chemicals mutual acceptance of notifications (MAN).

Scope

The scope of this Cooperative Arrangement between the Participants, includes, but is not limited to, exchanging information on the Participants’ respective chemicals management 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.

This Cooperative Arrangement is intended to focus on areas of mutual priority, in particular:

- Exchanges of health and safety data and information;
- Exchanges of chemical assessments;
- Sharing risk reduction and risk management tools, including those used in the review of new chemicals, and characterization and assessment approaches with existing chemicals;
- Sharing of information on related pollution prevention and partnership efforts including on topics of specific interest, such as import safety and product quality, (Quantitative) Structure Activity Relationship ((Q)SAR) analysis, Design for the Environment (DfE), Green Chemistry and Stewardship activities (e.g., Perfluorooctanoic Acid (PFOA) and nanomaterials);
- Exploration of opportunities for further collaboration; and,
- Exchange of expertise.

Potential Benefits

The potential benefits of this Cooperative Arrangement include, but are not limited to, the following:

- Using resources more efficiently by making greater use of work carried out by the other jurisdiction, without compromising the right of each government to make sound decisions associated with the risk assessment and management of chemicals;
- Improving risk assessment methodologies, processes and practices;
- In the case of notification of new chemicals in Australia, government and industry working towards applying “foreign schemes provisions” under the *Industrial Chemicals (Notification and Assessment) Act 1989* that could emerge from this Cooperative Arrangement;
- Fostering greater exchange of scientific, policy and regulatory expertise;
- Implementing a strategic approach to the management of chemicals of global concern and seeking safer alternatives to chemicals of global concern;
- Reducing duplication of efforts in areas of mutual interest such as review of existing chemicals;
- Saving government scientific resources associated with the assessment and notification of new industrial chemicals;
- Providing greater public access to health and safety information for a larger number of industrial chemicals in use;
- Promoting the manufacture and import of safer new chemicals as alternatives to existing chemicals of concern;
- Improving import safety and public outreach on import safety;
- Improving health and environmental outcomes;
- Facilitating informed and active public engagement in chemical safety issues;
- Reducing expenses associated with data generation, and preparing and submitting new chemicals notifications and reviews of existing chemicals;
- Alleviating further testing on well-defined categories of chemicals;
- Improving risk assessment through the use of best available scientific methods (e.g., appropriate use of Structure Activity Relationships (SAR) analysis to address data requirements);
- Reducing time to introduce or market new chemicals, allowing access to Australian incentives and increased access to markets;
- Improving information sharing between the Participants on new chemical notifications and reviews of existing chemicals;
- Creating an information sharing process on the new chemical regimes that is dependable and predictable; and,
- Improving the available models 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) environmental program.

Roles and Responsibilities

The Participants intend to do the following through this Cooperative Arrangement:

- Work co-operatively to achieve the objective of the Cooperative Arrangement;
- Develop a joint Work Plan of activities related to that objective;
- Identify strategies that foster co-operative problem solving;
- Ensure that actions in the Work Plan are carried out;
- Participate in regular meetings/teleconferences;

- Remain flexible and open to new ideas;
- Seek and obtain input and feedback from stakeholders; and,
- Respect and recognize differing views.

Special Issues

- *Exchanging Information* - Strict procedures for exchanging information between the Participants are necessary to ensure that the security safeguards within the systems are not compromised.
- *Maintaining Equivalent Protection of Confidential Business Information (CBI)* - The Participants are to only disclose CBI or deal with intellectual property in a manner consistent with applicable law and policy. The Participants intend to implement protocols to ensure that information and materials are appropriately managed.
- *Reporting to Stakeholders, including industry and the public*- Participants are aware of the significant role that stakeholders will play in the success of this Arrangement, particularly when the results are promoted internationally. The Participants intend to regularly consult and inform stakeholders as appropriate.

Duration and Administrative Conditions

This Cooperative Arrangement is to commence two (2) weeks following the signature of the Participants and is intended to continue for a period of five (5) years. This arrangement is intended to renew automatically for equivalent five-year periods. Either Participant may provide the other written notice of its intent to discontinue, or not to renew, this Cooperative Arrangement, but such notice should be provided at least six months prior to the date cooperation is intended to cease.

In addition, the Cooperative Arrangement may be modified at any time, by the mutual written consent of both Participants, and in accordance with applicable law and the relevant procedures of each Participant.

The Participants intend to review this Cooperative Arrangement on a regular basis with a view to ensuring that the objective is being met in a mutually satisfactory way.

The Participants intend to communicate on a regular basis concerning each area of co-operation.

The Participants intend to invite stakeholders to provide periodic insights concerning implementation of the Cooperative Arrangement.

The Participants intend to develop a Work Plan and administrative procedures in a manner consistent with applicable law and the Participants' respective priorities.

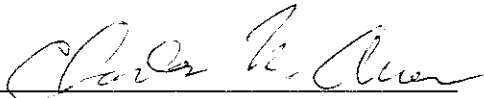
Legal Effect of Agreement and Commitment of Resources

This Cooperative Arrangement is a statement of intent. It does not create any legal obligation, or any legal right or benefit, substantive or procedural, enforceable against either Participant;

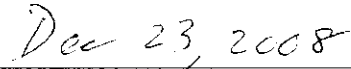
This Cooperative Arrangement is to be carried out subject to the availability of appropriated funds and other resources, and nothing in this Cooperative Arrangement legally obligates the Participants to expend funds or provide other resources; and,

This Cooperative Arrangement affirms the Participants' joint commitment to continued and intensified cooperation toward the sound management of chemicals.

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

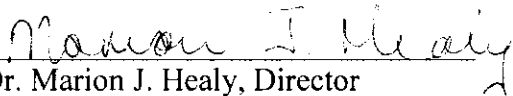


Charles M. Auer, Director
Office of Pollution Prevention & Toxics
U.S. Environmental Protection Agency

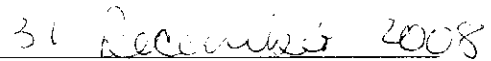


Date

For the Australian Government Department of Health and Ageing, National Industrial Chemical Notification and Assessment Scheme (NICNAS):



Dr. Marion J. Healy, Director
NICNAS
Australian Government Department of Health and Ageing



Date