

NICNAS'S EXISTING CHEMICALS PROGRAM REVIEW

2010-11 developments

NICNAS's Existing Chemicals Program (ECP) Review aimed to assess the efficiency and effectiveness of the ECP and make it more flexible and responsive to all stakeholders' needs. The Implementation Strategy for ECP Review recommendations divided them into six implementation streams. Progress with these recommendations in 2010 and early 2011 is provided below.



STREAM 1: COMMUNICATIONS: IMPROVED COMMUNICATION AND OUTREACH

NICNAS exploited every opportunity to promote community awareness, education and participation in the ECR program during 2010 – at meetings, conferences, through newsletters, the NICNAS website and elsewhere.

The *Who's who in industrial chemicals regulation* (to provide an online overview of agencies and departments which oversee chemicals regulation in Australia), with accompanying information sheets (on topics such as cosmetics, perfluorinated chemicals and formaldehyde) will be published in 2011.

Each issue of *NICNAS Matters* included an item on International Chemical Safety which examined technical developments and agreements/arrangements which promote greater chemical safety.

On 18 August 2010, the NICNAS 20th Anniversary Symposium brought together many NICNAS stakeholders. NICNAS's Director, Dr Marion Healy, reported:

The Symposium explored the topic 'The Changing Face of Industrial Chemicals Regulation' in terms of the current environment as well as those challenges that face us in the future and from the perspectives of all stakeholders.

Participants had lively discussions about their understanding of 'risk' and the level of risk that NICNAS should consider acceptable; the level of precaution that should be adopted and the levels of evidence required to assure protection of human health and the environment; as well as the balance between protecting our population and environment and deriving the benefits from an innovative and vibrant industry sector. Some of the challenges and observations to consider into the future related to the safe and sustainable use of industrial nanomaterials; adoption of the next generation of assessment methodologies; the changing nature of chemicals being introduced into the marketplace; and the changing approach to the regulation of industrial chemicals globally.

Symposium feedback and discussions are continuing to help guide NICNAS's implementation of recommendations in each stream.



STREAM 2: SCREENING AND PRIORITISATION OF CHEMICALS LISTED ON THE AUSTRALIAN INVENTORY OF CHEMICAL SUBSTANCES (AICS) AND DEVELOPMENT OF NEW ASSESSMENT PRODUCTS

Develop new types of assessment products based on intended output and purposes

Following the development of new assessment "products"¹, NICNAS's stakeholder advisory group – the ECR Implementation Steering Group (ISG) – supported guidance material for the proposed mandatory powers to gather information that will be applicable to all regulatory assessment products (not just Priority Existing Chemical (PEC) assessments). According to the guidance, these mandatory powers can be invoked where the Director, NICNAS, holds a reasonable belief that a chemical poses a risk to human health, safety or the environment, and where NICNAS requires business to respond in no less than 28 days.

The ISG also supported guidance on internal dispute resolution procedures concerning the proposed recommendations from new assessment reports that don't involve regulatory outcomes. Under the proposed changes to the ECP, recommendations of a regulatory nature (from new assessment products) will be appealable to the Administrative Appeals Tribunal. However, the ISG also supported an internal appeals process for recommendations that do not involve regulatory outcomes, and guidance has been developed on

¹ Three general Assessment Activity Types (Information, Advisory and Regulatory that NICNAS currently utilises) were proposed by NICNAS, with each giving rise to particular assessment products. These could be supplemented with new products as circumstances require. Each involves specific consultation mechanisms and appeals processes, and a mandatory call for information (if warranted) precedes the decision about which assessment product is most suitable. The Regulatory activity type includes current PEC assessment reports, and includes two new types of assessment products that provide for more streamlined assessment processes than those provided for by the current PEC process: Existing Chemical Risk Assessment, and Selective Assessment.

this internal process. The final decision maker will be the Director, NICNAS, and – depending on the complexity of each dispute – internal or external reviewers will be engaged.

New assessment products, streamlined secondary notification procedures and the associated calls for information, transparency provisions and appeal provisions have been developed – and draft amendments to the *Industrial Chemicals (Notification and Assessment) Act 1989* to give effect to these proposals – prepared. These proposed amendments will be progressed as soon as practicable.

Develop an overall framework for screening chemicals of concern (prioritisation)

NICNAS has been actively working with its advisory bodies and other key stakeholders to develop an overall framework for prioritisation and assessment of chemicals on the Australian Inventory of Chemical Substances (AICS). Prioritisation is the tiered assessment of chemicals on the AICS against human health hazard, environmental and exposure indicator criteria to determine those chemicals that are not expected to pose concern to workers, public health and the environment and those that require further assessment to determine their risk and recommend risk mitigation measures to ensure safe use.

A range of options for the framework has been developed by NICNAS taking into account the final ECR report, advice from stakeholder advisory bodies and information on industry practices gained from a workshop with industry representatives held in December 2010. While the stakeholder advisory groups assisting with the implementation of the ECP Review have supported a risk-based approach, a final framework has not been decided.

NICNAS is continuing to work with its advisory bodies and other key stakeholders to finalise the preferred option for the framework and at the workshop in December 2010, participants provided input into the development of an agreed framework. The outcomes will be reported in 2011.

Screen AICS listed chemicals for hazard and/or risk indicator elements

The tiered assessment of chemicals on the AICS against human health hazard, environmental and exposure indicator criteria is expected to commence in 2011-12, depending on finalisation of the framework. It is currently proposed that as exposure information on chemicals introduced into Australia in high volumes is held by NICNAS, the framework will be first applied to this subset of AICS chemicals to provide early outcomes.

Develop a framework to identify the circumstances under which down-stream use information is sought as being necessary for prioritisation

The implementation of this recommendation is linked with the above recommendation on developing an overall framework for screening chemicals of concern/prioritisation. This recommendation will be progressed once a preferred option for the overall framework has been agreed.

Develop scientifically based criteria for prioritisation of chemicals for assessment

Assisted by its two expert working groups (the Environmental Expert Working Group – EWG and the Human Health Expert Working Group – HHEWG) NICNAS developed the scientific criteria for indicating human and environmental health hazards against which chemicals on AICS will be screened.

A trial hazard evaluation is being conducted of 1000 randomly chosen AICS-listed chemicals to evaluate the criteria developed.

An analysis of chemicals on AICS indicates that only limited hazard information is available for more than 80% of all listed chemicals. NICNAS will use approaches to allow read-across of data from “data rich” to “data poor” chemicals, and use predictive modelling where possible when toxicity data are not available. NICNAS is enhancing its capability in this area and NICNAS staff recently undertook extensive training by a world expert.

Publish the prioritisation process and decisions

The framework for prioritisation will be published once all aspects have been finalised. Prioritisation assessment information will be published as it becomes available.

★ **STREAM 3: SCOPING A MONITORING SYSTEM FOR ADVERSE EFFECTS**

Examination of the feasibility of a nationally coordinated system of surveillance, monitoring and post-market reporting has been deferred while NICNAS focuses on the Stream 2 work.

If sufficient resources are available, NICNAS is planning to establish a technical working party, during 2011-12, to begin implementing recommendations relating to surveillance, monitoring and post-market reporting.

★ **STREAM 4: IMPROVED CONSULTATION – WITH NATIONAL AND INTERNATIONAL BODIES**

NICNAS engages with national and State/Territory bodies from the public health, environment and occupational health and safety (OHS) sectors, using processes such as EnHealth, NCheM and the NICNAS State and Territory Memorandum of Understanding Group (concerned with OHS issues). Relevant regulatory recommendations are referred to the appropriate regulatory process, for example scheduling in the Standard for Scheduling of Medicines and Poisons.

NICNAS and Environment Canada/Health Canada have developed a revised workplan for new and existing chemicals. Activities with Canada included an Environment Canada officer participating as an expert on the EEWG and a NICNAS staff member undergoing intensive training in Canada's prioritisation processes, in late 2009. Under the bilateral relationship, NICNAS has benefited from guidance material, approaches and tools that were developed by Canada for prioritisation. NICNAS continues to liaise with the Canadian agencies to avoid duplication of effort and maximise efficiency in prioritising chemicals on the AICS.

NICNAS has explored arrangements with other trading partners. NICNAS now has a Cooperative Arrangement with the Office of Pollution Prevention and Toxics (OPPT) of the United States Environmental Protection Agency (US EPA). The arrangement provides for the sharing of information and expertise in chemical risk identification and management. It is intended that NICNAS work with the US EPA to develop mechanisms to achieve efficiencies of resources in the review and management of new and existing chemicals.

In addition NICNAS has taken opportunities to strengthen its relationship with the European Chemicals Agency (ECHA). The relationship will enable NICNAS to make use of information that becomes available through the European Union's REACH (Registration, Evaluation, Authorization, and restriction of Chemicals) process in the prioritisation of the chemicals on the AICS.

★ **STREAM 5: ADDRESSING BARRIERS TO EFFECTIVE IMPLEMENTATION OF NICNAS ASSESSMENT RECOMMENDATIONS, & ON NEW POWERS TO BAN, RESTRICT & CONTROL CERTAIN CHEMICALS**

Referral of issues to the Council of Australian Governments (COAG) Ministerial Taskforce has been completed. The issue of NICNAS's roles and responsibilities was considered further by the Productivity Commission (PC) report on the regulation of the chemicals and plastics industry. PC recommendations Implementation is monitored by the recently-formed Standing Committee on Chemicals (SCOC). The Department of Innovation, Industry, Science and Research has established a webpage to provide information to stakeholders on the progress of the work program of the SCOC (see:

www.innovation.gov.au/Industry/ChemicalsandPlastics/Pages/StandingCommitteeonChemicals.aspx).

A Chemicals Working Group comprising officials from relevant Commonwealth Departments and State/Territory officials from Ministerial Councils has been established to assist the SCOC in its functions. NICNAS is a member of the Chemicals Working Group.

★ **STREAM 6: CURRENTLY IMPROVING PRACTICE – IMPROVING REGULATORY OUTCOMES STEMMING FROM REPORT RECOMMENDATIONS**

Complete. NICNAS participates in various national chemicals processes – such as the SCOC's Chemicals Working Group – which relate to the recommendation concerning NICNAS continuing engagement in national chemicals fora.