

**Submission to the Productivity Commission Study
into Chemicals and Plastics Regulation**

by

**Australian Government
Department of Health and Ageing**

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Introduction

The Australian Government's Health and Ageing portfolio (the portfolio) is responsible for assessing the potential risks to public health and safety of an estimated 40,000 to 50,000 industrial, agricultural and veterinary chemicals available for use in the community.

The growing pervasiveness of chemicals in the environment raises serious concerns from time to time over the exposure of people and the environment to potentially toxic chemicals. These concerns have led Governments to create regulatory systems to manage the risks of chemicals which also acknowledge the ability of stakeholders to make meaningful risk management choices based on enhanced access to reliable chemical safety information.

This submission is framed around the relevant Terms of Reference (ToR) of the Productivity Commission Study. This submission does not address ToR 3 as ammonium nitrate is not managed within the portfolio. At this point, the portfolio has no recommendations to offer for reforms (ToR 5).

The Australian Government regulator for industrial chemicals, NICNAS, has also made a separate more detailed submission to the Productivity Commission.

Regulatory Policy Framework

The Government provides a policy and regulatory framework to ensure the safe and sustainable use of these chemicals, through the identification, management and communication of the potential health and environment risks posed by chemicals, in consultation with the public, industry and other stakeholders.

The current system of overall chemicals management operates within a complementary, whole of Australian Government framework, and consists of a range of federal and state/territory agencies. At a national level, risk assessment and registration of chemicals is undertaken by a number of Australian Government agencies including the Office of Chemical Safety (OCS), Food Standards Australia New Zealand (FSANZ), the Australian Pesticides and Veterinary Medicines Authority (APVMA) and the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). This framework is illustrated in the attached diagram ([Attachment A](#)).

Responsible agencies within the Health portfolio are:

- NICNAS, a statutory agency responsible for the regulation of industrial chemicals;
- FSANZ, a statutory agency responsible for the setting of food standards for Australia and New Zealand; and
- OCS, a unit of the Office of Health Protection, is responsible for undertaking risk assessments and provides policy advice on potential public health risks posed by chemicals used in the community.

ToR 1: Investigate and document the current system of regulation of chemicals and plastics in Australia, including the interrelationships between the Australian, State and Territory government agencies, and local government layers of regulation and the effect of these relationships on economic, public health and safety, occupational health and safety, and environmental outcomes.

Office of Chemical Safety

In responding to an industry initiated review of regulation, the Government agreed to establish the Office of Chemical Safety in 2002-2003 and moved all relevant chemical policy, regulation and health standard setting activities and compliance roles with the Department of Health and Ageing (DoHA) into a single structure. OCS was established and has since operated as a “one-stop shop” for human health safety policy and practice.

The head of the Office of Chemical Safety reports to the Secretary of the DoHA through the First Assistant Secretary of the Office of Health Protection.

The Australian Pesticides and Veterinary Medicines Authority (APVMA) seeks advice from OCS on all matters relating to the human safety (including worker exposure) of agricultural and veterinary products. The scope of the advice includes an assessment of the risks (hazard and exposure) and recommendations on risk mitigation measures.

OCS undertakes toxicology, public health and occupational health and safety assessments including data evaluation, hazard assessment, exposure assessment, risk assessment and consideration of regulatory approach/options. Where appropriate OCS establish an acceptable daily intake and acute reference dose (as relevant), suggest poison scheduling for consideration by the National Drugs and Poisons Schedule Committee (NDPSC), propose impurity limits, determine first aid instructions and warning statements, determine hazard based safety directions, recommend occupational health and safety risk management instructions, re-entry and precautionary statements and occupational health and safety related safety directions including personal protective equipment.

The main functions of the Office which are relevant to this submission are:

- chemicals assessment for public health risk assessment for veterinary chemicals, pesticides and other environmental chemicals through a Service Level Agreement with the Australian Pesticides & Veterinary Medicines Authority; and
- public health controls/standards setting through membership on, and secretariat support for, the NDPSC.

National Industrial Chemicals Notification and Assessment Scheme

The regulation of chemicals and plastics is performed by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), which is located within the portfolio. NICNAS was established in 1990 under the *Industrial Chemicals (Notification and Assessment) Act 1989* to aid in the protection of people at work, the public and the environment from the harmful effects of industrial chemicals.

NICNAS assesses industrial chemicals that are new to Australia for their health and environmental effects before they are used or released to the environment. NICNAS also

assesses those chemicals that are already in use in Australia (known as “existing chemicals”) on a priority basis in response to concerns about their safety on health and environmental grounds.

While NICNAS undertakes scientific assessment to identify the potential risks associated with industrial chemicals, the actual control and management of chemical risk is undertaken by other national agencies and/or regulatory authorities in the states and territories.

To work with its stakeholders NICNAS has established formal governance arrangements involving industry and government (Industry Government Consultative Committee) the states and territories (State and Territory Memorandum of Understanding Group).

The Director, NICNAS is a statutory office holder with specific functions and powers under *Industrial Chemicals (Notification and Assessment) Act 1989* and associated *Industrial Chemicals (Notification and Assessment) Regulations 1990*. In the exercise of these functions, the Director is directly responsible to the Minister through the Parliamentary Secretary to the Minister for Health and Ageing.

NICNAS submission to the Productivity Commission has further details.

Food Standards Australia and New Zealand

Food Standards Australia New Zealand (FSANZ) is an independent statutory agency established by the *Food Standards Australia New Zealand Act 1991*. Working within an integrated food regulatory system involving the governments of Australia and the New Zealand Government, it sets food standards for the two countries. FSANZ is part of the Health portfolio.

FSANZ is responsible for the development of food standards which includes the use of chemicals and setting of Maximum Residue Limits (MRLs) in all aspects of food production and processing. After registering the agricultural or veterinary chemical product APVMA makes applications to FSANZ to include MRLs in the Food Standards Code. FSANZ reviews the information provided by the APVMA and validates whether the dietary exposure is within agreed safety limits. If satisfied that the residues do not represent an unacceptable risk to public health and safety and following consultation, FSANZ makes recommendations to Australia New Zealand Food Standards Council (ANZFS) to adopt a draft variation to the Food Standards Code and include the MRLs in the Food Standards Code.

FSANZ will provide a submission, including a description of its role, directly to the Productivity Commission.

ToR 2: Investigate the degree to which Australian regulations diverge from accepted standards (both international and those applying in similar jurisdictions overseas) and the costs and benefits of those variations. In doing so, the Commission should examine Australia's implementation of the United Nations' Globally Harmonised System of Classification and Labelling of Chemicals, and take into account the work underway to achieve mutual recognition and harmonisation with New Zealand in relation to industrial chemicals under the Trans-Tasman Mutual Recognition Arrangement.

Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)

The Australian Government has supported in principle the adoption of GHS wherever practical, providing it does not lower current public health standards. While no government decision has yet been taken on the form or timing of GHS adoption, work on the implications of adopting the GHS in Australia for the classification and labelling of consumer products and pesticides is progressing through consultation with stakeholders, including industry.

To this end, the Health portfolio has:

- established a working group of the National Drugs and Poisons Scheduling Committee (NDPSC) (comprising industry, Commonwealth and State and Territory government representatives and New Zealand), to undertake a situational analysis of the possible implications of implementing GHS across the domestic and agriculture sectors;
- organised and chaired an informal roundtable discussion on GHS implementation issues prior to the Asia Pacific Economic Cooperation (APEC) Chemicals Dialogue Meeting with the aim of discussing GHS implementation and promoting international harmonisation of approach; and
- initiated a joint OCS/DEWR roundtable with various Australian industry sectors to explore the implementation of the GHS in Australia having regard to the global context and the implementation arrangements now emerging in major trading partners.

International Harmonisation of Assessment and Regulatory Requirements

Consistent with the Government's commitment to minimise uniquely Australian requirements, the portfolio participates in several key international fora on harmonisation of the health and safety and environmental assessment and risk management of new and existing industrial chemicals. These include multilateral fora established under the auspices of the Organisation for Economic Cooperation and Development (OECD) and the World Health Organisation (WHO)/International Program on Chemical Safety (IPCS) and bilateral arrangements with various overseas regulatory agencies.

Participation in these international fora promotes the alignment and harmonisation of standards and approaches to chemicals assessment and management, such as the GHS.

NICNAS has developed links with the Canadian industrial chemicals regulatory scheme because of the significant similarities between the two schemes which include assessment methodologies and standards. These similarities provide a sound platform for developing cooperative approaches that were the basis for the recent recognition of the Canadian New Substances Regulations as an approved foreign scheme under the *Industrial Chemicals*

(Notification and Assessment) Act 1989. Australian and Canadian authorities are exploring opportunities to extend this cooperative arrangement to existing industrial chemicals.

Activities Associated with Trans-Tasman Mutual Recognition Agreement

The Health portfolio is involved in the following key areas of the Chemicals Cooperation Program of the TTMRA that affect the free trade of chemicals:

- notification and assessment of industrial chemicals;
- domestic poisons scheduling; and
- packaging and labelling of hazardous substances and dangerous goods.

Notification and assessment of industrial chemicals

In New Zealand (NZ), industrial chemicals are regulated under the *Hazardous Substances and New Organisms Act 1996* (the Act). This legislation implements the principles of the GHS and has resulted in differences between how New Zealand and Australia regulate industrial chemicals. The New Zealand Environmental Risk Management Authority (ERMA) makes decisions on applications made under the Act.

The Act essentially provides for a product approval and registration scheme as opposed to NICNAS' chemical entity based scheme. Most OECD member countries have chemical entity-based regulatory schemes for industrial chemicals.

In addition, ERMA only approves and registers industrial chemicals that are hazardous substances. New Zealand utilizes the GHS system for hazard classification, which differs from Australia's Workplace Hazardous Substances classification system. NICNAS scheme applies to all industrial chemicals irrespective of their hazard status. However, there is a Memorandum of Understanding (MoU) in place between NICNAS and ERMA that establishes a co-operative relationship between the parties. While work undertaken through the MoU has identified some structural issues that may present impediments to mutual recognition for industrial chemicals, opportunities for harmonisation and cooperative work have also been recognised.

NICNAS submission to the Productivity Commission provides further details.

Packaging and labelling of hazardous substances and dangerous goods

Product labelling, inner packaging (end-use product labelling) is currently regulated in some sectors, but is fragmented. Some packaging is prescriptive, eg scheduled poisons and transport, however workplace use is largely performance based. The Department of Employment and Workplace Relations (DEWR) is consulting with OCS and New Zealand on a solution to this issue.

ToR 4: Report on the efficiency and effectiveness of current institutional and regulatory frameworks for chemicals and plastics regulation in Australia in achieving economic, public health and safety, occupational health and safety, and environmental outcomes.

The Health portfolio has established a partnership approach with industry and the community in developing and delivering regulatory reform and better regulatory processes. The key reform activities to date and those activities planned for the future are outlined below.

Consumer Products and Pesticides

In developing new processes that will increase the efficiency and effectiveness of current regulatory frameworks for chemicals, the portfolio, through OCS, has:

- Established the Science Forum for Best Practice Human Health Risk Assessment (HHRA) Methodology – a forum that engages all Commonwealth agencies involved in human health including agriculture, veterinary, food and environmental regulatory compliance;
- Reinvigorated the Chemicals Clearing House to facilitate information exchange and coordinate policy advice and provide whole of government views on international chemical management and negotiation activities;
- Actively participated in the World Health Organisation/International Program on Chemical Safety (IPCS) Harmonisation Project on HHRA Methodology;
- Together with the Advocate for the Consumer, Cosmetic, Hygiene and Specialty Products Industry {ACCORD} led the preparation of an APEC Chemical Dialogue Paper on Principles for Best Practice in Chemical Regulation.

Poisons Scheduling

The National Drugs and Poisons Schedule Committee (NDPSC), a statutory committee established under the *Therapeutic Goods Act 1989*⁸, makes recommendations on appropriate scheduling of medicines, agricultural and veterinary chemicals, and household chemicals, for inclusion in the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP). Scheduling is designed to prevent and minimise harm from exposure to drugs and poisons by regulating supply and access to such substances.

The SUSDP is the document by which the states and territories achieve a uniform national approach to product availability, labelling and packaging. The SUSDP is given legal effect through relevant state and territory drugs, poisons and controlled substances legislation, and has no legal force in Commonwealth law.

The *National Competition Policy Review of Drugs, Poisons and Controlled Substances Legislation* (Galbally) *Report*⁹ has recommended that the NDPSC be disbanded and replaced with two separate committees; one responsible for medicines (the medicines scheduling committee) and the other responsible for agricultural, veterinary and household chemicals (the poisons scheduling committee). The Australian Health Ministers' Conference (AHMC) has agreed to these reforms. AHMC has agreed to the scheduling of non-medicines being streamlined through the establishment of a separate Chemicals Scheduling Committee administered by the DoHA with responsibilities delegated within OCS.

These proposed new scheduling arrangements will provide a significant improvement in the efficiency, consistency and effectiveness of the scheduling process itself and the opportunity to further streamline over time. Importantly, the arrangements will also promote a “one-stop-shop” approach to health standard setting as scheduling becomes fully integrated into the notification and assessment and/or registration regulatory processes for chemicals, pesticides and veterinary products. These reforms will deliver reduced regulatory costs to industry and government.

Industrial Chemicals and cosmetics

The portfolio, through NICNAS, has moved to increase the efficiency and effectiveness of the industrial regulatory system through a series of reforms, which are summarized below. These reforms are described in more detail in the separate NICNAS submission.

NICNAS Reforms introduced between 1997-2003

Since 1997, NICNAS has operated a program of regulatory reform specifically aimed at promoting the introduction of safer chemicals, industry technological innovation, and a streamlined pathway to commercialisation onto the Australian market. Early reforms addressed industry concerns about the timeliness of assessment processes, the use of overseas assessment data and the inflexible notification categories. These reforms provided efficiencies for industry through reduced data generation, reduced notification costs and reduced time to market. Benefits to the community included a greater number of low risk chemicals resulting in prevention of environmental degradation and/or of adverse human health effects.

NICNAS Reforms introduced from 2004 to date

A key stimulus for a further suite of reforms, the Low Regulatory Concern Chemical (LRCC) reforms¹⁰, was the Government's Response to the Chemicals and Plastics Action Agenda Steering Group Report, *Underpinning Australia's Industrial Growth, Report to Government*⁵.

These reforms introduced flexibility into the assessment process that enabled the fast tracking of low regulatory concern chemicals through the system while maintaining existing levels of worker safety, public health and environmental standards. These reforms also enabled the regulatory effort expended by the government and industry to be commensurate with the risk posed by these chemicals.

The majority of the LRCC reforms have already been implemented, with implementation of outstanding measures currently underway. Consistent with NICNAS' policy to evaluate major reform activities to determine impacts on industry (including cost savings), the community and government (including the impact on NICNAS), an evaluation of the LRCC reforms is planned for 2007-08.

Cosmetic reforms

During the LRCC reforms industry and government agreed that there was an urgent need to review and clarify regulatory requirements for lower risk products at the interface between therapeutics and cosmetics. DoHA, through NICNAS and the TGA, in partnership with industry and the community developed the *NICNAS Cosmetic Guidelines*¹¹ which formed the basis for these reforms. The *Industrial Chemicals (Notification and Assessment) Amendment (Cosmetics) Act 2007*¹² came into effect in September 2007 and provides for the Minister for Health and Ageing to make standards, by legislative instrument, for cosmetic products imported into or manufactured in Australia, and introduces penalties for non-compliance with these standards.

Review of the Existing Chemicals Program

NICNAS is undertaking an extensive review of its Existing Chemicals Program. The final report *Promoting safer chemical use: towards better regulation of chemicals in Australia – Final report and recommendations* was published in December 2006¹³.

The recommendations arising from the review are expected to enhance regulatory efficiency and lead to more effective outcomes for the community, industry and government. They will provide greater access to information about more chemicals, enhance relationships between stakeholders, including government, and lead to improvements in the safe and sustainable use of chemicals in Australia. The proposed reforms are consistent with international trends towards best practice regulation for existing industrial chemicals. A number of the reforms are similar to those adopted by other international regulatory bodies and therefore present opportunities for greater international cooperation and harmonisation on chemical safety issues.

These reforms will be implemented as an integrated package, which will ensure full community confidence in the government and its Existing Industrial Chemicals Program while enabling greater efficiency and effectiveness to flow on to all stakeholders.

Post 2006: Disinfectants

The Banks Review⁴ recommended that the Australian Government progress industry reforms for regulating disinfectant products. In response the Government announced a review of the regulation of disinfectant products to be led by NICNAS and the Therapeutic Goods Administration. This review is currently underway and will also report on progress to the Council of Australian Governments (COAG).

An independent review on current regulatory arrangements for disinfectants in Australia, examination of the regulation of disinfectants in other countries and presenting best practice options for streamlining the regulation of disinfectants is expected to be released for public comment shortly.

Chemical residues in food

Removing duplication

The recently passed *Food Standards Australia New Zealand Amendment Act 2007* removes unnecessary duplication between APVMA and FSANZ. Since 1 October 2007 APVMA is required to notify FSANZ of applications to register chemicals that are likely to remain as residues in food if they are used in primary production. FSANZ and APVMA are to conduct joint consultation in relation to the proposed maximum residue limit (MRL) and if appropriate issue relevant standards in close succession.

References

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