



Australian Government
Department of Health and Ageing

Discussion Paper: Review of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), June 2012

Making a submission

**Submissions must be received by the Department of Health and Ageing by
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Please use this form to make your submission in response to the discussion paper. You may delete any sections that you do not wish to comment on.

While submissions may be lodged electronically or by post, electronic lodgment by email is preferred. For accessibility reasons, please email responses in a Word or RTF format not as a .pdf.

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Summary

Please provide a short summary, up to half a page, outlining the key points of your submission:

The National Toxics Network (NTN) supports the role of NICNAS as the regulator of industrial chemicals. In order to do their job effectively, NICNAS requires the legislative framework, regulatory tools and resources to undertake its primary role of industrial chemical assessments to protect public health and environment. Funding in particular is key. The current 100% industry-cost recovery model has not provided adequate resources for NICNAS to effectively complete its job and meet the public's expectations as the regulator of industrial chemicals in Australia. NICNAS must be resourced if it is to redress the full backlog of all existing chemicals on AICS that have not been assessed, not just those that have been prioritized, and to fulfill all recommendations made under the Existing Chemicals Review, including a National Adverse Reporting mechanism.

Part 4 – The regulatory framework for industrial chemicals (options A1 – A3)

- Do you think that an industrial chemicals risk assessment and risk management manual would assist? If not, why not?
- If so, what are the specific matters that could usefully be addressed in the manual?
- What are the strengths and weaknesses of the options?

Please keep your responses to each option no more than one page:

A1 - NTN supports the concept of a manual to provide transparency about the role and responsibilities of NICNAS and the processes used for risk assessment and management. A manual could strengthen the advice provided to importers of industrial chemicals about their requirements under the legislation and more specifically the data they need to provide in relation to chemical assessments. Of particular use would be requirements to provide data on endocrine disruption, children's environmental health protection, waste disposal and fate data and climate change impacts and mitigation measures. Such a manual could be a very supportive tool for NICNAS but also provide transparency for the public, particularly in relation to publicizing risk assessment methodologies as is provide in other jurisdiction such as Japan and other OECD nations. The benefits would see better environmental and public health outcomes for Australia, increased certainty for industry; and for greater transparency for the Government especially in meeting its international obligation for sound chemical management under the chemical conventions and SAICM.

A2 - Australia is a signatory to a number of international conventions supporting the participation of civil society in chemicals regulation and management (eg SAICM, Stockholm & Rotterdam Convention). It has a responsibility to provide for equitable representation of civil society so they may participate meaningfully in the policy-decision making relating to chemical safety and management in Australia.

The CEF Community Engagement Charter was developed to provide NICNAS and the DoHA with advice on effective community engagement and should be utilised in relation to this recommendation.

The current role of the SCOC is a limited one (to oversee the implementation of the Productivity Commission recommendations). It is not an adequate forum for discussion and consideration of broader chemical issues, as bodies such as NICNAS and SafeWork are not formally represented. Community stakeholders are also unrepresented except for occasional invitations to participate on narrowly defined matters.

In light of this, a ‘cross portfolio group’ with a broader remit than SCOC (as suggested by the Discussion Paper) should be formed. Stakeholder involvement in this group needs to be formalized. NTN supports the establishment of a ‘cross portfolio group’. It should, however, have a broader remit than the current role of the SCOC, as suggested by the Discussion Paper. Areas that we consider to be of particular importance are:

(1) Consideration of overall policy issues, in particular development of proposals that would incorporate the “precautionary principle” into appropriate legislation (as in the European Union’s REACH system).

(2) Ensuring that prompt action is taken when new science reveals previously unknown risks from exposure to chemicals in current use.

We would emphasize that the role of the SCOC has been limited to overseeing the implementation of the Productivity Commission’s recommendations as accepted by Government and that the emphasis has been on ‘competitiveness and productivity’, *not* the protection of public health and safety or the environment. And we are aware that industry lobbyists are well organized, well funded and highly persuasive to Government. It is essential, therefore, that any new ‘cross portfolio group’ have formal structures in place to ensure that civil society NGOs promoting consumer safety, public health and the environment are also equitably represented.

A3 – NICNAS has limited powers to control, ban and restrict industrial chemicals in Australia and depends on other agencies to implement its risk management recommendations. It is therefore, very important that at the MOUs be strengthened and adhered to so the uptake of risk management measures actually occurs in all states of Australia. The coordination, review, updating, implementation, auditing and compliance of risk management measures should be one of the responsibilities of the cross portfolio group, (as per Option A2) at least in the first instance. It is imperative that any MOU arrangement has the representation and support of the Ministries for Health, Environment, Local Government and any other agencies involved in administering risk management measures.

Part 5 – New industrial chemicals (options B1-B6)

- What are the strengths and weaknesses of the options for addressing the problems and objectives identified?
- If weaknesses are identified in relation to any of the options, are there other options that also meet the objectives?
- If these options were to be adopted, what are some of the implementation issues that would require consideration?
- What would be the likely impact on your organisation, if this approach were adopted?
- If NICNAS were able to refuse both an assessment certificate (Option B4) or listing on AICS (Option B5), under what circumstances would this be appropriate?

Please keep your responses to each option to no more than one page:

NTN supports reforms that strengthen the role of NICNAS to ensure public health and environmental protection. This requires that the long-term public health of its citizens and the Australian environment to be the prime purpose and mission of the role and functions of NICNAS. Fundamental to this objective is the importance of risk management measures to deliver these protections.

Therefore any reform involving exemptions or any reduced regulatory burden on industry must demonstrate with evidence that the objectives of human health and environmental protection can be adequately met.

B1 – NTN supports the harmonization of Australian chemical regulation with comparable overseas schemes such as REACH. Critical to the effectiveness and integrity of accepting overseas schemes is the acceptance of associated management measures and responses. For example, if an overseas scheme has identified a chemical hazard and imposed measures such as restrictions and /or bans, then Australia should acknowledge this and provide for the equivalent hazard mitigation measures. There is a strong community expectation that the Australian Government already employs these mechanisms yet there is a growing public awareness that this is not the case and subsequent community dissatisfaction and disillusionment is ensuing. The community rightly expects that Australian citizens and the environment are afforded the same protections as their European and other international neighbors.

There is a need to ensure that acceptance of an overseas chemical assessment includes consideration of the specific Australian context. This is particularly important in determining unique usage patterns, species specific impacts, climate change impacts and the specific climate conditions under which chemicals behave in all parts of Australia.

There also needs to be consideration of the differing regulatory authorities in Australian Government in relation to chemicals regulation and any associated differences in definitions that Australia uses.

B2 – Exemptions must support continued protection of public health and the environment. Therefore any exemption proposals must demonstrate with evidence and data that there is no decline in the standards or actual outcomes under these protections. For example the LRCC which was instigated with community support and expectation of health and environmental benefits has not provided such evidence, despite this review referring to the incomplete LRCC review report. The absence of community evaluation and key data supporting the LRCC has not been provided and therefore such a program requires urgent evidenced justification to continue with confidence.

B3 +4 – NTN supports NICNAS in having powers to reject chemical applications and assessment certificates based on any lack of information necessary to determine that the chemical is for safe use by industry and community in Australia.

Communities have an expectation that NICNAS has these powers already.

B5 – NTN supports NICNAS in determining the controls that are needed for the safe use of a chemical and if these controls have not been implemented by the relevant risk managers, then these controls must either (a) carry over to AICS or (b) the chemical should not be listed on AICS.

If options under B4 are implemented, no chemical would be allowed to be introduced *unless* adequate conditions have been imposed – either by NICNAS, or by other risk managers at time of introduction

B6 – NTN supports any necessary consequential changes following changes to legislation to progress above options must be made to ensure fairness, etc

NICNAS should have the ability to refuse an assessment certificate and/or list a chemical on AICS on the basis of an assessment that the chemical poses a risk that cannot be adequately controlled using standard controls or that there are no control/conditions in place. Any ‘conditions of control’ must be evidenced and proven to the satisfaction NICNAS and DoHA for the long term protection of public health and the environment. This may require cross-sector and inter-agency involvement with other regulators and civil society representation.

Part 6 – Existing industrial chemicals (options C1-C6)

- Do these options address the problems identified in relation to existing chemicals? If not, why not?
- What are the implementation implications?
- If these options were (or were not) to be adopted, how would this impact on your organisation?

Please keep your responses to each option to no more than one page:

Any reform in the area of existing chemicals must acknowledge that Australia is at an international disadvantage because of the failure to require volume and use data from industry when the scheme was established. The broad and far reaching unknown impacts for the Australian community and environment remain as a result of this lack of critical exposure data. Any reform must aim to redress this.

As such NTN supports the full implementation of recommendations that were made to the Australian Government under the National Community Engagement Strategy for the Existing Chemicals Review 2006. Key recommendations are still yet to implemented such as the National Adverse Experience Reporting mechanism critical to any closed loop regulatory model for the assessment of industrial chemicals.

C1 – There are several problems with the current PEC process – inability to mandatorily call for information until a chemical has formally been declared a PEC; the legislated time frames; and other issues, hence there have been very few PEC assessments done in the past 20 years AND the implementation of the recommendations coming from the PEC assessments has been inconsistent.

Consequently maintaining the current system is not going to achieve any of the objectives. NICNAS must have powers to require a mandatory call for information related to existing chemicals.

C2 – NTN supports this proposal but there must be a time frame attached to it so as to provide information and any associated risk management advice as soon as possible.

C3 – NTN supports this proposal but would suggest that these powers be able to ensure that NICNAS can request information when there is a lack of data and not just where the request is deemed proportional to a risk. There is potential risk in the unknown and common sense would suggest, that in regards to chemical impacts we simply do not know, what we do not know"! New advances in the assessment of the toxicology of industrial chemicals make it imperative to take a more precautionary approach to the assessment of the hazards of industrial chemicals

C4 – NTN strongly opposes this proposal. NICNAS as the risk assessment regulator for Industrial chemicals is the best authority to provide risk management advice. It is important for a closed loop regulatory model that the assessor is involved in the risk management measures so as to be able to feedback the effectiveness of these measures into the regulatory assessment process so as to measure the effectiveness and reliability of that assessment. The problem in Australia has not been that NICNAS proposes risk management advice but rather that those authorities responsible have not ensured the uptake of NICNAS risk management advice.

The collaboration that NICNAS undertakes with other overseas regulators, assessors and the scientific community mean that they are the best placed authority to propose risk management advice and would be best placed to have a key role in ensuring their implementation.

Therefore NTN supports the ability of NICNAS to annotate AICS and it was a community expectation that NICABNS be able to do this under the Existing Chemicals Review. The community believed it was a natural and obvious function of our AICS to have this information held there for both industry and the public.

C5 –NTN does not support the timeframe attached to this proposal. If a chemical is not in use in Australia it should be quarantined for five years and then removed. It is already the case that these chemicals have been sitting on AICS for years already without critical exposure data and any further time concessions should be rejected. The community expect that AICS would have the function of providing advice on safe alternative chemicals, promote the LRCC and ultimately achieve the removal of all chemicals that have unacceptable hazard and risk determinations for Australia or as defined under comparable overseas schemes.

C6 – NTN support this proposal as a necessary consequence of any changes being made under this review.

Part 7 – Post market monitoring and enforcement (Options D1-D3)

- What are the strengths and weaknesses of the options?
- Does an adverse effects reporting system address the problems and objectives identified?
- What would be the impact of an adverse effects reporting system on introducers?
- Are there other ways in which NICNAS' post-market monitoring and enforcement capacity could be improved?

Please keep your responses to each option to no more than one page:

D1 – NTN supports streamlining the secondary notification process – secondary notifications should be required when a new use is identified and/or new health/safety or environment information becomes available which may necessitate amending required controls.

D2 – While there is a clear need for secondary notifications, we note again that a serious shortcoming of the existing system is that when additional information (eg adverse effect reports, changes in use, international exposure standards, etc) becomes available for the vast majority of chemicals on AICS that have not been assessed, NICNAS cannot declare/require a secondary notification. The only clear thing that NICNAS can do is to declare the chemical a PEC – as noted above, a cumbersome and lengthy process, not necessarily suited to the immediate need to do something in such circumstances.

Consequently the NTN supports this proposed option, but the circumstances which could trigger a secondary notification should be expanded to also include other triggers – such as changes to overseas exposure standards, new research, etc. The NTN supports the proposal that anyone can report adverse effects or any other relevant information to NICNAS (including the public).

D3 –NTN supports the implementation of this option as providing a more comprehensive, contemporary and flexible compliance regime would increase the ability of NICNAS to more effectively monitor and ensure compliance.

Part 8 – Other reforms – release of information and confidential commercial information (Options E1-E2)

- How would the release of information to other relevant government agencies impact introducers?
- What are some of the implementation issues that would require consideration?
- What would be the impact of these options?
- Are there any other ways in which the identified problems can be addressed?

Please keep your responses to each option to no more than one page:

E1 – NTN supports this option, as provision of necessary information by NICNAS to other risk managers will increase their ability to fulfill their obligations –it does not seem logical that NICNAS is currently unable to share such information with other agencies. NTN would assume that any ‘commercially in confidence’ information supplied by notifiers to NICNAS would maintain its status with the other agencies – that is, it would not be released publically but used only in relation to ensuring compliance with conditions, monitoring, and so on. This change would increase protections to the public, workers and the environment. If there is such information that the risk managers felt needed to be more generally released to ensure management of risk, then this would have to be released with notification/consultation with the notifier.

E2 –NTN supports this proposal.

Part 8 – Other reforms – use of foreign schemes / international assessments (Options F1-F2)

- Do these options strike an appropriate balance between the use of international assessments/harmonisation and the need to ensure that Australia retains the capacity to undertake Australian relevant risk assessment and management where necessary?
- If these options were to be adopted, what are the implications?
- If these options were (or were not) adopted, how would this impact on your organisation?

Please keep your responses to each option to no more than one page:

F1 – NTN supports the use of overseas assessments but this must include any associated risk management advice including controls, restriction and bans. NTN supports global harmonization of chemicals assessments but Australian conditions and context must be included in this process. It must ensure that Australia’s unique climate conditions, regulatory definitions and chemical uses are consistent and reflected in any assessment process.

F2 – NTN supports this where it ensured that there is no reduced regulatory or assessment outcome for Australian public health and environmental protection.

Part 8 – Other reforms – chemicals in articles (Options G1-G2)

- Do these options address the problems relating to articles?

Please keep your responses to this option to no more than one page:

G1 – NTN supports the role of NICNAS in assessing chemicals in articles. Collaboration with overseas regulatory agencies is showing that the science available to assess articles and chemical combinations is available. It would be unwise to change the INCA act so that NICNAS would not be able to address this critical data gap in knowledge. NICNAS is the appropriate authority as the chemical assessor to undertake such work and the future capacity building of NICNAS as the scientific assessor of industrial chemicals would only be undermined if the Act was changed to remove this function.

As previously stated chemical risk assessment methodology is only valuable when feedback mechanisms and follow up monitoring are built into the process. Data on the behavior of multiple chemicals, and their synergistic and cumulative properties is vital to any chemical risk assessment methodology. Current risk assessment methodologies do not adequately address mixtures of chemicals or the non monotonic behavior of endocrine disrupting chemicals.

There are current regulatory gaps in the assessment of chemical articles such as the failure of the ACCC to regulate “non domestic” articles such as public playground equipment and other “public exposures” to articles not defined as domestic under the ACCC.

G2 – comments above apply also to imported articles.

Part 8 – Other reforms – chemicals in cosmetics (Option H1-H2)

- If these options were (or were not) to be adopted, how would this impact on your organisation?

Please keep your responses to this option to no more than one page:

H1 – NTN does not support transfer of enforcement of the *Cosmetics Standard* to the ACCC. This would lead to duplication and the loss of NICNAS expertise in the area of cosmetics. NICNAS should maintain this responsibility.

H2 – NTN supports the development of provisions specific to cosmetics (including potentially those listed in the Discussion Paper) into the ICNA Act – in consultation with stakeholders. It should be noted that although a product may be labeled a ‘cosmetic’ it can be extensively used in industrial settings.

Part 8 – Other reforms – Import and export of chemicals under the Stockholm and Rotterdam Conventions (Option I1-I2)

- What are the implications of maintaining the status quo?

Please keep your responses to this option to no more than one page:

I – NTN supports the retention of NICNAS’s role in the implementation of the Stockholm and Rotterdam conventions.

Part 8 – Other reforms – Governance – Committees (Option J1)

- If the options in this Discussion Paper are preferred, what does this mean for the governance committees of NICNAS?
- What committees are needed? For example, would it be useful to have a strategic advisory committee advising the Director of NICNAS?

Please keep your responses to this option to no more than one page:

NTN supports the full engagement of civil society in chemicals regulation and management in Australia as required under our international obligations.

The CEF has been leading in the area of civic engagement at a Federal level and should continue to be supported.

There is a need for greater involvement on NICNAS working groups from the Federal environment agencies and the absence of comparable civic engagement mechanisms continue to undermine the DEWSCAP and subsequent chemical regulatory framework as it relates to the protection of the Australian environment.

NTN supports the concept of a strategic advisory committee as long as it is established with equitable resourced public interest representation. Such as committee could address as a priority the current gaps in chemical regulation and the failure of risk management implementation across Australia.

Part 8 – Other reforms – Governance – Relationship with the Department of Health and Ageing (DoHA) (Option K1)

Please keep your responses to this option to no more than one page:

KI -agree