

To: NICNAS Reforms

26th October 2016<https://www.nicnas.gov.au/media/web-forms/have-your-say-cp4>From: **Jeff Simpson**

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Dear Colleague,

Please find on the following 2 pages my key concerns (plus additional issues) about the proposed NICNAS Reforms (see: <https://www.nicnas.gov.au/about-nicnas/nicnas-reforms/consultation-paper-4>). I regard my key concerns need to be carefully considered by all affected groups in Australia, so that the finally agreed NICNAS Reforms will work in a cost effective way for industry, for workers, for the community, for the environment, and for NICNAS.

The final version of the NICNAS Reforms will have a major impact on whether businesses will be able to easily innovate, with new chemicals, in Australia, whilst the community knows that NICNAS is alerted to ALL new chemicals.

However, the current NICNAS "Reforms" proposals are replacing an expensive toxicological evaluation system with another expensive toxicological evaluation system (to be maintained inside each Business), that on the surface looks like it will protect us, but if the costs are too high, we won't be easily able to have new industry processes that need these new chemicals, to employ us in new industries IN Australia.

It is important that we ALL make a carefully considered decision on what is the best balance for Australia. At present I don't believe others in industry and the community (who are not "NICNAS aware" persons), are even aware of, nor have properly understood how important these Reforms are to Australia's ability to quickly innovate.

Under the proposed Reforms (as currently presented by NICNAS), new "Polymers of Low Concern" are the only chemicals that have been reasonably dealt with, by picking up agreed worldwide PLC classification systems.

Other new chemicals require a much higher level of toxicological information, that must be first legally obtained, and then regularly re-checked in detail (at least for each yearly sign-off), that they still meet the Chemical Category they have been introduced under. This is a major on-going toxicological cost, that needs to be minimised by using different processes, with NICNAS becoming a key chemical information manager in conjunction with Businesses.

In my key concerns I have suggested that we need to be more pragmatic about the level of information we collect and that this is the opportunity to work with New Zealand to create a workable system between their NZ system and our proposed new Australian chemicals system, particularly if we want the Trans Tasman Mutual Recognition Agreement (TTMRA) to start to include at least some industrial chemicals in 2019.

I have suggested we need to minimise industry's ongoing costs to maintain a workable system of chemical hazard information, and that NICNAS should only carry out audits on key chemicals that their tracking alerts them to. To this end, I have suggested that industry should inform NICNAS of ALL their new chemicals and then industry be allowed to rely on NICNAS's access to the various recognised databases around the world to have NICNAS check the industry CAS No.s, so that NICNAS can then alert companies to changes in classifications.

a/ for Reported Chemicals when significant classification changes may require Review or Assessment.

b/ for Exempt Chemicals when new classifications may require that these chemicals need to be Reported Chemicals.

To Reiterate: The checking process under the currently proposed NICNAS Reforms process is very expensive and must be done in detail, at least annually, by each individual business; and it is not realistic to expect hazard changes for all these chemicals to be picked up comprehensively and uniformly by ALL businesses. We need the NICNAS Computer to help do this, so that such on-going checking costs are minimised in every Australian Business.

In 2017 it will probably be necessary to ask the Federal Parliament to make adjustments to the NICNAS Reforms legislation, so that we get a workable system that looks after industry, workers, the community and the environment.

Any feedback to NICNAS, industry, unions, community groups and myself, on how to further improve the system for new chemicals, so that we actually end up with new jobs in Australia, will be greatly appreciated.

Regards

Jeff Simpson

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3 Key Continuing Concerns with the NICNAS “Reforms” - following release of Consultation Paper 4

These issues need to be properly addressed for the Reforms to be successful for ALL Businesses in Australia.

A/ Exempted Chemicals are not required to be individually alerted by each importing or manufacturing business (as they are currently under the No Unreasonable Risk Exemption Categories), so where some “non hazardous” chemicals are found to have hazards, NICNAS will NOT know which businesses are importing the specific chemical, and will need a Call for Information. Their proposal to have a declaration that an Exempted Chemical Category is being imported, will not be of much use to calm down a concerned community (including Unions and Groups concerned about chemicals) that NICNAS is appropriately managing Exempted Chemicals coming into Australia.

There are Several Direct Benefits for businesses to have the individual chemical in the Exempted Chemical Category tracked by NICNAS:

1/ The proposed NICNAS Audit system would be able to be focussed on chemicals with possible issues IF NICNAS knows which chemicals each business is introducing in this category. So broad brush audits would be not necessary.

2/ If NICNAS knows which chemicals are being introduced into Australia by which business in the Exempted Category, the NICNAS computer can be set up to track when they gain a Hazard Category (e.g. when the ECHA Registered Substance Database classification outcomes change) and the computer should then alert NICNAS and the businesses introducing that chemical that a change had occurred. This would lift a large “checking for change” requirement off the introducing businesses as they could then rely on the NICNAS computer for this.

NOTE: Individually alerting these chemicals to NICNAS is NOT a Pre-Assessment of the chemical, it just allows a very efficient management system to occur, which will minimise Businesses having to reassess these “Exempted Chemicals” every year, because the NICNAS computer should then be set up to track these chemicals, as I have identified in 2/ above and do this yearly checking work for Businesses.

B/ Australia has not come up with a New Industrial Chemical process that can also be implemented in New Zealand when the TTMRA is ALSO meant cover Industrial Chemicals by 2019, just at the time when our NICNAS “Reforms” are finally in place!

To do this, Australia would need to have a pragmatic process similar to New Zealand, but with an appropriate increase in Health, Safety and Environmental management outcomes (for our Excepted Chemicals and Reported Chemicals categories) that the New Zealand community should expect.

Such an approach would be an opportunity to promote a “reasonable balance model” to the rest of the world, with reasonable internal costs to introduce chemicals in the Exempted Chemicals and Reported Chemical Categories.

C/ The proposed “Reform” scheme essentially transfers the internal NICNAS toxicologist review costs to external qualified toxicologists working for every business in Australia. This is because the underlying tox data will need to be accessed, retained and reviewed by a person with recognised toxicological experience.

The business’s chemical review Databases to hold this data will need to be highly robust, to last over several decades. This means they are still likely to need to be hard copy as well, with significant hardcopy and electronic storage.

This cost could be minimised IF NICNAS would accept GHS Classification Outcomes from agreed databases (such as the ECHA Registered Substances Database⁽¹⁾), AND enable all businesses to store their data in a suggested “NICNAS Central Chemical Review Database” (where a business could allow NICNAS to have agreed levels of access, making NICNAS Audits simpler). This would then enable chemical hazard classification specialists with experience (who are not qualified toxicologists) to review and decide whether a new chemical fits in the Exempted Chemicals or Reported Chemicals Categories.

NOTE: IF the NICNAS Reforms go through as they currently propose, I don’t expect to be able to offer my hazardous chemicals classification services in this New Chemical area, as I don’t regard I have adequate toxicological experience to offer this service as consultant under my Professional Indemnity Insurance, at the data level NICNAS wants. I

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suggest such services will be like the sign-off of an Environmental Auditor, with bigger risks of claims when NICNAS audits a business.

(1) <https://echa.europa.eu/information-on-chemicals/registered-substances>

Other Lesser NICNAS “Reforms” Issues - following release of Consultation Paper 4.

These lesser issues also need to be properly addressed for the Reforms to be successful for ALL Businesses in Australia.

Page 4: Exec. Summary – 2nd last paragraph “The 12 month transition period”. And also on Page 47 “Transition Periods”.

Comment: Once the Reforms are implemented, 12 months is likely to be too short, due to insufficient toxicology specialists to support industry to convert “No Unreasonable Risk Exemptions” to Exempted Chemicals & Reported Chemicals.

Page 17: Part 4 – “To reduce the reporting burden on introducers, it is proposed that the requirements relating to annual compliance declarations would be included as part of Annual Registration. Introducers would be required to make declarations regarding the chemicals that they imported in the previous registration year.”

Comment: This does not recognise that two different Sections in a Business would see the possibly confidential Annual Compliance declarations IF done WITH the Financial Registration payment. The Financial Section and the Regulatory Compliance Sections need to be kept separate.

Page 19 & 21: Part 5 – Exempted Chemical Introductions & **Part 6** – Reported Chemical Introductions

Comment: The effort to convert the current No Unreasonable Risk Exemption chemicals to Exempted Chemicals and Reported Chemicals will require major work and information to change these. The test for ‘No Unreasonable Risk Exemption chemicals’ is very simple compared to the proposed requirements for Exempted Chemicals & Reported Chemicals.

Pages 21 & 24: Parts 5 & 6 – Post Market Monitoring by NICNAS - IF, as part of post-market monitoring, information to demonstrate that the chemical introduction falls within the Exempted category OR the Reported Category is requested by NICNAS, the introducer must produce the information within 28 days of receiving a request.

Comment: 28 days is not realistic for companies with no permanent staff or only one specialist who may be on leave. This period needs to allow for up to 3 months, e.g. where a specialist consultant needs to be contracted to do this work.

Page 46: Part 14 – Other Changes - Certain functions currently undertaken by NICNAS will be transferred to other Commonwealth Departments. These include mechanisms to give effect to the policy decision to **remove** from NICNAS the **responsibility for administering the Cosmetics Standard** and the **Regulation of Import and Export of Chemicals in accordance with the Rotterdam Convention**.

Comment: The Cosmetics Standard needs to be administered by a Federal Authority that technically understands the issues for Cosmetic chemicals that are **applied** to the body and may inadvertently enter the body. I suggest this must be under the TGA, which should be renamed the Therapeutic & Cosmetic Goods Authority (TCGA).

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