For the NICNAS Reforms Paper 3, see: https://www.nicnas.gov.au/about-nicnas/nicnas-reforms/consultation-paper-3

Key Issues:

a/ The NICNAS Authority has not understood that what they are proposing, has very little chance of Small and Medium Sized Businesses in Australia implementing in a technical, effective and cost efficient manner for them to introduce chemicals NOT on the AICS. Small and Medium Sized Businesses will want to introduce chemical products with ingredients not on the AICS, but are unlikely to have the capability to do so, which will be much the same as now.

Note: Very few of Small and Medium Sized Businesses have given attention (so far) to the proposed changes (as can be estimated by their complete lack of attendance at the NICNAS Workshops). These reforms are SO important that several hundred representatives out of the just under 6000 registered NICNAS entities should have been at the NICNAS Workshops, but I estimate that less than <3% came! Also there have been very few comments on the NICNAS website from Small and Medium Sized Businesses.

b/ It is not clear (so far) whether NICNAS will maintain an online database where Businesses have the option to enter their new chemical evaluations into it and attach relevant data for each tox/ecotox endpoint, rather than setting up their own spreadsheets / databases, that will need to be carefully maintained over many decades.

c/ The Exempt Chemicals that are "non hazardous" or are hazardous chemicals in a non-hazardous product, both need to be simply tracked (preferably each year) so the community can be assured that at least NICNAS knows of these new chemicals (which is required by the ICNA Act). With this simple tracking, incorrect evaluations or if significant information is alerted to NICNAS, will enable NICNAS to inform the specific businesses to take action. It will also enable NICNAS to carry out minimal (and for most businesses, nil) audits for the Exempt Category Chemicals as NICNAS will have been informed by the simply tracking data.

d/ The Trans Tasman Mutual Recognition Agreement (TTMRA) between AU and NZ, which is expected to also cover Industrial Chemicals in 2018 (but currently doesn't), has not been taken into account (to be achieved) in the proposed NICNAS Reform approach. This is a major regulatory omission for this Agreement to not be addressed in any manner. The Reforms need to consider how the more pragmatic NZ risk management approach with 210 Group Standards plus site and storage conditions, could be modified and used in Australia, making one system for AU and NZ.

e/ Small (and most medium) sized businesses are not likely to have ready access to a technical specialist on NICNAS requirements with good access to the necessary tox databases and tox software. Auditing small (and most medium) sized businesses is likely to be problematic as they won't normally have a technical specialist on NICNAS available. They are likely to use an occasional specialist consultant, who is very likely to be unavailable when NICNAS comes Auditing, due to their consultant's other commitments. The Businesses' normal admin and trading staff don't understand the NICNAS regulatory requirements except in a minimalist way. So a 1 month response to a NICNAS Initiated Audit needs to be 3 months or more.

f/ It is not realistic that companies can obtain the chemical's actual endpoint tox & ecotox data in the ECHA Registered Substances Database (RSD), as the EU SIEF members won't make it available to Australian Businesses. This lack of access to data also applies to many other tox and ecotox databases, or if available, has a very significant cost for new chemicals. It should accepted by NICNAS for businesses to provide SIEF agreed classification outcomes rather than each endpoint data (which ECHA RSD will expand significantly by early 2019) and then AU businesses rely on being advised by the NICNAS computer when the ECHA RSD entry has an updated classification outcome.

g/ I don't regard NICNAS should be either assessing or regulating cosmetic chemicals. Up until cosmetic chemicals where brought under NICNAS, the principal approach for industrial chemicals was for users to NEVER have contact with chemicals as even "non hazardous" chemicals might be hazardous or be contaminated with hazardous chemicals. I don't regard that the ACCC has the chemical technical expertise to manage cosmetic chemicals, and I suggest that cosmetic chemicals would best managed under the TGA (which manages chemicals that are intended to come in contact with our bodies, and I regard that cosmetic chemicals have a close overlap with many therapeutic action chemicals).

NICNAS Reform Paper 3: Jeff Simpson's Updated Full Range of Comments

After seeing the Consultation Paper 3 and attending the Melbourne NICNAS Reform Workshop 3, my previous comments are still NOT resolved and I have restated, rearranged and added to them, with some clarifying comments.

1/ IT IS IMPORTANT this NICNAS Reform must enable Australia to be more innovative and thus be able to have industry and jobs IN Australia, whilst still adequately protecting workers, the public and the environment. This needs to be done at a reduced overall cost to industry, not just a transferred cost from paying NICNAS, to having to pay an in-house specialist to prepare reports and maintain their own business's NICNAS data system.

2/ The NICNAS proposed reforms all make superficial sense from a pure risk management perspective; and we have been doing this in a managed way, from our NUR exemption chemicals to different amount of information required for each type of permit or registration, BUT I expect this process is now going to be a lot more complex for

each business to manage internally, and will need very capable (and expensive) specialists to be available to each NICNAS registered business, or to use NICNAS's paid services to help them meet their assessment obligations.

3/ I am seriously concerned that many importing businesses will not being able to manage the complexity of the "reforms".

I would like to see a system of NICNAS reforms that is much closer to the NZ approach, except that NZ "non-hazardous" chemicals or NZ hazardous chemicals in non-hazardous formulations **must** be tracked, as a "responsible care" assurance for the community to accept the NICNAS Reforms. This would make much easier to satisfy the Trans Tasman Mutual Recognition Agreement (TTMRA) to include industrial chemicals in 2018.

For formulated products, **using the New Zealand Group Standard approach** (plus the additional NZ Site & Storage Condition documents), would mean most formulated products would have **an agreed risk management approach**, if applied in the same way as New Zealand; and I suggest this would be a lot simpler and cheaper than the proposed NICNAS Reforms in Consultation Papers 2 & 3 (**for formulated products**).

Then we are only left with the "**single component chemicals**": Only these high concentration "single component chemicals" would then be managed in the Risk Matrix – Hazard Band vs Exposure Band NICNAS process and then have the Exempted, Reported, Assessed outcomes proposed.

We also need this system to eventually (certainly within 10 years) be extended to cover ALL existing Hazardous Chemicals, & so finally fully harmonise with NZ.

4/ There are many chemicals in the ECHA Registered Substances Database that have endpoints with the "Data Lacking" tag where EU Company SIEFs have defaulted to "not classified" against the tox or ecotox hazardous chemical endpoints. As data becomes available, EU companies are required to update these classification endpoints. NICNAS needs to manage this by accepting the reality of this situation (and also allow significant data waiving) where the update of tox and ecotox info process will capture classification changes. This is one reason why all new chemicals (hazardous and currently not hazardous) need to be at least tracked by NICNAS, so that the NICNAS computer can be used to highlight significant changes on key world databases (of equivalent or better standing to the ECHA Registered Substances Database).

The alternative in Australian Reforms is that many "not classified" chemicals in the ECHA Registered Substances Database will need to be in the NICNAS Reported Chemicals and future NICNAS IMAP reviews will need to default to the highest Hazard Bands for these "Data Lacking" endpoints. Australia would be better off with all new chemical being tracked by NICNAS, particularly the Exempt (with simple tracking) chemicals, where companies can then be alerted to changes by the NICNAS computer to upgrade their Company Risk Evaluation or participate in a NICNAS Assessment.

The allowance for tox and ecotox information waivers needs to clearly explained by NICNAS, as this appears to be very important option where detailed tox and ecotox information is not available.

5/ Industry must be able to ask NICNAS for a technical opinion to decide a chemical is an Exempted, Reported or Assessed Chemical. (I assume this will be a "pay for" NICNAS Categorisation / Classification Service)

6/ This Exposure Band determination does not ease the work to be done to import chemicals into Australia, as it will generate a much higher level of expectation to import by businesses who have previously given up on importing new chemicals However these businesses will not have the in-house expertise to achieve this new Risk Matrix approach.

7/ Company chemical management software will need to be created or re-written to include tracking uses and release volumes against each use of these chemicals. This will be particularly difficult / expensive for small business.

8/ It will cost businesses more to track the each chemical's Hazard & Exposure Data against each final product in the market. **NICNAS must offer an online system** to companies who don't have the ability to easily upgrade their in-house software systems.

9/ Hazard Endpoint Data will need to be held for each required Hazard Band Criteria endpoint, and Exposure Data will need to be maintained for all Exempted and Reported chemicals. Businesses will need official support documents to help them achieve their requests to their suppliers/manufacturers and further trading companies/customers/end users.

10/ There needs to be simple "<1%" management scenarios available so that Australian manufacturers can also take advantage of this concession, so "<1%" is not just available for their overseas business competitors.

E.g. "The chemical (when present at >1% and wanting to use the ≤1% management scenarios) shall only be imported and transported under highly controlled conditions; and stored and processed in an industrial workplace under highly controlled conditions until present at ≤1%." The existing "Commercial Evaluation Permit" could be modified to enable this.

11/ "The <1% ingredient should not itself classify the product as a Hazardous Chemical." I suggest the previous sentence be added **OR** another sentence such as "Concentration to be ≤0.1% for CMR chemicals as introduced" criterion, so a <1% chemical in a product cannot classify the product as a GHS Hazardous Chemical to the CMR criteria.

12/ There is also a case to <u>allow ALL hazardous chemicals</u> that don't cause the manufactured or imported product to be GHS classified, which are well below their lowest GHS classification cut-off concentration, e.g. <50% of the lowest GHS concentration cut-offs, (so they have minimal additive hazardous effects with similar hazard chemicals).

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This would also need an arrangement for Australian manufacturers similar to **10/** above.

13/ For Exempted Chemicals, NICNAS must at least be provided (preferably each year) the Chemical Names / CAS No.s, and IF a Hazardous Chemical (e.g. for R&D, or in a Non-Haz product) its maximum percentage in the product range it is in, so the NICNAS computer can initially do a "double check", but NO quantities required, as calculating quantities is very costly to do. This will also enable NICNAS (in later years) to alert these companies that a "non hazardous" chemical has become a Hazardous Chemical, or that a Hazardous Chemical in an Exempted product has a changed classification.
This provides the community a "Responsible Care" assurance that no chemicals are missed out.

14/ It should be possible for NICNAS to have flexibility to allow a company to postpone a response to a NICNAS Initiated Audit for 3 months or more, to accommodate industry regulatory workloads or staff not being available (due to leave, sickness, bringing in a specialist, etc). This is particularly important for small and medium sized businesses who don't have a permanent or regularly connected NICNAS specialist available.

15/ As I evaluate it, this Risk Matrix system will transfer the costs from paying NICNAS to review the industry chemical hazard assessments, to costing Industry the same (or maybe more) to prepare their Exempt or Reported Chemicals evaluations and to understand and maintain their NICNAS chemical management endpoint data, exposure data and risk evaluation system.

16/ Due to the NICNAS data requirements, all "data lacking" hazard endpoints are likely to be up-rated as hazardous, which will make these chemicals at least Reported, and many Assessed. These will all have added risk evaluation costs.

As there are no authoritative Endocrine Disruptor (ED) Lists currently available, do businesses decided that their chemical is not an Endocrine Disruptor (at the time of their review) if there is no ED data available for the chemical?

17/ We still need to remember the NICNAS Act & Regulation are about an Inventory of Chemical Substances, not an Inventory of CAS No.s. There are many CAS No.s that should be automatically added to the AICS. Such as where there are mixture CAS No.s, but the individual CAS No.s in the mixture are not on the AICS, but these chemicals are clearly already in Australia. And a group entry such as "Alkyd Resins CAS 63148-69-6" that covers many simple Alkyd Resins.

18/ The sheer volume of chemicals coming through the IMAP process, and then through the Schedule Poisons process, has not been able to be adequately addressed by industry or the community, due to these groups not having any extra funding to do this. It has also caused a massive workload increase for the Schedule Poisons Committee.

I suggest that the existing chemical review process (IMAP currently) needs to be done at a rate so that everyone can reasonably make input at the time of existing chemical review.

The existing chemical review comment periods need to be longer (I suggest 3 months & 4 months over Christmas).

19/ Nanomaterials for R&D in Exposure Band 1 need to be limited to a lower amount (say <10kg per annum) as it has not been my experience that R&D scientists (in Universities) really understand the hazards that they are required to manage, and they tend underestimate the issues and the controls that need to be in place for novel materials. I suggest that new Nanomaterials need to be handled as if they are a significant biohazard, following biohazard protocols.

20/ I don't regard NICNAS should be either assessing or regulating cosmetic chemicals. Up until cosmetic chemicals where brought under NICNAS, the principal approach for industrial chemicals was for users to NEVER have contact with chemicals as even "non hazardous" chemicals might be hazardous or be contaminated with hazardous chemicals. I don't regard that the ACCC has the chemical technical expertise to manage cosmetic chemicals, and I suggest that cosmetic chemicals would best managed under the TGA (which manages chemicals that are intended to come in contact with our bodies, and I regard that cosmetic chemicals have a close overlap with many therapeutic action chemicals).

There are **no** restrictions on how my comment may be posted or distributed.
e.g. Posting on the web, distribution by email, hardcopy documents are all unrestricted methods.

Selected comments from this Submission on Consultation Paper 3 will be published in the
April-June 2016 Hazmat & Environment Notes.

Regards

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END: Comment on the NICNAS Reform Paper 3 by Jeff Simpson, Haztech Environmental, 9 June 2016