

My discussion and comments, are based on my interpretation of the NICNAS Reforms Consultation Paper 1, attending the NICNAS Reform Melbourne Workshop on Tuesday 24th Nov 2015, and liaising with colleagues.

The NICNAS Reforms Consultation Paper 1 (79 pages) is available at www.nicnas.gov.au/about-nicnas/nicnas-reforms/implementation-of-the-reforms

This Comment by Jeff Simpson, Haztech Environmental, is available at www.haztech.com.au

To prepare my comment and to help others prepare comment I have included brief explanations of how I regard the new NICNAS Risk Evaluation processes will work.

Comment 1: A Name Change from “Class x Chemical” to “NICNAS Type x Chemical” is Requested:

The name “Class 1, 2 or 3 chemical” in this paper, uses the same term as Class in the Dangerous Goods Regulations. The Class of Dangerous Goods will come up in our evaluation of these chemicals such as Class 3 FLAMMABLE LIQUIDS.

So that there can be no confusion in the future with Dangerous Goods Classes, when we discuss the NICNAS type of chemical, I suggest it is better to use another term such as “**NICNAS Type 1 Chemical**” etc.

1-1/ The Classification Hazard Bands and Exposure Bands are published in Appendix A (p63-79)

where they are presented as **Risk Matrices**, for a decision process of what will be Class 1, Class 2 and Class 3 chemicals, based on “Indicative Risk”.

Comment 2: The Appendix A Risk Matrices part of Consultation Paper 1 **needs to be read and understood first**, as the rest of the new chemical management process in Paper 1 relates directly to this. Data requirements are proposed to be “set such that the chemical’s Class can be determined based on its Indicative Risk, rather than as an Outcome of a Risk Assessment”.

1-2/ NICNAS are after Hazard Bands to be a “balance between ensuring that the Indicative Hazard Profile of the chemical is not required to be characterised to a level that would impose unnecessary delay for its introduction in the market, while at the same time ensuring that it is developed with sufficient scientific robustness to adequately protect workers, consumers and the environment”.

“Consultation Paper 2 and Consultation Paper 3 will present refined versions of these Risk Matrices, and will propose data requirements for each Hazard Band, as a function of a chemical’s anticipated exposure.”

Based on both Indicative Hazard and Anticipated Exposure Considerations, two Matrices were created - one relating to Human Health Criteria and one relating to Environmental Criteria.

A chemical must be placed into a Class for Human Health and a Class for Environment.

1-3/ To Place a Chemical in its Class (p67-69):

- Firstly, determine the appropriate Exposure Band, using the proposed introduction volume, use and/or concentration, as relevant.
- Secondly, determine if the chemical meets the criteria for Hazard Band E for the respective exposure band.
- IF Not, move down to the next Hazard Band until the Criteria are met for any of the chemical’s hazards.
- For any Hazard, no matter its band, the absence of data to satisfy the required criteria is deemed to be positive data for the purpose of allocation of a chemical to a Class.
- the Criteria must be addressed for all Hazard Endpoints, such that a full Hazard Characterisation of the chemical is made.

1-4/ Note: For a chemical to fall into Hazard Band A, there must be Sufficient Evidence to prove that it is Not Hazardous (i.e. absence of data for a Hazard Endpoint does not mean absence of the hazard; a chemical without available data does NOT default into Hazard Band A). (p68)

Comment 3: It is not clear where there is an absence of data, what the estimated Hazard Band level should become. Should it be deemed as one level up from “not hazardous” or the top Hazard Level E? There are many chemicals in the ECHA Registered Substances Database that have the “Data Lacking” tag where they are not classified as tox or exotox hazardous chemicals.

Also many “not hazardous” chemicals ON the AICS have no data for many Toxicity and Ecotoxicity GHS endpoints.

Comment 4: Will future NICNAS IMAP reviews default to higher (highest) hazard levels for these “data lacking” endpoints?

Comment 5: Industry needs to be able to ask NICNAS for a technical opinion to decide if a chemical is a Class 1 or Class 2 Chemical, as this will be a problem for importing companies without adequate technical expertise, or classification specialists, who may need to ask for a paid opinion from NICNAS to help them decide the Hazard Class. This could be like the NZ Status of Substance request at www.epa.govt.nz/hazardous-substances/about/SOS/Pages/default.aspx

1-5/ Exposure Band Cut-Off Quantities chosen are 100kg, 1000kg and 10000kg

The Exposure Bands Cut-Off Quantities for both Human Health & Environmental Hazards are still based around the 100kg, 1000kg and 10000kg amounts, as in the current NICNAS system. (p70-72)

Comment 6: This Exposure Band determination does not ease the work to be done to import chemicals into Australia, as:

a/ it does not recognise that standard chemicals are normally available in 200L or 1000L packages meaning if 100kg and 1000kg continue then these package sizes don't fit;

b/ it will require Exposure Band expertise to be available in a lot of small companies now hoping to introduce “not hazardous” Class 1 chemicals, or PLC Class 2 chemicals, who have opted out years ago from introducing new chemicals due to the uncertain returns for costly efforts.

Comment 7: I suggest there is a case to increase these amounts with a five fold increase of each, to become: 500kg, 5000kg and 50000kg. For a >90% single chemical, at the lowest amount, this would allow two 200L drums depending on the density, or at the next higher level this would allow 3-5 1000L IBCs depending on the density, to be brought into Australia, which would make the delivery and handling process of such chemicals a lot simpler; and the quantities more viable to innovate with in Australia.

Comment 8: Company chemical management software will need to be created or re-written to include tracking uses of chemicals. Uses of chemicals are only estimated at present, as raw material importers and manufacturers have minor information feedback arrangements for how their raw material chemical is actually used in industry or used by domestic consumers. **This is a major change** and there will be a major cost to obtain such detailed exposure information, particularly for small raw material trading companies who only have a minor part in developing final use products with their initial customers.

Comment 9: There will need to be the hazard data for each Hazard Criteria endpoint and exposure data to be maintained for all Class 1 and Class 2 chemicals. Companies need to be particularly aware of impending changes of products into higher Exposure Bands, that will cause a Class increase.

At the moment the NUR Exemption quantity of $\leq 100\text{kg}$ is the only common quantity that is tracked, as most companies do not introduce new chemicals due to the NICNAS Registration costs.

1-6/ Environmental Release Guidance will be provided by the Australian Department of the Environment based on the OECD Emission Scenario documents. Some examples in Consultation Paper 1 of potential environmental release volumes of chemicals based on their use are: Cosmetics, domestic products 100%; Printing inks 50%; Paints and coatings 5%. (p71)

OECD Emission Scenario Documents are at:

www.oecd.org/chemicalsafety/risk-assessment/emissionsscenariodocuments.htm

Comment 10: The exposure scenarios in these documents are not as simple (see below) as the three examples from NICNAS, so hopefully our Federal Dept of Environment guidance will simplify this. e.g. Number 22 EMISSION SCENARIO DOCUMENTS ON COATING INDUSTRY (Paints, Laquers & Varnishes) (201 pages) at: [www.oecd.org/officialdocuments/displaydocument/?cote=env/jm/mono\(2009\)24&doclanguage=en](http://www.oecd.org/officialdocuments/displaydocument/?cote=env/jm/mono(2009)24&doclanguage=en)

1-7/ $\leq 1\%$ as introduced Human Health Exposure Criterion: for chemicals in Exposure Band 2 for both Industry use and consumer use. This extends this advantage to overseas manufacturers of industrial chemical products, similar to already formulated overseas cosmetics. (p72 table). This includes CMR chemicals which are only managed as Class 2 chemicals. (p67 Human Health Matrix)

Comment 11: There needs to simple “ $< 1\%$ ” management scenarios available so that Australian manufacturers can also take advantage of this concession. E.g. New chemical raw materials that are to be finally used at $\leq 1\%$ can only be opened, handled, manufactured in premises that have additional controls to manage possible exposures, emissions or losses, such as should be required for Research & Development New Chemicals, until they are finally present at $\leq 1\%$.

Comment 12: I suggest an additional “Concentration $\leq 0.1\%$ for CMR chemicals as introduced” criterion, so the product could not be classified as a GHS Hazardous Chemical to the CMR criteria. IF the $\leq 0.1\%$ for CMR chemicals criterion is introduced I would then be comfortable with the Human Health Risk Matrix on p67.

Comment 13: There is also a case to allow all hazardous chemicals that don't cause the product to be GHS classified, which are below their lowest GHS classification cut-off concentration, or maybe <50% of this lowest GHS concentration so they have minimal additive hazardous effects. This would be similar to the NZ system and so enable Australia to partly harmonise with the NZ HSNO regulations for this lowest hazard & level.

1-8/ Polymers of Low Concern (PLC) with no classifications

Comment 14: The NICNAS Draft has indicative criteria for each Hazard Band A to E, however Polymers of Low Concern (PLC) with no classifications under any of the GHS Criteria for Australia, nor under the GHS Environmental Criteria, will NOT fit into Category A, as NICNAS deem ALL PLCs as Class 2 chemicals, presumably because PLCs will not have >70% biodegradation in 28 days nor >60% biodegradation within 10 days. But it is generally the intention of industrial polymers once cured, to not degrade.

Unless the PLC or a Non Hazardous Polymer, will eventually breakdown to Hazardous decomposition products, this does not make sense. I suggest PLCs and Non Hazardous Polymers all be placed in Class 1 unless the environmental decomposition data shows an environmental hazard will occur.

Comment 15: Australia needs to review its definitions of Polymers and preferably reasonably align with the European &/or the USA Definitions, so they will default to being Class 1 chemicals, except in specific cases agreed with NICNAS, industry and the community.

2-1/ Class 1 Chemicals – Basic Information Should be Provided to NICNAS

There is no requirement to even inform NICNAS that a company is bringing a Class 1 chemical into Australia, so how NICNAS would track such chemicals and audit these chemicals will be difficult. This is a significant change from our current system.

Comment 16: For Class 1 Chemicals NICNAS must at least be provided the chemical names / CAS No.s, and maximum % in the product (or product range) so the NICNAS computer can check them.

This would catch any products that are actually hazardous chemicals, and should be at least be Class 2 chemicals, and avoid such hazardous chemicals / products causing a problem for users or for the environment.

This is lack of ability to track such chemicals is also a problem in current NZ HSNO non-management of "non-hazardous" products.

3-1/ NICNAS will undertake post-market auditing of a proportion of registrants who are introducers of **Class 1** chemicals. Introducers of Class 1 chemicals will be required to keep records to demonstrate that their chemical meets the requirements of Class 1, and to make these documents available to NICNAS on request and must produce the information within 28 days of receiving a written request.

Comment 17: Small companies importing chemicals into Australia, if not required to provide their Class chemical tracking data to NICNAS (see 2-1/ above), are likely to "overlook" Class 1 ingredients, so would not have any Class 1 chemicals when NICNAS comes auditing, and NICNAS would not have any easily accessible basis to disagree or search their systems. Reputable companies would have this information and suffer an unfair disadvantage, due to added internal chemical tracking time and NICNAS audit time required.

3-2/ NICNAS will undertake assessment of approximately 10% of Class 2 pre-market notifications to validate that they are compliant with their notification against the Class 2 criteria.

The information NICNAS receives through notification of Class 2 chemicals will enable NICNAS to target the post-market audit towards those chemicals posing the highest risk.

If, as part of a post-market audit, information is requested by NICNAS to demonstrate that the chemical falls within Class 2, the introducer must produce the information within 28 days of receiving a written request. (p40).

Comment 18: It should be possible for NICNAS to have flexibility to allow a company to postpone a response to an audit for up to 3 months, to accommodate industry regulatory workloads or staff being on leave.

Comment 19: It might be worthwhile for an introducer to choose to seek NICNAS assessment of a Class 1 or Class 2 chemical. This does not make those chemicals Class 3; it simply enables an assessment to be undertaken and a pathway to AICS achieved. (p30). An AICS assessment would mean that a NICNAS post-market audit would not disrupt the operation of a Company via its Regulatory Department, just when other issues in the Company should have priority.

3-3/ Post-Market Auditing

Comment 20: It is not clear for Class 1 and Class 2 Chemicals who will pay NICNAS for a Post-Market Monitoring Audit when you have been selected. There are no notification fees for either of these Classes. There is an indication on p28 under Cost Recovery, there will be changes once the framework has been agreed.

4-1/ New Risk Matrix System Costs:

Comment 21: 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 them using Specialists, but getting no feedback as to their adequacy until a NICNAS audit at a possibly inopportune time.

Comment 22: It will also cost more to track the each chemical's Hazard and Exposure Data against each product. I suggest there is **a case for NICNAS to offer an online system** to companies who don't have the ability to upgrade their in-house software systems. These companies could then use the NICNAS online system (probably at a basic cost) so that NICNAS might not even have to visit to audit the Risk Matrix data points.

Comment 23: Due to the NICNAS data requirement, all "data lacking" hazard endpoints will be uprated as hazardous, which will make chemicals at least Class 2 and many Class 3. These will all have added evaluation costs.

5-1/ AICS and CAS No.s

Comment 24: We 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 alternative CAS No.s that come up on REACH; or various Hydrates; or CAS No.s that cover a range of chemicals such as: Phosphoric Acid, Potassium Salt CAS 16068-46-5, H₃O₄P.xK that covers all Potassium salts of Phosphoric Acid, but where an importer had to pay NICNAS to add a specific salt! Or Fatty Acids in the C6-C22 range then all the even Fatty Acids would be expected to be on the AICS as there are entries for the various mixtures covering this range.

Comment 25: We need information on Restrictions included on AICS for chemicals that have been assessed. The current process of having to go and find the information from historic assessment reports is not viable.

6-1/ International Assessments

Comment 26: NICNAS needs to accept **International Assessments** that are submitted by the notifier rather than having to wait for the International Organisation to supply a copy of the Assessment (which can add another 6 months onto the Assessment time).

6-2/ NICNAS IMAP Assessments: have been an effective process to review many existing hazardous chemicals to a reasonable standard. The IMAP summary data are now another useful source of reviewed data for persons preparing SDSs and chemical management procedures. NICNAS has been fully funded by an industry levee to carry the IMAP process out.

Comment 27: 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 not having any extra funding to do this. It has also caused a massive workload increase for the Schedule Poisons Committee.

Comment 28: I suggest that the existing chemical review process (IMAP) needs to be done at a rate so that everyone can reasonably make input at the IMAP time of review. The comment periods need to be longer (I suggest 3 months) as hazardous chemical specialists can't just drop one task to suddenly take on an IMAP chemical review task where it may even be a no income task!

This document may be used and modified by anyone to make their own comment on the NICNAS Reform. My information and comments may be posted on the NICNAS Reform website or on other websites such as Industry and Professional Associations, or used/posted on forums, such as CHCS or Linked In.

Regards

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