

Consultation Paper 2 – Key Issues

TOPIC	ISSUE	PROPOSED CHANGE IN APPROACH	APMF POSITION
Categorisation	Changes in terminology	Following feedback from stakeholders, NICNAS is proposing to change some of the words and terms used to describe key components of the reforms. For example, stakeholders suggested that referring to the categories of new chemicals as Class 1, Class 2 and Class 3 risks confusing these terms with those used for Dangerous Goods Classification. These categories are now proposed to be called Exempted, Reported and Assessed.	Support
Categorisation	Allow use of international assessment material for self-categorisation against hazard bands	Introducers would be permitted to use international assessment materials to self-categorise against hazard bands.	Support
Risk Matrix	Hazard information requirements for Exposure Band 1 in the health risk matrix	In recognition that the indication of very low risk for chemicals in Exposure Band 1 is driven by the very low exposure (ie, either research and development $\leq 100\text{kg}$, or transhipped chemicals), no health hazard characterisation will be needed prior to introduction of these chemicals for the purposes of NICNAS obligations.	Support
Risk Matrix	Simplifying and refining hazard and exposure bands in the health risk matrix	The hazard and exposure bands of the health matrix have been rationalised and simplified. There were many and varied proposals from stakeholders on ways to improve the matrix, and so the revised matrix is the result of considering all of these to come to the most practicable and risk-based framework that achieves the policy objectives agreed by Government.	The framework is supported. Further consideration is still needed to achieve the appropriate eligibility criteria to be used for class cut-off levels.
Risk Matrix	Aligning hazards with the Globally Harmonised System of Classification and Labelling (GHS)	The hazard band criteria for the environment incorporate the GHS classification thresholds. The hazard band criteria for human health have been reviewed to emphasise alignment with GHS classification for each particular hazard endpoint. This means that if the introducer has classified their chemical as corrosive to the skin according to the GHS criteria, then the chemical would be considered corrosive for the purposes of	The APMF recommends that current verifiable GHS classification should be the primary determinate for hazard points.

		<p>categorising the chemical in the risk matrix. However, NICNAS is proposing to not limit the acceptable hazard information to only that required for GHS classification, so as to allow maximum use of analogues and non-animal test methods and models as they become available.</p>	
Risk Matrix	Assistance for industry in categorising chemicals	NICNAS will provide a categorisation advisory service and make a variety of tools available online to assist industry to categorise their chemicals.	The APMF supports the development of online assessment tools to assist industry categorise their chemicals.
Assessment Timeframe	Reduce assessment timeframe	It is proposed that the assessment timeframe be reduced from 120 calendar days to 90 calendar days.	Support
Information (data) Requirements	Reduce use of animal testing	Information requirements will include greater acceptance of data from similar chemicals (analogues) and non-animal test methods. The expansion of the number of chemicals that do not require pre-market NICNAS assessment due to their relatively low exposure means more chemicals will not require information to be available on all hazard endpoints (such as those in Exposure Bands 1 and 2 of the health risk matrix). Thus, there will be even greater flexibility in the information used to determine any risks of introducing the chemical. Waivers to information requirements will also offer an avenue for reducing toxicological testing (especially of animal testing).	Support
Polymers of Low Concern (PLCs)	More appropriate treatment of PLCs	Based on feedback on Consultation Paper 1, NICNAS has modified the original proposal relating to the treatment of new PLCs. Specifically, it is now proposed that most new polymers meeting the PLC criteria be categorised as Exempted chemicals. This means that the regulatory burden is less than that imposed on introducers in the United States of America (USA) in respect of the same polymer. Introducers of polymers eligible for polymer exemption in the USA (equivalent to PLCs in Australia) are required to submit annual reports whereas under NICNAS, PLCs would have no annual or pre-market reporting requirements.	<p>Support</p> <p>A simpler approach to consider would be adopting the OECD definition of polymers and EU regulatory treatment where all polymers are exempt from registration and evaluation under REACH.</p>

Risk Matrix	Better definition of 'environmental release' and clarification of calculating release volumes	Based on stakeholder feedback and identification of inconsistencies with the current definition, NICNAS is developing a new definition for 'direct release to the environment'. This will ensure that only chemicals with releases to the environment of a significant nature are captured in the definition.	Support
Class 2 (Reported Chemicals)	Simplified annual declaration	Stakeholders expressed concern that a requirement for annually declaring Reported (formerly Class 2) chemicals would be cumbersome. NICNAS proposes to introduce a simple, automated online declaration system that will simply record a declaration that the chemical continues to meet the criteria for Reported chemicals (no additional information required regarding volume, use, etc).	Support
Australian Inventory of Chemical Substances (AICS)	Pathways to AICS for Exempted and Reported chemicals (previously Class 1 and 2 chemicals)	As raised in Consultation Paper 1, an introducer of a chemical that falls within the categories of Exempted and Reported (previously Class 1 and 2 respectively) may choose to apply for an assessment of the chemical. This will provide a pathway to AICS.	Support
AICS	CAS registry number (RN)	A single substance can sometimes have multiple CAS descriptors. When only one of the CAS RNs for such a chemical is on the AICS, there can be uncertainty as to whether the chemical can be introduced into Australia as an existing chemical under the other CAS RN. NICNAS proposes to introduce a new mechanism for adding CAS RNs to AICS.	In principle support, however the mechanism to achieve this objective needs further discussion. Refer to the ACCI Submission.
Transition Period	Length of transition period for new chemicals under exemptions, permits or certificates at the commencement of the reforms.	In Consultation Paper 1, NICNAS proposed a transition period of 6 months. A number of stakeholders commented that this period was too short or that decisions about a transition period could not be made at this early stage in the development of the reforms. NICNAS therefore proposes deferring the decision on the length of the transition periods until later in the consultation period but can confirm that the proposed period would be greater than 6 months.	Needs further discussion (noted that a meeting is scheduled on 4 April to consider this further).
Risk Matrix	Addition of 'contained import/export' scenario to the health matrix	Following feedback from stakeholders on business practices that do not meet the current transshipment criteria (but which are still low risk) a new scenario has been added to Exposure Band 2 of the health matrix. This is to accommodate the situations in which there is	Support

		low worker and public exposure to a chemical due to it being imported and stored at the introducer's warehouse, and then exported without any repackaging or processing.	
Use of International Assessments	As alternative pathways for assessing chemicals	Allow acceptance of Canadian/EU (REACH) Risk Assessments.	Support