

The Secretary
Budget Policy Division
Department of Treasury
Langton Crescent
PARKES ACT 2600

Dear Secretary

Email: prebudgetsubs@treasury.gov.au

Email: <u>prebudgetsubs@treasury.gov.at</u>

On behalf of Accord Australasia please find attached our submission in response to the invitation by the Minister for Small Business, the Hon Michael McCormack MP for 2017-18 pre-Budget submissions.

The formulated chemical products sector is a heavily regulated sector which has resulted in an overly complex system made all the more difficult through the duplication of roles and responsibilities for chemical management between Commonwealth entities, state and territory governments as well as some local government bodies. Governments have recognised the complexity of the regulatory system and the chemicals and plastics sector has been the focus of multiple reform efforts including the Productivity Commission¹ study into chemicals and plastics regulation which was released in 2008.

Australia's costly, complex and fragmented regulatory system for the management of chemicals is a serious issue for our industry. Members have raised concerns at the very slow pace of reform, the ongoing loss of innovation and business opportunities, as well as continuing problems with the decision making and operational performance of key regulatory agencies involved in chemicals management.

Australia's regulatory system needs to be redesigned to accommodate the global economy. Unique Australian requirements which do not add value should be abandoned and Australia should reduce its regulatory costs by adopting a deemed-to-comply approach to accept compliant products from advanced comparable economies. Regulatory equivalence should become the accepted norm rather than the exception. Sovereignty is maintained through high level risk management using a proper graduated risk profile unlike the current system where it appears that every product is considered to have an inherent risk; all risks are treated as equal and a zero tolerance is the predominant basis of control.

In our 2016-17 submission, we raised concerns regarding the costs to industry of the proposed reform measures to the industrial chemicals framework. We also provided some recommendations for improvements to the reform process which we believed would provide a greater return in savings to industry by expanding the reform to include the following measures:

- removing cosmetics from the scope of industrial chemicals; and
- removing sunscreens from the scope of therapeutic goods and regulating them as cosmetics.

The government's election promise to introduce a ban on animal testing for cosmetics should have provided sufficient impetus to remove cosmetics from the industrial chemicals framework

¹ Productivity Commission Research Report Chemicals and Plastics Regulation July 2008

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which is heavily reliant upon animal test data. Disappointingly there has been no such reform proposal put forward by government.

The government response to the Independent Review of Medicines and Medical Devices Regulation provides industry with an opportunity to explore sunscreen reform. While we do not believe that we will achieve our ultimate goal of having sunscreens regulated as cosmetic products as is done by most of our trading partners, we remain confident that a reform opportunity exists to achieve a lighter regulatory touch more consistent with the regulatory treatment of our major trading partners and hence, possibly reduce the non-tariff trade barrier for these products.

While industry welcomed the Government's 2015-16 Budget decision to streamline the chemical assessment process by moving to a more proportionate risk-based framework, we continue to hold serious reservations regarding the government's promise to deliver savings to industry.

Given the complexity of the proposals which increases the regulatory burden on industry we do not believe that the saving of \$23M per annum is achievable and a further examination of the cost impacts is required.

The proposals increase complexity for industry, are out of step with other global economies and will not result in business simplification. Again another potential non-tariff trade barrier.

The proposed system if implemented is unique to Australia. Lack of international harmonisation will not assist with trade, improve productivity or create jobs.

We attach for your information an independent analysis of publicly available submissions to NICNAS' Consultation Paper 3 which outlines the details for the reform proposals. You will note the significant number of concerns raised in the submissions regarding the complexity of the proposed system.

Accord's key priority for 2017-18 is to ensure that the current reform proposals for industrial chemicals, therapeutic goods and agvet chemicals deliver real outcomes for our members.

There have been several significant reviews into Australia's chemical management framework, however, very few of the recommendations have been implemented or led to any significant improvements by way of reduced costs and improved time to market. Most reform measures have required industry to contribute through cost recovered funds, for example in 2012 the implementation of the recommendations arising from the Existing Chemicals Review which the Productivity Commission recommended be budget funded cost industry \$8.6M over 4 years from 2012-13. This is now an ongoing cost as the programme is being continued. The 2015-16 Budget reform measure will cost industry an additional \$12.4M over 4 years commencing 2015-16.

It is no surprise that industry is jaded by the constant reviews with little outcome but increased costs.

In 2004 the Chemicals and Plastics Action Agenda Steering Group recommended amongst other things the development of a national chemicals policy. No action to date.



In 2006 the Banks Review² made certain recommendations regarding the regulation of disinfectants. No outcome to date.

Industry welcomed the Productivity Commission's report and recommendations into the chemicals sector. In particular, we strongly supported Recommendation 4.3, which to date, has been largely ignored.

The Australian Government should generally limit the role of NICNAS to the scientific assessment of the hazards and risks of industrial chemicals. The power to annotate the Australian Inventory of Chemical Substances to ban or phase out chemicals, the responsibilities for administering the Cosmetics Standard 2007, and for implementing the Rotterdam Convention, should be removed from NICNAS.

The Productivity Commission's³ review into mutual recognition arrangements and trans-Tasman arrangements made recommendations regarding aligning the regulatory treatment of industrial chemicals with that of New Zealand. Recommendation 4.2 from the final Productivity Commission (PC) research report on mutual recognition schemes:

The Australian, State, Territory and NZ Governments should strengthen their collaborative efforts to streamline the regulation of hazardous substances, industrial chemicals and dangerous goods and work together in adopting risk-based approaches. The TTMRA permanent exemption for these goods should then be removed by the end of 2018.

In developing this recommendation, the PC was of the view that it had not received any evidence to suggest that the outcomes achieved by Australia and New Zealand's regulatory regimes for hazardous substances, industrial chemicals and dangerous goods substantially differ, or that mutual recognition of these goods would pose a real threat to public health and safety or the environment in either country. Furthermore, the recent policy developments and reform activities in both Australia and New Zealand were considered likely to reduce the differences in the two countries' approaches, which would decrease the likelihood of significantly different outcomes. Unfortunately, this has not yet proved to be the case.

The COAG Chemicals Consultancy should be completed as a matter of urgency. This project was expected to be completed end 2015. The review was to examine the Commonwealth chemicals assessment functions and:

- identify the costs and benefits of structural change to Commonwealth chemical assessment functions and any subsequent impacts on the chemicals regulatory framework:
- investigate how to improve responsiveness of agencies at all levels of government in setting appropriate controls on the use, transport and storage of chemicals following their assessment;
- explore opportunities to improve interactions between regulators across jurisdictions; and
- identify opportunities for greater efficiency and cost savings in the operation of the framework.

³ Productivity Commission Research Report Mutual Recognition Schemes September 2015

² Report of the Taskforce on Reducing Regulatory Burdens on Business Rethinking Regulation January 2006



This COAG review has the potential to improve the efficiency and effectiveness of Australia's chemicals management framework and should be a priority for the government.

The cost of doing business in Australia is quite high, especially for imported products already subject to a high degree of regulatory control which are then subjected to additional uniquely Australian controls. The cost of these additional controls is an unnecessary burden and negatively impact both industry and consumers. Industry was optimistic when the Government announced its trusted international standards policy on 14 October 2014. The policy states that:

If a system, service or product has been approved under a trusted international standard or risk assessment, then our regulators should not impose any additional requirements for approval in Australia, unless it can be demonstrated that there is a good reason to do so.

But it appears that the spirit of this policy has been lost in discussions of the differences between overseas regulatory systems, and barriers to the acceptance of international assessments and standards rather than the opportunities this could provide. Industry held high hopes for this policy but again, the government's policy intent to reduce red tape and the regulatory burden has been thwarted by regulatory agencies failure to adopt the policy in the spirit with which it was intended.

The government's cost recovery policy is a drag on industry. Australia is the only advanced economy which imposes 100% cost recovery on industry to fund its major regulatory agencies. There is little accountability and oversight of regulatory agencies regarding performance against budget. There is no transparency in budget papers regarding outputs and productivity performance as portfolio costings are aggregated. While government departments have been required to apply an efficiency dividend to contain costs and increase productivity, cost recovered regulatory agencies have been able to increase costs and staffing. The recently introduced regulatory performance reporting framework does not address the issue of accountability and performance reporting as the measures are process and not outcomes based. It is difficult to assess if value for money is being achieved by a monopoly provider. Industry has argued for a long time that there should be contestability for some of the services for which the government is currently the sole provider.

Industry's ask is quite simple, we do not ask for public handouts, we simply want the unnecessary burdens on business removed through the application of minimum effective regulation which is internationally aligned and facilitates trade.

Please do not hesitate to contact me should you require clarification on any of the points raised in this submission. I can be contacted on 02 9281 2322, 0422569222 or dsa.ru discourse description of the points raised in this submission. I can be contacted on 02 9281 2322, 0422569222 or dsa.ru discourse description discourse description of the points raised in this submission. I can be contacted on 02 9281 2322, 0422569222 or dsa.ru discourse description d

Yours sincerely

Dusanka Sabic

Director, Regulatory Reform

February 2017

THIS DOCUMENT WAS DEVELOPED FOR

Accord AUSTRALASIA

BY CHRIS HEALEY

OF MEDICINES REGULATORY SOLUTIONS PTY LTD



CONSOLIDATED STAKEHOLDER RESPONSES

NICNAS CONSULTATION PAPER (CP) 3

Purpose

To provide Accord Australasia with a consolidated document that identifies the major issues arising from the stakeholder responses to NICNAS's reform agenda as identified in Consultation Paper 3.

Context

In October 2015, the Australian Government commenced a reform agenda concerning the regulation of industrial chemicals. This agenda seeks to ensure that the assessment of industrial chemicals is more proportionate with the risks posed by such chemicals while ensuring that appropriate health, safety and environmental standards are maintained.

The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) reforms include the following objectives -

- Rebalancing pre- and post-market regulatory requirements to match the indicative risk profile of a new chemical
- Streamlining the existing risk assessment process for new and existing industrial chemicals
- Much greater utilisation of international assessment tools
- More appropriate compliance tools

Consultation Paper (CP) 3

CP3 is the third in a series of four consultation papers which seeks to summarise the main stakeholder comments arising from Consultation Paper 2, as well as building on the themes detailed in CP2 to describe key changes to the reform process. The consultation paper has been drafted in a question and answer format that addresses specific subject matter.

Stakeholder Responses to CP3

A total of thirty-two responses were received by NICNAS in relation to CP3. These responses represented a broad spectrum of stakeholders who, either directly or otherwise, are affected by the current industrial chemicals legislative framework.

Section Specific Responses

Twenty-one of the 32 submissions received included specific comments on the subjects detailed in sections C to M of CP3.

For ease of reference the comments dealing with each section have been tabulated and have been given priority colouring as follows –

Red An issue identified by stakeholders as being of a high priority

Yellow An issue identified by stakeholders as being a medium level priority

Green An issue identified by stakeholders as being of a low priority or not directly relevant

to the consultation process

General Responses

Eleven (11) stakeholder responses to CP3 were general in terms of the comments made and issues raised. These comments have been collated in table form and assigned a priority as detailed above.

SUMMARY OF GENERAL STAKEHOLDER RESPONSES

In order of priority, stakeholder responses have identified the following issues in their general responses -

- Complexity of the proposed reforms and increased regulatory burden, especially for small and medium-sized businesses
- Status of exempted ingredients under proposed reforms
- Integration of the "Accepting Trusted International Standards Policy" into revised legislation
- Acceptance of recognised assessment processes by US, Canadian and European agencies
- No recognition of TTMRA arrangements
- Maintenance of online database for new chemical evaluations

SUMMARY OF STAKEHOLDER RESPONSES TO PART C

THE ROLE OF NICNAS

In order of priority, stakeholder responses have identified the following issues in their responses to Part C of CP3 –

- Concern over increased risk management powers
- Assessment and regulation of cosmetics not appropriate for NICNAS

SUMMARY OF STAKEHOLDER RESPONSES TO PART D

CATEGORISATION OF NEW CHEMICALS AND THE RISK MATRICES

In order of priority, stakeholder responses have identified the following issues in their responses to Part D of CP3 –

- Complexity of risk matrices and the requirement for further refinement to address overly conservative volume banding
- Inclusion of Endocrine Disruptors and Nanomaterials as CMRs in proposed legislative framework
- Proposal to require a greater number of industrial chemicals to be classified as "reportable"
- Excessive regulatory controls concerning cosmetic ingredients
- Proposal to use international authoritative lists in relation to EDs
- Clarification on the use of waivers to fill data gaps
- Lack of clarity around the term "sufficient exposure and hazard information."

SUMMARY OF STAKEHOLDER RESPONSES TO PART E

USE OF INTERNATIONAL INFORMATION AND ASSESSMENTS

In order of priority, stakeholder responses have identified the following issues in their responses to Part E of CP3 –

- Limitations around what is considered an acceptable/trusted international assessment
- Requirement to recognise and align with international standards from comparable economies
- Requirement to work towards common regulatory definitions, data format and language
- Building on the current bi-lateral relationship with the US EPA

SUMMARY OF STAKEHOLDER RESPONSES TO PART F

EXEMPTED AND REPORTED CHEMICALS

In order of priority, stakeholder responses have identified the following issues in their responses to Part F of CP3 –

- Lack of flexibility in relation to proposed Exempt category
- Absence of detailed information concerning data requirements for assessed products
- Requirement for increased recognition of international and local assessments to enable new chemicals to be classed as exempt

SUMMARY OF STAKEHOLDER RESPONSES TO PART G

ASSESSED CHEMICALS AND NICNAS INITIATED ASSESSMENTS

In order of priority, stakeholder responses have identified the following issues in their responses to Part G of CP3 –

- Clarification concerning the grounds and processes for removing chemicals from the AICS, including necessity for this power based on documented instances where risk could not be managed
- Use of information arising from IMAP review to inform current reform processes

TREATMENT OF CONFIDENTIAL COMMERCIAL INFORMATION

Stakeholder responses have identified the following issues in their responses to Part H of CP3 -

- Need for NICNAS to continue to protect confidential information concerning new chemical notifications
- Maintain the confidential portion of the AICS
- Should not be a link between the assessment statement and the AICS entry
- Continued need to use approximated quantitative data to protect identity of compounds
- Masked names on balance this proposal was not supported and the status quo was favoured
- Disclosure of CCI to other Government risk management agencies

SUMMARY OF STAKEHOLDER RESPONSES TO PART I

SECONDARY NOTIFICATIONS AND PROPOSED OBLIGATIONS TO INFORM NICNAS

In order of priority, stakeholder responses have identified the following issues in their responses to Part I of CP3 –

- Increased complexity of proposed reform
- Process for dealing with chemicals with a secondary notification
- Difficulty associated with introducers notifying of new Adverse Events (AEs)

SUMMARY OF STAKEHOLDER RESPONSES TO PART J

MONITORING AND ENFORCEMENT

In order of priority, stakeholder responses have identified the following issues in their responses to Part J of CP3 –

- Publication of enforceable undertakings not supported
- Requirement for an explanatory procedure to support proposed compliance policy
- Evidence of historical non-compliance to support reforms concerning post-market compliance activities

OTHER CHANGES

In order of priority, stakeholder responses have identified the following issues in their responses to Part K of CP3 –

- Numerous suggested changes to current and proposed definitions were made by stakeholders
- Repeal Cosmetics Standard

SUMMARY OF STAKEHOLDER RESPONSES TO PART L

REFORMS PROPOSED FOR EARLY COMMENCEMENT

In order of priority, stakeholder responses have identified the following issues in their responses to Part K of CP3 –

- Support for reforms arising from CP1 to be implemented first
- Clarification around current requirements to continue following implementation of reform proposals

SUMMARY OF STAKEHOLDER RESPONSES TO PART M

TRANSITIONAL ARRANGEMENTS

In order of priority, stakeholder responses have identified the following issues in their responses to Part K of CP3 –

• Proposed timeframe for transition to reform proposals insufficient

GENERAL STAKEHOLDER RESPONSES		
STAKEHOLDER	ISSUES	PRIORITY RATING
3M	Proposed system more complex and	
	information requirements less well defined.	
	Some expedited low volume notifications	
	and fast tracked assessment processes	
	should remain – reforms result in a costly	
	and lengthy approach if chemical is not a	
	polymer or PLC.	
Accord	Proposes an alternative regulatory model to	
	that developed under the reform proposal.	
	This model identifies three classes of	
	industrial chemicals with graduated risk	
	proportionate regulatory requirements for	
	each class. This is consistent with	
	Government's decision to pursue	
	implementation of a system as described in	
	Option 3 of the RIS. This model includes	
	various eligibility criteria for each class of	
	new chemical and the corresponding	
	regulatory requirements, together with Acord's rationale and the available	
ASEAN Cosmetics	safeguards concerning non-compliance. Proposed system highly complex –	
Association	regulatory categorisation too high for	
Association	cosmetics and personal care ingredients.	
	Ensure exempted ingredients have same	
	status under revised arrangements. Exempt	
	polymers.	
	Include "Accepting Trusted international	
	Standards Policy" in Act. Act to be consistent	
	with cosmetic annex of TPP.	
Australian Food and	NICNAS reform proposals increase	
Grocery Council	regulatory burden in relation to cosmetics.	
·	Proposal complex and does not reflect the	
	Government's Competitiveness Agenda. Halt	
	reform process subject to re-assessment.	
Shirebiz	Reforms more complex, no acceptance of	
(Barry Alchin)	accreditation by mainstream US and	
	European bodies.	
Canadian Consumer	Understanding of how Australia/Canada co-	
Specialty Product	operative arrangements will be considered	
Assoc.	and utilised under reform model.	
	Acceptance of Canadian NSN by NICNAS –	
	unclear whether there will be a requirement	
	for additional information to accompany the	
Cancer Council of	NSN. Current system complex – reforms should	
Australia	not result in diminishing health and safety	
Australla	standards. How will reforms improve	
	NICNAS's ability to perform its key role – no	
	clear rationale has been provided.	
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a limited set of information.		·	
ASEAN Cosmetics Limit scope of ICNA to hazardous substances.			
Association Replace proposed assessment process with	Association	·	
use of existing scientific data – avoid		_	
technical barriers to trade.			
Refer to SCCS exposure data to determine			
public health standards concerning cosmetic		•	
ingredient exposure.		-	
Cancer Council of Post-market auditing activities – how will this Australia be managed?			
Ecolab Fully supports Accord submission.		-	

GENERAL STAKEHOLDER RESPONSES		
STAKEHOLDER	ISSUES	PRIORITY RATING
GSK Consumer Healthcare	Repeal of the Cosmetic Standard only acceptable if its content is reflected in the TGA's Excluded Goods Order.	
Haztech Environmental (Jeff Simpson)	Simple tracking of non-hazardous chemicals/products – awareness by NICNAS and community assurance.	
Proctor and Gamble	Existence of TGA's Excluded Goods Order is sufficient regulatory control for cosmetics and personal care products. NICNAS Cosmetics Standard has implied agency has responsibility for these classes of product and not just the chemicals used in same. Repeal Cosmetics Standard to provide increased clarity of roles and responsibilities of relevant regulatory agencies.	
RG Chemical Safety (Richard Greenwood)	Requirement for NICNAS to track all hazardous and non-hazardous chemicals — assists in identifying key changes — allowance for toxicological and eco-toxicological information waivers requires clear explanation.	
Adrian Thomas	NICNAS to repeal the Cosmetics Standard and make parallel changes to the TGA's Excluded Goods Order.	
American Petroleum Institute	Separation of WH&S regulatory requirements re labels and SDSs from any NICNAS requirements. Appropriate protections for confidential	
Shirebiz (Barry Alchin)	commercial information (CCI). Re-locate NICNAS from Health to Industry and Science portfolio – better understanding	
Canadian Consumer Specialty Product Assoc.	of environment and health. Inclusion of fee for service arrangements.	
Cancer Council Australia	Reduction in pre-market assessment – shift towards self-regulation a concern. 38,000 unassessed chemicals on AICS – how will these be assessed?	
Haztech Environmental (Jeff Simpson)	Auditing of small and most medium businesses – problematic due to absence of technical specialists aware of NICNAS requirements.	

PART C – THE ROLE OF NICNAS		
STAKEHOLDER	ISSUES	PRIORITY RATING
3M	Increased risk management powers – refusal of certificates and removal of chemicals for the AICS – absence of case studies to support extended powers – is there Government agreement to these extended powers?	
Accord	Serious concerns in relation to the inclusion of risk management powers in the ICNA Act – at cross-purposes with streamlining the regulatory scheme – will further confuse the roles and responsibilities of the industrial chemicals control system. Based on previous experience where NICNAS imposed conditions above and beyond risk management measures detailed in the SUSMP.	
	Interaction between NICNAS and the new National Standard for Environmental Risk Management of Industrial Chemicals – current process duplicative and a regulatory burden on industry.	
Haztech Environmental (Jeff Simpson)	NICNAS should not be assessing or regulating cosmetic chemicals.	
Australian Paint Manufacturers' Federation	General support – expects industry consultation prior to applying new controls.	
PPG Industries Australia	Supports ability to apply for certificates with conditions.	

PART D – CATEGORISATION OF NEW CHEMICALS AND THE RISK MATRICES (GENERAL)		
STAKEHOLDER	ISSUES	PRIORITY RATING
3M	Assessment period timeframe – 90 days – should remain a statutory timeframe. Clarification on "pausing" the assessment clock while awaiting further information.	
3M	Error on page 14 of CP3 – PBT chemicals may not be suitable for exemption.	
Public Health Association of Australia	Proposed definition for new industrial chemicals introduced into Australia under the proposed reforms does not include the many chemicals already listed on the AICS – vast majority of these have not undergone risk assessment concerning harm to human health or the environment.	

PART D – CATEGORISATION OF NEW CHEMICALS AND THE RISK MATRICES (INTRODUCER RESPONSIBILITIES)		
STAKEHOLDER	ISSUES	PRIORITY RATING
Accord	Duplicative requirements for introducers under proposed reforms and National Standard for Environmental Risk Management of Industrial Chemicals.	
ChemSkill	Concern that small and medium-sized enterprises (SMEs) will not have the resident expertise to interpret regulatory requirements – explanations/interpretations concerning requirements needed for SMEs.	

PART D – CATEGORISATION OF NEW CHEMICALS AND THE RISK MATRICES (HAZARD CHARACTERISATION)		
STAKEHOLDER	ISSUES	PRIORITY RATING
3M	Increased complexity of the scheme in having two matrices – one for health and one for environment.	
Accord	Concerned at the proposed level of hazard characterisation required to substantiate the non-hazardous nature of a chemical to meet the Exempted classification.	

PART D – CATEGORISATION OF NEW CHEMICALS AND THE RISK MATRICES (HAZARD CHARACTERISATION)		
STAKEHOLDER	ISSUES	PRIORITY RATING
ChemSkill	Proposal's requirement to make classify more industrial chemicals as "reported" – reliance on waivers – requires specific clarification and consultation on this aspect of the reforms.	
European Chemical Industry Council	Reference to "sufficient exposure and hazard information" — term lacks clarity and can be equivocal — more clarity on data requirements needed. Strategy to fill data gaps — mention of waivers but no indication how nontest data can be used to confirm or otherwise the hazardous properties of a chemical.	
Fire Protection Association Australia	Inclusion of CMRs in human health matrix with EDs and nanomaterials — not all EDs and nanomaterials are CMRs — automatically classified as a higher hazard under this proposal — requires differentiation and EDs and nanomaterials to be included in a hazard band D, not E.	
Plastics and Chemicals Industry Association	Proposed risk matrix requires further refinement to deliver on the Government's commitment to reform — where the assessment effort is proportionate to risk. Current proposed volume banding is overly conservative when measured against exposure. De minis threshold should be increased to support a more proportionate risk base level.	
Proctor and Gamble	Proposed risk matrices complex and exclusive to Australia. NICNAS' approach to hazard categorisation and the level of requirement to allow a known chemical of a non-hazardous nature to be classified as "exempt" is of concern. The 'exempt' category is overly strict and unreasonable for industry.	
	Environmental matrix and release scenarios – need to consider release volume across all types/forms of industrial chemicals. The default assumption of 100% release volume for things such as cosmetics, household goods without considering,	

PART D – CATEGORISATION OF NEW CHEMICALS AND THE RISK MATRICES (HAZARD CHARACTERISATION)		
STAKEHOLDER	ISSUES	PRIORITY RATING
317 III ZIII ZIII	for example, chemical reaction and	THISTHIT IN THIS
	product usage – not sensible or	
	pragmatic.	
Public Health Association	Doesn't support submissions that	
of Australia	industrial chemicals categorised as	
	non-hazardous should be exempt	
	from the legislative framework. No	
	community confidence when there is	
	no public listing for all chemicals	
	introduced or in use in Australia.	
	Believes there is potential for mis-	
	classification and an unacceptable risk	
	when exempted chemicals are	
	regulated via industry decisions.	
	Supports human bio-monitoring.	
US Personal Care Product	Disappointed in relation to the	
Council	classification of cosmetic ingredients	
	as high risk based on "relatively	
	greater exposure" resulting in lower	
	volume threshold compared to other	
	industrial chemicals. NICNAS not	
	aligned with other major markets by	
	using a starting point of 100kg per year	
	for the lowest limit for cosmetic	
	products.	
	Data requirements required to	
	categorise a new chemical as exempt	
	 extremely onerous – increases time to market. 	
Wilson Consulting	Proposed matrice banding assumes all	
Wilson Consuming	per and poly-fluorinated chemicals	
	have the same hazard profile – human	
	health matrix band D and	
	environmental matrix band E –	
	misleading and inconsistent in terms	
	of each matrix.	
Adrian Thomas	Establish a separate evaluation	
	pathway for chemicals being assessed	
	for commercial evaluation.	
3M	No clear guidance on acceptance of	
	analogues and non-animal test	
	methods.	
Fire Protection Association	Environmental hazard matrix Band E –	
Australia	no mention of Persistent Organic	
	Pollutants (POP) as listed by the	
	Stockholm Convention.	
	Grouping all perfluorinated or	
	polyfluorinated chemicals into	
	environmental hazard matrix Band E –	
	considered restrictive.	

PART D – CATEGORISATION OF NEW CHEMICALS AND THE RISK MATRICES (HAZARD CHARACTERISATION)			
STAKEHOLDER	ISSUES	PRIORITY RATING	
GSK Consumer Healthcare	Use of FDA GRAS and recognition by FSANZ then no further assessment by introducer should be required.		

	ORISATION OF NEW CHEMICALS AND TH	
STAKEHOLDER	ISSUES	PRIORITY RATING
Accord	Volume thresholds as set out in proposed reforms are prohibitively small and disadvantage Australian introducers due to the disproportionate level of regulatory scrutiny required – volume thresholds implemented must reflect modern regulatory science.	
European Chemical Industry Council	Consider a de minimis threshold for exemption/reporting depending on known hazard profile. Exempted criteria under reform proposal overly strict – full set of hazard data required to make an assessment – makes this category impractical and less meaningful for industry.	
Shiseido	Does not agree that the annual exposure threshold for cosmetics should be set at 100 kg/year. Should be harmonised with other international regulatory schemes.	
Unilever	Concerned about the punitive volume thresholds for cosmetic products.	
United States Council for International Business	No justification for treating cosmetic ingredients as a higher risk than other industrial chemicals. Australia's regulatory model needs to be harmonised with trading partners.	
The Estee Lauder Companies	Reforms don't address low volume and introductory exemptions.	
Plastics and Chemicals Industry Association	Concerned that the proposed ≤ 1% concentration rule will adversely affect Australian manufacturers.	

PART D – CATEGORISATION OF NEW CHEMICALS AND THE RISK MATRICES (TRANS-SHIPMENT AND CONTAINED IMPORT/EXPORT CHEMICALS)		
STAKEHOLDER	ISSUES	PRIORITY RATING
Accord	Transhipment and contained import/export chemicals should be excluded from new chemicals obligations.	

PART D – CATEGORISATION OF NEW CHEMICALS AND THE RISK MATRICES (ENDOCRINE DISRUPTORS, CMR AND NANOMATERIALS)		
STAKEHOLDER	ISSUES	PRIORITY RATING
Australian Paint Manufacturers' Association	Concerned that terminology of nanomaterials will inadvertently capture common paints and coatings – supports limiting regulation to industrial nanomaterials.	
BASF Australia	Inclusion of Endocrine Disruptors (EDs) in the same hazard band D — human health — as CMRs. Ignores fundamental differences between these substances — endocrine disruption may be one possible mode of action for the induction of CMR effects, therefore "covered" by the indicative CMR criteria. Separate listing creates wrong impression, is inappropriate and should be avoided. Fail to understand the allocation of EDs in different hazard bands for human health and environment — identification should take place on a population level in the environment — doesn't trigger a difference in the assessment of hazard — requires clarification. Identification of EDs should be based on the internationally accepted WHO/IPCS definition of an ED as a scientific basis. Not appropriate that nanomaterials have been assigned to the most hazardous bands of the human health and environment matrices — risk assessment on a case-by-case basis is required due to variable toxicity. Proposal will prevent innovation.	
European Chemical Industry Council	Disagrees with the proposal to use international authoritative lists of recognised EDs while there is no internationally accepted definition or	

PART D – CATEGORISATION OF NEW CHEMICALS AND THE RISK MATRICES (ENDOCRINE DISRUPTORS, CMR AND NANOMATERIALS)

STAKEHOLDER	ISSUES	PRIORITY RATING
STARLITOLDER	scientific criteria to identify and	TRIORITTRATING
	confirm the ED properties of a	
	chemical. Regulation of chemicals	
	based on "suspected" EDs not	
	supported. Should be based on	
	WHO/IPCS definitions.	
	Non scientific evidence to consider	
	nanomaterials as a group of hazardous	
	chemicals per se – composition and	
	material properties determine toxicity.	
	Internationally validated testing	
	methods can be used to test the toxicity	
	of nanomaterials. Assessment required	
	on a case-by-case basis.	
Haliburton	Concerned chemicals will be screened	
	for ED hazards when no authoritative	
	ED list exists. Concerns with using	
	endocrine disruption as a criterion in	
	matrix and assigning the highest hazard	
	level to it.	
Plastics and Chemicals	Endocrine disruption is a model of	
Industry Association	action which has the potential to	
(PACIA)	induce hazards – proposal to introduce	
	EDs into framework needs to be	
	scientifically sound and pragmatic.	
	Proper consultation required in relation	
	to the development and use of any	
	future authoritative lists. Unclear how	
	NICNAS defines endocrine disruption –	
	should be based on WHO/IPCS	
	definition. Additional information also	
	required about the hazard	
	characterisation.	
	Proposed reforms assume high risk on	
	all nanomaterials based on its physical	
	state without consideration of its	
	toxicological properties and exposure.	
Proctor and Gamble	Proposal to assign an "assessed"	
Troctor and dampic	categorisation to all CMRs is out of step	
	with current approaches in comparable	
	markets, eg EU and Canada. Automatic	
	"assessed" categorisation not	
	warranted so long as safety control	
	principles not compromised.	
United States Council for		
	Concerned the proposed reform to include EDs is not evidence or risk-	
International Business		
Characteristic	based.	
ChemSkill	No authoritative ED lists available – will	
	this be subject to a generic waiver?	

PART D – CATEGORISATION OF NEW CHEMICALS AND THE RISK MATRICES (POLYMERS)		
STAKEHOLDER	ISSUES	PRIORITY RATING
Adrian Thomas	Expand number of polymers to that come under the PLC definition to achieve greater international alignment.	

PART D – CATEGORISATION OF NEW CHEMICALS AND THE RISK MATRICES (THE ENVIRONMENT MATRIX)		
STAKEHOLDER	ISSUES	PRIORITY RATING
Accord	Concept of considering release volumes rather than introduction volumes when assessing likely environmental impacts is only effective if realistic scenarios are considered for all classes of industrial chemicals. The default assumption of 100% emission for all classes of industrial chemicals, other than printing inks and paints and coatings (as developed by the OECD) is unrealistic.	
	Wash off cosmetics and personal care products do not directly enter the environment the way some industrial or factory-use products might — completely different scenario to cleaning chemicals used in industry — any risk assessment which assumes complete emission of chemicals in personal care, cosmetic and household cleaners straight into the environment does not reflect environmental reality.	

STAKEHOLDER Accord Previous suggestions relating to recognition of international regulations and standards, including ingredient Annexes of the Cosmetic Regulation and IFRA standards to avoid duplicative reassessment and animal testing not well understood. Small number of chemicals on AICS compared with US and European inventories poses a significant problem for Australian industry — must recognise global activities to avoid costly reassessments etc. European Chemical Industry Council Expectation that regulators work towards common regulatory definitions, data format and language to prevent regulatory divergence, allow transferability and reduce the need for duplicative testing—global data sharing. Plastics and Chemicals Industry Association industry has access to latest chemistry at the same time as overseas competitors — achieved through accepting assessments carried out by trusted overseas regulators. Needs to be discretionary acceptance of overseas regulatory decisions. Proctor and Gamble NICNAS position on what is an acceptable/trusted international assessment — if jurisdiction is operating on equivalent principle and similar control for the safety of the chemical — no need for a duplicate assessment. Additional NICNAS assessment adds further complexity and places an
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additional burden on industry. NICNAS
encouraged to look neighbouring Asia-
Pacific markets in terms of acceptance
of assessments etc.
Public Health Association Advocates for more timely assessment
of Australia of information relating to overseas bans
of chemicals.
Encourages further work with the US
EPA through current bi-lateral
relationship.
Unilever NICNAS to consider how it can recognise
and align with international standards
from comparable economies while
maintaining public health and safety.
Smaller manufacturers and importers
rely on existing international standards

PART E – USE OF INTERNATIONAL INFORMATION AND ASSESSMENTS		
STAKEHOLDER	ISSUES	PRIORITY RATING
	by virtue of the origin or the raw materials used in their products.	
3M	Advocates for strong links with US EPA	
	to facilitate use of chemical	
	assessments.	
Australian Paint	NICNAS to build on its current bilateral	
Manufacturers' Federation	relationship with the US EPA.	
European Chemical	Recommends expansion of assessment	
Industry Council	acceptances – equivalent principles and controls.	

PAR	F – EXEMPTED AND REPORTED CHEMICA	ALS
STAKEHOLDER	ISSUES	PRIORITY RATING
3M	Lack of flexibility diminishes the reform proposals — Exposure Band 2 moves most Limited notifications to Reported — due to notifications being submitted in the Limited Category being partially based on volume and limited data availability. Rare occasions where full toxicological data set available and where all endpoints are non-hazardous to utilise the exempted category. Practically, the exempted category in Exposure Band 2 will have very little use aside from PLCs. Proposal just	TRIORITINATING
	moves current exemptions to reported chemicals and associated requirements.	
Accord	Current NICNAS exemption categories used for some time with no demonstrable failure – requirement to alter this given no identified unacceptable risk? Proposed risk matrix model adopts a	
	"one size fits all" approach – chemicals in formulated products subject to same regulatory treatment as single chemicals where well-defined and different risk profiles exist.	
	Proposed reforms will see the majority of chemicals currently under exemption will transition to the proposed Reported category – increase in regulatory burden.	
Croda	Detailed information on data requirements for assessed products required. Critical to understanding how reform will affect the regulatory burden on substances imported in high volume.	
Unilever	Supports immediate acceptance of new chemicals into the Exempt category if they are polymers, comply with requirements of EU Cosmetic Regulation or NZ Cosmetic Products Group Standard Schedules, comply with IFRA standard, assessed by CIR, accepted by TGA, APVMA and/or FSANZ or comparable overseas regulator, in formulated products complying with EU, NZ, US or Canadian requirements and currently in	

	commerce and included in the US FDA GRAS list.	
PART G – ASSESSED CHEMICALS AND NICNAS INITIATED ASSESSMENTS		
STAKEHOLDER	ISSUES	PRIORITY RATING
3M	Proposal to remove chemicals from the AICS – evidence by NICNAS of instances/new chemical reviews where the risk could not be managed. Clarification required on grounds and process to remove a chemical from the AICS.	
Accord	A specified standard of information is needed in order to initiate an assessment or a mandatory call for information, including that the information has a sound scientific basis for concern and is from a credible source. The NIA process must provide business certainty for industry and ensure public confidence in the NICNAS assessment process.	
3M	Not aware of finalisation of IMAP review and how this will inform the current process.	
ChemSkill	Suggests contacting introducers that have utilised CEPs to gain their views.	
Haliburton	Recommends an increase in the allowable tonnage limit for commercial trials for low-risk or non-hazardous chemicals.	

PART H – TRF	ATMENT OF CONFIDENTIAL COMMERCIAL INI	FORMATION
STAKEHOLDER	ISSUES	PRIORITY RATING
3M	Protection of CBI is a critical topic globally – NICNAS should continue to protect confidential information in new chemical notifications and maintain the confidential portion of AICS – will not continue under proposed reforms.	
	Companies need to claim chemical identity, submitter identity and specific use as confidential. Link between assessment statement and	
	AICS entry – provided assessment statement has been redacted to protect substantiated CBI claims.	
	Increasing difficulty in having confidentiality claims accepted by NICNAS – should be able to withdraw an assessment certificate to provide protection and security to CBI.	
Accord	Industry does not support the implementation of masked names — offers little in the way of protecting chemical identity — system inherently flawed.	
	Status quo, including the option to list on the confidential AICS, is necessary to maintain current CCI protections.	
	Disclosure of CCI to an enquirer is not acceptable. Information provided should be limited to listing on confidential AICS and any specific restrictions or conditions of use.	
	Disclosure of CCI to other government authorities and international regulators should only occur after permission has been granted by the owner of that information.	
5 Chariad	The proposal to link the assessment statement to the AICS entry for all assessed chemicals has serious implications in terms of protection of IP.	
European Chemical Industry Council	Removal of confidential inventory and replacement with masked names on AICS – prefer option 2 as detailed in CP3. If link provided to assessment certificate NICNAS would be disclosing substantial CCI.	
Haliburton	In order to protect the identity of a compound, will the approximation of quantitative data by providing ranges or limits still be an acceptable practice under the proposed reforms?	

PART H – TREAT	MENT OF CONFIDENTIAL COMMERCIAL IN	IFORMATION
STAKEHOLDER	ISSUES	PRIORITY RATING
	Requests that no information, other than the AICS listing status and whether or not the proposed use is within the scope of the assessed use, be extended for bona fide proposed chemical introductions. Introducer to be notified before CCI disclosed to other Government risk management agencies.	
Proctor and Gamble	Do not support the implementation of masked names – will discourage entry of innovative chemicals and products as minimal protection offered to the introducer. Approach concerning bona fide enquiries should be the same as is currently occurring – provision of a link on AICS entry to the assessment statement would be disclosing substantial information with no appropriate intellectual property/innovation protection.	
United States Council for	The proposed reforms must protect CCI	
International Business 3M	for publishing risk assessments. Masked names – supports development of structurally descriptive generic names where a specific chemical identity is confidential. Also supports development of generic use information where a specific use in an assessment is a trade secret.	
Australian Paint	Retention of confidential section of AICS	
Manufacturers' Federation	favoured over use of masked names.	
3M	Prefer the retention of the term CBI.	

PART I – SECONDARY N	IOTIFICATIONS AND PROPOSED OBLIGATIO	NS TO INFORM NICNAS
STAKEHOLDER	ISSUES	PRIORITY RATING
3M	Confusing – adds complexity to an already complex scheme –	
	contradictory statements – p41 of CP3. Difficult to see the benefits to a notifier as flexibility will be determined by the	
	defined scope of assessment.	
Accord	More information required concerning the ability of the Director of NICNAS to impose an obligation specific to a	
ChemSkill	chemical or class of chemicals. How will NICNAS deal with chemicals	
	that have a Secondary Notification associated with them? Only applicable to new chemical entities and not retrospective due to information currently available? Secondary Notifications on current AICS listed chemicals required to stay in place? Consultation paper doesn't deal with this issue. Major impact as there are currently around 600 chemicals with Secondary Notification conditions.	
Proctor and Gamble	Notification of new Adverse Events (AEs) to NICNAS by introducers – not simple when importing finished goods – numerous chemicals – root cause of AE?	

PART J – MONITORING AND ENFORCEMENT		
STAKEHOLDER	ISSUES	PRIORITY RATING
3M	Does not support the publication of enforceable undertakings.	
Accord	Proposed reforms suggest little in relation to an increased reliance on post-market audit and compliance activities – still appears to favour high pre-market regulatory requirements – existence of current information on non-compliance to justify proposed reform in this area? Does not support the publication of enforceable undertakings – publication should be limited to general data only.	
Adrian Thomas	Does not support the publication of enforceable undertakings.	
ChemSkill	Explanatory procedure to support compliance policy for SMEs.	
GSK Consumer Healthcare	Minor non-compliances should not be enforceable or published. Higher risk non-compliances should be enforceable.	
Plastics and Chemicals Industry Association	Does not support the publication of enforceable undertakings. Details of enforceable undertakings should also be exempt from FOI requirements.	

PART K – OTHER CHANGES			
STAKEHOLDER	ISSUES	PRIORITY RATING	
3M	Provision of the revised definition of "article" for review.		
Accord	Supports Cosmetic Standard being repealed as it mirrors the provisions of the TGA's Excluded Goods Order No. 1 (2011).		
Chemskill	Current definitions in ICNA – proposed changes?		
Adrian Thomas	Changes should be made to the definition of "new synthetic polymer" to achieve closer alignment with the approach taken by the US and Canada.		
ChemSkill	NICNAS implementation of decision to transfer the Cosmetics Standard to ACCC – how is this being implemented?		

PART L – REFORMS PROPOSED FOR EARLY COMMENCEMENT			
STAKEHOLDER	ISSUES	PRIORITY RATING	
Accord	Re-iterates submission to CP1 concerning early implementation of IFRA Standards and relevant EU Annexes, shorter timeframes for assessments with information from international assessments, no annual reporting under 821 AA of the ICNA Act, faster market entry for the current SA-PLC and for non-hazardous chemicals currently eligible for self-assessment and faster market entry for chemicals at ≤ 1% in all formulated products regardless of the introduction volume.		
Australian Paint Manufacturers' Association	Believes early harvest reforms identified by stakeholders as a result of CP1 should be implemented.		
ChemSkill	Clarification required on requirements that would still apply following implementation of reform proposals.		

PART M – TRANSITIONAL ARRANGEMENTS				
STAKEHOLDER	ISSUES	PRIORITY RATING		
3M	Transitional timeframe of 12 months is			
	insufficient. Recommend 2 years to			
	minimise impact on business.			
Proctor and Gamble	NICNAS encouraged to adopt step-wise			
	transitional arrangements – suggest 2			
	to 3 years from commencement of			
	reforms. Prefer no retrospective			
	transition of ingredients already			
	provided to NICNAS.			
Accord	Tiered or step-wise transitional			
	arrangements may be appropriate			
	based on consideration of several			
	factors.			
Plastics and Chemicals	Permits and certificates issued under			
Industry Association	the current regulatory regime should			
	still be valid until their expiry date.			