Dear Madam/Sir

Accord provides this submission in response to the Discussion Paper on the Review of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) of June 2012 (the Discussion Paper). Accord also appreciates the extension of time to lodge our submission.

By way of overall comment, very disappointingly the Discussion Paper:

- appears to have ignored both the Productivity Commission’s earlier review and stakeholder submissions received for this Review
- is somewhat narrower than the stated objective of the Review; and
- does not expand the options being considered in any policy context.

There also appears to be limited understanding of the broader system of chemicals regulation i.e. ‘how the system fits together’ and we would question the evidence base and objectivity applied to the rationale behind some of the options, which seem overly influenced by the self-interest and indeed expansion of the role of NICNAS.

Further, and most importantly, the options presented fail to adequately differentiate between the very distinct risk assessment and risk management functions within the system, nor do they acknowledge the wide spectrum of chemicals to be assessed. In fact many of the options put forward are contrary to improving clarity in the role and responsibilities of the respective regulators.

**Earlier Productivity Commission Review and Stakeholder Submissions**

Accord made a number of detailed and considered policy recommendations for chemical regulation improvements in our submission of 11 January 2012.

There appears to be no consideration and/or critical analysis of these in the Discussion Paper and therefore industry is left seriously questioning the rationale behind the call for these initial submissions or indeed the objectivity with which the Review has been undertaken.

Our recommendations put forward a comprehensive programme for reform based on the recommendations contained in the Productivity Commission’s (PC) research report *Chemicals and Plastics Regulation* (July 2008).

They included recommendations for improvements to national hazard and risk management with particular reference to PC Recommendation 4.3 – NICNAS’ role as a scientific assessment body.
There appears to have been no consideration in the Discussion Paper of this recommendation; and instead many of the options presented in the Paper would seem to run entirely counter to the following:

**Recommendation 4.3**

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 Chemicals Substances to ban or phase out chemicals, and the responsibilities for administering the Cosmetics Standard 2007, and for implementing the Rotterdam Convention, should be removed from NICNAS.

**Response**

COAG welcomes the response of the Commonwealth as set out below.

The Commonwealth Government agrees with the intention that the primary role of the National Industrial Chemicals Notification and Assessment Scheme’s (NICNAS) should be as a scientific risk assessment body for industrial chemicals, noting that any change to current arrangements should not introduce regulatory gaps that would weaken health and environmental protection.

In light of the Productivity Commission’s preferred governance framework, the Commonwealth Government supports further efforts to clarify the role of NICNAS and ensure that the institutional location of standard setting and risk management powers provide a cohesive and integrated industrial chemicals framework across Commonwealth and state and territory regulatory authorities.

In this regard, reducing the power of NICNAS to annotate the Australian Inventory of Chemical Substances requires further consideration to ensure that the existing levels of human health and environmental protection are maintained and that equivalent powers are established in another national body.

The Commonwealth Government supports the transfer of responsibility for implementing the Rotterdam Convention from NICNAS to the Department of the Environment, Water, Heritage and the Arts (DEWHA).

The transfer of responsibility for the Cosmetics Standard is dealt with under Recommendation 5.5.

The options put forward in the Discussion Paper give little confidence to industry that the PC report has been properly considered and even less confidence that the intention is to implement the improved and streamlined system proposed by the Commission and agreed by COAG.

Notwithstanding, Accord has provided detailed comments for each option contained in the Discussion Paper – these can be found at Attachment 1.

Accord’s submission of 11 January 2012 was based on the aforementioned cohesive and integrated industrial chemicals framework and included a detailed plan for moving forward.

We resubmit our submission (see Attachment 2) and request that it be given proper consideration.

To summarise, the key features of Accord’s proposal for a more efficient and effective chemical regulatory framework for Australia, include:

- Risk management through risk prioritisation of industrial chemicals with a focus on hazardous chemicals - risk management decisions would be made by three independent expert bodies in the areas of OHS, public health and safety and the environment
• Harmonising the regulatory treatment of new industrial chemicals with that of other advanced economies to improve Australia’s competitiveness and innovation
• Removing cosmetic products and ingredients from the scope of industrial chemicals regulation and harmonising their treatment with that of the EU, ASEAN economies and New Zealand
• Lowering the costs of regulation through notification only of certain low risk categories such as polymers, non-hazardous new chemicals and recognition of chemicals on international inventories
• Introducing a new definition for “new industrial chemical”
• Developing an Australian Integrated Chemical Inventory (AICI); and
• Clarifying roles and responsibilities for the distinctly different functions of risk assessment and risk management as represented in Figure 1.

Streamlining the management of chemicals in Australia, would refocus regulators at the high end of the risk spectrum as well as reduce unnecessary costs on industry, facilitating a more innovative and competitive chemical manufacturing sector for Australia without undermining public health and safety.

Figure 1 of our submission is a diagrammatic representation of how the proposed new model could operate (whereas Figure 2 represents the current arrangements). As highlighted in Figure 1 the advantages of this improved system are reduced fragmentation, overlap and duplication.

The revised NICNAS function (i.e. as the Scientific Assessment body) would see this agency responsible for an existing chemicals programme, maintaining the proposed Australian Integrated Chemical Inventory (AICI), maintaining a register of introducers and assessing new industrial chemicals referred to it by one of the risk management bodies.

However, to maximise the efficiency of the system, the circumstances of what constitutes ‘new’ should be redefined. For example, to be considered ‘new’, a chemical would not be in commercial use in an approved comparable advanced economy, not appear on an inventory in those economies and would be of a hazardous nature.

Any new non-hazardous ingredient would only require notification, as is currently the approach of New Zealand.

The risk management entities would play a greater role in determining a ‘new’ chemical entity for the purposes of Australian regulation.

This would have the advantage of facilitating more rapid introduction of innovative chemical entities at a lower cost for Australia - those with a history of safe use and prior approval from carefully selected advanced economies which Australia would recognise as having comparable (or superior) chemical assessment and management systems in place.

Through this, Australia would leverage the technical expertise from these economies, rather than re-create a costly and burdensome system which is duplicative and stifles innovation and competition. This streamlined approach would align with the way New Zealand already efficiently and effectively manages its hazardous substances.

While this is a departure from the current arrangements, it does not lessen the control of chemicals; rather it appropriately recognises assessments and hazard decisions undertaken by comparable advanced economies with which Australia trades and from which the vast majority of chemical innovations emanate.
National sovereignty on the control of chemicals in Australia is maintained through the risk management bodies, being expert bodies with the power to take advice about the use (and any relevant limitations) from a range of sources including overseas entities or Australia’s own scientific assessment body.

**Narrower than the Objective of the Review?**
Perplexingly, the Discussion Paper states … As the review focusses specifically on NICNAS and the assessment and regulation of industrial chemicals, this review will not address the institutional and regulatory arrangements for chemicals more broadly (p6). This limited interpretation of the role of the Review appears to contradict the objective for the Review as outlined on the DoHA website and contained in the Discussion Paper:

**Objective**
The review will investigate how the regulatory settings may be improved to enhance both the competitiveness of the Australian chemical industry and public health and environmental outcomes. The review will include, but is not limited to, assessing and making recommendations in relation to:
- the role and functions of NICNAS as set out in the Act and the extent to which they adequately reflect stakeholder expectations and international best practice, having regard to the broader context of chemicals regulation in Australia;
- the governance and consultation arrangements of NICNAS and the extent to which they support the effective delivery of NICNAS’ functions;
- the efficiency and effectiveness of NICNAS’ operating arrangements and business processes, with particular regard to the protection of human and environmental health, the management of risk, and compliance costs for business; and
- any implications for the resourcing of functions currently cost recovered, should the review recommend changed responsibilities.

The review will have particular regard to the recommendations of the Productivity Commission Research Report: Chemicals and Plastics Regulation, July 2008 and relevant commitments made under the Council of Australian Governments’ Seamless National Economy National Partnership Agreement.

**Policy context?**
There appears to be no real consideration of recommendations in the context of the Government’s reform agenda for a seamless national economy nor of Australia’s trade policy goals including our nation’s role in international efforts aimed at removing trade obstacles such as unique domestic regulatory requirements, despite this being cited as an element of the Review.

Key to this policy are the number of bilateral and multilateral trade agreements currently under negotiation as well as the Ministerial Agreement for the APEC regulatory cooperation plan which has a particular focus improving regulatory efficiency and effectiveness through enhanced co-operative activities. A copy of the APEC plan is provided at Attachment 3.

Further, the Government is currently involved in discussions on the Trans Pacific Partnership (TPP) which involves the following negotiating partners: Brunei Darussalam, Chile, New Zealand, Singapore, Peru, Vietnam, Malaysia, Mexico, Canada, Australia and the USA. Japan has indicated that it too is interested in joining the negotiations. Of importance to the TPP negotiations is the consideration of a specific Cosmetic Annex.

Accord believes that the timing of these TPP negotiations with the NICNAS Review presents an opportunity for helpful reform for the cosmetic products sector.

This does not mean an opting for greater complexity by trying to cobble an Annex to the ICNA Act, but instead the more streamlined removal of these products from the scope of industrial chemicals in order
to harmonise their regulatory treatment with that of our TPP partners and the ASEAN Economic community.

Both the high priority being given to the TPP Agreement by the Australian Government and the steady progress being made during its negotiating rounds, makes this the best opportunity for further international and domestic harmonisation of cosmetics regulation.

While we understand that the Discussion Paper cannot pre-empt the Australian Government’s decision with regard to the final outcome of the TPP negotiations, a discussion of the relevance of this work to the final outcome of Australia’s regulatory position would have been useful.

Accord strongly supports the inclusion of a “Cosmetics Annex” in the TPP negotiations to achieve closer alignment of international regulations for our highly globalised industry. We believe that regulatory alignment (and approvals recognition) for cosmetic and personal care products is critical to facilitating trade, in order to provide the safe, quality products sought after by Australian consumers, and indeed all consumers globally. We are convinced that the TPP agreement would contribute to the industry’s growth and competitiveness, both within Australian and internationally.

Evidence base and objectivity?
The Discussion Paper appears to have been heavily influenced by NICNAS’ self-perpetuation and/or expansion rather than an objective assessment of regulatory best practice.

In the internal report on Efficiency and Effectiveness Review of the National Industrial Chemicals Notification and Assessment Scheme (January 2012) there is clear evidence that NICNAS does not understand its role within Australia’s chemical management framework.

NICNAS is a notification and assessment scheme for chemical entities – it does not control chemicals – this is the responsibility of the states and territories. NICNAS’ apparent frustration at not having its risk management recommendations taken up in a timely manner by states and territories is now being promoted as a regulatory gap.

The PC, following multi-stakeholder engagement and sound evidence-based assessment, found the chemical regulatory system was effective but not efficient. NICNAS’ internal review also found that “A strong indicator of organisational effectiveness is the fact that there has not been a significant, acute industrial chemical-related incident in Australia in the past 20 years (p3).”

While the Discussion Paper makes references to regulatory gaps and/or has difficulty clearly identifying a regulator in a specific case, this speaks more to a lack of understanding of how the system fits together and indeed underpins the need for greater clarification of roles and responsibilities.

In its chapter on national hazard and risk assessment, the PC report did not make reference to any identified regulatory gaps. Instead the PC argued that ‘Further functional separation is warranted and may be relatively easy to achieve. NICNAS is already primary a chemical assessment body with limited regulatory power. Limiting NICNAS’s regulatory powers to those necessary to undertake the assessment function need not have a significant effect on the management of chemical risk (p63).

The states and territories have certain responsibilities regarding enforcement in relation to public health, OHS and environmental issues over which the Commonwealth has limited jurisdiction. Any encroachment on the roles and responsibilities of the states and territories should raise significant constitutional issues, particularly if the Commonwealth sought to usurp their risk management powers.

As such, it is the prerogative of the risk managers to make decisions regarding the use or otherwise of industrial chemicals. NICNAS can make recommendations based on risk assessment but the risk
managers must also weigh up the recommendations and balance these with additional information and other priorities such as an impact assessment of the economic and social consequences of imposing such conditions upon the regulated sector.

This is something which NICNAS does not do and perhaps should be required to do, when making any recommendation which has an effect upon the way industry behaves. This is consistent with PC recommendation 4.1:

*The Australian Government should impose a statutory obligation on NICNAS to ensure that:*

- *the costs of chemical assessments are commensurate with the risks posed by the chemicals concerned*
- *its assessment priorities are directed to the most efficient management of the aggregate risk of all industrial chemicals.*

Hence a reason why NICNAS recommendations may not be taken up by risk managers in a timely way may be because they lack validity in the context of the aforementioned parameters and/or international risk management and/or the spectrum of risk across all industrial chemicals.

Very often industry has experienced NICNAS making recommendations for use which is not consistent with their regulatory treatment elsewhere. Risk managers have the responsibility to ensure that decisions are relevant, substantiated and can be implemented.

It has not been adequately explored why it is suggested that risk managers are somehow at fault when they do not adopt NICNAS recommendations – rather the question should be asked if the correct risk management recommendations are being put forward, whether all the issues have been adequately considered and/or are capable of being implemented.

We note in contrast that chemical scheduling decisions are generally taken up by the states and territories in a timely manner. The advice of an independent expert committee which also includes representatives of the states and territories is a better model than an independent agency which has no independent expert oversight or source of advice to ensure the quality and relevance of the decision making.

Again, this was another recommendation of the PC research report which has failed to materialise. Recommendation 4.2 stated:

*The Australian Government should establish a technical advisory committee within NICNAS, as a statutory requirement.*

Likewise, the NChem proposals for better national coordination of environmental risk management for industrial chemicals, which ironically has continued to be delayed due to the failure to reform NICNAS as per PC recommendations, are also designed to ensure better quality risk management decisions that could be more readily adopted by the states and territories.

It is a disappointment to industry and no doubt also to other NGO groups that years of policy development for NChem within federal and state environmental policy portfolios and, with input from industry and environmental groups under the direction of a ministerial council, have been delayed due to inaction in reforming NICNAS as per PC recommendations.

The strength of the chemical scheduling system and the NChem model is that experts with on the ground experiences make the risk management decisions for chemicals that would pose a public health or environmental risk. In comparison, it is a naïve policy maker indeed who would think that a desk-bound scientific assessor in an agency like NICNAS can make appropriate risk management decisions.
**Risk assessment versus risk management**

Regrettably, the limitations of the Discussion Paper only serve to demonstrate the lack of understanding of the difference between risk assessment and risk management regulatory functions. Many of the options do not even appear to accept the argument that there is a need for a clearer delineation of roles and responsibilities between risk assessment and risk management functions – as mentioned previously they run counter to that objective and serve to further confuse the distinction.

NICNAS assesses chemical entities, not finished products. Risk managers make the decisions regarding end use and the resultant regulatory controls around particular ingredients are based on their hazard assessment and use profile.

It is important to note that NICNAS does not make risk management decisions in relation to exemptions. These are statutorily based in the ICNA Act. The decisions are self-assessable by the introducer. The need for NICNAS to seek a further role in this process has not be adequately substantiated and only reinforces both the risk-averse nature of the current administration as well as a propensity to expand operations without regard to either efficiency, effectiveness or policy.

However, industry has serious concerns with NICNAS’ power to restrict the use of ingredients under permit conditions. There are instances when the regulator seemingly makes a decision for the use of an ingredient in a manner which is entirely unique to Australia. Such decisions are not transparent, not adequately scrutinised and such controls should probably be referred to the Advisory Committee on Chemical Scheduling (ACCS). It is certainly not helpful to Australian industry when trying to export product which they cannot formulate to international standards because of such NICNAS-imposed restrictions, nor for importing companies which are required to reformulate global products just for the Australian market.

The 100% cost recovery nature of NICNAS also impedes action in this area as it will now cost more than $4,000 for businesses to seek a variation to an assessment report. It will be cheaper for businesses to go to the Administrative Appeals Tribunal, costing $831 for a review of a decision.

And this is precisely what the PC recommendation 4.3 was endeavouring to overcome – to create an environment whereby the appropriate risk assessment and risk management decisions were made with consistency and transparency so that industry had certainty with regard to the chemical ingredients it wished to use.

For example, the enhanced disclosure requirements under the new national work, health and safety legislation has further obviated the need for NICNAS involvement in many OHS issues i.e. streamlining of policy controls in the workplace should ensure that these controls are the sole prerogative of Safe Work Australia.

Notwithstanding, NICNAS continues to require enforcement capabilities to ensure that industry is complying with their own legislation whether through exemptions, self-assessment, permit or certificate requirements.

We do not understand how the problem identified in the Discussion Paper (p22) that if NICNAS were to focus on hazard and risk assessment only, would result in NICNAS having to give up its role in monitoring and enforcement in relation to low risk chemicals and uses such as exemptions and permits. It is unclear how this scenario is the end result of NICNAS giving up risk management decisions. There is no logical flow to the argument.

**Permits and exemptions**
Accord supports an alignment of exemptions and permits consistent with other advanced first world economies. We are pleased that the Discussion Paper does include consideration of this important reform issue for industry.

Notwithstanding, the scope of industrial chemicals management should be primarily limited to hazardous chemicals only.

Australia should align its definition of polymer with that as used by the OECD and all polymers with known monomers should be exempt from notification. The range of exemptions by volume should be increased and there should be consideration of treatment regarding reducing notification and data requirements.

Australia is the only advanced economy which requires annual reporting for small volumes of low risk chemicals – this burdensome unique requirement should be removed immediately.

Australia participates in the work of the OECD New Chemicals Clearing House. One of the Clearing House’s priority work areas has been to look at the exemptions of participating OECD Member Economies with a view to harmonisation. In light of work which is being undertaken through the OECD New Chemicals Clearing House, Accord recommends that the following exemptions should be fundamental features of the new industrial chemicals regime:

- align Australia’s definition of polymer to that of the OECD
- polymers of known monomers should be exempt from notification
- non-hazardous chemicals should be exempt from notification and assessment requirements. (The definition of non-hazardous should be based on that adopted by SafeWork Australia under the GHS.)
- low volume exemptions (LVE) ≤100kg per 12 month period should not be required to be notified to authorities
- there should be exemptions for new chemicals in volumes ≤1000kg per 12 month period
- that for LVE>100-1000kg per 12 month period a simple notification to authorities be required. (Simple notifications to authorities should only require the following information: chemicals identity, intended uses and the relevant SDS. No toxicological or eco-toxicological data should be required.)
- industry would be obliged to keep records for the relevant exempt chemicals for five years (The government should have the power to conduct compliance audits and post market monitoring.); and
- annual reporting is an unnecessary administrative burden and should not be continued.

These exemptions would harmonise Australia’s regulatory controls for low risk chemicals with those of its major trading partners with a new chemicals programme. A lighter touch for market entry of these chemicals could be complemented by the introduction of greater post marketing monitoring and compliance and enforcement capability as proposed in the Discussion Paper.

**Regulatory spectrum for formulated chemical products**
Existing Australian regulation of our industry’s products has been recognised as being overly complex, fragmented and often out-of-step with that of other advanced nations.

This has been a major concern expressed in the PC study and the ongoing COAG “seamless national economy” agenda. Australian regulation acts as a potential barrier to easy introduction of new products, ingredients and innovations already in safe and approved use in other advanced nations.
This is especially when compared to New Zealand’s more ‘trade friendly’ regulatory regime for our sector’s products which employs ‘deemed to comply’ approaches for products in safe, approved use overseas.

As is the case for advanced technology items – like smart phones and the iPad – Australian consumers are increasingly demanding access to the latest products and innovations available in the global marketplace, without delay, including formulated chemical products. Greater regional regulatory alignment will help consumers and industry alike access products on the global market.

The Australian-based formulated chemicals manufacturing industry has a unique selling point in the global marketplace. Australian products are sought after in the region, and in growing Asian markets, because of their reputation for quality and their ‘clean, green, natural’ image including those locally made products derived from Australian-grown botanical ingredients. Greater regional regulatory alignment, facilitated also via a “Cosmetics Annex” in the TPP negotiations, will open export opportunities for this developing Australian manufacturing industry.

**Cosmetic ingredients as a subset**

The observation in the Discussion Paper (p40) regarding cosmetic chemicals requiring different considerations to other industrial chemicals because they are widely used without additional protective measures indicates a poor understanding of the chemistry of formulated products, risk management and existing controls.

It is the manufacturers’ responsibility under the general provisions of Australia’s strong product safety laws to ensure that the products they offer consumers are safe. A product may contain an ingredient which on its own may be corrosive, for example salicylic acid is used in cosmetic formulations as an exfoliant. However, in a formulated product, the concentration of that ingredient (e.g. controlled if necessary by the risk framework i.e. the scheduling system) will render it safe for use.

Globally the cosmetics industry is a major investor in research and development. The consumer demands innovative products that are safe, effective and of high quality and the industry is committed to meeting those demands. Indeed, the cosmetics industry is amongst the most innovative and responsive as demonstrated by the number of new products launched globally each year. Australia’s regulatory system needs to recognise and accept that imported formulated cosmetic products from comparable economies have already been subjected to a high level of regulatory oversight.

The unique Australian requirement which demands assessment of each and every individual ingredient in formulated products is inconsistent with the regulation of cosmetics elsewhere. It does not recognise that such formulated products are inherently safe and do not need to be re-assessed on the basis of an individual ingredient which is potentially ‘new’ to Australia but not other markets.

We are very pleased that the Discussion Paper has raised the issue of the most appropriate model for cosmetic regulation. However, any reform measure should not include regulation under the industrial chemicals framework but rather be recognised through more streamlined alignment within other regulatory arrangements i.e. that of consumer goods. This issue is discussed more fully in Attachment 1.

As mentioned previously, Accord has provided additional comments in relation to the options contained in the Discussion Paper which supplement the key points raised here.

We are also pleased with some of the clarifications provided in the consultative working groups convened following the release of the Discussion Paper, in particular that:

- the options contained in the Discussion Paper should be considered just that, and that these were to tease out some the additional issues to supplement the PC recommendations, and
• this is not an opportunity to cost-shift more of the chemical control functions and/or policy considerations from the Department to a currently 100% industry cost-recovered regulatory agency

We look forward to working constructively with the NICNAS Review team to further develop the reform proposals for an integrated management control system for industrial chemicals in Australia.

We also look forward to understanding the next steps in the process e.g. the development of final reform recommendations and their dissemination, the compilation of a consultation Regulatory Impact Statement etc.

Should you have any questions in relation to this submission, the contact officer is Ms Dusanka Sabic, Director of Regulatory Reform who can be contacted on 02 921181 2322 or by email at dsabic@accord.asn.au.

Yours sincerely

Authorised for electronic submission

Bronwyn Capanna
Executive Director

7 August 2012
ACCORD COMMENTS ON OPTIONS CONTAINED IN THE DISCUSSION PAPER

THE REGULATORY FRAMEWORK FOR INDUSTRIAL CHEMICALS

A1. A detailed industrial chemicals risk assessment and management manual be developed. The manual would:
   - describe the roles and responsibilities of each of the agencies involved in risk assessment and management of industrial chemicals
   - describe NICNAS’ processes and approach to risk assessment and management
   - explain how NICNAS’ processes and approach interact with other risk assessors and managers of industrial chemicals.

Accord Comment
We do not see implementing option A1 as a priority. For industry the priority is to implement PC Recommendation 4.3 which limits NICNAS’ role to that of a scientific assessment body with risk management functions undertaken by other agencies. When PC Recommendation 4.3 is implemented this will lead to a clear delineation of roles and responsibilities for risk assessment and risk management. As the PC noted in its research report well established frameworks are already in place for setting controls on chemicals in public health (poisons) and workplace safety reasons (chapters 5 and 6) p63. The PC also noted that environmental standard setting was being addressed.

A2. Following the cessation of the Standing Committee on Chemicals¹, an ongoing Australian Government cross-portfolio group be established to consider chemical policy issues for the Australian Government. The group could for example: work to minimise duplication between Australian Government agencies; identify and develop options to address ‘gaps’ in regulatory coverage; and facilitate a co-ordinated approach to risk.

Accord Comment
Accord supports option A2. We have consistently argued that the Australian government should develop a national chemical policy and mechanisms to manage the issues identified above such as the minimisation of duplication between government agencies and the facilitation of a nationally co-ordinated approach to risk. We do not believe that there are any regulatory gaps within Australia’s chemical management framework system and are disappointed that the Discussion Paper makes constant referral to these gaps without any evidence to substantiate the claim. The one example cited in the Discussion Paper on p21 is in relation to water purification chemicals for home water filters. Home water filters are consumer products and hence the ACCC has jurisdiction over these products. Another source of advice is FSANZ which provides advice on water filters. We contend there are no gaps – just poorly informed regulators.

¹ The Standing Committee on Chemicals (SCOC) was established by the Council of Australian Governments under a Memorandum of Understanding to achieve an effective and efficient national system of chemicals and plastics regulation. The Memorandum of Understanding establishing SCOC expires on 7 December 2014. Further information on SCOC is available at http://www.innovation.gov.au/INDUSTRY/CHEMICALSANDBPLASTICS/SCOC/Pages/default.aspx
A3. Memoranda of Understanding (MOU) between NICNAS and other agencies (both Commonwealth and State and Territory) be reviewed and re-negotiated (or new ones developed) to ensure clarity regarding relative roles and responsibilities.

Accord Comment
As referenced above, industry's priority is for the implementation of PC Recommendation 4.3 which clarifies roles and responsibilities. Once this has been finalised and agreed, then it is appropriate for the consideration of how the MOUs would be reviewed and redrafted.

NEW INDUSTRIAL CHEMICALS

Please note that each of the options detailed below would be likely to result in changes to the ICNA legislation (either the Act or the Regulations) as well as changes to administrative documents.

Accord comment
Accord does not support ad hoc amendments to the ICNA Act to bring about minor reform. We have consistently argued for a wholesale review of the ICNA Act to bring it in line with that of comparable economies with regard to their treatment of industrial chemicals. The review of the LRCC programme by the independent consultants demonstrated the failure of the current ICNA Act to act as a vehicle for reform despite the best efforts by all parties involved in the reform process.

The Discussion Paper lacked a comprehensive discussion of PC Recommendation 4.1. It is essential that this be an integral part of any new chemicals management regime, particularly in a cost recovered agency as industry has not seen any evidence that NICNAS takes into account that costs are commensurate with the risks, or that assessment priorities are directed to the most efficient management of the aggregate risk of all industrial chemicals.

For example in a recent decision to transfer ingredients from the ARTG to AICS, NICNAS is seeking to impose its own risk management controls in ingredients freely available for use as cosmetic ingredients throughout the world. Not only is it beyond the role to impose such additional requirements (these should be considered by the chemical scheduling system), NICNAS has not undertaken a cost benefit analysis of the impact of this decision, which Accord believes is required under the Government’s regulatory impact analysis requirements insofar as when a decision is made which will affect how business operates then a RIS is required to assess the costs and benefits of such a decision.

B1. In relation to all notification and assessment categories (for exemptions, permits and certificates):

- reduce the number of categories
- review current volume thresholds, data requirements and applicability criteria with a view to harmonising these with overseas arrangements where possible\(^2\). The objective of this would be to better clarify and harmonise data requirements and reduce complexity for industry.

\(^2\) Option F1 also explores the use of foreign schemes and international assessments (Refer Part 8)
Accord Comment
Accord supports an alignment of exemptions and permits consistent with other advanced first world economies. The scope of industrial chemicals management should be limited to hazardous chemicals only, as is done in New Zealand. Australia should adopt the OECD definition of polymers and polymers known monomers should be exempt from notification, similar to that as is the current arrangement in the EU. The range of exemptions by volume should be increased and there should be consideration of treatment regarding reducing notification and data requirements. Australia is the only advanced economy which requires annual reporting for small volumes of low risk chemicals and this burden should be removed immediately.

Accord recommends that the following exemptions should be features of any new industrial chemicals regime:

- adopt the OECD definition of polymer
- polymers of known monomers should be exempt from notification
- non-hazardous chemicals should be exempt from notification and assessment requirements. The definition of non-hazardous should be based on that adopted by SafeWork Australia under the GHS in Work, Health and Safety legislation
- low volume exemptions (LVE) ≤100kg per 12 month period should not be required to be notified to authorities
- there should be exemptions for new chemicals in volumes ≤1000kg per 12 month period
- that for LVE>100-1000kg per 12 month period a simple notification to authorities be required. Simple notifications to authorities should only require the following information: chemicals identity, intended uses and the relevant SDS. No toxicological or eco-toxicological data should be required
- industry would be obliged to keep records for the relevant exempt chemicals for five years. The government should have the power to conduct compliance audits and post market monitoring
- annual reporting is an unnecessary administrative burden and should not be continued.

These exemptions would harmonise Australia’s regulatory controls for low risk chemicals with those of its major trading partners offering a new chemicals programme. It should be noted however that USA EPA has the highest LVE limit amongst all notification schemes with an annual limit of ≤ 10,000kg/annum. A lighter touch for market entry of these chemicals is complemented by the introduction of greater post marketing monitoring and compliance and enforcement capability as proposed in option D3. For a Limited Certificate category we would recommend increasing the allowable amount to ≤10,000kg or 10 tonnes per year rather than the current limit of ≤1 tonne/year. Members have advised that although the Standard Certificate is not limited in volume per year which can be introduced, NICNAS is increasingly making this a requirement.

B2. In relation specifically to exemptions:

- consider new or expanded exemptions (e.g. options described in the LRCC evaluation report on increasing the volume limits and extending the 1% concentration exemption for non-hazardous chemicals in products).3

---

3 LRCC Reforms: An evaluation of the impact on industry Final Report, June 2009
Accord Comment
See Accord response to option B1 above.

B3. In relation to permits and assessment certificates:

- introduce a pre-assessment statutory screening process, with timeframes, to enable NICNAS to refuse an application if it does not include all the necessary information. Additional information would only be able to be provided following a request from NICNAS or under the legislative obligations to provide new relevant information (note the PC Report – recommendation 4.5).

Accord Comment
Accord does not support option B3 without further consideration as to the benefits of this proposal. Accord notes that NICNAS has now introduced a screening fee by withholding 15% of the assessment fee. The proposed introduction of the screening fee was raised as part of the CRIS consultation process. Accord did not support the introduction of a screening fee. We support enhanced efficiencies in the screening process which would benefit both industry and NICNAS. Accord understands that when the new screening arrangement was introduced in 2007, following industry consultation, NICNAS advised that it would evaluate the screening trial and discuss the results with industry on how to proceed. The PC in its report on chemicals and plastics regulation also noted that the NICNAS screening process was new and that at that time in 2008, it was too early to tell if this would be a success or not. NICNAS should be required to justify the introduction of the 15% screening with a proper analysis of the pilot undertaken since 2007. This has not been provided to date.

Furthermore, we do not believe that NICNAS has the power to withhold a screening fee under its current cost recovery arrangements and Accord will be exploring this further.

There is no penalty on NICNAS should it fail to comply with timelines. There should be a reciprocal introduction of a penalty on NICNAS with funds reimbursed to industry should NICNAS fail to meet its statutory timelines.

B4. In addition, in relation specifically to assessment certificates:

- streamline the assessment process (note the PC Report – recommendation 4.1). For example, a model operating in the US EPA involves four distinct successive technical phases: chemistry review, hazard evaluation, exposure evaluation and the risk assessment/risk management phase. These phases are structured to ‘drop’ (from further assessment) chemicals of low risk early in the review enabling resources to focus on higher risk chemicals. As an example, polymers which meet select criteria are commonly dropped during the chemistry review. Such an approach could be considered for the assessment of new chemicals

- enable NICNAS to refuse an assessment certificate in prescribed circumstances if NICNAS considers that there is unacceptable public health, worker safety or environmental risk and risk management strategies cannot manage the risk to an acceptable level. The legislation would clearly define the very limited circumstances in which this power would be used and would also ensure there are in-built procedural fairness and consultation mechanisms
• enable NICNAS to impose conditions of use on an assessment certificate where such conditions must be removed/lifted once NICNAS receives notification from the relevant risk manager that they have implemented measures that the risk manager has determined are necessary to manage the risk. Any conditions of use imposed by NICNAS would only extend to the introducer (importer or manufacturer) as is the case with permits. Further, NICNAS would not impose conditions which are general obligations under, for example, work health and safety law. Conditions would only be imposed where a control is necessary beyond a generic obligation. For example, where a concentration limit is necessary.

Accord Comment
The first dot point in option B4 has merit and is worthy of further consideration. However, Accord has always recommended that polymers be regulated as they are in Europe, i.e. if an approved monomer is on the list then the polymer is exempt from notification requirements.

The second dot point is not acceptable. It is unclear what is trying to be achieved by the option proposed in this second dot point.

With regard to the last dot point Accord does not support the new scientific assessment body having any risk management powers. This is contrary to what was objectively assessed and recommended by the PC in its report with regard to clarifying the roles and responsibilities of those agencies within Australia’s chemical control framework. As noted previously the PC found that Australia already has well established frameworks for risk management. To give the scientific assessment body these limited powers would only increase rather than decrease the complexity and potential duplication which currently exists and cannot be supported – in the rounds of the consultations Accord and its members have cited examples of how this proposal would diminish the effectiveness of the current system and was not supported.

B5. In relation to AICS:

• provide that after five years, or if the holder of an assessment certificate applies to NICNAS to have the chemical entered on AICS (to enable its introduction by anyone), require that if the chemical is subject to conditions of use (because risk management measures have not yet been imposed by the relevant risk manager) that either: the chemical not be entered on AICS until these measures are in place; or these conditions also carry over to AICS. As for assessment certificates, the conditions on AICS would be removed once other risk managers have ‘filled the gap’ (note the PC Report – recommendation 4.4)

• enable NICNAS to refuse to enter a chemical on AICS in prescribed circumstances if NICNAS considers that there is unacceptable public health, worker safety or environmental risk and risk management strategies cannot manage the risk to an acceptable limit. The legislation would clearly define the

---

4 An alternative to this approach is to delay the issue of an assessment certificate (or delay the date of effect) until such time as the relevant risk managers have notified NICNAS that appropriate risk management strategies/conditions of use are in place. This option was not supported by the PC (refer page 70 of PC Report).

5 On the basis of a preliminary examination of past assessment certificates it is estimated that approximately 10% of assessment certificates would include recommendations that require controls that go beyond general legal obligations.
very limited circumstances in which this power would be used and would also ensure there are in-built procedural fairness and consultation mechanisms

- provide that if, during the 5 years following assessment of a new chemical, the introducer decides (for commercial reasons) to stop introducing the chemical, NICNAS may choose not to enter the chemical on AICS provided this occurs with the agreement of the company.

**Accord comment**

Accord does not support any of the proposed options in B5. Furthermore the linking of PC Recommendation 4.4 with the first dot point in option B5 indicates a serious misunderstanding of the PC recommendation with regard to NICNAS’ role in risk management. Recommendation 4.4 stated that all relevant national standard setting bodies should be required to respond to NICNAS recommendations within defined time limits. This would be done through improved communication between the hazard assessment body, i.e. the new scientific assessment body and the risk management bodies. B5 appears to indicate that NICNAS should make risk management decisions which are within the jurisdiction of other control entities such as state and territory OHS authorities or environmental agencies. This would be a completely inappropriate role - what is required is improved communication and coordination of hazard information with that of the risk management authorities. This issue has been addressed in the main body of Accord’s Submission in relation to risk management.

**B6.** Ensure that, if the legislative changes detailed above are progressed, that all necessary consequential changes are made to the legislation. For example, to ensure the protection of applicant’s appeal rights, align confidentiality provisions and provide for adequate transparency and input into regulatory decisions. Statutory timeframes for regulatory decisions would also need to be reviewed and adjusted in line with the new processes.

**Accord Comment**

Accord has argued that a wholesale change to the ICNA Act is required and not piecemeal ad hoc amendments which only make the legislation more complicated; not less complicated.

**EXISTING INDUSTRIAL CHEMICALS**

Amend the ICNA Act to:

**C1.** Maintain the existing assessment process for PECs but remove unnecessary prescriptive detail (including, for example, the requirement for both a preliminary assessment and a full assessment).

**Accord Comment**

While Accord supports the intent of option C1, we believe that this could be achieved by subjecting PECs to a prescribed timeframe within which to report, such as six months. If the data indicates that further time is required then this could be extended upon Ministerial approval for a period of no longer than a further 12 months. NICNAS appears on average to take five years to complete a PEC. Five years to undertake a review of a chemical of concern is far too long and NICNAS should be able to undertake its review and evaluation in a considerably shorter timeframe than its current process. The PEC process should be more transparent with regard to commencement and end dates. (If this is put into context, a
PhD student undertakes a comparable piece of research work within 3 years and on their own. NICNAS has a team of researchers taking up to 5 years on average to complete one PEC. In terms of cost it would be more cost effective to offer PhD scholarships to undertake this work as it is currently performed.)

C2. Introduce a new legislative assessment process for non-PECs. Assessment outcomes would be published to ensure transparency but the assessment process would be simplified, could be carried out in relation to more than one chemical at the same time (e.g. assessment of a group or class of similar chemicals) and assessments could be more focused. For example, assessments could focus on a particular health effect or use pattern.

Accord Comment
The intent of option C2 is unclear and therefore cannot be supported. Accord does not understand why a legislative amendment would be required in these circumstances when NICNAS has just introduced a new framework to provide a faster and more flexible approach to assessing the impact of industrial chemicals on human health and the environment through its Inventory Multi-tiered Assessment and Prioritisation (IMAP). This was done without any legislative amendments. If the purpose is to mandate the collection of additional information from industry and downstream users then this cannot be supported.

C3. Broaden the mandatory information-gathering powers to enable NICNAS to better undertake risk assessment activities and to adequately manage AICS (for example, to enable NICNAS to seek information from industry in support of option C5). The circumstances under which NICNAS may request such information would need to be tightly defined and proportional to the risk. Care would also need to be taken to ensure that introducers are not required to submit the same information to multiple regulatory bodies.

Accord Comment
Accord does not support the proposed option C3. There is no clear justification for this proposal or its scope. If imposed it would introduced a significant burden on industry and raises similar concerns to that identified in option C2.

C4. Remove the general power for NICNAS to impose conditions of use on chemicals after a chemical has been entered on AICS. This would be replaced with a much more limited power which would enable NICNAS to:

- impose a condition of use on a chemical listed on AICS only if an assessment of an existing chemical has been undertaken and the assessment has demonstrated that a condition of use is necessary, in order to protect public health, worker safety and the environment, and that there is no other means by which the risk can be addressed
- remove a chemical from AICS if NICNAS considers that there is unacceptable public health, worker safety or environmental risks, and risk management strategies are inadequate to manage the risk to an acceptable limit. The legislation would clearly define the very limited circumstances in which this power
would be used and would also ensure there are in-built procedural fairness and consultation mechanisms\(^6\).

**Accord Comment**
Accord supports the first statement in option C4 to remove the general power for NICNAS to impose conditions of use on chemicals after a chemical has been entered on AICS. This is consistent with the PC recommendation regarding NICNAS’ power to annotate.

Accord does not support any of the additional sub points introduced under option C4. The new scientific assessment body should have no risk management powers hence it would not be able to make or impose any conditions of use on a chemical. These conditions of use could only be applied by the appropriate risk management body. The PC report did not support NICNAS retaining any powers in relation to risk management decisions or annotation. Further NICNAS annotating chemical ingredients only complicates the situation as this could be in conflict with other well-known controls such as the poisons schedule.

C5. Establish a new Part on AICS for chemicals that are no longer being introduced into Australia. It is proposed that NICNAS would seek information from industry regarding those chemicals that have been introduced into Australia over the previous 5 years. Those chemicals that are on AICS but have not been introduced by any manufacturer or importer over the last 5 years would be placed on a separate list within AICS. If, after a further 5 years, no-one introduces the chemical the chemical would be removed from AICS following public notification and opportunity to comment.

**Accord Comment**
Accord does not support option C5. The burden on industry in complying with constant requests for information would be significant. Accord cannot see any merit in this proposal.

C6. Ensure that, if the legislative changes detailed above are progressed, that all necessary consequential changes are made to the legislation. For example, to ensure the protection of applicants’ appeal rights, align confidentiality provisions and provide for adequate transparency and input into regulatory decisions. Statutory timeframes for regulatory decisions would also need to be reviewed and adjusted in line with the new processes.

**Accord Comment**
Accord supports legislative amendments to remove the power to annotate as described in option C4. However the government can give effect to this immediately by making a policy decision not to utilise this power under the ICNA Act due to the current powers not being well described, transparent or logical in the regulatory system (NICNAS Discussion Paper p22).

**POST MARKET MONITORING AND ENFORCEMENT**

D1. Streamline the secondary notification process for existing chemicals. Consistent with the possible changes described at C2, the ICNA Act could be amended such that:

\(^6\) Currently NICNAS has the power to add a chemical to AICS and impose conditions if responsibility for the regulation of the chemical has been transferred from another Commonwealth regulator such as the TGA or APVMA (refer section 15AA and 15AB of the ICNA Act). If Option C4 were adopted, it is proposed that the power to add such chemicals to AICS (and impose necessary conditions) would be retained.
• NICNAS re-assessment following secondary notification could either occur using a streamlined approach or through the more comprehensive PEC-style approach, depending on the nature of the hazards and risks

• AICS could list the function or use of the chemical related to the original assessment. This gives clarity to the existing secondary notification obligations for significant variations to use.

**Accord Comment**
Accord does not support option D1. Accord’s submission to NICNAS on its consultation on secondary notification is attached for information at Attachment 4. Consideration should be given to removing the secondary notification function from the ICNA Act.

**D2.** Supplement existing secondary notification requirements with a more comprehensive system of adverse effects reporting for new and existing industrial chemicals. Such a system would require introducers to mandatorily report adverse effects but would also enable anyone else, including users and risk managers, to report adverse effects to NICNAS. This could be similar to the APVMA system for adverse experience reporting.

**Accord comment**
Accord does not support option D2. NICNAS assesses ingredients not products. There are a number of adverse event reporting systems already available: for consumer products there is a comprehensive mandatory product safety reporting scheme; for poisoning there are the Poisons Information Centres; and there is a comprehensive regime in place for workplace incident reporting as well as a large number of epidemiological studies around workplace chemical use. In a practical sense option D2 could not work, the costs would be significant and NICNAS staff would be distracted from their function of scientific assessment. The PC report (p86) considered this and advised that the adequacy of current systems should be established before developing a new system and that further scoping was required. This has not been expanded in the Discussion Paper.

**D3.** Introduce into the ICNA Act a comprehensive, graduated and contemporary compliance regime to enable NICNAS to better manage compliance by tailoring penalty provisions to the degree and seriousness of the non-compliance. For example, consideration could be given to the introduction of compliance tools such as assisted resolution, infringement notices and civil penalties.

**Accord Comment**
Accord has no in-principle objection to option D3 subject to a considerable reduction to pre-market entry requirements such as outlined in option B1. Generally within a regulatory control system, a decision is made to have either high level of pre-market entry requirements with a light touch post-market or low entry level pre-market entry supported by high level post market surveillance and compliance regime. NICNAS’ focus to date has been for a high level of pre-market entry requirements. We would only support an increased compliance regime if it was consequential to a lighter pre-market approach as proposed by Accord.

**OTHER REFORMS AFFECTING BOTH NEW AND EXISTING CHEMICALS**

Release of information and confidential commercial information
E1. Amend the ICNA Act to enable release of information (including confidential commercial information) to other Commonwealth and state and territory agencies where it is necessary for them to fulfil their regulatory responsibilities. For example, to undertake an assessment of risk, to consider risk management strategies in relation to industrial chemicals or to monitor compliance with regulatory requirements.

**Accord Comment**
Accord does not support option E1. Any risks to the treatment and/or disclosure of commercial-in-confidence information is not supported. Furthermore, the Discussion Paper does not include any consideration of the trade and international ramifications that any such proposed changes may have, particularly with regard to Australia’s ability to accept data from international regulators.

E2. Amend the ICNA Act such that at the time of listing on AICS, the chemical name would be subject to contemporary confidentiality criteria to increase transparency (e.g. align with work health and safety confidentiality arrangements relating to chemical name).

**Accord Comment**
Accord does not support option E2 for the same reasons we cannot support option E1.

Use of foreign schemes/international assessments

F1. Increase utilisation of international assessments to support and streamline the assessment for permits (noting that chemicals subject to permits are lower risk because there are ongoing post-market conditions and controls and there is a narrower set of uses)\(^7\).

**Accord Comment**
Accord supports option F1. The utilisation and adoption of international assessments is a decision for policy makers and for risk managers to assess the veracity of the data – not for NICNAS which has shown itself to be risk averse. New Zealand has no such issues in its approach to chemical management and Australia should follow its example. First world regulators such as the EU, US EPA, Health Canada and METI in Japan all have the same objectives. While the pathways to achieving these objectives may differ, the outcomes are inevitably the same. The regulators are in constant dialogue and as such there should be no reason why the Australian risk management entities should not accept hazard assessments from first world economies and make their own decisions regarding the management of particular chemical entities within the Australian context.

F2. Better align the categories of, and data requirements for, exemptions, permits and certificates with, for example, the US, Canada and the EU\(^8\).

---

\(^7\) This also has linkages with Option B4, streamlining the assessment process for certificates.

\(^8\) This is also discussed in relation to Option B1.
Accord Comment
Accord supports option F2 and has provided examples of this alignment in in response to option B1.

Chemicals in articles

G1. Clarify the role of NICNAS in relation to chemicals in articles as part of the development of the industrial chemicals risk assessment and management manual (option A1) and through the re-negotiation of MOUs where necessary (option A3).

Accord Comment
Accord does not support option G1 as the “problem” has not clearly been articulated.

G2. Amend the ICNA Act to clarify the role of NICNAS in the assessment of chemicals in articles, particularly imported articles.

Accord Comment
Accord does not support option G2 as the ICNA Act is quite clear regarding chemicals in articles. There is no need for any modification.

Chemicals in cosmetics

H1. Responsibility for administration and enforcement of the Cosmetics Standard 2007 be transferred to the ACCC but the assessment of chemicals in cosmetics would remain with NICNAS

Accord Comment
Accord supports the regulation of cosmetic products as consumer goods under the Australian Consumer Law, regulated by the ACCC. This issue was addressed by Accord in our supplementary submission. See below under option H2 for a further explanation of Accord’s position regarding the regulation of cosmetic products in Australia.

While we supported this recommendation initially, i.e. the transfer of responsibility for administration and enforcement of the Cosmetics Standard 2007 to the ACCC, the considerable delay in any movement towards implementation in the past 4 years has given us time to refine our policy position and we now believe we can provide a better policy solution, consistent with the PC’s intent and that of the Government’s reform agenda.

Industry has always questioned the need to create a Cosmetics Standard as the existing regulatory controls through the use of the TGA’s Excluded Goods Order (in place since 1998 for this class of products) has proven to be more than adequate. The reforms of 2007 merely expanded the group of product categories excluded from the TGA’s jurisdiction – they did not seek to make NICNAS the cosmetic product regulator.

We believe the introduction of the Cosmetics Standard to mirror the cosmetic provisions of the Excluded Goods Order was detrimental to chemicals regulation in Australia. It perverted the fundamental nature and focus of NICNAS. NICNAS is a notification and assessment scheme for chemical entities. The Cosmetics Standard implies NICNAS has responsibility for cosmetic products – not just chemical entities – a role which the PC was critical of in its report.
It also changed an important reform measure of 2004 when the ICNA Act was amended to align the definition of a cosmetic product with that used in the Trade Practices Regulations and enforced by the ACCC, and closely harmonised to that of our major trading partners.

Instead, due to the reforms of 2007, Australian now has a unique cosmetic definition – a retrograde step – particularly given the situation that Australia is a net importer of cosmetic products and only constitutes 1.4% of global trade.

We believe that the Cosmetics Standard could be repealed altogether without any adverse consequences to public health and safety given that it mirrors the provisions of the TGA’s Excluded Goods Order No 1 (2008).

This would be a more effective reform measure since it would also repeal unnecessary regulatory duplication and address the PC’s concerns by:

- refocussing the scientific body on its notification and assessment work; and
- clarifying the roles and responsibilities of the regulators involved in dealing with cosmetic products.

By repealing the Cosmetic Standard:

- the new entity would continue to have responsibility for notification and assessment of industrial chemical entities
- the TGA would continue to define the boundary between therapeutic and cosmetic products as it always has
- the ACCC would continue to have responsibility for regulation of cosmetic products as consumer goods as it always has, (a role which we note has recently been strengthened through the new Australian Consumer Law amendments)
- the Government would progress an important reform component of the PC recommendations to clarify the roles and responsibilities of regulators; and
- the Government would also repeal an unnecessary and duplicative piece of legislation.

It is Accord’s view that this policy approach offers advantages in terms of both its procedural simplicity and the outcomes it delivers.

**H2.** New provisions could be introduced into the ICNA Act (and on AICS) to specifically deal with chemicals in cosmetics (rather than continuing to treat them like industrial chemicals). This could include a separate inventory of cosmetic ingredients, a list of ‘pre-approved’ cosmetic ingredients, a list of ingredients that are not to be utilised (based on risk), and a separate list of data requirements for the assessment of cosmetics chemicals. Better alignment with international approaches would also be explored.

**Accord Comment**
Accord does not support option H2 as the best means to regulate cosmetic products in Australia. Accord believes that cosmetic products should be regulated as consumer goods in Australia and should be under the auspices of the ACCC. Accord was specific about how cosmetic products should be regulated in its Supplementary Submission to the NICNAS Review and we are disappointed that there has been no analysis of Accord’s position and recommendations in the Discussion Paper. It is quite clear that the INCA Act cannot
regulate chemicals in products and that cosmetic products should be removed from the scope of industrial chemicals immediately.

From data based on the United Nations Commodity Trade Statistics Database (COMTRADE) for 2010, Australia constituted 1.4% of global trade in imports and 0.51% of global cosmetic export trade. Australia has a unique regulatory system for the management of industrial chemicals and one that is even more unique for the management of cosmetic products. Why the Discussion Paper would recommend the perpetuation of unique regulatory requirements for these low risk products is unfathomable. On a trade basis Australia is involved in a number of bilateral and multinational trade agreements. Predominantly Australia’s interests lie in the Asia Pacific region yet the Discussion Paper makes no mention of this move and no analysis of the system for regulating cosmetic products in this region.

Australia must move to a harmonised and flexible regulatory system. New Zealand has adopted a pragmatic and flexible approach for the regulation of cosmetic products. While we are not advocating the New Zealand model for adoption in Australia we are advocating the adoption of a pragmatic and flexible regulatory regime which recognises Australia’s place in global trade and accepts imported products from comparable first world economies as deemed to comply with Australian regulatory requirements.

In our Supplementary Submission we pointed out that the ACCC already has responsibility for consumer product safety and cosmetic product ingredient labelling. In essence, there are three specific areas for cosmetic product regulation: product safety (including ingredient and manufacturer/importer labelling); the substantiation of efficacy and consumer claims; and the avoidance of therapeutic claims – all of which are currently regulated by the ACCC and the Australian Consumer Law. As to whether Australia needs to adopt specific regulation such as the EU Regulation for cosmetics, or leave it under the general provisions of the Australian Consumer Law, are matters which require further consideration.

Given that the ACCC already has the power to control consumer products, this would provide for more flexibility by providing deemed-to-comply provisions which could apply to imported products from comparable regulatory regimes such as the EU, USA, Canada, Japan and New Zealand, as meeting the regulatory requirements for Australia. This would reduce costs and allow more timely access to innovative products by Australian consumers – something they are already able to do via on-line purchasing. Public health and safety would be managed by the risk management bodies the Advisory Committee on Chemical Scheduling (ACCS) and/or the ACCC.

The TTP negotiations on a cosmetics annex are about aligning global cosmetic regulations whilst maintaining high standards of product quality and safety. The cosmetics and personal care industry is a truly global industry and any regulatory changes to the management of cosmetics in Australia should reflect this global nature and ensure harmonisation of regulatory controls to minimise barriers and maintain open and competitive markets. This is in keeping with APEC’s Regulatory cooperation plan as referenced in Attachment 3.

Furthermore, New Zealand has demonstrated how it efficiently manages the sensitive issue of fragrances through recognition and adoption of the International Fragrance Association (IFRA) Code of Practice. Accord recommends that Australia also considers full adoption of the IFRA Code as an efficient and effective low cost method in dealing with fragrance ingredients.
Import and export of chemicals under the Stockholm and Rotterdam Conventions

I1. Remove regulations relating to the import and export of Stockholm and Rotterdam Convention chemicals from the ICNA legislation, once appropriate alternative legislation has been enacted.

**Accord Comment**
Accord supports option I1 as this is consistent with the PC Recommendation 4.3.

I2. Retain regulations for the import and export of Stockholm and Rotterdam Convention chemicals under the ICNA Act.

**Accord Comment**
Accord does not support Option 12 which is inconsistent with PC Recommendation 4.3.

Governance - Committees

J1. Once the preferred reform options have been identified, consider the most appropriate role and membership of committees to best support the Director of NICNAS.

**Accord Comment**
Accord supports further consideration of option J1. We note that PC Recommendation 4.2 recommends the establishment of an independent technical advisory committee to provide advice to the Director, NICNAS. Furthermore the independent review into the efficiency and effectiveness of NICNAS also made a number of observations regarding NICNAS’ governance and stakeholder arrangements. These matters need to be explored once the role and future structure of the regulator is agreed.

Relationship with the Department of Health and Ageing

K1. DoHA work with NICNAS to clarify roles and responsibilities and address any administrative and resource inefficiencies

**Accord Comment**
Accord supports option K1. We note that the independent review of NICNAS made observations regarding investigating the transferring of operations to Canberra. We recommend that this be part of the considerations with particular regard to implementation of Recommendation 4.3. We see this very much as a center of scientific and technical excellence which may be better located in Canberra. The issue of policy oversight needs to be addressed. It is clear from the independent review that a significant amount of cost shifting has occurred as DoHA has abrogated its policy responsibility for chemical safety management, and NICNAS has undertaken this role without any central Departmental oversight. This clearly needs to be addressed as a matter of priority.