



Advocate for the Consumer, Cosmetic,  
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Dear Marion

Thank you for the opportunity to provide comment on the consultation document *Further Consultation on Proposed Amendments to the Schedule to the Act and the Requirements to Prepare and Publish Summary Report* (NICNAS Proposal). ACCORD has serious reservations regarding the proposals put forward and provide the following comments.

We provide our comments in two separate sections. The first section titled "Administrative Issues" will deal with the issues around the NICNAS consultation process. The second section titled "The Proposal" will deal with the specifics of the proposed amendments to the Schedule of the *Industrial Chemical (Notification and Assessment) Act 1989* (ICNA Act).

### **Administrative Issues**

The consultation on the NICNAS Proposal is not consistent with the Australian Government's Principles for Best Practice Regulation. NICNAS has not undertaken a Regulatory Impact Assessment (RIS), which would include consideration of options, cost/benefit analysis and an assessment of compliance costs to determine the most efficient and effective outcome. In the absence of any analysis, ACCORD is not convinced that NICNAS' preferred option is the optimal regulatory outcome.

We note that Drafting Instructions have already been issued and the Bill is scheduled for introduction in the Spring Session albeit with a B status. This then smacks of token consultation at best since NICNAS appears to have a preferred option in mind and seems to be just going through the motions of consultation.

We understand that NICNAS is claiming that the amendments proposed are "minor" and therefore presumably do not require a RIS. However, NICNAS has not properly assessed the impact of the proposed changes to industry, and therefore is not in a position to determine whether these amendments are "minor" or not. ACCORD believes that the proposed changes to the various parts of the Schedule of the ICNA Act will add considerable burden on industry, and should not be considered minor. We will discuss this in more detail under "The Proposal" section.

When the initial consultation appeared in the April 2010 Chemical Gazette we were surprised to see the proposal from NICNAS to amend the ICNA Act. ACCORD is an active participant in a number of different NICNAS/industry engagement fora including the Industry Government Consultative Committee (IGCC) and Industry Engagement Group (IEG). Apart from the proposed

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changes to the UV filters, as far as we are aware, NICNAS has not discussed with industry that it was considering the proposed amendments to the ICNA Act.

Best practice consultation should include a pre-consultation discussion with industry. This not only ensures that the industry is made aware of a forthcoming consultation but also provides an opportunity to “road test” options for feasibility and industry applicability before being put into the public domain, such as the proposal to remove the option to provide the International Union of Pure and Applied Chemistry (IUPAC) chemical name as part of the chemical’s identity. We hope that for future consultations, NICNAS will discuss its consultation proposal with its many engagement groups in order to ensure a better consultation process.

At the 4<sup>th</sup> IEG meeting the ACCORD’s Industry Engagement Group (IEG) representative raised the question of NICNAS consultation only being available through the Chemical Gazette and the concern that this may not be appropriate for a proper consultation. When this was raised, NICNAS assured industry representatives that NICNAS has a consultation section on its website and that the proposal will be put on the consultation section. Regrettably, we have not been able to locate this consultation section, and seek clarification from NICNAS whether this section exists.

We believe it is good practice for regulatory agencies to maintain a consultation section within their respective websites containing current and past consultations, and the results of those consultations available on the same site. This is a practice adopted by other Australian national regulatory agencies such as the Australian Pesticides and Veterinary Medicines Authority (APVMA) and the Therapeutic Goods Administration (TGA). It is ACCORD’s experience that random consultation notices in the Chemical Gazette and “Latest News” section of the website makes tracking current consultations, and the results of those consultations, including summary of outcomes extremely difficult.

Disclosure of the outcomes of a consultation is also an important part of the consultative process for industry. Without published consultation outcomes, industry is left to second guess decisions taken by NICNAS. ACCORD is aware that NICNAS does not always summarise or publish outcomes of its consultations. An example of this is a consultation which appeared in the February 2009 Chemical Gazette regarding the provision of chemical names. As far as we are aware, no decision has been taken from that consultation process, as there are no summaries published anywhere of the result from that consultation, nor has any decision taken by NICNAS been made available.

A proper consultation process should include publication of outcomes and reasons for decisions made resulting from the consultation process to inform all stakeholders. As this can be best achieved via a consultation section in a website, we strongly urge NICNAS to include a consultation section on its website which includes all current consultations and the outcomes from past consultations.

ACCORD has previously raised with NICNAS our concerns that ACCORD’s submissions which take into account our multiple members’ views are seemingly only counted as a single submission. We were assured by NICNAS that it is aware that ACCORD represents the views of our members and that our submissions will be given due weight in its consideration.

However, this appear not to be happening, and we seek clarification from NICNAS on the weight of consideration given to submissions from industry representative bodies and professional bodies compared with individual or single company submissions.

## **The Proposal**

### *Summary reports*

In our previous submission on the proposal to remove the requirements on NICNAS to publish summary reports, ACCORD raised concerns with the ease of finding information on notified chemicals. Before making our previous submission, we decided to test whether finding the full report would be as simple as finding the summary report in the Chemical Gazette. When we eventually located and tested the links to full reports from the NICNAS website we found that some of these links were broken.

The refined NICNAS proposal appears to address these concerns. ACCORD provides in-principle support to the proposal to remove the requirement to publish the summary report subject to the proposed NICNAS conditions being met at all times and that a working link to the full public report and key information about the assessed chemical listed in the proposal are published in the Chemical Gazette instead of the summary report.

### *New NICNAS requirements for UV filters*

While we support the intent by NICNAS to align UV filter assessment requirements with the TGA, we do not believe that the NICNAS proposal will achieve this outcome.

ACCORD understands that the TGA is flexible with the requirement of information on UV filters as outlined in the Australian Regulatory Guidelines for Over-The-Counter Medicines (ARGOM). Therefore, although the questions NICNAS has put in the newly created Part E of the Schedule for UV filters (and we assume that it will be made clear somewhere in the Schedule that Part E only needs to be completed for UV filters) are aligned with the types of questions that TGA is likely to ask in assessment of the UV filters, NICNAS has always been much less flexible with its Schedule of requirements and this could lead to a more onerous data requirement than the TGA for potentially the same ingredient and one which is not to be used as a medicine!

Further, when considering the alignment of the requirements for UV filters with the TGA, NICNAS appears only to have considered additional information requirements, without considering removal of existing information requirements in order to align with the data requirements with the TGA. This will lead to a situation where the same UV filter must be assessed through the TGA and then NICNAS, with additional information for NICNAS notification. This is duplication of regulatory effort and will cost companies two separate notification and assessment fees, as well as the duplication of effort to introduce products into Australia.

This is contrary to the aim of the exercise, which is to align data requirements with the TGA, presumably to ensure that the assessment only needs to happen once, either by TGA or NICNAS then mutually recognised. Industry supports a more innovative approach which is either that NICNAS accepts the TGA assessment or that the TGA and NICNAS develop a single assessment application form and approach.

As the NICNAS proposal does not define "UV filters" concern is also raised that NICNAS definition may be out of step with the international definition. In the EU, only UV filters used on skin are captured in the "UV filters" definition. UV filters for use on nail and hair and light stabilisers used to improve product stability are excluded.

As mentioned in the previous section "Administrative Issues", if this consultation had been conducted properly following the Australian Government's Principles for Best Practice Regulation, a RIS would have taken place and different options assessed. ACCORD believes that this would have led to a better, more workable proposal for NICNAS, the TGA and industry that is

internationally aligned and in alignment with government policy to reduce duplication of regulatory effort and drive down regulatory costs for business.

#### *Screening new chemicals for Persistent Organic Pollutants (POPS)*

As the NICNAS proposal indicates, NICNAS announced in January 2004 in a Chemical Gazette that it will be looking at new chemicals with potential POPS characteristics. However, the notice from January 2004 was pragmatic and recognised that most new chemicals would not have POPS characteristics – the notice stated:

*“... from the beginning of 2004, NICNAS will undertake the screening of new industrial chemicals to identify potential POPS chemicals. Additional data in accordance with the Information Requirements and Screening Criteria of Annex D of the Convention may be requested, in particular, information relating to persistence, bioaccumulation and toxicity (PBT).”* (our underlining)

This is a much less onerous approach than requesting additional information for every new chemical going through Limited and Standard notifications, which is the proposal NICNAS has put forward in the April 2010 Chemical Gazette, then again in the current proposal.

Further as NICNAS can already request further information from the introducer if the new chemical is suspected of being a potential POPS, the additional burden on industry produces no benefit.

Again, if NICNAS had conducted a RIS, we believe that the proposal would have been identified as only introducing additional regulatory burden on industry with no expected beneficial outcomes.

In the NICNAS proposal, it is suggested that the proposal to increase requirements for POPS assessment is in line with the recommendation in the Productivity Commission’s Research Report on Chemicals and Plastics Regulation (July 2008) (PC Report).

*“The other submission questioned whether this proposal was consistent with government policy, in particular, recommendation in the Productivity Commission’s Report on Chemicals and Plastics Regulation (July 2008) (PC Report) whereby NICNAS should become an assessment-only body. In fact, the proposed amendments are to satisfy NICNAS’s requirement to assess industrial chemicals for their persistence, bioaccumulation and toxicity.”*

The recommendation from the PC Report is as follows:

*“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, and the responsibility for administering the Cosmetics Standard 2007, and for implementing the Rotterdam Convention, should be removed from NICNAS.”*

Given this very clear recommendation that NICNAS should be distancing itself from the administration of the Rotterdam Convention, we fail to see how mandating additional information from industry on POPS than what was already established and accepted in 2004 can be seen as being in line with the PC Report recommendations. The addition of this requirement will impose a significant impost on industry and is not a minor change.

#### *Public Exposure information*

We need to understand the reason for the need for increased public exposure information requirements. As far as ACCORD is aware, there has not been any demonstrated need or market failure which requires increasing the information burden on industry in regards to this area. This is not a minor change.

The NICNAS proposal states:

*“Regarding comment on the expansion of the data requirements for public exposure (Part B.8), this amendment was designed to assist notifiers in providing relevant information to NICNAS and to assist in carrying out an adequate risk assessment. The amendment as originally proposed is retained. There will be occasions where the data required under this item will be minimal.” (our underlining)*

There is no evidence to date that NICNAS has not been able to carry out adequate risk assessment on new chemicals. There is no evidence, data or market failure to demonstrate potential concerns with the current level of data requirements. Australia’s data requirements for new chemicals is considered the most onerous of our major trading partners.

It is ACCORD’s view that the introducers of new chemicals have always provided ample information to NICNAS to carry out adequate assessment of new chemicals. We believe this is demonstrated by the safe use of chemicals in Australia. Therefore the new information requirements are not warranted, particularly as most of the time, the data required is expected to be onerous and burdensome, as suggested by the sentence “There will be occasions where the data required under this item will be minimal.”

#### *Clarification of requirements for some physical and chemical properties*

ACCORD is concerned that NICNAS’ proposal may limit the flexibility of data requirements.

*“Over time, some of the properties listed in the Schedule (below) have become inconsistent with these classification systems and therefore inconsistent with current test protocols, e.g. OECD and EU. The revision of these data requirements for some physical and chemical properties is intended to make NICNAS requirements more consistent with hazard classification requirements and international test protocols.”*

We believe that before suggesting any amendments on information requirements, NICNAS should first consider what information is necessary for risk assessment then provide the most flexible option to industry within that consideration.

For example, we do not believe that it is of relevance for risk assessment whether melting point or density or water solubility is measured to the OECD and EU test methods or by using another method. The difference between test methods are expected to be minor, therefore resulting in small difference in measured values. We question how melting point or density or water solubility of a new chemical substance measured using the OECD test methods would improve the risk assessment by NICNAS, compared to when the same properties are measured using other available test methods.

#### *Polymer Reaction Scheme*

We note that NICNAS is requesting the provision of polymer reaction scheme to assist in identification of the notified chemical.

NICNAS has been assessing polymers for many years – contrary to other major regions, such as the EU and the US that do not assess polymers (in case of EU when monomers are listed on the

inventory, in case of the US if the polymer meets the set definition for low concern). It has been a long held view of ACCORD that NICNAS should cease to assess polymers of low concern and do not support increasing the requirements for assessment of polymers.

Also, ACCORD assumes that until this point, NICNAS has correctly identified polymers being assessed. Therefore, this new proposed requirement appears to be an additional burden on industry without any tangible benefits. Again, the consequences of this proposal are not minor for industry.

*Provision of International Union of Pure and Applied Chemistry (IUPAC) chemical name*

ACCORD notes that NICNAS has amended its initial proposal to remove the IUPAC as an acceptable chemical name, and is no longer proposing to remove IUPAC name from the list of acceptable chemical names. As indicated in our previous submission, we believed this to be a nonsensical proposal and we are pleased to note that NICNAS is now in agreement.

However, we remain disappointed that NICNAS continues to assert that the Chemical Abstract Services (CAS) chemical name is required for listing on the Australian Inventory of Chemical Substances (AICS). The NICNAS proposal cites Regulation 5 for this requirement.

Regulation 5 of the *Industrial Chemical (Notification and Assessment) Regulation 1990* reads as follows:

**“5 Prescribed form of Inventory**

*For the purposes of subsection 11 (2) of the Act, the Inventory must:*

- (a) *be divided into a confidential section and non-confidential section; and*
- (b) *consist of lists of chemicals in the following form:*
  - (i) *the names of the chemicals in the same order as the sequence of the names followed by the Chemical Abstracts Service;*
  - (ii) *the Chemical Abstracts Service numbers of the chemicals in the same order as those numbers or, if those numbers are not available, in accordance with an alternative numbering system;*
  - (iii) *the molecular formulas of the chemicals in the same order as the sequence of the formulas followed by the Chemical Abstracts Service.”* (our underline)

Regulation 5 does not mention that CAS name or number must be provided. All it indicates is that the ordering of the inventory should be in the same order as CAS. Further, Regulation 5(a)(ii) which states “the Chemical Abstracts Service numbers of the chemicals in the same order as those numbers or, if those numbers are not available, in accordance with an alternative numbering system” indicates that contrary to NICNAS’ insistence, the regulation allows identification and assessment of chemicals without CAS name and number.

We have significant concerns that NICNAS appears to attach too much importance on CAS identification, to the detriment of other chemical identification means.

ACCORD does not dispute that CAS is one of the best recognised, utilised and most extensive database of chemical substances internationally. However, it is only one of the internationally recognised and used chemical identification systems. For cosmetic ingredients, the International Cosmetic Ingredient (INCI) name is a better used and recognised chemical identifier. Similarly for colourants, Colour Index (CI) number is used more frequently for identification internationally.

While we support chemical introducers using CAS name and number where it is available, we do not support limiting chemical identification only to CAS name and number, particularly as the intent of the ICNA regulation is to accept other forms of chemical identification.

### **Summary**

The proposals put forward by NICNAS confirm the findings of the PC report in that “elements of undue risk aversion are creeping back into the system” (p59). It recommended in Box 4.2 features of an effective and efficient chemical assessment scheme. It made the point that unnecessary data requirements on introducers of chemicals should be eliminated and duplication with other national and international assessments minimised. This is presumably why it recommended that the Australian Government should impose a statutory obligation on NICNAS to ensure that the costs of the chemical assessments are commensurate to the risk posed and that assessment priorities are directed to the most efficient management of the aggregate risk of all industrial chemicals (Rec 4.1). There is nothing in the NICNAS Proposal which indicates it is pursuing this PC recommendation.

As discussed in some detail under the heading “Administrative Issues” we do not believe that the consultation for the NICNAS Proposal has been conducted properly. We are particularly concerned with the lack of RIS by NICNAS.

Further, we are disappointed that NICNAS does not appear to have taken our comments from May 2010 seriously. We have stressed that the amendments proposed by NICNAS are not minor:

*“Generally speaking “minor amendments” are limited to editorial changes and does not include policy changes adding burden on industry. From industry’s perspective this Gazette notice appears to be NICNAS’ attempt to amend its Act to increase regulatory burden on industry without any regulatory impact assessment or cost benefit analysis.”*

The NICNAS Proposal which appeared without a RIS despite our comments raises cynicism that NICNAS is not really interested in the legitimate concerns of industry.

Apart from our in-principle support for the change to Summary Reports, ACCORD cannot support any of the other proposals put forward by NICNAS in its consultation. We believe NICNAS should review and revise its consultation process - as a minimum the consultation document should be re-circulated after a RIS has been conducted.

Thank you for the opportunity to provide this input. If you or any of your staff require any clarification on any of the matters raised in this letter, please contact our Science and Technical Manager, Catherine Oh at [coh@accord.asn.au](mailto:coh@accord.asn.au) or (02) 9281 2322.

Yours sincerely

A handwritten signature in black ink, appearing to read "Bronwyn Capanna".

Bronwyn Capanna  
**Executive Director**

13 August 2010