

NICNAS Cost Recovery & Cost Recovery for Accelerated Assessment of Existing Industrial Chemicals

Comment has been given by Jeff Simpson, Haztech Environmental;
They are supported by Tina Matene, Regulatory Affairs & Product Safety, Wacker Chemicals Australia Pty Limited,
dated 10 August 2010

NICNAS Cost Recovery (pages 1-7)

Cost Recovery for Accelerated Assessment of Existing Industrial Chemicals (AAEIC) (pages 8-10)

The numbering is based on the NICNAS question numbers.

NICNAS Cost Recovery

Q1 I regard that all persons who want to Introduce Chemicals into Australia need to be part of the NICNAS system. The advantage to the Tier 1 introducers is that they then become aware of their responsibilities via NICNAS to the Australian community.

Comment: I suggest that it is the responsibility of NICNAS to alert the Tier 1 introducers to the scope of Federal and State chemical management regulations these introducers may need to comply with (this then captures potentially ignorant introducers into the total chemical regulatory system).

Q2.1 The fee structure for each Tier should be adjusted in sensible increments with inflation. E.g. in \$50K increments for Tier 1 and \$500K increments for Tier 2. (I do not want to see some minor in between value of \$639,000 or \$6,390,000.

Q2.2 The original fee structure was kept simple so that it was easy for companies to decide which Tier they fitted into. For the \$5M+ companies they currently have no cost to decide which Tier they are in. There is no real problem that knowledge of which Tier a company is in can be a commercial advantage to competitor. IF a new Tier at the \$50M point was introduced this would create significant cost and time problems for the companies to determine this each year compared to the current system.

Q2.3 I see the current three Tier structure as reasonably fair for the system maintenance side of NICNAS's work as large companies trading \$50M+ may very well have a smaller range of chemical ingredients / products traded into Australia compared to a moderate trading company in the range of \$5M to \$50M.

Q3 The Tier 1 introducers with very small values have the option to work through a larger introducer (there are many chemical introducing trading companies which can be used). To allow the very small introducers under a Threshold to opt out means there are likely to be problems for both these introducers, and for NICNAS.

NICNAS Cost Recovery & Cost Recovery for Accelerated Assessment of Existing Industrial Chemicals

Comment has been given by Jeff Simpson, Haztech Environmental;
They are supported by Tina Matene, Regulatory Affairs & Product Safety, Wacker Chemicals Australia Pty Limited,
dated 10 August 2010

-
- Q4 Late Penalty Fees: these should be set to cover the average administrative burden cost so they are cost neutral for NICNAS. Maybe NICNAS should reassess at what point they apply and how to collect these late penalties?
- Q5 If the Late Penalty Fees are not paid at the final deadline, should the company then be required to cease introducing chemicals until they are? Otherwise it is not a level playing field for complying companies.
- Q6 A multi-year registration would ONLY get attention if there was a discount of say 5% for 2 years and 10% for 3 years. Otherwise it is currently quite straightforward as part of the financial year trading costs to have a yearly NICNAS fee.
- Q7 Alignment of the registration and reporting cycle to the financial year makes sense as for chemical introduction. HOWEVER this still needs to be done by the same time limits as now so that we don't expect companies to be collating the NICNAS registration and reporting data at the same time as the financial year records are being finalised.
- Q8.1 Cross-Subsidisation of New Chemical Activities: Currently Low Regulatory Concern Chemicals are already cross-subsidised by lower fees in proportion to the actual NICNAS costs.
I see that this is an essential way to lower the introduction costs for new innovative chemicals. However we need to extend the scope of the LRC chemicals to include chemicals which significantly improve "sustainability" ratings (see 12/ Reform suggestion below). These chemicals may have regulatory concerns when used in manufacture but if managed properly have significant benefits for the sustainable products they produce.
- Q8.2 Cross-Subsidisation – Other Issues: I am okay with minor cross-subsidisation (of up to 20% of an area's costs in a year) to occur which allows minor flexibility within NICNAS to administer their income and avoiding a necessary aspect of NICNAS coming to a halt due to lack of income specific to that function (but not to the detriment of the fund providing area).
However NICNAS needs to be careful (just like any business) to ensure they are not spending money for one purpose on another purpose, and must return the borrowed funds to the providing area in the following year or two.
- Q9 Screening submissions takes time (even if submissions are incomplete or withdrawn). NICNAS should be able to recover some or all of the costs (as anyone in business would expect to do). An average screening fee could be introduced (but this would then lower the registration or permit fee).
- Q10 The importance of the Electronic Template Rebate is how the data is provided. The screening fee suggested in 9/ should account for ensuring it is filled in correctly or withdrawn. Once correctly filled in the 15% rebate should apply and no partial rebates would then need to be calculated.
- Q11 The issue of Secondary Notification preliminary review costs will depend a lot on the knowledge and ability of the NICNAS reviewer. I regard that such an evaluation is really part of improving the knowledge



Wacker Chemicals Australia Pty Ltd
1/35 Dunlop Road
Mulgrave Vic 3170
Tel: +61 3 9541 8900
Fax: +61 3 9541 8989
Order Hotline: 1800 809 921
Email: info.australia@wacker.com

Wacker Chemicals Australia Pty Ltd ACN 005 712 489
Postal Address : PO Box 686, Mulgrave Vic 3170

Representative office for :-
Wacker Chemie AG
81737 Munich, Germany
Tel: +49 89 6279-01
Fax: +49 89 6279 1770
www.wacker.com

NICNAS Cost Recovery & Cost Recovery for Accelerated Assessment of Existing Industrial Chemicals

Comment has been given by Jeff Simpson, Haztech Environmental;
They are supported by Tina Matene, Regulatory Affairs & Product Safety, Wacker Chemicals Australia Pty Limited,
dated 10 August 2010

and ability of NICNAS staff to be able to cover such situations. As such this is really part of the normal
NICNAS staff training costs to carry out their role. I don't agree with this cost being recovered.

NICNAS Cost Recovery & Cost Recovery for Accelerated Assessment of Existing Industrial Chemicals

Comment has been given by Jeff Simpson, Haztech Environmental;
They are supported by Tina Matene, Regulatory Affairs & Product Safety, Wacker Chemicals Australia Pty Limited,
dated 10 August 2010

Q12 Level of Reform Activity Factors:

The key problem companies trading into Australia encounter is for their innovative new chemical(s) is that the costs to are too high (to get through the NICNAS process their costs are a combination of the NICNAS costs plus their own costs to provide the data and submit it).

Companies may never recover these costs for several reasons: e.g.

- a. With profit margins being generally <10% for a chemical the time to recover the registration or permit and additional costs means for an up front cost of \$25000 it takes >\$250K of product to be sold before any income occurs for a company. This problem stops most new chemicals being introduced.
- b. The person with the knowledge & links to implement the new chemical may no longer be with the company by the time the chemical is registered or permitted (and there is not another person to take over). The chemical is then never sold, has a significant negative cost, which puts off financial managers.

Q12.1 Suggestion: the reform activity Australia needs is to introduce innovative chemicals that improve the sustainability of Australia (in any way).

To have companies actively looking to do this, the future NICNAS reforms need to help them. The products of these companies need to be cross-subsidised by someone. This could be done by companies following the current process, NICNAS following the current process, then NICNAS would need to assess the chemical against agreed "Green Chemistry" standards and decide on a sustainability rating.

Not meeting the Green Chemistry" sustainability rating standard – no cost reductions

Bronze rating - 50% of NICNAS costs to be returned

Silver rating - 100% of NICNAS costs to be returned

Gold rating - 100% of NICNAS costs to be returned PLUS a Dept of Innovation or R&D grant (of say \$10K) towards development and marketing costs.

Comment: This would then mean NICNAS would need to create and maintain the knowledge base to be able to do this. This would activate many companies who have previously decided not to bring in an innovative chemical to have a go. There may be disputes over such assessments so the program would need strong links into the "Green Chemistry" etc research worldwide.

Q13 Special Levies specific to a sector for reform activity

On the surface this seems okay BUT the key problem is how to make it fair and include all those who might join in, once the reform has been finalised, without the costs of those in the sector who have been levied. Or does NICNAS introduce a similar 5 year right to continue trading for those who were levied (as occurs for new chemicals)?

NICNAS Cost Recovery & Cost Recovery for Accelerated Assessment of Existing Industrial Chemicals

Comment has been given by Jeff Simpson, Haztech Environmental;
They are supported by Tina Matene, Regulatory Affairs & Product Safety, Wacker Chemicals Australia Pty Limited,
dated 10 August 2010

Q14 No comment

Q15 The cost of Regulatory Impact Assessments is part of normal business for NICNAS, similar Authorities and indeed normal companies. I am surprised to find that this is not the case for NICNAS. The 5 year cost should be averaged over each year as part of the industry fees and govt revenue that NICNAS collects

or

The Regulatory Impact Assessment as a regulatory cost to be borne by the whole community through the general Govt revenue process from taxes (provided to NICNAS at the time of the RIS or averaged over 5 years).

Q16 NICNAS Reserve: In business when income dips significantly below costs, cost cutting is what needs to occur. For NICNAS this may mean that their reviewing specialists all become consultants (who can then be cut back when such NICNAS income dips occur and brought back when the NICNAS workload increases). These consultants could then work in industry and gain valuable reality check experience.

Q17 With 16/ as suggested in place NICNAS would have a much tighter control on their funds.

Q18 Training and New Assessment Methodologies: I expect these costs to come directly out of the fees that industry pays each year (including any Tier 1 fees left over if NICNAS cuts the bureaucracy to collect them). There will always be some form of new Methodologies.

Q19 Compliance Effort: Tier 1 Issues: A lot of time was spent at the 16 July 2010 Melbourne meeting about the bureaucracy cost to collect and administer the Tier 1 fees. We were advised that these fees for 3100 companies amounted to about \$2M out of the about \$9M NICNAS income.

Comment: I find it hard to believe (for a pure Tier 1 administration cost recovery to have them in the system) that it cost \$2M to collect the 3100 lots of \$381, including chasing up those who failed to register.

I see this Tier 1 cost as also including the cost of alerting the Tier 1 companies to the scope of Federal and State regulations they may need to comply with (as mentioned in 1/) and if any money is left over to help support the training in new methodologies of NICNAS staff (as in 18/ above).

Suggestion: The Tier 1 fees may need to be collected by a website option of electronically sending the money by credit card or BPay so that it does not need time to be spent on sending a hardcopy or scanned in document.

NICNAS Cost Recovery & Cost Recovery for Accelerated Assessment of Existing Industrial Chemicals

Comment has been given by Jeff Simpson, Haztech Environmental;
They are supported by Tina Matene, Regulatory Affairs & Product Safety, Wacker Chemicals Australia Pty Limited,
dated 10 August 2010

In particular for the very minor introduced quantities (of say <\$1000 per year) this MUST all be done electronically with only minimal review from staff (to ensure the capture, registration, & chase up of electronic processing does not cause problems for introducers).

- Q20 Outreach Activities: As mentioned in 1/ above I regard that for Tier 1 Introducers it is the responsibility of NICNAS to alert the Tier 1 introducers to the scope of Federal and State chemical management regulations they may need to comply with (this then captures potentially ignorant introducers into the total chemical regulatory system).
If NICNAS limits the Outreach Activities to just control schemes like NICNAS, this does not ensure introducers are alerted to the scope of chemical management regulations they need to be competent in.
- Q21 Cost Recovery Policy Document: This should include how the cost recovery, to bring in Low Regulatory Concern Chemicals, more Sustainable chemicals, more innovative chemicals with clear benefits, needs to be reviewed so that industry is positively advantaged to do this, and how the Government who wants such changes to occur can consider funding from general revenue (as e.g. in 12.1 / Suggestion above).
- Q22 Downstream Users of Industrial Chemicals are proposed to be included into the NICNAS Scheme.
*The 1989 NICNAS Act has under **3 Objects of the Act***
- (a) *a national system of notification and assessment of industrial chemicals for the purposes of:*
(i) *aiding in the protection of the Australian people and the environment by finding out the risks to occupational health and safety, to public health and to the environment that could be associated with the importation, manufacture or use of the chemicals;*
.... being a system under which information about the properties and effects of the chemicals is obtained from importers and manufacturers of the chemicals;

COAG has since clarified that NICNAS's functions be limited to the scientific assessment of hazards and risks of industrial chemicals.

Comment: The scope of the Act & COAG clarification clearly covers the industrial use of chemicals. Currently many introducers of chemicals do not have good understanding of the final industrial uses of chemicals they have introduced, which will add significant costs to them if they are not the final formulator for each use.

On this understanding it does seem relevant to consider that the industrial chemical formulators in Australia take some required part in the NICNAS process.

So as not to pick up minor formulators or minor downstream users (where it will be bureaucratically difficult to administer), only major industrial chemical formulators should be considered for inclusion. I suggest that this could start at the \$500k Tier 2 level at the current Tier 2 cost (or less).
For formulators I do not regard that there needs to be a Tier 3 cost level, as the reason for including them is to have them in the system so that the information knowledge base is improved for both the

NICNAS Cost Recovery & Cost Recovery for Accelerated Assessment of Existing Industrial Chemicals

Comment has been given by Jeff Simpson, Haztech Environmental;
They are supported by Tina Matene, Regulatory Affairs & Product Safety, Wacker Chemicals Australia Pty Limited,
dated 10 August 2010

formulators and for NICNAS. (Companies already covered by being a manufacturer should not be required to additionally register as a formulator).

Q23 I regard that there should be no automatic indexation of NICNAS fees nor of the Tier 1, Tier 2 or Tier 3 points. However changes to these should occur each year in discussion with all parties as has routinely occurred (this is standard business practice).

For the changes to Tier 1, Tier 2 or Tier 3 values, these also need to be considered for change each time they go through a 10% or so change otherwise bracket creep disadvantages the companies which move up a Tier. I want to see Tier 1 \$50K or Tier 2 \$500K increments so as to make them easier to work with.

Q24 I do not want an automatic annual adjustment for full CPI (as most businesses can't do this themselves). I suggest it may be useful to have an automatic 2/3rd CPI adjustment is a reasonable compromise (where NICNAS and industry both avoid to cost to notify and discuss the full CPI increase).

Q25 Fee for Service Activities: I support the fee for service arrangement (provided it is fairly collected). "Technical services relevant to industrial chemicals" would enable chemical companies having difficulty with understanding the properties and effects of their chemical product to ask for advice from NICNAS.

E.g. There are no Authorities in Australia except NICNAS that are maintaining the ability to help companies classify "difficult to classify" chemicals. In the past industry had 2 Dangerous Goods classification specialists (one in Worksafe Vic and one in Workcover NSW), but they both retired and were not replaced. I understand that the ability to provide this sort of service would need to be added into the Act or the Regulation or both.

There will be scope for where the service is for the general community benefit that such a service be funded from general government revenue (i.e. not collected via the industry Tier 1, 2, 3 fees).

Q26 No comment.

NICNAS Cost Recovery & Cost Recovery for Accelerated Assessment of Existing Industrial Chemicals

Comment has been given by Jeff Simpson, Haztech Environmental;
They are supported by Tina Matene, Regulatory Affairs & Product Safety, Wacker Chemicals Australia Pty Limited,
dated 10 August 2010

Cost Recovery for Accelerated Assessment of Existing Industrial Chemicals (AAEIC)

COAG Nov 2008:

“The Productivity Commission's recommendation envisages a resource intensive, Government-funded approach to assessment of existing chemicals. The extent and speed of implementation of this recommendation would be dependent on available funding. The recommendation for budget funding of this activity is not consistent with current cost-recovery policy as implemented in the National Industrial Chemicals Notification and Assessment Scheme. Resource implications require consideration in the development of an implementation plan.”

General comment: COAG has indicated above that this activity is resource intensive, but COAG has not laid out the scope of how it is to be done, nor has it required it to be a fully industry cost recovered activity.

Note: In the Discussion Paper NICNAS is only covering Prioritisation process and not mentioning the actual Assessment process.

From Jeff Simpson's Hazmat & Environment Notes April-June 2010 edition

“The cost of the EU REACH scheme to look at all existing chemical substances manufactured or imported at >1 tonne / year in the next 8 years is a massive cost and massive resource undertaking (they are unlikely to get through this task within the allowed timeframe).

It is important ensure that the Australian approach piggy backs its efforts as much as possible on the back of such efforts, and does not carry out any aspect before equivalent data is generated out of REACH or other schemes. We must also ensure the time allowed for this process to take place will be appropriate length periods for each hazard level and resource availability. This may mean an additional decade or two to get the results in an affordable manner for Australia.”

Recollecting chemical volume and use data for all chemicals in use in Australia is very difficult;

- Q27.1 View on the Benefits of Addressing Prioritisation and Assessment within a Reasonable Period of Time: We already have a set of 817 High Production Volume Chemicals (>20t per year) which can be addressed with prioritization and assessment. I do not regard that the small Australian chemical industry (compared to the EU and the USA) has the resources to provide additional information across every industrial chemical and use in Australia (see 27.2 below) in a cost effective way. However it is important that an Australian Chemical Authority tracks and then manages (in a timely manner) the chemicals of concern as they are found, in the accelerated review, evaluation and authorization of chemicals currently occurring in Europe (REACH). NICNAS could then have a call for information on whether and how these chemicals are used in Australia. As other major recognized world authorities (such as the USA EPA) also alert to chemicals of concern NICNAS should follow the same approach.

NICNAS Cost Recovery & Cost Recovery for Accelerated Assessment of Existing Industrial Chemicals

Comment has been given by Jeff Simpson, Haztech Environmental;
They are supported by Tina Matene, Regulatory Affairs & Product Safety, Wacker Chemicals Australia Pty Limited,
dated 10 August 2010

NICNAS needs to accept the outcomes and summary information of these REACH and USAEPA, etc reviews, as there is neither time nor money in Australia to independently reassess each of them.

Q27.2 To keep within the funding potential of industry and the government for AAEIC we must use the limited resources in Australia to do this type of work with great care.

NICNAS has asked for \$3M per year for 6 years, just to do JUST the prioritization work. Assuming a much higher level of "Use" detail (compared to the High Production Volume Chemical limited range uses) this will generate a very difficult situation and thus high cost problem for existing importers and manufacturers (many of who have limited access to use details and many ingredients where the chemical is on the inventory BUT the CAS No. is not known to an importer).

Even if NICNAS keeps to the existing scope of the 817 HPVCs and doesn't require new use information to be collected, as they prioritise they will still need to call for information on the chemicals of concern. These additional calls for information on the 200-300 of "sufficient concern" (as indicated by NICNAS at the 16th Jul 2010 meeting) will require significant time and resource costs for industry.

Q28 Raising of Funds for Prioritisation of Chemicals on the Inventory: I don't regard that Australia (industry and Government) has the funds to do this in the way NICNAS has indicated. Also NICNAS has not mentioned the funds they would need to carry out the actual chemical assessments (or the cost to industry to provide the required information for these chemical assessments). At the 16th July 2010 meeting (once prioritization has been done) NICNAS estimated 30-40 of these would need to be assessed. There will be a significant cost to industry to provide the required information for these accelerated chemical assessments.

Assuming we have a basic system that just looks at the 817 High Production Volume Chemicals (>20t per year) I suggest that the accelerated review of existing chemicals is an initiative that will help government, industry and the community.

IF NICNAS wants to prioritise and independently assess all the chemicals of concern on the AICS (because they are not satisfied with the REACH or USA EPA outcomes) and the Government agrees, then there needs to be recognition of the massive costs to do this and to fairly share these costs across all who will benefit. Because of the requirement to look at all chemicals over a short time frame of 6 years rather than say 18 years then industry's costs need to be say 1/36th of the upfront total cost to be paid over the next 18 years (where industry and government contribute 50:50 each).

To gain an indication of these massive costs NICNAS needs to urgently review the EU REACH costs.



Wacker Chemicals Australia Pty Ltd
1/35 Dunlop Road
Mulgrave Vic 3170
Tel: +61 3 9541 8900
Fax: +61 3 9541 8989
Order Hotline: 1800 809 921
Email: info.australia@wacker.com

Wacker Chemicals Australia Pty Ltd ACN 005 712 489
Postal Address : PO Box 686, Mulgrave Vic 3170

Representative office for :-
Wacker Chemie AG
81737 Munich, Germany
Tel: +49 89 6279-01
Fax: +49 89 6279 1770
www.wacker.com

NICNAS Cost Recovery & Cost Recovery for Accelerated Assessment of Existing Industrial Chemicals

Comment has been given by Jeff Simpson, Haztech Environmental;
They are supported by Tina Matene, Regulatory Affairs & Product Safety, Wacker Chemicals Australia Pty Limited,
dated 10 August 2010

Q27&28 There is an URGENT need for a Regulatory Impact Statement to be prepared by NICNAS for several scenarios of how the **Accelerated Assessment of Existing Industrial Chemicals** might be implemented in Australia, so that the Government, Industry and Community have the opportunity to understand the likely costs and benefits against each scenario, and decide which makes the most sense for Australia.

Postscript :

Wacker continue to support the ongoing efforts of PACIA and Haztech Environmental. We support harmonised, and cost-effective regulatory improvement across all facets of government. We support a sustainable future through innovative chemistry.

My thanks for your time and consideration.

TINA MATENE
REGULATORY AFFAIRS &
PRODUCT SAFETY

Wacker Chemicals Australia Pty Limited
1/35 Dunlop Road
Mulgrave Vic 3170, Australia
Postal address: PO Box 686, Mulgrave Vic 3170

Tel: +61 3 9541 8900
Fax: +61 3 9541 8989
Email: tina.matene@wacker.com

WACKER
CREATING TOMORROW'S SOLUTIONS