Australian Government
Department of Health and Ageing
NICNAS

National Industrial Chemicals Notification and Assessment Scheme

Proposal for Regulatory Reform of Industrial Nanomaterials

Public Discussion Paper – October 2009

Have Your Say Questionnaire

All submissions will be placed on the NICNAS's website. For submissions made by individuals, all personal details other than your name will be removed from your submission before it is published on the NICNAS website. Confidential material contained within submissions should be clearly marked. Reasons for a claim to confidentiality must be included in the submission coversheet. Where possible confidential material will be redacted from information published on the NICNAS website.

1. What is the significance and/or consequence of this working definition for 'industrial nanomaterials'?

   CHOICE welcomes the move by NICNAS to propose reform of the regulation of industrial nanomaterials.

   We recognise that new technologies can bring benefits to consumers and the environment. Some nanomaterials may raise little concern, others could present safety risks because of their new properties. Australian consumers expect a strong and consistent framework for ensuring their safety whilst helping to deliver improvements in things such as health services, food production and everyday consumables.

   CHOICE believes that steps urgently need to be taken in order to ensure that products which contain nanoparticles (or made using nanoparticles in the production process or equipment) are safe and beneficial to consumers and do not lead to human health and environmental risks. Regulatory systems for consumer and environmental protection must be updated in order to address the special characteristics of nanomaterials.

   There should be a standard definition for nanomaterials across all levels and arms of government in Australia, not one that NICNAS develops in isolation, solely for industrial nanomaterials.

   Nanomaterials are very complex. The definition may not be adequate, because it is not just about size, but also form, function and performance. For instance titanium dioxide had many forms, some of which are toxic and others aren't. What is biologically important is not possible to distinguish using an arbitary maximum of 100 nanometres. Testing of the final product, not solely the ingredients, is also important.

Australia has an array government authorities responsible for chemicals regulation: The TGA, APVMA, NICNAS, and FSANZ. And regulation of nano-technology has slipped through the cracks at the moment. The Australian government itself doesn't have a firm definition for nanoparticles yet.

The definition covers intentionally produced industrial nanomaterials, and so fails to take into account those that may be unintentionally produced, such as those milled further and mixed with other ingredients by formulators. Ingredients may be nano without producers realising it, for example, micronised zinc in sunscreens. Consumers Union, CHOICE's sister organisation in the United States, uncovered instances of sunscreens claiming to be nano-free which, when tested, in fact did include nanomaterials (Consumers Union, 2009). For consumers, the unfair result is that by explicitly choosing a product claiming to be nano-free, they are being exposed to nano. Regulators and producers should ensure that this does not occur in Australia.

CHOICE concurs with the conclusion expressed by Wickson (2009), that in order to provide a safety buffer Australia should adopt a broad and inclusive definition which will 'recognise nanomaterials as new materials for the purposes of regulation and safety assessment and use a broad definition based on functional characteristics'.

2. How do you think the proposal to limit access to exemptions for nano-forms of new chemicals will contribute to protecting health and the environment?

   Nano materials, in both new and existing chemicals, should be proven safe before they're allowed onto the market.

   There should be an evidence basis for the roll-out of nanotechnologies, to ensure, that they do not harm workers, consumers or the environment. Lack of evidence of harm is not evidence of safety. If there is no data, there should be no market. The European Union's Registration, Evaluation, Authorisation and Restriction of Chemical substances (REACH) scheme, puts more onus on industry to prove the safety of chemicals pre-market.

   NICNAS and other regulators have a duty to withhold nano-forms of all chemicals until their safety has been demonstrated. Where best available scientific evidence is insufficient to support the safety of the product/chemical, market access should not be granted.

   If NICNAS proceeds with a risk assessment approach, the detailed and transparent risk assessments must be made publicly available in full, as should the evidence on which a decision is based. The public should be entitled to help determine whether and under what conditions these technologies are researched and commercialised.

   Consumers should also have the ability to make informed choices about the products they purchase – the processes used to produce them and the ingredients and materials they contain. Consumers must have access to full and reliable information, including mandatory labelling of products that they come in direct, close or regular contact with which are derived from nanomaterials. (e.g. foods and cosmetics). This does not remove the need for full and mandatory pre-market assessment and approval of nano-products. It is about the public's right to know and choose.

   There should be thorough independent safety assessments of the nanotechnologies and materials, accompanied by strong government control over market access, and for consumers to be given the ability to avoid particular substances, by requiring full nano-particle ingredient labelling.

As Wickson (2009) rightly points out, the questionable social benefit of some uses of nano technology, such as increasingly widespread use nanoparticles of silver in socks, fridges and washing machines, should be weighed against public interest concerns, such as risks of antibiotic resistance and destroying 'good' bacteria that humans depend on. See CHOICE (2009a) for a similar argument.

3. Describe any ways in which you think self-assessment by an independent third party could be used to effectively achieve the same results?

   First party (self) assessment is not acceptable and will not achieve the same results.

   The responsibility should be on manufacturers and importers to prove safety, before market access is granted. However, assessments should be based on independent, published, peer-reviewed evidence of safety and efficacy rather than relying heavily on proprietary-generated data.

   Excitement about new technology must not lead to sloppy or biased risk assessment processes. Thorough, timely, balanced investigations not only of the potential benefits but the efficacy and potential safety risks of new technologies, are essential.

   Responsibility for sign-off of the safety of a nanomaterial should lie with an independent body, not a pharmaceutical, cosmetic, chemical or other company with a vested interest in marketing that product.

   In the United States, there are recently announced plans to undertake a raft of public interest research on nanotechnology. The questions for which have been developed with broad stakeholder input. Similar efforts should be made here – to balance proprietary-generated data. For example, it would be in the public interest to replicate the Bluescope Steel study and fully explore the implications of highly photo-catalytic nano-sunscreens on public health. Although some in the industry claim to have stopped using them, Consumers Union recently confirmed to CHOICE that both crystal forms of titanium dioxide, zanotase and rutile are in fact still in use.

4. If in R&D, what, if any, practical issues arise from the proposed administrative amendment for annual reporting of R&D exemptions? Would it require a significant increase in reporting? If so – how much?

   N/A

5. What are your views on the impact of the proposal to regulate nano-forms of new chemicals with the above changes to the permit and certificate categories? Can you identify additional advantages or disadvantages?

   See response to Q2.

6. What are your views on a system that is sufficiently flexible to amend permit conditions where new data indicates a new risk profile?
   Community and environmental safety is paramount. It is essential that when information becomes available indicating that a product previously permitted, is less safe than previously thought, that permit conditions are able to be amended, or the permit can be revoked.

   The government must act to protect consumer safety by placing the precautionary principle at the heart of nanotechnology regulation and should act swiftly when new

evidence comes to light that raises concerns about the safety of already approved substances.

7. What are your views on the impact of the proposal for mandatory once-off, use specific reporting for nano-forms of 'existing chemicals'? Can you identify additional advantages or disadvantages?

   Producers and manufacturers should be required to report all uses of nanomaterials to government. Although the chemical is existing, in nano form they should be regarded as new substances, because they are specifically engineered this way for their new behaviours and properties. This creates more of a level playing field for producers.

   Permits should be revoked when safety is found lacking, or not proven for an existing chemical. The bottom line should be removal of existing permitted uses if they can't be demonstrated to be safe, by a generous but firm cut-off date.

   Nano particles are on the market in products and the risks of them remain unestablished. Nanoparticles are now used in many Australian sunscreens and cosmetics, including mineral foundation. The extent of use is currently unknown. An audit of nano-forms of existing chemicals is essential. All manufactured nanoparticles should be treated as new chemicals and subject to rigorous new safety testing – even those previously used in bulk form. For example, chocolate with nanotitanium dioxide (added to improve its appearance) should not be allowed on the market without undergoing any safety assessment simply because titanium dioxide in its bulk form is a permitted additive.

   The way in which a product is ultimately used is vitally important to its safety assessment. CHOICE's mineral make-up investigation found two brands that contain nano particles: Elizabeth Arden and the Body Shop. Although not intended as a product to ingest, the some of the product unavoidably gets inhaled when swept across the face with a large brush. Triallists reported "dust clouds" during application and complained about the powder getting in their eyes, ears and mouths. We struggled to find any conclusive findings on the safety of inhaling nanoparticles. Some experts we interviewed expressed concern to us that there is still not enough known about the long term effects of this very new technology. (See CHOICE 2009b).

   There must also be independent, thorough, timely and transparent reviews and investigation of all adverse events associated with nanotechnologies. Specifically, any voluntary or mandatory withdrawals overseas should trigger a review in Australia. Complaints and concerns raised domestically should also be thoroughly investigated.

   See also response to Q2.

8. Explain how you think the potential burden of once-off, use specific reporting could or could not balance community expectations in relation to health and environmental standards?

   Once-off reporting will not go far enough. The community expects government systems to protect public health and the environment, in an ongoing manner. Consumers have an expectation that products which carry risks are carefully regulated so that their safety is maintained.

   In recent weeks, the US Environmental Protection Agency's Scientific Advisory Panel determined that knowledge of nanosilver is such that risk assessment in absolute

numbers may not be possible. Among other crucial things, minutes of its November 2009 meeting observe that information on basic nanosilver properties still needs to be collected, a definition is still needed for nanomaterials, dose metrics need to be resolved, and to find out how much of the substance is in various products (US EPA SAP 2010). With so many critical pieces of information missing, it is astonishing that such materials are not more tightly regulated.

At the moment in Australia, there are many products on the market using nano-silver apparently without evidence showing there is even a problem to address, let alone evidence that its use is safe. From our washing machine test CHOICE (2009a);

"The Samsung SW80USP claims to use nanotechnology, which is the manipulation and use of matter at the nano scale — that is, at atomic or molecular levels. Nanoparticles are used in products such as self-cleaning windows and long-lasting paints, and silver nano particles are also thought to effectively fight bacteria and fungi, which is why whitegoods manufacturers are jumping on the bandwagon.

On the Samsung website it's claimed that during the cold-water 'silver wash', 400 billion nano-sized silver ions are injected into the fabric, which creates an anti-bacterial 'coating' on your clothing.

At CHOICE we'd like to know if manufacturers are addressing a real problem, or is it just a marketing gimmick? How much research has been done? When asked to explain the reasoning behind the inclusion of nanotechnology in its washing machine, Samsung reiterated the benefits of bacterial-fighting properties, but didn't give us any evidence of whether there's really a problem with bacteria in washing machines."

9. What are your views on making the information gathered through streams 1A and 1B publicly available?

   The system should be sufficiently robust that it can confidently submit itself to community scrutiny. Moreover, the public deserve to know when nanomaterials are used in production processes, packaging, or as ingredients. Consumers deserve the right to know what's in the cosmetics and personal care products that they're putting on their skin (and inhaling).

   Presently there is no legal requirement for information on nanoparticles to be included on the label of cosmetics and sunscreens, so it's impossible to know what you're getting, short of contacting the manufacturer.

   Even then, claims by manufacturers may be made in good-faith, but wrong. For example, CHOICE's sister organisation Consumers Union tested 'nano free' sunscreens. And found that 'Nano Free' claims couldn't be trusted in the United States (Consumers Union 2008).

   Nano marketing claims should be properly regulated. Claims made about the purported benefits of nanoproducts will be subject to the Trade Practices Act like all other marketing claims, and should therefore not mislead the average consumer. NICNAS and other government chemicals regulators should assist the Australian Competition and Consumer Commission (ACCC) with expertise to ensure that unsubstantiated claims are promptly withdrawn and that these withdrawals are publicised.

   Rather than claims of 'nano-free', CHOICE has been calling for some time now for Australian regulators to mandate clear labelling / disclosure in the ingredient lists of

consumer products (such as cosmetics and foods) that use nano materials, so that consumers are given the information and the right to choose. Again, the ACCC and NICNAS along with other chemicals regulators, should work together for timely labelling of nano consumer products.

Nanomaterial permits for new or existing chemicals should all be listed on a public register, as in the United States Toxics Release Inventory, or Australia's National Pollution Inventory. This sort of publicly available information strengthens the credibility of the system.

10. What are the advantages and disadvantages of the introduction of a system that required a mandatory notification and assessment program for all nano-forms of existing chemicals? What are the reasons for this answer?

    CHOICE agrees with the idea of a once-off mandatory notification to get started, followed by an on-going system requiring mandatory notification for all nano-forms of chemicals – both existing and new.

    Mandatory reporting schemes can keep track of the introduction into the marketplace of manufactured nanomaterials and exchange information obtained about products being introduced. It will enable an extensive public inventory to be built up of all nanomaterials used in products on the market.

    See also response to Q7.

11. What are current issues that affect the feasibility of such a program?

    Any program will only be successful in protecting the health and safety of Australians and the environment, if the regulator is strong. At the stakeholder forum in Sydney it was raised that historically, NICNAS has not ever refused a permit.

    See response to Q10.

12. What are your views on making the information gathered from assessments of nano-forms of existing chemicals publicly available?

    It is essential to make the information gathered from assessments of nano forms of existing chemicals publicly available.

    See reasons given in response to Q9.

13. How might an integrated approach provide for more effective regulation of industrial nanomaterials compared to the package of options proposed in sections 3a and 3b?

    The aim should be a whole-of-government approach, not just whether regulation of nanomaterials is part of NICNAS's usual program of work or not. In other words, agencies such as the Therapeutic Goods Administration and the Australian Pesticides and Veterinary Medicines Authority should be working together to ensure the coordinated and responsible use of nanotechnology in Australia.

    The scope of the proposal needs to be broader. CHOICE believes that a full review of the regulation for nanotechnologies is required, because there are so many omissions in the current system. The government should be taking the health and environmental risks associated with nanotechnology seriously and addressing the new regulatory challenges it creates. Better assessment of nano and biotechnologies is required to

ensure that they are safe, effective and supported by the community.

The international community is facing similar challenges to Australia. Consumer representatives across the European Union and the United States issued a 'Resolution on consumer products containing nanoparticles' (Trans Atlantic Consumer Dialogue 2009), urging the governments of the EU and US to take prompt action to address regulatory needs for:

- Agreed definitions;
- Identification of products containing nanomaterials;
- Development of testing methods and technology to assess the safety of products containing nanoparticles with various characteristics;
- Address research gaps in understanding health and environmental risks;
- Develop and adapt regulatory frameworks to address the special characteristics of nanomaterials;
- Mandatory labeling of consumer products containing nano-ingredients; regulate nano marketing claims;
- Consult the public about their views on nanotechnologies, for both regulatory matters and government investments and subsidies;
- Government commissioned studies into the social and economic consequences of displacement of existing industries and commodities by industries based in manufactured nanoparticles.

WHO WE ARE

CHOICE is a not-for-profit, non-government, non-party-political organisation established in 1959. CHOICE works to improve the lives of consumers by taking on the issues that matter to them. We arm consumers with the information to make confident choices and campaign for change when markets or regulation fails consumers.

CHOICE is fiercely independent: we do not receive ongoing funding or advertising revenue from any commercial, government or other organisation. With over 200,000 subscribers to our information products, we are the largest consumer organisation in Australia. We campaign without fear or favour on key consumer issues based on research into consumers' experiences and opinions and the benefit or detriment they face.

To find out more about our campaign work visit www.choice.com.au/campaigns and subscribe to CHOICE Campaigns Update at www.choice.com.au/ccu.

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