Australian Council of Trade Unions

Submission to NICNAS regulatory consultation on
Proposal for Regulatory Reform on Industrial Nanomaterials
February 2010

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ACTU General Comments

The Australian Council of Trade Unions (ACTU) supports the views articulated in the submission of the Victorian Trades Hall Council (VTHC) regarding the NICNAS proposal for regulatory reform of industrial nanomaterials (NMs), which has been developed as a preliminary response to address the 'regulatory triggers' and 'gaps' identified in Australia's current regulatory system (as listed in Attachment 3 of the NICNAS discussion paper: Summary of findings of the 'Monash Report'[i])

The ACTU represents 50 affiliate unions and some two million members across Australia. Campaigning for the rights of workers to a healthy and safe working environment is core union business, and the ACTU has a proud history of fighting successfully for the rights and protections of all workers in Australia. In conjunction with our affiliates across the country, the ACTU has significant expertise and experience not only in the assessment of legislative effectiveness when it comes to Occupational Health and Safety (OHS), but in the improvements needed to ensure protections of the highest standard for all workers.

The ACTU adopted a number of recommendations on nanotechnology – (in April 2009[ii]):

- Nanoscale chemicals must be classified as new chemicals under the National Industrial Chemicals and Notification and Assessment Scheme (NICNAS)
- Government agencies should develop new standards for the handling of nanotechnology
- A mandatory requirement that all commercial products containing nanomaterials be labelled
- That a federal registry be established of all companies and organizations manufacturing, importing and supplying products containing nanomaterials.
- A tripartite body to be established to oversee the implementation of this regulatory framework
- Adoption of the "Precautionary Principle" when dealing with nanomaterials
- Development and improvement of hazard identification, assessment and control mechanisms for nanomaterials
- Enforcement of new exposure standards using an active inspectorate
- Monitoring of the health impacts on Australian workers involved in nanotechnology and investment in related medical research.

The ACTU is also a signatory to the International Center For Technology Assessment *Principles for Nanotechnologies and Nanomaterials Oversight*[iii].

The ACTU shares the VTHC position that it is very likely that "nanotechnology" will impact all industries and sectors of the Australian economy – and the use of this technology is growing daily[iv]. We have no doubt that nanotechnology has many potential benefits to Australia, including job creation. The overall 'social' benefits need also to be considered. However, there is still a great deal of uncertainty regarding the potential hazards of nanotechnology to workers, the general community and the environment. There is little doubt that nanotechnology introduces potentially serious new risks to both human health and the environment. We do not want to have another tragedy like the asbestos one in our history – yet the potential risks of nanotechnology are many times greater. The failure of government regulators to take seriously the early warning signs surrounding nanotoxicity and ensure that the Precautionary Principle is applied suggests that they have learnt nothing from any of the long list of disasters that resulted from the failure to respond to early warning signs about previous perceived 'wonder' materials, where '"Misplaced certainty about the absence of harm played a key role in delaying preventive actions [in most of the case studies]"[v]. The tragic example of these case studies we are most familiar with is asbestos.

International initiatives

The ACTU acknowledges that Australia is not alone in grappling with the challenges of regulating NMs – the same questions and challenges on how to regulate this emerging technology are being faced internationally. It will be important to ensure that, no matter what the outcome of the current proposal and how it is picked up in legislation, there is a built-in mechanism to monitor international developments, increased data on toxicity, risk assessments, etc so that necessary changes are made.

While there is a growing amount of research, there continues to be:

- Inadequate knowledge on the behaviour, biokinetics, biopersistence and risk of NMs
- Unreliable information on characterisation and measurement of NMs both 'pure' and in products
- Inadequate/insufficient methods of risk assessment

Governments and researchers are grappling with these challenges; and unions and union organisations, and NGOs have the same concerns and are asking the same questions.

Consequently, any changes to legislation based on the current consultation must be reviewed as more data becomes available as well as changes to legislation internationally. The ACTU proposes that a review of the regulatory measures taken for nanotechnology be undertaken after two years of their implementation.

2A Objectives of reform

The discussion paper states 'The proposed strategy addresses the uncertainty surrounding risks posed by industrial NMs, appropriateness of current risk assessment protocols and acknowledges NICNAS's links with national and international agencies that are actively considering similar issues. It aims to ensure appropriate regulatory oversight, industry cooperation and community confidence.'

However, the strategy, as outlined, only begins to address these uncertainties: while NMs of *new* chemicals will be 'captured', it must be acknowledged that the greatest challenge is posed by *existing chemicals* in nano form. The strategy just begins to address these. Increasing research on carbon nanotubes – nano forms of an existing, *non-hazardous* substance – has led to increasing concerns on their toxicity, and a move to declare CNTs as hazardous, as outlined below. From all indications, by far the majority of NMs in commercial use are nano-forms of *existing* chemicals. For this reason, nano-forms of existing chemicals should be considered *new* chemicals.

Overarching principles of the NICNAS regulatory strategy

The ACTU acknowledges that the NICNAS NAG is tripartite and includes union and community representation. However, while the NAG 'signed off' on the principles, the ACTU position is that they need to be stronger in their commitment to protect workers, the community in general and the environment.

We make the following comments:

1. *"Managing the risks posed by new technologies"* in (a) must be replaced with *"Eliminating, or where not possible, minimising, the risks posed by new technologies"*
2. Point (a)(iii): *"Review undertaken using inclusive and transparent processes"* needs to be expanded to ensure that all relevant stakeholders (unions, community) are provided with sufficient information, assistance and opportunity to participate in any such reviews.

3. Point (c): as it has been stated and acknowledged here and elsewhere, it is undeniable that there is insufficient 'scientific evidence' to support the safety of the majority of products/chemicals containing NMs. Studies reporting close associations between nanoparticles and their adverse effects on human health are constantly being published. Therefore, it is crucial that the Precautionary Principle (see below) be adopted with regard to industrial NMs, as called for by the ACTU. The overarching principles **must** include the Precautionary Principle. To repeat an often quoted line: "Absence of evidence is not evidence of absence."
4. This is crucial, not simply 'prudent', but necessary to ensure that, as in the first point: *"Any risk from the use of the nano-form of a chemical **is no greater than that posed by the conventional form of the chemical** or is at or below the level of acceptable risk ie humans and the environment are not exposed to unknown/unacceptable risk."*
5. Also, we argue that it is not only "prudent" but again, critical that *'Risk (including uncertainty) is addressed **pre-market'***
   (our emphases)
6. We believe that the third point, *'Industry innovation is supported through an appropriate level of regulatory oversight'*, should be eliminated from these principles. There are other government bodies whose main role is to promote innovation in industry, through provision of funding, expertise, etc.

   NICNAS' stated mission is: *'the integrated regulation of industrial chemicals **for the protection of human health and the environment through scientific excellence and regulatory efficiency** to deliver the **safe and sustainable** use of chemicals'*. That is, NICNAS should be primarily providing the 'checks and balances' to industry innovation.
7. In relation to the point: *"Risk assessments should be undertaken on a case-by-case basis"*, the ACTU stresses that risks assessments must be done on a case-by-case basis, given the wide diversity of physico-chemical properties of NMs will have a diverse effect on toxicity of these NMs. However, it is also important that a standardised nano-specific safety assessment is developed and applied to ensure confidence in individual assessments. Such an assessment is being considered internationally, though not yet finalised. This work should be considered by NICNAS.

   For example, the European Commission's Scientific Committee on Emerging and Newly Indentified Health Risks (SCENIHR)[vi] (2007) proposed the following properties as necessary for hazard characterisation:

   - Elemental composition;
   - Density;
   - Crystal structure;
   - Solubility;
   - Charge;
   - Conductivity;
   - Melting point;
   - Hardness;
   - Magnetic and optical properties;
   - Morphology;
   - Size and size distribution;
   - Surface area and surface layer composition;
   - Photo-activation; and
   - Potential to generate reactive oxygen species.

In 2009 the European Food Safety Authority (EFSA) recommended[vii] that nano-specific risk assessments include:

- Particle size (including distribution of particle size within the sample)
- Surface area and specific surface area of particles
- Shape (including aspect ratios such as fibre-like structures where appropriate)
- Chemical composition (including impurities and processing chemicals)
- Surface properties (e.g. coating, charge, surface adsorption properties)
- Solubility (in fats and water)
- Agglomeration/ aggregation and
- Biodegradability and biopersistence

The Precautionary Principle

This principle is fundamental in providing protection to health, safety and the environment when dealing with potentially serious, but unknown/uncertain risks, such as those associated with NMs.

The call to apply the Precautionary Principle to nanotoxicity risks – not just the ACTU

It is not just unions, in seeking to protect the health of workers, who have called for the application of the Precautionary Principle to nanotechnology. The need to adopt such an approach has been recognised by not only NGOs, but also by a number of governments.

In 2004 the United Kingdom's Royal Society – the world's oldest scientific institution – in conjunction with the Royal Academy of Engineering made very explicit recommendations for the precautionary management of nanotoxicity risks[viii]:

- "We recommend that chemicals in the form of nanoparticles or nanotubes be treated as new substances …in the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)… (Section 8.3.2: paragraphs 18 & 19)"
- "We recommend that ingredients in the form of nanoparticles undergo a full safety assessment by the relevant scientific advisory body before they are permitted for use in products… (Section 8.3.3: paragraph 24 & 23)"
- "We recommend that the ingredients lists of consumer products should identify the fact that manufactured nanoparticulate material has been added (Section 8.3.3: paragraph 26)"
- "Until more is known about environmental impacts of nanoparticles and nanotubes, we recommend that the release of manufactured nanoparticles and nanotubes into the environment be avoided as far as possible (Section 5.7: paragraph 63)"
- "Specifically, in relation to two main sources of current and potential releases of free nanoparticles and nanotubes to the environment, we recommend:
  (i) that factories and research laboratories treat manufactured nanoparticles and nanotubes as if they were hazardous, and seek to reduce or remove them from waste streams. (Section 5.4: paragraph 41)
  (ii) that the use of free (that is, not fixed in a matrix) manufactured nanoparticles in environmental applications such as remediation be prohibited until appropriate research has been undertaken and it can be demonstrated that the potential benefits outweigh the potential risks. (Section 5.4: paragraph 44)"

Even insurance companies are concerned. To safeguard against a repeat of the asbestos experience, one of the world's largest insurers, Swiss Re, believes that conservative regulation that puts health and safety first must be adopted to manage nanotechnology's risks, irrespective of uncertainties in scientific circles: "In view of the dangers to society that could arise out of the establishment of

nanotechnology, and given the uncertainty prevailing in scientific circles, the precautionary principle should be applied whatever the difficulties"[ix].

At the 2008 International Forum on Chemical Safety in Dakar, 71 governments, 12 international organisations and 39 NGOs recommended *'applying the precautionary principle as one of the general principles (of nanotechnology) risk management'*[x].

The ACTU believes that it is critical that the Precautionary Principle be adopted both in the overarching principles and in any subsequent implementation of regulation. This would require importers/manufacturers to provide evidence of safety specific to the NMs they are importing/manufacturing. The onus would be, as it should be, on those looking to promote and profit from NMs.

This will mean an 'added cost' and will no doubt be objected to by industry. However the ACTU points out that in 2005-06[xi] the ASCC (Australian Safety and Compensation Council) estimated that of the total cost of workplace injury and illness to Australia of $57.5 billion. Of these costs:

- (only) under four per cent ($2.2 billion) was borne by employers
- 49 per cent ($28.2 billion) was borne by workers and their families
- 47 per cent ($27.1 billion) was borne by the community.

These costs do not include costs to the environment. Government is already providing industry with financial and other support to promote nanotechnology, yet the vast majority of OHS and environmental costs in Australia are borne by the community. Industry stands to gain and at the very least should be made to accept that there will be an added cost to them to allow government to protect the community from the risks of this emerging technology. The ACTU makes this point in relation to every time the question of an 'added cost' to industry is raised in the Discussion Paper. The ACTU also makes the point that there may also be added costs to government; but it is a fundamental role of government to protect its citizens and the environment.

2B What are industrial nanomaterials? Issues of definition

Defining nanotechnology and nanoscience is currently extremely problematic, and this is recognised around the world. The ACTU acknowledges that a definition is essential to regulators so that there can be legal security – only once a definition has been adopted can the necessary legal institutions be created.

However, to date most of the definitions in use have focussed on scale – limiting the length from 0.10nm to 100nm. The definition proposed in the discussion paper is even more limiting, with the lower end being 1nm. While this has been a 'working definition', it has been raised in many fora, including the NAG, that this definition has been and is being constantly questioned and is the subject of an ongoing battle between academia, institutions, governments and stakeholders.

The problem is that this approach of defining NMs by scale is arbitrary, because its essential criterion is exclusionary: some effects and even new functions of nanoparticles occur above 100nm[xii]. The 100nm is an arbitrary indicator. What is to prevent the intentional manufacture of NMs just over the 100nm length, still exhibiting the same novel properties as those just under this length, simply to 'escape' requirements? It would be the 'economically sensible' thing to do! Furthermore, as the manufacture and fabrication of particles is still at this point imprecise, there could be exposure to nanoparticles outside these parameters. (Studies have found substantial differences between the actual dimensions of nanoparticles and those claimed by the manufacturer - eg with carbon nanotubes).

Nevertheless, as what NICNAS is currently proposing is a definition based on size alone - that is, between 1nm and 100nm – this is an unsatisfactory one as it is too narrow and excludes many particles that have already demonstrated novel nano-specific properties, behaviour and toxicity risks. Even though this 'working definition' is currently being used internationally, it is inevitable that this definition will be adjusted, and there is no reason why Australia cannot be at the forefront of developing a better and more appropriate definition. Any new legislation/revision to current legislation will take at least a year to implement and so we need to ensure that we do not 'lock in' a definition that has already been shown to be inadequate.

It is true that the focus has been on nanoparticles measuring between 1nm and 100nm, however there are already examples of both larger and smaller particles that have been found to exhibit novel and concerning properties. Fullerenes and single-walled carbon nanotubes, for example, can be smaller than 1nm; multi-walled carbon nanotubes (MWCNT) can be larger. These variations can be intentional or unintentional, yet if these NMs are excluded due to a too-narrow definition, then workers and the community will be put at risk.

Much concern has been raised regarding the toxicity of carbon nanotubes – sparking a number of articles on whether nanotechnology was going to be the new asbestos, including the question being posed in 2004 a report produced by the UK's Trade Union Congress[xiii]. The question is not a frivolous one. MWCNTs generally range from 10-200nm in diameter[xiv]. In their study into the potential of MWCNT to induce mesothelioma-like effects in mice, Poland et al. measured one of the two long MWCNT samples tested to have a diameter of 165.02 ± 4.68nm[xv]. More than 40% of the commercial MWCNT tested by Takagi et al had a diameter greater than 100nm[xvi]. Should the current definition be used, these MWCNT would not be classified as nanoparticles. This is clearly ridiculous and unacceptable.

Nano particles of zinc oxide, already commonly used in sunscreens, cosmetics, paints, etc have been found to be between 30nm and 200nm in size and even at the bigger end satisfy the requirement to be transparent[xvii].

It has been pointed out to us that there have been numbers of studies demonstrating that particles greater than 100nm share many of the novel characteristics of nanomaterials smaller than 100nm. These characteristics include:

- high reactivity
- bioavailability
- increased influence of particle surface effects
- strong particle surface adhesion
- strong ability to bind with proteins
- the ability to be taken up into individual cells – eg macrophages
- access the central nervous system through transport to the brain via the neurons from the nose

Just last year, at aural hearings for the UK's House of Lords Science and Technology Committee Inquiry into Nanotechnologies and Food, Professor Ken Donaldson said that was "no toxicological basis whatsoever" for the definition of a nanoparticle as a particle with at least one dimension of less than 100nm. "The idea that a 102 nm particle is safe and a 99 nm particle is not is just plain daft, it does not work that way. It is a sliding scale: … as particles get smaller their surface area per unit mass increases; and it is surface area that interacts with biological systems..." [xviii]

Professor Donaldson urged the Inquiry "not to be too hung up" on the 100nm definition, but to be also concerned about particles 200nm in size. He said that he didn't know where the cut-off point

was to define 'bulk' or 'natural' size, "but certainly we should not be too struck on the idea that 100 nanometres means harmfulness beneath it and harmlessness above it" [xix]

Further, there are more studies that suggest that even 200nm is not an appropriate upper limit. An example is a study of Linse et al. (2007) which found that in an in vitro study, along with smaller nanoparticles, the large surface area and surface charge of 200nm nanoparticles catalysed protein fibrillation (mis-folding)[xx] Protein fibrillation has now been shown to be involved in human prion diseases, such as Fatal Familial Insomia and Creutzfeld-Jacob disease, as well as Alzheimer's and Type 2 diabetes.

Consequently, the ACTU proposes that nanoparticles be defined as particles which:

1. Measure between 0.1nm and 300nm in one or more *external* dimension, or which have an *internal* structure that exists at this scale (for example in an agglomerate or aggregate, or where a nanoparticle has been designed to be attached to another particle); AND
2. For which SIZE affects function or properties, OR results in differences in toxicity when compared to its bulk form.
3. That the nanoparticle regime should be defined as the point at which a substance undergoes changes in physico-chemical properties at the nano-scale, when the properties of the particles differ from those of the bulk materials[xxi].

2C What is the current regulatory environment for industrial nanomaterials?

The ACTU strenuously disagrees with the fundamental conclusions of the 'Monash Report' that:

> *"Australia's federal regulatory frameworks are generally well suited to allowing adequate management and control of risks posed by engineered nanomaterials (NMs) and products incorporating NMs, and their manufacture, use and handling."*

The very 'triggers' and 'gaps' identified in the report mean that nanomaterials 'slip' under the current regulatory controls and thus while the regulatory framework *in principle* covers all hazardous substances, *including hazardous forms of substances which are NOT hazardous in their bulk form,* 'on the ground' this is not what happens. It would be beyond the expertise of most duty holders to be able to even question whether the nano form of substances that are not hazardous present risks, or question whether controls implemented in workplaces to eliminate/reduce the risks of hazardous substances in bulk form are in any way adequate for the same substance in nano form.

The current framework does not in any way guarantee protection of health, safety or the environment. The lack of specific legislation on nanotechnologies, the significant lack of data and information on the potential risks of NMs, the lack of even the most fundamental information on NMs, such as whether they are present in the workplace, as well as a lack of appropriate methods of risk assessment mean that it is highly likely that workers are being exposed to risks and have no idea. It is also highly likely that their employers do not have this information, and so would not even think to implement controls.

This is because, as noted by the European Commission's independent Scientific Committee on Emerging and Newly Indentified Health Risks (SCENIHR), "information on the presence of manufactured nanomaterials solely relies on information provided by manufacturers. In addition, exposure estimation is also hampered by lack of information on product use and use of multiple products containing manufactured nanomaterials."[xxii]

In fact there is no requirement for importers or manufacturers to even notify government or workers or other people who are potentially exposed that they are importing, using or manufacturing nanomaterials, much less a requirement for nanomaterials to be subject to new safety assessments either during manufacture or prior to release. Employers cannot implement the controls required under the OHS Act and the Hazardous Substances regulations unless they have the information. Workers cannot know that they may be being exposed to unacceptable risks unless they are given this information.

The ACTU notes that there has been work done, even in Australia, regarding good occupational health and safety practices to limit the exposure of workers to nanomaterials[xxiii]. But again, because there is no mandated duty to even inform workers that they may be being exposed, we are concerned that they are being unknowingly exposed. It should be noted that the authors of the SafeWork Australia report: *Engineered Nanomaterials - Evidence on the Effectiveness of Workplace Controls to Prevent Exposure*, in any case recommend that the Precautionary Principle be adopted in workplaces.

Clearly the greatest challenge in protecting health, safety and the environment is in dealing with nanoforms of existing chemicals. The ACTU recommendation is that all nano forms of existing chemicals be classified as 'new' chemicals, thus requiring a new assessment.

This is neither a new nor radical proposal:

1. As noted above, the UK's Royal Society and Royal Academy of Engineering recommended that nanomaterials be treated as new chemicals, and be subject to new safety assessments prior to their inclusion in consumer products. They further recommended that factories and research laboratories should treat nanomaterials as if they were hazardous, and until the environmental impacts of nanomaterials are better known, their release into the environment should be avoided as far as possible.
2. In 2008, the first recommendation of the NSW Inquiry into Nanotechnology was: "That the New South Wales Government recommend that nano-versions of existing chemicals are assessed as new chemicals, during the review of the national regulatory framework."[xxiv]

3A Regulation of nano-forms of 'new chemicals'

All 'standard' applications for 'new' chemicals (that is, not made under any of the exemption, permit or certificate categories) must contain information on particle size and other characteristics. This *should* allow NICNAS to identify whether any such 'new' chemicals contain nanoparticles. If so, then a nano-specific assessment must be made, as these chemicals cannot now be considered to be 'conventional'. As noted above, standardised nano-specific safety assessments must be developed and applied to ensure confidence in individual assessments.

a Proposal concerning NICNAS exemption categories (Low volume, transhipment and R&D)

Low volume exemptions:

The ACTU **agrees** that nanomaterials which are 'new' chemicals be exempted from low volume/low concentration exemptions and supports this proposal. This exemption category was based on low volumes of chemicals in their bulk form and is totally inappropriate when applied to NMs. It is crucial that these materials undergo a full assessment **prior to introduction** (nb, not simply 'pre-market')

Transhipment exemption:

The ACTU supports this proposal ONLY where it can be guaranteed that there can be no human or environmental exposure. In order to ensure that no exposure can take place, the company shipping the materials must:

- disclose the contents of the containers and provide information in the form of SDSs
- label the containers appropriately, including information on presence of NMs
- ensure that the containers are of a suitable type and standard to prevent any spills/exposure

It should be acknowledged, however, that it would still be possible for accidental exposure – and consequently companies applying for this exemption must be required to provide Customs with information on known/suspected hazards and any other relevant information.

R&D exemptions:

The ACTU continues to have concerns with this proposal.

Under this proposal, it would still be possible for a company to introduce up to 100kg of a 'new' chemical in nanoform and use it in a wide variety of circumstances without a full assessment of the chemical having been made. Under the proposal there are no restrictions related to the hazard of the chemical: the introducer does not even have to demonstrate that the NM would not pose unreasonable risk.

The stated assumption, that *"(the NMs) are handled only by trained personnel in a controlled environment"* is flawed in a number of ways:

1. It cannot be guaranteed that all personnel in research laboratories is appropriately trained, has been provided with adequate information and appropriate PPE.
2. It cannot be guaranteed that all research facilities have appropriate engineering controls in place
3. While there was some discussion at the NAG of a definition of "R&D" that can give some certainty that the NMs do not end up being in the broader community or in many workplaces, no satisfactory conclusion was reached and there is nothing on this in the proposal. Even in quantities much lower than 100kgs, the ACTU has no doubt that many workers in 'normal' workplaces will be placed at an acceptable risk of exposure particularly during the 'development' stage of R&D.
4. Introduction of any quantity of a nanoscale 'new' chemical has the potential to put workers at risk
5. A regulatory requirement to simply report quantities of over 100g/yr to NICNAS will do little to protect workers; as the quantities increase towards the 100kg, so too do the risks.

The proposal in effect puts the onus on NICNAS to scrutinize the introduction of potentially large quantities of 'new' chemicals in nanoform for R&D purposes. How will NICNAS ensure safety to workers and the environment? What checks will there be that R&D employers take action to protect the health of researchers, support staff, cleaners and others in 'R&D' facilities and the environment?

The ACTU proposes that an **alternative system** be considered for 'new' chemicals in nano form for R&D use.

This is a system similar to that currently in place around the nation governing the use of Scheduled Carcinogens, developed in particular to cater for the needs of laboratories, etc. This is justified given the uncertainty of the toxicity of nanomaterials. The model regulations[xxv] require that scheduled carcinogens be 'notified' to the authority: but the notification includes providing the regulatory authority with specific information. In addition, the employer must keep specific records,

including details of employees who may have been exposed to the carcinogen, for a period of 30 years (see Attachment 1). The employer must also provide subsequent information and advice to the regulator if there is an incident or spill, or if results of health surveillance indicate excessive exposure.

In this way, there would be some level of confidence that employers using NMs in R&D were in fact complying with their duties under the generic OHS regulations and implementing the sorts of controls needed to protect human health and the environment. The current proposal does not go far enough.

The administration of such a scheme could be 'shared' between NICNAS and the relevant jurisdictional health and safety authorities. The initial notification could be sent to NICNAS and any further information would go to the relevant OHS authority. The ACTU believes that the requirement to provide NICNAS with more detailed information on proposed use conditions in the workplace is valid.

With regard to the potential disadvantage of increased costs to industry, the ACTU re-iterates that the cost to workers, their families and the general community of occupational injury, disease and illness is growing, and of that cost, only 4 per cent is borne by the employer.

b Proposal concerning NICNAS notification categories (Permits and certificates)

The ACTU agrees that applicants seeking to introduce a 'new' chemical under a permit or certificate must provide information 'up front' on whether the chemical is or contains nanoparticles, irrespective of the quantity (but note earlier discussion regarding inadequacy of current definition of nanoparticles). We also agree that nanomaterials must be excluded from certificates sought and granted on the basis self-assessments, due to the high level of uncertainty regarding toxicity. This will mean that these will be notified to NICNAS, which will itself undertake assessments of all NMs to assess the level of concern and what further information will need to be provided prior to granting of the permit or certificate as appropriate.

However, there is insufficient information in the discussion paper with regard to how this assessment will be done by NICNAS. NICNAS must ensure that the Precautionary principle is applied across all nano-related activities.

While the proposal is that more specific information will be sought in certain circumstances (as per Attachments 6 & 7 to the Discussion Paper), on the basis of which NICNAS can further assess the chemicals, there are some concerns:

1 - An assumption that if nanoparticles are soluble they are of low concern

This is an incorrect assumption, perhaps based on what was previously thought to have been the case prior to recent toxicology work.

SCENIHR (2009) stated that solubility nanoparticles in water and their rate of dissolution is complex and remains poorly understood, and further that establishing the water solubility of a particular particle does not of necessity provide an accurate measure of its solubility in the body or in the environment.

SCENIHR stated with regard to risk assessments:
"For (partially) soluble nanomaterials the toxicity may be governed at least in part by the soluble species/fraction released from the nanomaterial. For low solubility or a slow release, the particulate nature of the substance may be relevant with regard to potential tissue distribution and local release of toxic species which should then be considered in the risk assessment of such nanomaterials."

There is much evidence that that water soluble and partially soluble metal and metal oxide nanoparticles can exert both ion and particle-mediated toxicity which can be greater than that of ions alone.[xxvi]

In addition, by only requiring further information only *'if particulates have, or known to have water solubility of 1.0mg/L or less'*, that is, almost wholly insoluble, would *exclude* many particles that have been shown to display novel behaviours, biotkinetic properties and bioavailability.

2 – An assumption that if nanoparticles are not biopersistent they are of low concern

This is an incorrect assumption. Biopersistence too is poorly researched and poorly understood. Even particles that do not show significant biopersistence may pose acute nano-specific toxicity (eg Bai *et al* 2009, Brunner *et al* 2006, and Xia *et al* 2008[xxvii])

The above problems, which can be described as 'definitional issues' together with those associated with particle size as discussed above, must be resolved if NICNAS is to be able to provide an acceptable level of protection to health and the environment in its assessment of NMs.

The ACTU applauds NICNAS in proposing changes to the current permit and certificate schemes which will provide some extra level of information and scrutiny to NICNAS. It is acknowledged that the implementation of these changes will go some way to addressing the 'triggers' and 'gaps' identified by the Monash Report, and *should be* achievable in the short term. However, the ACTU believes that the proposals for new chemicals do not provide adequate assurances that health and the environment will be protected.

The ACTU proposes that a **separate category of permits be introduced for NMs**.
In order to apply for and secure such a permit, thereby being granted permission to introduce commercial quantities of NMs, introducers must be able to demonstrate to NICNAS that the nanomaterial is of 'no unreasonable risk' or 'low hazard'. This means the provision of a full nano-specific health and environmental assessment, with a full physico-chemical characterisation and safety data specific to the nanomaterial in question. In addition, these risk assessment reports should be available publicly. The permits need to retain a maximum duration period to ensure that as more toxicological information becomes available, permits can be varied or even cancelled. If a substance for which a permit has been issued is proven to be safe, then it can be moved onto AICS.

Substances with 5% of particles <100nm, or <50% of particles 200nm and substances with 'nanomaterial properties' should automatically trigger mandatory notification and assessment (nb both 'new' and 'existing').

3B Regulatory 'package' for nano-forms of 'existing chemicals'

This is the area of greatest concern to the ACTU and our affiliates. From all available information, there are a growing number of industrial nanomaterials which are nano-forms of 'existing chemicals' in our workplaces and in the general community – and we don't know about them. As noted in the Paper:

- NICNAS is unable to reliably identify introducers of nanoforms
- Most conventional chemicals on the inventory have not been assessed
- The nano-form of these conventional chemicals can be legally introduced, without notification to, and assessment by, NICNAS
- Any existing risk management measures have been assigned on the basis of the characteristics of the conventional form of the chemical
- *It may not be apparent* to introducers of nanomaterials that secondary notification provisions (which operate for assessed chemicals) apply to their nano-forms.

In our view, it is unlikely that many introducers of assessed chemicals in nano-form are complying with the secondary notification requirements, whatever the reason. In addition to this, there are no such requirements for non-assessed chemicals.

The situation as it currently stands is appalling and totally unacceptable to the ACTU and our affiliates. More and more evidence is emerging that nanomaterials used in commercially available consumer and industrial products present very serious new toxicity risks to human health. Some of these have been referred to in this submission. Yet we have no idea of the potentially countless numbers of workers and members of the public who are being exposed to manufactured nanomaterials daily while there is little data on potential long-term or chronic effects of these materials[xxviii]. The duty holders who need to know about nanomaterials in the products their workers may be exposed to in workplaces do not have this information, and even worse, are probably not aware that they are lacking the information to be able to apply the Precautionary Principle and implement controls, and so on.

The proposal

Stream 1

The Discussion Paper notes that voluntary calls for information on nanomaterials have had 'limited success'; in fact, these calls have been spectacular failures. This has been the experience in the UK, the United States and elsewhere. These governments have acknowledged that years after initiating such voluntary reporting schemes, there is still little information available on the extent of nanomaterials in commercial goods.[xxix]

The two previous NICNAS voluntary calls for information on nanotechnology yielded poor results, despite a huge effort by staff to contact companies. In our view, the second call in particular was a waste of time, energy and resources. The community representatives on NAG voiced their concern when the second voluntary call was initially put forward. Even one of the industry representatives voiced a view that the only way to ensure getting the information was to make it a mandatory requirement, but agreed to 'give it one more go.' In our experience, duty holders too often do not comply with mandatory requirements, much less agree to undertake activities as part of voluntary initiatives. Why should they? A large part of the role of unions and elected OHS representatives is to raise issues of non-compliance in workplaces, 'inspectors' on the ground. The other point to be made is that it is unfair to those companies which DO respond to voluntary initiatives, when many

of their competitors don't bother. The ACTU does not in any way support *another* voluntary call for information, as proposed in Stream 1A.

Stream 2

In our view, NICNAS should be introducing an amended Stream 2, as discussed above (new permit category to encompass all nanomaterials).

The information that is gathered through the mandatory call for information, as well as information from the assessments MUST be made publicly available. At the very least the following information must be made available, and cannot be repressed due to 'confidentiality' claims:

- Use or uses of the chemical/nanomaterial;
- Estimation of quantities of the chemical/nanomaterial produced, imported, exported and used;
- Physico-chemical, toxicological and ecotoxicological properties;
- Information contained in safety data sheets (SDSs)*;
- Hazard classification;
- Information on precautionary measures;
- Information on regulatory requirements;
- Information submitted by other parties, international organizations, nongovernmental organizations or other relevant sources;
- Information on alternatives and their relative risks, and industrial practices and processes, including cleaner technology.

NICNAS should set up a database of all introduced NMs together with the above information.

The ACTU believes that there clearly needs to be an integrated regulatory approach to nanomaterials which will need to involve a number of different regulators and government 'bodies'. However, this will require new legislation, which will take time, potentially a long time. Consequently, it is imperative that NICNAS ensure that there be a mandatory call for information, and that nano-forms of existing chemicals face mandatory notification and assessment as soon as possible. In the short term, this may require NICNAS to issue secondary notifications to all manufacturers/notifiers whose products may contain NMs, requiring them to investigate the properties of their products (as discussed above). We believe that NICNAS should be proceeding with the "Stream 2" proposal – only in this was will the community expectation of protection of health and the environment be satisfied.

Attachment 1 Notification requirements under the
National Model Regulations For The Control Of Scheduled Carcinogenic Substances

NOTIFICATION OF SCHEDULED CARCINOGENIC SUBSTANCES

6(1) An employer or supplier shall not use a scheduled carcinogenic substance unless:

a) a suitable and sufficient assessment has been carried out; and
b) the relevant public authority has been notified of the intention to use a Schedule 2 carcinogenic substance; and
c) the conditions have been met for use of a Schedule 2 carcinogenic substance which may have been specified by the relevant public authority under sub-regulation 7(2).

(2) A supplier shall not supply any carcinogenic substance listed in Schedule 2 except where the purchaser provides evidence that the relevant public authority has been notified of the intention to use that substance.

(3) Notwithstanding regulation 11 of the *National Model Regulations for the Control of Workplace Hazardous Substances* [NOHSC:1005(1994)]1, a suitable and sufficient assessment shall include:

(a) a review of the current Material Safety Data Sheets and other relevant supplementary information which is available; and
(b) an assessment of the specific work involving potential exposure to any scheduled carcinogenic substance.

(4) An employer or supplier shall notify the relevant public authority with the following information in respect of the intended use of a carcinogenic substance listed in Schedule 2:

(a) the business address of the employer;
(b) the address of any place where the carcinogenic substance will be used or produced;
(c) the name of the carcinogenic substance;
(d) the name(s) and address(es) of the supplier(s) of each carcinogenic substance;
(e) details of the activity or process using carcinogenic substances and the reasons for the use or production;
(f) the quantity of each carcinogenic substance to be used or produced per annum;
(g) the number of employees exposed to each carcinogenic substance;
(h) the name and business address of the person or organisation carrying out the assessment;
(i) justification that elimination and substitution are not practicable and that the controls in place are the best practicable; and
(j) a description of the measures taken to prevent or minimise exposure of persons to the carcinogenic substance and to protect the health of persons.

(5) Notwithstanding sub-regulation 6(4), where any carcinogenic substance listed in Schedule 1 or Schedule 2 is used in a laboratory or laboratories for the purpose of bona fide research or analysis, the employer shall make a Laboratory Notification to the relevant public authority in relation to all such notifications.

(6) A Laboratory Notification shall be in writing and contain the following information in respect of the intended use of a carcinogenic substance listed in Schedule 1 or Schedule 2:

(a) the business address of the employer;
(b) the address of the location where the carcinogenic substance(s) will be used or produced;
(c) the name(s) of the carcinogenic substance(s);
(d) the quantity of each carcinogenic substance to be used or produced per laboratory per annum;
(e) a statement that the carcinogenic substance(s) will be used for bona fide research or analysis;

(f) a justification that elimination and substitution are not practicable and that the controls in place are the best practicable; and
(g) a description of the measures taken to prevent or minimise exposure of persons to the
(h) carcinogenic substance and to protect the health of persons.

(7) Notwithstanding sub-regulation 6(6), where one or more Schedule 1 or Schedule 2 carcinogenic substances are to be used in a laboratory or laboratories for the purpose of bona fide research or analysis, the employer may make a single Laboratory Notification for the information required under sub-regulation 6(6) for all such carcinogenic substances.

(8) Any significant changes to the information provided under sub-regulations 6(6) and 6(7) shall be notified to the relevant public authority.

(9) A notification under sub-regulation 6(1)(b) shall be revised by the employer:
(a) whenever there is evidence to indicate that it is no longer valid;
(b) when there has been a significant change in the use of a scheduled carcinogenic substance; or
(c) when the assessment is reviewed.

The new information shall be notified to the relevant public authority.

(10) A new notification under sub-regulations 6(1)(b) or 6(5) shall be submitted at intervals not exceeding five years.

RECORD KEEPING
8 (1) An employer shall maintain the following information, as a record in a suitable form, for at least 30 years from the date of the last entry in the record:
(a) a list of employees whose position has been identified as a result of an assessment as having a likelihood of exposure to a carcinogenic substance listed in Schedule 1 or Schedule 2, including full names, dates of birth and addresses during the period of the persons' employment with the employer;
(b) a copy of any notification made to, and any exemption granted by, the relevant public authority; and
(c) a copy of the conditions for use of a scheduled carcinogenic substance which may have been specified by the relevant public authority under sub-regulation 7(2).

(2) A supplier shall retain as a record, for a period of five years, the following information for each scheduled carcinogenic substance they supply:
(a) the name of the purchaser; and
(b) the name and quantity of each scheduled carcinogenic substance supplied.

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