Attachment B

(excerpt from *Australian Government position on NSW Government's nanotechnology inquiry* developed by the Enabling Technologies Health, Safety and Environment Working Group)

General Statement made in response to labelling for any purpose

Recommended Approach
At this early stage of use of nano products, labelling for informed choice should not be supported. At present there are significant technical difficulties associated with the reliable physical measurement and chemical characterisation of nanoscale particulates in complex matrices such as food and cosmetics. This could be reviewed in the light of international developments – such as metrological advances or the introduction of viable consumer choice labelling of relevant goods by trading partners.

Commonwealth Advice
Labelling of nanomaterials is an important element to manage health, safety and environmental hazards. Under existing regulatory frameworks, any product with safety concerns is required to be appropriately labelled, as is the case with chemicals and explosives. Reviews of regulatory frameworks being undertaken in response to the Monash report are considering where labelling of nano-products may be appropriate to address health or safety implications arising from normal use of a product, exposure in the course of manufacture (Occupational Health and Safety (OHS) requirements), unusual circumstances such as accidents, disposal at end of useful life, harm resulting from long term use, exposure or disposal. However, there have also been calls from NGOs and the ACTU for labelling of products containing nanomaterials to assist consumers to make informed product choices. The issue of labelling is complex, as the properties of a specific nanoparticle may be altered and controlled by various means.[2] International discussions relating to labelling are progressing in the ISO nanotechnology group.

Some of the issues raised by labelling for informed choice include:

- nanotechnology will have wide applications across medicines, food, industrial chemicals, and ICT, leading to possible confusion on what the labelling was attempting to achieve;
- it could be difficult to present the level and type of information required to inform choice in a meaningful way on a label;
- most samples or products containing larger (non-nano) particles of a certain chemical are also highly likely to contain a small proportion of nano-particles, depending on the method of manufacture, and so there is an issue surrounding the absolute or percentage mass (or another metric) that should trigger labelling, and how the relevant metric can be quantified;
- there is the risk that such labelling information might imply that all nanoparticles are dangerous without any proof and details of danger; and

[2] This includes choice of internal structure (eg Titanium dioxide with either rutile or anatase structure), doping the lattice structure with trace amounts of other elements, and coating the surface of the nanoparticles with a variety of other molecules.

- it detracts from and blurs specific labelling that provides health and safety warnings.

Some of the arguments supporting the addition of informed choice labelling include:

- to promote a standardized approach to labelling;
- to ensure that users of manufactured nanoparticles (MNP) and products containing manufactured nanoparticles (PCMNP) can correctly identify the MNP contents for the purposes of assessing risk in selection, purchase, distribution, handling, use and disposal, and especially while information is being acquired on effects on the natural environment and human health from both short and long-term exposure to nanoparticles;
- to inform regulatory authorities and assist healthcare professionals, technicians, health and safety officers and others to make informed decisions in relation to matters of occupational, consumer, public and environmental health and safety; and
- to provide guidance on the use of other specific terms in these labels.

Statement made in response to labelling of Sunscreens and cosmetics

Recommended Approach

At this time, it is not recommended to introduce mandatory ingredient labelling for sunscreens and cosmetics that identifies the presence of nanoscale materials, as it would not be informing consumers of any hazard nor is it technically feasible to enforce at present. There are a number of established regulatory mechanisms for addressing sunscreen/cosmetic safety issues. The TGA has the ability to withdraw sunscreens from the Australian Register of Therapeutic Goods (ARTG) if evidence becomes available of any adverse health effects from the nanoparticles in them. NICNAS can restrict or prohibit use of chemicals through annotating the Australian Inventory of Chemical Substances or recommending scheduling on the Standard for the Uniform Schedule of Drugs and Poisons (SUSDP). The ACCC can also recommend that the Minister for Competition Policy and Consumer Affairs ban unsafe goods or introduce a mandatory product safety standard.

However, it is in response to the European developments that the industry association ACCORD has approached the Government to introduce mandatory labelling. Discussions are being arranged for officials to discuss this issue both internally and with representatives of ACCORD.

Commonwealth Advice

NICNAS has responsibility for regulating sunscreen chemicals where they are used in a "secondary sunscreen product" (i.e. a product whose primary purpose is not to provide sunscreen protection, such as a moisturiser), and have an SPF up to 15. The Therapeutic Goods Administration regulates sunscreens with a higher SPF.

The TGA has advised that there are a number of factors that dictate the various warnings, statements and declarations that are made on any individual medicine label. The aim of this information is to support the consumer using the medicine appropriately and safely. To date, the TGA has not identified a requirement for a specific safety warning regarding nanoparticles of zinc oxide and titanium dioxide in

sunscreen medicines. Mandatory labelling of sunscreens and cosmetics that contain nanoparticles would require legislative change.

The TGA has reviewed the safety of nanoparticles of zinc oxide and titanium dioxide in sunscreens and concluded that there is currently no evidence that these substances pose health risks to people that use them. The TGA is continuing to actively monitor and assess the literature to ensure that this conclusion remains valid in light of new scientific information. Given the public interest in this issue, in July 2009 the TGA published an updated review of the scientific literature on the safety of zinc oxide and titanium dioxide nanoparticles in sunscreens. The review is available on their website.

Given that the TGA has concluded that there is currently no evidence that these substances pose health risks to people that use them, the costs of mandatory labelling of goods containing nanoparticles to the community require serious consideration.

The ACCC is responsible for administering the *Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991* which requires that cosmetic ingredients must also be declared on the label of the product. Physical particle characteristics for chemical substances are not required to be declared on cosmetic labels and these details have not typically been captured and recorded on the Australian Inventory of Chemical Substances (AICS) as part of the NICNAS regulatory processes. Generally suppliers are aware that under the *Trade Practices Act 1974* (TPA) they are liable for injuries (or property damage) caused by a defective product. The strict liability provisions of the TPA would apply to injuries that result from any ingredients in cosmetics should it cause the product to be defective.

The ACCC notes that changes to cosmetics ingredient labelling to include the identification of nanomaterials would need to be justified according to the provisions of the TPA and a Regulatory Impact Statement assessing the costs and benefits of any proposed regulation would need to be prepared. In the case of a product safety standard, the Minister for Competition Policy and Consumer Affairs would have to be satisfied that it is reasonably necessary to prevent or reduce risk of injury to any person. The health impact assessment would need to be conducted under the auspices of the Department of Health and Ageing, probably by NICNAS. Should a particular ingredient be determined to be harmful when used in cosmetics it is considered more likely that the ACCC would recommend that its use in cosmetics be prohibited.

Internationally, in March 2009, the European Parliament (EP) approved an update of Cosmetics Directive[3] to require labeling and notification of nanomaterials in cosmetics. Similar to proposed changes to NICNAS assessment processes, this introduces a safety assessment procedure for all products containing nanomaterials, which could lead to a ban on a substance if there is a risk to human health. Members of the European Parliament also pushed successfully for any nanomaterials present in cosmetics to be mentioned in the list of ingredients on the packaging. Australian

[3] In the EU, a **Regulation** is defined as a legislative act which becomes immediately enforceable as law in all member states. **Directives** are required to be transposed into national law (at least in principle) by each Member State. Enforcement of directives becomes the responsibility of each Member State.

regulators will monitor how successfully these requirements are able to be implemented and assess whether there are any identifiable consumer benefits.

The European developments have resulted in ACCORD, the national industry association for the consumer, cosmetic, hygiene and specialty products industry, to put forward a proposal requesting the introduction of mandatory labelling. The ACCORD secretariat met with Minister Roxon and the then Parliamentary Secretary Butler on 16 June 2010, to discuss nanomaterials in sunscreens and cosmetics and issues relating to safety assessment and consumer information. At this meeting ACCORD tabled its labelling proposal. ACCORD has also wrote to Minister Carr and Minister Emerson bringing this proposal to their attention. Quoting from the proposal of 15 June 2010:

'An ACCORD member company consensus has been obtained for the following proposal, which mirrors the content and timing of the nano-labelling approach that will be introduced in the EU:

- Industry proposes that ACCC (the cosmetic ingredient labelling regulator under the TPA) and TGA commence separate but complementary processes to amend their respective regulations.
- It is proposed that ACCC amend 'Cosmetic & toiletry - ingredient labelling, product information, a mandatory guide' standard under Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulation 1991 to introduce an EU-style labelling of nanomaterials - e.g. "All ingredients present in the form of nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word 'nano' in brackets
- Likewise, TGA amend its Therapeutic Goods Labelling Order No. 69 - which focuses on active ingredients, like zinc oxide and titanium dioxide.
- And that both regulators aim to have the new requirements come into force on (or no earlier) than 11 July 2013, which is the entry into force date specified in the new EU cosmetic (inc sunscreens) labelling laws.'