Attachment 3

SUMMARY OF FINDINGS FROM REVIEW OF THE POSSIBLE IMPACTS OF NANOTECHNOLOGY ON AUSTRALIA'S REGULATORY FRAMEWORK)

Chapter 5 Regulatory Triggers, Gaps and Additional Comments

5.1 Summary of Findings

Australia's federal regulatory frameworks are generally well suited to allowing adequate management and control of risks posed by engineered NMs and products incorporating NMs, and their manufacture, use and handling. This conclusion uses as the baseline comparator the level of HSE protection provided by the regulatory frameworks in relation to conventional products. This review found that there was no case where a particular regulatory framework generally did not apply to a nanofamily as a result of the presence of NMs. Accordingly, whilst not all frameworks applied to all nanofamilies, this was not due to the involvement of nanotechnologies or presence of NMs.

Further, the application generally of the federal regulatory frameworks to NMs and products in the nanofamilies meant that regulation throughout the whole of the lifecycle of these materials is largely the same as for conventional products. Therefore, for example, those regulatory frameworks put in place to protect Australians and their environment from harm from imported products, such as the Customs and AQIS Regulatory Frameworks, and from imported and locally produced products, including the APVMA, FSANZ, GTR and NICNAS Regulatory Frameworks generally were relevant. The application of multiple regulatory frameworks at the one lifecycle stage means that, as for conventional products, there will be overlap between the regulators. For example, crops genetically modified for pest resistance are regulated under the APVMA, GTR and FSANZ Regulatory Frameworks. Functional foods whether incorporating NMs or not, will raise issues of the boundaries between FSANZ and the TGA Regulatory Frameworks.

The general repercussions of such applications were also the same as for conventional products – for example, some regulatory regimes involve regulatory approval prior to undertaking the particular regulated activity (such as the supply of a pesticide under APVMA or the use of a GMO under the GTR Regulatory Framework). But this also meant that steps not required to be taken under particular regulatory frameworks were also not taken for NMs. For example, food and therapeutic goods used by consumers are regulated without an environmental risk assessment having occurred. Whether this is appropriate for NMs depends upon whether the presence of NMs or involvement of nanotechnology in those products increases the potential environmental risks significantly when compared to the conventional products considered when determining the general operation of those frameworks. That assessment is outside the remit of this review. Nevertheless, as highlighted in the following Sections 5.1.1 to 5.1.6 (and in Table 5.1), some gaps were found where the regulatory frameworks either do not apply at all to NMs and products incorporating them or do not apply to NMs or nanoproducts as appropriately as they apply to conventional products in the same families. In summary, these gaps arose because of the following –

5.1.1 Triggers on the Basis of Name – 'New' or 'Existing' Substances or Products?

This is possibly the most significant potential gap because of its relevance, to varying degrees, to all regulatory frameworks with the exception of the GTR Regulatory Framework. For many NMs and products incorporating them, particularly chemicals, uncertainty exists as to whether the nanoentity would be considered as 'new' or 'different' to or the same as its' conventional counterpart. The ramification of this is that either the regulatory framework as a whole, or parts of the framework, may not properly apply to NMs or products incorporating NMs or produced using nanotechnology.

Particularly for regulation directed at protecting OH&S and public safety, where products are transported, and environment protection, regulation is often on the basis of the naming of particular substances or articles. In some cases these named products are prohibited (for example, particularly hazardous pesticides under the APVMA regulatory framework) and in other cases, permitted (for example, industrial chemicals under the NICNAS Regulatory Framework and therapeutic goods under the TGA Regulatory Framework). Uncertainty as to whether the nanoform of a conventional product is the equivalent to an existing entity means there is also uncertainty in the application of such regulations to NMs or products incorporating them. This is particularly the case in relation to industrial chemicals.

Addressing this issue will require not only a decision as to whether nanoforms should be considered as a 'new' substance or product or as an 'existing' substance or product when compared to their conventional counterparts, but would then require revision of most frameworks to ensure this is made clear.

5.1.2 Triggers on the Basis of Weight or Volume

Some regulatory triggers depend upon thresholds determined by weight or volume being met or avoided. For example, the transport of small quantities of DG does not trigger the application of the *RTR Regulations* and *ADG Code*. This can cause gaps in the application of the regulatory frameworks to NMs and products incorporating NMs because of three reasons. First, current scientific knowledge is such that it may not be known whether these thresholds are appropriate for NMs and products incorporating them. Second, difficulties in measuring the presence of NMs may mean the thresholds are not meaningful. Finally and possibly the most significant at this time, the presently low production levels of NMs mean that thresholds that set a ceiling that must be met before the regulations apply are unlikely to be met, as highlighted in relation to industrial chemicals. This means regulatory frameworks requiring such satisfaction in order to be triggered will not apply.

5.1.3 Triggers Requiring Knowledge of Presence or Implications of Presence of NMs

In some instances, appropriate regulation requires particular knowledge of either the presence of NMs and / or risks posed by the presence of NMs. Current public awareness and scientific knowledge is such that these triggers are unlikely to be met. For example, in the FSANZ Regulatory Framework, articles and materials are not to be in contact with food if such contact is 'likely to cause bodily harm'. It is probable that deficiencies in current knowledge regarding the effects of NMs on human health are such this trigger could not yet be satisfied, even if eventually it could be when science has improved our understanding of this branch of knowledge.

In some instances this may at first glance seem to mean that NMs and products incorporating NMs could be prevented from entering the market. An example of this is provided in the APVMA Regulatory Framework. Before APVMA registers or approves a chemical product, it is to be satisfied of certain things including that the use of the product would not be an undue hazard to the safety of people handling it and not likely to have unintended harmful effects on the environment. Theoretically, APVMA could use this provision to justify refusal to register or approve chemical products that are or incorporate NM or were produced using nanotechnology. However, APVMA must have grounds for reaching these conclusions and the matters relevant to those grounds are set out in the legislation. Whilst these grounds include matters important to the safety and environmental risks of NMs and nanotechnology, such as the form of the chemical constituents and the toxicity of the product, gaps nevertheless remain. Such gaps arise for the reasons discussed in 5.1.4 below – because of difficulties and uncertainty in applying risk assessment protocol and data collection techniques such as toxicity and ecotoxicity testing methodologies that were developed for conventional products.

5.1.4 Triggers Reliant on Risk Assessment Protocols or Conventional Techniques

Risk assessment protocols are in some instances involved in the triggering process. If those protocols are not appropriate for NMs, the regulatory arrangements of which they are part will not be triggered. For example, in the APVMA Regulatory Framework analytical techniques may not necessarily be suitable for NM. Whilst in the instance of this regime, APVMA could refuse to be satisfied where inappropriate analytical techniques are used this does require APVMA to know that these techniques are not appropriate. Those regulatory frameworks which have human and environmental risk assessments as part of their regime, will also face difficulties given it is not known whether current toxicology testing techniques are suitable for NMs.

5.1.5 Research and Development Exemptions

There were some specific gaps relevant to research and development. These gaps are not unique to NMs and products, applying to any research and development. However, in light of the stage in development at which many NMs and products incorporating them currently are, this deliberate exception for research and development may be of greater significance for NMs and their products and therefore is included as a 'gap' for the purposes of this review. Examples of this arise in both the APVMA and ASCC – HS Regulatory Frameworks. In the case of APVMA, the research and development exemption is linked to a weight threshold, raising another possible gap as discussed in 5.1.2. The ASCC – HS exemption relates to bona fide research into certain listed carcinogenic substances.

5.1.6 Triggers Reliant on International Documents

A number of the regulatory frameworks incorporate or allow applicants to rely on international documents or documents produced by bodies other than the regulator. This is a potential gap if those documents themselves do not adequately address HSE concerns raised by NMs. For example, in the FSANZ Regulatory Framework, the *Plastics Standard* references international documents compliance with which satisfies the Standard. The DEW Regulatory Framework, the import and export of hazardous waste must be in compliance with the *Basel Convention.* In the APVMA Regulatory Framework, the *Agvet Regulations* allow the use of tests specified by bodies outside the control of the regulator such as the Association of Official Analytical Chemists.