

17 August 2009

Enabling Technologies Policy Section
Pharmaceuticals, Health Industries and Enabling Technologies Branch
Department of Innovation, Industry, Science and Research
Level 10, 10 Binara Street,
Canberra City ACT 2600
GPO Box 9839, Canberra ACT 2601

Dear Sir/Madam,

National Enabling Technologies Strategy Discussion Paper

The Monash Centre for Regulatory Studies welcomes the opportunity to comment on the National Enabling Technologies Strategy (NETS). Further to the recent consultation meeting conducted in Melbourne on Monday 10 August 2009 following the release of the NETS Discussion Paper, this submission formalises some of the brief comments which were made in this consultation session.

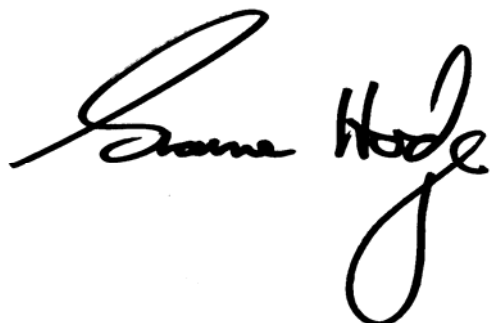
1. It is firstly great to see a formal National Enabling Technologies Strategy. The development of an explicit statement makes the policy position of the government clear and forms a strong basis for subsequent policy and research discussions around the topic. This statement also makes clear the belief that supporting new scientific frontiers such as nanotechnologies is likely to result in significant benefits to Australian citizens at the same time as acknowledging the need for work in a range of ethical, legal, social and environmental areas to intelligently deal with risks or impacts which may arise in moving forward.
2. This strategy also clearly covers a wide range of implicit issues. For example, we applaud the idea of foresighting and make the point that foresighting presumably needs to cover this breadth. In our experience of nano-debates thus far, such issues are likely to vary from narrow technical risk concerns around specific products (where debates centre on health effects and regulatory protections) through to broader questions of how citizens can contribute to the democratic setting of directions for scientific research efforts rather than just consuming its products.
3. In terms of the major outcomes possible from the Enabling Technologies Strategy we make the following four suggestions:
 - a. There is clearly a need for the national strategy to learn from the experience and current initiatives of other major world centres. These include for example the European Commission and European Union where risk regulation has

recently seen advances so that both nano-labelling and the testing of nano-forms of old products will be required in future. The future reporting requirements with new nano products is another initiative from which we could learn. The policy and regulatory choices to be made from these initiatives will not only be drawn from either the more precautionary European approach or, say, the more commercially focussed approach of the US, but from the work of International organisations such as ISO, OECD and the FAO as well as others.

- b. Likewise, the move federally towards the language of “Evidence Based Policy” in Australia is a useful one. However, there are also multiple definitions of what constitutes evidence, how this can be framed and the purposes to which evidence may apply. Again, evidence here may vary from narrow science based risk knowledge (from double blind randomised experiments), through to evidence on possible economic impacts arising from nano-initiatives, right through to broader evidence around issues of social policy and political debate. Throughout these arenas, there is a need to clarify this breadth of evidence and acknowledge multiple roles, rather than focus solely on narrower domains such as the risks and legal dimensions often adopted. Such broader evidence based discussions will underpin the social licence and regulatory legitimacy required of new technologies.
- c. The food sector (as well as other ‘up close and personal’ products) is likely to be at the frontline of nano-debates over the next few years in our view. There is real need at this point in time for an accessible research exercise to be undertaken which maps the terrain for foods and items which we put in or on our bodies in both scientific as well as everyday commonplace terminology. Such a terrain mapping exercise would aim to outline the degree to which naturally occurring foods contain nano-sized materials; the degree to which (as well as their history) manufactured and processed foods along with food packaging contain such materials; and those foods and packaging products containing nano- sized materials which are just around the corner. All of these foods ought to feature in informed nano-debates over the coming years. And in each case, it will be necessary to clarify the extent to which existing regulatory arrangements ensure that our health is maintained as well as pointing to those areas where some potential dangers may be facing us in future.
- d. There is also a crucial need for an open and transparent discussion on the topic of ‘regulatory discretion’. Regulators constantly tread a difficult path between at the one extreme operating quietly, reactively and with low visibility behind a narrowly interpreted legal mandate and at the other extreme, pushing the boundaries, naming and shaming, and being seen as more visible and proactive. The difference between these two approaches might be viewed as regulatory discretion. There appears to have been little discussion to date as to the degree to which regulators in Australia have such discretion in the area of nanotechnologies and the choices being made regarding these discretions. Measured discussions articulating these areas are highly desirable.

We thank you for this opportunity to comment on the National Enabling Technologies Strategy.

Best Regards,

A handwritten signature in black ink that reads "Graeme Hodge". The signature is written in a cursive style with a large, sweeping initial 'G'.

For

Professor Graeme Hodge, Dr Karinne Ludlow and Dr Diana Bowman

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