Submission

to the

Senate References Committee
<community.affairs.sen@aph.gov.au>

on exposure to toxic dust,
including nanoparticles

by the

GeneEthics Network
Level 1, 60 Leicester St, Carlton 3053 Australia
Tel: 03 9347 4500 {Int Code +613} or 1300 133 868
Fax: 03 9345 1166
Email: info@geneethics.org
WWW: http://www.geneethics.org

August 2005

Summary

This GeneEthics Network submission to the Senate Inquiry into workplace exposure to toxic dust addresses reference g – "The potential of emerging technologies, including nano-particles, to result in workplace related harm."

We define 'workplace' to extend beyond the strictly industrial context, into homes, workshops, kitchens, bathrooms and any open environment where humans may be exposed to and adversely affected by the use of nano-technologies or their particulate products.

GeneEthics Network supports and endorses the excellent submission by Friends of the Earth Australia and urges the Senate Committee to adopt the submission's recommendations.

GeneEthics particularly supports the FoE recommendation for an immediate moratorium on all research, development, commercial production and sale of synthetic nano-technologies, nano-particles, other nano-materials and products that contain them. The nano-technology moratorium should remain in force, at a minimum, until new laws and a regulatory system are developed and implemented.

GeneEthics proposes that the Senate Committee recommend:

- the establishment of a proactive, comprehensive, integrated (one-stop-shop) national regulatory system to be known as the Office of New Technology Assessment and Regulation (ONTAR), with responsibility for the registration, assessment, licensing and monitoring of all new technologies and their products including, but not limited to, all nano-technologies, nano-particles, other nano-materials and nano-products that contain them;
- an iterative process to develop the laws and ONTAR - along the lines of the process used to establish the Gene Technology Act 2000 and the Office of Gene Technology Regulator (OGTR) - including public hearings around Australia and sequential draft proposals, issued for critical comment by all interested parties;
- that ONTAR's initial brief be to accept applications for the registration, assessment and, where appropriate, the licensing of all existing nano-technologies and their products;
- that ONTAR be developed under a COAG agreement, be responsible to the Health Ministers Ministerial Council and also be required to report comprehensively to both houses of the Commonwealth Parliament.

GeneEthics also asks the Committee to recommend that a minimum of 25% of the budgets for all nano-technology research and development, both privately and publicly funded, be allocated to experiments on worker, public and environmental health and safety. We note that Australian state governments have already expended hundreds of millions of dollars on nano-technology research and development but that none of those resources were spent on health and safety research.

GeneEthics also asks the Committee to recommend that Australian governments develop policy and allocate substantial resources to creating a health and safety niche for Australia's nano-technology research and development effort. This research effort would focus on creating vanguard systems, policies and standards for the protection of worker, public and environmental health and safety. This array of safety services would be marketed world-wide to the many nations (already in excess of 40) now heavily investing in nano-technology with inadequate safety assurance for their communities.

The Regulatory Framework

GeneEthics proposes that the open and robust participatory and consultative processes used to design the Gene Technology Act 2000 (GT Act) and establish the Office of Gene Technology Regulator also be used to develop the ONTAR regulatory system.

While we were satisfied with the processes used to establish the OGTR, the GT Act and the operation of the OGTR regulatory system are poor models for ONTAR. GeneEthics recommended the following suite of provisions in the GT Act which would have greatly improved its operation. ONTAR would be most effective if it included:

- a one-stop-shop regulatory system! Instead, the OGTR was established as a gap filler, to assess and regulate only those dealings not evidently covered by other regulatory agencies;
- the assessment of the benefits as well as the (narrowly defined) risks of dealings with genetically engineered organisms! Instead, the OGTR considers only a narrow range of poorly defined 'risks'

and assumes that any benefits which may accrue to applicants are sufficient to justify applications being accepted and licensed;

- community appeal rights! Instead, only applicants may now appeal OGTR decisions, leaving other interested parties without an effective voice when the OGTR has erred. We have been very disappointed that wherever the OGTR has a discretionary power, it appears generally to be exercised in the interests of applicants and licensees rather than in the public interest;
- parity among the committees advising the regulator! Instead, the technical advisory committee (GTTAC) alone can effectively influence OGTR decisions, while the ethics committee (GTEC) and the community consultation committee (GTCCC) are rarely consulted and their advice to the OGTR and the Gene Technology Ministerial Council is effectively ignored;
- a fully developed and enforceable precautionary principle! Instead, in a last minute parliamentary compromise that responded to widespread public concern, the community was belatedly given section 4 (aa) of the GT Act which is generally ignored by the OGTR;
- sustainability goals and the participatory principle! Instead, the OGTR defines environmental impacts so narrowly that environmental sustainability is not assessed, and one-way consultation replaces genuine community participation in OGTR operations and decisions;
- strict applicant liability for any damage or injury! Instead, responsibility is ill-defined and may fall on everyone involved in dealings under the Act except the licence holders and patent owners, even though the inherent hazards and flaws in GE organisms make negative impacts inevitable;
- scientific rather than 'science-based' assessment methodologies, with clear benchmarks, standards and QA systems set *a priori*, so that the objectivity, replicability and relevance of evidence supporting applications can be objectively assessed! Instead, the OGTR uses a so-called case-by-case, science-based approach which is used to legitimise ad hoc, unscientific data production, evidence gathering and assessment processes, often based on unfounded assumptions rather than facts. For instance, the regulators assume that canola will not outcross to weedy relatives, despite the compelling evidence which shows it can and does occur;
- the burden of proof on the applicants to show why a project should be licensed! Instead, the OGTR and the interested public must attempt to produce evidence that shows why a licence should not be granted. Thus, applications are rarely rejected, despite good scientific reasons for doing so.

Recommendations:

GeneEthics recommends that the Act to establish ONTAR include:

1. strict liability on all dealings with nano-technologies, their products and other novel technologies that may be in future regulated by ONTAR. The owners and makers of novel technologies and their products should always be responsible for any deleterious impacts of their technologies or products. This provides a much needed incentive for them to adopt precautionary strategies and undertake more rigorous research as part of their triple bottom line responsibilities. The alternative is accelerating litigation through the courts, where individuals or even classes of plaintiff are generally at a serious disadvantage, particularly because of limited financial and specialist resources.

2. an integrated one-stop-shop regulatory system, to register, assess, licence and monitor all aspects of all dealings with nano-technologies, nano-particles, nano-materials and nano-products. As a gap filler, ONTAR could not deliver robust, objective and scientific decisions on applications to deal with vanguard new technologies and their products. With parts of the system vested in other regulators such as FSANZ, APVMA, etc., that apply different methodologies, standards and degrees of public participation, the ONTAR regulatory system would also be subjective, inaccessible, opaque, and inequitable.

3. equivalent assessment of all the benefits and risks of the proposed dealings with novel technologies and their products. ONTAR should not assume that proposed dealings with novel technologies are adequately justified by the benefits which may accrue to applicants from being licensed. These benefits must be weighed against the public interest. Assessments should be required to evaluate broadly defined risks, costs and hazards, as well as the potential benefits of new technology. The safety, social, environmental, ethical and economic aspects of new technologies all need objective assessment before the issuing of a licence would be justified.

4. community appeal rights, including merit reviews and open standing, should all be available on contentious decisions made by ONTAR. All interested parties must have the standing and means to responsibly appeal ONTAR decisions through official appeal and review mechanisms.

5. provide ONTAR with the resources and mandate to deal strongly, decisively and publicly with licence infractions eg: safety breaches, contamination, unauthorised releases, and accidents.

6. responsibility to the New Technology Ministerial Council (NTMC), composed of Health Ministers from each Australian state, territory and the Commonwealth jurisdiction. Establish ONTAR under a COAG agreement.

7. advisory committees, all empowered to give influential and wide-ranging advice to both ONTAR and NTMC. Each committee's advice should be accorded equal weight, be fully considered, receive a considered response with reasons, and be incorporated into ONTAR and NTMC decisions.

8. objects that require the regulator to always apply the precautionary principle to the risks, hazards and possible benefits of new technologies and their products by regulating all dealings with novel technologies and their products.. The precautionary principle is enunciated in the Convention on Biological Diversity and in section 3.5.1 of the Intergovernmental Agreement on the Environment, signed in May 1992 by all Australian Heads of Government, which says:

   > "Where there are threats of serious or irreversible environmental damage, lack of full scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation."

   In the ONTAR Act, the precautionary principle must explicitly apply to all reasonably foreseeable health and environmental impacts, both short and long term.

9. objects that also require the regulator to:

   - apply the principles of ecological sustainability and participation;
   - evaluate the risks, hazards and possible benefits of new technologies and their products,;
   - protect the health and safety of people and the environment.

   All dealings with novel technologies and their products should be regulated. The principles of ecological sustainability would ensure that new technologies do not contribute to the long term destabilisation and decline of our national and global life support systems, human and animal health, the natural and built environments and biological diversity.

10. a requirement that the onus of evidence-based proof of safety resides exclusively with applicants for licences and the technology owners. Applicants and owners must be required to show beyond a reasonable doubt why a proposed dealing should be licensed.

11. scientific rather than 'science-based' assessment methodologies, with unambiguous benchmarks, standards, QA systems and environmental goals set a priori. These rules are basic to the rigorous assessment of the objectivity, replicability and relevance of scientific evidence tendered in support of applications. ONTAR's standards must require all data to be contemporary, scientific and independent. Full public access to all the data submitted with each application is also essential.

    In contrast, most existing regulatory regimes allow evidence that is generated or commissioned by the applicants, is rarely peer reviewed, is never replicated, is not experimental in design (including double blind, random sampling, experimental and control groups, and statistical analyses) is conducted for commercial not scientific purposes, and is so small-scale and short-term that the data and results are at best inconclusive.

12. a requirement that all experiments licensed by ONTAR include public interest goals, including release of all data and information to enable independent evaluation and monitoring of methodologies, processes and experimental design.

13. a definition of ‘environment’ that is consistent with other environmental laws, Ecologically Sustainable Development and the Convention on Biological Diversity.

14. broad, independent, multi-disciplinary expertise and advice, embedded in ONTAR risk assessment requirements, processes, and assessment methodologies, especially on ecological and epidemiological issues.

15. improved transparency and accountability, especially by limiting commercial in confidence approvals to legitimate trade secrets only, that must be fully justified by the applicants.

16. a requirement that a response to all substantial matters raised in submissions be published;

17. a full statement of reasons for issuing a licence be issued by ONTAR, for further public comment prior to any licence being issued;

18. strong, clear, mandated fitness criteria like those in Sections 57 (2) and 58 of the GT Act. ONTAR would be required to assess the suitability of all applicants for licences. Any conduct by the applicant or its parent organisation which is against the public interest (including criminal convictions) must be discussed, assessed and decisions published with reasons.

19. that the reserve powers held by state and territory governments, like those conferred under Section 21 of the GT Act, be fully retained and extended. In particular, the NTMC should have more policy-making powers than those accorded the Gene Technology Ministerial Council which has been extremely unpro-active in setting a precautionary agenda for the OGTR and exercising oversight of the regulatory system.

GeneEthics will supply further supporting material when meeting the committee.