

OGTR comments in relation to development of the National Enabling Technologies Strategy and the discussion paper

The Office of the Gene Technology Regulator (OGTR) is grateful for the opportunity to provide comments on the 'National Enabling Strategies – Discussion Paper'.

OGTR has prepared some general comments for your consideration, framed against the questions posed from the perspective of a regulator of an enabling technology.

The Gene Technology Regulator (the Regulator) supported by the OGTR is responsible for the administration of *Gene Technology Act 2000* (the GT Act), the *Gene Technology Regulations 2001* and corresponding state and territory legislation. The GT Act regulates dealings with genetically modified organisms (GMOs). (A brief description of the operations and responsibilities of the OGTR, and the relationship to other regulatory schemes, is provided at Attachment A.)

The OGTR participated in activities under the former National Biotechnology Strategy (NBS) and National Nanotechnology Strategy (NNS).

We note a significant focus of NETS on nanotechnology. While OGTR is not directly responsible for nanotechnology we maintain a watching brief to identify technology developments where there may be a nexus between nanotechnology and gene technology. The OGTR participation in the NNS has mainly been through the coordinated input of the Department of Health and Ageing (DoHA).

The OGTR therefore also has an interest in being kept apprised of and participating in the activities proposed under the National Enabling Technologies Strategy (NETS).

One aspect of the proposed NETS activities that is of particular interest to the OGTR is in relation to public awareness and community engagement. The GT Act requires considerable public consultation on proposals for environmental release of GMOs. The Gene Technology Ethics and Community Consultative Committee (GTECCC) is also established under the GT Act its functions include providing advice to the Regulator, on ethical issues relating to gene technology, community consultation on applications for environmental release, and risk communication.

NETS community engagement activities, in particular the continuation of the community attitude surveys undertaken by the former Biotechnology Australia, will provide information that can inform these considerations. The experience and deliberations of OGTR and GTECC might also inform the development of community engagement activities. We would welcome opportunities to provide input in this regard.

If there is further information that you would like from OGTR please do not hesitate to contact me.

Yours sincerely

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1. Key issues and challenges that need to be addressed by the NET Strategy

The NETS by definition will be looking at new technology. Identifying opportunities and constraints for Australian industries will need a high level of knowledge and experience including in relevant technical areas to underpin and inform research and analysis and public policy formulation. Identifying technical information needs and gaps may be provided by experts or networks of other organisation but ‘in-house’ staff with relevant training and expertise would also be a benefit. It will therefore be important to ensure that solid networks are established within the Australian and State and Territory Governments, include the relevant regulatory agencies, as well as with industry (including rural) and the public to both gather and distribute information.

Ensuring sound technical underpinning of documents and activities will also be important in achieving the goal of being a credible and trusted source of information.

OGTR possesses significant in-house expertise and remains ready to provide advice in relation to issues related to gene technology.

2. How should these issues and challenges be addressed?

As outlined in the discussion paper, one focus of NETS will be on providing unbiased, balanced and factually correct information and that this is desirable when raising public awareness and essential to being recognised as a trusted provider of information.

The discussion paper makes a number of references to regulation. Public awareness raising activities should include a focus, as appropriate, on informing the public about existing Government regulations, and their roles in ensuring protection of the public and the environment.

The discussion paper identifies international engagement as a focus for activity in the Strategy. The OGTR supports efforts to engage in international forums in the enabling technologies sectors, in particular with a view to the global harmonisation of regulatory requirements for new enabling technologies. The functions of the Regulator under the GT Act include international liaison. Participation in relevant international fora enables Australia to inform and influence developments in GMO regulation based on Australian experience and helps to ensure that the regulatory scheme takes account of international practice.

The discussion document identifies the development of testing and measurement capabilities as a significant focus. This includes work to be undertaken to develop methods for “genetic material such as RNA and modified DNA”. We support the point made in the paper that the focus of these activities needs to be informed by the needs of regulators and industry as these will frame the realistic end use requirements.

Development of these activities in consultation and collaboration with the relevant end users will ensure that the most practical outcomes.

We also note that OGTR has an ongoing collaboration with the National Measurements Institute on GMO detection techniques. There may therefore be intersections between existing activities or synergies for new work under the strategy.

3. Desired main outcomes of the NET Strategy

The OGTR has interest in obtaining up to date information on public attitudes to gene technology. Such information can inform the design and targeting of OGTR activities for public consultation on applications, risk communication, and providing information on the regulatory system generally.

The OGTR would appreciate the opportunity to have input into the design of future public attitudes surveys. As indicated above, this is of particular interest to the GTECCC.

The OGTR is supportive of achieving greater public understanding and trust in Australia's regulatory systems for new and emerging technologies.

4. How could the OGTR work with the NET Policy and Public Awareness Section to address issues and challenges?

The OGTR would like to be kept informed in relation to the ongoing development of the strategy and would welcome the opportunity to participate in/contribute to the development of communication activities under the strategy.

The OGTR would be happy to provide advice on the regulation of GMOs under the GT Act as required, both in regard to public awareness activities undertaken by DSIIR and to parties contracted under the NETS to prepare reports which refer to the regulation of GMOs in Australia.

OGTR participated in the regular communications meetings held under the former NBS and found these to be a useful forum for the exchange of information and ideas.

OGTR attended the recent meetings in July arranged under NETS. OGTR will continue to participate in these meetings.

Attachment A – Regulation of Genetically Modified Organisms in Australia

The *Gene Technology Act 2000* (the GT Act) and the *Gene Technology Regulations 2001* (the GT Regulations), corresponding state and territory legislation, and an inter-governmental agreement (*the Gene Technology Agreement 2001*) signed by all jurisdictions underpin the national scheme for the regulation of live and viable genetically modified organisms (GMOs) in Australia. The implementation of the scheme is overseen by the Gene Technology Ministerial Council, which comprises representation from all Australian jurisdictions.

The Gene Technology Regulator (the Regulator), Dr Joe Smith, is an independent statutory office holder who administers the GT Act and corresponding state and territory laws and has extensive powers to monitor and enforce the legislation.

The object of the legislation is to protect the health and safety of people and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks by regulating certain dealings with GMOs.

The GT Act operates in conjunction with other Commonwealth and State regulatory schemes relevant to GMOs and genetically modified products (GM products). The Regulator forms part of an integrated framework of regulatory authorities with complementary responsibilities and expertise including Food Standards Australia New Zealand (FSANZ), the Australian Pesticides and Veterinary Medicines Authority (APVMA) and the Therapeutic Goods Administration (TGA). This arrangement is designed to assist coordinated decision making while avoiding duplication.

Gene technology is a relatively new and frequently contentious field, and the release of GMOs into the environment can generate significant public debate, particularly if the GMO is a food crop. Openness and transparency are built into the regulatory system through requirements in the legislation for the Regulator to:

maintain a publicly accessible record of GMO and GM product dealings;

provide quarterly and annual reports to the Australian Parliament; and

conduct extensive consultation on applications proposing environmental release of GMOs.

The OGTR maintains a comprehensive website (www.ogtr.gov.au) which includes extensive information on the regulatory system and decisions made by the Regulator and has a 1800 free call number and an OGTR email address which provide points of contact for members of the public and other interested parties. Interested parties may also register on the OGTR client register to receive notifications from the office.

OGTR and nanotechnology

OGTR maintains a watching brief to identify technology developments where there may be a nexus between nanotechnology and gene technology. Nanotechnology involving dealings with GMOs would attract regulation and risk assessment under the GT Act. OGTR has included a section in application forms to identify GMO dealings that involve the use of nanotechnology or the inclusion or production of engineered nanomaterials. The OGTR has not received any GMO licence applications involving nanotechnology. Such applications would be subject to the same case by case, science based risk assessment to identify and assess any risks to the health and safety of people and the environment required of all applications.