Review of the Gene Technology Regulatory Scheme: Department of Economic Development, Jobs, Transport and Resources input to scoping consultation

The Department of Economic Development, Jobs, Transport and Resources (DEDJTR) reiterates the importance of gene technology regulation remaining science based and proportionate to risk, as detailed in Agriculture Victoria's submission to the Gene Technology Regulator's Technical Review of the Gene Technology Regulations (2017). Further, to ensure that the Gene Technology Regulatory Scheme (the Scheme) continues to enable innovation, DEDJTR considers that the Scheme must be agile to new technologies with efficient, timely and cost effective interactions with other regulators. The Scheme should not seek to regulate scenarios in which outcomes cannot be distinguished from those that could have been achieved through unregulated technologies; rather it should focus on scenarios in which DNA from sexually incompatible species is stably incorporated into the genome of the genetically modified organism, consistent with the Scheme's original intent. DEDJTR considers that this likely involves consideration of the outcomes of a technology in addition to the process of creating a potential genetically modified organism (GMO). If the Gene Technology review team is of the view that this cannot be achieved within the current policy settings of the Scheme, then the review team should consider alternative enabling policy frameworks.

As the biotechnology sector matures, the number of dealings regulated under the Scheme will grow in number, and the scale of the regulated dealings and facilities required to undertake the dealings will grow also. The increasing burden that the maturation of the sector will impose on the resources of the regulator and the organisations conducting the activities should be considered in the review.

DEDJTR draws the review team's attention to the interface between the Scheme and the national biosecurity framework. DEDJTR notes that this interface is not referenced in the review scoping paper. However, regulation of GMOs potentially interacts with national biosecurity regulation, particularly in relation to biological control agents. DEDJTR notes the following:

1. Interaction with other legislation

   The interactions with other legislation is an area where reform is needed. The release of a biological control agent requires approval under multiple pieces of legislation [e.g. importation of an agent (*Biosecurity Act 2015*); product registration (APVMA); environmental approval (*Environmental Protection and Biodiversity Conservation Act 1996*); and biological control approvals (e.g. *Biological Control Act 1986*)]. The issue is that one piece of legislation may be prepared/ready for the development of new technologies such as gene drive (i.e. the current Scheme), but other pieces of legislation related to the application of the technology may not be ready/prepared. For example, given the intent of the Scheme is to protect the health and safety of people and to protect the environment, it is unclear how a gene drive technology would be considered under the EPBC Act or state environment legislation.

2. Authorising environment

   The legislative environment is compartmentalised along a supply chain with no single oversight of the total risk or benefit. There are examples in the biological control space where it has been considered that once an organism has 'approval' under one regulatory instrument it is clear to proceed, when in fact, additional approvals are required.

Because the Scheme (and other regulatory requirements) consider each issue in isolation, overall risks may not be fully considered.

3. Co-ordination of government frameworks

The National Biosecurity Committee (NBC) reports to the Agriculture Senior Officials Committee, which reports to the Agriculture Ministers Forum. This is essentially a similar, parallel, structure to the governance of the Scheme by the Gene Technology Standing Committee (which reports to COAG's Legislative and Governance Forum on Gene Technology). There will likely be overlap between the two governance frameworks and co-ordination between the two sectors is essential. This is particularly important for biological control agents, for example sterile insect technologies, gene drives, and daughterless/sonless technologies, which are managed through the NBC stream.

DEDJTR wishes to ensure that the Legislative and Governance Forum on Gene Technology and the National Gene Technology Regulatory Scheme maintain ongoing recognition of:

1. The need to be able to rapidly import and use GMO vaccines in the event of an emergency animal disease outbreak.

Part 5A of the *Gene Technology Act 2000* was inserted into the Act by the *Gene Technology Amendment Act 2007* (the Amending Act). The object of the Act 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 through regulating certain dealings with GMOs.

The emergency provisions give the Minister power to expedite an approval of dealings with a GMO in an emergency. This recognises that situations may arise in which approval of a dealing with a GMO may be required in a limited time. The emergency provisions also further the objects of the Act to protect the health and safety of people and to protect the environment. The existence of emergency provisions in the Act is consistent with other regulatory schemes. Other relevant product regulators for vaccines, such as the Australian Pesticides and Veterinary Medicines Authority, possess the ability to expedite approvals in an emergency.

The purpose of making the 2007 Determination was to permit administration of the GMO to address an actual threat to the horse population in various parts of Australia from the equine influenza virus. A threat to the horse population is a threat to the environment from an animal disease (Office of the Gene Technology Regulator, 2008 Explanatory Statement).

2. The use and import of bacteriophages

Bacteriophages (genetically modified viruses) provide an opportunity to reduce antimicrobial use, by offering alternatives to conventional antibiotic treatments for bacterial infection. As reduction of antibiotic use in animals is inextricably linked to combatting antimicrobial resistance, and with the advance of CRISPR technology, the agricultural and research sectors in Australia must maintain access to these products and developments.