



**Australian Government**

**Department of Health**

Office of the Gene Technology Regulator

## **Gene Technology Ethics and Community Consultative Committee**

**Meeting of 21 September, 5 October and 21 October 2021**

### **Communiqué**

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***This Communiqué covers matters considered at the 15<sup>th</sup> meeting of the Gene Technology Ethics and Community Consultative Committee***

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#### **Background**

The Gene Technology Ethics and Community Consultative Committee (GTECCC) is a statutory advisory committee established under the *Gene Technology Act 2000* to provide advice on the request of the Gene Technology Regulator (Regulator) or the Gene Technology Ministers' Meeting, on issues of ethical or community concern relating to gene technology.

The purpose of this Communiqué is to provide a brief overview of the key matters considered by GTECCC at its 15<sup>th</sup> meeting, held by videoconference over three sessions on 21 September, 5 October and 21 October 2021.

#### **Session 1 – 21 September 2021**

##### Community attitudes to gene technology

Members discussed the results of the 2021 survey of community attitudes to gene technology, which has since been published on the [OGTR's website](#).

##### Reports

GTECCC received reports on:

- recent OGTR activities including celebrating the 20<sup>th</sup> anniversary of the gene technology regulatory scheme
- recent activities of the Gene Technology Technical Advisory Committee
- the launch of the new [OGTR website](#).

#### **Session 2 – 5 October 2021**

##### Third Review of the National Gene Technology Scheme

###### *Update on implementation of recommendations from the Review*

GTECCC received an update on implementation of recommendations from the Third Review of the National Gene Technology Scheme (the Review). GTECCC discussed the Review recommendations relating to public understanding and trust.

### *Humans as GMOs*

GTECCC was provided with information on mitochondrial donation legislation introduced to Parliament in March 2021, and its intersection with the *Gene Technology Act 2000* (the Act). Members were advised that the Review recommended amending the definition of genetically modified organism (GMO) under the Act to clarify that humans are not considered to be GMOs.

Members discussed ethical issues that might arise if humans were to be regulated as GMOs, including those relating to consent and privacy. GTECCC agreed it remains appropriate that humans are not regulated as GMOs, and noted that several bodies already exist which look at ethical issues relating to human research. GTECCC agreed that there are other mechanisms in place to consider social and ethical issues associated with humans being modified and that the Act is not designed to manage these issues.

### *Proposed consultation requirements for licence applications*

GTECCC was informed of current consultation requirements for licence applications and how these might be affected by implementation of the Review recommendations. Members discussed the impact on public trust of transparency/public consultation and the need to balance this with ensuring that regulation is commensurate with risk.

GTECCC noted that the purpose of consultation is to gather information for the Regulator to take into consideration when making regulatory decisions, not to provide information to the public. The Committee agreed that different levels of consultation might be appropriate for applications with different risk levels. GTECCC suggested criteria such as novelty could be a trigger for public consultation.

## **Session 3 – 21 October 2021**

### National Framework of Ethical Principles in Gene Technology 2012

#### *Ethics Framework and application trends*

GTECCC was advised that the OGTR has been observing an increase in applications in the area of human therapeutic GMOs. The Committee discussed the relevance of the [National Framework of Ethical Principles in Gene Technology 2012](#) (the Ethics Framework) in this context.

#### **Resolution** – GTECCC agreed that:

- All 10 Principles in the Ethics Framework remain relevant in the current context of increased applications in the area of human therapeutic GMOs
- Some Principles need review and refinement, including consideration of who they are most relevant to and whether any additional concepts need to be included
- The most relevant Principles in this context are:
  - Principle 4 – Caring for the environment and sustainability
  - Principle 5 – Avoiding harm to humans and animals
  - Principle 6 – Assessing long-term impacts

#### *Ethics Framework and gene drives*

GTECCC was provided information on gene drive organisms and advised that environmental release of a gene drive GMO could require approval under multiple pieces of legislation including the Act. Members discussed whether the Ethics Framework is still relevant in the context of the potential environmental release of gene drive GMO.

**Resolution** – GTECCC agreed that:

- All 10 Principles in the Ethics Framework remain relevant in the current context of development of gene drive GMOs
- Some Principles need review and refinement
- The most relevant Principles in this context are:
  - Principle 4 – Caring for the environment and sustainability
  - Principle 5 – Avoiding harm to humans and animals
  - Principle 6 – Assessing long-term impacts
  - Principle 9 – Ensuring transparency
  - Principle 10 – Considering responsibility beyond national borders

Guiding principles for communication on gene technology

GTECCC agreed to establish a working group to progress the development of guiding principles for communication on gene technology, which had been started by members of the previous triennium.

**For all inquiries, please call the Office of the Gene Technology Regulator on 1800 181 030 (free-call) or email [ogtr@health.gov.au](mailto:ogtr@health.gov.au)**