Australian Government

Department of Health

Office of the Gene Technology Regulator

MINUTES OF THE

GENE TECHNOLOGY TECHNICAL ADVISORY COMMITTEE

Meeting 47 – 8 April 2015

AMA House, Canberra

About these Minutes

These minutes are intended to summarise discussion during the Gene Technology Technical Advisory Committee (GTTAC) meeting of 8 April 2015. They reflect key elements of the discussion, the outcomes, matters agreed and actions arising. They are not intended to be a verbatim record of the meeting.

Attendance

Members:

- Professor John Rasko AO (GTTAC Chair)
- Dr Jason Able
- Professor Craig Atkins
- Professor Ross Barnard
- Professor Jacqueline Batley
- Professor Gabrielle Belz
- Dr Graham Bonnett
- Ms Laura Fell
- Professor Ian Godwin
- A/Prof John Hayball
- Dr Rodney Mahon
- Dr Michael Michael
- Dr Gabrielle O'Sullivan
- A/Prof Marie Ranson
- Dr Kelly Shaw
- Professor Kevin Smith
- A/Prof Jason Smythe
- Dr Diane Webster

Apologies:

- Professor Paul Young

Guests:

- Dr Robyn Cleland (A/g Gene Technology Regulator)
- Dr Paul Keese (A/g GTTAC Secretary)

Presenters:

- Dr Dennis Dowhan
- Dr Sarah Weisman
- Dr Vijay Mareddy
- Dr Markus Koeck
- Dr Brian Weir
- Dr Louisa Matthew

Observers:

- Dr Heidi Mitchell
- Mr Will Tucker

Secretariat:

- Dr Peter Thygesen
- Dr Gillian Colebatch
- Mr Dimitri Kun

The meeting commenced at 08:50 am

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Agenda Item 10. New technologies

The Chair welcomed Dr Louisa Matthew, who updated members on the issue of regulatory coverage of organisms generated with new technologies. The following key issues were raised:

- The scope of Australian regulation of genetically modified organisms (GMOs) is determined by the legal definitions in the *Gene Technology Act 2000* (the GT Act) and the Gene Technology Regulations 2001 (the Regulations).
- The Regulations were drafted prior to a range of new techniques being contemplated. In response to queries from the regulated community, the Regulator is considering whether organisms generated with particular new technologies are captured or excluded by the regulatory scheme.
- The Regulator is preparing to review the Regulations to ensure regulation of these organisms is commensurate with risk and to provide clarity about their capture.

GTTAC was asked to discuss the following questions:

- Does GTTAC support a review of the Regulations?
- What technical considerations should inform the review?

The Chair asked what the timeframe for reviewing the Regulations would be, noting the context of rapidly evolving technology. The Regulator answered that the OGTR is hoping that it will not take as long as the previous review, which is partly why this review will focus on a single issue, albeit a complicated one. The aim is one year but this may be optimistic, and will depend on obtaining policy approval. The Chair asked whether that would include three months for consultation, and the Regulator replied that it is not yet clear. She added the Intergovernmental Gene Technology Agreement required the Act to be reviewed every 5 years, which would mean the next review may occur in 2016. If so, the reviews of the Act and Regulations may converge. The Regulator advised

that the next step regarding a review of the Regulations would be to develop sensible principles to take forward.

Dr Smythe asked whether there was an internal process that could be done before formal approval to undertake a review was sought. The Regulator commented that the OGTR has already been looking at this issue, including development of a consistent approach for providing guidance to queries regarding regulation of new technologies, and to provide clarity both to applicants and the OGTR. This is essentially a definitional issue which can only be changed through the legislation.

Dr Smythe asked if the Regulator has any discretion to define what is a GMO. The Regulator replied that it is more of a legal question and we can only make decisions within the scope of the legislation. Operationally, we are trying to make consistent case-by-case decisions.

The Chair referred to the first discussion question and asked if members supported a review of the Regulations being undertaken. Members indicated unanimous support for a review of the Regulations.

Professor Barnard asked what was the status of an organism made with CRISPR technology that removed DNA. He suggested that it is the product that should be looked at, and that process based regulation in Europe was problematic. Dr Matthew commented that at this stage the OGTR is considering a review of the exclusions in the regulations rather than a review of the definitions in the Act. The Chair noted that the Australian regulatory scheme for GMOs is very robust and gross changes to the legislation are not needed.

Professor Godwin suggested it would be difficult to distinguish sorghum developed with CRISPR from naturally occurring mutants. The Regulator commented that this is not a new issue for the OGTR as naturally occurring deletions can also be similar to deletions created with gene technology. The Chair added that a modification not being detectable may not mean it is not a GMO, and there would be a paper trail documenting its development. The Regulator added that this becomes a compliance issue.

Dr Bonnett made the distinction between intending to make a specific change to the genome versus unintentionally achieving the same change using mutagenesis, which is not regulated. The Chair agreed and suggested that using gene technology to make deliberate changes should be regulated.

Dr Michael noted that RNAi techniques can also cause issues for IBCs, and suggested they could be excluded if no change to the DNA occurs. Dr O'Sullivan commented that the intention should be broad enough capture to allow the Regulator to assess the risks appropriately. She suggested that some changes to the definitions in Schedule 1 and 1A of the Regulations could help remove ambiguity between them; such as replacement of the term 'foreign nucleic acid' with 'gene technology' in item 1 of Schedule 1. She noted that some commentators from the field of ethics, such as Nuffield Council[2], consider that genome editing techniques give rise to concerns because of their potential to increase the scope and scale of genetic modification due to their greater applicability and precision.

Dr Thygesen reminded members that the gene technology regulatory scheme is precautionary and based on risk. He added that any amendments should have a technical basis and resolve regulatory ambiguity.

GTTAC advised the Regulator as follows:

Resolution:

1. The committee supports a review of the Regulations.
2. Technical issues to consider:
    a. ability to detect the modification from some technologies may not be feasible, and

[2] *Identifying key developments, issues and questions relating to techniques of genome editing with engineered nucleases - Background paper* by Ainsley J. Newson & Anthony Wrigley for Nuffield Council on Bioethics

differentiating changes obtained through gene technology from random events may be difficult in some cases

b. similar technologies may produce modified organisms that differ in whether or not they are considered to be classified as GMOs
c. focus on risk as the starting consideration to determine the need for regulatory oversight