

[REDACTED]

From: [REDACTED]@health.gov.au> on behalf of
ogtrcommittees <ogtrcommittees@health.gov.au>
Sent: Wednesday, 10 December 2014 13:02
Subject: Re: Question on CRISPR/CAS, TALEN [SEC=UNCLASSIFIED]

Dear [REDACTED]

[REDACTED]

[REDACTED]

The OGTR currently considers queries regarding whether or not techniques or organisms are regulated under the *Gene Technology Act 2000* on a case by case basis. I'm sure that you can appreciate that provision of the Regulator's view on whether something is or is not subject to regulation under the legislation requires proper consideration, so it can take some time to provide responses.

[REDACTED]

Kind regards

[REDACTED]

[REDACTED]

Office of the Gene Technology Regulator

Committee Secretariat

Ph: [REDACTED]

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Email: ogtrcommittees@health.gov.au

MDP 54, PO Box 9848, Canberra, ACT 2601

From: [REDACTED]

To: "ogtrcommittees@health.gov.au" <ogtrcommittees@health.gov.au>,

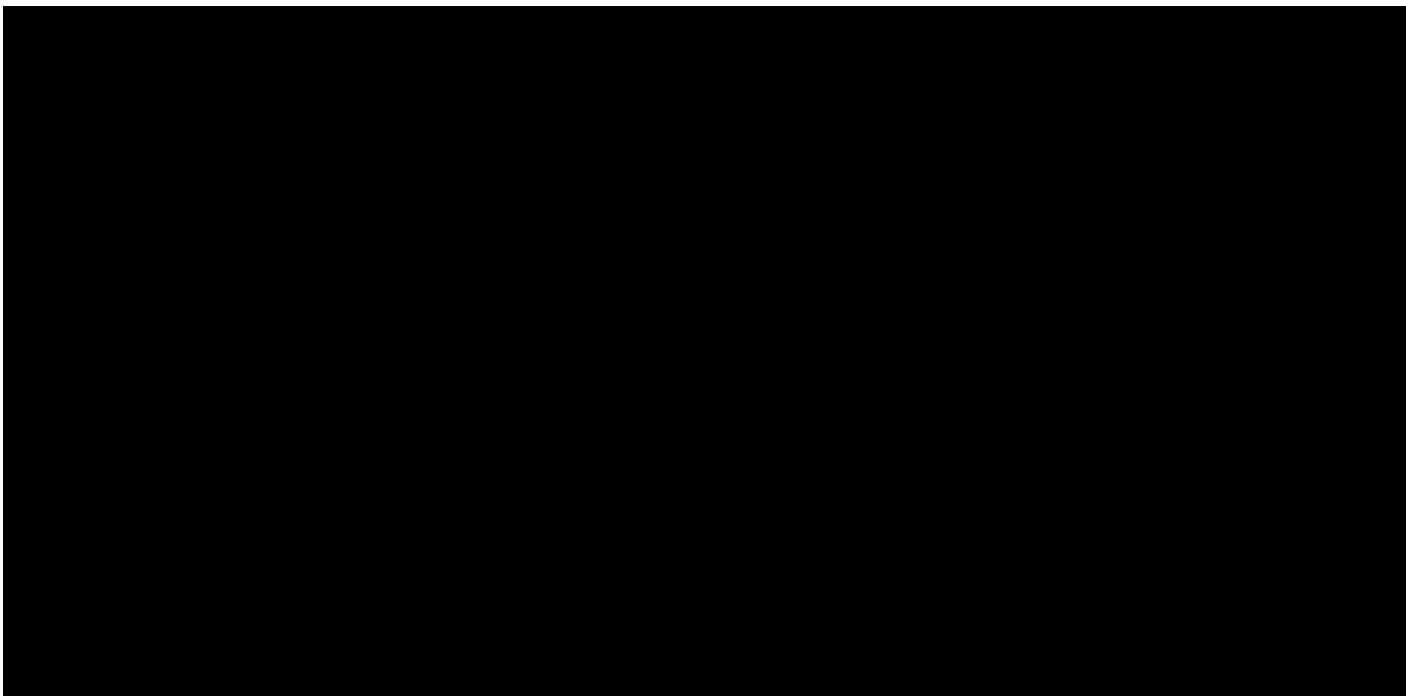
Date: 05/12/2014 10:00

Subject: Question on CRISPR/CAS, TALEN [SEC=No Protective Marking]

Hi [REDACTED]

I have been approached by a senior executive staff member within the University to seek clarification from the OGTR on the following hypothetical question briefly outlined below. Based on the documents that we have been supplied with in the past through the committee (e.g. the recent BBSRC New Techniques PDF), it is still ambiguous to me as to whether the organism in the hypothetical scenario below would be classed as a GMO according to the OGTR current rulings.

The question raised centres on the use of the new CRISPR/CAS and TALEN technologies where a researcher can readily create a specific mutation (that they could also create, at much greater expense and over a much longer time period, by traditional mutagenesis and PCR analysis). As I understand it based on everything the committee has discussed since I have been a member and to the best of my knowledge, the former could/does come under the 'genetically modified organism' category but there has been no cases to test this to date. The latter (traditional mutagenesis) will not, even though the lines produced from the two approaches would be identical (i.e. the same DNA base change, for example). As we know, using the CRISPR/CAS, TALEN technologies does not introduce any foreign DNA sequences. In this day and age when we can readily verify the genome sequence to show that we have made the precise change that could be made by a traditional mutagenesis approach, an organism produced through the CRISPR/CAS, TALEN technology could theoretically be classed as a non-GM organism, as in this case there is no introduction of any foreign DNA to achieve the desired change.



Sincerely,

[REDACTED]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

The University of Adelaide

South Australia 5064

[Redacted]

[Redacted]

[Redacted]

[Redacted]