Questions & Answers on the Technical Review of the Gene Technology Regulations 2001

What is the purpose of the technical review?

To ensure the Gene Technology Regulations (the GT Regulations) reflect current technology and scientific knowledge. The review aims to provide clarity about whether organisms developed using a range of new technologies are subject to regulation as genetically modified organisms (GMOs) and ensure that new technologies are regulated in a manner commensurate with the risks they pose.

What is the scope of this review?

The technical review aims to focus on new technologies and examine:

- cases where the capture or exclusion of these techniques is not clear, and whether those new technologies should be regulated, and
- scientific evidence relating to risks posed as a result of using new technologies.

What is out of scope of this review?

The Gene Technology Regulator's (the Regulator's) technical review cannot alter the policy settings of the scheme. Any changes to the policy settings would need to be addressed in a review of the *Gene Technology Act 2000* (the GT Act).

Regulation of food produced from organisms developed using new technologies, including labelling, is outside the scope of this review. Food Standards Australia New Zealand has responsibility for food regulation, including labelling.

Regulation of the application of new technologies to humans is outside the scope of this review. The National Health and Medical Research Council's oversight of research and reproductive applications in human embryos will continue, regardless of how techniques are described in the GT Act and GT Regulations.

Why is the review being done now?

Since the Regulator last conducted a technical review of the GT Regulations several technologies have developed rapidly, in particular site-directed nuclease techniques and oligonucleotide-directed mutagenesis. It is not clear enough whether organisms produced using these techniques meet the definition of "genetically modified organism" in the GT Act.

What stage is the review up to?

The Regulator has consulted the public on a discussion paper detailing four options for how new technologies could be regulated. The consultation was open from 17 October to 16 December 2016 and sought views on which options submitters supported and why. The Regulator is now considering the issues raised in submissions and will decide which option to pursue. The Regulator is also considering scientific understanding, potential risks, the regulatory burden implications for stakeholders, whether regulatory burden would be commensurate with risks, and the policy intent of the GT Act.

What can I do if I missed the submissions period?

The Regulator undertakes periodic reviews of the GT Regulations. If you would like to identify an issue for consideration in the next review you can contact OGTR at any time. A commencement date for the next review has not been set.

What are the next steps in the review?

The legislation is not changing in the near future.

If amendments are recommended, the Regulator will publicly consult on any amendments before they are finalised. If you want to ensure you are informed of any future consultations, please subscribe to OGTR News.

How are new technologies and gene drives regulated in the meantime?

Although there are challenges in applying the current definitions to some new technologies, the Regulator is obliged to perform the functions required by the Act and apply the legislation as it stands today. The Regulator has provided general advice on regulatory coverage of new technologies on the OGTR website.

During the discussion paper consultation the OGTR learned that some stakeholders are not aware that organisms genetically modified to contain gene drives are GMOs. The Regulator has now issued guidance for Institutional Biosafety Committees and researchers on the regulatory requirements for organisms containing engineered gene drives.

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