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

What is the purpose of the technical review?

This review is undertaken 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 technical review?

The technical review is examining the technical details in the GT Regulations, within the existing policy settings of the gene technology regulatory scheme.

What is out of scope of this technical 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 the Review of the National Gene Technology Scheme, currently underway for the Legislative and Governance Forum on Gene Technology (independent of OGTR).

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, and is currently reviewing how the Food Standards Code applies to the food products of several new technologies.

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 technical 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 technical review up to?

The Regulator has finalised the draft amendments, taking into account issues raised in submissions. This resulted in some minor drafting changes. The Commonwealth, States and Territories are now considering the proposed amendments through the Legislative and Governance Forum on Gene Technology.

What are the next steps in the technical review?

If the Legislative and Governance Forum on Gene Technology approves the proposed amendments, the OGTR will commence the Commonwealth regulation-making process which requires approval from the Governor-General and tabling in Parliament. The finalised amendments would be released once they are made by the Governor-General, and OGTR would provide further information to accredited organisations, IBCs and OGTR News subscribers once the commencement date is known.

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.

Any progressed amendments will not commence until the above described steps have been completed. Organisations or individuals working with GMOs are cautioned to continue complying with all current requirements contained in the GT Regulations (as well as any guidance provided by the Regulator) until any the amendments come into force.

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