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

The gene technology legislation is a scientific risk based scheme. The Regulator has reviewed the Gene Technology Regulations (the Regulations) to ensure they keep pace with technological change, and the level of regulation is appropriate given the potential risks. Amendments to the Regulations to address risks to human health and safety and the environment were agreed by the Legislative and Governance Forum on Gene Technology and made by the Governor-General in April 2019.

When do the amendments come into effect?

The majority of the amendments came into effect on 8 October 2019 with further amendments to Notifiable Low Risk Dealing assessment and reporting commencing on 1 July 2020. Repeal of an item on the list of organisms that are not GMOs will take effect on 8 October 2020.

What do the amendments change?

The amendments adjust the level of regulation to match current understanding of the risk posed by different organisms, so as to protect people and the environment. The amendments also resolve previous legal uncertainty about the regulation of several new technologies. This clarifies requirements for regulated organisations, which supports compliance enforcement with the regulatory scheme.

Do the amendments strengthen the regulation of genome editing techniques?

Yes. These amendments explicitly capture most genome editing techniques as requiring regulation under the legislation. One technique, known as SDN-1, is excluded because SDN-1 organisms present no different risk than organisms carrying naturally occurring genetic variations and cannot be distinguished from conventionally bred animals or plants.

Do the amendments change genetically modified food safety assessment and labelling?

No. The amendments do not impact current requirements for food, which are set separately by Food Standards Australia New Zealand through the Australia New Zealand Food Standards Code.

Could this affect medical research?

Medical researchers routinely use SDN-1 and other genome editing techniques to examine the role of human genes in disease. For example, researchers use SDN-1 to remove genes from mice or cultured cells, and study whether that causes a disease or changes development of a medical condition. Medical researchers have been facing uncertainty about regulatory requirements, and will be able to progress their work more easily with the clarity provided by the amendments. This should speed up research progress, increasing innovation and international competitiveness.

The OGTR website has further information on the amendments, including a detailed overview.

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