

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 Regulations to ensure they keep pace with technological change, and the level of regulation is appropriate given the potential risks. The amendments address risks to human health and safety and the environment for the purposes of the gene technology legislation. The amendments have been agreed by the Legislative and Governance Forum on Gene Technology and made by the Governor-General, and will commence on 8 October 2019.

When will the amendments come into effect?

The amendments have now been legislated, but their commencement is delayed for six months to allow time for states and territories to update their gene technology legislation, which is part of the national regulatory scheme. On 8 October 2019 the majority of the amendments will come into effect.

Will the amendments strengthen the regulation of genome editing techniques?

Yes. There has been legal uncertainty about the regulation of new technologies, including genome editing techniques, and these amendments will explicitly capture most genome editing techniques as requiring regulation under the legislation. One technique, known as SDN-1, will be excluded because SDN-1 organisms present no different risk than organisms carrying naturally occurring genetic changes.

Are genome editing techniques, including CRISPR, potentially unsafe and therefore need to be regulated?

Most genome editing techniques will be explicitly regulated. The technique known as SDN-1 will be excluded because, based on the scientific evidence, SDN-1 organisms present no different risk than organisms carrying naturally occurring genetic changes. Organisms modified using SDN-1 cannot be distinguished from conventionally bred animals or plants, and there is no evidence that they pose safety risks that warrant regulation.

Is Australia the first country in the world to deregulate gene edited animals?

No. Most new genome editing techniques including those using CRISPR will continue to be regulated in Australia. Whereas, Brazil and Argentina have gone further than Australia and implemented measures to allow animals to be produced using these techniques.

Will the amended Gene Technology Regulations deregulate the use of a range of new genetic modification techniques in animals, plants and microbes?

No. The amended Regulations will now explicitly capture most new genetic modification techniques as requiring regulation under the legislation. Only one technique, SDN-1, will be excluded based the scientific evidence that it has no different risk than organisms carrying naturally occurring genetic changes.

Would genetically modified food safety assessment and labelling change?

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

Could there be trade impacts for agricultural exports?

Agricultural industry groups, including exporters, strongly supported the amendments in relation to SDN-1 being excluded from regulation. USA, Brazil, Argentina and Chile have made similar exclusions and Japan is proposing to do the same. As with trade generally, there are market risks to non-alignment in regulatory approaches, however these trade risks are not unmanageable and are quite common and familiar to the industry. A range of non-regulatory mechanisms can support trade between jurisdictions with differing regulatory requirements.

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.