

GENE TECHNOLOGY AMENDMENT REGULATIONS 2019

January 2020

- The Gene Technology Amendment (2019 Measures No. 1) Regulations 2019 came into force on 8 October 2019. The amended regulations exclude organisms modified using the genome-editing applications known as SDN-1 from the scope of GMO regulation.
- There have been incorrect perceptions and speculation about how genome-editing is regulated in Australia.
- The amendments excluding SDN-1 represent the first time a country has expressly excluded a genome-editing application from the scope of GMO regulation. Further, there is no requirement for consultation or data submission; the latter are requirements in some other countries that have set out new regulatory processes for the products of genome-editing.
- The other genome-editing approaches that were specifically included in the Technical Review (namely SDN-2, SDN-3 and ODM) are captured within the scope of GMO regulation. However, this is considered to be an interim solution while the work flowing from the concurrent review of the National Gene Technology Scheme progresses.
- The scope of the Technical Review of the Gene Technology Regulations was limited to certain technologies, specific genome-editing applications and policy settings that limited the extent of the resulting amendments. The review of the National Gene Technology Scheme does not have these restrictions, and therefore presents the potential for more substantial legislative changes and broader genome-editing exclusions.
- Consultations on the implementation of the recommendations following the Review of the Gene Technology Scheme are ongoing and CropLife Australia will continue to advocate for evidence-based regulation that is proportionate to the risks presented by the novel characteristics of the product.

Following the 2016 Technical Review of the Gene Technology Regulations, amendments to Australia's Gene Technology Regulations were formally lodged in the Federal Register on 8 April 2019. The majority of amendments came into force on 8 October 2019.

The amendments draw a distinction between organisms modified using site-directed nucleases and different DNA repair mechanisms. Those that do not involve the use of a template to guide repair (i.e. SDN-1) are not being regulated as GMOs, whereas those that do utilise a template to guide repair (i.e. SDN-2 and SDN-3) are regulated as GMOs, as are organisms modified using oligonucleotide-directed mutagenesis (ODM). Excluding organisms developed using SDN-1 is a positive first step towards proportionate regulation of applications of genome-editing, ahead of further regulation reform.

Some reports on the matter have presented these amendments as final and supporting the need for stringent regulation of genome-editing applications. This has led to an incorrect perception of both the process underway and the reasoning behind the resulting amendments. CropLife Australia welcomes the exclusion of SDN-1 from the scope of regulation as a world-leading first step towards proportionate regulation of new technologies, enabling innovative agricultural tools to be made available to Australian farmers in a timely manner. CropLife highlights that work is ongoing in this area.

To place these outcomes into perspective, it is important to note that the Technical Review was limited in scope in terms of the genome-editing applications it examined: it did not take into account more recent technological developments in this area, such as base-editing. Most of the scientific literature examined as part of the Review strongly supported broader exclusion (e.g. SDN-2 and ODM). As the Review could not result in amendments that are inconsistent with the underlying policy setting (e.g. definition of a GMO under the Gene Technology Act), such exclusion was not possible under the current legislation.

The review of the National Gene Technology Scheme has progressed (in part) in parallel to the Technical Review of the Gene Technology Regulations. It takes into consideration the entire Scheme,

including the underlying policy settings, and opportunities for “future-proofing” it in an era of rapid technological development. The review has produced a set of recommendations including the review of relevant definitions in the Gene Technology Act 2000. This provides further opportunity to clarify the scope of regulation (including exclusions from the scope of GMO regulation) in light of ongoing technical advances in gene technology.

CropLife supports the view that plant varieties developed through the latest breeding methods should not be differentially regulated based on the techniques employed during their development if they are similar to, or indistinguishable from, varieties that could have been produced through earlier breeding methods. CropLife will continue to advocate for regulation that is scientifically sound, evidence-based and proportionate to the risks presented by novel characteristics of the product and not the technology used to create it.

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About CropLife Australia

CropLife Australia is the national peak industry organisation representing the plant science sector in Australia. CropLife’s members are the worldleading innovators, developers, manufacturers and formulators of crop protection and crop biotechnology products. The plant science industry, worth more than \$20 billion a year to Australian agricultural production, provides products to protect crops against pests, weeds and diseases, as well as developing crop biotechnologies key to the nation’s agricultural productivity, profitability and sustainability. CropLife is part of the plant science industry’s 91 country international federation.