

International Policy/Regulatory Overview on Plant Breeding Innovation

No DNA sequence from different species								DNA sequence from different species	Trigger, and timelines (if known)	Current status (if known), Reference(s) to legal and regulatory provisions
Country	Agency	Targeted deletions	Targeted edits	Targeted allele replacements	Targeted insertions	Null Segregant	Targeted Insertion			
Enacted Policy / Official Statement										
Argentina	MAGYP	No	No	No	Yes	No	Yes	Case-by-case consultation—60d Novel combination of DNA trigger	18 (11 plants) consultations response within 60 days; decisions not published Resolution 36/2019 (updating 173/2015); data requirements described in Disposition 1/2019 DI-2019-1-APN-DB#MPYT boletinoficial.gob.ar	
Chile	SAG	No	No	No	Yes	No	Yes	Case-by-case consultation—20d Novel combination of DNA trigger	4 consultations Consultative process for the applicability of Resolution N°1523/2001 on propagation material developed by new plant breeding techniques: SAG consultation	
Brazil	CTNBio	No	No	No	Yes	No	Yes	Case-by-case consultation—90d Recombinant DNA trigger	7 consultations response within 60 days, decision published Normative-Resolution-16-of-January-15-2018.pdf	
Colombia	ICA	No	No	No	Yes	No	Yes	Case-by-case consultation—60d New combination of DNA (foreign DNA) trigger	1 consultation Resolucion R29299 (2018) pdf ica.gov.co/normatividad/normas-ica	
Paraguay	CONBIO	No	No	No	Yes	No	Yes	Case-by-case consultation	Resolucion MAG 565 pdf	
Honduras	SENASA	No	No	No	Yes	No	Yes	Case-by-case consultation—45d New combination of genetic material trigger	Acuerdo C.D.SENASA 008-2019 Official Gazette.pdf	
Guatemala	MAGA	No	No	No	Yes	No	Yes	Case-by-case consultation – 90d	Acuerdo 217-2019 See pages 13-15; Implementing regulation 65.06.01:18 on biosafety of GMOs and excludes from regulation organisms that do not meet the definition for a GMO	

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Japan	MOE/MAFF (environment)	No	No	?	No	No	Yes	Case-by-case notification; MOE/MAFF online guidance to developers	<p>Comprehensive policy for GE products issued by MOE (In Japanese) https://www.env.go.jp/press/106439.html Policy: https://www.env.go.jp/press/20190208_shiryu1.pdf Policy diagram in English: MOE diagram (en)</p> <p>Guideline and requirements for GE product (plant) issued by MAFF (In Japanese only) MAFF requirements (jp); MAFF Guideline and requirements (jp)</p> <p>Targeted edits and inserts: if regarded as similar to self-coming/natural occurrence, not subject to the Cartagena Law.</p>
Japan	MHLW (food)	No	No	?	No	No	Yes	Case-by-case notification; MHLW online guidance to developers	<p>Guideline and requirements for Food product (plant product) – with some text available in English https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/shokuhin/bio/genomed/index_00012.html</p> <p>ENG translation of the MHLW guideline & requirements https://www.mhlw.go.jp/content/000550824.pdf</p> <p>Targeted edits and inserts: edits of 1 ~ a few bps, not subject to the GM Food law. Guiding principle is to define whether the edits and insertion can be achieved by conventional breeding method or not. The criteria will be updated with accumulation of experience over time.</p>
Japan	MAFF (feed)	No	No	?	No	No	Yes	Case-by-case notification; MAFF Feed online guidance* to developers	*Guideline and requirements for Feed (plant product) passed public comment stage (Nov 2019). No final version is available yet.
Israel	NCTP	No	No	No	Yes	No	Yes	Case-by-case consultation Foreign DNA trigger	Israeli National Committee for Transgenic Plants (NCTP) decision from 2016
Australia	OGTR	No	Yes (repair DNA template used) No (no DNA repair template used)	Yes (repair DNA template used)	Yes	No	Yes	Excluding SDN-1 applications	<p>Gene Technology Amendment Regulations 2019 commenced 8 Oct 2019 http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/reviewregulations-1</p> <p>https://www.legislation.gov.au/Details/F2019L00573</p>
Australia	FSANZ							Review ongoing	<p>FSANZ considering proposal to amend their legislation https://www.foodstandards.gov.au/consumer/gmfood/Pages/Review-of-new-breeding-technologies-.aspx</p>

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Australia	Department of Health							Review ongoing	<p>Consultations ongoing on the implementation of recommendations from review of entire national gene tech scheme. Risk-tiering and streamlining regulatory requirements and processes in scope</p> <p>https://www1.health.gov.au/internet/main/publishing.nsf/Content/ohp-gene-tech-implement-phase1.htm</p>
USA	USDA	No if no plant pest trigger	No if no plant pest trigger	No if no plant pest trigger	No if no plant pest trigger	No	No if no plant pest trigger	USDA statement of 3/2018 "Am I Regulated" Process (voluntarily) Plant Pest Trigger	<p>30 replies to letters of inquiry to APHIS AIR since 2015 for gene edited plants confirming non regulated status</p> <p>Regulated Article Letters of Inquiry</p> <p>Proposed rule to revise current biotech regulations - biotech-rule-revision/340 proposed rule</p>
Canada	CFIA	<p>Environment/Plants with Novel Traits</p> <p>i. Novel trait is: a) new to stable cultivated populations of the species in Canada, or b) is present at a level significantly outside the range of that trait in stable, cultivated populations of that plant, ii. and the trait has a potential to affect the safety of the plant with respect to the environment and human health.</p> <p>Novel Feed</p> <p>A feed derived from a plant source can be considered novel if the feed contains a novel trait.</p>							
	HC	<p>Novel Food</p> <p>Food is derived from an organism that has been genetically modified such that:</p> <p>i. the organism exhibits characteristics that were not previously observed in that organism,</p> <p>ii. the organism no longer exhibits characteristics that were previously observed in that organism,</p> <p>iii. one or more characteristics of the organism no longer fall within the anticipated range for that organism</p>							
New Zealand	NZ High Court (EPA ?)	Yes	Yes	Yes	Yes	Yes	Yes	Only chemical and radiation mutagenesis excluded from regulation following legal challenge	<p>https://www.epa.govt.nz/assets/FileAPI/hsno-ar/APP201381/03e845f138/APP201381-APP201381-Decision.pdf</p>

Yes = Under current biotech/GMO regulations

No = Not under current biotech regulations

? = uncertain