

## Regulatory Framework to GMO

	USA	EU member states	Australia/NewZealand	Canada
<b>Regulatory Law</b>	<p><b>USDA</b> <u>Animal Health Protection Act (AHPA)</u>: protect livestock from animal pest and disease risk <u>Plant Protection Act (PPA)</u>: protect agricultural products from damage caused by organisms that pose or plant pest.</p> <p><b>FDA</b> <u>Federal Food Drug and Cosmetics Act (FD&amp;C)</u>: ensure human and animal food is safe, sanitary, and properly labeled, ensure human and animal drugs are safe and effective</p> <p>For GE animals, the genetic materials and recombinant DNA construct, that is integrated into the DNA of an animal and is intended to affect the animal's structure or function meets the definition of "a drug" under FD&amp;C Act. Therefore, a premarket approval is required. CVM (Center for veterinary Medicine) is responsible for evaluating the safety and effectiveness of the rDNA construct. FDA review process has seven categories: product definition, molecular characterization of construct, molecular characterization of GE animal lineage, phenotype, durability, environmental food safety, claim validation.</p> <p><b>EPA</b> <u>Federal Insecticide, fungicide, and rodenticide Act (FIFRA)</u>: For dietary or residential human health effects, the sole standard is the safety of all the combined exposures to the pesticide and related compounds. <b>FD&amp;C</b>: ensure that no harm will result from aggregate exposure to the pesticide chemical residue <u>Toxic Substance Control Act (TSCA)</u>: prevent manufacture, processing, distribution in commerce, use, disposal of chemical substances...</p> <p>If plant-incorporated protectant is produced by plant, EPA regulates the pesticide substance and related genetic material for human safety.</p>	<p><b>European commission GMO legislation</b> <u>Directive 2001/18/EC</u> on the deliberate release of GMOs into the environment: In accordance with the precautionary principle, the objective of this Directive is to approximate the laws, regulations and administrative provisions of the Member States and to protect human health and the environment.</p> <p><u>Regulation (EC) 1829/2003</u> on genetically modified food and feed: (a) provide the basis for ensuring a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed, whilst ensuring the effective functioning of the internal market; (b) lay down Community procedures for the authorisation and supervision of genetically modified food and feed; (c) lay down provisions for the labelling of genetically modified food and feed.</p> <p><u>Directive (EU) 2015/412</u> amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory. The following Articles are inserted: Article 26b, Cultivation</p> <p>1. During the authorisation procedure of a given GMO or during the renewal of consent/authorisation, a Member State may demand that the geographical scope of the written consent or authorisation be adjusted to the effect that all or part of the territory of that Member State is to be excluded from cultivation. This is important.</p> <p><u>Regulation (EC) 1830/2003</u> concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms.</p> <p><u>Directive 2009/41/EC</u> on contained use of genetically modified micro-organisms. Regulation (EC) 1946/2003 on transboundary movements of GMOs.</p>	<p><b>FSANZ (Food Standard Australia/NewZealand)</b> GM foods are regulated under <u>Standard 1.5.2</u> – Food produced using Gene Technology, in the Food Standards Code. The standard has two provisions – mandatory pre-market approval (including a food safety assessment) and mandatory labelling requirements.</p> <p>GM foods are regulated under Standard 1.5.2 – Food produced using Gene Technology, in the Food Standards Code. The standard has two provisions – mandatory pre-market approval (including a food safety assessment) and mandatory labelling requirements. This standard ensures that only assessed and approved GM foods enter the food supply. Approved GM foods are listed in Schedule 26 of the Food Standards Code. Anyone seeking to amend the Code to include a new GM food should refer to the Application Handbook. Details on FSANZ's assessments of GM foods and current approvals can be found here.</p> <p>Not every approved GM food enters the marketplace. Many GM crops approved for use as food, are grown for animal feed and some GM approved plants don't make it to market because of a variety of reasons, for example if they are not commercially viable.</p> <p><u>In Australia, the Office of the Gene Technology Regulator (OGTR)</u> oversees the development and environmental release of GM organisms under <u>the Gene Technology Act 2000</u>.</p> <p><u>In New Zealand, similar functions are undertaken by the Environmental Protection Authority, under the Hazardous Substances and New Organisms (HSNO) Act 1996.</u></p>	<p><b>Health Canada</b> Role: Health Canada assesses the safety of all genetically-modified and other novel foods proposed for sale in Canada. Companies are required to submit detailed scientific data for review and approval by Health Canada, before such foods can be sold.</p> <p><u>Food and Drug Regulations</u> <u>C.R.C., c. 870, FOOD AND DRUGS ACT</u> What are Novel Foods and Genetically Modified (GM) Foods? Novel Foods are: Foods resulting from a process not previously used for food. Products that do not have a history of safe use as a food. Foods that have been modified by genetic manipulation, also known as genetically modified foods, GM foods, genetically engineered foods or biotechnology-derived foods.</p> <p><u>novel food means</u> (a) a substance, including a microorganism, that does not have a history of safe use as a food; (b) a food that has been manufactured, prepared, preserved or packaged by a process that (i) has not been previously applied to that food, and (ii) causes the food to undergo a major change; and (c) a food that is derived from a plant, animal or microorganism that has been genetically modified such that (i) the plant, animal or microorganism exhibits characteristics that were not previously observed in that plant, animal or microorganism, (ii) the plant, animal or microorganism no longer exhibits characteristics that were previously observed in that plant, animal or microorganism, or (iii) one or more characteristics of the plant, animal or microorganism no longer fall within the anticipated range for that plant, animal or microorganism.</p>
<b>GMO Definition</b>	<p>There is no GMO definition.</p> <p>For GE plants, <b>FDA</b> established a <u>premarket consultation</u> process to help ensure that any safety or other regulatory issues associated with food from a new plant variety are resolved. FDA reviews description of biotech foods, ifunctions of introduced genetic materials, identity and function of expression products, toxicity and allergenicity, info comparing the composition of biotech and conventional foods, etc.</p> <p>GE organism is considered if the donor organism, recipient organism, vector or vector agent used in engineering the organisms belongs to one of the ataxa listed in 7C.F.R. section 340.2 and also considered a plant pest. Required data and info to conduct a plant pest risk assessment is provided in 7C.F.R. 340.6 (c). GE organism is also regulated when APHIS has reason to believe that the GE organism may be a plant pest.</p>	<p>Directive 2001/18/EC Article 2 Definitions</p> <p>(2) "genetically modified organism (GMO)" means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination; Within the terms of this definition: (a) genetic modification occurs at least through the use of the techniques listed in Annex I A, part 1; Techniques of genetic modification referred to in Article 2(2)(a) are inter alia: (1) recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation; (2) techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation; (3) cell fusion (including protoplast fusion) or UK, Germany, Sweden, Italy, France, Ireland, Netherland, Finland showed signs of welcome about genome-editing plants.</p>	<p>Standard 1.5.2–2 Definitions</p> <p>food produced using gene technology means a food which has been derived or developed from an organism which has been modified by gene technology.</p> <p>Note This definition does not include food derived from an animal or other organism which has been fed food produced using gene technology, unless the animal or other organism is itself a product of gene technology. gene technology means recombinant DNA techniques that alter the heritable genetic material of living cells or organisms.</p> <p><u>OGTR's definition</u> Definition: The full definition of a GMO appears under section 10 of the Gene Technology Act 2000 (the Act). In essence, a GMO means: An organism that has been modified by gene technology; or An organism that has inherited traits from an organism, where the traits occurred in the initial organism because of gene technology.</p> <p><u>EPA's definition</u> all organisms developed through conventional and longstanding chemical and radiation treatments do not require HSNO Act approval as GMOs. NewZealand has decided not to deregulate ZFN-TALEN-based biotech product.</p>	<p>There is no regulation specific to GMO. Instead, GMO is treated as a novel food.</p> <p>DIVISION 28 Definition of Novel Foods B.28.001 The definitions in this section apply in this Division. genetically modify means to change the heritable traits of a plant, animal or microorganism by means of intentional manipulation.</p> <p>major change means, in respect of a food, a change in the food that, based on the manufacturer's experience or generally accepted nutritional or food science theory, places the modified food outside the accepted limits of natural variations for that food with regard to (a) the composition, structure or nutritional quality of the food or its generally recognized physiological effects; (b) the manner in which the food is metabolized in the body; or (c) the microbiological safety, the chemical safety or the safe use of the food. (changement majeur)</p> <p>ODM-based Cibus rapeseed will be approved</p>
<b>How to deal with NPBT</b>	<p>Intragenic Potato (Simplot Inc) and CRISPR/Cas9-based mushrooms (Univ.), intragenic GALA apple (Okanagan) and Maize (deleted a whole gene Waxy seq, Monsanto) have approved by USDA. ODM-based Rape seeds of Cbus Inc. approved.</p>	<p>France asked the judgement to European Court of Justice.</p>		