Regulatory Framework to GMO

**USA**

**Regulatory Law**
- USDA Animal Health Protection Act (AHPA) protects animal health and food safety.
- Plant Protection Act (PPA) protects agricultural products from damage caused by organisms that pose a plant pest risk.
- FDA (Federal Food Drug and Cosmetics Act) regulates food, drug, and cosmetics, and ensures they are safe, wholesome, truthful, and properly labeled, and ensures human and animal drug safety and effectiveness.

**GMO Definition**
- There is no GMO definition.
- For GE plants, FEDA established a `presumption of safety` but other regulatory issues associated with food from a new plant variety, are reviewed/FDA reviews description of biotech foods, functions of introducing genetic materials, and risk assessment processors, toxicity and allergenicity, info comparing the composition of biotech and conventional foods, if new functions of introduced DNA of an animal and is intended to affect the animal’s structure or function.

**How to deal with NBPT**
- Intragenic Potato (Simplici) and CRISPR/Cas9-based mushrooms (Univ.) and eggs. GM and other novel foods are 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.

**EU member states**

**Regulatory Law**
- EU member states regulate the use of GM foods. The EU has a clear legislative framework that includes the European Commission’s GMO legislation and the European directive 2001/18/EC as regards the possibility for the traceability of food and feed, whilst ensuring the effective functioning of the internal market. (b) lay down Community procedures for the authorization and supervision of genetically modified foods.
- Member States to restrict or prohibit the cultivation of GMO or during the renewal of consent/authorisation.

**GMO Definition**
- An organism that has been altered by genetic manipulation, also known as genetically modified foods.
- Novel foods: Foods that have been modified by genetic manipulation, also known as genetically modified foods. Novel foods are from a process that is not previously used or fed food means;

**How to deal with NBPT**
- FDA assesses the safety of all generally 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.

**Australia/New Zealand**

**Regulatory Law**
- FSANZ (Food Standards Australia/New Zealand) is responsible for evaluating the safety and effectiveness of GM foods. New Zealand has decided not to deregulate ZFN-based ODM-based Cibus rapeseed.
- In Australia, the OGM is regulated under the Food Standards Code. The standard has two provisions – Standard 1.5.2 – Novel foods regulated under FSANZ (Food Standards Code). The standard has two provisions – mandatory pre-market approval (including a food safety assessment and mandatory labelling requirements).

**GMO Definition**
- `Genetically modified organism (GMO)` means an organism of heritable material prepared outside the body; or
- A food that is derived from a plant, an animal or other organism which has been modified by genetic manipulation, also known as genetically modified foods.

**How to deal with NBPT**
- FDA assesses the safety of all generally 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.

**Canada**

**Regulatory Law**
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- FDA assesses the safety of all generally 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.

**GMO Definition**
- There is no GMO definition. Instead, a food-derived food means;

**How to deal with NBPT**
- There is no regulation specific to GMO. Instead, a food that is derived from a plant, an animal or other organism which has been modified by genetic manipulation, also known as genetically modified foods.
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**New Zealand**

**Regulatory Law**
- An organism that has been modified by gene technology means a food produced using gene technology, unless food produced using gene technology, in the Food Standards Code.
- FSANZ (Food Standards Australia/New Zealand) is responsible for evaluating the safety and effectiveness of GM organisms and the traceability of food and feed.

**GMO Definition**
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