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GEC'S vs. GMO's

It is common knowledge that conventional breeding for crop improvement is limited by the ability to introduce novel or new traits not present in the domesticated or wild germplasm of a species. This restriction has been overcome in the last 2+ decades by genetic modification (GM) or genetic engineering (GE) techniques which were used to insert DNA sequences from other species. However, such GM crops, commonly referred to as transgenics* or genetically modified organisms (GMO's*), are heavily regulated in most countries.

- *Transgenics is the alteration of plant DNA by adding a gene from another species.
- *GMO or genetically modified organism is a plant or animal whose genetic material (DNA) has been altered through genetic engineering/biotechnology techniques (insertion/deletion of genes) to produce a genotype that possesses a modified trait that is not found in naturally occurring plants of that species. When genes are inserted, they usually come from a different species. The principle of producing a GMO is to add new genetic material into an organism's genome.

The leadoff article in the Jan. 19, 2016 issue of eBean News from the American Soybean Association is titled "Soy Growers: Proposed Rule on Biotech a Progressive Step for Plant Breeding Innovation", and contains ASA's response to a notice of proposed rule-making from USDA on the regulatory framework for plant breeding innovation. The gist of this announcement centered on the decision by USDA's Animal and Plant Health Inspection Service (APHIS) to exclude products resulting from new breeding innovations such as **gene editing** (see below) from the requirement of pre-market approval that transgenic derivations or GMO's must submit to. Two fact sheets–"Questions and Answers: APHIS requests public input on next steps towards revision of its biotechnology regulations" and "Questions and Answers: Biotechnology and the USDA"–published by the Biotechnology Regulatory Services of APHIS should be checked for further details on APHIS' goals and their process for regulation of GM organisms.

On Jan. 18, 2017, the US Food and Drug Administration (FDA) released draft revised Guidance for Industry (GFI) #187 "Regulation of Intentionally Altered Genomic DNA in Animals". In a followup to this draft, the FDA defined "intentionally altered genome/genomic DNA" as "alterations introduced into the DNA of an organism using modern molecular technologies, such as genetic engineering (also referred to as recombinant DNA technology) and genome editing". Furthermore, the agency defines genome editing as "a term used to describe a relatively new set of technologies that enable one to make precise changes in the DNA of a plant, animal, or other living organism". These "technologies can be used to introduce, remove, or substitute one or more specific nucleotides (letters in the DNA code) at a specific site in the organism's genome". The agency also differentiates between genome editing and genetic engineering; i.e., gene editing is the alteration of an organism's DNA that does not involve insertion of genetic material from another species as is the case with transgenic DNA modification.

On Mar. 28, 2018, US Secretary of Agriculture Sonny Perdue issued a statement that provides clarification of USDA's policy on the oversight of plants produced through innovative new breeding techniques that include genome or gene editing.

According to this press release, USDA neither now regulates nor has any plans to regulate plants that could otherwise have been developed through traditional breeding techniques as long as they are not plant pests or were not developed using plant pests. According to Secretary Perdue, "With this approach, USDA seeks to allow innovation when there is no risk present". Secretary Perdue goes on to say that USDA will continue with its regulatory responsibilities that protect consumers and plant health by evaluating products that have used modern biotechnology in their development.

Since it is obvious from the above that USDA considers genetically modified (GM) crops derived from gene editing (**GEC–gene-edited crop**) to be

significantly different from those derived from transgenic genetic modification (GMO), the remainder of this narrative will attempt to delineate the GMO and GEC forms of genome manipulation.

Gene editing is a genetic engineering technique that is used to precisely modify DNA **within an organism**. The process involves making cuts at specific DNA sequences with enzymes called engineered nucleases, which are made up of two parts–a nuclease that cuts the DNA, and a DNA-targeting component that is designed to guide the nuclease to a specific DNA sequence in an organism. The technique can be used to add, remove, or alter a genome's DNA, and the resulting change or mutation in the DNA will affect the function of that section of DNA. This process can be used to insert a new section of DNA, or to replace an existing section of DNA with an altered version to effect a point mutation within a gene. In effect, gene editing can direct and effect a mutation at a specific site in an organism's genome. **No outside DNA is introduced into the organism's DNA in this process**.

Presently, there are three genome editing systems that are used, and they all contain a nuclease component to cut the DNA and a DNA-targeting component to recognize the DNA sequence to be cut.

- **CRISPR-Cas9**–[click here and here (CRISPR = clustered regularly interspaced short palindromic repeats; Cas9 = CRISPR associated protein 9)]: CRISPR is the DNA-targeting part of the system, and Cas9 is the nuclease or enzyme that cuts the DNA. This system is recognized as being faster, cheaper, and more accurate than previous techniques. A Corteva Agriscience website is an excellent resource for more detail about CRISPR-Cas technology.
- **ZFNs**: zinc-finger nucleases composed of a DNA-binding component (zinc-finger proteins–ZF) and a nuclease.
- **TALENs**: transcription activator-like effector nucleases composed of a DNA-binding component (transcriptor activator-like effect–TALE) and a nuclease that cuts the DNA.

An editorial in Nature Genetics (Vol. 48, No. 2, Feb. 2016) states that "As a technology, genome editing applied in agriculture represents a more efficient and precise method for genetic manipulation but does not fundamentally differ from classic breeding in terms of outcomes." Furthermore, it is stated that "A distinction must be established, particularly in the public sphere, between 'genetically modified organisms' (GMO's) generated through the **transgenic** introduction of foreign DNA sequences and 'genome-edited crops' (GEC's) generated through precise editing of an organism's **native** genome."

In a commentary article in Nature Genetics (Vol. 48, No. 2, Feb. 2016), the authors state that "Genome editing begins with the introduction of a targeted DNA double-stranded break at a predetermined locus using a sequence-specific nuclease. Three types of sequence-specific nucleases are in general use, namely ZFNs, TALENs, and CRISPR/Cas9." These nucleases or enzymes act as molecular scissors to precisely cut into specific DNA sequences to remove genes and replace (introgress) them with better ones from the same species. The "CRISPR/Cas recruits a guide RNA to direct an endonuclease to a target DNA sequence via base-pairing." The authors of the above commentary further state that "Geneticists have been quick to adopt genome editing as a powerful tool for crop improvement. It is in principle straightforward to mitigate an unwanted trait or to create a favorable trait by introducing knockout mutations in the causal genes by genome editing." Also contained in this article is the authors' reasoning–based on the precision of genetic changes introduced in GEC's–for product-based rather than technology-based regulation of GEC's.

A Feb. 4, 2016 article in Business Insider titled "There's a totally new way to genetically modify our food" raises additional points regarding the GEC vs. GMO issue.

- GMO's provide food sources whose DNA has been modified to include genes from other organisms to produce a particular trait such as disease or pest resistance.
- GEC's are derived from genetic modifications that

don't involve using genes from another species.
- One of the first applications of gene editing is likely to be in agriculture in order to enhance food production and food quality.
- Genome or gene editing is a more efficient and precise method than conventional breeding methods for manipulating genes within an organism, but the outcome is similar. By comparison, GMO's are derived by introducing DNA from other organisms.

It is a well-known fact that foods and food products derived from GMO's have inspired and continue to inspire a strong public backlash against their presence in the human food chain. All of the above supports the stance that food and food products derived from GEC's should not be regulated with the same rigor as GMO's, nor should they be considered as "frankenfoods" by the entities that have such contempt for food and food products from GMO's. Hopefully, this new technology and the subsequent products derived from its use will be viewed by all parties as a real breakthrough in the ongoing efforts to feed a rapidly growing world population.

As stated in the editorial cited above, "The potential benefits of GEC's should not be impeded as a result of misinformation, so disclosure and education are the best ways to promote sound policies" regarding their use.

An Aug. 2018 article titled "Why Gene Editing is the Next Food Revolution" by Eric Niiler (National Geographic, Aug 2018) provides several cases of how gene editing can benefit food crops as well as its potential application toward solving human diseases and maladies. It also provides a very good narrative and pictorial presentation of the processes involved in this genetic modification technique. Of special importance is how gene editing is viewed differently by U.S. (they don't need strict regulation) and European Union (they should be regulated the same as GMO's) regulators. Additionally, the author cites two special advantages from using gene-editing vs. GMO techniques; 1) it is simpler, cheaper, and faster, and 2) it might allow developing nations to develop and grow enhanced crops without buying expensive seeds from large seed companies.

The following articles can be accessed for further information about GMO's vs. Gene Editing.

GMOs and gene editing: What's the difference? by Nicholas Karavolias (May 2022)

What's the Difference Between Gene Edited Foods and GMOs? by Alexandra Emanuelli

Gene-edited crops vs. GMOs: What's the difference–and why does it matter? Genetic Literacy Project (April 2018)

Since finding new ways to boost food production for a growing population is imperative and should be the primary goal of all sustainability initiatives, the end result from using gene editing is that more efficient ways of improving crop productivity will be available to practitioners in all countries that will allow them to be used.

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