Frequently Asked Questions

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Can you detect genome edited products?

It is technically feasible to detect DNA sequence changes resulting from genome editing applications in plants with currently available technology. However, without additional information about the specific sequence change and its location in the genome, it would not be possible to uniquely identify a genome edited product as the DNA change could have arisen by various means (e.g. through the use of genome editing tools, conventional breeding tools, or as a result of spontaneous genetic variation from generation to generation.)

Why it is much easier to detect genetic changes in transgenic plants (GMOs) than genome edited plants?

The process of developing a GMO creates a relatively large and unique DNA sequence in the plant based on the junction created between the DNA inserted and adjacent endogenous plant DNA (Figure 1(b)). This provides unique sequence for the development of a DNA-based detection method that is specific for the specific transformation event. Genome editing may not result in a DNA sequence change that is large enough, or unique enough to develop a detection method that is reliable or practical.

If genome edited products are detectable, does that mean they should be regulated in a certain way?

The ability to detect and uniquely identify a genome edited plant has no bearing on the appropriateness of a particular regulatory approach. Detection and unique identification methods exist for conventional and GMO varieties alike and the inherent similarity of the outcomes of genome edited to conventional plant breeding, with its long history of safe development, reinforces the strong principal that products which *could* have been created using conventional breeding *should* be treated the same from a policy and regulatory standpoint.

Do governments have positions /issued guidelines on the detectability of genome edited products?

The European Commission Joint Research Center (JRC) and the EU Network of GM Laboratories, in a recent report,[1] agree that it is questionable if "event-specific" identification and quantitative detection methods can be readily developed for all genome edited plants. The JRC[2] and German BVL[3] also recently issued statements refuting claims of broad-based detectability from a recent, highly publicized, paper[4]

Are there genome edited crops currently being commercially grown?

Currently there is no single compiled list of commercialized genome edited products, but there are public sources of information (e.g. the USDA "Am I Regulated" list, the Federal Gazette in Brazil, etc). However, this type of information is not indicative of a products' actual commercial status or even of its pre-commercial development status. Based on industry and government dialogues, it appears that the only genome edited product commercially cultivated since 2019 is a high oleic soybean in the Upper Midwest United States.[5]

When genetic changes from genome editing aren't identifiable, how can consumers make informed choices?

Traceability and/or certification processes from breeders to consumer could hypothetically be setup when products are sold on the basis of their variety name, or using value added, contract-based approaches going

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[1] https://gmo-crl.jrc.ec.europa.eu/doc/JRC116289-GE-report-ENGL.pdf

[2] https://gmo-crl.jrc.ec.europa.eu/ENGL/docs/ENGL Evaluation of the scientific publication 02-10-2020.pdf

[3]https://www.bvl.bund.de/SharedDocs/Fachmeldungen/06_gentechnik/2020/2020_09_09_Fa_Nachweismethode-genomeditierte-Pflanzen.html

[4] https://www.mdpi.com/2304-8158/9/9/1245/htm

[5] https://ir.calyxt.com/news-events/press-releases/detail/39/first-commercial-sale-of-calyxt-high-oleic-soybean-oil-on

back to the seed supplier. The approach would be the same as those that facilitate informed consumer choice around other potential value-added products for which there is no detection method (e.g. shade grown coffee, cage-free eggs).

Genome editing can be used to make different types of DNA changes ranging from a single nucleotide change to a transgenic insertion. Are there different testing considerations depending on the type of change? If I know the sequence created by genome editing, can laboratories create a test for that genome edited product?

The ability to detect a specific DNA sequence in a plant genome depends on the sensitivity of the method and the purity and homogeneity of the DNA sample. Detection methods based on real-time PCR presently used in GMO detection depend on the amplification of a unique sequence of DNA associated with a random transformation event. PCR methods for GMO detection depend on the existence of this unique sequence as it differentiates the GMO and non-GMO counterpart. In the case of using genome editing to introduce a transgene, the sensitivity and performance of a detection method would be similar to that currently used to detect GMO events. Where genome editing is used to modify native genes, which can involve single or a few nucleotide changes, it becomes more difficult to develop a detection method with comparable sensitivity and specificity. For such genome edits with reduced sensitivity of the PCR method, the DNA variation may still be detectable in laboratory samples where the DNA is highly pure and homogenous (provided sequence difference between edited and non-edited plant is known). Difficulties arise with the ability to routinely and reliably detect the same types of changes in bulk (mixed or heterogeneous) grain samples.

When genome edited products are detectable in seed or grain, can finished foods also be tested?

The ability to detect a specific DNA sequence in a food depends on the sensitivity of the method and the purity and homogeneity of the sample. A food product (e.g. a protein bar) may contain little DNA from the plant and it is mixed with many other components which can inhibit PCR reactions. Detection of small amounts of a GMO DNA, for example, in such complex products using presently available PCR methods is already challenging due to the low amounts of DNA present and/or DNA from multiple sources. In the case of finished foods containing genome edited ingredients, the sensitivity of the PCR methods may be below that typical for detection of GMO events. The reliable detection and identification of genome edits in food samples will be more challenging in comparison to the issues encountered already in detecting GMO DNAs in complex finished foods.

Why might something be detectable in small volumes but not in larger grain volumes?

The ability to detect a specific DNA sequence in a plant depends largely on the sensitivity of the method and the purity and homogeneity of the sample. Detection methods based on real-time PCR (presently used in GMO detection) depend on the amplification of a unique sequence of DNA associated with a random transformation event. PCR methods depend on there being sufficient enough unique sequence to distinguish between the GMO and non-GMO counterpart. Where genome editing is used to modify native genes, which can involve single or a few nucleotide changes, it becomes more difficult to develop detection methods with comparable sensitivity and specificity. For such genome edits and reduced sensitivity, they may still be detectable in seed or grain samples that are highly pure and homogenous; however detecting these changes in bulk grain samples using presently available PCR methods will be challenging as they are usually not pure and heterogenous. Regardless of whether sample is highly pure and homogenous or heterogeneous and originating from mixed grain, the process used to introduce sequence changes would not be possible to determine (natural variation, conventional breeding, mutagenesis or gene editing)

If companies can identify their varieties for intellectual property purposes, how is that different than identification for marketing purposes?

The foundation of variety identification for intellectual property purposes continues to be based on phenotypical characteristics. In certain jurisdictions and with certain crops, genetic information can be useful in addition to support a plant variety protection application; however, the genetic information that could be

used in this case is not necessarily associated with specific sequence change that may or may not be introduced through genome editing.

Figure 1 – Similarity of outcomes from random mutation and genome editing