# Concepts around detection methods and genome edited crops

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- **"Adoption of genome editing policies is progressing" -** The regulatory status of products developed with the use of genome editing is still under discussion globally, however an increasing number of countries are providing clarity on the regulatory status of genome edited crops.

- **"Many governments exclude products of certain genome editing applications from GMO regulations and thus, also from applicable GMO identification requirements" -** With the exception of the European Union and New Zealand's Environmental Protection Authority (EPA NZ), the majority of countries that have provided regulatory clarity have excluded products of certain genome editing applications from the scope of their biotech/GMO regulations. In these countries, such products are handled as conventional breeding material. This also means that GMO-associated labelling and detection requirements are not applicable to such products..

- **"Some genome edited products are similar to GMOs while some are similar to conventional products" -** Genome editing applications are versatile and can be used in the development of a wide range of products. One type of products are GMOs (e.g., using genome editing tools to introduce a transgene). However, other types of genome editing products may be similar to those that could occur in nature or produced by conventional breeding methods, including induced random mutagenesis (Figure 1).

- **"On a technical level, GMOs can be identified as specific "events" with a unique genetic sequence combination" -** An "event" (or "transformation event") is defined by the insertion of a transgenic DNA sequence into the plant genome as a result of the transformation process. This creates a unique sequence combination between the inserted sequence and the adjacent plant DNA (Figure 2(b)). This event specific fingerprint can be used to develop an event-specific detection method, which is a regulatory requirement in certain jurisdictions for products that are regulated as GMOs.

- "**Most genome edited products do not have specific genetic fingerprints in the same fashion as transgenic events" -** Genome editing applications that result in plants that are similar or indistinguishable to that which could occur in nature or produced by conventional breeding methods do not result in "events" with a specific genetic fingerprint in the same manner as GMOs (Figure 2(c)). Other applications of genome editing do not result in the insertion of DNA sequences in the final product, rather simply influence the outcome from the crossing of two breeding lines or varieties. (Figure 3).

- **"With prior knowledge of the specific genetic change and a reference genome for comparison, sequence modifications are detectable. However, current detection methods cannot distinguish how the genetic change occurred" -** While not producing a unique genetic sequence combination in the same manner as GMOs, it is technically feasible to detect small specific DNA sequence change resulting from genome editing in a sample derived from identical source material (seed or grain). However, without additional information, it is not possible to determine whether a specific sequence change is a result of spontaneous or induced mutation, breeding or genome editing. DNA sequence changes from different mutagenesis methods can be similar or even identical. Consequently, the detection of a particular DNA sequence alone may not uniquely identify a specific technology, product, or developer in the same way a GMO event specific detection does.

Detection and identification challenges are amplified when samples subject to analysis come from multiple sources and are heterogenous, rather than from a single plant or seed.

- **"Practical challenges exist in developing a detection assay for every edit that would work reliably and would meet legal performance requirements" -** Detection methods that support legally mandated labelling and traceability requirements for GMOs must be able to detect, quantify and uniquely identify GMO events in bulk seed or grain while meeting strict minimum performance and full 'validation' criteria before use.[1] For genome edited plants, depending on the specific DNA sequence change, its size, and its genomic location,[2] DNA detection methods may or may not be able to meet similar performance criteria in terms of identification, sensitivity and accuracy.[3]

- **"Although detection assays for genome edited plants may not be practicable, this doesn't mean traceability is not possible; however, current traceability tools are not suited for bulk commodity products" -** Given the current technical limitations around fast, easily deployable detection methods for certain genome edited products, other approaches may be considered where traceability is required for regulatory (or other) purposes, including documentation, chain of custody and identity preservation schemes. However, these schemes are presently not applied for tracing of commodity bulks but are reserved for niche or value-added products and are associated with additional costs for consumers.

- "**Just because it is detectable it doesn't imply need (or appropriateness) of GMO treatment" -** Just because a genome edited plant may be detectable, uniquely identifiable or traceable through DNA detection or other means, it does not mean that it should be subjected to GMO regulation. Inherent similarity of the outcomes of genome edited to conventional plant breeding, with its long history of safe development, reinforces the principle that products which *could* have been created using conventional breeding *should* be treated the same from a policy and regulatory standpoint.

1 For example in the EU, https://gmo-crl.jrc.ec.europa.eu/doc/JRC116289-GE-report-ENGL.pdf

2 In the future emerging sequencing approaches may enable an assay development approach. However, application of such approaches would require knowledge and constant updating of all known sequence variations in species, and they will be further limited by high possibility of false positives. Moreover, any such assays may not be feasible for bulk shipments in a way that can be applicable to import/exports.

3 http://db.zs-intern.de/uploads/1549640768-Genome%20editing%20report_final%20version%20ENGL.pdf

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

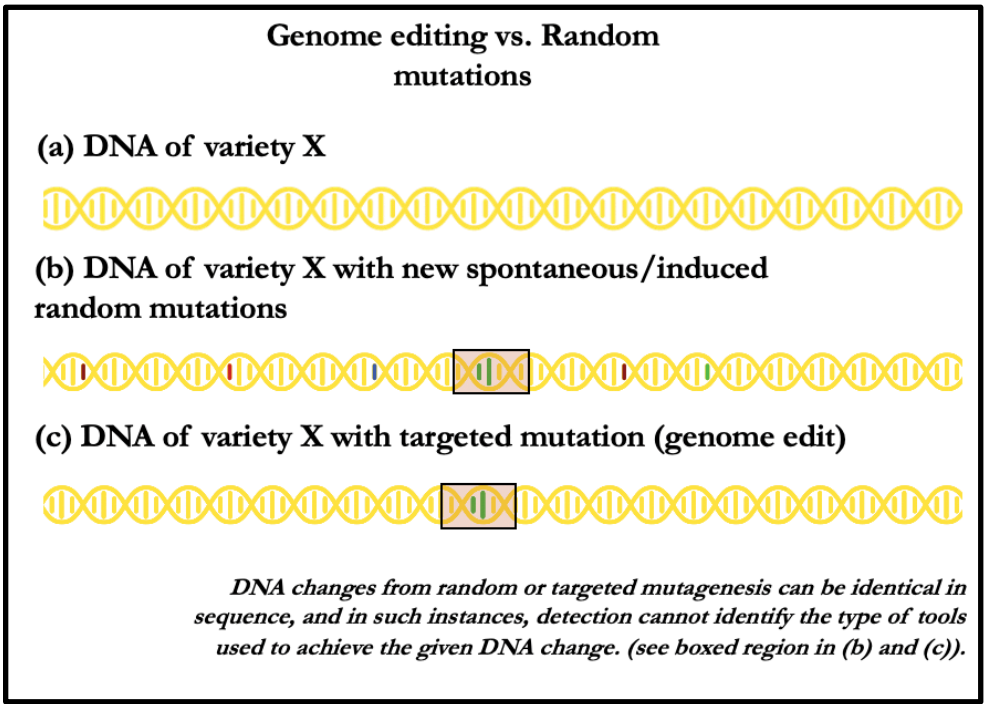

Figure 2 – Detection of GMO vs. Genome Editing

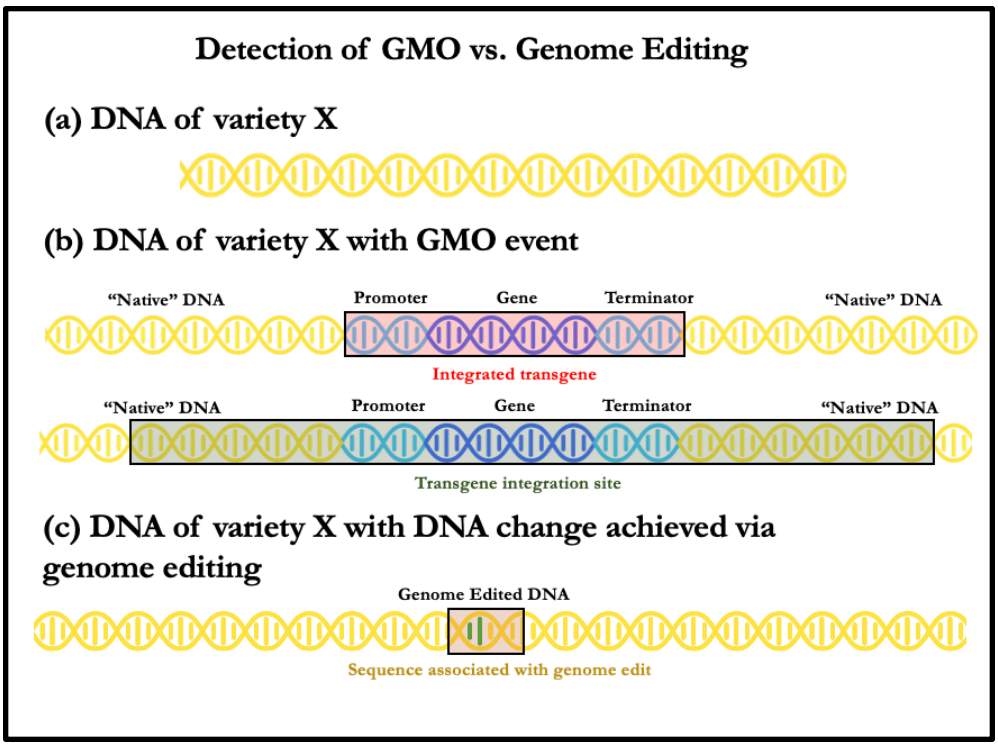

Figure 3 – Genome editing applications that do not result in "non-native" sequence changes