5. Gene-edited products are detectable

MYTH

Gene-edited products cannot be distinguished from products developed through conventional breeding.

REALITY

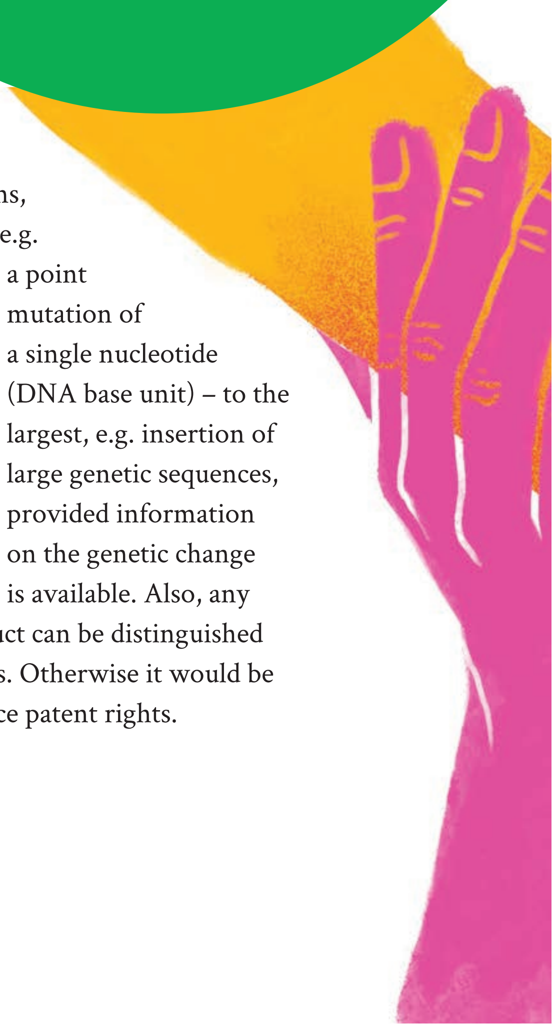
Methods can be developed to detect all products of gene editing, provided information on the genetic change is available.

Industry associations have claimed that many gene-edited products cannot be distinguished from products developed with conventional breeding.[1] And according to Bayer, a change made through gene editing is "indistinguishable from a conventional breeding breakthrough or a natural mutation".[2]

The objective of these claims seems to be to persuade the EU authorities not to even try to apply the EU's GMO regulations to gene editing.

However, already-available, standard GMO detection techniques allow unambiguous detection and identification of a wide range of genetic modifications, from the smallest – e.g. a point mutation of a single nucleotide (DNA base unit) – to the largest, e.g. insertion of large genetic sequences, provided information on the genetic change is available. Also, any patented seed product can be distinguished from other products. Otherwise it would be impossible to enforce patent rights.

> Any patented seed product can be distinguished from other products



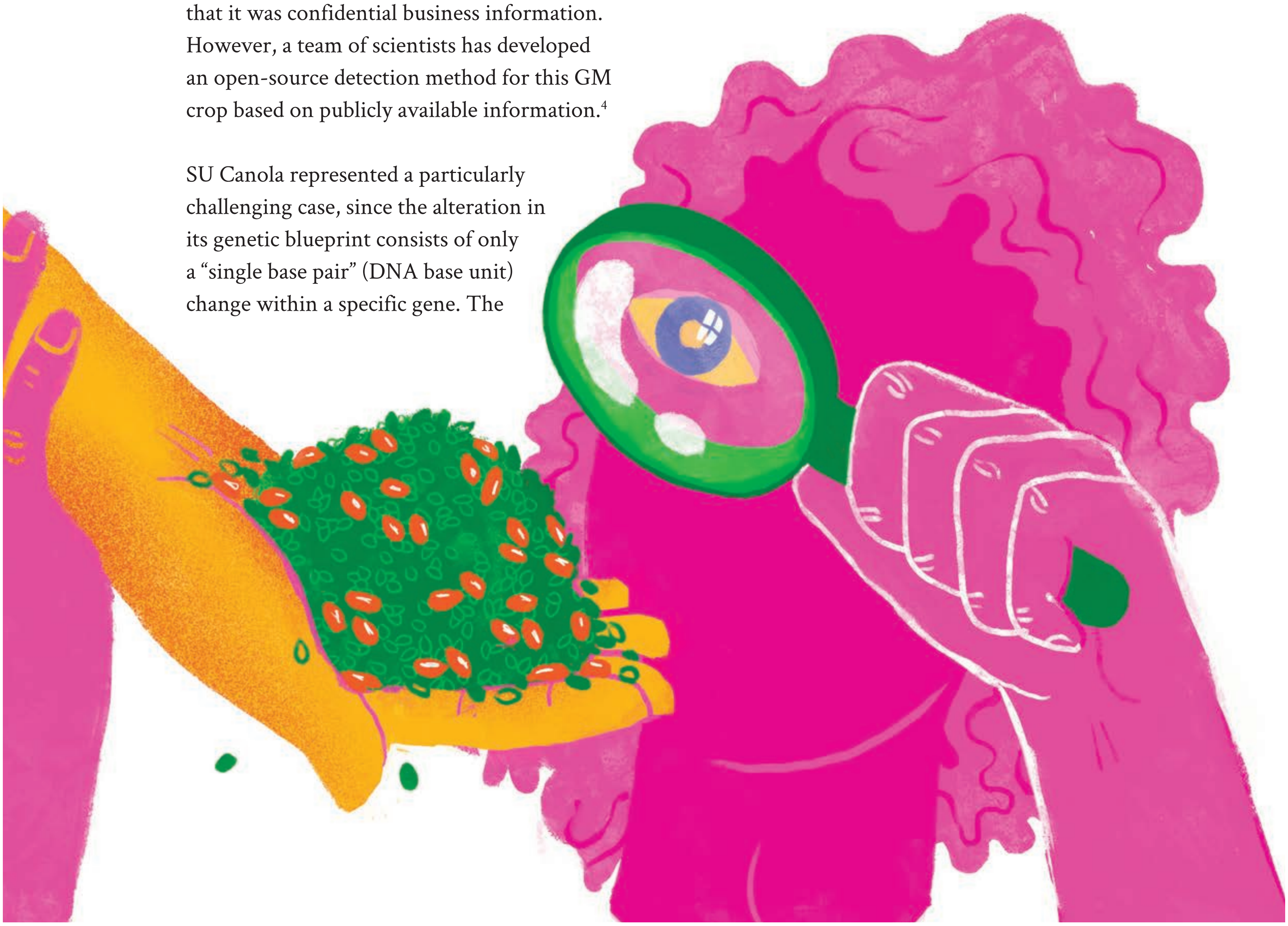
In fact, patents generally encompass specific genomic sequences independently of how they are derived. For example, crops developed through mutation breeding can be identified on the basis of the specific sequences that characterise them and that are described in the patent.

When these specific sequences are known, not only the developer but also others can develop specific detection methods for these crops. This has been done for Cibus' SU Canola. Cibus has developed its own detection method to identify its product, and submitted it to Canadian authorities,[3] but the authorities refused to make it available to Canadian NGOs on grounds that it was confidential business information. However, a team of scientists has developed an open-source detection method for this GM crop based on publicly available information.[4]

SU Canola represented a particularly challenging case, since the alteration in its genetic blueprint consists of only a "single base pair" (DNA base unit) change within a specific gene. The researchers confirmed that a single base pair change can be detected with standard GMO detection technology based on polymerase chain reaction (PCR) methodology. Thus it is likely that detection methods can be developed for most, if not all, gene-edited organisms, according to the researchers, provided enough information on the nature of the edit is available.[4]

When the specific sequences that characterise a crop are known, not only the developer but also others can develop specific detection methods

They stated: "Our work demonstrates that it may be possible to develop event-specific, GMO regulation compliant detection methods for virtually any gene-edited organism based on information disclosed by the developer or gathered from the public domain."[4]



UNKNOWN GENE-EDITED CROPS

Critics of the open-source SU Canola test have focused on the fact that it does not detect the GM method used. Some – like the European Plant Science Organisation (EPSO) – also said that it does not solve the problem of unknown genetic modifications.[5]

However, EU law does not require that detection tests are able to specify the GM method used to develop the crop. A scientific review by researchers from Germany's Federal Office of Consumer Protection and Food Safety (BVL) and Julius Kühn Institute recognised that GMO detection methods generally do not allow any conclusions on the process used, whether they be gene-editing techniques or older-style transgenic genetic modification techniques. However, the researchers commented that "bioinformatics and statistical considerations might help to evaluate whether a detected sequence was potentially introduced by genome modification".[6]

The detection of unknown GMOs has never been solely reliant on the detection methods used in the laboratory

The detection of unknown GMOs has never been solely reliant on the detection methods used in the laboratory. The EU's Joint Research Centre said in 2017 that the most efficient way to test imports for unknown GMOs was to check authorisations in other countries, patent applications, scientific publications, and other information to apply a targeted approach. The laboratory detection test can then be used to provide confirmation of information gathered through other means.[7]
In addition, it is unlikely that a large number of unknown gene-edited crops will be in circulation. Seed companies talk about gene editing when they use it because they want to be able to profit in the marketplace from the use of these new GM techniques.

So far, only two gene-edited crops have been commercialised : Cibus's SU Canola and Calyxt's "high oleic" asoybean with an altered oil profile. Thus far it has proved possible to track a significant number of gene-edited products developed worldwide for commercial markets, as the Julius Kühn Institute in Germany has done for a peer-reviewed publication.[8]

Also, the potential for unknown GMOs to slip through official controls is not new. The same is true for the GM crops that have been successfully regulated in Europe and other countries for the last two and a half decades.

Today's strategies for screening for unknown GMOs do not capture all of them. They only identify those that carry certain common genetic sequences that are used as "screening targets". But the number of GM crops lacking common sequences has been increasing in recent years. It is possible that currently there are unauthorised GMOs in the marketplace that have not been detected because they do not carry any common sequences. No one claims that for this reason, the EU GMO legislation is impossible to enforce and thus useless.
By analogy, no one would suggest legalising burglary because criminal laws do not prevent all burglaries.

Unknown gene-edited crops are just another category of GM products that GMO screening methods can miss and that must be detected by event-specific methods such as the one developed for SU Canola. The presence of gene-edited products in the commercial food system does not create a new set of circumstances that demands fundamental changes in the regulatory regime for GMOs.

The researchers who developed the test for SU Canola believe it may be possible in the future to develop screening methods for various classes of gene-edited crops.[4]

TRANSPARENCY REQUIRED

In the meantime, transparency must be demanded from developers of gene-edited organisms. Under the EU's GMO regulations, agricultural biotech companies are required to provide a detection method and "reference" sample material for each GMO that is authorised, though the sector has not yet submitted any gene-edited GMOs to be marketed in the EU.

Meanwhile researchers at North Carolina State University are calling for a coalition of biotech industry, government and non-government organizations, trade organizations, and academic experts to work together to provide basic information about gene-edited crops to lift the veil on how plants are modified and provide greater transparency on the presence and use of gene editing in food supplies. They believe that such transparency is crucial to building public trust and confidence in gene-edited products.[9]

However, the primary responsibility for transparency over gene-edited products lies with their developers. It cannot be the job of governments, civil society, or academia to fill knowledge gaps created by industry secrecy.

> It cannot be the job of governments, civil society, or academia to fill knowledge gaps created by industry secrecy

Once information has been disclosed by the developer, it should be organised in a publicly accessible resource. We can use what is already there – the Biosafety Clearing-House of the Cartagena Protocol on Biosafety,[10] the EUginius GMO database of the Federal Office of Consumer Protection and Food Safety (BVL) in Germany and Wageningen Food Safety Research in The Netherlands,[11] and the register set up by the European Commission for EU-authorised and withdrawn GMOs.[12] The EU must ensure that countries wishing to export to the bloc participate in these registers.

The European Commission's register of EU-authorised GMOs is required by EU law to also "contain, where available, relevant information concerning GMO which are not authorised in the European Union".[13] The Commission and/or member states should work with international partners to meet this requirement.

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