Detection of new GMOs – possible and necessary for transparency and public trust

Detection methods must be demanded from the developer as a condition of approval. Briefing by Claire Robinson of GMWatch and Pat Thomas of Beyond GM / A Bigger Conversation

12 January 2024

The European Commission's proposals for the regulation of new genetically modified organisms (new genomic techniques or NGTs) state that detection of these GMOs may be challenging or impossible.[1] The Commission uses this as a reason to remove them from the requirements of the current GMO legislation – which include risk assessment, traceability, and labelling.

However, this is misleading. Detection of new GMOs is possible, given prior knowledge of the relevant genetic sequence and reference materials, which can – and should – be demanded from the developer as a condition of their approval.

Indeed, under the current GMO laws, developers must provide the regulator with a validated detection method and reference materials (seeds or other plant material). All that is needed for the detection of new GMOs is for these requirements to continue. GMO developers will certainly have an in-house detection method to detect their own GMOs – otherwise they could not enforce their patents. All GMO products, and the techniques used to make them, are patented.

Even without prior knowledge of the genetic sequence and reference materials, detection may be possible. This would require further research and investigation of the molecular markers or "signatures" of new GMOs, combined with other types of information on any given new GMO (genetic sequence, geographical origin, nature of the processed product, or whistleblower alerts). Together, this information can be used to detect and identify the GMO in a "weight of evidence" or "matrix" approach.[2]

The main challenge in detecting new GMOs lies in distinguishing mutations induced by new genetic engineering methods, such as CRISPR/Cas, from naturally occurring mutations. However, progress has been made in this field and new detection methods are already being developed. For example, a method has been developed to distinguish CRISPR/Cas9-induced mutations from naturally occurring mutations in plants.[3]

While there is no doubt that the further development of detection methods is desirable, methods exist right now that can be used and built on. For known/authorised new GMOs, detection methods can be required from the developer. For unknown and undeclared GMOs, detection methods are evolving. For

---

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52023PC0411
[2] http://www.sciencedirect.com/science/article/pii/B9780081005965218349 ; https://hal.inrae.fr/hal-02790049/document ; https://www.bdschapters.com/webshop/open-access/advances-in-identifying-gm-plants-toward-the-routine-detection-of-hidden-and-new-gmos/ ; https://bdspublishing.com/_webedit/uploaded-files/All%20Files/Open%20Access/9781801462037.pdf
[3] https://link.springer.com/article/10.1007/s00122-020-03600-5

example, in 2022 a US government collaboration announced the development of "an initial set of computational tools… that assist trained analysts to identify genetic engineering in next generation sequencing (NGS) datasets. This software aims to make it possible for scientists to detect engineered DNA at scale."[4]

Most recently, an important literature review and analysis[5] commissioned by the UK Food Standards Agency and written by Malcolm Burns, Specialist Adviser on DNA Analysis to the Government Chemist,[6] and Gavin Nixon, Science Leader, Molecular Foods Analysis at life science tools company LGC, concluded: "As per conventional GMOs, products of genome editing can only be readily detected and quantified in commodity products by enforcement laboratories if prior knowledge on the altered genome sequence is known, alongside a validated detection method and access to CRMs [certified reference materials]."

The authors also noted that development of detection methods for new GMOs would "support the safety, transparency, proportionality, traceability and consumer confidence associated with the UK food chain".

They did not underestimate the challenges, but neither did they see them as insurmountable.

The authors state that given prior information on the genetic sequence of interest and the neighbouring regions of the genome, modern techniques such as qPCR, dPCR, and NGS currently offer the best analytical potential for detecting products of gene editing and have the technical potential to detect small DNA alterations.

Although they highlight that it is currently challenging to distinguish mutations obtained by gene editing from those obtained through traditional processes, they recommend that "further research is conducted, supported through practical laboratory work, to provide a more evidenced based approach to inform whether different potential detection methods could be developed" for products of new GM techniques. They add that confidence in applying analytical techniques for detection of new GMOs will depend on the efficacy of databases and the availability of suitable reference materials.

They further advise that regulators "address both the analytical challenges presented, as well as progressing the infrastructure for working towards a toolkit for the design, development and implementation of analytical methods for detection of PBO ["precision bred organism", or new GMO] products".

While the field of detection of new GMOs will continue to develop, it is crucial to bear in mind that full traceability and labelling are not dependent on the availability of laboratory detection tests.

---

[4] https://www.prnewswire.com/news-releases/iarpa-ginkgo-bioworks-and-draper-announce-new-technologies-to-detect-engineered-dna-301650505.html. See also https://www.iarpa.gov/index.php/research-programs/felix/felix-baa

[5] https://www.food.gov.uk/research/novel-and-non-traditional-foods-additives-and-processes/literature-review-on-analytical-methods-for-the-detection-of-precision-bred-products

[6] Burns' full title is: Principal Scientist and Special Advisor for the Government Chemist and Manager for the UK National Reference Laboratory for Genetically Modified Organisms in Food and Feed.

Currently, a mixture of audit trails combined with different methods of laboratory detection are the primary way in which GMOs in the food system are identified, traced (and therefore labelled) along the food chain.

However, even without laboratory detection, these existing and well-developed audit trails can also be used on their own to identify and track new GMOs in the food system from lab to fork, provided developers are legally required to make an honest declaration of the GMO status of their products at the point of origin.

To ensure transparency, safety and consumer confidence, many other food products, from organic to products of designated origin, are traceable and labelled according to their provenance; and in livestock farming, each individual animal is tracked, via audit trails, from farm to table. There is no reason why new GMOs cannot be identified and tracked in the same way.