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GENETICALLY MODIFIED ORGANISM

Hansa Mathur

Mody University of Science and Technology, School of Liberal Arts and Sciences, Laxmangarh Sikar, Rajasthan

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Introduction

New agricultural technologies are introducing structural changes and transitional challenges, from their initial wild crop cultivars to more productive, pest resistance, or better quality product lines than earlier ancestral lines, through continuous selection and controlled breeding. The term "genetically modified organisms" (GMOs) was used to characterise organism whose genetic material has been altered in a way that does not occur in nature under natural cross-breeding or recombination settings Peter R. et. al. 2011). In agriculture, the word refers to plants in which a gene or genes from different species have been stably introduced into a host genome via genetic transfer procedures, and where such imported genes have been shown to produce a gene product in the majority of cases. (Peter R. et. al. 2011) The new genes are translated, and the new protein is produced. This confers new characteristics on the plant, such as insect resistance or herbicide tolerance.

GMOs are provided as genetically modified (GM) food or feed when consumed directly or after processing. These foods are genetically modified during the raw material production phase, and GM plants are the most prevalent source of raw material for GM foods (Peter R. et. al. 2011).

The introduction of genetically modified organisms (GMOs) into the environment and the marketing of GM foods have sparked public discussion in many regions of the world. This broader discussion has prompted concerns about whether GM food and feed are safe for human and animal consumption, as well as whether they would have negative consequences for environmental health and biodiversity (Aristidis M. at. al. 2017).

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This discussion is likely to continue, most likely in the context of additional uses of biotechnology and its implications for human communities, and it will undoubtedly require scientific investigation. Many rules, restrictions, and legislations have evolved in an attempt to reduce such uncertainties, and in most countries, legislative procedures for the approval of any GM crop used for food or feed currently exist. (Yaqoob et. al., 2016; Waigmann at. al., 2012).

In the European Union, the use of genetically modified organisms (GMOs), their release into the environment, production, importation, and, most importantly, their usage as food additives are all subject to stringent regulations. The first community legal instruments (Council Directives 90/220/EEC and 90/219/EEC) were created in 1990 with the explicit purpose of protecting human and animal health and the environment (European Parliament & Council of the European Union, 2001).

RISKS IN CONNECTION

Unintended consequences of GM plant cultivation include unintended gene flow, reduced genetic diversity, effects on non-target species, weediness, reduced pesticide and herbicide efficiency, herbicide and insecticide toxicity, changes in soil and water chemistry and quality, and a reduction in ecosystem complexity by reducing biodiversity (Aristidis M. et. al. 2017). Second, the usage of genetically modified plants as human food and animal feed may pose a health risk.

The most pressing worry is the need to investigate the effects of the transplanted gene as well as the possible toxicity of produced proteins. The transfer of the gene (nptII) from GM plants to soil bacteria, as well as the discovery of Agrobacterium tumefaciens genes in sweet potatoes, indicate that the interplay of alleles in plants and microbes is a well-established phenomenon that cannot be overlooked (Kyndt et. al., 2015). Tyshko et. al., 2014; Tyshko and Sadykova, 2016) fed laboratory animals GM rice, soybean, maize, and wheat, alone or in combination, and recorded pathological, haematological, histopathological, serum chemistry, morphological, food intake, and reproduction-related parameters.

The first controversy arose when a study published in Food and Chemical Toxicology by French molecular researcher Gilles-Eric Seralini found that animals given GM maize and roundup had larger tumours (Seralini et. al., 2012, 2013, 2014).

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According to a recent assessment published by the National Academy of Sciences in the United States, GM crops have had no harmful impact on the environment, ecosystems, biodiversity, or human health. The amount of pesticide and herbicide used has been reduced while yield has grown by producing herbicide and insect-resistant crops. The survey also discovered that there are statistically significant changes in chemical composition and nutrient content between GM and non-GM plants.

It's also worth remembering that humans are exposed to a diverse range of GM foods rather than a single event. Different GM organisms have different genes that have been added in various ways. This means that each GM food and its safety should be reviewed on a case-by-case basis, and that blanket claims about the safety of all GM foods are not viable (Fraiture M.A., et. al. 2017).

DETECTION OF GMOS USING VALID METHODS

The difference between the unmodified variety and the transgenic plant is exploited by every sort of GMO detection equipment. This can be done by recognising the newly inserted transgenic DNA or the newly expressed protein, or if the protein serves as an enzyme, by employing chemical analysis to detect the enzymatic reaction's result (Peter R. et al. 2011).

The first approach to be approved at the EU level was a standard PCR-based screening technology capable of detecting the majority of GMOs currently allowed for commercialization (Lipp et. al, 1999). The control sequences flanking the newly introduced gene, particularly the 35S promoter and the Nos terminator, are detected using this approach devised by Pietsch et. al. (1997). It has the capability of detecting one or a few copies of a gene or target sequence of interest inside an organism's genetic material or genome. The requirement to quantify the amount of GMO in a sample prompted the development of a number of PCR-based techniques that provide not only a qualitative answer concerning the presence or absence of a transgenic line, but also a more exact estimate of the relative proportion of GMO present in a particular sample (ROSA S. ET. AL. 2016). Real-time PCR and digital PCR are the two most competitive PCR-based approaches.

The real-time PCR system detects the PCR products as they accumulate and monitors the reaction as it happens in real time. The PCR reaction is linked to the emission of a fluorescent

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signal that is proportionate to the amount of PCR product produced in successive cycles in this type of device. The amount of PCR product created in each subsequent reaction cycle causes this signal to increase proportionally. It is possible to monitor the PCR reaction during its exponential phase by detecting the amount of fluorescence emission at each cycle. The initial amount of target template correlates with the first major increase in fluorescence. Rosa S. et. al. 2016 and Ahmed F.E., 2002 Real-time PCR, on the other hand, has a number of technical restrictions, including the requirement for assay calibration with standards of comparable quality to the samples being tested. This can result in a repeated workflow process as well as difficulties in providing acceptable standards for comparison.

Digital PCR (dPCR) is a new approach for determining the precise amount of nucleic acids in a sample. It employs analogue assay chemicals but counts the total amount of individual target molecules in a digital format, allowing it to be employed in a variety of applications that demand high sensitivity but have limited sample availability (Rosa S. et. al. 2016).

Digital PCR measurements are made by dividing the sample into a large number of tiny volume reactions, each of which contains either zero or one target molecule (Pohl et. al. 2004, Dube et.al. 2008), this is the core idea behind digital measuring. Any compartments that contain targets will become brilliantly fluorescent, while compartments that do not contain targets will just have background fluorescence. By directly counting single molecules, digital PCR platforms that partition the sample into a higher number of compartments will have the maximum accuracy (Whale A.S. et al. 2012, Rosa S. et al. 2016, Buermans, H.P.J. et. al. 2014, Fraiture M.A., et. al. 2017) describe a new method for monitoring GMOs on the market that employs Next-generation Sequencing (NGS) technology for massively parallel DNA sequencing of multiple samples, which are distinguishable during subsequent bioinformatics analysis by unique barcodes added to each sample during the library preparation step (Buermans, H.P.J. et. al. 2014)

PROCEDURES IN THE LEGISLATIVE PROCESS

The European Union established a tight legal system for tracing GMOs and derived products, with the goal of ensuring human, animal, and environmental health safety. An

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obligatory labelling of any GMO-derived or GMO-containing food or feed has been implemented as part of this regulatory framework, with the goal of ensuring customers' freedom of choice (European Parliament & Council of the European Union, 2001).

Furthermore, a 0.1 percent "Minimum Required Performance Limit" was established for feed containing GMOs that had already been approved elsewhere and for which an application for EU authorisation had been submitted (European Commission, 2011). According to these laws, EU control laboratories must be able to detect small amounts of GM materials, assess their authorisation status, and, if necessary, quantify the GM content in order to ensure conformity with legal requirements. 2003 (European Commission).

CONCLUSIONS

As more precise and well-regulated technologies, like as CRISPR (clustered regularly interspaced short palindromic repeats), CRISPR-associated (Cas) genes, and novel breeding methods, emerge under suitable legislation, their use will rise. Concerns concerning long-term use of GM food and feed continue in terms of safety evaluation and health dangers. Several legal instruments have addressed the specific issue of GM food labelling in order to ensure that the ultimate consumer is aware of any change in the characteristic or food property (European Parliament & Council of the European Union, 2004)

Labelling should be required and regarded a fundamental consumer right. Crops with improved nutritional value to functional meals and nutraceuticals will be the next generation of GM foods, and evaluations will increasingly have to include the impact of next generation GM on food safety assessment methodologies.

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