

Genome-edited crops for improved food security of smallholder farmers

Widespread enthusiasm about potential contributions of genome-edited crops to address climate change, food security, nutrition and health, environmental sustainability and diversification of agriculture is dampened by concerns about the associated risks. Analysis of the top seven risks of genome-edited crops finds that the scientific risks are comparable to those of accepted, past and current breeding methods, but failure to address regulatory, legal and trade framework, and the granting of social license, squanders the potential benefits.

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Genome-editing technologies, which enable targeted precise changes to genomes, can improve a wide range of crop plants, including those that underpin food security in low- and middle-income countries (LMICs). Building on the increasing availability of pangenomes¹ and whole-genome DNA sequences for many crops, genome-editing technologies offer a level of accuracy and predictability that was previously unavailable when attempting to modify crop genomes. Applications promise benefits — for consumers, this includes nutritional enhancement, improved food safety and reduced food waste; for farmers, this includes resistance to disease, weeds and pests, greater seed affordability due to cheaper seed production, and enhanced climate resilience including tolerance to drought²; for society, this includes ecosystem services, such as increased biodiversity in cropping systems³. The opportunities and potential benefits of genome-editing technologies are widely acknowledged^{4,5}, including by the award of the Nobel Prize in Chemistry in 2020.

One of the main advantages of using genome editing is that it can accelerate the delivery of improved varieties to smallholder farmers. Genes can be edited directly in elite breeding lines or commercial varieties^{6,7}, eliminating the need for backcrossing — a technique used in conventional plant breeding to introgress a trait from a non-elite or wild relative ‘trait donor’. This reduces the time needed to develop an improved variety by nearly two-thirds and eliminates linkage drag caused by non-elite residual genes from the donor parent, which are impossible to eliminate by conventional backcross breeding.

While not a panacea, genome-editing technologies are widely accessible and could help democratize the benefits

of science. Because they are relatively inexpensive to implement, they are being used to diversify agricultural systems and improve major and minor crops, including so-called orphan crops^{8,9}, for which funding is scarce despite their importance for food security in LMICs. The widespread accessibility of genome-editing technologies means that they can be used by public sector institutions, including the Consultative Group for International Agricultural Research (CGIAR)¹⁰, to develop public goods that are unattractive to the profit-driven private sector, and to bring the benefits of genome editing to smallholder farmers. Genome editing is being applied to more than 40 crops across 25 countries, mostly addressing agronomy, food and feed quality, or abiotic stress tolerance¹¹. Despite the apparent potential, however, we are only aware of six genome-edited crop traits — in soybean, canola, rice, maize, mushroom and camelina — that have been approved for commercialization to date.

Many countries are still uncertain about whether to grow and how to regulate genome-edited crop varieties¹². Scientific, political and social considerations impact these decisions, which are complicated by the rapidly evolving features of the science and inconsistent use of genome-editing terminology¹³. For example, genome editing may or may not involve the transitory introduction of foreign DNA sequences, may or may not result in transgenic products, and may or may not generate products that substantially differ from varieties bred through conventional breeding. Precise consistent use of accurate terminology (for instance, as proposed by the National Academies of Sciences Engineering and Medicine¹⁴) to transparently explain the process, products, benefits and potential risks and mitigation strategies is essential to

build public trust and consistent regulatory oversight of technologies, including genome editing.

Here we focus on site-directed nuclease type 1 and 2 (SDN1 and SDN2)^{11,15}-edited varieties. SDN1 produces a double-stranded DNA break that is repaired via nonhomologous end joining, which randomly deletes or adds nucleotides, often causing a frameshift mutation. In SDN2, the double-stranded break is repaired by homologous recombination, which uses a synthetic DNA template to add, delete or replace specific nucleotides. By contrast, SDN3 introduces a gene segment, or whole gene(s) at a specific site in the genome using homologous recombination, which could result in a transgenic product depending on the nature and origin of the introduced segment. CGIAR and its partners focus on SDN1 and SDN2 edits to address issues such as climate resilience in rice; disease resistance in banana, maize, potato, rice, wheat and yam; and nutrition improvement and consumer and environmental safety traits in cassava (Fig. 1). Additional traits where CGIAR envisions using genome editing include brown streak virus resistance and haploid induction in cassava; nutritional quality and digestibility in bean; *Striga* resistance in sorghum; low phytate and high provitamin A in maize; reduced acrylamide, phytate and polyphenol oxidase in wheat; reduced aflatoxin in groundnut; delayed flour rancidity in pearl millet; reduced glycaemic index and apomixis in rice; and heat tolerance and apomixis in potato.

The recently concluded G20 Meeting of Agricultural Chief Scientists (G20 MACS) held a special session on genome-editing technologies, focusing on their potential contributions to food security, sustainability and adaptation to climate change, with







Crop	Trait	Edited genes	Stage
 Banana	Disease resistance (BXW, Fusarium wilt, BSV)	<i>DMR6</i> , BSV sequences	3,1
 Cassava	Disease resistance (BB)	<i>SWEET</i> gene promoters	3
	Food safety (cyanide-free)	Linamarin synthase	3
	Quality (waxy starch)	<i>GBSS1</i>	3
 Maize	Disease resistance (MLN)	<i>C6 QTL</i>	1
	Weed resistance (<i>Striga</i>)	Strigolactone	3
 Potato	Disease resistance (PVY ^a , late blight)	<i>elf-4E</i> , <i>SDMR6-1</i> , <i>StCHL1</i>	2
 Rice	Disease resistance (BLB, RHB)	<i>SWEET</i> gene promoters, <i>AGO4</i> , <i>STV11</i>	4,3
	Food safety (low arsenic and cadmium)	<i>OsNRAMP5</i> , <i>OsPT8</i> , <i>LS1</i> , <i>LS2</i>	3
	Nitrogen remobilization, and methane emission reduction	Unpublished	3
	Insect resistance ^a (BPH)	BPH resistance alleles	2
 Wheat	Disease resistance (rusts, mildew) ^a	<i>Lr67</i> and others	3

Fig. 1 | Current genome-editing projects taking place at CGIAR centers. ^aSDN2 editing required. All other current projects are SDN1. Stage of current development: (1) discovery; (2) proof of concept; (3) early development; (4) advanced development; (5) commercialization. BXW, banana Xanthomonas wilt; BSV, banana streak virus; BB, bacterial blight; MLN, maize lethal necrosis; PVY, potato virus Y; BLB, bacterial leaf blight; RHB, rice hoja blanca virus; BPH, brown plant hopper; *DMR6*, downy mildew resistance 6; *SWEET*, sugar transporters; *GBSS1*, granule-bound starch synthase 1; *C6 QTL*, unpublished gene on chromosome 6; *elf-4E*, eukaryotic translation initiation factor 4E; *SDMR6-1*, *Solanum tuberosum* downy mildew 6-1; *StCHL1*, *Solanum tuberosum* chlorophyll 1; *AGO4*, argonaute 4; *STV11*, rice stripe virus 11; *OsNRAMP5*, *Oriza sativa* natural resistance-associated macrophage protein 5; *OsPT8*, *Oriza sativa* phosphate transporter 8; *LS1* and *LS2*, low silicon rice 1 and 2; *Lr67*, leaf rust 67.

particular focus on the perspective of LMICs. Although noting the tremendous potential of genome editing, the G20 MACS encouraged further analysis of the risks¹⁶.

Possible risks of genome-edited crops

The risks of genome-edited crop varieties should be considered alongside their benefits, and in the context of plant breeding. Traditional conventional breeding is not free of risks, such as unintended increased levels of toxic alkaloids in fava bean and potato, introduction of disease susceptibility, or the reduction of protein content when breeding for increased grain yield¹⁷. Secondly, mutations occur spontaneously with every generational advance, giving rise both to favorable and unfavorable (sometimes lethal to the variety, such as chlorophyll deficiency) alleles that

drive natural selection for fitness and enable farmer- and consumer-guided selection for preferred traits. These risks provide a baseline and context to assess the risks of genome-edited plants.

Non-target edits. One frequently cited risk of genome editing is whether it could lead to additional mutations that compromise the safety or agronomic performance of a variety. From the initial deployment of clustered regularly interspaced short palindromic repeats (CRISPR) technology, and as for previous double-strand break technologies (such as transcription activator-like effector nucleases (TALENs), zinc-finger nucleases or meganucleases), it was apparent that sites other than the target site could be inadvertently edited following introduction of a double-stranded

break¹⁸. An appropriate context when considering the implications of this potential non-target mutagenesis is the frequency of spontaneous natural mutagenesis (10⁻⁸–10⁻⁹ per base pair (bp), or perhaps 5–140 per plant genome)^{19,20}. For perspective, the genomic data of 3,010 accessions of Asian cultivated rice identified diversity as high as 1 single-nucleotide polymorphism for every 22 bp in the 370-Mbp rice genome²¹. Another consideration is whether non-target edits in plants present new concerns relative to the risks that are inherent to other breeding approaches. The frequency of chemical- or radiation-induced mutations introduced during the development of more than 3,200 horticultural and crop varieties is around 1,000 times greater than natural frequencies. Current genome-editing technology options generate non-target mutations at a similar frequency to natural mutations that result from spontaneous mutagenesis^{15–17}, and at a frequency much lower than that of induced mutation methods.

Continuous improvement in the bioinformatic tools and approaches used to design genome-editing targets works to mitigate and reduce the likelihood of occurrence of non-target edits in crop plants. Much effort has been invested to develop robust assays for mutations, and to understand the frequency and nature of non-target site mutations resulting from CRISPR technology²². These efforts have resulted in CRISPR systems with increased fidelity and fewer non-target edits. With technological advances that help limit non-target mutations, we believe that there are no significant safety concerns that are unique to the deployment of genome-edited crops when assessed in the context of the long history of safe use of conventionally bred varieties, including those derived from mutagenesis.

Breaking of natural reproductive barriers

Another concern could be that genome editing, similar to chemical- or radiation-induced mutations¹⁷, breaks reproductive barriers that would prevent some mutations from occurring in nature. For example, some DNA segments are tightly linked, effectively preventing recombination during sexual reproduction. Although this feature can be seen equally as an advantage or an opportunity of mutation and genome-editing technologies, ultimately, as in conventional breeding, genome editing is followed by extensive field evaluations in target environments to select and deliver to farmers only those crops that are superior to current varieties, considering all agronomic and consumer criteria.

Inadequate stewardship. Today, most genome-edited plants are produced using an intermediate step that involves insertion of foreign DNA sequences that are removed in subsequent steps, so that the final genome-edited plants are not transgenic. However, use of an intermediate transgenic step presents technical risks that require appropriate stewardship, both in the lab and greenhouse. Molecular tools can then be used to demonstrate that the transgenic intermediate has been resolved before field trials, with country-appropriate stewardship for edited crops. As genome-editing technologies evolve, the use of an intermediate transgenic step may become unnecessary, further simplifying genome-edited plant development and greatly enhancing its utility for editing clonally propagated crops — for which removal of the intermediate transgenic elements is challenging.

Enhanced inequity between rich and poor. Another risk can arise if advanced technologies disproportionately benefit wealthy players, including multinational corporations and large-scale farmers, or disadvantage smallholders or farmers engaged in alternative agricultural systems such as organic agriculture^{4,23}. One response to mitigate this risk may be misuse of regulatory processes, such as differential labeling, that work to stigmatize and inhibit adoption by food companies and discourage consumption. Some organizations have already sought to define products developed using genome-editing technologies as transgenic, which could lead to unwarranted avoidance of genome-edited crops by food and ingredient companies, smallholders and trade-dependent developing countries. Labeling rules should be framed in a harmonized global system that is based on transparent science-based consideration of risks, in which new traits in food would be included as a label if they introduce new allergens or toxins or fundamentally change the composition of the food; production method should not be part of mandatory labeling requirements. We propose that the most effective approach to mitigate this risk is to ensure that genome-editing technology remains accessible to those who will use it to democratize its benefits, particularly for resource-poor farmers and consumers in LMICs.

Lack of transparency. Lack of transparency regarding the products of genome-editing technologies would create a ‘social license risk’ by fuelling a lack of trust in product developers, regulators, producers and ultimately in the resulting genome-edited products⁴. By ‘social license for a new

technology’, we refer to the willingness of potential users and consumers, and society at large, to accept products developed using that technology. Although social license is influenced by governmental policies, including local regulatory frameworks, global regulatory harmonization, trade and product-labeling requirements, and by public perceptions of risks and benefits, it is ultimately granted by the public locally and globally. One mechanism for transparency is an easily accessible registry through which developers of genome-edited crops can disclose the use of genome-editing technologies and meet public interest in knowledge about how specific foods are produced. Such registries should remain separate from the patent and regulatory risk-assessment systems. One such registry, developed by The Center for Food Integrity through their Coalition for Responsible Gene Editing in Agriculture (<https://foodintegrity.org/programs/gene-editing-agriculture/>), uses a consumer-focused approach that is designed to address transparency concerns, and incorporates needs of the concerned public and civil society through consumer and related engagements.

Unclear intellectual property landscape. Another risk for genome-editing technologies is the intellectual property landscape, which has evolved around the foundational patent dispute between the Broad Institute (Harvard–Massachusetts Institute of Technology) and Berkeley groups^{24,25}. Although this dispute is not fully resolved, those who control the foundational intellectual property for agricultural applications have signaled their willingness to license their technologies to public institutions and companies to develop and commercialize genome-edited products²⁶. This has been demonstrated through the granting of licenses to multiple CGIAR centres and others²⁷ that are working on crops for smallholders. The availability of CRISPR alternatives to CRISPR-associated protein 9 (Cas9), some of which may have independent patent estates, could facilitate the development of genome-edited crops. However, lack of resolution about the ultimate ownership generates long-term uncertainty for the products developed using the technology. Clear legal rulings are needed to guide plant breeders, especially those in the resource-constrained public sector, who otherwise may avoid or delay using genome-editing technologies until these intellectual property uncertainties are resolved²⁸.

Although the business model for commercialization of crop varieties

developed using genome editing within CGIAR is not yet fully developed, CGIAR implements various models to advance new varieties through national agricultural research programs, and local and global seed companies that serve smallholder farmers. For example, maize hybrids are licensed to seed companies, which then compete naturally in the marketplace. Various models would be explored to maximize the value of edited products to smallholder farmers and their communities, ensuring access.

Inadequate public sector institutional infrastructures to support use of genome-editing technologies. While the innovation infrastructure for genome-edited crops and other biotechnologies within institutional frameworks in LMICs varies significantly, there are projects, institutes, strategic alliances and explicit biotechnology and bioeconomy policies that can help overcome some of the environmental factors that limit widespread use of genome-edited crops. Examples from Africa include the African Orphan Crops Consortium (<http://africanorphancrops.org>) and the African Agricultural Technology Foundation (<https://www.aatf-africa.org>). In Latin America, the Inter-American Institute for Cooperation on Agriculture (IICA) proposed the Hemispheric Program for the Bioeconomy and Productive Development²⁹, and existing networks such as BIOTECSUR and MAIZALL³⁰ provide models to help develop effective partnerships that support deployment of genome-edited crops. Public sector institutions are already engaged in genome-editing research to develop improved crop varieties⁵ (Fig. 1). Pertinent global science, policy and trade communities, including G20, should seize this opportunity to support the development of the necessary institutional capabilities.

Policy questions for genome-edited crops

The future of genome-edited crops is contingent on the effective governance of national and international regulatory, policy and socioeconomic landscapes²³. In addition to benefits described above, genome-editing technologies can reduce costs of breeding and accelerate delivery of novel varieties to farmers; however, some or all benefits may be offset if the technologies are poorly regulated. Part of the initial attraction of genome-editing technologies grew from expectations that they would not encounter as much precautionary regulation as transgenic ‘GMO’ (genetically modified organism) methods. These expectations were dampened in 2018, when the Court of Justice of the European Union (CJEU) ruled

that genome-edited crops will be considered as transgenics in the EU for regulatory purposes. The EU stance on transgenics in the past discouraged developing countries that traded foods with the EU from using such varieties, as they are unable to bear costs incurred to meet the differentiated market requirements. As a result, smallholders in many LMICs have been unable to access transgenic technology and are becoming less competitive with farmers in countries that approved and adopted the technology³¹. The same could happen with genome-edited crops.

The CJEU judgment that classified gene-edited crops as transgenics was at odds with an emerging consensus among western-hemisphere countries that saw no justification in regulating crops that were edited with only single-point mutations (SDN1) as transgenics. Later in 2018, a coalition of nine countries, led by the United States, Canada and Argentina, and joined by Australia, signed a statement within the World Trade Organization (WTO) to affirm that cultivars derived from genome editing should be regulated in the same way as conventional cultivars³². The United States, joined by Argentina and Paraguay, also raised a specific concern within the WTO regarding the unjustifiable trade restrictions that could emerge from the CJEU decision, plus a stifling of agricultural research and innovation¹¹.



The United Kingdom began freeing itself from the CJEU ruling on gene-edited crops soon after its exit from the EU. Other countries, including Japan, signaled their intent not to classify most genome-edited crops as transgenic¹¹. China's position on the regulation of genome-edited crops could also prove decisive for global harmonization. China has invested heavily in genome editing, and by 2019 it was publishing twice as many CRISPR-related agricultural papers as the United States³³. The situation in Latin America is still evolving, with several countries, including Brazil, Colombia, Honduras, Uruguay and Chile, converging towards the 'Argentina model', which only regulates genome-edited plants with permanent insertion of foreign DNA^{12,34}.

The market may respond to genome-edited crops in different ways. If they are not strongly regulated, the faster speed and lower cost of developing varieties by using genome editing could democratize their use by researchers at public universities and scientific institutions, including for orphan or commercially minor crops, and could differentially benefit smallholder farmers and consumers. If the products of genome editing are instead regulated in the same way as transgenics, then

genome-edited crops may not reach farms in countries that adopt such policies, or in the countries that want to export foods to those markets; the research and varieties would be highly managed and controlled by multinational seed companies, and remain mostly unavailable to smallholder farmers in LMICs.

The challenge for genome-edited crops LMICs face a daunting situation where demand for food, feedstuff and fiber, climate change and productivity threats adversely impact their food, nutrition and livelihood security. Even before the COVID-19 pandemic, the world was off-track to meet its commitments to end hunger and malnutrition in all their forms by 2030 (ref. ³⁵). Almost 12% of the global population was severely food insecure in 2020, representing 928 million people — 148 million more than in 2019 (ref. ³⁶).

We recommend that policies are made and social license is granted to support the use of genome-editing technologies and genome-edited crops to help improve the livelihoods of smallholder farmers and LMIC populations in general. As regulatory, trade and intellectual property frameworks, and social license, are currently being discussed and decided, the time for action by policy makers and society is now, to ensure that the best that science can offer contributes to equity and is not available only to the privileged or wealthy. □

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Competing interests

N.G. is partner and Chief Technology Officer at Radicle Growth, an early stage, sustainable agriculture and food venture fund. All other authors declare no competing interests.