

REVIEW ARTICLE

Challenges in the Development and Commercialization of Genome-Edited Crops: A Critical Review of Technical, Regulatory and Socio-Industrial Bottlenecks

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ABSTRACT

Since 2020, hundreds of proof-of-concept traits have been created using genome editing technologies such as the CRISPR/Cas nuclease, base editors and prime editors that can modify the genome of crops with high precision—many times without transgenes. Despite this technical maturity, few genome-edited crops have moved beyond lab demonstrations to market, such as high-oleic soybean, waxy corn and non-browning mushroom, demonstrating a chasm between the lab and the market. This review aims to identify and synthesise the peer-reviewed and policy literature to critically appraise the non-molecular bottlenecks to this transition. Despite progress in this area including GRF–GIF mediated regeneration and AI-assisted guide-RNA design, at the technical level, the deployment of these advances is being hindered by genotype-dependent regeneration, polyploid genome complexity and the need for thorough off-target and transgene-free verification of new cultivars. Regulatory philosophies differ between product-based (United States, India, United Kingdom) and process-based (European Union), which creates a mix of trade friction, asynchrony in approvals and enforcement issues related to the analytical indistinguishability of SDN-1/SDN-2 edits and spontaneous mutations. A high number of patents block commercialization of CRISPR and the issue of Essentially Derived Variety has yet to be resolved and is focused on the perceived benefit rather than the process or naturalness of the product, all leading to concentration of market entry by well-resourced multinational companies. We define convergence towards outcome-based and risk-proportionate regulatory exemptions as most immediate steps towards harmonization, while calling attention to open-source licensing platforms and investment in delivery technologies for recalcitrant and orphan crops as priorities for equitable access globally. We believe that facilitating the commercialization of promising technologies of genome edited crops will necessitate an integrated multi-disciplinary programme of development, which must include both improvements in editing efficiencies and regulatory harmonisation and the development of an equitable regime for the governance of intellectual property, not just the former.

KEYWORDS

CRISPR/Cas; genome editing; New Genomic Techniques (NGTs); regulatory harmonization; SDN classification; intellectual property; consumer acceptance



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1. Introduction

1.1 The Evolution of Crop Breeding

In the last 50 years, plant improvement has passed through three phases of broad technological regimes: classical mutagenesis and cross breeding, first-generation transgenic genetic modification (GM) and most lately site directed nucleases (SDNs) and the large family of New Genomic Techniques (NGTs) such as the CRISPR/Cas system, base editors and prime editors [1,2]. SDN allows for the introduction of small targeted changes in the genome, often not distinguishable from naturally occurring or induced mutations found in breeding populations [3-5], while classical transgenic GMOs are defined by the stable integration of foreign DNA from sexually incompatible species. The transition to transgene-free edits has reduced the number of generations in which crops must be backcrossed—usually 10 years or more—to fewer than a handful—and permitted the correction of a single locus at a time in elite, already-adapted germplasm, eliminating linkage drag from wide crosses [1,6,7]. This shift is significantly different among crops and traits. Strategies that have already been developed for multiplex, transgene-free approaches to crop editing in research settings, as well as advances in regeneration biology and reagent delivery, continue to make new species amenable to editing [8,9]. But the key molecular tools have advanced much quicker than the institutional framework to get an edited line to a registered, marketable variety [4,10,11].

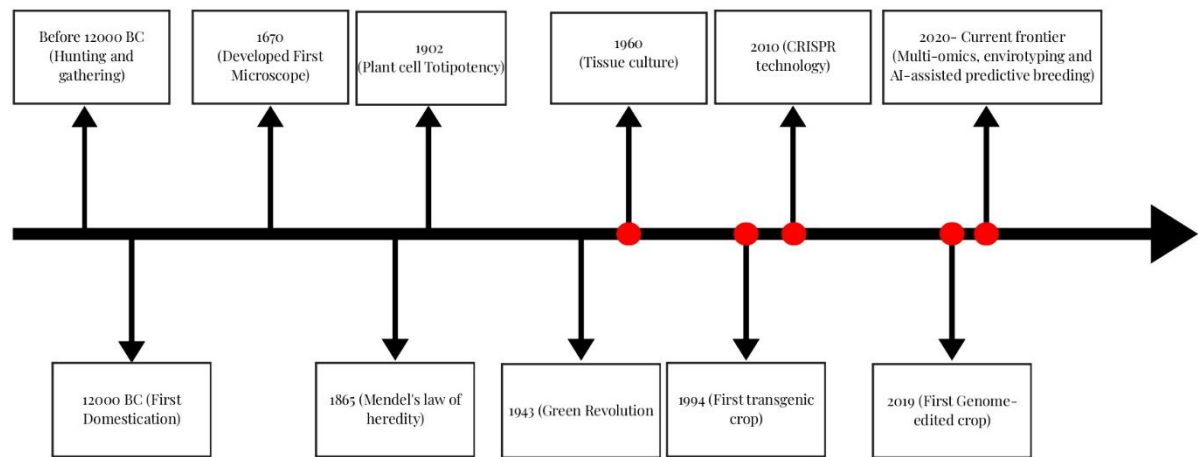


Figure 1. Timeline of major milestones in plant breeding and crop improvement technologies, from early hunter-gatherer plant use to current genome-editing approaches [12,13].

1.2 Core Rationale

Even with this technical maturity, it is notable that proof-of-concept gene-edited traits are published much faster than commercial products are released [14-16]. A 50:1 ratio of published proofs-of-concept to commercialized traits points definitively to structural, not molecular, origins of the innovation gap [17,18].

This review moves beyond molecular editing mechanisms to critically appraise downstream non-molecular, regulatory and socio-industrial bottlenecks. Instead, commercialization is hindered by an intertwined array of technical delivery challenges, an evolving and still confusing global regulatory framework, IP/Variety-Registration conflicts and a lack of societal acceptance [15,19,20]. The sections that follow examine each of these constraints individually, in light of peer-reviewed and policy literature published since 2020 and offer a pathway to a more coherent governance system based on products.

1.3 Methodology and Literature Search Strategy:

The review was structured and a critical review of peer reviewed and grey literature was carried out between January 2020 and August 2025. The search strategy was carried out using three search databases: Scopus, Web of Science (Core Collection) and PubMed. Boolean search strings were applied across title, abstract, and keyword fields using the following terms: ("CRISPR" OR "genome edit" OR "base edit" OR "prime edit" OR "SDN" OR "New Genomic Techniques") AND ("crop" OR "plant" OR "agriculture") AND ("intellectual property" OR "patent" OR "consumer accept"). The following additional and targeted search terms were used: "CRISPR patent landscape", "Essentially Derived Variety", "plant regeneration protocol", and "off-target detection plants". Grey literature (such as regulatory guidance documents, UPOV communications, and FAO/WHO policy reports) was identified using Google Scholar and institutional repositories.

Articles were selected if they met the following inclusion criteria: (i) the source had addressed non-molecular factors that impede the development or commercialization of genome-edited crops, regardless of whether it focused specifically on that question or not; (ii) source was published in English; and (iii) the article would have been a primary research article, rigorous systematic review, or authoritative policy document in its original language. Research that only considered molecular editing mechanisms but not translational and regulatory/commercialization barriers were excluded. The screening procedure was title and abstract assessment and then full text assessment against the inclusion criteria, after identification of the duplicates using the software EndNote X9. Approximately 120 records were screened, and approximately 85, which had to satisfy the inclusion criteria, are cited herein. All studies included have been reviewed for methodological quality, geographic scope and timeliness, with studies only since 2020 given priority to capture the current regulatory and commercial environment.

2. Technical Bottlenecks in Genome Editing and Crop Regeneration

2.1 Deliverability Barriers

While the addition of a DSB or base editing has become the standard procedure in the model system, the regeneration of an edited cell into a field ready plant remains a notably protracted and laborious undertaking process, which relies almost entirely on tissue culture. These procedures take several weeks to months for callus induction, cultivar selection and shoot regeneration; and most importantly, they are genotype dependent with a protocol that is successful in one cultivar often not in an elite, commercially preferred cultivar [15,21]. Regeneration protocols are also typically optimized and validated on a small number of highly amenable model or reference genotypes and transferring an established transformation pipeline to a new elite cultivar often requires months of re-optimization of hormone ratios, explant type and selection regime, resulting in a delay that is hard to predict and add to the cost of a commercial editing project [21]. This is a structural mismatch because editing tools are easiest to apply to a limited number of adaptable highly transformable cell lines in the laboratory, but the varieties farmers and seed companies

desire to edit are often recalcitrant. The most difficult to transform are woody perennials, many grain and forage legumes and even some monocots, in which somatic cells remain dedifferentiating or do not redirect shoot formation even if the process of transformation is successful. A key breakthrough to overcome this hurdle has been the engineering of a GROWTH-REGULATING FACTOR–GRF-INTERACTING FACTOR (GRF₄–is thus the first order constraint on the kind of crop and cultivar which could be edited on a commercial scale.GIF₁) protein module which greatly improved regeneration efficiency and reduced the wheat transformation cycle, bringing in the integration of CRISPR-Cas9 to produce the fertile, transgene-segregated edited lines. In commercial applications, however, it is crucial to eliminate the potential for pleiotropic developmental abnormalities and transient expression or subsequent elimination of the morphogenic regulator constructs from elite germplasm [8,22,23]. Such morphogenic-regulator strategies are now being extended to maize, citrus and perennial grasses but genotype dependency has not been removed but merely decreased – and

2.2 Precision and Detection Bottlenecks

While early reports indicated high levels of off-target activity, empirical off-target activity in plants is generally lower [24,25], partly because the majority of plant editing is transient or segregating delivery as opposed to the ability to promote sustained expression of the nuclease as seen in some mammalian systems [26]. Even if they find no off-target changes, confirmation of an absence of them requires deep resequencing of the edited lines and an unedited isogenic control across the entire genome [25,27], which is labor intensive and requires a resource-intensive breeding program that many public breeders would not be equipped to do on a regular basis, especially depending on genome size and ploidy [24,28]. Another and growing problem is the persistent presence of a 'CRISPR footprint' as most of the editing constructs are still delivered through *Agrobacterium*- or biolistic-mediated transformation with a selectable marker and the nuclease construct itself [29], resulting in the need for a further generation of segregation to remove the transgene [26,30] from the product along with molecular confirmation of the absence of vector backbone sequence, usually by whole genome resequencing or targeted PCR. This segregation step will be time consuming and expensive where commercialization pressure is highest and in vegetatively propagated or long generation interval crops, complete elimination of the transgenes is not always possible [30,31].

2.3 Genomic Complexity

Most of the world's important staple crops are polyploid [32] (6x = 42, AABBDD for bread wheat; tetraploids for durum wheat; autotetraploid for potato) and have multiple homoeologous or homoeoallelic copies of most of the genes. These copies are often redundant and cutting one homoeolog has little to no effect on the phenotype [33,34]; the researchers have to construct highly multiplexed guide-RNA arrays that can simultaneously cleave multiple conserved homoeologous targets [34]. The power and technical challenge of multiplexed editing in highly redundant genomes has been demonstrated in tRNA-spaced or Csy4-processed polycistronic gRNA arrays [35] for knocking out all three homoeologous copies of single-copy-equivalent genes in one generation of hexaploid bread wheat and by 49 of 59 alleles at a chlorophyll-biosynthesis locus being mutated in a two-gRNA approach in autopolyploid sugarcane [9,36]. Bioinformatic and molecular verification of gRNA specificity for discriminating between near-identical homoeologs and verification of the chimeric or heterozygous mutation spectrum across the set of subgenomes, is an additional layer of bioinformatic and molecular verification burden that increases with ploidy [9].

2.4 Integration of Multi-Omics and AI

Post-editing analysis of regulatory gene expression networks via transcriptomic, proteomic and metabolomic profiling is becoming common practice [37,38] to ensure that a desired change has not affected off-target gene expression networks or metabolically (or phenotypically) consequential pathways, thereby offering a molecular safety case in addition to DNA-sequence based off-target analysis [24,38,39] and supporting regulatory dossiers and breeder confidence of phenotypic stability. Concurrently, the sequence and, where available, epigenetic properties are used to predict on-target cleavage efficiency and off-target propensity using machine learning and deep learning models that are becoming incorporated into the guide-RNA design pipeline itself [40,41]. These advances have been expanded to crop species, which have been trained with methods specifically developed from plant genomic data [42] and have been shown to have significantly different chromatin accessibility, GC content and homoeolog similarity compared to the human and animal datasets used in many previous models [43]. These computational tools alleviate the experimental screening burden but do not eliminate it; as of today, gRNA design with the aid of AI still requires experimental validation in every new crop and genomic background [44,45].

3. Global Regulatory Divergence and Geopolitical Disharmony

3.1 The "Regulatory Mixture"

The two philosophies of regulation that have grown up seemingly in isolation and are still being revised on divergent schedules and drawn from distinct sources of evidence, represent the single biggest non-technical commercialization hurdle [46,47]. Product-based systems (such as the *U. S. and* modified, Canada) question whether the plant produced is a novel risk and usually do so regardless of how it is produced [48], provided that no foreign genes are added to the genome. In contrast, process-based systems, such as the one in use by the European Union with the GMO framework, would control any organism created using in vitro nucleic-acid techniques – even if the organism is identical to a spontaneous mutation [48] – and would subject it to a complete GMO authorization pathway, which is

not the case until very recently . This difference is not purely academic, as grain, oilseed and produce shipments regularly cross borders where there are different regulations; meaning that a variety that is approved for conventional supply in one country can cause a zero-tolerance GMO contamination event in another country [49], which makes it less attractive to exporters and grain handlers to market edited varieties until approval is achieved in every major market [10].

3.2 SDN-1, SDN-2 and SDN-3 Classifications

There is, however, a convergence—albeit, patchy one—toward a technical vocabulary that distinguishes the three types of SDN [3,50]: SDN-1 edits are those that result from a small indel created by a nuclease-induced double strand break repaired by the plant's endogenous repair machinery, SDN-2 edits are those involving a short donor template that guides a precise nucleotide substitution and SDN-3 edits are those involving the insertion of a long donor sequence that is functionally equivalent to conventional transgenesis [3]. The amount of products not subject to GMO regulation has grown, with SDN-1 products typically not being regulated and SDN-2 products, often, not being regulated, while SDN-3 products are nearly always kept in the GMO regulatory stream [51]. India has codified this effect- (phenotype-) based exemption in a March 2022 Office Memorandum announcing SDN-1 and SDN-2 genome-edited plants to be exempted from biosafety assessment requirements as plants without exogenous DNA and detailed guidelines for safety assessment were released in October 2022. China has taken an alternative yet separate path by releasing simplified guidelines for low hazard GE plants and having a centralized, staged biosafety-certification system for GE maize and soybean crops [51]. The EU, however, has only recently started to take steps: The European Commission’s proposal from July 2023 distinguishes between NGT₁ plants, which are considered as plants traditionally developed and do not require GMO authorization with a maximum of 20 genetic modifications and NGT₂ plants, which are still subject to full GMO risk assessment, authorization and labelling.

3.3 The Precautionary Principle versus Risk-Proportionate Assessment

Historical approach of the EU to gene technology is process based [52,53], based on the precautionary principle: When the potential long-term effects of any deliberate use of genetic intervention is considered uncertain, then the activity is subject to oversight [54,55]. Supporters of risk-proportionate assessment claim that it combines two different risks [56]: The introduction of novel genetic material from sexually incompatible organisms, which is not possible with conventional breeding and changes at a single nucleotide or small indel that are not distinguishable from changes that occur naturally, through radiation mutagenesis, or chemical mutagenesis and receive no similar regulatory review. As per this perspective, the same level of precaution should be applied to an SDN-1 mutation as to a multiple gene transgenic insertion, resulting in a disproportionate cost and delay and diverting regulatory resources away from products that, for example, involve SDN-3 constructs or edits of known toxin or allergen pathways where the risk would be most appropriately subjected to scrutiny.

3.4 Technical Challenges in Regulatory Detection

Another complication is mostly terminological as it is not necessarily a biological one in the sense that an SDN-1 edited crop with a single base substitution or a small deletion, at the DNA-sequence level, is often indistinguishable from a plant with the same variant resulting from spontaneous mutation or conventional mutagenesis breeding [53,57]. A method cannot be used to certify the production of any given plant as a genetically edited plant without a known reference sequence and prior knowledge of the specific edit [58]. In turn, this makes it difficult to enforce traceability and border-control regimes based on analytical detection for the specific category of these products; a point several regulators have made as another reason to exempt SDN-1 and SDN-2 products from process-based regulation [51]

Zimny and Sowa [47] directly connect divergent regulation with difficulties of detecting and supervising gene-edited products in international trade and explain why small nucleotide changes create particular problems for EU enforcement.

Table 1. Comparative snapshot of national and regional regulatory treatment of genome-edited crops by SDN classification.

Jurisdiction	Regulatory approach	SDN-1 / transgene-free edits	SDN-2	SDN-3	Primary Sources / Regulatory Mandate
United States	Product-based; case-by-case USDA-APHIS review	Generally exempt if no foreign DNA	Generally exempt if no foreign DNA	Regulated	USDA-APHIS Am. Biotechnology Regulatory Services; EPA; FDA
India	Outcome-based exemption (2022 Office Memorandum)	Exempt from biosafety assessment	Exempt from biosafety assessment	Regulated as GMO	DBTC Office Memorandum, March 2022

Jurisdiction	Regulatory approach	SDN-1 / transgene-free edits	SDN-2	SDN-3	Primary Sources / Regulatory Mandate
China	Streamlined pathway (2022 Safety Evaluation Guidelines)	Reduced-requirement pathway	Case-by-case, reduced requirements	Regulated as GMO	MOA Biosafety Evaluation Guidelines for Gene-Edited Plants, 2022
European Union	Process-based; NGT proposal creates two new categories	NGT ₁ : exempt from GMO rules if within threshold; unlabelled on-shelf	Generally NGT ₁ if within size/number thresholds	NGT ₂ : full GMO authorisation and labelling	EC Proposal COM (2023) 411; Regulation (EC) 1829/2003; European Parliament resolution, 2024; Council of the EU, 2025
United Kingdom	Precision Breeding Act; product-based notification	Exempt from GMO rules; notification only	Exempt from GMO rules; notification only	Regulated as GMO	Precision Breeding Act 2023 (UK); DEFRA notification guidance, 2023

4. Lab-to-Market Transition and Socio-Industrial Barriers

4.1 Intellectual Property Landscapes

The CRISPR-Cas9 patent estate has been marred by lengthy priority proceedings, for the most part between the Broad Institute and the University of California, Berkeley, with conflicting results at the USPTO and European Patent Office, all of which has made freedom-to-operate analysis particularly complicated for a technology as widely used as CRISPR-Cas9 [59,60]. An estimated 11,000 patent applications have been filed related to CRISPR [61], with a significant number filed by large agricultural biotechnology companies and licensed on exclusive or semi-exclusive terms and the prospect of navigating a 'patent thicket' to secure rights to even a single edited trait is now much more expensive: 'A commercial product can require licenses to nuclease, delivery, guide-design and germplasm-specific patents held by different owners,' says [62]; [61]. These costs and associated legal uncertainty are disproportionately borne by public sector breeding programmes and small-to-medium enterprises, which tend to have limited legal resources to negotiate multi-party licenses and to defend against infringement claims, resulting in early commercialisation being concentrated in a handful of well-resourced multinational companies [59,60]. Proposals include calls for royalty-free licensing of publicly funded researchers in low income countries and clearing-house licensing platforms, as well as patent pools, but these attempts are not compulsory and not all are successful [63].

4.2 Institutional Gaps

Many public research institutes do not have established pathways between them and commercial seed multiplication, certification and distribution networks [64], even if IP is cleared and/or a lab-validated edited line is available. Academic and national programme breeders often have the genomic and editing skills to develop a trait but not the seed-scale-up infrastructure [65], quality-control systems, or distributor network to get that trait into farmers' fields, particularly for certain orphan or regionally important crops where a private seed industry is not well developed [66,67].

This gap generally needs to be filled through formal technology-transfer agreements between the research institution and a commercial or parastatal seed multiplier, agreements which are often not in place from the beginning of a public breeding project because the seed is published and proofs-of-concept are used to fund and evaluate academic research rather than downstream commercial pathways [68].

4.3 Variety Registration and Essentially Derived Variety Rules

The introduction of the Essentially Derived Variety (EDV) concept in the Act of the UPOV Convention in 1991 [69] also necessitates consideration of plant variety protection (PVP) systems established around the concept. An EDV is a variety that is mainly based on an initial protected variety with the same essential characteristics, which differs only in the added characteristic derived. The breeder of the EDV can protect his variety, but cannot market it without permission from the protected variety breeder. Often a single locus is modified in an existing elite variety background [6,70], meaning that edited derivatives are also good candidates for EDV status [71]. A variety is still ED if it involves a change that consists of a single gene or single locus in the genome because this is not, in itself, a sufficient basis for distinguishing it from its ES. However, recent UPOV guidance suggests that the essential characteristics of a variety, the nature and extent of derivation, and the dominance of derivation by the protected initial variety should all be taken into account when assessing whether the variety is essentially derived. However, one-locus editing of elite germplasm that maintains the key traits of the elite variety does not automatically make the variety an EDV, but may lead to an EDV assessment [59,60]. As a result, commercial developers may want to check for potential issues of potential rights to exploit the original variety and in some cases, negotiate with that same rights holder. Litigation and commercialization concerns do exist due to the practical application of EDV criteria, which may be complex, especially

with close relatives of an edited variety and where the boundary between an EDV and an independently protectable variety may not be clear [63].

5. Societal Acceptance, Consumer Perception and Market Integration

5.1 Consumer Psychology

Many cross-national consumer studies have shown that acceptance is not universally high, but rather follows a predictable pattern across the different types of genetic interventions. While gene edited food crops appear less risky and more acceptable than transgenic GMOs, in general, there is a perception gap between them and conventional crops and perceived benefit — not perceived naturalness — is a strong predictor of acceptance of purchase (both in the USA and in Japan and Germany) [72]. Also, survey data in the United States indicates that when a clear and specific consumer or environmental benefit (e.g., dependence on fewer pesticides or longer shelf life) is emphasised over focus on the process or abstract benefit, it can significantly enhance behavioral intentions around the consumption of CRISPR-edited foods compared to abstract or process-focused framing [73]. The study also reveals that acceptance is not determined by a single attitude towards the category of “gene editing” alone, but is influenced by both perceived risk and trust in the regulatory bodies, as well as the specific trait and crop concerned [74]. A point-mutation approach, such as cisgenic or SDN-1, which does not involve the introduction of genes from sexually incompatible species, generally has a measurable acceptance premium over transgenesis – a premium not guaranteed, however, unless good public communication is affected.

5.2 Traceability and Labeling Policies

A radical change in the labeling of foods and feed containing, or derived from, GMOs is challenged, both on technical and ethical grounds [59,60]. As discussed in Section 3.4, there is no way to enforce a label on a product that contains transgene-free SDN-1 edits without a complete documentary chain of custody [53,57,75]; meanwhile, some consumer and civil-society groups consider no disclosure to be a failure in transparency and choice. Public, voluntary variety registries as the EU's NGT proposal would implement for NGT₁ plants is a middle ground that maintains traceability and public information on varieties developed with NGTs, while not requiring a label that consumer perception studies show can do more than warn consumers of a potential safety concern, if any [76,77].

5.3 Equitable Access and Smallholder Integration

The above commercial pipeline is focused on limited number of commodities that are traded globally in well-established markets instead of the climate resilient crops such as orphans and staple crops [78,79] which are the staple of most smallholder farmers in Sub-Saharan Africa, South Asia and parts of Latin America. Unlike other crops, the genome resources of orphan crops are not as well developed as other major crops in the food basket [80,81] and their capacity to undergo genome editing and variety development is not as robust and they also face transformation-recalcitrance and regeneration bottlenecks [82]. For staple crops and climate-resilient crops, such as those of Africa, the capacity building, technology transfer and protection of farmers' rights to save and exchange seed is as crucial as the underlying technology of the CRISPR-based approach to ensure that benefits reach smallholder farmers [83]. As the technology evolves, the equity divide between commodity-crop editing in the wealthy world and orphan-crop editing in food-wary areas will probably increase, without targeted, coordinated public investments and technology transfer mechanisms. This asymmetry is exacerbated by the regulatory and IP-related conflicts described in Sections 3 and 4, as the jurisdictions where it will be most difficult to implement extensions of authorization periods and more difficult to negotiate multi-party patent licensing are likely to be those where the greatest need for public breeding programs exists to serve smallholder farmers [79].

6. Future Perspectives and Roadmap to Global Harmonization

6.1 Technical Synthesis

Minimizing reliance on tissue culture has substantial downstream commercial value [84,85] and this is a research priority that would also alleviate genotype dependence and speed up development time and eliminate the dependence on labor that prevents many public breeding programs from engaging in routine editing work. There is proof-of-concept transient and, in some cases, stable transformation in plants using nanomaterial-mediated delivery systems [86,87], such as polymer-functionalized carbon nanotubes for delivery of plasmid DNA, ribonucleoprotein complexes and RNA directly into intact plant cells without a protoplast or callus intermediate, in mature rice leaves [21]. Complementary approaches that are still in their early stages of development are also pollen-magnetofection and spray-on nanoparticle-DNA complexes and grafting-based, transgene-free delivery strategies to the same end goal. None of these methods has yet been shown to be as reliable or as crop-broad, but if the work continues, this might be a solved problem for a growing number of species in the near future (say, over the next ten years) [88,89].

6.2 Regulatory Harmonization

Problems of trade friction, such as those described in Section 3, would be resolved if such a principle-based, product-oriented approach could be paired with thresholds for a “conventional-equivalent” edit that are mutually recognised and internationally harmonised [79,90,91]. Even though this EU proposal retains its process-based aspects, it constitutes a step towards this model by exempting a defined class of small, conventional-equivalent edits from the full GMO authorization procedures; and convergence between this emerging EU threshold and the outcome-based

exemptions already in place in India, the United States and the United Kingdom would have a material effect in reducing the risks of asynchronous approval trade for grain-exporting countries [92-94].

6.3 Inclusive Innovation

Open-source biotechnology platforms would directly tackle the access asymmetry caused by IP [78,95], by providing validated vector systems, guide-RNA libraries and royalty-free licensing of research use to core CRISPR patents for application in orphan-crop improvement as well as by public research institutions in LMICs. Combined with continued investment in local genomic infrastructure and capacity building – as previously recommended in reviews of the use of CRISPR in African smallholder farming [83] – this is the most promising path to ensuring that the benefits of genome editing reach beyond commodity crops of high-income export markets [78].

7. Conclusions

The commercialization hurdle for genome-edited crops needs an integrated (multi-disciplinary) approach, not just a technical approach. The molecular tools needed to fine-tune crop editing with increasingly lower and lower amounts of transgenes are clearly advanced and innovations in the delivery and design of the guide sequences using artificial intelligence will further reduce technical hurdles. However, if the product-to-market pathway is further hindered by regulatory fragmentation between product-based and process-based jurisdictions, patent thickets and essentially-derived-variety uncertainty that centralize the commercialization benefits to a small number of large companies and public mistrust – as evidenced by the recent emergence of the new product – then overcoming these delivery hurdles will prove to be of little use. The clearest way from lab proof-of-concept to the field is a coordinated agenda – harmonized, risk-proportionate regulation; open, equitable licensing pathways; and ongoing technical investment in recalcitrant and orphan crops. This review has some limitations that should be considered. First, the regulatory landscape for genome-edited crops is rapidly changing, and the policy positions outlined here may not address either developments or other regulatory developments subsequently. Second, English-language publications were the only items searched for because literature searching in other languages might underestimate policy scholarship from non-Anglophone jurisdictions, especially Asia and Latin America, where much policy activity is taking place. Third, this is a structured narrative critical review and not a formal systematic review or meta-analysis, although the search methodology has been made clear (Section 1.3), the synthesis is based on qualitative appraisal and does not involve quantitative effect size synthesis. The results as set forth herein should be viewed in the light of such limitations.

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