The Costs of Genome Editing Governance

Context

The advent of genome editing tools to make targeted edits to plant DNA brought a revolution for research and crop improvement, but raised concerns regarding regulatory processes and public perceptions. Given that genome editing technologies can result in both non-transgenic and transgenic outcomes, the former are expected to be marketed as equivalent to conventional counterparts, whereas the latter as equivalent to genetically modified (GM) products.

Scope of the Issues

The combined effects of increasing population and climate change exacerbate global food insecurity. Plant breeding innovations like genome editing provide cost-effective solutions to these issues. Using techniques like CRISPR/Cas9 to copy, delete or rearrange specific genes, genome editing can increase resistance to disease and drought, enhance food nutrition and shelf life, and make agricultural and food systems more sustainable [1]. While benefits exist, any innovation involves some degree of risk, as does every product that is consumed by humans, what is important is that the risk of any new product be no greater than for current products. A surveyed pool of experts (n=113) viewed that genome-edited crops pose little to no risk to society (76%), the economy (71%), human health (75%) or the environment (71%) [2]. With the relative novelty of genome editing, countries have taken steps to revise and clarify their regulatory frameworks. One result is that regions are choosing divergent strategies to address the regulation of genome-edited products. Some countries, like many in the Americas, aim at promoting innovation by enacting risk appropriate regulations, whereas others like the European Union (EU) have chosen to regulate genome-edited products by rigid application of the precautionary principle.

Quite a few countries are approving new genome-edited crops. The United States Department of Agriculture exempts genome-edited crops if the changes could have been obtained by conventional breeding, as long as they do not present a plant-pest risk. Currently, a soybean variety with less saturated fat has been commercialized in the US, with several other crops in the commercialization pipeline. Similarly, genome-edited crops that do not contain inserted DNA, such as high-starch corn, will not be subject to safety assessment by Health Canada and the Canadian Food Inspection Agency. The Japanese Ministry of Environment has stated that products free from foreign DNA or RNA are not considered ‘living modified organisms’ within the meaning of the Cartagena Protocol on Biosafety. A CRISPR/Cas9-edited tomato, containing high levels of an amino acid believed to help relaxation and lower blood pressure, was recently approved in Japan as a non-GM product [3]. In Australia, genome-edited products with small changes at a precisely defined location in the genome are not GM organisms and thus are out of the scope of Australia’s Gene Technology Act. Meanwhile, the EU has used the precautionary principle to require that genome-edited varieties be deemed transgenic and regulated as equivalent to GM crops (via the 2018 ruling of the Court of Justice of the EU on the regulatory status of organisms obtained by mutagenesis including both transgenic and genome-edited organisms).

The process-focused regulatory framework in the EU comes with heavy costs, both locally and globally. Surveyed experts estimated it could take up to 14 years and cost US$24.5M to develop and bring a genome-edited crop to market if regulated as a GM event [4]. Scientists and investors will lose interest in pursuing this innovative tool under these conditions. European agro-chemical investors have already signaled they will shift effort to other markets, resulting in EU farmers facing delays in accessing new technologies. Moreover, the EU approach to regulating genome editing raises the potential for further trade disputes among key trading nations.

Conclusion

Genome editing has been applied to several traits in various crops, generating risks that are no different from conventional crop varieties. These innovative breeding technologies are essential to improving food security and mitigating climatic change on agriculture. While the EU may be able to afford to forgo this valuable tool, their actions threaten to disrupt diffusion of new technologies to key developing nations.

References

1. Lassoued et al. 2019. Benefits of genome-edited crops. Transgenic Research 28: 2: 247-256.
2. Lassoued et al. 2019. Risk & safety considerations of genome edited crops. Current Res. In Biotech. 1: 11-21.
3. https://www.isaaa.org/kc/cropbiotechupdate/article/default.asp?ID=18668.
4. Lassoued et al. 2019. Estimating the cost of regulating genome edited crops. GM Crops & Food 10: 1: 44-62.