How CRISPR and other gene-edited crops are regulated in the United States and around the world: A scholarly review

Genome editing in agriculture and food is leading to new, improved crops and other products. Depending on the regulatory approach taken in each country or region, commercialization of these crops and products may or may not require approval from the respective regulatory authorities. This paper describes the regulatory landscape governing genome edited agriculture and food products in a selection of countries and regions.

[su_panel color="#3A3A3A" border="1px solid #3A3A3A" radius="2? text_align="left"]**Download a PDF of the full article "Regulatory approaches for genome edited agricultural plants in select countries and jurisdictions around the world."**[/su_panel]

Introduction

This article provides an overview of proposed or adopted regulatory approaches in selected countries around the world for plants improved using genome editing (GEd) techniques. It describes the various directions taken by several countries, recognizing that other important trading countries, including, for example, China, have not released a specific regulatory approach tailored to GEd plants and their products. This article presents the most recent legal and regulatory developments in each jurisdiction described. The global landscape of regulatory developments for genome edited plants is rapidly changing and will continue to evolve as more countries release their regulatory policies.

An overview of additional background information on the legal and regulatory frameworks for biotechnology and regulation of products of genetically engineered/modified plants in these jurisdictions is available in the supplementary information (SI) section. While not a comprehensive systematic collection, this review is meant to provide a broad overview of the various directions of regulatory approaches taken or under consideration in selected countries. It thereby adds to other recent reviews on the development of the regulatory landscape for GEd crops and updates or completes the information contained therein (Eriksson et al. 2019; Menz et al. 2020).

Genome editing is a generic term used to describe a host of methods for altering the genetic information in a cell, as described in other articles in this issue (see, for example, T-K Huang and H. Puchta. Novel CRISPR/Cas applications in plants—from prime editing to chromosome engineering in this Special Issue). Briefly, GEd encompasses several distinct types of alterations generating different products: site-directed deletions, allele replacement, site-directed insertions (or SDN-1/2/3 according to the terminology of Podevin et al. 2013) and base conversion (Marzec and Hensel, 2020).

Some of these GEd processes involve insertions of DNA via the use of DNA templates (either cisgenic or transgenic) and others do not. These may each elicit a different regulatory approach, depending on the

jurisdiction. Developers of new plant varieties improved using one or more of these ‘genome editing’ techniques face different research, legal, regulatory, and marketing requirements around the world. Adding further complications, different jurisdictions may apply different terminology.

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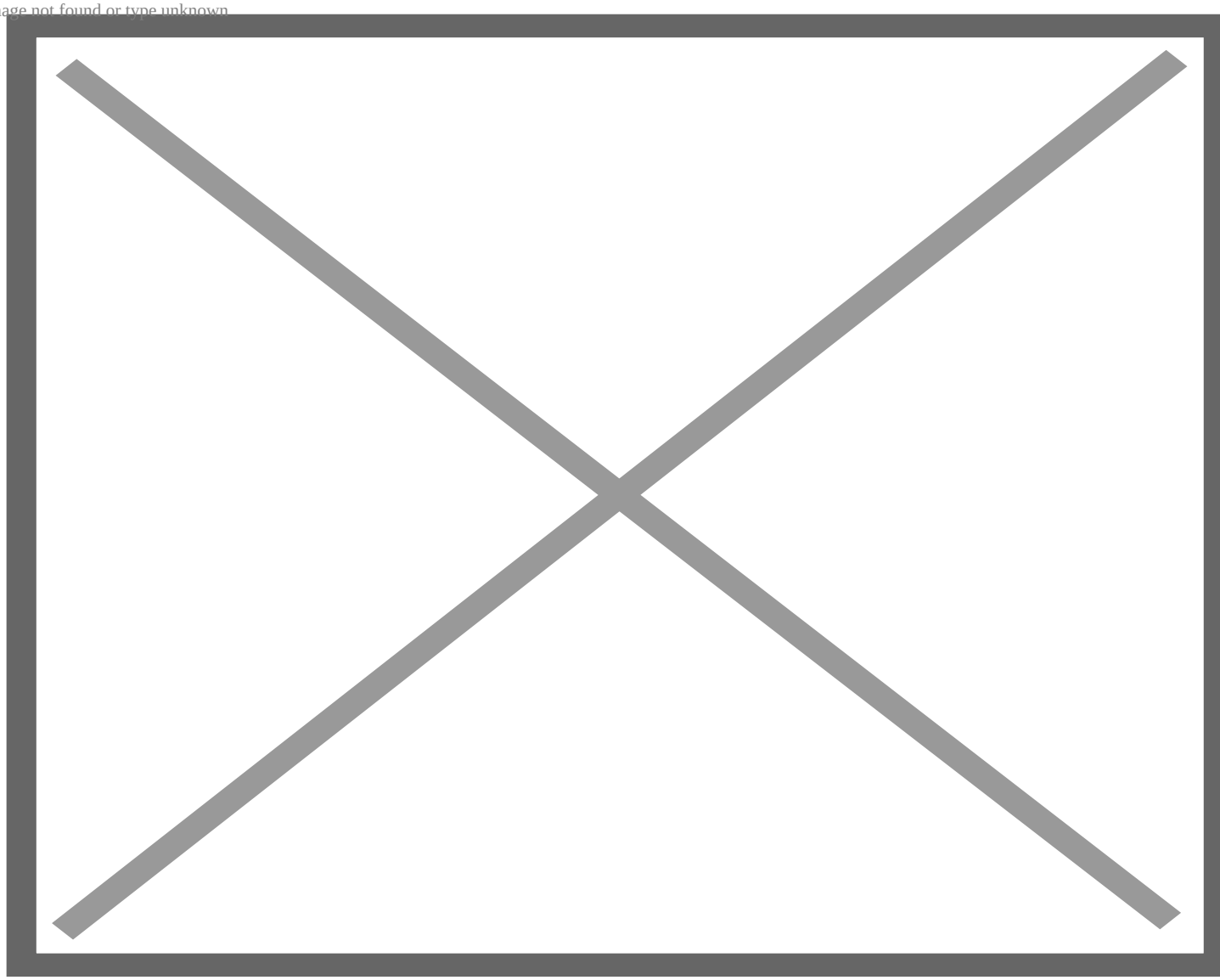

Credit: Illinois Soybean Association

In this paper, we use the term genetic engineering (GE) to refer to the use of recombinant DNA (rDNA) technologies to alter the DNA base sequence of an organism. GE technologies can be used to create a transgenic organism, which contains a genome consisting of DNA segments originating in different species. The modified organisms might also contain DNA segments originating in the same species but introduced through rDNA technologies, resulting in cisgenic organisms.

The definition of a genetically modified organism (GMO) may vary between different jurisdictions; however, most countries have based their definition on the Cartagena Protocol on Biosafety (CPB) and its definition of a Living Modified Organism (LMO). The CPB defines a LMO as “any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.” The CPB also defines the terms ‘living organism’ and ‘modern biotechnology’.

Regulations, whether for conventional or biotech products, are intended to protect public health and safety, ensuring that products released into the market are as safe as possible for humans, animals, and the environment. Although all countries seek to promulgate regulatory approaches and processes to protect the common good of human, animal and environmental safety, the regulatory details in different jurisdictions can differ widely, and these differences and how they are implemented can have large impacts on the time required and cost of bringing new plant products of biotechnology to the global market place.

Different laws and regulations for products of technologies using rDNA are in place around the world. The regulatory triggers for these products are generally based on the techniques used to create them, rather than the identification of any specific or novel potential hazards that such products may pose. While these laws and regulations differ among countries and regions, there is general agreement in each regulatory regime as to what products and processes are covered by these regulations for rDNA-derived products.

Divergent regulatory approaches may be a result of different economic, social and political prerequisites. Such divergence may not pose problems when applied to locally produced and consumed products (though time and cost of getting local products through the regulatory process could prove prohibitive). However, non-compatible, and unpredictable regulatory processes are problematic when applied to commodities entering into international trade, such as is the case for most agricultural biotech products currently on the market. Global trade in agricultural goods allows harvesting of economic benefits across regions. In order to facilitate such trade, globally harmonized or compatible regulations and policies can be an asset.

As GEd technologies emerged and started being used by developers and breeders of new plant varieties, regulatory authorities around the world began to examine their regulations and how these might apply to products improved with these new techniques. With the emergence of these new technologies, hope also emerged among breeders, researchers, and developers that with these new technologies new regulatory approaches would focus on the products developed and any risks they might pose, rather than the technologies used to create them. The previous global biotechnology regulatory landscape, which had general agreement as to what products required further regulation, has not been without its trade disputes , however the advent of GEd has introduced new challenges, especially with regards to regulatory distinctions and to traceability, potentially creating new types of regulatory and trade dilemmas. The sections below provide an overview of the different regulatory approaches being taken by severalcountries and regions in different parts of the world. It includes descriptions of the definitions ordistinctions they are using to determine which plant products are included within the jurisdiction of theirbiotech or “GMO” regulations, with a special focus on recent developments.

Conclusion

The various potential products of GEd carry the promise to contribute to solving many of the great challenges of the twenty-first century, from medical and health issues to food and agricultural production. This may certainly be one of the reasons why the 2020 Nobel prize in Chemistry was awarded to Emmanuelle Charpentier and Jennifer Doudna for their discovery and development of one of the most popular GEd tools; CRISPR-Cas 9.

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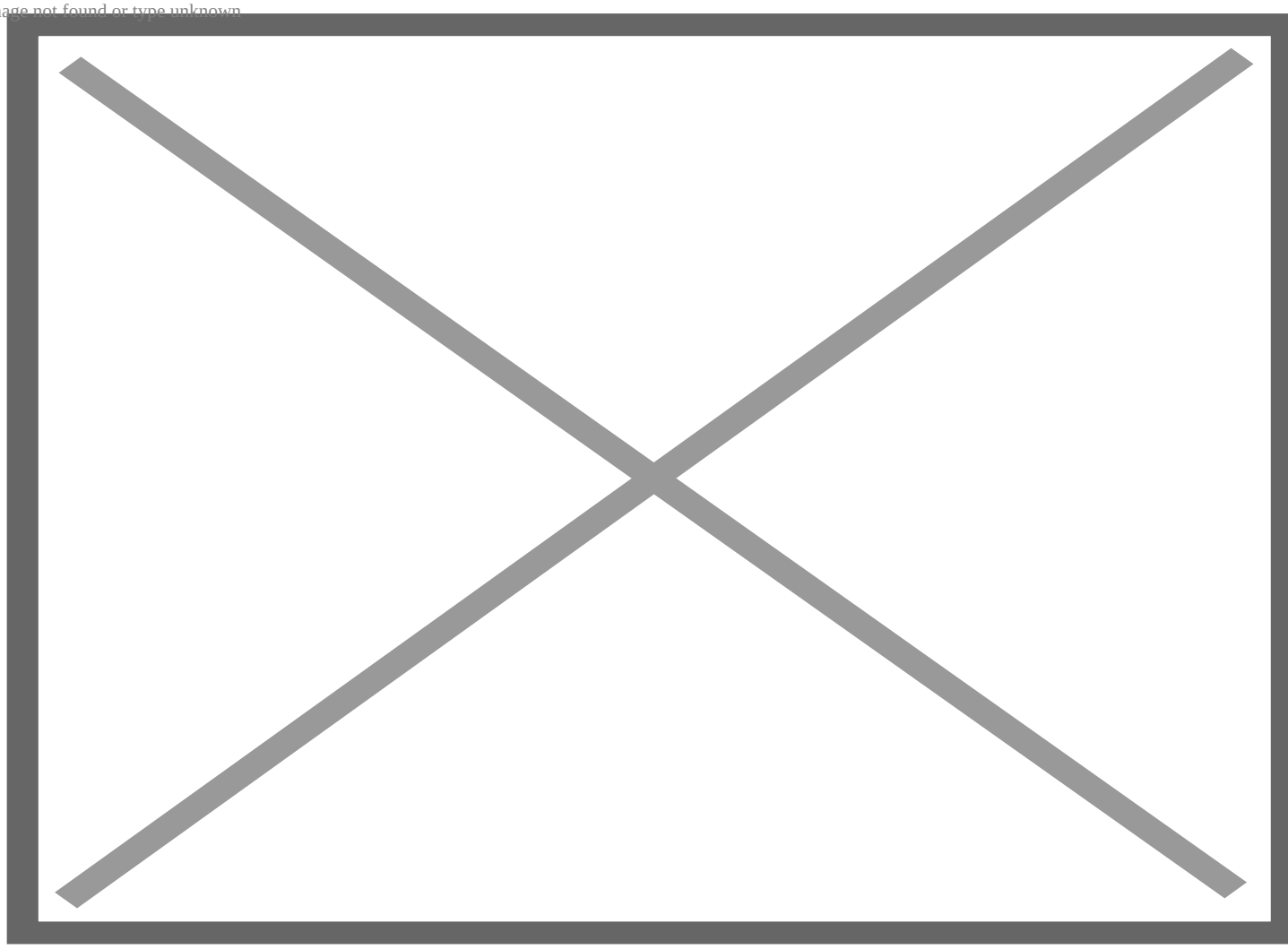

Emanuelle Charpentier (left) and Jennifer Doudna. Credit: C&EN

Regulatory policy cannot keep pace with the fast-moving scientific advances. To name just some of the challenges: the speed at which new technologies are being developed, new technologies not fitting into old regulatory definitions and paradigms, difficulties with international coordination, lack of harmonized definitions and laws, lack of public understanding and trust, lack of regulatory certainty for developers, lack of political will, and regulatory policies taking longer to put in place than the uptake of breakthroughs in the global scientific community. Regulatory and policy officials are frequently tasked with the sometimes conflicting goals of ensuring public and environmental safety while addressing public perception and expectations and doing so without slowing down innovation.

A number of scientific societies, regulatory agencies and other relevant organizations around the world have investigated various regulatory, safety and policy issues surrounding GEd techniques, issuing science-based opinions and proportionate recommendations to policymakers formulating regulations (see,

e.g., ASSAf 2017; CAST, 2018; EASAC, 2015; EFSA 2012, 2015, 2020; FSANZ 2019b; JRC 2011; Leopoldina 2015; USDA 2018a, VIB 2018). Some of these studies, scientific opinions, and statements (and their recommendations) are discussed in the relevant country sections, above. The common conclusions in these opinions include imposing regulatory scrutiny based on the documented risks of the product, rather than on the process used to breed them, and that many products of GEd may not warrant additional regulation beyond those required for conventional plants, especially if they could have been generated using 'conventional' methods of breeding.

Many countries are still in the process of developing regulatory approaches for products of GEd plants, so the opportunity remains for enhancing global regulatory coordination. The positive consequences for sustainable agricultural innovation and international trade could be considerable. Among many countries that have already finalized their GEd regulatory approaches some positive alignment is emerging in terms of using a "case-by-case" approach (offering the ability to balance science-based risk management and societal requirements) using a "novel combination of genetic material" as the GMO regulatory threshold (offering the ability to distinguish between GMOs and non-GMOs).

We hope this paper has provided insight into the diverse incipient regulatory policies governing GEd agricultural products in a range of countries and jurisdictions. We hope that these insights spurs action leading to increased collaboration and coordination among countries to better align regulatory processes and enhance coordination of approaches globally.

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