GENE EDITING IN AGRICULTURE – ITS UNCERTAIN FUTURE

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ABSTRACT

Genetic editing arrived on the agriculture scene a few years before the new USDA regulations arrived in May 2020.[1] At the same time, foreign regulatory bodies began erecting barriers to entry for these new plant breeding methods.[2] The lack of international approval can cause liability risks here at home in the US. This article will discuss the regulatory status and current status of the lawsuits filed against Syngenta for disrupting the U.S. corn export market to China. I will suggest that the outcome of these cases could pose a challenge to the future use of agricultural biotechnology in the United States.

I. INTRODUCTION

Genetic editing has come to agriculture promising new traits created with more speed, lower cost, and greater precision than any plant breeding tool to date.[3] Each past transition in breeding, from hybrids to mutagenesis to recombination,

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1. Press Release, *USDA, USDA Secure Rule Paves Way for Agricultural Innovation* (May 14, 2020), https://www.usda.gov/media/press-releases/2020/05/14/usda-secure-rule-paves-way-agricultural-innovation [https://perma.cc/Z3M2-G27P].

2. *See* Stuart J. Smyth et al., *Regulatory Barriers to Innovative Plant Breeding in Canada*, 2 FRONT. GENOME ED., Oct. 2020, at 1, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8525381/ [https://perma.cc/ZR63-DBQB].

3. *What Benefits Can Gene Editing Bring to Food Quality and Sustainability?*, BEST FOOD FACTS (Sept. 24, 2021), https://www.bestfoodfacts.org/what-benefits-can-gene-editing-bring-to-food-quality-and-sustainability/ [https://perma.cc/AYQ8-CYY6].

and now gene-editing, has had challenges in acceptance.[4] There are still corners of the world where hybrid corn is shunned in favor or planting open-pollinating varieties whose seed can be saved and replanted. Some proponents, particularly in Europe, continue to promote this seemingly outdated, lower productivity approach to plant breeding. Too many nations are banning biotech crops while endorsing hybrids and mutagenesis breeding. While such older-style breeding tools have expanded food production exponentially over the past 100 years, newer plant breeding tools will prove necessary to feed a growing global population.

Gene editing, in theory and in practice, is of great interest to future flora and fauna agriculture due to inherent limitations in conventional breeding. The high efficiency of CRISPR-based systems is well documented.[5] With the use of "clean" edits, many expect gene editing to both avoid and reduce contemporary regulatory burdens while also improving market acceptance.[6]

II. GENE EDITED CROPS AND THEIR REGULATORY CONTEXT

"In the [United States], the 1986 Coordinated Framework for the Regulation of Biotechnology ("Coordinated Framework") focused on regulating the process of recombinant DNA ("rDNA") when used in plant and animal breeding."[7] The USDA-APHIS initially utilized and applied the "Am I Regulated" process for gene editing of flora.[8] Under this process, the first inquiry would be whether the DNA had a plant pest gene.[9] Absent such DNA sequences—which were not found in most of the crops submitted through this process—the USDA had no legal basis to regulate gene edited crops whatsoever.[10]

"In May 2020, USDA-APHIS announced the Final Rule for its biotechnology regulations 7 CFR part 340, called the Sustainable, Ecological,

4. *See id.*

5. *See, e.g.*, Jeffrey Wolt et al., *The Regulatory Status of Genome-Edited Crops*, 14 PLANT BIOTECHNOLOGY J. 510, 510 (2016).

6. *Id.*; Greg S. Goralogi et al., *Gene Editing in Tree and Clonal Crops: Progress and Challenges*, IN VITRO CELLULAR & DEV. BIOLOGY – PLANT, July 2021, at 683.

7. Goralogi et al., *supra* note 6, at 693; OFF. OF SCI. AND TECH. POL'Y, COORDINATED FRAMEWORK FOR REGULATION OF BIOTECHNOLOGY (1986), https://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf [https://perma.cc/4HEA-N239].

8. ANIMAL PLANT AND HEALTH INSPECTION SERV., MODERNIZING THE REGULATORY SYSTEM FOR BIOTECHNOLOGY PRODUCTS: FINAL VERSION OF THE 2017 UPDATE TO THE COORDINATED FRAMEWORK FOR THE REGULATION OF BIOTECHNOLOGY 24 (2017), https://www.aphis.usda.gov/biotechnology/downloads/2017_coordinated_framework_update.pdf [https://perma.cc/YX6H-PKJC].

9. Jorge Martínez-Fortún et al., *Potential Impact of Genome Editing in World Agriculture*, 1 EMERGING TOPICS IN LIFE SCI. 117, 127 (2017).

10. *Id.*

Consistent, Uniform, Responsible, Efficient ("SECURE") rule (APHIS, 2020)."[11] As a result, this rule—used to assess the environmental safety of biotech crops—will be implemented by USDA's Biotechnology Regulatory Services ("BRS").[12] 7 CFR part 340 broadly defines genetic engineering as "[t]echniques that use recombinant, synthesized, or amplified nucleic acids to modify or create a genome."[13] Pursuant to this, developers can—under USDA's new "Regulatory Status Review (RSR)"—ask APHIS to evaluate and decide whether novel plants fall within the 2020 Rule's permit scope.[14] This ultimately requires less data than the petition process it replaces, including an explicit statement that field trial data are not generally required.[15] "In a historically significant move, the USDA in this Rule focused on the product, not the process, used to make the organism."[16] This new approach could bode well for genetically-edited crops submitted into this system.

Interestingly, there are certain organisms—both new and old—that are specifically exempted from the 2020 Rule.[17] Included amongst those exempted are types of innovative plant breeding methods.[18] Of substantial interest is the exemption of genome editing when the change could have been obtained by conventional breeding.[19] Also included are "plant-trait-mechanism of action that have already been approved (i.e., MOAs, which are combinations of plant genera, gene functions, and traits) rather the individual gene insertions, and all "Am I Regulated" plants that were allowed under the past USDA process."[20] The door is also left open for the USDA to exempt flora modifications that may be achieved by way of conventional breeding.[21] Additionally, under the 2020 Rule, parties are

11. Goralogi et al., *supra* note 6, at 693; *About the SECURE Rule*, ANIMAL PLANT AND HEALTH INSPECTION SERV. (Apr. 29, 2021), https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/biotech-rule-revision/secure-rule/secure-about/340_2017_perdue_biotechreg [https://perma.cc/R8PZ-9W4J].

12. *Biotechnology Regulations,* ANIMAL PLANT AND HEALTH INSPECTION SERV. (Jun. 25, 2020), https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/sa_regulations [https://perma.cc/WT8X-QXXJ].

13. 7 C.F.R. § 340.3 (2021).

14. *See* Goralogi et al., *supra* note 6, at 693; *Petitions and Regulatory Status Review (RSR) Process Overview,* ANIMAL PLANT AND HEALTH INSPECTION SERV., (Aug. 24, 2021), https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions [https://perma.cc/8CRK-WK5V].

15. *See Petitions and Regulatory Status Review (RSR) Process Overview*, *supra* note 14.

16. Goralogi et al., *supra* note 6, at 693; *see Petitions and Regulatory Status Review (RSR) Process Overview*, *supra* note 14.

17. 7 C.F.R § 340.1 (2021); Goralogi et al., *supra* note 6, at 693.

18. *See* 7 C.F.R. § 340.1 (2021).

19. *See* 7 C.F.R. § 340.1 (2021).

20. Goralogi et al., *supra* note 6, at 693; *see* 7 C.F.R. § 340.1 (2021).

21. *See* 7 C.F.R. § 340.1 (2021).

empowered to independently request an exemption, but APHIS itself may grant one.[22] If APHIS grants an exemption or agrees with a party's requested one, then APHIS must provide public notice and opportunity for public comment.[23]

This regulatory shift does not change the legal landscape of the National Environmental Policy Act (NEPA), which can be used to enjoin the commercial launch of a biotech organism having potential adverse environmental impact where a failure to assess environmental impact is alleged.[24] "The rule also exempts minor DNA changes: (1) Cellular repair of a targeted DNA break without an externally provided repair template, (2) A single deletion of any size, (3) natural DNA repair mechanisms, (4) targeted single base pair substitutions, and (5) Insertions from compatible plant relatives."[25] Developers were permitted to request confirmation letters for the exemption of their organism as of August 2020 by the USDA.[26] APHIS would then, in turn, post the confirmation letters on the APHIS website and made available to the general public.[27] The purpose of doing so was, in part, to "help [developers] market their products domestically and overseas."[28]

"For regulated crops undergoing a RSR, if BRS finds no significant plant pest risk or other impact after a review of the public comments under the National Environmental Policy Act (NEPA), the deregulation notice allows the developer to commercialize the biotech crop."[29] Crops that resist herbicides or pests covered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) are also regulated by the EPA.[30] While the FDA intends to continue to utilize its cumbersome veterinary drug approval process,[31] USDA attempted to transfer that regulatory role to itself during the final days of the Trump administration.[32] As an example of the cumbersome nature of the FDA's regulations, it took approximately

22. 7 C.F.R. § 340.1 (2021).

23. 7 C.F.R. § 340.1 (2021).

24. *See* U.S. DEP'T OF AGRIC., Movement of Certain Genetically Engineered Organisms [Docket No. APHIS-2018-0034] 81, https://www.aphis.usda.gov/biotechnology/340-secure-rule.pdf [https://perma.cc/QPD6-AX4R].

25. Goralogi et al., supra note 6, at 693 (citing 7 C.F.R. § 340.1(b)(2) (2021)).

26. 7 C.F.R § 340.1 (2021).

27. Movement of Certain Genetically Engineered Organisms [Docket No. APHIS-2018-0034], *supra* note 24, at 37.

28. *Id.*

29. Goralogi et al., *supra* note 6, at 693; *see* 7 C.F.R. § 340.1(b)(4)(v).

30. Goralogi et al., *supra* note 6, at 693.

31. *See* Alison Van Eenennaam et al., *Proposed U.S. Regulation of Gene-edited Food Animals is Not Fit for Purpose*, 3 NPJ SCI. FOOD, Mar. 2019.

32. *See* Press Release, U.S. Dep't of Agric., Secretary Perdue Statement on MOU on Animal Biotechnology (Jan. 19, 2021), https://www.usda.gov/media/press-releases/2021/01/19/secretary-perdue-statement-mou-animal-biotechnology [https://perma.cc/6ZND-D7PF].

20 years for the FDA to approve the Aquabounty AquAdvantage® Salmon.[33] These 20 years were filled with excessive regulatory review and legally dubious moratoria.[34] "Many commentators are calling for a more reasonable approach than FDA has taken with GE animals, particularly when there is no drug-related aspect (e.g., a gene to prevent allergy that does not influence the structure and function of the animal or intended eater)."[35] The controversies associated with GE animals have a parallel in GE trees.[36] The potential for ecosystem impacts led anti-biotech activists to file for injunctive relief under the National Environmental Policy Act.[37]

A. International Regulation

In July 2018, "the European Union's High Court of Justice . . . ruled that most crops and other organisms produced through genetic editing will be regulated as if they were a "GMO" under its long-standing "precautionary approach" to regulatory approval."[38] What this means in practical terms is that the EU approval time for crops will increase—sometimes longer than even two years—beyond the time required for approval in individual nations within the EU.[39]

The 171 nations that are parties to the Cartagena Protocol on Biosafety ("CPB") follow the EU's "precautionary approach."[40] These parties met for the tenth time (COP-MOP 10) in October 2021 in Kunming, China.[41] In November 2018, at MOP 9, the parties labeled gene editing under a "synthetic biology" descriptor.[42] One can expect the parties to follow the lead of the EU as it relates to gene editing, for the EU is, in many instances, a key trading partner and source of

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33. *See* Alison L. Van Eenennaam & William M. Muir ,*Transgenic Salmon: A Final Leap to the Grocery Shelf?*, 29 NAT. BIOTECHNOLOGY no. 8, 2011; Julie Steinberg & Andrea Vittorio, *'Frankenfish' Salmon Can Be Overseen by FDA Despite Concerns*, BLOOMBERG L. (2019), https://news.bloomberglaw.com/product-liability-and-toxics-law/fda-can-regulate-genetically-engineered-frankenfish-salmon [https://perma.cc/H6XB-SAY8].

34. Goralogi et al., *supra* note 6, at 693.

35. *Id.*

36. *See id.*

37. *See id.*

38. *Id.*; *see* Ewen Callaway, *CRISPR Plants n\Now Subject to Tough GM laws in European Union*, NATURE (July 25, 2018), https://www.nature.com/articles/d41586-018-05814-6 [https://perma.cc/4JGU-SWFB].

39. *See* Callaway, *supra* note 38.

40. *See* Goralogi et al., *supra* note 6, at 693; *About the Protocol*, CONVENTION ON BIOLOGICAL DIVERSITY (MAY 18, 2022, 6:30 PM), https://bch.cbd.int/protocol/background/ [https://perma.cc/62LQ-YVYP].

41. *See Meetings of the COP-MOP*, CONVENTION ON BIOLOGICAL DIVERSITY (May 18, 2022, 6:33 PM), https://bch.cbd.int/protocol/cpb_mopmeetings.shtml#mop10 [https://perma.cc/W77M-A4HB].

42. Goralogi et al., *supra* note 6, at 693.

foreign aid.[43] This is especially the case in certain parts of Africa, where the EU's influence on GMO policy is notably strong.[44] The EU's influence over the parties as it relates to gene editing is present despite the fact that the United States, Canada, Australia, Argentina and many other grain exporting nations are not signatories to the CPB.[45]

Many of the nations that are parties to the CPB have enacted legislation—such as the European Traceability Directive—which imposes zero-tolerance for the import of any GMO that lacks regulatory approval. Because genetic editing is considered a GMO under EU law, it is likely that many parties to the CPB will enact zero tolerance legislation for genetically edited crops.[46] I In short, more and more "nations are imposing regulatory approval requirements for genetic editing as the Biosafety Protocol is implemented."[47] As a result of this trend, many exportable biotech crops—which includes gene edited crops or derived foods—may also require approval in the markets of parties to the CBP.[48]

Moving across the Atlantic, Canada imposes regulations on all "novel foods." It has included gene editing in this regulatory category.[49] Specifically, Canada includes crops created using non-rDNA methods within "novel foods."[50] "For example, both herbicide-resistant crops created using older methods, such as chemical-radiation, and newer methods, such as gene editing, are regulated."[51] Older forms of plant and animal "mutagenesis" breeding are at more susceptible to "pleiotropic" changes.[52] This point is frequently raised by activists opposed to gene editing and who are concerned with risks in off-target effects in genes—the adverse nature of which remain unlinked to health concerns.[53] Such activists espouse this concern in the face of credible and strong evidence that off-target

43. *Id.*

44. *Id.*

45. *See id.*

46. *See id*; *About the Protocol*, *supra* note 40.

47. Goralogi et al., *supra* note 6, at 693.

48. *See id.*

49. *See* HEALTH CANADA, PROPOSED CHANGES TO HEALTH CANADA GUIDANCE ON THE INTERPRETATION OF DIVISION 28 OF PART B OF THE *FOOD AND DRUG REGULATIONS* (THE NOVEL FOOD REGULATIONS) (2021), file:///C:/Users/dusti/Downloads/Proposed%20HC%20Guidance%20-%20Novelty%20Interpretation%20-%20%202021_03_12.pdf [https://perma.cc/6EAT-DPE6].

50. *See Gene Editing Techniques*, CANADA (Feb. 24, 2020), https://inspection.canada.ca/plant-varieties/plants-with-novel-traits/gene-editing-techniques/eng/1541800629219/1541800629556 [https://perma.cc/9VGP-REU3].

51. Goralogi et al., *supra* note 6, at 694; *see Gene Editing Techniques*, *supra* note 50.

52. *See* Wolt et al., *supra* note 5, at 510–18 (2016).

53. *NEW REPORT: Gene Editing in Agriculture Poses New Risks to Health, Environment*, FRIENDS OF THE EARTH, (Sept. 12, 2018) https://foe.org/news/gene-editing-risks-health-environment/ [https://perma.cc/6VWU-KX6A].

mutagenesis from gene editing in crop plants is negligible when compared to other instances of natural and breeding-induced mutagenesis.[54] Because "many of these crops have similar ecological effects (e.g., there are mutagenic, rDNA and genetically edited crops with herbicide resistance, all of which can outcross to wild relatives or cause problematic herbicide-resistant weeds to develop after widespread use), Canada's regime at least has a consistent approach to similar risks."[55]

13 nations, including Argentina and other major grain exporting nations like Canada, Australia, Brazil, Paraguay and the United States, explicitly support agricultural applications of gene editing in agriculture ("precision biotechnology").[56] In 2018, these nations issued a joint statement in which they noted that governments should "avoid arbitrary and unjustifiable distinctions between end products [crop traits] derived from precision biotechnology and similar end products, obtained through other production methods."[57] Signatories to this statement were from all parts of the globe and included Argentina, Australia, Brazil, Canada, Colombia, the Dominican Republic, Guatemala, Honduras, Jordan, Paraguay, the United States, Uruguay, Vietnam, and the Secretariat of the Economic Community of West African States.[58] It is the hope of many scholars and commentators who specialize in this area that common sense and credible science prevail over the "arbitrary and capricious 'precautionary approach' to regulating gene editing that may be applied to these products under the Cartagena Protocol on Biosafety."[59]

There are two routes for opponents of gene technology to stop the launch of a gene edited crop, both of which relate to economic and environmental impacts.[60] "First, injunctions to stop the launch of biotech crops have been granted against beets, eucalypt trees, and alfalfa for 'interrelated economic effects' and forced environmental reviews under NEPA after USDA had conducted

54. *See* Nathaniel Graham et al., *Plant Genome Editing and the Relevance of Off-Target Changes*, 183 PLANT PHYSIOLOGY 1453, 1453 (2020).

55. Goralogi et al., supra note 6, at 694; *see* Kenneth W. Ellens et al., *Canadian Regulatory Aspects of Gene Editing Technologies*, 28 TRANSGENIC RSCH., Aug. 2019.

56. *See* Goralogi et al., supra note 6, at 694.

57. INTERNATIONAL STATEMENT ON AGRICULTURAL APPLICATIONS OF PRECISION BIOTECHNOLOGY**,** WORLD TRADE ORGANIZATION (Jan. 11, 2018), https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=249321 [https://perma.cc/XH3G-QL5L].

58. *See id.*; Goralogi et al., *supra* note 6, at 694.

59. *See, e.g.*, Goralogi et al., *supra* note 6, at 694; Kimball A. Nill et al., *Precautionary Priority in Approving Imports of Genetically Improved Commodity Crops*, 19 BIOTECHNOLOGY L. REP. 546 (2004).

60. *See* Goralogi et al., *supra* note 6, at 694.

Environmental Assessments (but not a full environmental impact statement)."[61] Second, if an export-related economic interest is involved, then opponents may seek either an injunction under "anticipatory nuisance" or by filing post-marketing litigation seeking recovery for economic impacts to export-related interests.[62]

Success—whether it be delaying integration into the marketplace or something more dramatic—opposition to gene editing is dependent on the trait modified and its connection to environmental and economic or market impacts. "To avoid such tactics, new laws that coordinate regulations across agencies in directing attention to comparative outcomes vs. use of recombinant methods, similar to what SECURE is hoping to achieve, might be needed in the United States."[63]

III. SYNGENTA LITIGATION & MAJOR MARKET APPROVAL

For the first time in the history of litigation over biotech crops, a claim for negligence went to trial alleging that a crop that had full approval for marketing in the United States, but disrupted an overseas market, causing economic impact.[64] Syngenta plaintiffs followed in the footsteps of similar litigation involving StarLink corn and LibertyLink® ("LL") rice,[65] but the Syngenta litigation recognized that a seed developer whose product was approved for commercialization in the United States "had a duty of reasonable care with respect to the timing, manner, and scope of the seed's commercialization."[66]

Some have observed that companies which make lists of nations where they must seek approval for their new biotech crops before marketing it to growers may find it challenging to predict which markets may become "major" in a few years, thereby making the lack of approval in this market troubling years after it was first marketed.[67] The Court in Syngenta, however, concluded in its order denying Syngenta's motion to dismiss on duty grounds that "[q]uestions about whether an export market is 'key' or whether that market is subject to a functioning regulatory

61. *Id.*

62. *See id.*; Margaret Rosso Grossman, *Anticipatory Nuisance and the Prevention of Environmental Harm and Economic Loss from GMOs in the United States*, 18 J. OF ENV'T L. & PRAC. 107 (2008).

63. Goralogi et al., *supra* note 6, at 694.

64. *See* In re Syngenta AG MIR 162 Corn Litig., 131 F. Supp. 3d 1177, 1186 (D. Kan. 2015) [hereinafter *Syngenta AG MIR 162 Corn Litig.*].

65. *See* Non-Producer Plaintiffs' Third Amended Master Complaint at 12, In re Syngenta AG MIR 162 Corn Litig., 131 F. Supp. 3d 1177 (D. Kan. 2016) (No. 14-md-2591-JWL) [hereinafter *Non-Producer Complaint*].

66. Syngenta AG MIR 162 Corn Litig., *supra* note 64, at 1188.

67. *See, e.g.*, *Time and Cost of Bringing a Biotech Crop to Market*, CROPLIFE (MAY 19, 2022, , 2022, 10:44 AM), https://croplife.org/plant-biotechnology/regulatory-2/cost-of-bringing-a-biotech-crop-to-market/ [https://perma.cc/TT4Z-69H2].

system are properly subject to evidence and proof" and Syngenta had not shown that "a complete change of practice of the entire genetically-modified crop industry would result unfairly if manufacturers were held to a duty of reasonable care not to created unreasonable risks of widespread harm in the market."[68]

Given the risk of significant liability, it has been argued companies may overspend resources by seeking approval in more markets than may be necessary at the time of marketing the crop. Conversely, others have argued that protection of markets for export is necessary to protect the legitimate interests of producers. Courts have traditionally adapted common law claims to address novel challenges and economic harms occurring in society, and this case fulfilled a prediction that the present author made—as counsel to the American Soybean Association—in 1998 in a dispute over major market approval for the AgrEvo Liberty Link Soybean. In that negotiation, and without the benefit of current court precedents, my grower clients insisted that unapproved-overseas biotech crops seek a specialized market (e.g., not organic or specialty crops, but one seeking to protect the benefits of export markets). Growers were paid premiums over commodity price to ensure that they took steps to maintain their own identity preserved production (to avoid commingling in an unapproved market overseas).

With the implications that an expanded view of what is a "major" market, costs of regulatory approval increase. Since this Syngenta precedent goes beyond what some grower organizations have set as "major" in their own stewardship standards after consulting with grain traders, I believe this precedent could cause a seismic shift in biotech crop innovation, shutting down some product lines and limiting others to carefully contained production that does not disrupt trade.

A. Negligence

Plaintiffs' core claim of negligence[69] prevailed at trial (with one notable exception in Ohio) succeeding in a settlement for $1.5 billion after a significant "bellwether" trial verdict in Kansas federal court.[70] To prevail on their negligence claim against Syngenta, the plaintiffs proved that Syngenta had a legal duty to exercise reasonable care in manner, scope, and timing of its commercialization of Viptera and Duracade, causing plaintiffs to incur actual damages.[71]

In response, Syngenta argued that it owed no duty to growers or grain traders to wait for approval from China and that segregation for export interests is

68. Syngenta AG MIR 162 Corn Litig., *supra* note 64, at 1192.

69. *See* Non-Producer Complaint, *supra* note 65, at 93-108.

70.RJ Vogt, *Syngenta Agrees To Pay $1.5B To End Corn GMO Class Claims*, LAW360 (Mar. 12, 2018), https://www.law360.com/articles/1021322/syngenta-agrees-to-pay-1-5b-to-end-corn-gmo-class-claims [https://perma.cc/RPP3-KGWM].

71. Non-Producer Plaintiffs' Third Amended Master Complaint, supra note 65, at 93-108.

the growers' challenge, depending on the buyers' needs.[72] In support of its position, Syngenta relied in part on the National Corn Growers Association's ("NCGA") policy which did not require such approvals before launching Viptera.[73] Syngenta also relied in part upon the Biotechnology Industry Association's ("BIO") published standards for stewardship in launching Viptera corn, which discuss the need to seek approval in "key export markets" with "functioning" regulatory systems.[74]

While Syngenta was not a member of BIO, it has been a member of BIO's Excellence Through Stewardship (ETS) program since 2008.[75] ETS is a program that BIO members sign up for, which requires companies to engage in stewardship for exports, including analyses of market acceptance.[76] Syngenta allegedly failed to implement stewardship to protect exports to China by segregating Viptera to domestic uses.[77]

To defeat public nuisance claims, Syngenta argued that the benefits of getting corn traits into production outweighed the alleged adverse economic impacts.[78] Its experts may claim that lower corn prices in the United States were due to high United States' corn production and were not caused by Chinese rejection of United States corn. Indeed, there is no disputing that China had not made any signals of an intent to buy significant shipments of United States corn as of spring 2011 when nationwide planting of Viptera began in the United States.[79]

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72. Syngenta AG MIR 162 Corn Litig., *supra* note 64, at 1188-90.

73. *See* Syngenta's Third-Party Complaint at 14, In re Syngenta Corn Litig., No. 2:14-md-02591-JWL-JPO (D. Kan. Nov. 19, 2015) [hereinafter *Third-Party Complaint*]; *Plant with Confidence*, SYNGENTA (2014), https://www.syngenta-us.com/viptera_exports/images/agri-sure-viptera-fact-sheet.pdf [https://perma.cc/E8B2-DAPE]; *Our Organization*, EXCELLENCE THROUGH STEWARDSHIP, http://excellencethroughstewardship.org/about [https://perma.cc/HD2R-2NC6].

74. *See* Third-Party Complaint, *supra* note 73, at 13; *Our Organization*, *supra* note 73.

75. *See* Suzanne Bopp, *Breaking Down Trade Barriers*, THRIVE (2018), https://www.syngenta-us.com/thrive/policy/breaking-down-trade-barriers.html [https://perma.cc/B4WD-MWLM].

76. *See BIO Launches Excellence Through Stewardship Program Initiative Introduces Best Practices for Quality Management of Plant Biotechnology Products*, BIO (MAY 18, 2022, 7:33 PM), https://archive.bio.org/media/press-release/bio-launches-excellence-through-stewardship-program-initiative-introduces-best-p#:~:text=The%20Excellence%20Through%20Stewardship%20program%20is%20a%20global%20initiative%20that,extended%20globally%20within%20three%20years [https://perma.cc/9VE7-XXHH].

77. *See generally* Kristine A. Tidgren, *Syngenta Litigation Still Pending Despite China's Viptera Approval*, IOWA STATE UNIV. (Dec. 27, 2014), https://www.calt.iastate.edu/article/syngenta-litigation-still-pending-despite-chinas-viptera-approval [https://perma.cc/5JE5-CY56].

78. *See* Syngenta AG MIR 162 Corn Litig., *supra* note 64, at 1188.

79. *See* MAX FISHER, NAT'L GRAIN & FEED ASS'N, LACK OF CHINESE APPROVAL FOR

B. Damages

Experts testified in various ways for each side on the subject of damages. Syngenta's experts opined that the lower corn prices were not impacted by loss of the Chinese market for around a year during a time of high United States corn production.[80] Syngenta also cited NCGA's policy of only requiring approval from Japan and other markets with functioning regulatory systems and BIO's policy of only requiring approval from Japan and Canada.[81] Plaintiffs' experts countered by saying that Syngenta's negligence caused damages up to $5.77 billion for the nationwide class and up to $235.4 million for the Kansas class, based upon opinions of plaintiffs' damages experts. These experts' views prevailed at trial.[82]

IV. CONCLUSION

As noted above, the court precedents may mean that any grower or grain trader seeking a specialized market (e.g., the benefits of export markets) should maintain their own identity preserved production (to avoid commingling in an unapproved market overseas). Any failure to implement such self-imposed measures may lead to economic loss, but the court may find this loss cannot be recovered in tort against the seller of a United States-approved biotech crop that lacked approval in certain export markets. The decisions from this Syngenta litigation could define the boundaries of tort law in agricultural biotechnology for years to come.

IMPORT OF U.S. AGRICULTURAL PRODUCTS CONTAINING AGRISURE VIPTERA™ MIR 162: A CASE STUDY ON ECONOMIC IMPACTS IN MARKETING YEAR 2013/14, 15 (April 16, 2014), http://www.ngfa.org/wp-content/uploads/Agrisure-Viptera-MIR-162-Case-Study-An-Economic-Impact-Analysis.pdf [https://perma.cc/UBW3-WMJ3] (China imports of US corn dipped below one million metric tons ("1 MMT") from 1.2 MMT in 2009-10 (6th largest) to 980 in 2010-11 (5th largest)).

80. *See generally* Syngenta AG MIR 162 Corn Litig., *supra* note 64, at 1188-90.

81. *See id.*

82. Greg Edwards, *Record Payouts of $1.51 Billion Begin in Syngenta Case Involving St. Louis lawyer*, ST. LOUIS BUS. J. (May 18, 2020), https://www.bizjournals.com/stlouis/news/2020/03/18/syngenta-begins-payout-of-record-1-51-billion-in.html [https://perma.cc/FQT4-7GQY].