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Adapting to the Changing World of Biotechnology: Syngenta AG MIR162 Corn Litigation as Regulation by Litigation

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ADAPTING TO THE CHANGING WORLD OF BIOTECHNOLOGY: SYNGENTA AG MIR162 CORN LITIGATION AS REGULATION BY LITIGATION

by Paul Goeringer*

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I. INTRODUCTION

Agriculture has relied on plant breeding to improve genetics since the first domestication of agricultural plants 10,000 years ago.¹ More recently, Gregor Mendel and his hybridization experiments on peas led to what we know as modern genetics.² The rise in recombinant-DNA technology has opened up many possibilities in plant breeding, including Roundup Ready technology and crop varieties designed to resist a number of pests.³

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1. See Ania Wieczorek & Mark Wright, *History of Agricultural Biotechnology: How Crop Development Evolved*, SCITABLE (2012), <http://www.nature.com/scitable/knowledge/library/history-of-agricultural-biotechnology-how-crop-development-25885295> [<https://perma.cc/VLW3-G9F4>].

2. See *id.*

3. See Doug Farquhar & Liz Meyer, *State Authority to Regulate Biotechnology Under the Federal Coordinated Framework*, 12 *DRAKE J. AGRIC. L.* 439 (2007); Elizabeth G. Hill, Comment, *Nature's Harvest or Man's Profit: Environmental Shortcuts in*

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At the same time, governments and the private sector have sought to institute regulations for handling the releases of new biotechnology to ensure the technologies will have limited environmental impacts and provide safe foods to the public. These rules and requirements vary from nation to nation.

This Article uses a recent example—the Syngenta AG MIR162 corn litigation—and its potential impact on the future development and releases of biotechnology as an illustration. Although Syngenta received proper approvals for the use of genetic events MIR162 and Event 5307 in the U.S. and with trade associations like the National Corn Growers Association prior to their commercialization, the genetic events were not approved in all markets.⁴

Part II provides an overview of this class-action litigation and where it currently stands. Part III discusses the current U.S. regulatory conditions that must be met to receive approval for new varieties of crops and the requirements put on the industry by trade associations prior to commercializing the new varieties. Part IV discusses the concept of regulation by litigation and how litigation can be used to place additional requirements on industries, and the impacts of the litigation on the biotechnology industry as a whole. Finally, Part V offers a brief conclusion.

II. BACKGROUND OF SYNGENTA AG MIR162 CORN LITIGATION

Syngenta developed genetic events MIR162 and Event 5307 and sold them in products known as Viptera and Duracade—corn-seed varieties that contain traits intended to make resulting corn resistant to certain pests.⁵ Syngenta petitioned the USDA to deregulate Viptera in 2007 and Duracade in 2011, and the products were approved for sale in 2010 and 2013, respectively.⁶

At the time Viptera and Duracade were approved in the United States, China, where the products were not approved,⁷ was becoming a larger purchaser of U.S. corn. In 2012, China imported 2.7 million metric tons of corn, or roughly 106 million bushels, and it was estimated that China represented almost 20 percent of the U.S. corn-export market in 2013.⁸ Also in 2013, China found traces of Viptera in

the Deregulation of Genetically Modified Crops, 44 TEX. TECH L. REV. 353 (2012) (discussing the birth of recombinant-DNA technology, genetically modified crops, and Roundup Ready).

4. See, e.g., *In re Syngenta AG MIR162 Corn Litig.*, 131 F. Supp. 3d 1177, 1186 (D. Kan. 2015).

5. *Id.*

6. *Id.*

7. *Id.*

8. Non-Producer Plaintiffs' Third Amended Master Class Action Complaint at 60, *In re Syngenta AG MIR162 Corn Litig.*, No. 14-md-2591-JWL-JPO (D. Kan. Sept. 19, 2016). While the import totals include imports from around the world, "virtually all" were from the United States. *Id.*

corn imports from the U.S. and began rejecting any corn shipment containing traces of the product, which had been introduced in corn shipments due to “cross-pollination from neighboring fields” and commingling at local “grain elevators and other storage facilities.”⁹ China finally approved *Viptera* in 2014.¹⁰

Over this same period, corn and other commodity prices fell from mid-2012 highs.¹¹ Many believe this decline could potentially be traced from lower yields due to a drought in 2012 to record yields in 2013 and 2014, but others have argued the decline is due to the loss of the Chinese market because of *Viptera* contamination.¹² Suggesting support for the latter theory, U.S. corn imports to China fell by 85 percent after the discovery of *Viptera* traces in November 2013.¹³

In September 2014, U.S. farmers began to file lawsuits against Syngenta for the disruption to the U.S. corn market caused by the release of MIR162 when it had not yet been approved in China.¹⁴ The farmers claim that Syngenta violated the Lanham Act and state consumer-protection laws, committed the torts of negligence and trespass to chattels, and created nuisances.¹⁵ A group of Arkansas farmers has even alleged that Syngenta violated the Racketeer Influenced & Corrupt Organizations Act—the same federal act used to go after members of the mafia.¹⁶ In December 2014, the U.S. Judicial Panel on Multidistrict Litigation ruled that hundreds of related lawsuits should be consolidated in the federal district court in Kansas.¹⁷

This litigation has been progressing through the stages. It has been certified as a large class action and, as of the writing of this Article, has yet to be resolved.¹⁸ In 2015, Syngenta brought third-party claims against grain handlers Cargill and Archer Daniels Midland, alleging that these companies actively commingled *Viptera* and Duracade corn

9. *In re Syngenta*, 131 F. Supp. 3d at 1186.

10. *See id.*

11. *See* Kristine A. Tidgren, *Syngenta Litigation Still Pending Despite China's *Viptera* Approval*, IOWA ST. U. CTR. FOR AGRIC. L. & TAX'N (Dec. 27, 2014), <https://www.calt.iastate.edu/article/syngenta-litigation-still-pending-despite-chinas-viptera-approval> [https://perma.cc/98VU-MDHH].

12. *See id.*

13. *Id.*

14. *See In re Syngenta*, 131 F. Supp. 3d at 1186.

15. *See id.*; Non-Producer Plaintiffs' Amended Master Class Action Complaint at 100–15, *In re Syngenta*, 131 F. Supp. 3d 1177 (D. Kan. 2015) (No. 14-md-2591-JWL-JPO).

16. *See* Jan Cottingham, *State Farmers Allege GMO Corn Conspiracy*, ARK. BUS., Feb. 23, 2015, at 10, WLNK 37144521.

17. *See In re Syngenta AG MIR162 Corn Litig.*, 65 F. Supp. 3d 1401 (J.P.M.L. 2014).

18. *In re Syngenta AG MIR162 Corn Litig.*, No. 14-md-2591-JWL-JPO, 2016 WL 5371856 (D. Kan. Sept. 26, 2016). The first bellwether trial is scheduled to begin in June 2017. *See* Scheduling Order No. 2, *In re Syngenta AG MIR162 Corn Litig.*, No. 14-md-2591-JWL-JPO (D. Kan. Oct. 21, 2015).

with the rest of the corn supply.¹⁹ The court ruled these claims were preempted by the U.S. Grain Standards Act (“GSA”),²⁰ which states:

No State or subdivision thereof may require the inspection or description in accordance with any standards of kind, class, quality, condition, or other *characteristics* of grain as a condition of shipment, or sale, of such grain in interstate or foreign commerce, or require any license for, or impose any other restrictions upon the performance of any official inspection or weighing function under this chapter by official inspection personnel.²¹

The court agreed with the grain handlers that “whether [the grain] contains the trait found in *Viptera*” was a characteristic under the GSA, that congressional intent was to fully regulate foreign commerce of grain, and that Syngenta was preempted from bringing a state-law tort claim against the grain handlers.²²

In the fall of 2016, the district court certified nine classes in this litigation.²³ These nine classes include one nationwide class and eight statewide classes for producers in Arkansas, Illinois, Iowa, Kansas, Missouri, Nebraska, Ohio, and South Dakota.²⁴ The classes are defined to allow all corn producers in the U.S. or in one of the eight states “who ‘priced their corn for sale after November 18, 2013,’ excluding Court personnel, Syngenta personnel, and government entities.”²⁵ The bellwether cases are scheduled for trial in June 2017.²⁶

19. Syngenta’s Third-Party Complaint, *In re Syngenta AG MIR162 Corn Litig.*, No. 14-md-2591-JWL-JPO, 2016 WL 1312519 (D. Kan. Apr. 4, 2016) (No. 14-md-2591-JWL-JPO); see also Kristine A. Tidgren, *Syngenta Fires Back*, IOWA ST. U. CTR. FOR AGRIC. L. & TAX’N (Nov. 23, 2015), <https://www.calt.iastate.edu/article/syngenta-fires-back> [<https://perma.cc/R9P4-MFL9>] (noting that Syngenta filed a third-party complaint against Cargill and Archer Daniels Midland); Paul Goeringer, *Potential Ramifications of Agrisure Viptera Class Action Litigation*, U. MD.: MD. RISK MGMT. EDUC. BLOG (Jan. 13, 2016), <http://www.aglaw.umd.edu/blog/potential-ramifications-of-agrisure-viptera-class-action-litigation> [<https://perma.cc/4RLW-BWYB>] (also discussing the third-party complaint).

20. *In re Syngenta*, 2016 WL 1312519; see also United States Grain Standards Act, 7 U.S.C. §§ 71–87k (2012).

21. § 87g(a) (emphasis added).

22. *In re Syngenta*, 2016 WL 1312519, at *2–3.

23. See *In re Syngenta*, 2016 WL 5371856.

24. *Id.*

25. *Id.* at *2.

26. See Steven Trader, *Final Bellwether Trials Picked in Syngenta Tainted Seed MDL*, LAW360 (Aug. 31, 2016, 3:49 PM), <https://www.law360.com/articles/834979/final-bellwether-trials-picked-in-syngenta-tainted-seed-mdl> [<https://perma.cc/TSP4-7AWK>].

III. CURRENT REGULATORY BACKGROUND AND TRADE-ASSOCIATION BACKGROUND

A. *Regulatory Background of Biotechnology in the U.S.*

In 1986, the Reagan administration announced the *Coordinated Framework for Regulation of Biotechnology*.²⁷ This framework was last updated in 1992, and recently calls have been made to further modernize it.²⁸ With this framework, the U.S. developed a “risk-based system to ensure that new biotechnology products are safe for the environment and human and animal health”²⁹ or an overarching system to regulate the development of new plant and animal varieties through the use of recombinant-DNA techniques.³⁰ Under the framework, the Environmental Protection Agency (“EPA”), Food and Drug Administration (“FDA”), and Animal and Plant Health Inspection Service (“APHIS”) each regulate different aspects of the biotechnology system utilizing existing federal laws.³¹

The APHIS has been granted authority under the Plant Protection Act (“PPA”) “to prevent the spread of disease and invasive plants by controlling plant movement within interstate and international commerce and restricting release of plant material into the environment.”³² It considers all newly created plant varieties to be potential pests that should be regulated under the PPA.³³

The EPA regulates biotechnology under the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”) and the Toxic Substances Control Act.³⁴ The FIFRA gives the EPA the authority to regulate the

27. *Coordinated Framework for Regulation of Biotechnology*, 51 Fed. Reg. 23,302 (June 26, 1986).

28. See Robbie Barbero, James Kim, Ted Boling, & Julia Doherty, *Increasing the Transparency, Coordination, and Predictability of the Biotechnology Regulatory System*, WHITE HOUSE: PRESIDENT BARACK OBAMA: BLOG (Jan. 4, 2017, 1:20 PM), <https://obamawhitehouse.archives.gov/blog/2017/01/04/increasing-transparency-coordination-and-predictability-biotechnology-regulatory> [<https://perma.cc/JP9J-4DMZ>]; *Modernizing the Regulatory System for Biotechnology Products: Final Version of the 2017 Update to the Coordinated Framework for the Regulation of Biotechnology*, WHITE HOUSE: PRESIDENT BARACK OBAMA: BLOG (Jan. 4, 2017), https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/2017_coordinated_framework_update.pdf [<https://perma.cc/LQ9J-DCQT>] [hereinafter *Modernizing the Regulatory System*].

29. *Coordinated Framework: How The Federal Government Regulates Biotech Plants*, U.S. DEP’T AGRIC. ANIMAL & PLANT HEALTH INSPECTION SERV., https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/sa_regulations/ct_agency_framework_roles [<https://perma.cc/BF3R-7H47>] (last modified Jan. 27, 2017) [hereinafter APHIS]; see also *Coordinated Framework for Regulation of Biotechnology*, 51 Fed. Reg. 23,302.

30. See Farquhar & Meyer, *supra* note 3, at 441–42.

31. *Id.*; see also APHIS, *supra* note 29; *Coordinated Framework for Regulation of Biotechnology*, 51 Fed. Reg. 23,302.

32. A. Bryan Endres, *Coexistence Strategies, The Common Law of Biotechnology and Economic Liability Risks*, 13 DRAKE J. AGRIC. L. 115, 120 (2008).

33. *Id.*

34. *Modernizing the Regulatory System*, *supra* note 28, at 10–15.

registration, manufacturing, and use of all pesticides in the U.S.³⁵ When a newly created plant variety includes a trait to produce a pesticide, it is regulated in the same manner as any other pesticide.³⁶

The FDA regulates the safety of the food system and feed products.³⁷ To ensure the safety of the food system, it looks at the characteristics of a new plant variety and not the methods used to develop the variety.³⁸ In other words, foods derived from both biotechnology methods and traditional breeding methods must “meet the same rigorous safety standards.”³⁹

After developing a new plant variety, seed developers will often face oversight by two or all of these federal agencies. For example, Syngenta sought approval of the MIR162 genetic event from the APHIS and EPA, and is subject to enforcement by the FDA.⁴⁰ This genetic event produced three pesticide products that controlled above-ground pests and, thus, required EPA approval.⁴¹ And in order to allow human consumption, the FDA enforces tolerance levels and residual tolerance levels.⁴²

As you can see, the process for getting a new plant variety deregulated is not easy and often requires years of work. During President Barack Obama’s administration, a call was made to modernize the existing system to take into account advances in science since the framework was last updated in 1992.⁴³ The APHIS published a proposed rule on January 19, 2017, that would have updated the regulatory system to reflect these advances.⁴⁴

It is also important to note that U.S. approval is not the final word on this issue. New plant varieties also need to be approved in other countries. As the next Section will highlight, seed companies work to gain approval in major international markets as required by various trade associations before new varieties can be marketed in the U.S.⁴⁵

35. See APHIS, *supra* note 29.

36. See *id.*

37. Farquhar & Meyer, *supra* note 3, at 450.

38. See *id.*

39. APHIS, *supra* note 29.

40. U.S. DEP’T AGRIC. ANIMAL & PLANT HEALTH INSPECTION SERV., SYNGENTA BIOTECHNOLOGY, INC. INSECT RESISTANT MIR162 CORN: DRAFT ENVIRONMENTAL ASSESSMENT 4–5 (2009), https://www.aphis.usda.gov/brs/aphisdocs/07_25301_pea.pdf [<https://perma.cc/EVE5-NMYA>].

41. See *id.* at 5.

42. See *id.*

43. *Modernizing the Regulatory System*, *supra* note 28. See generally Exec. Order No. 13,610, 3 C.F.R. 258 (2013) (“[S]teps should be taken, consistent with law, agency resources, and regulatory priorities, to promote public participation in retrospective review, to modernize our regulatory system, and to institutionalize regular assessment of significant regulations.”).

44. Importation, Interstate Movement, and Environmental Release of Certain Genetically Engineered Organisms, 82 Fed. Reg. 7,008 (proposed Jan. 19, 2017) (to be codified at 7 C.F.R. pt. 340).

45. See *infra* notes 46 to 52 and accompanying text.

B. *Trade Associations Play a Role in Biotechnology Releases*

Trade associations like the National Corn Growers Association have developed stewardship standards for biotechnology crops.⁴⁶ These associations require new plant varieties to receive major-market approval after being deregulated by the appropriate federal agencies. Developing these stewardship standards, such as requiring major-market approvals, allows trade associations to manage the economic issues associated with the releases of new plant varieties.⁴⁷

For example, when it was discovered that unapproved Liberty Link rice had commingled with “legal” rice and entered the world market, massive food safety recalls were triggered in Europe, and the world price of rice plunged 14 percent.⁴⁸ Bayer CropScience was forced to pay out 750 million dollars in settlements as a result.⁴⁹ And plunges in world commodity prices and large settlements are just some of the economic issues trade associations manage through stewardship practices.

As discussed earlier, the Syngenta class-action suit involves new corn varieties unapproved for the Chinese market being discovered in shipments of corn to China. The National Corn Growers Association, according to its website, requires approval in Japan and that companies be seeking “approval in all other markets.”⁵⁰ As another example, the North American Export Grain Association has a policy to require all-major-market export approval prior to commercializing a new seed variety.⁵¹

Although not regulations, these trade associations’ requirements for major-market approval do set standards that biotechnology-seed companies follow before commercializing a new seed variety. The Syngenta class-action suit could potentially lead to companies needing approval in additional markets if the plaintiffs are able to prove negligence due to Syngenta not receiving Chinese approval before marketing.

A less onerous potential change could be better education of producers on unapproved varieties to keep segregated based on market approval. This would be similar to what is currently being done with

46. Thomas P. Redick, *Coexistence of Biotech and Non-GMO or Organic Crops*, 19 *DRAKE J. AGRIC. L.* 39, 56–57 (2014).

47. *See id.*

48. *See* RASH BEHARI BHATTACHARJEE, *LIBERTY LINK RICE: A TRUE STORY OF GE RICE CONTAMINATION* (2009), <http://library.ipamglobal.org/jspui/bitstream/ipam-library/429/1/Liberty%20Link%20Rice.pdf> [<https://perma.cc/YJA6-94V8>].

49. Bloomberg News, *Bayer Settles with Farmers over Modified Rice Seeds*, *N.Y. TIMES* (July 1, 2011), <http://www.nytimes.com/2011/07/02/business/02rice.html>.

50. *Know Before You Grow*, NAT’L CORN GROWERS ASS’N, <http://www.ncga.com/for-farmers/know-before-you-grow> [<https://perma.cc/DR7H-WB26>].

51. Letter from Gary C. Martin, President and CEO, N. Am. Exp. Grain Ass’n, Inc., to Colleagues (Apr. 4, 2006), http://www.naega.org/images/AP%20for%20Sync_4-4-06.pdf [<https://perma.cc/XX4S-V322>].

identity-preserved crops.⁵² However, expanded segregation of varieties would require additional standards from grain handlers, and as will be discussed later in this Article, incentives may not currently exist for segregation.

IV. REGULATION BY LITIGATION

A. *Regulation by Litigation Background*

One aspect of the Author's job as an extension specialist is assisting agricultural producers in understanding the implications of pending lawsuits, legal and regulatory changes, and other legal issues. The Author has considered the implications of the Syngenta lawsuit insofar as how new biotechnology will come on the market if the litigation is successful. Essentially, this regulation by litigation will add additional requirements that biotechnology companies like Syngenta must meet before bringing a new product to market.

Many critics see regulation by litigation as costing billions of dollars and forcing public participation out of the rulemaking process.⁵³ Proponents see the process, also called "sue and settle," as a way around powerful political interests and as a path towards regulatory changes.⁵⁴ As will be discussed, the process has been successfully used by the environmental and health-care lobbies.

Regulation by litigation began in the 1990s.⁵⁵ The idea is that "agencies use enforcement actions against regulated entities to create new substantive obligations for the regulated."⁵⁶ Agencies "use the threat of a catastrophic loss in litigation to coerce agreement to forward-looking, substantive regulatory provisions in a settlement."⁵⁷ This process adds additional regulations and requirements on an industry—while allowing agencies to bypass normal administrative processes such as notice-and-comment rulemaking.

Regulation by litigation allows governmental agencies or private actors to place regulations on a company or industry using powers they may lack.⁵⁸ An often-cited example of this is the Tobacco Master Set-

52. See DENNIS STRAYER, *IDENTITY-PRESERVED SYSTEMS: A REFERENCE HANDBOOK* 89 (2002).

53. See, e.g., Andrew Grossman, *Regulation Through Sham Litigation: The Sue and Settle Phenomenon*, HERITAGE FOUND. (Feb. 25, 2014), <http://www.heritage.org/research/reports/2014/02/regulation-through-sham-litigation-the-sue-and-settle-phenomenon> [<https://perma.cc/VZ8T-ARH4>].

54. See Bruce Yandle et al., *Bootleggers, Baptists & Televangelists: Regulating Tobacco by Litigation*, 2008 U. ILL. L. REV. 1225, 1240–43 (explaining and opposing this view).

55. Andrew P. Morriss et al., *Choosing How to Regulate*, 29 HARV. ENVTL. L. REV. 179, 181 (2005).

56. *Id.*

57. Yandle et al., *supra* note 54, at 1240.

58. Andrew P. Morriss et al., *Regulation by Litigation*, ENGAGE, Feb. 2008, at 109, 110.

tlement Agreement, which effectively imposed a tax on the future sales of cigarettes in all states.⁵⁹ No state legislature imposed this tax through the constitutional path to impose taxes; instead, the tax was created by the actions of state attorneys general.⁶⁰ Imposing taxes is not a power traditionally assigned by state constitutions or the U.S. Constitution to attorneys general. As has been pointed out by some commentators, “the attractiveness of regulation by litigation is exactly this—that it enables regulators to assume powers that they otherwise lack.”⁶¹

Regulation by litigation has been used in agriculture as well. In 2004, the Texas Commission on Environmental Quality (“TCEQ”) announced stricter rules for the discharge of manure by dairies.⁶² The City of Waco was involved in the administrative rulemaking process, and many of its comments were ultimately rejected by the TCEQ.⁶³ The City then filed suit against fourteen dairies seeking to impose the proposed regulations rejected by the TCEQ.⁶⁴ The City asserted claims using the Comprehensive Environmental Response, Compensation, and Liability Act (“CERCLA”) against the dairies claiming they had improperly stored and transported manure in the waterways of the state and causing phosphorus pollution in Lake Waco.⁶⁵ According to one scholar, “[t]he use of CERCLA in this manner is a newly devised litigation shortcut to avoid the thorough and sometimes disappointing results of statewide environmental regulation.”⁶⁶

In the end, the City of Waco reached a settlement with the dairies⁶⁷ that included a requirement that the dairies sign what was essentially an additional permit with the City limiting field applications of waste.⁶⁸ The settlement allowed the City to effectively enforce its proposed regulations against dairies in Erath County, Texas—even though they had been rejected by the TCEQ.⁶⁹

The *City of Waco* case demonstrates how regulation by litigation can be effectively used as an end around the regulation process. The TCEQ had rejected the City of Waco’s proposals for the revised regu-

59. *See id.*

60. *Id.*

61. *E.g., id.*

62. Concentrated Animal Feeding Operations, 29 Tex. Reg. 6,652 (July 9, 2004); 30 TEX. ADMIN. CODE § 321.31 (2017).

63. *See* Jim D. Bradbury, *Regulation Through Litigation: CERCLA and CAFOs*, AGRIC. MGMT. COMMITTEE NEWSL. (Amer. Bar Ass’n Section of Env’t, Energy, & Res., Chicago, Ill.), Apr. 2007, at 15, 16.

64. *Id.*

65. First Amended Complaint, *City of Waco v. Schouten*, 385 F. Supp. 2d 595 (W.D. Tex. 2005) (No. W-04-CA-118).

66. Bradbury, *supra* note 63, at 16.

67. Settlement Agreement, *City of Waco v. Schouten*, No. W-04-CA-118 (W.D. Tex. Jan. 17, 2006).

68. Bradbury, *supra* note 63, at 16.

69. *Id.*

lations on dairies. Rejection of these proposed regulations should have allowed the TCEQ to develop regulations that worked for all parties, but it did not. Instead, the City was able to implement its proposed regulations through a settlement agreement with the dairies.

These are just a few examples of how regulation by litigation can operate. Private actors can also bring claims that if successful can essentially impose new regulations. As the next Section will highlight, the Syngenta class-action suit may similarly have the impact of requiring biotechnology companies to comply with additional standards prior to bringing a new plant variety to market.

B. *Regulation by Litigation: The Syngenta Class Action*

As discussed in the previous Section, regulation by litigation is one way to add additional requirements on an industry without going through the traditional notice-and-comment rulemaking process. The Syngenta class action presents a different type of regulation by litigation. Instead of a public actor suing an industry like the tobacco industry or truck manufacturers, we have private agricultural producers suing a single biotechnology company. A victory for the plaintiffs in this case would produce the same results as regulation by litigation by a public actor.

As discussed previously, biotechnology companies work to get new plant varieties approved by the appropriate federal agencies (the APHIS, EPA, and FDA). While companies are working through this process, they are also working on getting approval in major foreign markets as required by trade-association standards—and also to ensure that the new varieties will be accepted in world markets.

A victory by the plaintiffs could potentially expand the requirements placed on biotechnology companies. If Syngenta is found to have violated the duty of care owed to growers by not receiving approval in China prior to commercializing MIR162, biotechnology companies may have to obtain approval in additional markets before commercializing a new variety in the United States. Requiring additional markets to approve will likely delay market entrance for new plant varieties.

The question then becomes how companies determine the markets in which to seek approval. Could the Syngenta class action potentially cause seed companies to go beyond approval with major trading partners and seek approval in those markets the USDA is merely *projecting* to become major trading partners after the new variety is commercialized?

Prior to 2008, China was a net exporter of grain,⁷⁰ and prior to the 2009–2010 grain-marketing year, U.S. corn exports to China were

70. James Hansen & Fred Gale, *China in the Next Decade: Rising Meat Demand and Growing Imports of Feed*, U.S. Dep't Agric. Econ. Res. Serv.: Amber Waves

fewer than 1 million metric tons per year.⁷¹ But this figure surged to over 5 million by the 2011–2012 grain-marketing year.⁷² Since the discovery of MIR162 in shipments to China, corn exports to China have dropped back down to fewer than 1 million metric tons in the 2014–2015 and 2015–2016 grain-marketing years.⁷³ USDA projections since the 1990s had overestimated the true pace at which China would import grains due to increased demand for livestock and feed grains.⁷⁴ Determining which projections to use could potentially be an issue for seed companies. If using improper projections is seen as negligent, will biotechnology companies moving forward be required to get approval in *all* markets?

However, biotechnology companies do have potential options beyond seeking approval in unknown markets. They could consider utilizing agreements with growers who want to grow new varieties not approved for all potential trading partners (such as China prior to the spike in 2011–2012) to only take the grain to non-export locations. For instance, with an earlier release of Agrisure RW MIR604, designed to control rootworms in corn, Syngenta required producers to sign agreements before purchasing the MIR604 seeds to grow.⁷⁵ These agreements required producers to agree only to deliver to non-export locations, and Syngenta required them until the MIR604 variety had received major-market approval in Japan.⁷⁶

As discussed by Bryan Endres, Syngenta’s commercialization prior to major-market approval was denounced by the trade associations and seen as putting the U.S.’s corn and corn-product export markets at risk.⁷⁷ The corn-export market consists of not just corn, but also distillers dried grain and solubles (“DDGS”),⁷⁸ corn meal, and corn flour, among other products. Looking solely at DDGS, total world exports in the 2016–2017 marketing year are expected to be about \$713 million for the U.S.⁷⁹

During harvest time, producers may not be able to take all necessary precautions to ensure that these plant varieties end up at non-export locations. The plant varieties in question (new biotechnology)

(Apr. 7, 2014), <https://www.ers.usda.gov/amber-waves/2014/april/china-in-the-next-decade-rising-meat-demand-and-growing-imports-of-feed> [<https://perma.cc/R4W4-Q3SS>].

71. Kim Dillivan, *U.S. Corn Exports to China*, iGROW (Jan. 14, 2015), <http://igrow.org/agronomy/corn/u.s.-corn-exports-to-china> [<https://perma.cc/M6N6-XSDU>].

72. *Id.*

73. *U.S. Grains in All Forms Exports*, U.S. GRAINS COUNCIL, <http://www.grains.org/market-data/feed-grain-exports-in-all-forms> (enter “China” in “Type Country Name” field).

74. See Hansen & Gale, *supra* note 70.

75. Endres, *supra* note 32, at 129.

76. See *id.*

77. *Id.*

78. A byproduct of ethanol production used in livestock feeds.

79. *U.S. Grains in All Forms Exports*, *supra* note 73.

are not the normal varieties the market is designed to segregate for, such as organics and GMO-free.⁸⁰ Producers are not receiving a price premium for growing them as they do with organics, and they may be unlikely to segregate these varieties from other varieties, even with agreements.⁸¹

The other issue is whether not just producers, but also the processors and handlers, will segregate the new plant varieties. Will an ethanol plant be able to handle the segregation burdens to ensure these unapproved varieties stay out of the DDGS export market?⁸² Even if segregating varieties may be an option to limit the need for approval in unknown markets, processors and handlers may not be equipped to handle the burdens of segregation.

V. CONCLUSION

This Article highlights many of the challenges faced by grain producers in deciding whether to participate in a large class-action lawsuit involving agricultural biotechnology. Many producers rely on the innovation that new varieties allows them to grow food more efficiently, at lower costs, and with higher yields. Producers also rely on the fact that when new varieties are put on the market, the varieties will be approved for export to our trading partners.

The Syngenta class-action litigation highlights what can happen when a country increases exports of a commodity containing unapproved varieties—the loss of exports to the country that has not approved the variety and a decrease in the worldwide price for the product.

As this Article discusses, some potential outcomes of this class-action lawsuit could increase requirements on biotechnology companies associated with the release of new plant varieties. These new requirements could potentially range from increasing the markets approval is required in prior to releasing plant varieties to segregating new varieties not yet approved for export to all countries. Each of these requirements could present problems for both producers and the biotechnology companies.

Regardless of the outcome of the litigation, it will be interesting to see how biotechnology companies and producers react and adapt to the continued importance of advances in biotechnology in agriculture.

80. Endres, *supra* note 32, at 127.

81. *See id.* at 127–28.

82. *See generally id.* at 129–30 (noting the enormity of this burden and projecting that plants would likely leave the export market entirely).