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Issue Report

Agriculture and the Judicial Branch: The Third Leg of Governance

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About this Issue Report

This *Farm Foundation Issue Report* examines the role of the judicial branch of the U.S. government in shaping the nation's agricultural policies and regulations. The authors would like to thank Ellen Steen of the American Farm Bureau Federation; Danielle Quist of the International Dairy Foods Association; Kristin Landis of the Biotechnology Innovation Organization; Rachel Lattimore of CropLife America; and Stanley Abramson and Donald McLean of Arent Fox LLP, for the role each had in development of this paper. The authors are solely responsible for the content of this paper. *Farm Foundation Issue Reports* are made possible in part by a grant from Syngenta.

While perhaps not as obvious as activities in the legislative or executive branches, court decisions have the potential to significantly impact the agricultural sector and the policies directing its operations. The founders of the United States created three branches of government as part of an important system of checks and balances. Actions taken in Congress (the legislative branch) and by regulatory agencies (the executive branch) may ultimately give rise to litigation in the judicial branch, yielding decisions that can direct the actions of Congress, state and federal agencies, farmers and agribusinesses.

Litigation can be used as a tool—by agriculturalists, activists, consumers, or governments—to change policy and/or shape how agriculture is practiced. This *Issue Report* examines three areas of law where courts have been leveraged most to change policy and shape how agriculture is practiced. It also looks at one issue that encompasses all of these areas—litigation involving agricultural biotechnology—to illustrate how long, complicated and impactful the judicial process can be.

Laws and Litigation

In agriculture, litigation arises most frequently in the areas of administrative, environmental, and regulatory law.

Administrative Laws: Nearly every part of agriculture—from seeds, to food processing, to marketing—is regulated by federal, state and local governments. At the federal level, Congress authorizes executive branch agencies to administer laws and regulations. To regulate the regulators, Congress also passed certain

administrative laws to protect people from the actions, or inactions, of these federal agencies. While governing process rather than substance, these laws can be important tools to ensure fairness and transparency between federal regulators, those they regulate, and the public.

The Administrative Procedure Act[1] (APA), which includes the Freedom of Information Act[2] (FOIA) and the Privacy Act,[3] has four key functions. It provides the framework for most federal administrative law; establishes the process that governs formal interactions between federal regulatory agencies and the regulated community; provides for transparency and public participation; and, as to final agency actions, provides a basis for private citizens or entities to file lawsuits challenging an agency's processes. In some of those cases, courts find that an agency's actions are not "ripe" or ready for review, as a district court found in *Anderson v. McCarthy.* (See sidebar at right.)

FOIA establishes the principle that government records should be, as a general rule, available to the public. FOIA requires federal agencies to disclose agency records upon written request, subject to certain limitations on public disclosures of confidential business, personal, or otherwise privileged information or documents. The Privacy Act regulates how government agencies use and disseminate personal information. FOIA is frequently used as a tool to ensure government transparency. However, some in the agriculture sector have challenged how far some agencies have gone in sharing information, as in *American Farm Bureau Federation v. EPA* when American Farm Bureau Federation and other groups challenged EPA's release of farmers' information. (See sidebar at right.)

Environmental Laws: The United States passed its first environmental law, the Rivers and Harbors Act, in 1899, with modern environmental laws first emerging at the federal level in the 1950s. Since 1970, when many of the environmental responsibilities of the federal government were consolidated under the U.S. Environmental Protection Agency (EPA), environmental laws and implementing regulations have rapidly developed. Some of the most commonly cited environmental laws affecting the agricultural sector include the Clean Water Act (CWA), the Clean Air Act, the Endangered Species Act (ESA), and the National Environmental Policy Act (NEPA).

The Federal Water Pollution Prevention and Control Act was adopted in 1948; after amendments in 1972 and 1977, it became commonly known as the CWA.[6] The CWA

Anderson v. McCarthy.[4] Under a regulation of the U.S. Environmental Protection Agency (EPA) issued in 1988, if an "article" were treated to protect the article from pests with a pesticide lawfully registered for that use under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), then the article would be exempt from registration under FIFRA as a pesticide. In 2015, a group of bee keepers and others concerned about the effect of pesticides on pollinators sued EPA, claiming the agency had improperly applied the "treated article exemption" to seeds treated with neonicotinoid insecticides and had failed to regulate those seeds as pesticides. The plaintiffs based their claims on EPA statements in a 2013 bee guidance document. The court dismissed the case, finding the guidance document to be neither an "agency action" nor "final" under the Administrative Procedure Act and therefore unreviewable by a court. Shortly after dismissal, plaintiffs filed a petition with EPA, asking EPA to regulate treated seeds as pesticides. That petition remains pending.

American Farm Bureau Federation v. EPA.[5] In 2013, EPA, in responding to a FOIA request, released spreadsheets containing personal information (including names, home addresses, email addresses, telephone numbers, and GPS coordinates) of farmers and ranchers who raise livestock and poultry in 29 states. The American Farm Bureau Federation and the National Pork Producers Council filed suit, challenging EPA's release of the information. The Eighth Circuit Court of Appeals ruled that EPA "abused its discretion" by giving the FOIA requestors a "complete set of data on a silver platter." The parties ultimately reached a settlement agreement in 2017 that precisely described what personal information can be released by the Agency (only the city, county, zip code, and permit status of an operation). The settlement agreement also required EPA to conduct personnel training on FOIA and the release of personal information.

provides a comprehensive system for the regulation of pollutants in the "waters of the United States." The CWA authorizes water quality standards for surface waters, requires permits for point source discharges of pollutants into navigable waters, and plans for the control of nonpoint source pollution. EPA is the primary agency tasked with implementing and enforcing the CWA, though it works in cooperation with state environmental agencies and the U.S. Army Corps of Engineers (the Corps). The CWA, which regulates complex ecosystems, such as watersheds, and establishes evolving definitions of pollution, has been a fertile source for lawsuits that ultimately determine possible uses of private land, as seen in *Army Corps of Engineers v. Hawkes Co.* (See sidebar below.)

U.S. Army Corps of Engineers v. Hawkes Co.[7]
The CWA authorizes regulation of navigable waters, defined in the statute as the "waters of the United States" (WOTUS). This term has been further defined, albeit unclearly, by EPA regulations and judicial opinions. Because it is sometimes difficult to determine where waters of the United States are located, the Corps can issue jurisdictional determinations that specify whether property contains waters under CWA jurisdiction. In 2010, the Corps issued a jurisdictional determination that a property in Minnesota included waters of the United States because it contained wetlands that "had a 'significant nexus' to the Red River of the North." The landowners filed suit, challenging the Corps' jurisdictional determination. The Supreme Court ultimately held that a jurisdictional determination by the Corps is a "final agency action," which is reviewable by the courts. This allows landowners to sue in federal court on a Corps determination that the land contains waters of the United States and therefore falls under the jurisdiction of the CWA.[8]

The stated purpose of the ESA[9] is to "provide a means whereby the ecosystems upon which endangered species and threatened species depend may be conserved, to provide a program for the conservation of such endangered species and threatened species, and to take such steps as may be appropriate to achieve the purposes" of the international conservation treaties and conventions to which the United States is a party.[10] The U.S. Department of Interior's Fish and Wildlife Service (FWS) and the U.S. Department of Commerce's National Marine Fisheries Service (NMFS), collectively known as "the Services," share the responsibility for administering the ESA, in cooperation with other agencies whose decisions trigger ESA review. The three key components of the ESA are: the listing and protection of species; the designation of critical habitat and avoidance of its destruction; and the consultation by federal agencies regarding actions that may harm listed species. In addition, the ESA permits citizen suits to enforce the law. Therefore, lawsuits have played a major role in the enforcement and interpretation of many of the ESA's provisions.[11] This provision grants standing to citizens, whether speaking for their own economic interest or the endangered species' and gives rise to many of the ESA cases brought against agencies. Two examples of how procedural steps required under ESA have impacted agriculture are: *Permian Basin Petroleum Association v. Department of Interior* in which land owners challenged an endangered species designation; and *Washington Toxics Coalition v. EPA* in which an environmental coalition challenged a regulatory decision it deemed harmful to endangered species. (See sidebars on page 4.)

NEPA is a procedural environmental statute mandating that all federal agencies follow a formal process for considering potential environmental impacts of proposed actions, and fully disclose to the public its assessment of such impacts.[16] NEPA provides a decision-making agency with three options for assessing environmental impacts. It may:

- Prepare an Environmental Impact Statement (EIS), a detailed, comprehensive document required for every proposal for "major Federal actions significantly affecting the quality of the human environment";
- Prepare an Environmental Assessment (EA), a concise public document used to determine whether an EIS is needed; or
- For actions that do not have a significant effect on the human environment, categorically exclude those actions from further environmental review.

NEPA only requires that an agency follow a procedure for assessing environmental impacts; NEPA does not require any particular outcome. As a result, reviewing courts need not determine whether a particular action is good or bad for the environment. The court's task is limited to finding procedural flaws. Given its broad reach—to every agency and every proposed agency decision—NEPA is one of the most heavily litigated environmental statutes, with federal courts routinely weighing in to assess whether agencies have satisfied their NEPA obligations with respect to a proposed federal agency action.

Regulatory Laws: Several areas of agricultural production are highly regulated, including pesticides and genetically engineered (GE) plants. These products are regulated through numerous statutes, including the Plant Protection Act (PPA); the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); the Federal Food, Drug, and Cosmetic Act (FFDCA), and the Food Quality Protection Act (FQPA).

In the United States, pesticides are regulated under three statutes: FIFRA[17], which governs the sale and use of pesticide products; the FFDCA[18], which limits pesticide residues on food in interstate commerce, including imported food; and the FQPA[19], which amended FIFRA and FFDCA. All pesticides marketed in the United States must be "registered" by EPA. Under Section 3 of FIFRA, a product can be registered only if, among other things, EPA determines that it "will not generally cause unreasonable adverse effects on the environment."[20] As of 2011, there were an estimated 18,000 pesticide products in use.[21] Although FIFRA does not provide a private right of action, pesticide registrations are a common source of litigation, as illustrated in *League of United Latin American Citizens vs. Wheeler*. (See sidebar page 5.)

Permian Basin Petroleum Association v. Department of the Interior.[12] Section 4 of the ESA provides that the Secretary of the Interior shall "determine whether any species is an endangered species or a threatened species" based on several factors, such as loss of habitat, disease or predation, or other natural or manmade factors. Conservation efforts can avoid a listing decision by protecting the species to such an extent that listing is not warranted. In an attempt to keep the lesser prairie chicken (a species of grouse with feathered feet and striped plumage) off the endangered species list, the five states in the bird's habitat range (Colorado, Kansas, New Mexico, Oklahoma, and Texas) organized their own conservation program, offering economic incentives to landowners and companies that set aside land for conservation. In 2014, the lesser prairie chicken was nonetheless designated as threatened by the Services, one step from endangered status under the ESA. In 2015, landowners filed suit, claiming that the Services failed to make a proper evaluation of the states' conservation plans when it listed the lesser prairie chicken as threatened. The court ultimately vacated the listing and the bird's status under the ESA remains uncertain.

Washington Toxics Coalition v. EPA.[13] Section 7 of the ESA requires that "each Federal agency shall . . . insure that any action authorized, funded, or carried out by such agency. . . is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of habitat of such species."[14] The Washington Toxics Coalition, and several other concerned groups, brought suit claiming that EPA, in carrying out its obligations under FIFRA, had not adequately considered potential effects on endangered and threatened fish in the Pacific Northwest or consulted with the Services in registering 54 pesticide products. The Ninth Circuit Court of Appeals held that EPA was required to comply with the consultation requirements of the ESA and that the evaluation of environmental and species impacts it conducted as part of its comprehensive ecological risk assessments, a component of its pesticide registration process, was not sufficient. The court enjoined EPA's authorization of pesticide use within specified distances of salmon-supporting water in California, Oregon, and Washington until the ESA consultation requirements were fulfilled. Subsequent litigation and settlements have established a timeline by which EPA must complete the consultation process for certain pesticide products.[15]

Biotechnology Laws and Cases

Biotechnology, also referred to as genetic engineering, is the science of making changes to an organism's genome. In agriculture, genetic engineering is used to improve agronomic performance or resistance to pests or diseases. This technology has faced litigation challenges since the advent of its use.

By the 1970s, scientists had developed recombinant DNA (rDNA) capabilities. The National Institutes of Health (NIH) became the first federal agency to exercise oversight over the use of rDNA techniques, and in 1976 issued guidelines and established requirements for the handling of rDNA material by research scientists.[24] In 1983, NIH authorized the first field trial of a genetically engineered (GE) microbe. Specifically, the permit allowed scientists at the University of California at Berkeley to apply "ice minus bacteria," genetically engineered to confer frost tolerance, to potato plants in northern California. The field trial was scheduled to begin in May 1984. In September 1983, a group opposing this technology filed a lawsuit seeking to halt the field trials, and any other deliberate release permits, alleging that NIH had violated NEPA by failing to prepare an EIS or an EA relevant to the field trial. Plaintiffs won a preliminary injunction, halting the ice minus experiment.[25]

A short time later, the White House Office of Science and Technology Policy (OSTP) released the Coordinated Framework for Regulation of Biotechnology, and USDA adopted primary oversight of GE crops.[26] USDA's Animal and Plant Health Inspection Service (APHIS) regulates GE crops pursuant to its authority to regulate plant pests under the Plant Protection Act (PPA). Like the rest of the Coordinated Framework, the PPA emphasizes that regulatory decisions must "be based on sound science."[27] In implementing the PPA[28], APHIS promulgated a regulatory scheme governing the introduction in the United States of GE plants and other GE organisms that are derived from known or suspected plant pests.[29] FDA[30] and EPA[31] were also given important roles to play under the Coordinated Framework.

Over the next 20 years, USDA approved thousands of field trials and granted dozens of deregulation decisions, which permitted the commercialization of GE crops—including glyphosate-tolerant corn and soybeans—that were rapidly adopted by U.S. farmers due to increased yield and other valuable agronomic traits. During that time, USDA faced little legal scrutiny regarding its regulatory decisions and compliance with NEPA.

League of United Latin American Citizens v. Wheeler.[22] In 2006, after a FIFRA registration review, EPA issued a final decision to reregister the insecticide chlorpyrifos on the basis of a robust toxicological database. Disagreeing with EPA's assessment that chlorpyrifos is safe, the Pesticide Action Network North America and Natural Resources Defense Council filed a petition with EPA in 2007 to block the use of chlorpyrifos for any purpose.[23] The petitioners alleged, among other things, that epidemiology studies demonstrated that the pesticide damaged the developing brains of children and caused reduced IQ, loss of working memory, and attention deficit disorders. In 2017, EPA denied the petition, stating that the technical science used in support of the petition is "unresolved." The Agency said that it would continue to study the issue. In 2018, several groups filed a petition for review with the Ninth Circuit Court of Appeals, seeking review of EPA's decision. A divided panel of the court vacated EPA's order and remanded the matter to the Agency, with directions to revoke all tolerances and cancel all registrations for chlorpyrifos within 60 days. The Ninth Circuit granted EPA's request for an *en banc* review with a decision in the case still pending.

In 2005, USDA approved a petition to deregulate glyphosate-tolerant alfalfa (GT alfalfa), which was engineered to tolerate application of the herbicide glyphosate over the top of the crop while it grew in the field. USDA's deregulation decision paved the way for commercial sale. Before the first GT alfalfa crop could be harvested, consumer groups challenged USDA's deregulation decision, alleging NEPA violations, including that USDA should have prepared an EIS in connection with its approval. The court found that USDA violated NEPA in failing to prepare an EIS before deregulating, and ordered USDA to complete an EIS for GT alfalfa.[32] In the meantime, the court wiped out USDA's deregulation decision and halted the planting of GT alfalfa after March 30, 2007, placed restrictions on GT alfalfa that had already been planted, and prevented USDA from taking any action that would allow more planting of GT alfalfa before the EIS was complete.[33]

After the Ninth Circuit Court of Appeals upheld the trial court's decision,[34] the Supreme Court reversed in part, finding that the lower court had gone too far in issuing its injunction and that it was up to USDA, not the courts, to decide what kind of planting could be permitted while the EIS was underway.[35] But the Supreme Court's decision did not end the issues for GT alfalfa planting. After USDA completed its EIS, GT alfalfa was widely planted in spring 2011. The plaintiffs filed a new suit in alleging that the EIS was deficient and that USDA had violated the ESA. A different trial judge rejected all of the plaintiffs' claims, and the Ninth Circuit Court of Appeals upheld that decision in May 2013, bringing an end to the story after seven years—and numerous alfalfa growing seasons.[36]

GT sugarbeets followed a similar path. USDA deregulated GT sugarbeets in 2005. Consumer groups brought suit in 2008, again challenging USDA's decision based on alleged NEPA violations, arguing that USDA should have prepared an EIS and considered the socioeconomic impacts of GT sugarbeet deregulation on farmers and processors seeking to avoid GE sugarbeets and derived products. The court agreed and vacated the deregulation.[37]

Consumer groups then took it a step further and challenged USDA's decisions to grant seed companies' permits to allow the limited planting of sexually immature steckling plants—which permit holders were at one point ordered to destroy—and to allow additional cultivation of GT sugarbeets while the EIS was pending. That case became moot when USDA issued its EIS and issued a new deregulation decision.

Like its deregulation decisions, USDA's field trials have not escaped litigation challenge:

- In 2006, consumer groups challenged permits issued by USDA for Hawaii field trials of crops engineered to produce pharmaceutical compounds, arguing in relevant part that USDA had failed to satisfy its obligations under NEPA and ESA.[38] The court found that APHIS had violated ESA by failing to obtain information about listed species and critical habitat potentially relevant to the field trials, and violated NEPA by failing to adequately articulate its NEPA process. The court declined to issue an injunction since the field trials had expired by the time of the court's decision. The court granted a request by industry to keep confidential specific field trial location information requested by the plaintiffs to protect the trials against the risk of vandalism, a decision that was upheld by the federal appeals court.[39]
- In 2003, consumer groups successfully challenged on NEPA and other grounds USDA's grant of permits for field trials of creeping bentgrass and bluegrass engineered to tolerate application of glyphosate and denial of a request to list those plants as noxious weeds under the Plant Protection Act.[40]
- In 2010, consumer groups challenged USDA's grant of permits for the planting of eucalyptus trees engineered to be tolerant to frost on NEPA, ESA, and other grounds. The case was ultimately decided in USDA's favor.[41]

In addition to challenges originating with USDA's GE crop approvals, FDA's decisions relating to new animal drugs and food products have also been subject to challenge:

- Despite an extensive review by FDA of health and safety data, and an extensive environmental review under NEPA, a consumer group and dairy farmers challenged FDA's approval of recombinant bovine somatotripin (rBST), the first GE animal drug. The plaintiffs alleged that FDA, which regulated the drug under the FFDCA, had violated NEPA by failing to prepare an EIS, among other claims. FDA ultimately prevailed in that suit.[42]
- In 2016, consumer groups and an Indian tribe challenged FDA's November 2015 approval of

AquAdvantage salmon, an Atlantic salmon genetically engineered to reach market size faster than conventional salmon and intended for food use. The plaintiffs' challenge alleges flaws in FDA's approval process based on NEPA and the ESA, and contends, among other claims, that FDA is without authority to regulate GE animals under the FFDCA. That case remains pending.[43]

Since the earliest challenge to the first field trial of a GE microbe, litigation has been a frequent and important tool used by those opposed to agricultural applications of genetic engineering. Opponents have challenged field trials, sought to reverse deregulation decisions and product approvals, challenged the exercise of enforcement discretion,[44] and questioned agencies' authority to regulate biotechnology products.

These cases have pressure-tested the agencies' approval processes, including compliance with NEPA and other aspects of their regulatory review of biotechnology products. In the process, these cases have made those processes stronger, more protective of the environment, and more legally defensible. Biotechnology litigation has also complicated the regulatory process, slowed commercialization of new products, and slowed innovation, notwithstanding the fact that the technology's safety has been confirmed by major scientific organizations all over the globe.[45] Litigation has made the regulatory process more complicated and expensive, which some have argued has narrowed the playing field and made it more difficult for small companies and academics to bring new and innovative products to market.[46]

Conclusion

Farm bills, shifting international trade dynamics, and new and amended regulatory actions often focus agriculture's immediate attention on the executive and legislative branches. Actions taken in any or all of those areas, however, may ultimately give rise to litigation, whether brought by agricultural stakeholders or activists, and under one of the statutes identified above or otherwise. Those cases on the horizon, just as with the cases highlighted above, will provide an opportunity for the courts to further shape, for better or for worse, U.S. agricultural policy. While the agriculture sector's sights are set on Capitol Hill and the White House, the courts should never be too far from view.

Endnotes

[1] 5 U.S.C. §§ 500-596, 701-706, 801-808.
[2] 7 U.S.C. § 552.
[3] 7 U.S.C. § 552a.
[4] No. 16-00068, 2016 WL 6834215 (N.D. Cal. Nov. 21, 2016).
[5] *American Farm Bureau Federation v. EPA*, 836 F.3d 963 (8th Cir. 2016).
[6] 33 U.S.C. §§ 1251-1387.
[7] *United States Army Corps of Engineers v. Hawkes Co.*, 136 S. Ct. 1807 (2016).
[8] *See also Waterkeeper Alliance, Inc. v. EPA*, 399 F.3d 486, 522 (2d Cir. 2005) (holding that "agriculture stormwater," which is exempt from CWA permitting, included land application of discharges, if the land application met site-specific nutrient management practices); *Alt v. EPA*, 979 F. Supp. 2d 701 (N.D.W.Va. 2013) (holding that "incidental" runoff of litter and manure from concentrated animal feeding operations (CAFOs) was exempt from CWA permit requirements); *Hawaii Wildlife Fund v. County of Maui*, 881 F.3d 754, 760 (9th Cir. 2018) (holding that Maui's wastewater facility wells are "point sources" and therefore should have obtained CWA permits because waste from the plant's wells leaked into groundwater, which then flowed into the Pacific Ocean), *opinion amended and superseded on denial of reh'g en banc* 886 F.3d 737 (9th Cir. 2018).
[9] 16 U.S.C. §§ 1531-1544.
[10] 16 U.S.C. § 1531(b).
[11] *See, e.g., Babbitt v. Sweet Home Chapter of Communities for a Great Oregon*, 515 U.S. 687, 698 (1995) (holding that a "taking" of an endangered or threatened species does not require direct contact and that habitat modification is a legitimate application of the word "harm" in the ESA's definition of "take"); *Weyerhaeuser Co. v. Fish & Wildlife Serv.*, 586 U.S. _, 139 S.Ct. 361 (2018) (an area is eligible for designation as "critical habitat" under the ESA only if it is habitat for the listed species; an agency decision not to exclude an area from critical habitat is subject to judicial review).
[12] *Permian Basin Petroleum Ass'n v. Department of the Interior,* 127 F. Supp. 3d 700 (W.D. Tex. 2015).
[13] *Washington Toxics Coalition v. EPA*, 413 F.3d 1024 (9th Cir. 2004).
[14] 16 U.S.C. §1536.
[15] *See* Settlement Agreement in *Center for Biological Diversity v. U.S. Fish & Wildlife Serv.* (2014) (agreeing to consultations assessing the effect of five pesticides [carbaryl, chlorpyrifos, diazinon, malathion, and methomyl] on listed species) and Settlement Agreement in *Center for Biological Diversity v. U.S. Fish & Wildlife Serv.* (2016) (agreeing to consultations assessing the effect of four pesticides [atrazine, simazine, propazine, and glyphosate] on listed species). *See also Center for Biological Diversity v. EPA,* No. 14-1036, Slip. Op. at 10, 24 (D.C. Cir. June 30, 2017) (claiming EPA violated its duties under the ESA by failing to consult with the Services in registering cyantraniliprole); *Center for Food Safety v. EPA,* 14-73359 (9th Cir. 2014) (claiming the same for 2,4-D): *National Farm Family Coalition v. EPA*, 17-70196 (9th Cir. 2017) (claiming the same for dicamba); *Center for Biological Diversity v. EPA*, No. 16-1351 (D.C. Cir. 2016) (claiming the same for halauxifen-methyl).
[16] 42 U.S.C. §§ 4321-4347.
[17] 7 U.S.C. §§ 136-136y.
[18] 21 U.S.C. §§ 301-399.
[19] 7 U.S.C. §136.
[20] 7 U.S.C. § 136a(c)(5)(D).
[21] Linda-Jo Schierow and Robert Esworthy, *Pesticide Law: A Summary of the Statutes*, Cong. Research Serv., RL31921 (2012), http://nationalaglawcenter.org/wp-content/uploads/assets/crs/RL31921.pdf.
[22] No. 17-71636, 2018 WL 3763531 (9th Cir. Aug. 9, 2018). *See also In re Pesticide Action Network North America v. EPA*, 863 F.3d 1131 (9th Cir. 2017).
[23] Id., 798 F.3d 809, 811 (9th Cir. 2015) (*citing United Farm Workers v. Adm'r, EPA*, No. 5:07-CV-3950-JF (N.D. Cal. Aug. 1, 2007), ECF No. 1., Dismissal Order, *United Farm Workers v. Adm'r, EPA*, No. 5:07-CV-3950-JF.
[24] *Recombinant DNA Research*, 41 Fed. Reg. 27,902 (July 7, 1976).
[25] *Foundation on Economic Trends v. Heckler*, 756 F.2d 143 (D.C. Cir. 1985).
[26] *Statement of Policy for Regulating Biotechnology Products*, 51 Fed. Reg. 23,309 (June 26, 1986).
[27] 7 U.S.C. § 7701(4).
[28] The regulations were promulgated under the authority of two predecessor statutes to the PPA, the Federal Plant Pest Act and the Plant Quarantine Act, both of which were superseded by the PPA in 2000. *See Rules and Regulations; Dep't of Agriculture; Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which are Plant Pests or Which There Is Reason to Believe are Plant Pests*, 52 Fed. Reg. 22,892, 22,892-93 (June 16, 1987) and 7 U.S.C. § 7758 (2000).
[29] *See* 7 C.F.R. § 340.1 (definition of "regulated article").
[30] FDA has broad authority under the Federal Food, Drug, and Cosmetic Act (FFDCA) to regulate the safety of GE-derived food and food ingredients, including animal feed. 21 U.S.C. § 301 et seq. FDA regulates GE crops "[u]sing a science-based approach" to ensure that "foods and ingredients made from genetically engineered plants … are safe to eat." *FDA, FDA's Role in Regulating Safety of GE Foods*, at 2, https://njfb.org/wp-content/uploads/2013/07/FDA-GE-Answers.pdf. The agency has developed a premarket consultation process to assess whether foods derived from new GE crops are substantially equivalent to foods developed through traditional plant breeding. See Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984, 22,985-86 (May 29, 1992).
[31] EPA regulates the use of pesticides in conjunction with GE crops pursuant to its authority under the FFDCA and FIFRA, 7 U.S.C. § 136 et seq.
[32] *Geertson Seed Farms v. Johanns*, No. C 06–01075 CRB, 2007 WL 518624 (N.D. Cal. Feb. 13, 2007).
[33] *Geertson Farms Inc. v. Johanns*, No. C 06–01075 CRB, 2007 WL 776146 (N.D. Cal. Mar. 12, 2007).
[34] *Geertson Seed Farms v. Johanns*, 570 F.3d 1130 (9th Cir. 2009).
[35] *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 130 S. Ct. 2743, 2761–62, 177 L. Ed. 2d 461 (2010).
[36] *Center for Food Safety v. Vilsack*, 844 F. Supp. 2d 1006 (N.D. Cal. 2012), aff'd, 718 F.3d 829 (9th Cir. 2013).
[37] *Center for Food Safety v. Vilsack*, 734 F. Supp. 2d 948 (N.D. Cal. 2010).
[38] *Center for Food Safety v. Johanns*, 451 F. Supp. 2d 1165 (D. Haw. 2006).
[39] *Center for Food Safety v. Johanns*, 310 F. App'x 964 (9th Cir. 2009).
[40] *International Center for Technology Assessment v. Johanns*, 473 F. Supp. 2d 9 (D.D.C. 2007).
[41] *Center for Biological Diversity v. APHIS*, No. 10–14175–CIV, 2011 WL 4737405 (S.D. Fla. Oct. 6, 2011).
[42] *Stauber v. Shalala*, 895 F. Supp. 1178 (W.D. Wis. 1995).
[43] *Institute for Fisheries Resources v. Price*, 3:16-cv-01574 (N.D. Cal., filed Mar. 30, 2016)
[44] *International Center For Technology Assessment v. Thompson*, 421 F. Supp. 2d 1 (D.D.C. 2006).
[45] *See, e.g.*, American Association for the Advancement of Science, *Statement by the AAAS Board of Directors On Labeling of Genetically Modified Foods* (Oct. 20, 2012), http://goo.gl/82vY0A; National Academy of Sciences, *Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects 8 (2004)*, http://goo.gl/4PlC2u; The Royal Society of Medicine, *Genetically Modified Plants and Human Health*, 101 J. of the Royal Soc. of Med. 290, 292-93 (2008), http://goo.gl/h7JAUD; National Research Council, *Genetically Modified Pest-Protected Plants: Science and Regulation* 5–6, 8 (2000), http://goo.gl/it9bfk. *See The White House, Modernizing the Regulatory System for Biotechnology Products: Final Version of the 2017 Update to the Coordinated Framework for the Regulation of Biotechnology*, at 5 (2017), https://goo.gl/GUDhQ6.

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