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BIOTECHNOLOGY INDUSTRY
ORGANIZATION, RICHARD HA,
JASON MONIZ, GORDON INOUYE
AND ERIC TANOUYE

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF HAWAI'I

HAWAI'I FLORICULTURE AND NURSERY ASSOCIATION, HAWAI'I PAPAYA INDUSTRY ASSOCIATION, BIG ISLAND BANANA GROWERS ASSOCIATION, HAWAI'I CATTLEMEN'S COUNCIL, INC., PACIFIC FLORAL EXCHANGE, INC., BIOTECHNOLOGY INDUSTRY ORGANIZATION, RICHARD HA, JASON MONIZ, GORDON INOUYE AND ERIC TANOUYE, Plaintiffs, v. COUNTY OF HAWAI'I, Defendant.	) CIVIL NO. CV_____)) COMPLAINT FOR) DECLARATORY & INJUNCTIVE) RELIEF; EXHIBIT 1

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

PRELIMINARY STATEMENT

Representatives of farmers, ranchers, and flower growers whose livelihoods depend on the cultivation and production of four major agricultural products on the Island of Hawai'i—papaya, bananas, tropical flowers, and cattle—along with five individual Big Island growers and the Biotechnology Industry Organization

(collectively, "Plaintiffs") bring this action to invalidate and enjoin the County of Hawai'i from enforcing County Ordinance 13-121 (hereinafter "Bill 113") (attached as Exhibit 1). Bill 113 severely limits and, in many cases, wholly bans the cultivation, propagation, development, and open-air testing of genetically engineered ("GE")[1] crops[2] in the County.

1. Over the past 20 years, farming GE crops has become a critical and generally accepted part of agriculture throughout the United States, including Hawai'i. Some GE crops are engineered to tolerate specific herbicides, which increases yield by making weed control simpler and more efficient. Other crops have been engineered to be resistant to specific plant diseases, insect pests, and drought. Today, the vast majority of several major U.S. crops are GE varieties, including 93% of all soybeans, 90% of all corn,

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[1] GE crops are also often referred to as genetically modified organisms ("GMOs"). Because Bill 113 used the term "genetically engineered," Plaintiffs shall use that term or the abbreviation "GE" in this Complaint.

[2] Bill 113 applies to "GE crops and plants." Plaintiffs' use of the term "GE crop" in this Complaint shall refer to both "GE crops and plants."

and 90% of all cotton.[3] And 70-80% of foods eaten in the United States contain ingredients that have been genetically engineered.[4]

2. The federal government ensures the safety of new GE crops through a comprehensive regulatory regime that coordinates the scientific safety standards of multiple federal statutes under the supervision of three expert federal agencies: the Food and Drug Administration ("FDA"), the Environmental Protection Agency ("EPA"), and the U.S. Department of Agriculture's ("USDA's") Animal and Plant Health Inspection Service ("APHIS"). Every GE crop on the market today was thoroughly evaluated, through a complex multiyear scientific federal review process. Not only have GE crops been deemed safe by expert federal agencies, but multiple other governmental and non-governmental agencies have reached the same conclusions, including the U.S. National Academy of Sciences, the World Health Organization, the American Medical Association, the European Commission, and the British Medical Association.

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[3] *See* USDA, Economic Research Service, Adoption of Genetically-Engineered Crops in the U.S., http://ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us.aspx.
[4] Grocery Manufacturers Association Position on GMOs, http://factsaboutgmos.org/disclosure-statement.

Over 600 peer-reviewed scientific reports document the safety of GE foods. These are scientific issues, and should not be political or partisan—dozens of GE crops have cleared federal review in each of the Clinton, Bush, and Obama Administrations.

3. Farming GE crops has also long been a generally accepted agricultural practice locally; indeed, GE crops have been vitally important to the County of Hawai'i. In the 1990s, one of the County's largest agricultural industries, papaya, was devastated by a particularly virulent strain of the aphid-transmitted ringspot virus. The development of a GE variety of papaya that is resistant to the virus, by researchers at the University of Hawai'i and Cornell University, is widely credited with saving the industry. And the resulting Rainbow GE variety of papaya now accounts for approximately 85% of papaya grown in the County and is widely sold throughout the United States and in other nations.

4. Other County farmers also depend on access to GE technology to help their crops thrive and to ensure that they survive the *next* virus outbreak. For example, County floriculturists and nursery owners are currently working with the U.S. Pacific Basin Agricultural Research Center ("PBARC")—a USDA research center

located on the Big Island—on developing a new GE variety of anthurium that is resistant to bacterial blight and nematodes, two prevalent plant pest risks that threaten the anthurium industry. County farmers use other GE products to increase their crop yields, control weeds, resist insect pests, and minimize use of pesticide sprays and traditional tillage practices, which, in turn, avoids or reduces potential negative environmental impacts that might result from growing non-GE crops.

5. Despite the central role of GE crops in modern commercial agriculture and their long history of safe use in this County and around the world, Bill 113 imposes a near-blanket ban on new cultivation, propagation, development, and open-air testing of such crops in the County. Bill 113 is backed by no findings or evidence that GE crops are in any way harmful, or in any way endanger the local environment. In very sharp contrast to the extensive science-based approach taken by federal regulators, Bill 113 purports to justify its ban based on the so-called "precautionary principle," which is said to require that "if a new technology poses threats of harm to human or environmental health, the burden of proof is on the promoter of the technology to

demonstrate that the technology is safe." Bill 113 § 1. But any such burden has already been met; these types of safety determinations have already been conclusively made by the federal government for commercial GE crops, and the federal government also controls exactly how, when, and where any developmental GE crop can be field tested. In short, using the "precautionary principle" as its purported predicate, Bill 113 puts the County in direct conflict with determinations made after careful consideration by expert federal agencies, and purports to outlaw agricultural activities that the federal government has specifically authorized after performing a thorough scientific review.

6. Plaintiffs represent a broad cross-section of County farmers and related businesses that rely on GE crops, as well as technology companies that develop, test, and commercialize valuable, new GE agricultural products. Bill 113 imposes extreme burdens on Plaintiffs and cripples County farmers' current and future ability to farm GE crops with no corresponding local benefit. It also violates Federal and Hawai'i law. Plaintiffs recognize that certain activists believe that all genetic engineering should be halted (indeed, there have been many reports of anti-GE vandalism and

crop destruction on the Big Island), but such beliefs cannot save Bill 113 from its multiple fatal legal flaws.

THE PARTIES

7. The Hawai'i Floriculture and Nursery Association ("HFNA") is a nonprofit trade association organized in the State of Hawai'i to promote the interests of floriculturists and nurseries, including those in the County. Plaintiff Eric Tanouye, Plaintiff Gordon Inouye, and Grayson Inouye of Plaintiff Pacific Floral Exchange, Inc. are residents of Hawai'i, owners of nurseries located in the County, and members of HFNA. In conjunction with the USDA's Agricultural Research Service and under an APHIS-authorized permit, Eric Tanouye, Grayson Inouye, and Gordon Inouye have been conducting open-air testing of a GE variety of anthurium at their nurseries. Plaintiff Gordon Inouye's nursery, Floral Resources/Hawai'i, is located on land that is owned by the State of Hawai'i. The purpose of these tests is to develop a strain of anthurium that is resistant to nematodes and bacteria—two plant pests that can wreak havoc in an anthurium nursery. Because the tropical flower industry in the County is heavily dependent on anthurium sales, the development of a GE variety of anthurium

that is tolerant to these plant pests is critical to the survival of this industry. Bill 113, however, prohibits all open-air testing of GE crops, including the testing that is occurring on Plaintiffs' property to develop a GE variety of anthurium; could expose HFNA members to fines of $1,000 per day if they continue to engage in such testing; places HFNA members squarely in the middle of a conflict between the federal and local governments; and has caused other impacts to HFNA and its members.

8. Bill 113 will also affect HFNA members' ability to continue to grow orchids in the County, another flower that is vitally important to HFNA members' businesses. Specifically, there are a number of plant pests on the Big Island that are threatening to destroy the orchid industry. While research is underway on the Big Island to develop a GE orchid that is resistant to these pests, Bill 113 prohibits HFNA members from utilizing this GE orchid when it becomes available. Bill 113 also imposes a $100 annual registration fee on Eric Tanouye, Gordon Inouye, and Pacific Floral Exchange.

9. The Hawai'i Papaya Industry Association ("HPIA") is a nonprofit trade association organized in the State of Hawai'i to

promote the interests of papaya growers and related businesses, including businesses in the County. HPIA has hundreds of members in the County, many of whom grow a variety of GE papaya known as Rainbow papaya. Although Rainbow papaya is already resistant to certain strains of the ringspot virus, it is not resistant to some other well-documented strains of the virus. It is therefore critical to County papaya growers, and their investment and planting decisions, that open-air testing and other related research of GE crops be allowed to continue in the County. While research into new GE varieties of papaya that are resistant to these strains has begun, Bill 113's prohibition on open-air testing in the County meaningfully impedes that research and creates a significant risk that these growers will not survive the next crop virus epidemic. Bill 113 also imposes a $100 annual registration fee on each of the HPIA members who grow GE varieties in the County and imposes new regulatory compliance costs without any reasonable justification. Further, Bill 113 has stigmatized HPIA members by conveying a false message that GE crops and plants harm human health and the environment, and has imposed other costs on HPIA.

10. The Big Island Banana Growers Association is a nonprofit trade association organized in the State of Hawai'i to promote the interest of banana growers in the County. Plaintiff Richard Ha is a resident of Hawai'i, a banana grower in the County, and a member of the Association. Mr. Ha and other members of the Association have had their banana crops adversely affected by the bunchy top virus and are concerned about other viruses, including Race 4 Fusarium Wilt. Research into GE banana crops that would resist these viruses have begun. But Bill 113 materially diminishes the likelihood that Mr. Ha or other Association members will benefit from this research, and has imposed other costs on the Association. Mr. Ha is also a landowner who desires to lease land to growers of GE crops but cannot do so because of Bill 113.

11. The Hawai'i Cattlemen's Council is a nonprofit trade association organized in the State of Hawai'i to promote the interests of cattlemen and ranchers, including in the County, where 60% of the State's cattle are raised. The Cattlemen's Council includes a member that grows GE crops on its property. Before the enactment of Bill 113, this member was planning to expand the acreage on its land that it devoted to growing GE crops. Bill 113,

however, prohibits any County farmer from growing new GE crops on a new location, *even on their own property.* Accordingly, Bill 113 has forced this member to abandon its plans to expand its GE crop production. In addition, many members of the Cattlemen's Council currently export their cattle to the continental United States for "finishing," the final stage of the cattle-raising process, in which cattle are fattened prior to slaughter. Others are forced to pay a premium price for imported feed. Because exporting for finishing and imported feed are both extremely expensive, certain members of the Cattlemen's Council have developed or had intended to develop a local finishing technique using County-grown GE feed products, which produce higher yield and better products on the available acreage. Without access to County-grown GE feed products, however, finishing in the County would be prohibitively expensive due to a shortage of available feed at a reasonable price. Bill 113's prohibition on the propagation, cultivation, and development of any new GE crops in the County that could serve as cattle feed has foreclosed the plans of the Council's members, and has imposed other costs on the Hawai'i Cattlemen's Council.

12. Plaintiff Jason Moniz is a resident of Hawai'i and a member of the Hawai'i Cattlemen's Council who operates a cattle ranch in the County. Mr. Moniz had specific plans to finish certain of his cattle in the County using County-grown GE corn. But Bill 113's prohibition on the propagation, cultivation, and development of any new GE crops in the County—or even the propagation, cultivation, and development of *existing* GE crops by a *different* person or at a *different* location—eliminates Mr. Moniz's opportunity to implement these plans.

13. BIO is the world's largest biotechnology trade association. Headquartered in Washington, D.C., BIO provides advocacy, business development, and communications services on behalf of its more than 1,200 members, including corporate entities (from entrepreneurial start-ups to Fortune 500 multi-nationals), academic institutions, state biotechnology centers, and related organizations in all fifty U.S. states and thirty-three foreign nations. BIO has taken the lead in promoting the safety and benefits of GE crops. BIO advocates for scientific regulatory approaches for these crops both domestically and abroad, while also supporting the concurrent cultivation of conventional and organic crops. BIO's

members include HPIA. By prohibiting the propagation, cultivation, or development of new GE crops and all open-air field testing in the County, Bill 113 prevents BIO's members from expanding their efforts to grow, sell, or use GE crops in the County.

14. Defendant County of Hawai'i is a political subdivision of the State of Hawai'i. Its powers are governed by Article VII of the Constitution of the State of Hawai'i and Hawai'i state laws, including Hawai'i Revised Statutes Chapter 46.

15. As a political subdivision of the State of Hawai'i, organized and operated under the laws of the State of Hawai'i, the County and its governing officials were acting, in all respects and at all relevant times, under color of law in adopting Bill 113.

JURISDICTION AND VENUE

16. This Court has subject matter jurisdiction over Plaintiffs' claims pursuant to 28 U.S.C. §§ 1331, 1337(a), and 1343(a)(3).

17. This Court also has jurisdiction under 28 U.S.C. § 1367(a) because the claims that arise under Hawai'i law are so closely related to the claims which are otherwise within this Court's jurisdiction that they form part of the same case or controversy.

18. Venue is proper in this District pursuant to 28 U.S.C.

§ 1391(b) because Bill 113 was enacted in this District and a substantial part of the events giving rise to the claims occurred in the District.

FACTS AND BACKGROUND INFORMATION

Federal Regulation of GE Crops

The Coordinated Framework

19. Recognizing "[t]he tremendous potential of biotechnology to contribute to the nation's economy in the near term, and to fulfill society's needs and alleviate its problems in the longer term," the federal government created the Coordinated Framework in 1986 to provide a "coordinated and sensible regulatory review process" governing biotechnology in the United States. Proposal for a Coordinated Framework for Regulation of Biotechnology, 49 Fed. Reg. 50,856-50,857 (Dec. 31, 1984); *see also* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (June 26, 1986) . The Coordinated Framework is founded on three federal statutes. Under those statutes, three federal agencies—FDA, EPA, and USDA—have well-defined roles in the Coordinated Framework and exercise expert scientific judgment.

20. This comprehensive statutory and regulatory regime

establishes a uniform approach to GE crops that ensures regulatory decisions are "based upon the best available science." 49 Fed. Reg. at 50,857. Since its creation three decades ago, the framework has been formalized by regulation and affirmed by Congress.[5] To date, more than 100 GE crops have cleared the thorough federal review required by the Coordinated Framework.

21. Open-air field testing is an integral part of the development of improved plant varieties under these coordinated regulatory processes, and the typical GE crop requires many years of field testing and scientific analysis to clear the required regulatory hurdles. When a GE crop successfully completes federal scientific reviews, the crop is deemed the same as its non-GE counterparts for federal regulatory purposes. To understand the full scope of federal regulatory review requires a detailed discussion of each of the USDA, EPA and FDA processes.

USDA Regulation

22. USDA regulates GE crops pursuant to its authority under

[5] In the years since the Coordinated Framework was created, Congress has amended or reauthorized each of the subject statutes underlying the Framework, ratifying without change the Framework's use of each of these authorities.

the Plant Protection Act ("PPA"). The PPA grants USDA primary authority to regulate the "movement in interstate commerce" of all plant pests in the United States. 7 U.S.C. § 7711. In conferring this authority upon USDA, Congress found that "all plant pests, . . . plants, plant products, articles capable of harboring plant pests . . . are in or affect interstate commerce . . ." 7 U.S.C. § 7701(9). The PPA, like the Coordinated Framework, emphasizes that regulatory decisions must "be based on sound science." 7 U.S.C. § 7701(4). Plant pests—including fungi, disease, virus, insects, and bacteria—can have severe effects on plants and agricultural practices, and Congress gave USDA specific authority to address these issues.

23. The PPA reflects a Congressional determination that plant protection is a national problem that warrants a uniform, national solution. To that end, the PPA expressly preempts states and their political subdivisions from regulating "the movement in interstate commerce of any article, . . . plant, plant pest, . . . or plant product in order to control . . . , eradicate . . ., or prevent the introduction or dissemination of a . . . plant pest, . . . if [USDA] has issued a regulation or order to prevent the dissemination of the . . .

plant pest . . . within the United States." 7 U.S.C. § 7756(b).

24. The PPA's express preemption clause contains two exceptions, neither of which has been satisfied by the County. *Id.* The first exception authorizes states and political subdivisions to regulate in the field of plant protection ***if*** the Secretary finds that those regulations are "consistent with and do not exceed" regulations issued by the USDA. *Id.* The second exception authorizes States and political subdivisions to regulate ***if*** they petition USDA for permission ***and*** the Secretary agrees "that there is a special need for additional prohibitions or restrictions based on scientific data or a thorough risk assessment." *Id.*

25. Pursuant to its plant protection authorities, APHIS has promulgated a comprehensive regulatory scheme at 7 C.F.R. Part 340 governing organisms and products altered or produced through genetic engineering which are plant pests or which there is reason to believe are plant pests. The APHIS regulations prohibit the "introduction" (*i.e.*, the importation, interstate movement, and release into the environment) of plant pests, or other "regulated articles," without approval from APHIS. 7 C.F.R. §§ 340.0(a), 340.1. New GE crops are generally treated as "regulated articles" because

they are presumed to be plant pests until APHIS determines, based on a detailed scientific review, that the specific GE plant is "unlikely to pose a greater plant pest risk than the unmodified organism from which it is derived." *Id.* § 340.6(c)(4). As part of its assessment, APHIS analyzes data from field trials of the new GE crop and conducts an extensive scientific review of the plant, including its genetic structure and plant pest potential. *See id.* § 340.6.

26. Data gathered from open-air field trials are necessary for APHIS to assess whether a new GE crop poses plant pest risks. The introduction of a regulated article for a field trial or any other purpose is subject to APHIS's permitting authority. 7 U.S.C. § 7711(a). APHIS's regulations establish a detailed permitting regime for conducting field trials that yield this type of data, including specific provisions regarding how the GE material must be handled and moved. 7 C.F.R. § 340.3-.4. The regulations provide two procedural options for applicants to request APHIS's authorization for the introduction of a regulated article—"permits" and "notifications."

27. To obtain a permit to conduct a field trial, an applicant must submit an application detailing, among other things: (1) "the

molecular biology of the system (e.g., donor-recipient-vector) which is or will be used to produce the regulated article"; (2) "the processes, procedures, and safeguards which have been used or will be used in the country of origin and in the United States to prevent contamination, release, and dissemination in the production of . . . [the] regulated article"; (3) "any biological material (e.g., culture medium, or host material) accompanying the regulated article during movement"; and (4) "the proposed method of final disposition of the regulated article." *Id.* § 340.4(b). Upon receipt of an application, APHIS commences a 120-day review period. As part of this review, APHIS may inspect the site or facility where the applicant proposes to release the regulated articles. *Id.* § 340.4(d). APHIS also sends the completed application, along with its initial review, to the relevant state department of agriculture. *Id.* § 340.4(b).

28. If APHIS issues a permit, the permit holder must comply with specific conditions set out in 7 C.F.R. § 340.4(f), including: (1) maintaining and disposing of the regulated article "in a manner so as to prevent the dissemination and establishment of plant pests"; (2) keeping the regulated article "separate from other organisms,

except as specifically allowed in the permit"; (3) maintaining the regulated article only in areas and premises specified in the permit; and (4) any other conditions "as deemed . . . necessary to prevent the dissemination and establishment of plant pest." *Id.* The permit holder must also provide a report of the field test to APHIS that includes, among other things, "analysis regarding all deleterious effects on plants, nontarget organisms, or the environment." *Id.* § 340.4(f)(9).

29. APHIS's notification procedure is available only for field trials of regulated articles that meet a series of rigorous requirements set forth in 7 C.F.R. § 340.3. APHIS reviews each notification and advises the notifier within 30 days if it is appropriate to conduct the field trial under notification. *Id.* § 340.3(e)(4). APHIS reviews detailed design protocols for the proposed field trials that demonstrate how the trial will meet regulatory performance standards.[6] If a notification is denied by APHIS, the entity can apply for a permit with additional or different

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[6] *See* APHIS, *Notification User Guide* at 17-18 (Mar. 2011), http://www.aphis.usda.gov/biotechnology/downloads/notification_guidance_0311.pdf.

regulatory requirements. *Id.* § 340.3(e)(5).

30. The requirements and performance standards in 7 C.F.R. § 340.3 are designed to prevent the dissemination of plant pests during the field trial phase by, among other things, requiring that regulated articles "be planted in such a way that they are not inadvertently mixed with non-regulated plant materials of any species which are not part of the environmental release," and requiring that "plants and plant parts . . . be maintained in such a way that the identity of all material is known while it is in use, and the plant parts must be contained or devitalized when no longer in use." *Id.* § 340.3(c). Any entity that introduces a regulated article under APHIS's notification procedures must provide a report of its field tests to APHIS, including "analysis regarding all deleterious effects on plants, nontarget organisms, or the environment." *Id.* § 340.3(d)(4). APHIS personnel periodically inspect ongoing regulatory trials to ensure compliance. *Id.* § 340.3(d)(6). And USDA has authority to take a range of remedial actions to address any violations. *Id.* § 340.0(b) & n.2.

31. USDA has made clear that its regulations preempt inconsistent state and local laws. For example, in its Federal

Register notice accompanying the proposed rule that it issued on November 6, 1992 governing the notification procedures, USDA stated that "[t]his rule would preempt any State or local laws, regulations, or policies that are inconsistent with this rule."[7] Similarly, in the Federal Register notice accompanying the final rule, USDA explained "that where the Secretary of Agriculture has established an interstate ... regulation [under the Federal Plant Pest Act or the Federal Plant Quarantine Act[8]], neither the States nor Territories can establish additional requirements concerning the particular subject matter regulated thereby" if those requirements are "different than, or otherwise inconsistent with, the provisions of the" federal rule.[9] The States play a role in the regulation of these GE crops by consulting with USDA, but they may not enact

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[7] Genetically Engineered Organisms and Products; Notification Procedures for the Introduction of Certain Regulated Articles; and Petition for Nonregulated Status, 57 Fed. Reg. 53,036, 53,040 (Nov. 6, 1992).

[8] The Federal Plant Pest Act and the Federal Plant Quarantine Act were the predecessor statutes to the Plant Protection Act. The Plant Protection Act consolidated these two statutes (and other plant-related statutes) into one statute. 7 U.S.C. § 7701 *et seq.*

[9] Genetically Engineered Organisms and Products; Notification Procedures for the Introduction of Certain Regulated Articles; and Petition for Nonregulated Status, 58 Fed. Reg. 17,044, 17,053-54 (Mar. 31, 1993).

conflicting local laws. *Id.*; *see also* 7 C.F.R. §§ 340.3(e), 340.4(b), (c). "[I]t is APHIS' expectation that the process established under [the notification] rule will enable, with continued cooperation by the States, identification and communication of any issues of state or local concern, *so that those issues will be directly considered as part of the Federal actions* under notification."[10]

32. As part of its regulatory program, APHIS has developed a specific process for consulting with State Departments of Agriculture regarding proposed permits and notifications. APHIS invites review by State officials prior to making its decision on the requirements and conditions to impose on regulated field trials, but retains discretion on whether to accept any comments received from the State. 7 C.F.R. § 340.3(e)(1), .4(b). Indeed, APHIS regularly considers any comments of the Hawai'i Department of Agriculture as APHIS addresses pending permits and notifications. APHIS does not have any process for considering any comments or input by individual counties within a state.

33. If the field trials conducted in accordance with APHIS's

[10] 58 Fed. Reg. at 17,054 (emphasis added).

regulations indicate that the GE crop variety poses no more plant pest risks than its non-GE counterparts, an individual may petition APHIS by presenting significant field trial data and other scientific support for a determination of "nonregulated status." APHIS generally considers these voluminous petitions for multiple years, publishes preliminary draft determinations, and considers public comments before reaching a final scientific conclusion. APHIS's action to deregulate a GE crop is a regulatory determination that the GE crop may be used in the United States in the same way as its non-GE counterparts, including for commercial purposes. *See* 7 C.F.R. § 340.6.

EPA Regulation

34. EPA regulates GE crops in three ways, pursuant to its authority under the Federal Food, Drug, and Cosmetic Act ("FFDCA") and the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). First, under the FFDCA, EPA specifies the amount of pesticidal residue that may legally remain in or on foods, before a pesticide may be used on any food crop (GE or non-GE). *See* 21 U.S.C. § 346a. The FFDCA expressly preempts inconsistent state actions regarding such FFDCA tolerances, but allows States to

petition EPA for a local exception if a compelling need exists. *Id.* § 346a(n)(4)–(5).

35. Second, under FIFRA, EPA must approve any pesticide before it may be marketed or used on *any* crop (GE or non-GE, food or not) in the U.S. *See* 7 U.S.C. §§ 136a(c)(5), 136j(a)(1). EPA evaluates new proposed pesticides using a science-based review process designed to ensure that the pesticide will not have "unreasonable adverse effects on the environment" or "human dietary risk." 7 U.S.C. §§ 136(bb), 136a. The agency's review includes the pesticide's complete formula, its use on a particular crop, and its label. *See generally* 7 U.S.C. § 136a; 40 C.F.R. pt. 152. FIFRA expressly preempts States from imposing labeling requirements "in addition to or different from" those required under FIFRA. 7 U.S.C. § 136v(b).

36. Third, some GE crops have been genetically modified to produce so-called "Plant-Incorpo*rat*ed Protectants" ("PIPs"), typically proteins th*at* have a pesticidal effect when eaten by insects. The purpose of PIPs is to protect the plants from insect pests without the need for traditional pesticide applications. EPA has established a detailed and comprehensive regulatory regime, under FIFRA and

the FFDCA, to govern the approval process for PIPs that is based on strict scientific standards and extensive input from acad*emia, industry*, other Federal agencies, and the public. *See* Regulations Under [FIFRA] for Plant-Incorporated Protectants (Formerly Plant-Pesticides), 66 Fed. Reg. 37,772 (July 19, 2001); *see generally* 40 C.F.R. pt. 174. EPA is authorized to grant experimental use permits for PIPs during the developmental stage of those crops to allow prospective registrants to generate the data EPA needs to evaluate new pesticide registrations. If appropriate, EPA specifically approves PIP field trials under carefully controlled conditions.

FDA Regulation

37. FDA has broad authority under the FFDCA to regulate the safety of 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."[11] The agency has developed a premarket consultation process to assess whether

[11] FDA's Role in Regulating Safety of GE Foods, *available at* http://www.fda.gov/forconsumers/consumerupdates/ucm352067.htm.

foods derived from new GE crops are substantially equivalent to foods developed through traditional plant breeding.[12] FDA's analysis includes considering whether the foods differ in toxicants, nutrient concentrations, or allergenicity.[13] All GE crops on the market have cleared this FDA review.

Other Federal Regulatory Programs

38. In addition to the core statutory authorities that serve as the foundation of the Federal Coordinated Framework, other laws also address how farmers may market and sell various types of seed crops.[14] Congress has, for instance, made a deliberate decision to regulate issues of genetic purity through labeling standards. Under the Federal Seed Act, farmers may market their seed as "certified," "registered" or "foundation" seed if it meets specific standards for varietal purity (based on a lack of cross-pollination), typically ranging from 99.0% to 99.9%. *See generally* 7 C.F.R. pt. 201. Typically, neighboring seed crop farmers who wish to sell genetically

[12] *See* FDA, Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,985-87 (May 29, 1992).

[13] *See id.*

[14] "Seed crops" (as distinguished from crops grown for food or feed) are crops grown to produce seed that farmers in turn plant to grow other crops. Typically, "seed crops" comprise only a very small percentage of all crop acreage.

pure seed varieties work together to establish appropriate isolation distances between their crops to minimize cross-pollination. USDA also administers the National Organic Program under the Organic Foods Production Act ("OFPA"). *See generally* 7 U.S.C. §§ 6501–22. Under that program, certified organic farmers cannot intentionally plant GE seed and then market the resulting crop as "organic."

International Treaty Obligations Regarding GE Crops

39. The federal government's commitment to a science-based regulatory approach for GE crops extends beyond domestic law. In 1994, the United States, along with 123 other countries around the world, entered into the World Trade Organization's ("WTO's") Agreement on the Application of Sanitary and Phytosanitary Measures (the "SPS Agreement"). In so doing, the United States promised the international community that any U.S. law or regulation—national or local—enacted "to protect animal or plant life or health . . . from risks arising from the . . . spread of pests, diseases, disease-carrying organisms or disease-causing organisms" or "to protect human or animal life or health . . . from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs" would only be "*based on scientific*

principles" and would not be "maintained without *sufficient scientific evidence.*" SPS Agreement, art. 2.2, annex A (emphasis added); *see id.*, art. 13.

40. The United States takes this obligation seriously. For example, after the European Communities (EC) refused to approve the use of any new GE crops for use throughout the European Union from 1999-2003, the United States brought a successful challenge before the WTO.[15] The United States alleged that the *de facto* moratorium on GE crops violated the EC's obligations under the SPS Agreement—obligations that match our own.[16] The WTO panel agreed. When the EC defended the moratorium based in part on the "precautionary principle," the United States called the EC's statements about "the purported risks of biotechnology" "fundamentally misleading."[17] The United States explained:

> The safety of biotech products has been confirmed by scientific reports issued under the auspices of renowned international institutions, such as the FAO and WHO, seven

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[15] Panel Report, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS291/R, WT/DS292/R, WT/DR293/R 1 (Sept. 29, 2006).
[16] *Id.*
[17] *Id.* at 99.

> national and international academies of science, and the Organization for Economic Co-operation and Development, as well as independent scientists in the United States, Africa and Europe."[18]

Even the scientific advisory bodies of the European Union, it added, "have also confirmed the conclusion that, for both food and environmental risks, plants produced through modern biotechnology do not present new or novel risks."[19] In light of these studies, the United States concluded, the "notion of precaution" could not justify an across-the-board moratorium on new GE crops.[20]

State of Hawai'i Regulation of Agriculture and Farming

41. Consistent with the federal government's approach, the State of Hawai'i has deemed the promotion of "diversified agriculture" a vital public interest. This principle is enshrined in the Constitution of Hawai'i, which expressly directs the State—not the counties—to conserve and protect agricultural and farming resources. Article XI, § 3 of the Hawai'i Constitution provides:

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[18] *Id.* at 29.
[19] *Id.* at 100.
[20] *Id.* at 101.

> The State shall **conserve and protect agricultural lands, promote diversified agriculture**, increase agricultural self-sufficiency and **assure the availability of agriculturally suitable lands.** The **legislature** shall provide standards and criteria to accomplish the foregoing.

(emphasis added).

42. To effectuate Article XI, § 3, the State legislature has enacted a number of statutes to protect and preserve agricultural and farming resources, including the Hawai'i Right-to-Farm Act, the Hawai'i State Planning Act, the Hawai'i Agribusiness Development Corporation Statute, and the Hawai'i Pesticides Law.

43. The Hawai'i Right-to-Farm Act broadly declares a state policy under which "[t]he preservation and promotion of farming is . . . in the public purpose and deserving of public support." Haw. Rev. Stat. § 165-3. To promote this statutory policy, the Right-to-Farm Act specifies that "[n]o court, official, public servant, or public employee shall declare any farming operation a nuisance for any reason if the farming operation has been conducted in a manner consistent with generally accepted agricultural and management practices." *Id.* § 165-4.

44. The Hawai'i State Planning Act creates a State-level plan

"to improve coordination among different agencies and levels of government, to provide for wise use of Hawaii's resources and to guide the future development of the State." *Id.* § 226-1. The State Planning Act also specifically details the State's objectives with regard to agriculture and the specific State policies to achieve these agricultural objectives. *Id.* § 226-7.

45. The State legislature enacted the Agribusiness Development Corporation Statute to "create a vehicle and process to make optimal use of agricultural assets for the economic, environmental, and social benefit of the people of Hawaii." *Id.* § 163D-1. The law "establishes a public corporation to administer an aggressive and dynamic agribusiness development program." *Id.* The corporation is required to "prepare the Hawai'i agribusiness plan which shall define and establish goals, objectives, policies, and priority guidelines for its agribusiness development strategy." *Id.* § 163D-5.

46. The Hawai'i Pesticides Law sets forth a comprehensive pesticide regulatory scheme that broadly governs the registration, licensing, and use of all pesticides sold and used in the state. Haw. Rev. Stat. Ch. 149A. The Pesticides Law grants authority to

the Hawai'i Department of Agriculture ("HDOA") to promulgate regulations to implement the law and specifically confers on HDOA the authority to establish procedures for the registration of pesticides under § 24(c) of FIFRA. *Id.* §§ 149A-3 & 149A-19.

47. Further, under Article XI, § 5 of the Hawai'i Constitution, all legislative power over lands owned by or under the control of the State and its political subdivisions can be exercised only by general laws. Therefore the County may not enact any ordinance such as Bill 113 to the extent it would affect agricultural practices on state-owned lands.

County of Hawai'i Bill 113

48. The December 5, 2013 County ordinance at the center of this dispute stands in stark contrast to the careful, case-by-case, science-based federal regulatory scheme and the State's respect for and protection of generally accepted agricultural practices. Contrary to federal and Hawai'i law, Bill 113 severely limits the diversity of agriculture within the County, bans longstanding and valuable agricultural practices on which County farmers depend, sets agriculture policy based on conjecture rather than "sound science," and undermines—rather than promotes—agricultural

biotechnology.

49. Bill 113 imposes a general prohibition on the open-air cultivation, propagation, development, and testing of genetically engineered crops or plants. Bill 113 § 3, Haw. County Code § 14-130. This general prohibition applies regardless of whether the federal government has approved a regulatory field trial or granted deregulation of a GE crop, and entirely ignores applicable provisions of federal and state law. The County prohibition is subject to only three narrow exemptions. First, Bill 113 exempts persons engaged in the open-air cultivation, propagation, and development of deregulated GE papaya. Bill 113 § 3, Haw. County Code § 14-131. Second, Bill 113 includes a grandfathering provision that exempts persons who were engaged in the open-air cultivation, propagation, and development of deregulated GE crops before the enactment of the Bill, "but only in those specific locations where genetically engineered crops or plants have been customarily open air cultivated, propagated, or developed by that person." *Id.* Third, Bill 113 allows any person engaged in the cultivation, propagation, or development of a non-genetically engineered crop or plant that is being harmed by a plant pestilence to apply to the

County Council for an "emergency exemption," which is available in very limited circumstances and only after substantial harm has been caused to the person seeking the exemption. Bill 113 § 3, Haw. County Code § 14-132. The Council "may"—but is not required to—grant an emergency exemption by way of resolution after finding that: (1) "[t]he cited plant pestilence is causing substantial harm to that person's crop or plant; (2) "[t]here is no other available alternative solution"; and (3) "[a]ll available measures will be undertaken to insure that non-genetically engineered crops and plants, as well as neighboring properties and any water sources, will be protected from contamination or any other potentially adverse effects that may be caused by the genetically engineered organism or associated pesticides." *Id.* None of these exemptions allows open-air *testing* of GE crops (i.e., federally regulated field trials) of any kind. *Id.*; Haw. County Code § 14-131.

50. Persons exempt from Bill 113's prohibition on GE crops and plants must register with the County's Department of Research and Development and pay a $100 annual fee. *Id.*; Haw. County Code § 14-133.

51. The stated purpose of Bill 113 is to protect local non-GE plants and "to preserve Hawai'i Island's unique and vulnerable ecosystem while promoting the cultural heritage of indigenous agricultural practices." Bill 113 § 3, Haw. County Code § 14-128. However, Bill 113 is not backed by scientific evidence or factual findings of any risk posed by GE crops of any kind. Bill 113's "findings" section asserts that the Council determined that it is necessary to ban GE crops in its "trustee capacity" under the so-called "precautionary principle," which has no basis in federal law. Bill 113 § 1. The precautionary principle, according to Bill 113, "requires that if a new technology poses threats of harm to human or environmental health, the burden of proof is on the promoter of the technology to demonstrate that the technology is safe, not on the public or governments to demonstrate that the technology is unsafe." *Id.* Although this precautionary principle, by its own terms, applies only to "new" technologies that "pose[] threats of harm to human or environmental health," Bill 113 makes no findings and cites no evidence that the GE crops it bans (*i.e.*, nearly all GE crops in the County) pose any such threat. Nor does Bill 113 acknowledge, much less rebut, the contrary findings of federal

regulators based on their experience with GE crops since the 1980s. Without acknowledging these findings, the Council indicated that it should act "without having to first wait for definitive science." *Id.*

52. Any person who violates any provision of Bill 113 is guilty of a "violation," and upon conviction thereof, is subject to a fine of up to $1,000 for each "separate violation." Bill 113 § 3, Haw. County Code § 14-134. Bill 113 defines a "separate violation" as "each and every day a violation of this article is committed, continued, or permitted for each location." *Id.*

CAUSES OF ACTION

FIRST CAUSE OF ACTION
PREEMPTION UNDER FEDERAL LAW

53. Plaintiffs reallege and incorporate by reference herein all preceding paragraphs in this Complaint.

54. The Supremacy Clause of the United States Constitution provides that "the Laws of the United States . . . shall be the supreme Law of the Land." U.S. Const., Art. VI, cl. 2. Under the Supremacy Clause, state and local laws that conflict with federal law are preempted and are thus without effect. Preemption can be express, as when a federal law declares that it preempts state or

local laws, or implied. State or local laws are impliedly preempted whenever Congress has demonstrated an intent to "occupy the field" of that regulatory area, or to the extent that the local law conflicts in its operation with federal law. Specifically, implied conflict preemption can arise when a state or local law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

55. Through the PPA, FIFRA, the FFDCA and its coordinated regulatory framework, the federal government regulates the development, field testing, and commercial introduction of GE crops. Each crop is field tested under detailed USDA and/or EPA permitting and regulatory processes before it can be commercialized. Following years of field trials and regulatory review, expert scientists at USDA, EPA, and FDA make specific scientific judgments regarding the GE crops. In short, none of the GE crops at issue here can be grown in any open-air context—either in a field trial or commercially—without prior federal government review and authorization.

56. By enacting Bill 113, the County of Hawai'i has chosen to disregard and indeed specifically contradict the regulatory and scientific judgments of these federal agencies. Ignoring the specific controlling scientific determinations by the federal government, the County purports to rely instead on its own version of a "precautionary principle"—postulating without explanation or factual support that the federal government must be incorrect in its scientific and regulatory judgments.

57. Bill 113 thus regulates on matters specifically addressed by the detailed federal regime, expressly banning what federal law expressly allows. And Bill 113 stands as an obstacle to the accomplishment and execution of the purposes of federal law, which are to evaluate GE crops "based upon the best available science" and to treat them the same as their non-GE counterparts when they pose no unique risks. Bill 113's regulation of the open-air testing, cultivation, propagation, and development of GE crops in the County is expressly and/or impliedly preempted by federal law.

SECOND CAUSE OF ACTION
PREEMPTION UNDER STATE LAW

58. Plaintiffs reallege and incorporate by reference herein all relevant preceding paragraphs in this Complaint.

59. The Hawai'i Constitution vests exclusive authority over agriculture at the state level, specifying that "[t]he *State* shall conserve and protect agricultural lands, promote diversified agriculture, increase agricultural self-sufficiency and assure the availability of agriculturally suitable lands." Hawai'i Const. Art. XI, § 3 (emphasis added). In addition, that provision specifies that "[t]he *legislature*"—not the counties or any other governmental unit or authority—"shall provide standards and criteria to accomplish the foregoing." *Id.* (emphasis added).

60. The Legislature has fulfilled this obligation by enacting a series of statutes to protect and preserve the State's agricultural and farming resources. Among other things, the Legislature created the Hawai'i Department of Agriculture, and gave it comprehensive regulatory authority over agriculture and farming. *See generally* Haw. Rev. Stat. Ch. 141. In addition, as relevant here, the Legislature enacted, among other things, the Right to Farm Act, the State Planning Act, the Agribusiness Development Corporation Statute, and the Pesticides Law.

61. Bill 113 is invalid as unauthorized and/or preempted by the Hawai'i Constitution and statutes. Section 50-15 of Hawai'i's Revised Statutes "expressly reserve[s] to the state legislature the power to enact all laws of general application throughout the State on matters of concern and interest ... and neither a charter nor ordinances adopted under a charter shall be in conflict therewith." *Id.* And Section 46-1.5(13) further indicates that a county is without power to enact ordinances "inconsistent with, or tending to defeat, the intent of any state statute," and that a county may not legislate on a subject within the purview of a state statute "where the statute ... disclose[s] an express or implied intent that the statute shall be exclusive or uniform throughout the State." Bill 113 expressly seeks to regulate agriculture, which is the exclusive province of the Legislature, and has been comprehensively regulated by the Legislature on a statewide basis. Bill 113 usurps the State's constitutional power and responsibility to establish standards and criteria to promote diversified agriculture and accomplish other purposes relating to agriculture and farming in the State.

62. Further, under Article XI, § 5 of the Hawai'i Constitution,

all legislative power over lands owned by or under the control of the State and its political subdivisions can be exercised only by general laws. Some of the property Plaintiffs use or intend to use in Hawai'i County to grow GE crops is owned by the State of Hawai'i. Bill 113 is also invalid to the extent that it seeks to regulate agricultural practices on state-owned lands.

THIRD CAUSE OF ACTION
VIOLATION OF THE INTERSTATE COMMERCE CLAUSE
OF THE UNITED STATES CONSTITUTION

63. Plaintiffs reallege and incorporate by reference herein all relevant preceding paragraphs in this Complaint.

64. The Commerce Clause gives Congress the power "to regulate Commerce ... among the several states." U.S. Const., Art. I, § 8, cl. 3. The Supreme Court has long recognized that this grant of power contains an implicit "dormant" aspect that precludes state and local governments from regulating or otherwise unreasonably burdening interstate commerce.

65. Congress declared in the PPA that "all plant pests, noxious weeds, plants, plant products, articles capable of harboring plant pests . . . are in or affect interstate commerce." 7 U.S.C. § 7701(9).

66. Bill 113 unconstitutionally burdens interstate commerce in GE crops and plants by prohibiting the open air cultivation, propagation, development, or testing of such crops and plants except to the extent that such crops and plants were customarily open air cultivated, propagated, or developed by a particular person in a particular location before the Bill's effective date. Bill 113's impact on interstate commerce is substantial—it outright bans any new development of an aspect of interstate commerce within the County's borders—whereas the Bill's putative local benefits are illusory—especially because Bill 113 acknowledges that the County cannot identify any actual harm from GE crops and plants, and indeed the Bill "grandfathers" in existing GE cultivation, propagation, and development.

67. Plaintiffs are entitled to relief for the County's violations of the Interstate Commerce Clause pursuant to 42 U.S.C. § 1983.

FOURTH CAUSE OF ACTION
REGULATORY TAKING IN VIOLATION OF
THE CONSTITUTION OF HAWAI'I

68. Plaintiffs reallege and incorporate by reference herein all relevant preceding paragraphs in this Complaint.

69. Article I, § 20 of the Hawai'i Constitution provides that "[p]rivate property shall not be taken or damaged for public use without just compensation." Under this constitutional principle, a governmental body can take or damage private property, but is subject to the requirements of a "public purpose" and "just compensation" to the property owner.

70. Bill 113 represents a regulatory "taking" because it will deprive Plaintiffs and other landowners of substantial economic value, the economically beneficial or productive use of their land, or both. Specifically, Plaintiffs are prohibited from using their land to cultivate, propagate, and develop GE crops that do not fall within Bill 113's exemptions. Plaintiffs are also prohibited from conducting open-air testing of GE crops or allowing their property to be used for open-air testing of GE crops.

71. Bill 113 establishes no way by which these land use restrictions may avoid confiscatory or otherwise excessively burdensome results. Bill 113 does not establish any procedure, much less a constitutionally adequate procedure, for obtaining just compensation for applications of Bill 113 that trigger the Hawai'i Constitution's provision entitling property owners and lessees to

just compensation, notwithstanding the substantial takings liability that Bill 113 imposes on the County by virtue of its unconstitutional sweep.

72. Furthermore, Bill 113 defeats the reasonable investment-backed expectations of Plaintiffs to use their lands as intended because Plaintiffs not currently growing GE crops or leasing their land to others to grow GE crops but wishing to do so in the future are prohibited from growing or allowing others to grow most GE crops.

73. Because the County has engaged in a regulatory taking and has not offered to compensate any of the Plaintiffs for taking or damaging their property or even created a procedure by which affected individuals can seek just compensation, Bill 113 is invalid under the Takings Clause of the Constitution of Hawai'i both on its face and as applied to Plaintiffs.

REMEDY: DECLARATORY RELIEF

74. Plaintiffs reallege and incorporate by reference herein all relevant preceding paragraphs in this Complaint.

75. Plaintiffs seek declaratory relief pursuant to 28 U.S.C. § 2201, and for further necessary and proper relief pursuant to 28

U.S.C. § 2202.

76. There is a real, present, and genuine dispute between Plaintiffs and the County regarding Plaintiffs' rights and remedies under Bill 113, and under the Constitutions and laws of the United States and the State of Hawai'i, as alleged above, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment. There is uncertainty about the legality of Bill 113 and the Plaintiffs' alleged obligations thereunder. Further, as alleged herein, Bill 113 is causing Plaintiffs substantial harm.

77. Plaintiffs are entitled to a declaratory ruling establishing that Bill 113 is illegal and invalid, as alleged herein.

REMEDY: INJUNCTIVE RELIEF

78. Plaintiffs reallege and incorporate by reference herein all relevant preceding paragraphs in this Complaint.

79. Bill 113 violates the Constitutions and applicable laws of the United States and the State of Hawai'i, as alleged herein. Accordingly, Plaintiffs seek injunctive relief pursuant to this Court's general jurisdiction and the applicable portions of Title 28 of the United States Code.

80. If the County is not enjoined from enforcing Bill 113,

Plaintiffs and their members will continue to suffer various serious and irreparable injuries, including: (1) the inability to pursue their livelihoods of farming, cultivating flowers, and ranching using generally accepted agricultural practices; (2) harm to the reputation and goodwill of Plaintiffs who sell and market GE products, inside and outside of the County; (3) economic harm to Plaintiffs who may no longer begin or expand cultivation of GE crops; (4) the impairment of the advancement of useful scientific knowledge of great concrete benefit to Plaintiffs and their members, including research on and development of new varieties of plants and crops resistant to virus strains and other harmful plant diseases; (5) substantially increased costs of cattle feed and other products; and (6) the impairment of Plaintiffs' ability to continue to grow and deliver GE crops to their customers.

WHEREFORE, Plaintiffs pray that this Court:

A. Take jurisdiction over the parties and this cause;

B. Enter a judgment declaring Bill 113 to be invalid under the laws of the United States and the State of Hawai'i;

C. Enter an injunction enjoining the County and its agents and employees from enforcing Bill 113;

D. Enter a judgment declaring that any taking by the County through Bill 113 requires just compensation.

E. Award Plaintiffs their reasonable attorneys' fees and costs; and

F. Grant Plaintiffs all other relief in law and in equity to which they may be entitled.

Dated: Honolulu, Hawai'i, June 9, 2014.

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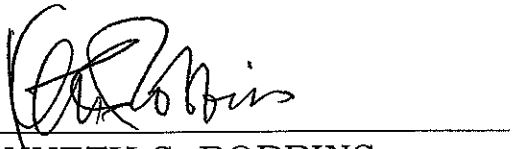

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