In the Know—Emerging Environmental Legal Challenges and Issues from an In-house Perspective

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I. CERCLA Statute of Limitations: A Chill is in the Air for Settling PRPs

A trend has emerged in the past few years in which courts are broadly interpreting and applying the CERCLA's three-year statute of limitations provision, resulting in early dismissals of contribution claims. Potentially responsible parties ("PRPs") on both sides of the caption are feeling the significant effect of this emerging and liberal interpretation of CERCLA. PRPs on the plaintiff side have experienced a chilling effect on their ability to recover response costs, as the three-year statute of limitations for CERCLA contribution claims now proves to be a problematic preliminary hurdle for PRPs who are seeking contribution for response costs incurred under any Administrative Settlement Agreement and Order on Consent ("AOC") entered into with the United States Environmental Protection Agency ("EPA") or similar state agencies. Some of these PRP plaintiffs are also seeing contribution claims dismissed as untimely, even when the costs were incurred under a private settlement agreement that was approved by a court. On the flip side, PRP defendants in CERCLA cases are successfully achieving early dismissals based on application of this liberal interpretation of the three-year CERCLA statute of limitations.

CERCLA §113(g)(3) provides: "No action for contribution for any response costs or damages may be commenced more than 3 years after (A) the date of judgment in any action under this chapter for recovery of such costs or damages, or (B) the date of an administrative order under section 9622(g) of this title (relating to de minimis settlements) or 9622(h) of this title (relating to cost recovery settlements) or entry of a judicially approved settlement with respect to such costs or damages." 42 U.S.C. §9613(g)(3). Historically, PRP plaintiffs have typically argued that the three-year statute of limitations does not apply absent the clear occurrence of one of the "triggering events" enumerated in Section 113(g)(3). In other words, the PRP plaintiff contends that this three-year limitation period does not apply unless there is either (1) a judgment against the PRP in a prior cost recovery action, (2) a cost recovery AOC with the EPA or similar state agency, (3) a de minimis settlement agreement with the EPA or similar state agency, or (4) a judicially approved settlement. In recent years, courts that have addressed this issue have begun to apply a broad interpretation of CERCLA §113(g)(3) and have determined that the three-year limitations period generally applies to <u>all</u> CERCLA contribution claims.

In *Hobart Corp. v. Waste Mgmt. of Ohio*, 758 F.3d 757, 772 (6th Cir. 2014), the Sixth Circuit affirmed the District Court's dismissal of a contribution claim based on the three-year statute of limitations. The Sixth Circuit held that the appellant's action was subject to CERCLA §113(g)(3) because the appellants previously resolved some of their liability to the government in an Administrative Settlement Agreement. The Sixth Circuit did not evaluate whether any of the "triggering events" under CERCLA §113(g)(3) had occurred, and ultimately determined that it did not matter because all contribution claims are subject to the three-year statute of limitations. The Sixth Circuit in *Hobart* noted that its position finds support from an array of federal courts.

The Northern District of Illinois recently followed the Sixth Circuit in *The Peoples Gas Light and Coke Co. v. Beazer East, Inc.*, 2014 U.S. Dist. LEXIS 125264 (N.D. Ill. 2014), *affirmed*, 802 F.3d 876 (7th Cir. 2015). Peoples Gas had entered into three separate AOCs with the EPA in 2007, 2008 and 2011. Beazer argued that People's CERCLA contribution claim was barred in part by the three-year statute of limitations. Specifically, Beazer argued that the contribution claims were time-barred with respect to the costs incurred under the 2007 and 2008 AOCs. The District Court agreed with Beazer, finding that each AOC constituted a cost recovery settlement under Section 122(h) of CERCLA because each AOC was entitled "Administrative Settlement

and Order on Consent," each AOC was entered into under the authority of CERCLA §122, and each AOC included a settlement for the recovery of response costs. The District Court went a step further in its analysis and held that the CERCLA contribution claim is subject to the three-year statute of limitations even if the AOCs did not fall within the category of a "cost recovery" settlement under CERCLA §122. In this regard, the District Court adopted the Sixth Circuit's holding in *Hobart* and concluded that the appropriate statute of limitations for a CERCLA §113 claim is the three-year statute of limitations under Section 113(g)(3).

In contrast, in *Florida Power Corp. v. FirstEnergy Corp.*, 2015 U.S. App. LEXIS 19309 (6th Cir. 2015), the Sixth Circuit held that the three-year statute of limitations did not bar the plaintiff's contribution claim because the AOCs did not constitute "administrative settlements" under CERCLA §113(f)(3)(B). The defining feature of an "administrative settlement" is that it resolves some or all of the PRP's liability to the United States for some or all of a response action. The Sixth Circuit looked to the terms of the AOCs at issue in that case to determine if liability was resolved. The language of the AOCs expressly conditioned resolution of liability on performance. In this regard, the plaintiff only resolved its liability to the EPA following its satisfaction of the requirements of the AOC. The Sixth Circuit noted that this language was starkly different from the language in *Hobart* where the AOCs resolved liability immediately as of the effective date of the AOC.

In *Asarco, LLC v. Celanese Chemical Co.*, 792 F.3d 1203 (9th Cir. 2015), the Ninth Circuit affirmed the District Court's grant of summary judgment as to the plaintiff's CERCLA §113 contribution claim. The Ninth Circuit held that judicial approval of the plaintiff's settlement of its CERCLA claims with two other PRPs in 1989 triggered the three-year limitation period in CERCLA §113(g)(3). Additionally, the Ninth Circuit found that the limitation period applied to all of the plaintiff's response costs addressed in the 1989 settlement, even if those response costs were yet to be incurred or were uncertain in type or amount. In *Asarco*, there was no settlement with the EPA or any state agency. However, the Court applied the three-year CERCLA contribution statute of limitations and used the date of the private settlement agreement as the "triggering event" to start the three-year limitations clock.

After the *Hobart*, *Peoples Gas* and *Florida Power* cases, PRPs entering into AOCs with the EPA or a similar state agency should be cognizant of the three-year statute of limitations and make sure that any suits against other PRPs are filed within three years from the effective date of the AOC. Regardless of whether the AOC squarely fits into the "de minimis" or "cost recovery" box, *Hobart* and the *Peoples Gas* cases tell us that courts will likely apply CERCLA §113(g)(3) to any CERCLA contribution claim. Moreover, the *Asarco* case puts settling PRPs of private-party CERCLA contribution matters on notice that judicial approval of their settlements may trigger the CERCLA §113(g)(3) three-year limitation period for pursuing contribution actions relating to the same response costs addressed in the private settlement.

II. U.S. Environmental Protection Agency's New Vapor Intrusion Guidelines: Are They Going to Vaporize Your Remediation Efforts?

In June 2015, the EPA released final guidance on how best to assess and mitigate vapor intrusion, which occurs when vapors from groundwater or soil contamination volatize, migrate or otherwise have the potential to affect the indoor air of overlying buildings. The EPA issued two separate guidance documents. One document is specific to petroleum vapor associated with underground storage tanks ("USTs"): "Technical Guide for Addressing Petroleum Vapor Intrusion at Leaking Underground Storage Tank Sites." The other guidance document covers vapor intrusion generally from other sources: "OSWER Technical Guidance for Assessing and Mitigating the Vapor Intrusion Pathway from Subsurface Vapor Sources to Indoor Air." The new EPA guidance documents provide recommendations for identifying, evaluating and managing vapor intrusion

risks, including technical approaches to accommodate site-specific conditions. The guidance documents apply to both residential and non-residential buildings. Businesses or residential homes overlying areas of potential vapor intrusion may require mitigation measures, such as a vapor barrier or a vapor migration system that diffuses vapors from the building's indoor air.

A. "Technical Guide for Addressing Petroleum Vapor Intrusion at Leaking Underground Storage Tank Sites"—Petroleum VI Guidance

The Petroleum VI Guidance applies to sites that once housed leaking USTs or that are contaminated with petroleum hydrocarbons, such as gasoline, diesel, and jet fuel. Petroleum vapor intrusion risks may also be associated with volatile chemicals other than petroleum hydrocarbons that can be found in petroleum fuels, such as ethers, alcohols, and other fuel additives. Methane, which is generated from biodegradation of petroleum hydrocarbons, is also associated with petroleum vapor intrusion. The EPA recommends the following actions when the EPA or state or local agencies are investigating releases of petroleum hydrocarbons:

(1) Assess and mitigate immediate threats to safety;

(2) Conduct a site characterization and develop a conceptual site model ("CSM");

(3) Delineate a lateral inclusion zone;

(4) Determine vertical separation distances for each building within the lateral inclusion zone;

(5) Evaluate potential vapor source and attenuation of petroleum hydrocarbon vapors; and

(6) Mitigate petroleum vapor intrusion risk, as appropriate and necessary.

The Petroleum VI Guidance contains a table setting forth recommended actions for addressing petroleum vapor intrusion risks and suggested procedures to implement those actions, as well as other technical information in support of the EPA's recommended actions. The Petroleum VI Guidance provides screening criteria based on the distance of physical separation between petroleum vapor sources and potential receptors. The vertical separation distance is measured from the lowest point of the overlying building basement floor, foundation, slab, or crawlspace surface and the highest vertical extent of contamination. Under the screening criteria, sites can generally be eliminated from further vapor intrusion investigation if the distance of separation is more than six feet for dissolved petroleum contaminants or greater than fifteen feet for light non-aqueous phase liquids. The Petroleum VI Guidance recommends early and frequent community engagement when conducting petroleum vapor intrusion assessments and actions.

B. "OSWER Technical Guidance for Assessing and Mitigating the Vapor Intrusion Pathway from Subsurface Vapor Sources to Indoor Air"—General VI Guidance

The General VI Guidance is more comprehensive and is aimed at assessing vapor intrusion risk at sites with non-petroleum contamination. It addresses preliminary assessments, sampling, risk assessments, exposure scenarios, mitigation, and subsurface remediation. The General VI Guidance identifies five factors that must be present for a "complete vapor intrusion pathway":

(1) A subsurface source of vapor-forming chemicals near a residential or non-residential building;

(2) A migration route towards the building;

(3) Susceptibility to soil gas entry;

(4) Vapor-forming chemicals present in the indoor air; and

(5) The building is occupied.

A complete vapor intrusion pathway indicates that there is an opportunity for human exposure, which warrants further analysis to determine whether there is a basis for undertaking a response action. Under the General VI Guidance, remediation actions should be based on building-specific and site-specific circumstances demonstrating that vapor intrusion has the potential to pose an unacceptable human health risk. On the other hand, when the vapor intrusion pathway is determined to be incomplete (*i.e.*, one or more of the five foregoing factors is currently absent and is reasonably expected to be absent in the future), then vapor intrusion mitigation is not generally warranted.

It is interesting to note that EPA's inclusion of factor (4) in the complete vapor intrusion pathway determination represents a departure from some state vapor intrusion approaches. Many states do not require the actual presence of chemicals in indoor air before the requirement of remedial measures is triggered. Rather, these states use screening level criteria to evaluate nature of the source (dissolved constituents only or presence of non-aqueous phase liquids), constituent concentrations and media (*i.e.*, soil) characteristics to then assume a complete pathway that must be addressed by implementation of remedial measures in existing buildings or future construction.

EPA's General VI Guidance also recommends that site managers evaluate whether subsurface vapor sources have the potential to pose unacceptable human health risks due to vapor intrusion in the future if site conditions were to change. The vapor intrusion pathway for a building is referred to as "potentially complete" when the following factors are present:

(1) A subsurface source of vapor-forming chemicals is present underneath or near an existing building or a building that is reasonably expected to be constructed in the future;

(2) Vapors can form from this source and have a route along which to migrate toward the building; and

(3) Three additional conditions are reasonably expected to all be met in the future, which may not all be met currently:

   i. The building is susceptible to soil gas entry;

   ii. One or more vapor-forming chemicals comprising the subsurface vapor source(s) is (or will be) present in the indoor environment;

   iii. The building is or will be occupied by one or more individuals when the vapor-forming chemical(s) is (or are) present indoors.

The General VI Guidelines recommend that community involvement be conducted from the earliest stage of the site assessment and risk assessment process, with on-going education, two-way communication, and discussion throughout the entire process to create community trust and acceptance. The EPA recommends initiating community involvement activities as soon as possible after determining that vapor intrusion may exist at a particular site.

C. Practical Implications of the New VI Guidance

Some of the practical implications of the EPA's new VI guidance are that it will increase the environmental obligations at contaminated sites, which will in turn increase the already high costs of remediation, increase toxic tort lawsuits alleging exposure to vapors from hazardous contaminants, and increase due diligence costs associated with real estate transactions where the buyer or lessee of the property demands investigation and mitigation. Another practical implication of the EPA's enhanced focus on vapor intrusion is the extending or re-opening of remediation efforts at a site. For example, CERCLA §121 requires that remedial actions which result in any hazardous substances, pollutants or contaminants remaining at the site be re-eval-

uated every five years to determine if the remedy is and will continue to be protective of human health and the environment. Superfund sites that already have a final remedy in place may require additional vapor intrusion remedial actions or evaluation as part of the five-year review process. Although the EPA's new VI guidance is not binding, the EPA is claiming "broad authority and distinct responsibilities" to protect workers from indoor air contamination. Prior VI guidance looked to the Occupational Safety and Health Administration ("OSHA") as the "lead agency" with respect to occupational exposure to vapor intrusion. The new VI guidance provides that the EPA's risk-based standards, as opposed to OSHA's permissible exposure limits, should be used for evaluating health risks from potential vapor intrusion in non-residential buildings.

D. New EPA Rule Adding Subsurface Intrusion to Hazard Ranking System

In June 2015, the EPA proposed a new rule that would add vapor intrusion to the pathways evaluated under the Hazard Ranking System for the National Priority List for Superfund sites. The EPA sent the proposed rule to the Office of Management and Budget ("OMB") for regulatory review on June 8, 2015. The OMB completed its regulatory review on December 21, 2015, and the EPA projected that the new rule would be published in the Federal Register in February 2016. As of the date of this article, the new rule has not yet been published. The new rule is likely to address the potential adverse impacts of vapor intrusion on children and women of childbearing age and would ensure that any such health risks are addressed as part of Superfund remediation. The potential and practical impacts of the new rule are that it could lead to more sites being listed on the National Priority List and that it will increase the remediation costs at sites being remediated under CERCLA, RCRA or a similar state statute.

III. All Politics Is Local: National Activist Activity Driving Local Agriculture Restrictions

A. Background

As the world population continues to grow and agricultural land and water resources grow scarcer, farmers and agricultural developers face greater challenges than ever in providing a safe, secure food supply. The last several decades have brought significant progress in terms of enhanced yields, decreased environmental footprint and increased sustainability – in part, through the development of new crop protection tools and seed. Through agricultural biotechnology, crops sometimes referred to as genetically modified organisms (GMOs) have provided an easier-to-produce, more abundant world food supply. Innovative new crop protection products address new and worsening pest challenges that will continue in a world of changing climates and extreme weather.

Agricultural biotechnology and crop protection tools are among the most tested, and most heavily scrutinized, products on the market today. The United States Environmental Protection Agency (EPA) regulates crop protection products, and all other pesticides, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. §136 *et seq.*, which requires numerous and detailed safety studies to assure human and environmental safety before EPA will allow their sale or distribution. GMO crops are also extensively tested prior to commercialization for assessment of potential environmental and food safety risks under the federal government's "Coordinated Framework for Regulation of Biotechnology," which typically entails review by the Food and Drug Administration and the United States Department of Agriculture (USDA), as well as EPA in some instances, each under their respective statutory authority. 51 FR 23302 (June 26, 1986) (the Coordinated Framework). Despite this extensive structure of federal review and regulation, these well-established regulatory processes have recently come under attack.

Certain national environmental activist groups with anti-pesticide and anti-GMO agendas have entered local communities spreading misinformation about agricultural technology and driving local initiatives to severely restrict or ban the use of pesticides and/or the cultivation of GMOs. Such activists have been particularly focused on Hawaii, which, because of its climate allowing for year round cultivation, is a state of particular importance to the agricultural research community. This focus has led to some measure of activist success in three counties, Kauaʻi, Hawaiʻi and Maui, all of which have passed initiatives restricting or outright banning certain pesticide use and/or cultivation of GMOs. Opponents of these initiatives, such as seed companies, local farmers, and other agricultural stakeholders, have had no other option than to defend their livelihoods, research, investments, and tools critical to American growers through lengthy and costly litigation. At the district court level, agricultural plaintiffs challenging these initiatives have been successful. All these cases are currently on appeal to the Ninth Circuit. This article focuses on the legal challenges made to these local initiatives and the learnings that can be gained from them.

B. Hawaii Under Attack

Syngenta Seeds, Inc. v. County of Kauai, Civ. No. 14-00014 BMK, 2014 WL 4216022 (D. Hawaii, Aug. 25, 2014), *appeals docketed*, Nos. 14-16833, 14-16848 (9th Cir. Oct. 2, 2014)

In November 2013, following months of sustained pressure by national activist groups, heated town meetings and seed company agreements on voluntary stewardship, the County of Kauaʻi passed Ordinance 960, which placed burdensome and arbitrary notification and buffer zone requirements on commercial growers using restricted use pesticides (RUPs). It also required commercial growers to make public annual reports disclosing information relating to the cultivation and propagation of GMO crops and imposed civil fines for non-compliance with the ordinance. Shortly after the ordinance was passed, Syngenta, DuPont/Pioneer, Agrigenetics and BASF brought suit in Hawaii district court to challenge the validity of the ordinance and to defend their right to do business in Kauaʻi County. The plaintiffs based their challenge on a number of arguments, including three primary points on which the court ruled: (1) the county's authority to pass such an ordinance, (2) state preemption, and (3) federal preemption.

1. The County's Authority

Plaintiffs first asserted that the county lacked the legislative authority to enact an ordinance regulating the field of agriculture because the Hawaii Constitution and various state laws vested exclusive authority over agriculture to the state. *See Syngenta Seeds*, 2014 WL 4216022 at *3. The court, however, disagreed. It held that Hawaii counties, under state law, were entitled to enact ordinances "protecting health, life, and property, and to preserve the order and security of the county and its inhabitants." *Id.* It also noted that Hawaiian land use law also recognized the role of counties in formulating agricultural policy. Taken together, the court found that these laws provided the county with at least some authority to regulate in the area of agriculture. *See id.* at *3-4.

2. State Preemption

Finding that the county could potentially have the authority to regulate some aspects of agriculture, the court moved on to address the plaintiffs' state preemption claims. First, the court found no direct conflict between any state law cited by the plaintiffs and Ordinance 960. *Id.* at *5-6. Then, the court analyzed whether the ordinance improperly attempted to legislate "in an area already staked out by the legislature for exclusive and statewide statutory treatment." *Id.* at *6. The court described the "critical determination to be made" in such an assessment as "whether the statutory scheme at issue indicates a legislative intention, either express or implied, to be exclusive and uniform throughout the state." *Id.* (internal citation omitted). The court

described this as a two-step analysis. First, the court must examine the local ordinance and relevant state laws and regulations to determine if the ordinance covers the same subject matter as those laws or regulations. Then, it must decide whether the state statutory scheme is uniform and exclusive. *See id*. If so, the local ordinance is preempted.

Undertaking that analysis, the court found Ordinance 960's pesticide reporting requirements to overlap with existing state regulations for RUP reporting and recordkeeping. *See id.* at *6-7. It also found that the ordinance's pesticide buffer zone requirements regulated planting areas, which were subject to state regulation. *See id*. With regard to publishing annual GMO crop data, the court found the stated purpose of the Ordinance's reporting requirement (to identify potentially harmful plants) to also be one of the Hawaii Department of Agriculture (HDOA)'s stated roles. *See id.* at *9. Thus, finding that Ordinance 960 covered the same subject matters regulated by state law, the court moved on to the second step in its preemption analysis.

The court analyzed whether the state regulatory scheme created a mechanism for regulating RUPs and GMO crops so as to reflect the legislature's intent that state law be both uniform and exclusive. *Id.* at *8, 9. For both the answer was yes, such that Ordinance 960 was preempted by state law. *Id.* With regard to pesticide use, the court found that HDOA established a comprehensive regulatory scheme controlling the distribution and use of RUPs, which included an advisory committee, inspections, and the ability to levy administrative and criminal penalties. Moreover, the court found that the state's regulatory scheme did not contemplate county or local government regulation. *Id.* at *8. The court held similarly with regard to HDOA's regulation of GMO crops, noting that the law and regulatory structure reflected a clear intent by the legislature that the state play an exclusive role in identifying potentially harmful plants. *Id.* at *9.

3. Federal Preemption

Although the court found Ordinance 960 to be entirely preempted by state law and regulation, it nevertheless went on to discuss whether Ordinance 960 was also preempted by federal law. The plaintiffs' federal preemption claims included express preemption under FIFRA and the federal Plant Protection Act (PPA), 7 U.S.C. §7701 *et seq.*, and implied preemption based on conflict between the ordinance and USDA field trial authorizations under the PPA. *See id.* at *12.

The court did not agree with the plaintiffs that FIFRA's provisions expressly preempted the ordinance's separate and independent state or local reporting requirements. *Id.* at *11-12. Instead, it interpreted FIFRA as envisioning independent federal and state record keeping schemes that would allow for the ordinance's requirements. *Id.*

Regarding Ordinance 960's GMO crop reporting requirements, the court found those requirements also not preempted by federal law. In the court's view, the ordinance's reporting requirements did not trigger the express preemption provision of the PPA. *See id.* at *13, 7 U.S.C. §7756(b)(1). The court also disagreed with the plaintiffs that Ordinance 960 was impliedly preempted by federal law by conflicting with or frustrating the purposes of the PPA regulations governing field trials of GMO crops. The court found that the ordinance's "reporting requirement does not interfere with any of the … informational requirements of the [USDA] field trial scheme, nor does the County's annual reporting requirement interfere with the conduct of field trials." *Id.* at *14.

4. Pending Appeals

Kaua'i County filed an appeal to the Ninth Circuit seeking review of the district court's determination that Hawaii state law preempts Ordinance 960 and also arguing that the district court abused its discretion by failing to certify the question of state law preemption to the Hawaii Supreme Court. *See Syngenta Seeds*

Inc. v. County of Kauai, No. 14-16833, Docket No. 7-1 (9th Cir. filed Dec. 31, 2014). Intervenor environmental activist groups also appealed the decision on similar grounds. *See Syngenta Seeds Inc. v. County of Kauai*, No. 14-16833, Docket No. 9-1 (9th Cir. filed Jan. 2, 2015). These appeals have been consolidated, fully briefed and are awaiting oral argument.

Hawai'i Floriculture and Nursery Association v. County of Hawai'i, Civ. No. 14-00267, 2014 WL 6685817 (D. Haw. Nov. 26, 2014), *appeal docketed*, No. 15-16552 (9th Cir. Dec. 26, 2014).

On December 5, 2013, Hawai'i County passed Ordinance 13-121, which attempted to ban most open air cultivation, propagation, development and testing of GMO crops (and other genetically engineered plants) on the island. *See Hawai'i Floriculture and Nursery Association v. County of Hawai'i*, Civ. No. 14-00267, 2014 WL 6685817 at*1 (D. Haw. Nov. 26, 2014). The Hawai'i Floriculture and Nursery Association, joined by the Hawai'i Papaya Industry Association, Big Island Banana Growers Association, Hawaii Cattlemen's Council, Inc., Pacific Floral Exchange, Inc., and the Biotechnology Industry Organization, as well as a number of individual growers brought suit in Hawaii district court asking the court to invalidate the ordinance on multiple grounds, including both state and federal preemption. Similar to *Syngenta Seeds, Inc.,* the court granted summary judgment to the plaintiffs on state preemption grounds and, in part, on federal preemption grounds.

5. State Preemption

The court's state preemption holding relied heavily on the reasoning in *Syngenta Seeds* with regard to the state's regulatory authority over the propagation and cultivation of plants. *Id.* at *4. The court found that the state's statutes and regulations authorized both HDOA and the Hawaii Board of Agriculture to develop and implement "rules concerning the introduction, propagation, inspection, destruction, and control of plants that may injure or harm agriculture, the environment, or public health." *Id.* at *5. The court then found "Ordinance 13-121's ban on open air cultivation, propagation, development, and testing of GMO crops or plants" to constitute an impermissible "attempt to regulate the same subject matter." *Id*

6. Federal Preemption

Although unnecessary to the disposition of the case, the court, as it did in *Syngenta Seeds*, addressed the plaintiffs' federal preemption claims, as well. *Id.* at *7. Here, the court found that Ordinance 13-121 was issued by the County "to prevent the dissemination, transfer, and spread of genetically engineered plants that may cause injury or harm to non-genetically engineered plants." *Id.* at *9. As such, the Court explained, it was "expressly preempted by the plain language of 7 U.S.C. §7756(b)(1) to the extent it bans field testing of genetically engineered plants that are 'plant pests' or 'noxious weeds' and are regulated under Part 340 [USDA regulations addressing GMO plants]. However, the court made clear that 7 U.S.C. §7756(b)(1) did not preempt Ordinance 13-121 to the extent it attempted to ban GMOs not subject to regulation under Part 340. On whether Ordinance 13-121 was impliedly preempted by the PPA, the court posited that Plaintiffs "have not shown a clear intent by Congress that the regulations in Part 340 or the Coordinated Framework so thoroughly occupy the field or establish a federal interest so dominant that field preemption applies." Similarly, the court found that the plaintiffs failed to establish "that compliance with Part 340 and Ordinance 13-121 is a physical impossibility or that the Ordinance stands as an obstacle to Congress' purpose and objectives." *Id.* at *10.

7. Certification to the State Supreme Court

In its opposition to the plaintiffs' motion for summary judgment, Hawai'i County urged the court to certify the question of state law preemption to the Hawaii Supreme Court. The court denied that request. *Id.* at *11.

8. Pending Appeal

Hawai'i County appealed the district court's decision that Ordinance 13-121 is impliedly preempted by Hawaii state law and expressly preempted by the PPA. *See Hawai'i Papaya Ind. Assoc. v. County of Hawaii*, Case No. 14-17538 (9th Cir. filed Dec. 26, 2014). The case has been fully briefed and is awaiting oral argument.

Robert Ito Farm, Inc. v. County of Maui, --- F. Supp. 3d ---, Civ. Nos. 14-00511 SOM/BMK, 14-00582 SOM/BMK, 2015 WL 4041480 (D. Haw. June 30, 2015), *appeal docketed*, No. 15-16552 (9th Cir. Aug. 5, 2015).

On November 12, 2014, in another national activist-led attempt to regulate pesticides and the cultivation of GMO crops, Maui County passed a sweeping ordinance rendering it illegal to grow virtually any GMO crop on the island and imposing stiff civil penalties on violators. Once again, seed companies operating in the county and other agricultural stakeholders were required to bring suit to protect their right to do business on the island. Opponents of the ordinance included Hawaii Farm Bureau, Molokai Chamber of Commerce, Monsanto, Agrigenetics, farmers and consumers. *Robert Ito Farm, Inc.*, 2015 WL 4041480 at *1. After much procedural wrangling, the district court was charged with determining whether the Maui ordinance was preempted by federal and/or state law. The court also addressed whether the county violated its charter when passing the ordinance.

9. State Preemption

The plaintiffs' state preemption argument again saw success in the district court, as the court again decided that the state's "extensive and broad" agricultural policy constituted a "comprehensive state statutory scheme" that necessarily precluded local regulation of GMO crops. *See id.* at *19-*20. The court also again refused to certify this question to the Hawaii Supreme Court, finding the standard relevant to determining state law preemption in Hawaii to be "reasonably clear." *See id.* at *16. This continued reliance on state law, even as some federal preemption arguments have prevailed, underscores the importance of state law in establishing a uniform and reliable agriculture policy and legal framework on which all growers in a state can rely.

10. Federal Preemption

As in *Hawai'i Floriculture and Nursery Association*, the plaintiffs argued that Maui's ban on the growing of GMO crops was preempted by the PPA, and the court found both express and implied federal preemption. *Id.* at *9-15. In part, the court reasoned that the ordinance frustrated "the Plant Protection Act's purpose of setting a national standard governing the movement of plant pests and noxious weeds in interstate commerce based on sound science." *Id.* at * 15, *citing* 7 U.S.C. §7701.

11.County Authority

In addition to the preemption arguments above, the court addressed whether the county even had the authority to pass its ordinance. It found that Maui County exceeded its authority in the county charter when it attempted to impose stiff penalties for violating the ordinance. *Id.* at *21-22. Maui's charter limited the council's authority to impose penalties of no more than $1,000 per violation. In light of the ordinance's exorbitant penalties ($10,000 for the first violation, $25,000 for the second violation, and $50,000 for each subsequent violation), it was clear to the court that the County had exceeded its authority in passing the ordinance. *Id*.

12. Pending Appeals

There have been multiple appeals to the Ninth Circuit on substantive and procedural grounds. The court has consolidated these appeals in *Robert Ito Farm, Inc., et al v. County of Maui, et al.*, Case No. 15-16466 (9th Cir. consolidated Oct. 27, 2015). Briefing is ongoing.

C. Litigation on the Mainland

Some of the same local ordinance strategies used in Hawaii are now being used in the continental U.S. As seen in Jackson County, Oregon, some localities are looking to impose bans very similar to those overturned in the Hawaii cases. *See Schultz Family Farms, LLC v. Jackson County*, No. 1:14-cv-01975, 2015 WL 3448069 (D. Oregon May 29, 2015) (upholding the county's GMO ban against a challenge based on the state's Right to Farm Act; relying, in part, on an exemption to the state's "seed preemption" law that had been drafted expressly to exclude Jackson County's then-pending referendum). The *Shultz Family Farms* decision underscores the importance of state law in providing uniform state agriculture policy on which all growers in a state can rely.

D. Conclusion

The challenges to agriculture described above are not unique to Hawaii. We can expect continuing threats from environmental activist groups attempting to regulate agriculture at the local level. Agricultural advocates must continue to stay abreast of local bills and ballot initiatives driven by national activist groups, and work to educate community members on the safe use and responsible regulation of agricultural products in advance of misinformed or unnecessary restrictions being passed into law. If ordinances, like those in Hawaii, are passed, the litigation discussed here provides valuable keys to preventing the implementation of regulations that violate federal and state law and unnecessarily restrict the development and use of tools growers need.

IV. TSCA Reform In 2016: Current Status of the Latest Effort to Reform a Statute that Hasn't been Reformed for Decades

On December 17, 2015, the Senate passed S. 697, the "Frank R. Lautenberg Chemical Safety for the 21st Century Act." Earlier in 2015, the House passed H.R.2576, the "TSCA Modernization Act of 2015." Now, both bills must be reconciled before they head to the President. Parties on both sides of the debate appear hopeful, for example, with the Environmental Defense Fund noting that "Key House and Senate members have said those differences are bridgeable,"[1] and the American Chemistry Council noting that "ACC and its members are committed to working with members of the House and Senate to reconcile the provisions of H.R. 2576 and S. 697."[2] The President is expected to sign the bill that emerges.

In general, S. 697 is more expansive and presents a more extensive revamp of TSCA than H.R. 2576. As of early January 2016, no further actions on either bills have occurred that are evident in public records. Considering that S. 697 will likely form the basis for further discussion, here is an overview of certain of its larger changes to TSCA:

- **New safety standard.** Now, "[t]he term 'safety standard' means a standard that ensures, without taking into consideration cost or other nonrisk factors, that no unreasonable risk of injury to health or the environment will result from exposure to a chemical substance under the conditions of use, including no unreasonable risk of injury to the general population." Furthermore, the EPA is able to identify potentially vulnerable populations against which this new safety standard must also be met.
- **Safety reviews of existing chemicals.** In contrast to the grandfathering-in of chemicals then in use, there is now a mandate on EPA to review all chemicals in commerce. First, manufacturers would identify all chemicals that they are currently manufacturing. Then, EPA would rank the chemicals, giving to chemicals scoring high for persistence and bioaccumulation using EPA's

TSCA Work Plan criteria a priority for assessment. Manufacturers could request and provide funds for EPA to assess their chemicals, but reviews pursuant to this avenue are limited. Once ranked, EPA would begin assessing chemicals against the new safety standard.

- **Greater ability to require testing.** S. 697 eliminates the need to make a finding of risk before requiring testing. Furthermore, EPA can issue an order requiring testing, as opposed to promulgating a rule.
- **New chemicals must be reviewed before entering commerce.** Requires that EPA determine whether the relevant chemical substance or significant new use is likely to meet the safety standard as a condition for market entry.
- **Restrictions on chemicals presenting significant risks.** Instead of requiring that EPA use the "least burdensome" requirements to control risks under Section 6, the bill would require analysis of costs and benefits, including a technically and economically feasible alternative.
- **Preemption.** Preemption is chemical-specific and applies only when EPA assesses a chemical, and is specific to the hazards, exposures, risks, uses and conditions of use of a chemical that are included in EPA's safety assessment and safety determination. Preemption applies on restrictions to chemicals; it does not apply to requirements on reporting, monitoring, or disclosure. States can request a waiver from preemption, but it generally requires a determination that the State's proposed action would not violate Constitutional principles and is based on a legitimate scientific concern. Additionally, preemption does not impact state restrictions in place prior to August 1, 2015.
- **Confidential business information.** Requires EPA to review past CBI claims for active chemicals on the TSCA Inventory. Certain CBI claims must be substantiated when made and are to be reviewed by EPA, with any approvals for protection expiring after 10 years unless re-substantiated. Some types of information, including health and safety data, are not eligible for CBI protection. If EPA bans or phases out a chemical, there is a rebuttal presumption that previously protected CBI will be disclosed. For the first time, CBI can be shared with state governments, health and environmental professionals, and first responders, subject to adequate protections and nondisclosure agreements.

V. FIFRA Snapshot: Overview of FIFRA Requirements Applicable to Antimicrobial Products

With few exceptions, pesticide products must be approved by EPA prior to entering the market. Environmental health and safety testing is required before these products can be sold or distributed. These data requirements apply to any company that seeks to register pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which include antimicrobial, wood preservative, and antifoulant products. 40 C.F.R. Part 158, Subpart W, concerns data requirements for these antimicrobial pesticides.

Here are the latest developments of note on antimicrobial registration under FIFRA:

- On September 4, 2015, the EPA issued a draft white paper titled "Consideration of Disinfection Hierarchy Concepts in the Registration of Antimicrobial Products." A disinfection hierarchy describes the descending order of susceptibility of various classes of microorganisms to antimicrobial chemicals, from the least susceptible class of microorganisms (*i.e.*, hardest to disinfect) to the most susceptible class of microorganisms (the easiest to disinfect). EPA's stated goals of this effort are to: (1) provide more expeditious guidance to health care officials and the public on the

most effective type of registered antimicrobial products on the market to use against an emerging pathogen; and (2) increase the efficiency of and lower resources associated with registering antimicrobial pesticides while maintaining a high level of public health protection.

- On August 26, 2015, the EPA's Inspector General opened an audit file on the Antimicrobial Testing Program (ATP) of the Office of Chemical Safety and Pollution Prevention (OCSPP), seeking to determine whether the ATP adequately ensures the efficacy of EPA-registered hospital sterilants, disinfectants and tuberculocides. As of early January 2016, there is no additional public information on this investigation.
- On June 17, 2015, EPA published notice that it was accepting comments on several 810 series, non-binding, draft test guidelines developed by the OCSPP, which are used by EPA, the public, and companies that are subject to data submission requirements under TSCA and FIFRA. The test guidelines included:
  - OCSPP Test Guideline 810.2000—General Considerations for Testing Antimicrobial Agents,
  - OCSPP Test Guideline 810.2100—Sterilants & Sporicides Recommendations for Efficacy Testing, and
  - OCSPP Test Guideline 810.2200—Disinfectants for Use on Hard Surfaces—Efficacy Data Recommendations.

  The EPA stated it was acting because users complained that the existing test guidelines were confusing and in some cases, inaccurate. Comments were accepted until August 17, 2015. As of early January 2016, there is no additional movement on this review.
- On June 5, 2015, EPA published guidance that expanded the applicability of the Bovine Corneal Opacity and Permeability (BCOP) assay for identifying toxicity category III eye irritants for antimicrobial cleaning products (AMCPs). Previously, the BCOP was applicable only to identification of AMCP category I and II eye irritants. EPA concluded that the additional analysis supports the use of the BCOP for identification of toxicity category III eye irritants for AMCPs. The test involves evaluating how cattle corneas react after being exposed to a chemical, and it is consistent with EPA's shift away from requiring live animal tests for pesticide registration.
- On April 30, 2015, EPA published interim guidance on the scenarios in which companies will be required to submit certain types of data to the agency to register their antimicrobial products. This guidance was prompted by a March 2, 2015, settlement agreement in *American Chemistry Council v. EPA* (No. 13–01207, D.C. Cir.), in which the agency was sued for vague data requirements on antimicrobial manufacturers following EPA's 2013 revisions of the same. The guidance sets out the following clarification (emphasis added):

  > No later than September 2, 2017, the Agency will propose a correction to 40 CFR Part 158W to make the rule's language as it pertains to the 200 ppb level established in 40 C.F.R. §158.2230(d) consistent with the U.S. Food and Drug Administration's use of that same level. The proposal will be to clarify that the 200 ppb level established in the rule is **based on total estimated daily dietary intake, and is not based on the amount of residue present on only a single commodity**. The Agency is providing this interim guidance to registrants that the referenced 200 ppb level is based on total estimated daily dietary intake rather than on the amount of residue present on only a single commodity. This interpretation is consistent with the U.S. Food and Drug Administration's policy.

Endnotes

[1] Environmental Defense Fund, EDFAction Hails Senate Passage of Chemical Safety Reform, http://www.edfaction.org/media/edfaction-hails-senate-passage-chemical-safety-reform (last visited January 12, 2016).

[2] American Chemistry Council, ACC Lauds Passage of Senate Bill to Reform TSCA, http://www.americanchemistry.com/Media/PressReleasesTranscripts/ACC-news-releases/ACC-Lauds-Passage-of-Senate-Bill-to-Reform-TSCA.html (last visited January 12, 2016).