MESSAGE FROM THE CHAIR
Todd J. Janzen

As the chair of Agricultural Management Committee, I am pleased to offer the first newsletter under my leadership.

This newsletter features a range of subject matters, from concentrated animal feeding operations (CAFOs) to coexistence of biotech crops with their organic counterparts. First, a case law update on “natural” litigation, from Thomas Redick. Second, Ronald Redick and Steve M. Krommendyk discuss federal preemption law in the context of state GM labeling laws. In the middle, we have a point-counterpoint on coexistence from Vice Chairs Amanda Kool and Megan Galey. Daryl Lim explains what happened in the seed-saving case of Bowman v. Monsanto. Rosewin Sweeney offers a summary of a contested CAFO case in Maryland. Lastly, I offer a summary of the new court ruling in Gulf Restoration Network v. EPA that could lead to an EPA-mandated “total maximum daily load” (TMDL) for nutrient pollutants and sediment for the Mississippi River Basin.

SEER’s 21st Fall Conference in Baltimore was once again full of interesting CLE content and networking opportunities. Programs of possible interest to the agricultural environmental lawyer included the following:

- Adapting After Natural Disasters: Building Resiliency Through Policy, Legal, and Regulatory Approaches
- TMDL Regulation: How EPA’s Chesapeake Bay Initiative May Spread to Your Watershed
- State Authority on Climate Change: Where Are the Commerce Clause Boundaries?
- Cooperative Federalism: Under Assault or In Balance (another timely TMDL session)

Demands for sustainability information from producers played a role in “The Corporate Supply Chain Goes Global: What You Need to Know to Counsel Your Multinational Client”—if the Fall Conference follows the pattern we saw in Salt Lake City, many sessions had agricultural content that emerges in other discussions. While it might be far afield for some agricultural management attorneys, fracking was also at the Fall Meeting session concerning “Energy Exports: A New Market with Legal Import!” The Agricultural Management Committee would welcome an article on this topic outlining the benefits and costs of fracking to farmers and rural communities.

Lastly, for anyone who needed ethics credits to meet an MCLE deadline, this year’s Fall Conference had another plenary session on professional ethics and we will have another one at the annual Spring meeting in Salt Lake City.

Our committees enjoy active participation by members, with quality programs arising from member involvement. If you would like to be a part of program planning, or have a good program to suggest, please let me or Agricultural Management Programs Vice
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Chairs Alix M. Murdoch (amurdoch@cbf.org) and Brandon Neuschafer (bwneuschafer@bryancave.com) know about your interest and ideas.

If you want to get more involved in any of our committee’s activities, please let me or the appropriate vice chair know. We are always looking for newsletter contributors and editors. If you have a good topic or article for submission, please contact Tom Redick (thomasredick@netscape.net). Additional contact information for our committee is available on the committee website. We also welcome periodic guest editors to help put together these newsletters.

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CASE LAW UPDATE—“NATURAL” NEEDS A DEFINITION
Thomas P. Redick

This update reports on “natural” advertising and legal challenges around the United States.

Kashi Cereal with “GMO” Cannot Be “Natural”

In April 2012, a Rhode Island grocer told customers he wouldn’t sell Kashi cereal because he found out the brand used genetically engineered, non-organic ingredients. Class actions lawsuits were filed claiming Kashi’s products are mislabeled. The lawsuit (Nadine Saubers v. Kashi Co., Case No. 13-cv-00899, U.S. District Court for the Southern District of California) states, “Nearly all of Kashi’s products’ labels list ‘evaporated cane juice’ as an ingredient despite the fact that FDA has specifically warned companies not to use the term because it is ‘false and misleading,’ is not ‘the common or usual name of any type of sweetener,’ and the ingredient is not, in fact, juice.”

The lawsuit is alleging that Kashi and Kellogg’s are not fully disclosing how much sugar is in a product by using words like “cane juice” instead of sugar.

Putative Class Claims Truvia® Falsely Advertised as “Natural”

A Hawaii resident filed a putative nationwide class action against Cargill, Inc., alleging that the company falsely advertises its Truvia® sweetener product as “natural” when it is actually made from ingredients that are “either synthetic or harshly chemically processed.” Howerton v. Cargill, Inc., No. 13-0336 (U.S. Dist. Ct., D. Haw., filed July 8, 2013). Cargill markets the product with “natural imagery such as the leaves of the stevia plant,” yet “the stevia-derived ingredient, Reb A, is not the natural crude preparation of stevia, but rather is a highly chemically processed and purified form of the stevia leaf extract,” and Reb A “comprises only 1% of Truvia.” The plaintiff alleges that “the main ingredient, erythritol, which Cargill also purports to be a natural ingredient derived through natural processes,
is not made like it is in nature, but rather is synthetically made. Cargill describes the process of obtaining stevia leaf extract as ‘similar to making tea,’ but does not tell the consumer that Cargill then adds ethanol, methanol, or rubbing alcohol to this so-called ‘tea’ in a patented multi-step process to purify it.” The plaintiff claims that the product is priced some 300 percent more than Sweet’N Low® and 67 percent more than Splenda® and that she “suffered an injury by purchasing the Product at inflated prices.” Seeking to certify a nationwide class and statewide subclass of consumers, the plaintiff alleges unjust enrichment, violation of a Hawaii law proscribing unfair methods of competition and unfair or deceptive acts or practices, violation of Hawaii’s uniform Deceptive Trade Practice Act, breach of express and implied warranty under multiple state laws, and violation of the states’ consumer fraud laws. She also seeks injunctive relief, a corrective advertising campaign, an order requiring the defendant to “notify each and every individual and/or business who purchased the Product of the pendency of the claims” to give them an opportunity to obtain restitution, disgorgement, and damages.

**Pepsi Settles on “Natural” Claim**

In a move that will only encourage more litigation challenging “GM” content in “natural” products, PepsiCo has agreed in July 2013 to pay $9 million to settle a class action suit pending in Los Angeles, California alleging that fraudulently sold Naked Juice products as “All Natural” even though they contained “genetically modified” soy.

**GMO Corn Chips “Natural”? Asks FDA**

In staying the lawsuit *Elizabeth Cox v. Gruma Corporation* claiming fraud in the “all-natural” claim on the label of Mission tortilla chips that contain GMO corn, District Court Judge Yvonne Gonzalez Rogers asked FDA to tell her whether genetically engineered foods can be labeled “natural.” Otherwise, the judge wrote in her decision, “the Court would risk usurping FDA’s interpretive authority.” The judge issued a “tentative ruling” in favor of Gruma, given the absence of regulatory guidance on “natural” or “all natural,” or whether GMO or bioengineered ingredients would be considered “artificial” or “synthetic.” The FDA released nonbinding draft industry guidance in 2001 stating that “Non-GMO” labeling cannot mislead. See **Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Availability.** Docket No. 00D-1598, CFSAN 123. See also http://www.non-gmoreport.com/articles/millenium/fdasallowsgmo-freelabel.php#sthash.zzwZU7g9.dpuf.

**Pepperidge Not Natural Down on the Farm?**

Another “natural is not GM” lawsuit (like the *Kashi* case above) was filed in Colorado against Pepperidge Farm (a putative nationwide class) in a $5 million fraud claim for a “natural” label on a product with GM soy ingredients; *Bolerjack v. Pepperidge Farm, Inc.*, No. 12-2918 (U.S. Dist. Ct., D. Colo., filed Nov. 6, 2012). The suit seeks equitable relief, restitution, disgorgement, actual damages, attorney’s fees, costs, and interest. With any luck, the court will follow the decision in *Briseno v. ConAgra Foods, Inc.*, Case No. CV 11-05379 (C.D. Cal. 2011), available at http://www.masstortdefense.com/uploads/file/brisn.pdf, dismissing and discussing federal preemption grounds.

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PREEMPTION OF STATE LAWS REQUIRING LABELING OF GENETICALLY MODIFIED FOODS
Ronald M. Redick and Steve M. Krommendyk

According to a recent survey, 82 percent of Americans think that foods containing genetically modified organisms (GMOs) should be labeled. However, while consumers are clearly in favor of GMO labeling laws, the federal government has made it equally clear that it will not mandate GMO labeling.

On June 3, 2013, Connecticut became the first state to pass legislation which would require all genetically modified foods to be labeled. Maine’s House of Representatives followed suit nearly a week later, passing similar legislation. In total, 26 states are considering requiring GMO labeling. While Connecticut’s and Maine’s bills contain caveats which require similar legislation to be enacted in other states before becoming effective, biotech industry companies have promised to challenge state GMO labeling laws in court, should they become effective. The battle between states and the biotech industry is heating up.

This article discusses whether state GMO labeling requirements could be preempted by federal law, and the grounds upon which preemption might be found.

Federal Regulation of Food Labeling

Congress has delegated the authority to regulate labeling of food to the Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA). The Federal Food Drug and Cosmetic Act (FDCA) grants FDA the authority to create a federal scheme for the labeling of foods such as GM crops and foods containing ingredients made with GM technology. USDA regulates the labeling of all meat and poultry products under the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA).

In 1992, FDA issued a statement of policy that “substantially equivalent” GM foods are not materially different from existing products, and are to be presumed “generally recognized as safe” (GRAS) under the FDCA. Thus, the use of GM technology need not be disclosed in food labeling. Later, in 2001, FDA issued a draft guidance for industry, again concluding that genetically modified foods are GRAS and that the use of GMOs need not be indicated on the food label. Additionally, FDA warned that voluntary labels stating that food is non-GM may be considered false and misleading if the label implies that the food is superior because it was not bioengineered, or is applied to a food with no ingredient that could be “GM” (e.g., has used one of the common food crops that are biotech—soybean, corn, canola, etc.).

In addition, under the Nutritional Labeling and Education Act (NLEA) of 1990, states are expressly preempted from establishing a labeling requirement of the type required by the various sections of the act related to misbranded articles that is not identical to the requirements of such section. 21 U.S.C. § 343-1. The misbranding sections of the FDCA to which this preemption language refers include prescriptions for “definition and standard of identity,” “standards of quality and fill of container,” and “nutrition levels and health-related claims.” See 21 U.S.C § 343(g), (h), and (r), respectively.

The FMIA and PPIA contain more broad express preemption provisions, precluding state law requirements for “marketing, labeling, packaging, or ingredients . . . in addition to, or different than, those made under” the acts. 21 U.S.C. §§ 467e; 678.

It is important to note that, while the FMIA and PPIA preempt all state-labeling requirements that are not identical to those listed in the acts, the NLEA expressly preempts only those state-labeling laws which conflict with its requirements. Thus, under the NLEA, states are not expressly preempted from establishing labeling laws where the NLEA is silent. As discussed below, however, field preemption may nonetheless apply.

Case Law

In International Dairy Foods Ass’n v. Amestoy, 92 F.3d 67, 70 (2d Cir. 1996), a Vermont statute
requiring GM milk to be labeled was challenged by a group of dairy manufacturers, claiming the statute violated (1) the First Amendment’s protection of commercial speech and (2) the Commerce Clause. Vermont argued that it had a legitimate state interest in requiring GM milk to be labeled because of consumer interest and the public’s “right to know.” Id. at 73. However, the court held that consumer interest alone is not a legitimate state interest sufficient to compel speech. Id. at 74. Because the court held that the statute violated the First Amendment, it did not consider the Dairy Association’s Commerce Clause claim. Id. at 70.

It is notable that Vermont failed to argue that its legitimate government interest was based on public health and safety concerns. The court determined, however, that such an argument would have failed, inasmuch as FDA had already determined that the GM milk at issue was not materially different than non-GM milk, and thus, presented no health risk. Id. at 73. Therefore, the court concluded, Vermont could not justify the statute on the basis of public health and safety concerns. Id.

In *Alliance for Bio-Integrity v. Shalala*, 116 F. Supp. 2d 166 (D.D.C. 2000), a coalition of groups and individuals brought an action seeking a declaratory judgment that FDA’s 1992 statement of policy regarding GM foods was arbitrary and capricious and, therefore, unlawful. As previously stated, the 1992 statement of policy provided that genetic modification was not a “material fact,” and therefore, that GM foods were not required to be labeled. In granting FDA’s motion for summary judgment, the court held that FDA’s determination that GM foods were GRAS was not arbitrary and capricious. Id. at 177–78. The court was not convinced by the plaintiffs’ argument that the policy statement was unlawful due to “significant disagreement among scientific experts.” Id. Rather, the court found that FDA had based its conclusion on technical evidence and that, although there was not unanimity among scientists, the disagreements were not material. Id.

The labeling of GM foods was most recently addressed in *Briseno v. ConAgra Foods, Inc.*, Case No. CV 11-05379 (C.D. Cal. 2011), available at http://www.masstortdefense.com/uploads/file/brisn.pdf. The plaintiffs in this class action alleged that, under a number of California statutes, ConAgra misleadingly advertised Wesson cooking oil as “100% Natural,” even though it was made with GM canola. Id. at 2. The case was ultimately dismissed on procedural grounds. However, before dismissing it, the court addressed several of ConAgra’s other arguments, including a claim that, to the extent its use of the phrase “100% Natural” was unlawful under the various California statutes, the statutes should be preempted by section 403A of the FDCA (21 U.S.C. § 343-1). The court concluded that, since FDA has never defined what constitutes “natural” or “all natural,” a definition of those terms under state law would not conflict with federal standards, so the California statutes were not preempted.

In addition to challenging ConAgra’s use of the phrase “100% Natural” in advertising Wesson cooking oil, the plaintiffs also demanded that the court require ConAgra “to adopt and enforce a policy that requires appropriate disclosure oingredients.” The court held that any California statute requiring such a disclosure policy was preempted, reasoning that while FDA has not taken action to define what constitutes “natural” on a food product label, it has taken action regarding when and how GM ingredients must be labeled. See FDA’s 1992 statement of policy; see also, Greg Conko, *Court Rules State Biotech Food Labeling Mandates Preempted by Federal Law* (May 1, 2012), http://www.openmarket.org/2012/05/01/court-rules-state-biotech-food-labeling-mandates-preempted-by-federal-law/.

**Preemption Analysis**

The NLEA, FMIA, and PPIA contain provisions that expressly preempt certain aspects of state GMO labeling laws. However, the distinction between the express preemption language within the statutes is noteworthy. The FMIA and PPIA contain much broader preemption clauses. In those statutes, any state-labeling requirement that is not identical to the requirements listed within the relevant act is
preempted. Thus, states likely have no authority to require labels for GM meat or poultry.

In contrast, the NLEA’s express preemption clause is relatively confined. Although it preempts states from enacting labeling requirements that are different from those found within the NLEA, states are not expressly preempted from enacting labeling requirements in areas where the NLEA is silent. Therefore, state-labeling laws for GM foods other than meat and poultry are not expressly preempted unless the state requirement is in direct conflict with a provision of the FDCA.

However, even those state-labeling laws that are not expressly preempted may nonetheless be preempted under the field preemption doctrine. Through FDA and its delegated authority to prescribe the content of food labels under the FDCA, the federal government has arguably “occupied the field” of food labeling, which would thus preclude all state regulation of the same subject matter. Specifically, FDA has examined the question of whether any retail food labels should contain information about the content of GM foods and has determined that no such information should be on the label, thus precluding any contrary determination by the states. Furthermore, FDA has suggested that even voluntary labeling of food as “non-GMO” might violate federal law because it would constitute the misbranding of food. FDA reached this conclusion based on research that found no scientific basis for the claim that there is a material difference between GM foods and non-GM foods. In this context, there is ample room to conclude that the federal government has occupied the field, to the exclusion of all state regulation of GM food labeling.

The Briseno Distinction

The recent Briseno decision, as discussed above, illustrates a distinction essential to consider when analyzing whether a state-labeling law will be preempted. The distinction is between state laws that require disclosure and those which merely define terms. Based on the reasoning of the Briseno decision, state-labeling laws defining terms that have not yet been defined by FDA would not be preempted. On that point, the Briseno court did hold that any California statute requiring that ConAgra disclose the use of GMOs in its products was preempted. But at the same time, the court also held that a California statute defining what constitutes “natural” or “all natural” was not preempted because FDA has not defined those terms. Therefore, the California statutes that gave rise to the plaintiff’s particular claim, arguing that ConAgra’s use of the phrase “100% Natural” on its product that contained GMOs was unlawful under state law, was deemed not to be preempted.

Put more simply, while states are certainly preempted from requiring GM food producers to label their products as containing GMOs, the Briseno decision suggests that states might be able to restrict what GM food producers include on their labels, if the restriction does not contradict federal law. That said, there are other important factors to consider, including free speech concerns, which will further limit state authority.

First Amendment Protection of Commercial Free Speech

In addition to preemption challenges, International Dairy offers a separate ground on which state-labeling laws could likely fail. Commercial speech, which includes the right not to speak, is protected by the First Amendment. If states require GM food producers to label their products as containing GMOs, they would be forcing commercial speech. Under the reasoning of International Dairy, this type of government-compelled speech cannot be countenanced, absent a legitimate government interest. The court in International Dairy made it clear that consumer interest alone is not sufficient. Furthermore, FDA has made its position clear that GM foods are GRAS, are not materially different than non-GM foods, and need not be disclosed on labels. Thus, it will be very difficult for states to argue that their labeling laws are based on legitimate public health and safety concerns.

Conclusion

Contrary to the desires of many consumers, state GMO labeling laws will almost certainly fail in the face of the legal challenges promised by the biotech industry. Those that are able to survive, if any, will
likely be much weaker than consumer advocates had hoped. First, the FMIA and PPIA expressly preempt any state-labeling requirements that are not identical to those contained within those statutes. This means that states have no authority to enact GMO labeling requirements pertaining to meat and poultry. As for other GM foods, the FDCA expressly preempts states from enacting labeling laws that conflict with those found within that statute. This might appear to leave states with some ability to legislate GMO labeling, but the field preemption doctrine and the First Amendment probably limit this ability even further.

States clearly do not have the authority to require producers to disclose the presence of GMOs in food. At most, they might be able to limit what producers include on their labels, if the food is not meat or poultry. States could potentially do this by defining certain terms that have not been defined by FDA. By doing this, a state might be able to prevent producers of GM foods from including certain statements on their labels, assuming, of course, that such laws would not be field preempted or violate the First Amendment—which could very likely be the case.

As tensions heighten between the biotech industry and the 25 states that have passed laws dependent on future condition (e.g., Alaska for GM fish, if FDA gets around to approving Aquabounty’s GM salmon, and conditional laws like Connecticut’s, which awaits other states) or are considering GMO labeling legislation, it is only a matter of time before a legal challenge is made on grounds of preemption, the First Amendment, or perhaps under dormant Commerce Clause principles. Despite having consumer support, it appears likely that most of these laws will fail—either in whole or in part—against the imminent legal challenges.

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COMPENSATION WITHOUT DETERRENCE: WHY THE AC21’S PROPOSED COMPENSATION MECHANISM WOULD FAIL TO ENHANCE COEXISTENCE
Amanda L. Kool

Overview

On November 19, 2012, the U.S. Department of Agriculture (USDA) Advisory Committee on Biotechnology and 21st Century Agriculture, commonly referred to as “the AC21,” submitted a 61-page report to Agriculture Secretary Tom Vilsack titled, “Enhancing Coexistence: A Report of the AC21 to the Secretary of Agriculture.” The AC21 comprised 23 members representing a cross-sector of the agricultural community, including farmers, seed companies, food manufacturers, organic farming organizations, state government, biotechnology companies, and medical professionals, among others. The report marked the culmination of five meetings held by the AC21 across the span of more than a year and provided recommendations in response to the following questions presented by Secretary Vilsack:

1. What types of compensation mechanisms, if any, would be appropriate to address economic losses by farmers in which the value of their crops is reduced by unintended presence of genetically engineered (GE) materials?

2. What would be necessary to implement such mechanisms? That is, what would be the eligibility standard for a loss and what tools and triggers (e.g., tolerances, testing protocols, etc.) would be needed to verify and measure such losses and determine if claims are compensable?

3. In addition to the above, what other actions would be appropriate to bolster or facilitate coexistence among different agricultural production systems in the United States?
The report was endorsed by all but one member of the AC21, though the 26 pages of recommendations were followed by 35 pages of often-critical commentary written by 18 of the AC21 members.

The lynchpin in the AC21 recommendations was an insurance-based compensation model. As opposed to a self-insurance model that would encourage farmers at risk of being affected by genetic drift of GE traits to individually purchase private insurance, the proposed model would rely on a combination of public funding and private insurance coverage to compensate for losses related to genetic drift. The recommendation also called for the development of “joint coexistence plans,” through which farmers who grow organic or other identity-preserved (IP) crops (IP farmers) and the neighboring farmers who grow GE crops (GE farmers) would agree to reduce the risk of genetic drift by implementing mitigation measures, such as staggered planting times and buffer zones between fields. Under the AC21 recommendations, IP farmers could choose to purchase insurance, implement a joint coexistence plan with neighboring farmers, or both. IP farmers who engage in a joint coexistence plan would be offered a reduction in the insurance premium for IP crops, and the GE farmers who enter into a joint coexistence plan would be incentivized to do so by receiving either a discount on the insurance premium for conventional crops or preferred status under USDA conservation programs.

In order for an IP farmer to recover for genetic drift under such a program, the farmer would need to show:

1. Prior intent to produce an IP product;
2. Use of practices appropriate for the production of the product;
3. That the product specifications were reasonable and that the product fell within the range of insurable products set forth in the insurance terms; and
4. That an actual financial loss was incurred and the magnitude of that loss.

The report also highlighted the need for an education and outreach initiative focused on coexistence (in which participation by agricultural stakeholders would be voluntary), the need for funding to conduct research on the efficacy of various coexistence strategies, and the importance of ensuring the availability of a diverse and high quality commercial seed supply.

Critique

1. The AC21 compensation mechanism fails to improve upon the self-insurance model. The report distinguishes the recommended compensation mechanism from self-purchased insurance by noting that the latter offers “the advantages of being focused on those suffering the losses,” but its disadvantage is that it “require[s] no involvement by any other parties whose cultivation or management practices may have directly or indirectly contributed to those losses.” Yet the AC21 compensation mechanism also fails to require involvement by the neighboring farmers who originally produced the GE crops and the technology providers that own patents for the GE materials. The GE farmers are involved only as voluntary participants in a joint coexistence plan that can earn them an insurance discount or preferred status under USDA conservation programs, and the technology providers remain completely uninvolved. Meanwhile, the IP farmers not only must purchase an insurance policy prior to the occurrence of genetic drift to cover any future losses, but in the event of the unwanted presence of GE traits, they also must persuade the insurer (whether a private insurance company, the federal government, or both) that they meet the four designated criteria listed above. These four criteria are likely similar to the requirements that any self-insured party must meet in order for his or her private insurance company to cover a loss, and thus the difference between private insurance coverage and the proposed compensation model is negligible.

2. The AC21 compensation mechanism fails to enhance coexistence. The AC21 recommendation clearly falls short of its aim to “enhance coexistence” when one critically views the equation from the intersection of law and economics. Some of the AC21 members who are sympathetic to the genetic engineering industry attempt to engage a cost-benefit analysis by contending that the higher price garnered by IP crops (as compared with GE crops) at
the point of sale is, at least in part, due to the risk of contamination (whether such contamination results from genetic drift from neighboring GE crops or otherwise) and thus, they argue that IP farmers should not be compensated for losses resulting from genetic drift. IP crops do have a higher sale price because there is a high demand for these crops and they are more expensive to produce on a large scale. This combination of high demand and low supply is due to the multitude of challenges that are involved in growing genetically pure crops without the easy and convenient use of commercial fertilizers, pesticides, or GE seeds that can tolerate pests, competing plants, and unpredictable weather. Growing IP crops often requires more labor and carries a higher risk of crop loss prior to harvest than GE crops do. The market for IP crops balances these higher risks with lower seed prices and higher returns at the point of sale.

In contrast, GE farmers can rely on an arsenal of readily available insecticides, herbicides, and fertilizers, which are sometimes already bred into the seeds themselves as a result of research and development that required years and fortunes to conduct. The price of GE seeds is often higher than that of IP seeds, and the price garnered for GE crops at the point of sale is often lower per unit than that for IP crops; the market for GE crops balances the burden of high seed prices with the hardiness of the seeds, the economy of large-scale methods of production, and high yields, and it balances the lower risk of crop loss with lower returns at the point of sale. Though the financial risks and rewards of GE farming are much different than those of IP farming, both industries rely on the market to impose a cost-benefit balance to ensure that growing a particular crop is financially viable.

Genetic drift represents a risk that falls beyond the scope of the IP farmers’ cost-benefit analysis; IP farmers cannot—and should not—be responsible for anticipating the actions of other industries. A closer look at the private insurance system reveals the incongruity of requiring IP farmers to be responsible for loss due to genetic drift. For example, suppose a homeowner who lives near a volatile body of water has purchased a flood insurance policy to protect his or her house from water-related damage. If this insured homeowner’s house is flooded after heavy rains, the homeowner’s insurance company would pay for the resulting damage. If the same insured homeowner’s house is flooded after a swimming pool on the neighboring property collapses, the homeowner’s insurance company will likely still pay for repairs, but the homeowner’s insurance company will subrogate the claim and seek retribution from the neighbor’s insurance company (or the neighbor directly, if he or she is uninsured), provided the legal fees and other transactional costs of doing so are less than the cost of repairs.

Various factors can be plugged into this hypothetical example and the analysis can be extrapolated in infinite permutations, but the private insurance industry will always attempt to shift risk in order to achieve maximum value. For example, if the neighbor’s insurance policy specifically disclaims losses resulting from swimming pools, the neighbor’s insurance policy will likely attempt to shift responsibility for the damage to the neighbor. Or if the neighbor’s insurance company was aware of the pool prior to its collapse and recognized the risk posed by its condition and placement, the neighbor’s insurance company may have agreed to cover any damages caused by the pool in exchange for a higher premium or higher deductible. Through a series of risk-shifting transactions, private insurance companies and the parties they insure allocate responsibility so that the risk of loss falls to either the responsible party or the party for whom assuming responsibility is worth the financial reward received for doing so. This analysis of burden-shifting not only assigns fault and compensation in a way that maximizes value for all parties involved but also achieves the ultimate goal of the compensation mechanism, which is to disincentivize the behavior causing the loss and thus minimize the risk of loss in the future.

3. The AC21 compensation mechanism fails to involve the party best positioned to foster coexistence.

GE farmers are the obvious defendants of claims of crop contamination brought by neighboring IP farmers, but the technology providers that own the patented traits are the more appropriate defendants for a
number of reasons. First, establishing causation against a particular farmer may be difficult to do in areas in which multiple farmers are using the same GE seeds. Second, farmer-to-farmer litigation often lacks the financial incentive that is present in farmer-to-corporation litigation. Third, the technology providers are entitled to assert patent infringement claims against farmers who are using their patented traits without a license, and thus the same technology providers should be held responsible when farmers who do not wish to have those patented traits in their crops nevertheless do, without a license, as a consequence of genetic drift. Coexistence is the ultimate aim of the AC21 recommendations, and thus a fourth reason to use the compensation mechanism to attach liability directly to the technology providers is that the providers have the financial and technological resources to mitigate the risk of future genetic drift. Holding the technology providers responsible for failing to prevent drift of their own GE traits will incentivize the providers to use their resources to minimize the risk of future genetic drift. As AC21 member Charles Benbrook noted in his comments, the Food and Drug Administration regularly accepts the research on safety and nutritional values put forth by a technology provider that is seeking approval for a newly developed seed; thus, in instances of new product approval, it is clearly in the technology provider’s best interest to overstate the safety and nutritional outcomes of a new product. However, if the responsibility for loss due to genetic drift is shifted to the technology provider, the provider is incentivized to thoroughly and accurately research the efficacy of buffer zones and other coexistence measures and to develop practices to minimize the risk of genetic drift. As an additional benefit, this approach would address the AC21’s call for research regarding the efficacy of coexistence strategies under recommendation IV of the report, and it would do so without requiring tax dollars to shoulder the expense.

Of course, just as IP farmers should not bear the costs of contamination caused by the errant actions of others, technology providers should not be held responsible for the willful disregard of established coexistence measures by farmers using their GE seeds. Just as a life insurance company can include a clause in its written policy that excludes coverage for deaths resulting from skydiving or other dangerous activities, a technology provider that is exposed to liability under a compensation mechanism can impose coexistence protocols on the GE farmers who purchase their seeds. New provisions could be added to the existing contract signed by farmers who purchase GE seeds to abdicate the technology providers from liability to IP farmers if the GE farmers fail to adhere to the established protocol. This allocation of risk would incentivize responsible science and farmer education by the technology providers and responsible farming by the GE farmers. Furthermore, an IP farmer who suffers a loss due to genetic drift should be afforded the convenience of seeking redress from the technology provider (as in the private insurance scenario); otherwise, the transactional costs of attributing causation to the GE farmer or the technology provider would be prohibitive for many IP farmers with valid claims. If the GE farmer adhered to the coexistence measures imposed in the seed purchase contract and a neighboring IP farm is contaminated, the technology provider would ultimately be responsible for the loss. However, if the GE farmer failed to implement the coexistence measures to which he or she was contractually bound under the seed purchase contract, then the technology provider could subrogate its losses from the GE farmer. The IP farmer does not need to be a part of this risk-shifting relationship; the IP farmers’ desire to maximize crop value provides sufficient incentive for them to protect their crops by imposing available coexistence strategies.

Conclusion

While all farmers engage in practices that internalize many of the costs of their respective operations, the government has an interest in promoting coexistence to prevent the consequences of farming that have indirect or latent costs (such as negative environmental or health impacts), as well as to secure a diverse food economy. The report recognized these governmental interests when it called for not only a compensation mechanism but also education and outreach initiatives related to coexistence as well as efforts to ensure the availability of a diverse and high quality commercial seed supply. However, the report addresses each of these concerns separately, advocating for an insurance-based compensation mechanism, voluntary participation in educational programs and behaviors promoting coexistence, and government-driven research regarding coexistence and commercial seed stocks. A great deal of taxpayer funds could be
The government should play a role in advancing coexistence strategies and supporting a compensation mechanism for aggrieved farmers, and thus the aim of Secretary Vilsack and the AC21 is not misdirected. Though the specific features of a well-designed compensation mechanism are beyond the scope of this article, such a mechanism should be guided by two principles. First, the mechanism should incentivize the development of coexistence strategies by technology providers and the dissemination of these strategies to GE farmers. Second, the mechanism should minimize the amount of time and money that farmers must spend seeking redress from technology providers when these coexistence strategies fail.

Developing a compensation mechanism that satisfies these two guiding principles will be difficult. Implementing the mechanism in a way that is both fair to all farmers and flexible enough to accommodate inevitable changes in the panoply of crops in the marketplace will be an even greater challenge. However, instituting a mechanism that misplaces risk and fails to incentivize risk-averse behavior, such as the mechanism proposed in the report, would result in a disservice to farmers on both sides of the equation. If Secretary Vilsack fails to appreciate these shortcomings in the body of the report, perhaps the reservations expressed by a majority of the AC21 members in their comments on the report will give him pause. In response, it should be incumbent on Secretary Vilsack and USDA to give the AC21 another chance to develop a body of recommendations that adequately addresses the questions with which it was tasked.

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Coexistence and the Role of Biotechnology in ANSI’s National Standard for Sustainable Agriculture

Megan Galey

Since the Plant Protection Act of 2000, there has been a lack of significant environmental statutory action at the federal level relating to agricultural biotechnology. Attempts to expand or shrink the scope of relevant federal statutes have had little success. In recent years, efforts to shift toward more environmentally sustainable production systems have focused on incentivizing voluntary changes in production practices and supply chain arrangements rather than advancing and implementing governmental mandates. In response to increased consumer interest in environmentally sustainable products, agricultural stakeholders have sought out opportunities to differentiate products in the marketplace based on production practices.

To meet this need, numerous third-party sustainable production certification and labeling standards emerged. Obtaining certification to a sustainability standard allows producers to differentiate their products in the marketplace, while providing access to new and potentially more profitable niche markets. Certification to a standard is a process whereby an independent third party evaluates the quality of management based on an established set of guidelines or characteristics. The emerging sustainability standards are performance based, relying on best management practices to achieve primarily environmental goals, such as erosion prevention and improvement in water quality. Some standards, however, also incorporate economic sustainability along with social goals, such as managing the migration of transgenic materials.

Although third-party certification standards serve a useful social function, the development of a sustainability standard in an inclusive, transparent, and scientifically objective manner can quickly become highly politicized. The following sections provide an update on the challenge of addressing transgenic crops in one, emerging sustainability standard, the National Sustainable Agriculture Standard, LEO-4000 (an
American National Standards Institute (ANSI) process).

**National Sustainable Agriculture Standard**

Leonardo Academy began the process of developing a comprehensive, continuous improvement framework consisting of environmental, economic, and social metrics for food, fiber, floral, and biofuel production in 2007. The draft version of LEO-4000 was released for public comment in April 2012. See Draft National Sustainable Agriculture Standard, Leo-4000, Leonardo Acad. (Apr. 2012). Leonardo Academy is currently in the process of launching a national pilot program for field tests.

LEO-4000 was designed to advance the adoption of environmentally responsible, socially just, and economically viable production and handling practices by certifying that these management practices are adequately followed. About the Sustainable Agriculture Standard, Leonardo Acad., http://www.leonardoacademy.org. Under the standard, agricultural producers implement management practices intended to (1) facilitate the right of consumers to know how and where agricultural products are produced; (2) minimize soil, water, and air pollution and degradation; (3) maintain and replenish long-term soil health, fertility, and productivity; (4) use inputs efficiently and minimize waste; (5) maintain or enhance biodiversity and habitats; (6) diversify land use on farms; (7) reduce, avoid, offset, and sequester greenhouse gas emissions; (8) foster fair work contracts and protect community rights; (9) plan and manage operations for the short, mid-, and long term; and (10) manage risk, increase resilience to economic, social, and environmental stressors, and minimize negative externalities. See Draft National Sustainable Agriculture Standard, Leo-4000, Leonardo Acad. (Apr. 2012).

If approved as an American National Standard, LEO-4000 will gain additional legitimacy in the marketplace, but the tumultuous and highly politicized standard-setting process may ultimately impact the number of agricultural producers who choose to follow the standard. Leonardo Academy’s oversight of the standard setting process was criticized by representatives of the organic sector who were concerned that a “sustainable” label would increase consumer confusion over the term “organic” and compete with the certified organic market. See Letter from Charles Conner, USDA, to Michael Arny, Leonardo Academy (June 6, 2008). On the other hand, commodity agriculture argued Leonardo was too closely aligned with the organic sector. See Letter from Agricultural Industry Representatives to Michael Arny, Leonardo Academy (Jan. 31, 2008). Opposition from commodity crop producers centered, in part, on a draft standard, Sustainable Agriculture Practice Standard for Food, Fiber and Biofuel Crop Producers and Agricultural Product Handlers and Processors, that promoted organic and fair trade standards, while discouraging the use of biotech crops, pesticides, and fertilizers.

USDA criticized the proposed standard because it was irreconcilable with the agency’s request for a national sustainability standard that was consistent with the definition of sustainability in the 1990 Farm Bill. See Letter from Lloyd C. Day, USDA, to Anne Caldas, American National Standards Institute (Sept. 11, 2008). Unlike the National Organic Program (NOP), a process-based standard that expressly prohibits organic producers from using transgenic materials, the definition of sustainability in the 1990 Farm Bill did not exclude the use of biotechnology, pesticides, synthetic fertilizers, or any other technology. Rather, the Food, Agriculture, Conservation, and Trade Act of 1990 defined sustainable agriculture as a production system that over the long term would (1) satisfy human food and fiber needs; (2) enhance environmental quality and natural resources; (3) efficiently use nonrenewable and on-farm resources; (4) sustain the economic viability of farm operations; and (5) enhance the quality of life of farmers and society. 7 U.S.C. § 3103 (2008).

Attempting to ameliorate the concerns of the U.S. Department of Agriculture (USDA) and commodity crop producers, Leonardo’s standards committee set aside the proposed standard and adopted a technology-neutral approach that allows for the use of biotech crops, pesticides, and fertilizers after they are demonstrated to facilitate agricultural sustainability.
Analyzing the debate surrounding the inclusion of transgenic cropping in a sustainability standard and the significance of USDA’s definition of a sustainable agricultural system requires considering a few of the issues impacting federal agricultural policy. Regardless of whether one prefers high-oleic/low-linolenic acid canola oil, organic canola oil, non-GMO canola oil, or the most inexpensive canola oil available, providing consumers with a variety of choices puts increased pressure on the agricultural industry to use a broad range of cropping systems. In addition to adapting to this increased demand for specialized production methods, the agricultural industry is striving to significantly increase the rate of food production to feed a growing population and combating the diminution of arable lands caused by soil erosion, water scarcity, and a changing climate. Surmounting all of these challenges while continuing to meet consumer preferences requires the continued coexistence of biotech, organic, identity-preserved (IP), and conventional cropping systems. A sustainable balance must be struck. From the perspective of USDA, a national sustainability standard should be a tool that drives the agricultural sector toward a sustainable system, as defined in the 1990 Farm Bill, rather than creating a niche market that operates as a subset of the NOP.

See Letter from Charles Conner, USDA, to Michael Arny, Leonardo Academy (June 6, 2008).

Coexistence Policy Options for a Sustainability Standard

Despite LEO-4000’s adoption of a technology-neutral approach, commodity agriculture has remained leery of LEO-4000 because, at present, its approach to the migration of transgenic materials favors organic and conventional producers who choose to be contractually bound to deliver crops with low levels of transgenic materials. The social criteria for the two lowest tiers of LEO-4000 require producers to describe policies and procedures to prevent genetic migration to neighbors and adjoining ecosystems. The two highest tiers also require biotech growers to implement “policies and procedures to prevent genetic migration to neighbors and adjoining ecosystems,” to cooperate with neighbors and community stakeholders to implement monitoring and preventative measures, and to provide tangible evidence of undertaking “measures to prevent germplasm migration.” See Indicator 5.16.4: Genetic Migration.

While the criteria for the two highest tiers are intended to reduce the risk of economic loss for organic and conventional farmers, the criteria could potentially expose biotech growers to additional liability. Requiring biotech growers seeking certification at the highest tiers to implement measures to prevent genetic migration potentially creates a voluntary standard of care for growers of biotech crops that might be used in judicial proceedings to establish liability for the migration of transgenic material to a neighboring farm or adjoining ecosystem. The risk of creating a heightened standard of care may deter biotech growers from seeking certification.

From the perspective of commodity agriculture, LEO-4000 veered away from a technology-neutral approach consistent with the 1990 Farm Bill and adopted a position that presumes the migration of transgenic materials is causing disputes among farmers. There are limited data available to support this presumption. The USDA’s Advisory Committee on Biotechnology and 21st Century Agriculture (AC21) examined a substantial amount of data on the economic risks directly borne by farmers from the migration of transgenic materials and concluded that, given current stewardship practices, disputes between farmers related to economic losses arising from the migration of transgenic crops are rare. See USDA ADVISORY COMMITTEE ON BIOTECHNOLOGY AND 21ST CENTURY AGRICULTURE, ENHANCING COEXISTENCE: A REPORT TO THE SECRETARY OF AGRICULTURE (Nov. 19, 2012). Growers, in fact, have been successfully pursuing diverse cropping systems for decades in response to consumer demand by relying on market rules and, as necessary, established legal remedies. Responsibility for implementing the production practices necessary to preserve the value of specialty crops traditionally has fallen on the producer of the higher-value specialty crop. The reason for this policy is that a producer of a specialty crop receives a price premium above commodity prices, in part, for the risk associated with producing a specific product for consumers.
Like numerous other agricultural issues, such as water use, pesticide drift, or escaping livestock, there have been disputes between neighboring farmers related to transgenic crops. In the United States, however, no legal disputes between farmers have been litigated because of economic loss caused by the migration of deregulated transgenic materials. The lack of litigation may be evidence that market rules, established legal remedies, and long-standing social norms in the agricultural community are currently providing adequate tools for neighboring farmers to resolve conflicts that emerge from the pursuit of diverse cropping systems.

One of the only reported international cases involving a legal dispute between neighboring farmers over the migration of transgenic materials is Marsh v. Baxter in Western Australia. [2013] WASC 209. Marsh was decertified by an organic certifying body due to the alleged migration of transgenic canola plant material, some of which was claimed to have self-propagated, from Baxter’s farm into Marsh’s neighboring certified organic wheat crop. Marsh sought an injunction to prevent Baxter from planting transgenic canola within 1.1 kilometers of Marsh’s farm and to restrain any harvesting by “swathing,” in circumstances where Baxter had confirmed that he would plant no closer than approximately 300 meters from Marsh’s farm even though he was only obligated to leave a five meter buffer pursuant to his licensing agreement with Monsanto. On April 23, 2013, the Supreme Court of Western Australia rejected the requested injunction based upon the balance of protecting Baxter from the real threat of tangible physical damage by poorly controlled weeds if he were unable to use transgenic canola as part of his normal crop rotation, against the speculative future economic loss to Marsh if he were unable to regain his organic certification, coupled to damages providing an adequate remedy if Marsh ultimately wins at trial.

Good stewardship effectively leads to coexistence. All farmers ought to implement prevention-based stewardship practices such as talking with neighbors about their cropping intentions to evaluate the potential for cross-pollination. In the rare situations where stewardship practices are insufficient, as alleged in Marsh v. Baxter, established legal remedies for the damages caused by the migration of transgenic materials provide a sufficient remedy. These factors in conjunction with the fact that organic production remains a relatively small and geographically concentrated market that involves a wide variety of crops, many of which cannot cross-pollinate with biotech commodity crops, suggest that risk-shifting mechanisms are currently unnecessary to manage coexistence.

With the current coexistence policy in LEO-4000, Leonardo Academy may continue to face intense scrutiny that could potentially prevent the standard from being approved as an American National Standard or otherwise undermine the viability of the standard in the marketplace. If the standard continues to mandate that biotech growers take certain actions to prevent genetic migration, the standard could address some of the liability concerns of commodity producers by incorporating the equitable obligation to mitigate damages. See Drew Kershen, Coexistence—Under-Explored Facets for a USDA Policy, in THE COEXISTENCE OF GENETICALLY MODIFIED, ORGANIC AND CONVENTIONAL FOODS—GOVERNMENT POLICIES AND MARKET PRACTICES (Nicholas Kalaitzandonakes et al. eds., forthcoming). Although an organic grower is not at risk of losing organic certification for a crop under the NOP solely because of the migration of transgenic material from a neighboring farm, if a grower’s certified organic crops are rejected, equitable principles require the grower to take reasonable steps to sell her rejected crops as conventional under the mitigation-of-damages doctrine. See USDA National Organic Program Final Rules 2000. The grower’s damages are therefore limited to the difference in value between the rejected crops as certified organic versus conventional. See A. Bryan Endres, Damage Caused by GMOs Under US Law, in DAMAGES CAUSED BY GENETICALLY MODIFIED ORGANISMS: COMPARATIVE SURVEY OF REDRESS OPTIONS FOR HARM TO PERSONS, PROPERTY, OR THE ENVIRONMENT 740 (Bernard A. Koch ed., 2010). Likewise, if a grower grew certified organic and non-GMO project verified crops, her damages would be limited to the difference in value between certified organic and non-GMO project verified crops versus certified organic crops. If the

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organic grower also entered into a contract with a company that imposed a low tolerance of transgenic material, the company could refuse to pay the price premium agreed to in the contract. While the organic grower bears the risk of receiving the conventional value of her crops, the company could still sell those crops at a premium price as certified organic.

A standard with a holistic coexistence policy that encourages all growers to communicate with their neighbors about cropping practices and, if necessary, to cooperate in developing a flexible coexistence strategy that accounts for variations in farming practices and the crops grown would be more likely to garner support from commodity crop producers in its adoption as an ANSI standard. This position would more closely align LEO-4000 with other sustainability standards, including the Roundtable on Responsible Soy (RTRS) and the Roundtable for Sustainable Biomaterials (RSB). The RTRS revised its coexistence policy in response to further input from legal experts and the concerns of commodity crop producers. The RTRS responded to concerns from the soybean industry by adopting a policy under which a grower of conventional or organic crops is responsible for maintaining a buffer in areas where production primarily consists of biotech crops, but a grower planting biotech crops must maintain a buffer in areas with primarily organic or conventional crops. See RTRS Standard for Responsible Soy Production, Version 1.0 (June 10, 2010). Similarly, the RSB established a GMO expert group to identify potential liabilities for biotech growers due to the wording of the requirements in the standard related to the migration of transgenic materials. Rather than requiring biotech growers to prevent migration of transgenic material, the group recommended adopting a technology-neutral approach that encourages neighbors to cooperate in determining how to avoid undesired commingling. See GMO Expert Group, Roundtable on Sustainable Biomaterials, http://rsb.org/archives/gmo-expert-group/ (last visited Aug. 5, 2013).

Coexistence is obtainable without imposing risk-shifting mechanisms to protect growers who choose to be contractually bound to deliver crops with low levels of transgenic materials. While providing better tools for risk management receives widespread support, agricultural producers have successfully crafted practical solutions when confronted with similar challenges in the past by relying on market rules, established legal remedies, and good stewardship. If USDA’s ongoing analysis of data regarding actual economic losses by farmers who grow crops for identity-preserved markets provides evidence of actual economic loss, an adequate remedy, as recommended by the AC21, can be determined at that time.

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Monsanto has won its suit against Indiana farmer Vernon Bowman for reproducing the company’s patented genetically altered soybean seed without its authorization. With the win, farmers must continue to honor their license agreements or risk being liable for patent infringement. Biotech companies, in turn, are assured of control over seed technology across successive generations of crops. But that assurance could also be crucial in swaying Monsanto and others in supporting farmers’ access to better seed varieties and selling their harvest in foreign markets after those patents expire. Monsanto, together with a number of other seed companies, has signed on to a remarkable private sector initiative designed to ensure uninterrupted exports and facilitate the stacking of traits as patents covering those them expire. Taken together, these developments may help align the interests of farmers and dominant biotech companies like Monsanto. It remains to be seen, however, whether the promised benefits to farmers will bear out in practice.

Monsanto Before the Supreme Court

Seed technology has contributed to vast increases in crop productivity. Most soybean, corn, and cotton seed are grown in an industry worth more than $25 billion worldwide. Monsanto produces and sells genetically altered soybean seed resistant to its Roundup herbicide. These seeds are “self-replicating” technologies because they lead to seed that can be replanted.

Bowman bought soybeans from a grain elevator, expecting most of them to be Roundup resistant. When sued, he argued that Monsanto’s initial sale to an unknown farmer who subsequently sold his seed to the grain elevator extinguished Monsanto’s right to control subsequent generations of its soybeans, including those that Bowman had bought. Both the district court and the Federal Circuit rejected that argument. The Supreme Court agreed with the lower courts. It held that the limitation on patent rights applied only as to the particular article sold. If purchasers could make and sell endless copies, patents would effectively protect only a single sale.

Bowman was part of the Court’s reassessment of the role of patents on living things. It sought to find the correct balance between innovation and reward. The Court recognized that siding with Bowman may result in more robust rights for farmers and users of patented technology in general. At the same time, interpreting this “first sale doctrine” too broadly could destabilize innovation incentives in these industries. The Court stressed the limited nature of its holding. It noted that in another case, reproduction might occur outside the purchaser’s control or might be a necessary but incidental step in using the item for another purpose.

With Bowman, Monsanto may no longer need its restrictive agreements. The decision therefore may loosen its practices, giving seed companies more freedom to make their own choices. The Court’s decision also reassures biotech companies that their pipeline projects will be protected for the time being.

Implications for Foreign Exports and Trait Combinations

What does Monsanto’s win mean for farmers? It is clear that farmers must continue to service their technology agreements with Monsanto and other seed companies as long as the relevant patents are in force. The certainty of reward over the life cycle of their products may encourage greater support by biotech patent owners that will be crucial if farmers are to continue enjoying access to foreign export markets and better seed varieties.

The United States is the largest producer and exporter of transgenic grain and crops. About 90 percent of soybeans, cotton and corn grown the United States are transgenic. Grain traded globally accounts for $40 billion in export revenue annually. Unlike the United States, where the U.S. Department of Agriculture accepts indefinite use of patented seed, foreign governments approve use for a specific time period. Transgenic grain exports thus require periodic renewals. Approvals in the EU expire after ten years, and those in China expire after three.
While biotech companies may have the incentive to maintain these approvals while their patents are in force, once those patents expire, the technology becomes part of the public domain, free to be used by all. Predictably, that incentive is lost. Without someone to maintain regulatory approvals, governments in key markets such as Europe, China, and South America would become closed to U.S. transgenic grain exports. In the EU and China alone, that would mean foregoing over $10 billion in export revenue.

In a remarkable private sector initiative led by the Biotechnology Industry Organization (BIO) and the American Seed Trade Association (ASTA), a voluntary framework called the Accord was created to manage the potential trade disruption from patent expiration. The Accord went into effect on November 15, 2012. As of June 2013, the ten signatories are the American Farm Bureau Federation, the American Seed Trade Association, the American Soybean Association, BASF Plant Science LP, Bayer CropScience, Dow AgroSciences LLC, Dupont Pioneer, Gro Alliance, LLC, the Monsanto Company, and the National Corn Growers Association.

The Accord was presented as an invitation for members of the agricultural value chain to participate and guide its evolution. It sets out the rights and duties involved in commercializing patented single-gene plant products and encourages patent holders to continue developing and commercializing their technology while ensuring that international regulatory and stewardship responsibilities are maintained. These goals are achieved via data access and compensation to the biotech companies. Patent owners are required to notify interested parties to the Accord three years prior to relevant patents expiring. Owners can choose to share or transition regulatory responsibilities through negotiation or arbitrations, if necessary.

The Accord contains two agreements, the Generic Event Marketability and Access Agreement (GEMAA) and the Data Use and Compensation Agreement (DUCA). GEMAA allows patent owners or generic competitors willing to pay for the necessary data to obtain regulatory approval to do so without conducting their own health and environmental studies. In this regard, GEMAA bears similarities to an abbreviated process where generic drug companies can “fast-track” approval of their drugs at FDA by showing bioequivalence to patented drugs. The effect of GEMAA is to ensure that seed exports can continue to be sold and processed after patents covering the crops expire.

GEMAA benefits seeds covered by at least one U.S. patent that are commercialized either by themselves or as stacked products in the United States at least four years prior to the expiration of the last U.S. patent. The events covered by GEMAA are fairly broad: patent term expiration, lapse in maintenance fees, invalidity or unenforceability of the relevant claims, and a declaration of non-infringement by the patent holder.

One significant limitation of GEMAA is that it may be nullified by a prior agreement to the contrary. Another limitation is that patent holders are only obligated to good faith negotiations for expired patents. While parties are to offer “reasonable and appropriate value,” neither is bound to accept the offer. The smartphone and tablet industries have been grappling with the question of what constitutes a “reasonable” royalty for many years, and the courts are only now beginning to define what that means. These may help inform the outcome of GEMAA disputes. Another element in GEMAA that dilutes its efficacy is that even “joint responsibility” parties who are bound by the arbitral award are not obligated to execute it.

Some companies, such as Monsanto, have chosen to independently maintain regulatory responsibilities. These companies may refuse data access to companies seeking to develop new stacked seed products. At the same time, these companies must maintain global regulatory authorizations at no charge to users of its technology unless the companies choose to share those responsibilities or discontinue maintaining them. Choosing to discontinue starts a seven-year transition phase where other seed companies can access data necessary to continue seeking foreign regulatory approvals.

DUCA promotes the range of crop options available to farmers through regulatory data sharing arrangements. Currently, more than 24 trait combinations are commercially available. After patents expire, seed companies may want to use off-patent technology to develop and offer seeds stacked with expired traits.
For example, as the last of many Roundup Ready patents expires in March 2015 in the United States (earlier in Canada), companies and universities with breeding programs using its patents can continue offering products containing the traits.

The measure of control DUCA provides patent owners encourages them to participate in the innovation and commercialization of products containing traits going off-patent. It also encourages licensing agreements without the obligation for farmers to pay post-expiration royalties, as well as destroy or return seed after licenses expire. Monsanto, for example, has committed not to exercise plant variety patent rights against farmers saving seeds for replanting on their own farms once the trait technology has expired. At the same time, Monsanto has stated that it will continue to enforce variety patents and plant variety protection certificate rights against unauthorized commercialization and development.

The Accord emerged from DuPont’s antitrust litigation against Monsanto in 2009 when it first commercialized Roundup Ready 2 Yield, its next generation herbicide resistant trait. DuPont sought to stack the Roundup Ready 2 gene with its own glyphosate resistant gene. DuPont’s suit prompted investigations by the state attorneys generals’ in 2007, and the Department of Justice initiated its own investigation in 2010. In all likelihood, the agencies would have sued Monsanto based on the theory that it used its monopoly in the provision of genetic traits both to exclude rivals and to gain advantage in the market for the breeding and retailing of seeds.

By March 2013, Monsanto settled with DuPont. As part of that settlement, DuPont’s Pioneer subsidiary will pay Monsanto at least $1.75 billion in royalties from 2014 to 2023 for the rights to develop Roundup Ready 2 Yield crops. In return, Monsanto will gain access to DuPont technology related to crop disease resistance. In November 2012, the Justice Department decided to close its investigation with no prosecution. National Sustainable Agriculture Coalition, Department of Justice Drops Monsanto Antitrust Investigation Without Explanation (Dec. 5, 2012), www.sustainableagriculture.net/blog/doi-drops-investigation/ (last visited Sept. 8, 2013). The Justice Department, in a terse response to inquiries on the closure of its investigation, stated that its investigation into “possible anticompetitive activity” in the seed industry was superseded by “marketplace developments that occurred during the pending of the investigation.” The state attorneys general followed suit in discontinuing their own investigations.

While not explicitly acknowledged, the inescapable conclusion is that both Monsanto’s settlement with DuPont and its willingness to support the Accord kept it out of further trouble with the antitrust enforcers. It has every incentive to stay its course in opening up access to its technologies in a manner that it can control, rather than to do so under an antitrust decree. Other seed companies with appreciable market power will do well to follow suit.

Conclusion

The Accord is a promising start to ensuring continuity to export markets and better seed varieties when trait patents expire. At least in theory, it opens the market to generic competition. However, this coalition of the willing few may not be enough. It will take an industry-wide adoption of the Accord, coupled with a commitment to speedy dispute resolution and a willingness to continually refine its terms that will infuse it with the longevity, legitimacy and effectiveness it needs to ensure product stewardship into the foreseeable future. The Supreme Court decision in Bowman reassures owners of seed patents that their investment in innovation is secure. This reassurance should encourage seed companies to join the Accord, which will help stakeholders focus on bringing farmers the best products possible while working to advance innovation and long-term opportunity for agriculture.

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REGULATION OF FAN EMISSIONS AT POULTRY CAfos: AN ONGOING CONTROVERSY
M. Rosewin Sweeney

Introduction
The U.S. Environmental Protection Agency (EPA) revised its concentrated animal feeding operations (CAFO) regulations on February 12, 2003 (2003 Rule) to expand the universe of CAFOs regulated under the Clean Water Act (CWA) to include dry poultry CAFOs and to adopt new effluent limitations guidelines. Agricultural interests and environmental organizations immediately challenged aspects of the new regulations, with mixed success. See Waterkeeper Alliance, et al. v. EPA, 399 F.3d 486 (2d Cir. 2005).

Of significance for this article is the provision of the 2003 Rule that required animal feeding operations of a certain size to obtain a National Pollution Discharge Elimination System (NPDES) permit unless the owner or operator could affirmatively demonstrate that it had “no potential to discharge,” a provision that was vacated by the Second Circuit in Waterkeeper in February 2005. As a result of this decision, EPA was required to engage in further rulemaking and repeatedly extended the deadline by which newly defined CAFO operations were to apply for NPDES permits. See the history of revised rule at 73 Fed. Reg. 70,418, 70,422 (Nov. 20, 2008)(“2008 Rule”). The 2008 Rule provided in relevant part that operations that were newly defined as CAFOs in the 2003 Rule and that “propose[d] to discharge” must “seek to obtain permit coverage under an NPDES permit by February 27, 2009.” 40 C.F.R. § 122.23(f).

Without the broad “duty to apply” provision of the 2003 Rule, it was much more difficult for EPA to force animal feeding operations to obtain NPDES coverage and to implement the best management practices (BMPs) required by the CAFO regulations. In the wake of Waterkeeper, an owner or operator no longer had to prove that its animal feeding operation could not discharge. Under the 2008 Rules, EPA was required to show that the facility would or did discharge.

Such proof is hard to come by at poultry CAFOs with dry manure handling systems because dry poultry manure is typically stored under a roof and therefore not subject to precipitation that would result in visible discharges. In apparent response to this permitting gap, EPA Region III has taken the position that the release of dust and feathers through poultry house ventilation fans could trigger an obligation to obtain a discharge permit. Similarly, the Waterkeeper Alliance has asserted in a citizen suit against a Maryland CAFO that dust from fan emissions could lead to CWA liability. This approach to fan emissions is vigorously opposed by the poultry industry.

EPA’s Evolving Position on Fan Emissions Is Inconsistent with Its Contemporaneous Explanation of the 2003 CAFO Rule

When EPA adopted the 2003 Rule it stated that it did “not include provisions addressing air pollutants from CAFOs” for reasons it summarized in an essay titled CAFOs as Sources of Air Pollutants, which was published as an appendix with EPA’s response to comments on the NPDES Permitting Requirements and Effluent Limitations Guidelines for Concentrated Animal Feeding Operations. Id., December 2002, at 21–68. EPA’s essay stated: “While EPA clearly recognizes that CAFOs are also a source of potentially harmful air pollutants, including those that cause surface water quality effects, health effects, and odor problems, today’s final rule does not include provisions addressing air pollutants from CAFOs . . .” Emphasis added. The long list of air pollutants that EPA stated it was not regulating in the 2003 Rule included particulate matter, ammonia, dust, and feathers. Id., Appx. at A-4. “EPA considered whether CAFO air pollutant emissions should be regulated under the CWA. However, EPA determined that the [Clean Air Act] has the authority necessary to control such emissions and they are most appropriately addressed by [that] statute.” Id., Appx. at A-5 & A-6.

Despite EPA’s contemporaneous statement disavowing its intention to regulate air pollutants via the NPDES program, the agency soon began asserting otherwise. EPA’s December 2003 Permit Writers’ Guidance Manual stated that, even though the newly adopted CAFO effluent limit guidelines did not address pollutants from poultry house ventilation fans, permit
writers could use best professional judgment to regulate material that fell to the ground immediately downwind from ventilation fans as “process wastewater” if it was carried by stormwater runoff to waters of the United States. See NPDES Permit Writers’ Guidance Manual and Example NPDES Permit for Concentrated Animal Feeding Operations, U.S. E.P.A. – 833 – B-04-001, December 31, 2003. Id. at 4-2, available at http://www.epa.gov/npdes/pubs/cafo_permit_guidance_entirepub.pdf. Despite EPA’s guidance, whether the Clean Water Act actually applies to such materials is debatable. See Chemical Weapons Working Group v. United States Department of the Army, 111 F.3d 1485, 1490 (10th Cir. 1997) (“common sense dictates that [defendant’s] stack emissions constitute discharges into the air—not water” and are therefore beyond CWA’s reach); No Spray Coalition, Inc. v. City of New York, 2005 U.S. Dist. LEXIS 11097, *12–13 (S.D.N.Y. 2005) (stating that CWA might apply to pollutants from sprayed pesticides, but only if pesticides were sprayed directly over a navigable water).

EPA’s assertions in guidance that fan emissions could prompt a need to obtain a NPDES permit appear to have initially gone unnoticed, likely because of the repeated extensions of the compliance deadline following the Second Circuit’s Waterkeeper decision. However, as the final February 27, 2009, compliance deadline approached, EPA Assistant Administrator Benjamin H. Grumbles asserted in guidance letters to members of Congress and a poultry company executive that “litter released through confinement house ventilation fans” could trigger the obligation to obtain an NPDES permit. See National Pork Producers, et al. v. E.P.A., et al., 635 F.3d 738, 747–48 (5th Cir. 2011). EPA’s guidance letters were challenged by the poultry industry in National Pork as rulemaking without proper notice and comment but their challenge was dismissed on the grounds that the letters neither created “new legal consequences” nor affected petitioners’ rights or obligations because they “merely restate[d] section 1342’s prohibition against discharging pollutants without an NPDES permit.” Id. at 756. (A review of the record in National Pork reveals that the Fifth Circuit was not provided with EPA’s essay stating that the 2003 Rule did not regulate pollutants released through fans.)

As early as September 2010, EPA Region III was issuing administrative orders directing poultry growers to apply for permit coverage because inspectors observed dust and feathers on the ground near poultry house ventilation fans. Those orders asserted, among other things, that, “on information and belief, dust from the ventilation fans includes fine particles of dander and manure” that was “exposed in a manner so that it would come into contact with precipitation and generate process wastewater” that could discharge to man-made ditches and eventually to waters of the United States. EPA further alleged that the facilities were “designed, constructed, operated and maintained in a manner that has proposed to discharge pollutants . . .,” prompting the respondents’ obligations to obtain a NPDES permit. See In the Matter of: FPNA Farms Incorporated, EPA Region III Docket No. CWA-03-2010-0400DN (Sept. 29, 2010); In the Matter of: Ryan L. Brady, EPA Region III Docket No. CWA-03-2010-0416DN (Sept. 29, 2010); emphasis added.

In addition to addressing EPA’s guidance on fan emissions, National Pork Producers, et al. v. E.P.A., et al., vacated that portion of the 2008 Rule that required CAFOs that merely proposed to discharge, rather than actually discharged, to apply for a discharge permit. Id. at 751. After this holding, EPA Region III apparently modified the boilerplate in its compliance orders so that they alleged that facilities were “designed, constructed, operated and maintained in a manner that has discharged pollutants.” See In the Matter of: Timothy Wilkins, EPA Region III Docket No. CWA-03-2012-0021DN (Nov. 14, 2011); In the Matter of: Mrs. Lois Alt, EPA Region III Docket No. CWA-03-2010-0023DN (Nov. 14, 2011); emphasis added. However, in neither of these orders did Region III assert that its inspectors actually confirmed a discharge to the waters of the United States. Both orders alleged simply that pollutants (including dust and dander) would, in the event of precipitation, be carried into man-made ditches that ultimately connected to waters of the United States.

Lois Alt Calls EPA’s Bluff

Lois Alt brought suit against EPA on June 14, 2012, seeking a declaratory judgment that EPA’s November 14, 2011, compliance order was invalid because it required her to obtain a permit under the CWA for
discharges she asserted were unregulated agricultural stormwater. *Lois Alt v. American Farm Bureau, No. 2:12-cv-00042-JPB (N.D. W.Va. April 22, 2013), ECF No. 88, at 1–2.* Although EPA later withdrew its compliance order to Alt, and then moved to dismiss her complaint as moot, the agency’s motion was denied on April 22, 2013. The court found that Alt’s claim was not moot because, based on the orders issued by Region III to other poultry growers, EPA’s actions could reasonably be expected to recur. The court also described the order that EPA issued to Alt as “morph[ing]” EPA’s finding that there was a potential for stormwater runoff containing manure and ventilation dust to enter the waters of the United States into a finding that Mrs. Alt had discharged pollutants. The court characterized this as a way for EPA “to circumvent the rule announced in *Waterkeeper Alliance, et al. v. EPA*, 399 F.3d 486 (2d Cir. 2005) that without an actual discharge the EPA has no authority and there can be no duty to apply for an NPDES permit.” *Id.* at 12–13.

The court established a briefing schedule for *Alt*, with motions for summary judgment and responses were filed by Alt, EPA, and multiple intervenors between July 1, 2013 and October 4, 2013.

**Waterkeeper Alliance Asserts CWA Liability for Fan Emissions**

Although EPA Region III has issued at least four compliance orders alleging CWA violations for fan emissions, it is not readily apparent that other regions have done so. Nor does EPA appear to have filed enforcement actions in any U.S. district court on this basis.

However, the Waterkeeper Alliance has attempted to hold a poultry grower and his integrator liable under the CWA for, among other things, dust exhausted from poultry house fans. *See Waterkeeper Alliance, Inc. v. Alan Hudson, et al., No. WMN-10-487, 2012 WL 6651930 (D. Md. Dec. 20, 2012).* The Waterkeeper Alliance sued in March of 2010, after sending a 60-day notice letter that alleged pollution was occurring as a result of stockpiled poultry manure. When that stockpile turned out to be Class A biosolids, not poultry manure, the plaintiff’s case shifted to a claim that ammonia and dust from poultry house exhaust fans and small amounts of poultry litter scattered on heavy use pads were the source of pollutants found in drainage ditches on and near the farm, which also raised cattle.

The parties briefed whether dust from fan emissions could be the basis for CWA liability but the court did not rule on that issue, deciding that *Waterkeeper Alliance* had not shown that the poultry operation discharged to the waters of the United States. (The court is currently considering defendants’ motions for attorneys’ fees under 33 U.S.C. § 1365(d).)

**Conclusion**

Although EPA is entitled to deference in interpreting its own regulations, the agency’s interpretation of its regulation at the time of its adoption should control over contrary later interpretations. *See, e.g., Taylor v. Progress Energy, Inc.*, 493 F.3d 454, 461 (4th Cir. 2007). EPA’s December 2002 essay, *CAFOs as Sources of Air Pollutants*, was explicit that the agency was not regulating fan emissions. Furthermore, had EPA planned on regulating fan emissions, it surely would not have determined, as it did, that “total containment” for new poultry sources was “technologically feasible and will not pose a barrier to entry for new sources subject to Subpart D.” *See* Response to comments on the NPDES Permitting Requirements and Effluent Limitations Guidelines for Concentrated Animal Feeding Operations, December 2002, at 11–410. Neither EPA’s response to comments nor the economic analysis that EPA prepared in support of the 2003 rule indicated an intention to control fan emissions under the rule. *See* Economic Analysis of the Proposed Revisions to the National Pollutant Discharge Elimination System Regulation and the Effluent Guidelines for Concentrated Animal Feeding Operations, January 1, 2001 *(EPA-821-R-01-001).*

If EPA opts to regulate air emissions from poultry CAFOs under any of its statutory authority, it should do so only after notice and comment, which has not yet been provided to the public.

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PROBLEMS IN THE MISSISSIPPI RIVER ARE FLOWING UPSTREAM: GULF RESTORATION NETWORK V. EPA
Todd J. Janzen

In 2008, various nonprofit environmental groups petitioned the U.S. Environmental Protection Agency (EPA) to create rules to reduce nitrogen and phosphorus pollution in the Mississippi River Basin. The environmental groups argued that because of the massive dead zone in the Gulf of Mexico—known as “gulf hypoxia”—the EPA was required to do a better job of reducing nitrogen and phosphorus run-off into the Mississippi River and its upstream tributaries. The groups asserted that the Clean Water Act required the EPA to create new rules for reducing nitrogen and phosphorus.

The EPA did not respond with sweeping new regulations for the states in the Mississippi River Basin. Instead, the EPA responded that the Clean Water Act provided the EPA with deference for how to address water pollution. With regards to nitrogen and phosphorus pollution, the EPA advocated for continued cooperation with state agencies to address the problem, rather than EPA preemption and new regulation. Not satisfied with this response, the environmental groups sued the EPA in the eastern district federal court in Louisiana.

On September 20, 2013, the district court issued its ruling in Gulf Restoration Network, et. al. v. Jackson, Case No.12-cv-677 (E.D. Louisiana 2013). The court sided with the environmental groups, holding that the EPA cannot avoid its rulemaking duties merely by asserting its “policy” was to work with state agencies in the Mississippi River Basin to reduce nitrogen and phosphorus run-off. The EPA can ultimately decline to regulate nitrogen and phosphorus run-off in the Mississippi River Basin, but to do so it must first explain a scientific or statutory basis for doing so. It is not adequate to merely state that individual states are addressing the problem. The court gave the EPA six months to fully respond to the petition for rulemaking.

The stakes are high in this matter. At issue is whether the EPA will impose new regulations for all states in Mississippi River Basin to reduce nitrogen and phosphorus run-off. These new regulations might include “numeric nutrient criteria”—specific limitations for allowable run-off in streams and rivers. Alternatively, if the EPA can make a proper response to the petition that EPA intervention is not necessary, the EPA will continue to work with state agencies to reduce run-off through state led programs, regulations and initiatives.

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