

# Agricultural Management Committee Newsletter

Vol. 9, No. 1

January 2005

## MESSAGE FROM THE CHAIR

**Daniel M. Krainin**  
*Beveridge & Diamond, P.C.*  
*New York, New York*

I am pleased to introduce the most recent issue of the Agricultural Management Committee Newsletter. This biotech-themed issue features three articles on the cutting-edge field of agricultural biotechnology. The first, by Jane Earley, expands on her 2004 Annual Conference on Environmental Law (Keystone) presentation by examining the liability issues that are emerging in light of the increasingly common practice by U.S. trading partners, such as the European Union, to impose "zero tolerance" or very low limits on the amount of genetically modified crops present in international commodity shipments. The second article, by Kimball Nill of the American Soybean Association reprises his speech at the 12th Section Fall Meeting in San Antonio about how biotech crops may help reduce run-off that creates marine "dead zones." The final article, by Committee Vice Chairs Tom Redick and Alan Sachs, provides a chronological overview of the development and commercialization of plant-made pharmaceuticals (PMPs), as well as offering some thoughts on the future of PMPs from an agricultural management standpoint. The Agricultural Management Committee has hosted three programs on biopharming and will continue to follow this issue as regulatory policy adapts to the pipeline of PMPs.

In addition, this issue of the Newsletter includes both a political roundup and a review of some of the more important recent agricultural management decisions to come out of state and federal (and, in one case, Canadian) courts. Cases covered include agricultural issues arising in the context of the Clean Water Act; the Endangered Species Act, Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA); the Emergency Planning and Community Right to Know Act (EPCRA); nuisance law; and local biosolids ordinances. Topics covered in the roundup include concentrated animal feeding operations, agricultural air emissions, biotech crops and aerial application of pesticides.

I hope you find this issue of the Newsletter interesting and informative. Please contact Newsletter Vice Chair Tom Redick with any ideas for upcoming issues. In particular, the Committee plans to publish two "theme" issues on "CAFOS" and "sustainable agriculture" in 2005. We are looking for additional contributors on those important topics, so please contact Tom with your ideas.

Likewise, please touch base with Program Vice Chair Brandon Neuschafer (bwneuschafer@bryancave.com) if you have suggestions for topics for upcoming Committee programs. Among other programs in 2005, the Committee intends to host a Question and Answer session

**Agricultural Management  
Committee Newsletter  
Vol. 9, No.1, January 2005  
Thomas P. Redick, Editor**

***In this issue:***

Message from the Chair  
*Daniel M. Krainin* ..... 1

Agriculture and Politics – Election Year  
Update  
*Thomas P. Redick* ..... 2

Agricultural Management Case Law Update  
*Daniel M. Krainin and Ami M. Grace* ..... 3

Potential Grower Liability for Biotech Crops  
in a Zero-Tolerance World  
*Jane Earley, Esq.*..... 8

Biopharming: Its Recent Past and  
Foreseeable Future  
*Thomas P. Redick and Alan J. Sachs* .. 13

How Biotechnology-Derived Crops Reduce  
the Run-Off That Creates “Dead Zones”  
*Kimball Nill* ..... 18

© 2005. American Bar Association. All rights reserved. The views expressed herein have not been approved by the ABA House of Delegates or the Board of Governors and, accordingly should not be construed as representing the policy of the ABA.

This newsletter is a publication of the ABA Section of Environment, Energy, and Resources, and reports on the activities of the committee. All persons interested in joining the Section or one of its committees should contact the Section of Environment, Energy, and Resources, American Bar Association, 321 N. Clark St., Chicago, IL 60610.



with U.S. Department of Agriculture General Counsel Nancy S. Bryson.

In the meantime, please contact us with your ideas for the Committee and check the ABA Web site at <http://www.abanet.org/enviro/committees/agricult/home.html> for information and new developments regarding the Committee.

---

**AGRICULTURE AND POLITICS –  
ELECTION YEAR UPDATE**

---

**Thomas P. Redick**

**Agriculture Secretary Veneman Steps  
Down**

On Nov. 15, 2004, Secretary of Agriculture Ann Veneman, the first woman to hold that post in the 142-year history of the U.S. Department of Agriculture (USDA), resigned after four years on the job. Veneman’s legacy includes advances in funding conservation easements and anti-bioterrorism initiatives, as well as her skillful handling of the “mad cow” crisis last winter. Secretary Veneman also oversaw the implementation stages of a Farm Bill that triggered worldwide controversy due to renewed farmer subsidies. Secretary Veneman will remain at USDA until a successor can be appointed and confirmed by the Senate.

On Dec. 2, 2004, President Bush nominated Nebraska Gov. Mike Johanns (Republican) to be the next secretary of Agriculture. Gov. Johanns is a proponent of biofuels, led the Western Governors Association on issues relating to drought relief and supported the Renewable Fuels for Energy Security Act in 2001. Analysts do not believe that the selection of Gov. Johanns signals a significant policy shift for the Bush administration on agriculture issues.

## Three California Counties Reject GMO Bans; Marin Goes Non-GMO

The California counties of Butte, Humboldt, Marin and San Luis Obispo all held votes on Nov. 2, 2004 to determine whether they would ban the cultivation of genetically modified (GM) crops in their particular counties. While the initiatives varied in their approach to GM crops, the three counties with significant commercial agriculture (Butte, Humboldt and San Luis Obispo) did not pass the proposed initiatives.

The only initiative to gain voter approval was Marin County's, which has some organic and homegrown agriculture, but is not home to a significant amount of commercial agriculture. Marin, following Mendocino and Trinity Counties, became the third California county to enact a ban on cultivation of biotech crops.

The Marin County ordinance evokes echoes of the Starlink litigation (where an allegation that a biotech crop was a "public nuisance" survived a motion to dismiss) by making the cultivation of GM crops a "public nuisance" and giving a private citizen allegedly harmed by commingling of GM crops a chance to sue as a "private attorney general" for the county. Given the relative geographic isolation of Marin County, however, there appears to be little risk of pollen drift or post-harvest mixing crossing over from a neighboring county to cause a public nuisance there.

Voters in the other three counties (Butte, Humboldt and San Luis Obispo) rejected similar proposed GM bans by substantial margins. The backers of these California county initiatives consider the Marin and Mendocino initiatives to be the start of a process to bring the United States into line with some nations in rejecting biotech crops. The more agriculture-intensive counties in California, however, allow farmers to plant biotech crops.

A future newsletter article will address legal challenges (constitutionality) of these ordinances.

## AGRICULTURAL MANAGEMENT CASE LAW UPDATE

---

Daniel M. Krainin  
Ami M. Grace

The following, arranged by topic, are some key agricultural management cases decided in the last several months:

### Clean Water Act

- *South Florida Water Management District v. Miccosukee Tribe of Indians*, 124 S. Ct. 1537, 158 L. Ed. 2d 264 (2004) (finding that water pumps can be clean water act point sources)

In March 2004, the U.S. Supreme Court decided a Clean Water Act case with potentially significant implications for the movement of agricultural water throughout the country. In *South Florida Water Management District v. Miccosukee Tribe of Indians*, the U.S. Supreme Court held that water pumps that pump phosphorus-laden water from one waterbody to another must be regulated as point sources under the Clean Water Act. The Court decided that a point source does not have to be the original source of a pollutant; rather, a point source requires a Clean Water Act permit if it conveys a pollutant to "navigable waters," otherwise known as "waters of the United States."

The case arose after the state of Florida instituted the Central and South Florida Flood Control Project (Project) to reengineer the Florida Everglades to open parts of the Everglades for development. Water pumps, impoundments, canals and levees helped a Florida agency to artificially separate areas that would naturally form one large wetland. The Miccosukee Tribe of Indians and the Friends of the Everglades sued the Florida water management district over five elements of the Project that were allegedly contributing to

elevated levels of phosphorus in the Everglades.

The Plaintiffs argued that the water management district could not operate the large pump station that transports water from the developed land to the wetlands without the National Pollution Discharge Elimination System (NPDES) permit that is required for point sources of pollution under the Clean Water Act. The Court held that point sources that convey pollutants require NPDES permits, even if the point source was not the original source of the pollutant. The Court remanded the case to the district court to determine if the waterbodies at issue could be considered to be two separate bodies of water. Although the waterbodies at issue were separated by two levees, the court found that the levees leak and allow water to flow freely between them. If the district court should find the waterbodies to be separate, an NPDES permit would be required to transfer phosphorus from one waterbody to another because, based on the Court's holding, the transfer would be a discharge of a pollutant into a navigable waterway. On the other hand, if the district court should find the water management district is merely redistributing water from one part of a large waterbody to another part of that same waterbody, then an NPDES permit would not be necessary because no pollutant would be discharged into a navigable waterway.

The Court also discussed, but declined to rule on, the government's unitary waters theory. Under this theory, an NPDES permit would not be required when water from one navigable waterbody is discharged, unaltered, into another navigable waterbody because all navigable waters should be treated as part of the single set of U.S. "navigable waters" under the Clean Water Act. The government argued that the absence of the word "any" prior to the phrase "navigable waters" in Section 502(12) of the Clean Water Act reveals Congressional intent to exempt engineered transfers of water from one

navigable waterbody to another from NPDES permit requirements.

The Bush administration, as well as New York City and 11 western states, supported the Florida water district. They argued in amicus briefs that the Court's ruling could impose substantial economic and regulatory costs on states and cities that move large amounts of agricultural and drinking water through pipes, aqueducts and reservoirs.

### **CAFOs and Nuisance Law**

- *Gacke v. Pork Xtra, L.L.C.*, 684 N.W.2d 168 (Iowa 2004) (holding that statute purporting to grant nuisance immunity to CAFOs violates state constitution)

In *Gacke v. Pork Xtra*, the Iowa Supreme Court held that a state law granting nuisance immunity to concentrated animal feeding operations (CAFOs) resulted in an unconstitutional taking of private property without just compensation, in violation of the Iowa Constitution. The Iowa statute at issue provided that CAFOs shall not be found to be public or private nuisances, nor shall they be found to interfere with one's use and enjoyment of life or property. Iowa Code § 657.11(2) (2004). The Gackes, who have resided in their home since 1974, filed a lawsuit against two hog feeding operations operated by Pork Xtra that moved in across the road from their home in 1996. The Gackes claimed that Pork Xtra's facilities were a nuisance, causing them personal injury and decreasing the value of their property.

The court found that the statutory immunity provision violated the takings clause of the Iowa Constitution and that the granting of an easement across the Gackes' property was an actual taking. According to the court, the appropriate remedy in such a case would be compensation for the decrease in fair market value of the property.

The court also found both that the Gackes had an inalienable right founded in state constitutional private property rights to enjoy their property without noxious odors, and that the state statute denying them this right was unduly oppressive and not a reasonable exercise of state police power. According to the court, the Gackes were suffering the negative consequences of the statute without realizing any of the public benefits the statute was enacted to confer. Lastly, the court found the Gackes did not come to the nuisance. The court concluded that Pork Xtra used the Gackes' property without due regard for the family's personal and property rights.

### **CAFOs and Federal Reporting Requirements**

- *Sierra Club, Inc. v. Seaboard Farms, Inc.*, No. 03-6104 (10th Cir. Oct. 28, 2004) (holding that uniformly managed CAFOs are to be treated as a single "facility" for purposes of CERCLA reporting requirements), available at <http://www.kscourts.org/ca10/cases/2004/10/03-6104.htm>.

In an opinion issued in late October 2004, the Tenth Circuit held that, even where feeding operations may contain multiple emission sources, uniformly managed CAFOs are to be treated as a single facility for purposes of federal reporting requirements under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA). In so holding, the appellate court reversed a decision by the U.S. District Court for the Western District of Oklahoma.

The *Seaboard* case involved an Oklahoma pig-farming operation consisting of two separate but adjacent farms, each with eight buildings, a total of 25,000 pigs and various emission points. The Sierra Club sued, arguing that the farm's owner, Seaboard Corp., violated CERCLA Section 103 by failing to report the

farm's total ammonia emissions. Section 103 requires reporting of hazardous substances that are knowingly released from a "facility" in amounts greater than the federally established reportable quantity; ammonia is listed as a hazardous substance under CERCLA.

Relying on the definition of "facility" found in Section 101(9)(B) of CERCLA and the statute's remedial purpose, the Tenth Circuit held that CERCLA is broad enough to require a farm operator to report the farm's total accumulated emissions. See 42 U.S.C. § 9601(9)(B) (defining "facility" to include "any site or area where a hazardous waste substance has been deposited ... or placed, or otherwise come to be located"). The Tenth Circuit relied heavily on the only other published federal court opinion on point (besides the decision it reversed), *Sierra Club, Inc. v. Tyson Foods, Inc.*, which is discussed below.

- *Sierra Club, Inc. v. Tyson Foods, Inc.*, 299 F.Supp.2d 693 (W.D. Ky. 2003) (holding that controlling contractor may be liable under CERCLA and EPCRA for failing to report emissions from contractees' facilities)

Last year, in a preview of the decision reached by the Tenth Circuit in the *Seaboard* case discussed above, the U.S. District Court for the Western District of Kentucky held that ammonia emissions from an entire chicken production facility should be aggregated for purposes of reporting requirements under CERCLA and the Emergency Planning and Community Right-to-Know Act (EPCRA). The court also held that Tyson Chicken (a subsidiary of Tyson Foods) was responsible for not reporting ammonia emissions emanating from several production facilities owned and operated by third parties pursuant to contracts with Tyson.

Tyson Chicken uses an increasingly common technique to produce chickens. Through a production contract, the company supplies

chickens to its contracting farmers which the farmers then raise using Tyson feed and management practices, eventually giving the chickens back to Tyson Chicken. The court held that Tyson Chicken qualified as both a “person in charge” under Section 103(a) of CERCLA and an “owner or operator” under Section 304(a) of EPCRA because the company retained power over each facility and could have prevented ammonia releases. Significantly, the court noted that Tyson Chicken employees visited each facility weekly to advise farmers on proper management practices.

### **Biotech Crops**

- *Monsanto Canada, Inc. v. Schmeiser*, 2004 SCC 34 (Can. May 21, 2004) (holding that farmer could not save seeds from genetically engineered plants he allegedly found growing in his field), available at <http://www.canlii.org/ca/cas/scc/2004/2004scc34.html>.

In a decision watched closely by the international legal community, in May 2004 the Supreme Court of Canada ruled that a Saskatchewan farmer violated a Monsanto patent on genetically engineered seeds when he planted Monsanto seeds without first purchasing them and then sold the crops produced. The farmer, Percy Schmeiser, had never purchased Roundup Ready seeds from Monsanto, nor had he obtained a license to plant them, but nearly all of his crop was comprised of Roundup Ready Canola. While the Court found the origin of the seeds to be unclear, the Court speculated that the seeds might have blown over from some of the neighboring farms using the patented seed. According to the Court, Mr. Schmeiser collected and planted gene-altered seeds, sprayed the plants with Roundup Ready and then kept the seeds of the plants that survived the Roundup spraying.

Under section 42 of the Canadian Patent Act, Monsanto has “the exclusive right, privilege and

liberty of making, constructing and using the invention and selling it to others to be used.” The Court decided that although Mr. Schmeiser did not make or construct the cells or genes that comprise the patented seed, he did use the patented gene or cell. First, the Court noted that when a defendant receives commercial benefit for another’s patented invention, it is more likely that patent infringement will be found because any commercial benefit from a patent belongs to the inventor. Second, considering other Canadian court interpretations of the word “use” under the Patent Act, the Court found that “use” refers to patented products themselves as well as their output if the patent is a significant part of production. In this case, the Court held that Monsanto’s patent on its seeds was significant because patented genes and cells were present throughout Mr. Schmeiser’s genetically modified crops.

This decision is widely considered a victory for proponents of genetically engineered crops. Ironically, though, the Court’s ruling might bolster lawsuits by opponents of biotech crops. Biotech crop opponents hope to use this decision in support of their theory that seed manufacturers and distributors such as Monsanto’s own gene-altered windblown pollen. Such a finding could make Monsanto and similar companies liable for polluting regular fields with gene-altered pollen. A group of Canadian organic farmers has already filed a class action lawsuit against Monsanto and another company claiming their fields were polluted with gene-altered pollen.

The Court was closely divided, 5 to 4, on whether Monsanto’s patent had actually been infringed. Dissenting judges found that the Patent Act does not apply to living organisms that can grow and reproduce because this would give holders of patents to genetically modified organisms greater rights than holders of patents to nonliving objects.

## Endangered Species Act

- *Washington Toxics Coalition v. Environmental Protection Agency*, No. 01-CV-00132-ANS (W.D. Wash., Jan. 22, 2004) (holding 100-yard buffer zones required for aerial pesticide application to protect salmon), available at <http://www.epa.gov/espp/wtc/index.html>.

Early this year, in an Endangered Species Act (ESA) challenge, the Washington Toxics Coalition won a motion for injunctive relief to establish 100-yard buffer zones for aerial-applied pesticides adjacent to waters that support salmon. The same court order also established 20-yard buffer zones for ground-applied pesticides. The injunction will be in place until the Environmental Protection Agency (EPA) and the National Marine Fisheries Service (NMFS) can conclude whether the endangered Pacific salmon and steelhead are sensitive to 55 pesticides.

CropLife America and 30 other organizations from western states filed a formal notice of appeal on Feb. 23, 2004, asserting that this case should never have gone to court because EPA found that the pesticides at issue do not harm public health or the environment. Moreover, CropLife estimates that the new buffer zone requirements would cause up to \$538 million in losses for western farmers unable to plant crops on the protected buffer zones. One of the original plaintiffs, the Northwest Coalition for Alternatives to Pesticides, however, calls this figure erroneous because it assumes farmers will cease all planting within the buffer zones.

This case and others like it might become moot if EPA, NMFS and the Fish and Wildlife Service finalize a rule under development that will allow EPA to bypass the ESA consultation process if the agency determines a pesticide is not likely to affect the environment.

## FIFRA Preemption

- *Chemical Producers and Distributors Association v. Helliker*, 2004 U.S. Dist. Lexis 8475 (C.D. Cal. May 12, 2004) (federal court finds California pesticide registration not preempted by FIFRA)

In one of the most important of the many Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) pesticide registration, data sharing and pesticide labeling cases to be decided in 2004, the U.S. District Court for the Central District of California ruled that state registration for generic pesticides does not frustrate the purpose of FIFRA.

Although FIFRA requires all pesticides sold in the United States to be registered with the Environmental Protection Agency (EPA), pesticides must also be registered in each state in which they will be sold or distributed. Under section 12811 of the state's Food and Agriculture Code, pesticide manufacturers must submit the same data they submitted to EPA for registration of the pesticide either by duplicating the test data or obtaining written permission from the original registration applicant.

According to the Plaintiff, the Chemical Producers and Distributors Association, (CPDA), while most state registration procedures are simple, California law is much more time consuming and costly. CPDA argued that the California statute is preempted by FIFRA because it frustrates Congress' purpose in enacting FIFRA, namely to encourage innovation in pesticide production and to promote new generic products once the patent on a pesticide has expired.

The court held that there was no conflict between the California law and FIFRA, or at least no adverse consequences that would impede the goals of FIFRA. In a fact-intensive analysis, the court found that generic applicants seeking to register a pesticide in California must negotiate with the original applicant in any

event to obtain a license under FIFRA and California law. Additionally, even if the costs of registering pesticides in California are higher in California than other states, the court found that because California has the largest population as well as the largest agricultural economy, paying an extra fee to register a pesticide in California does not frustrate FIFRA's goal of encouraging the registration of generic pesticides.

## **Biosolids**

- *O'Brien v. Appomattox County*, 293 F.Supp.2d 660 (W.D. Va. 2003) (state law found to prohibit local ordinances aimed at restricting biosolids)

In *O'Brien v. Appomattox County*, 11 Appomattox County farmers that apply biosolids to their fields under the Virginia biosolids permitting program sued saying local ordinances were inconsistent with their permitting rights under the state biosolids program. The district court agreed and struck down two local ordinances approved by the Appomattox County Board that would have required local zoning board approval for the use of sewage sludge, or biosolids, in areas outside of designated farming districts. One of the ordinances was based on the county's police power while the other was based on the county's zoning power.

The court granted the farmers' summary judgment motion on state law preemption grounds, holding that the county ordinances were void because they conflicted with state law. Virginia law only allows localities to enact a "testing and monitoring" ordinance during biosolids application, the court found, not additional biosolids application restrictions on top of the comprehensive state permitting scheme. According to James Slaughter of Beveridge & Diamond, P.C., counsel for the farmers, this decision "sends a clear message that Virginia localities cannot seek to interfere with valid state permits or block comprehensive federal biosolids programs."

*Daniel M. Krainin is chair of the ABA Section of Environment, Energy, and Resources' Agricultural Management Committee, and practices environmental law in the New York office of Beveridge & Diamond, P.C. He can be reached at [dkrainin@bdlaw.com](mailto:dkrainin@bdlaw.com).*

*Ami M. Grace is a student at the University of Maryland School of Law and was a 2004 summer associate in the Washington, D.C. office of Beveridge & Diamond, P.C.*

## **POTENTIAL GROWER LIABILITY FOR BIOTECH CROPS IN A ZERO-TOLERANCE WORLD**

---

**Jane Earley, Esq.**

### **Overview: U.S. Domestic Liability Precedents and EU Regulation**

Potential grower liability arises at a number of points in the crop production, handling and distribution, transport and retail process. This article will focus, however, on liability for U.S. growers arising from commingling on their farms conventional crops with biotech crops lacking approval in the European Union (EU) market, which would lead to shipments of grain being turned away from the EU under its newly updated "traceability and labeling" directives. See Regulation (EC) No 1830/2003 of the European Parliament and of the Council of Sept. 22, 2003 on genetically modified food and feed [Official Journal L 268 of 18.10.2003], summary description available at <http://europa.eu.int/scadplus/leg/en/lvb/l21154.htm>.

Under the precedent in the *Starlink* case, liability for economic loss for commingling an unapproved-in-EU crop could become a significant management challenge as the EU begins testing for varieties of biotech crops in commodities shipments. Liability is magnified in an environment that imposes "zero tolerance." In a zero-tolerance world, rigorously tested crops that have no proven adverse health or

environmental consequences and are responsibly grown and handled, are subject to rejection at foreign docks because they may contain either by intention or by accident, biotech crops that are not approved in importing countries. The requirements of extremely rigid specific documentation for biotech crops in commodity shipments, mandatory tracing of the food and feed components from farm to fork, and mandatory labeling as to biotech content, further add to the potential dimensions of liability.

The EU regulations went into effect on April 18, 2004. Since then (and in anticipation of the regulation), European food retailers and many U.S. food manufacturers serving the EU have switched to non-biotech ingredients in an effort to avoid mandatory labeling of food products with more than 0.9 percent genetically modified (GM) content. Traceability has also had repercussions among American organic and specialty growers whose EU exports may be lost or denied entry.

### **Biotech Crop Precedents**

The *Starlink* case set broad new boundaries of potential liability for biotech crops. *In re Starlink Corn Products Liability Litigation*, 212 F. Supp. 2d 828 (N.D. Ill. 2002) (nationwide “public nuisance” class action certified as class and survived motion to dismiss); *see also*, *Mulholland v. Aventis CropScience USA Holding Inc.*, No. 00-CV-922 (S.D. Ill. filed Dec. 1, 2000) (complaint alleges public nuisance, consumer fraud, deceptive business practices, and negligence for allowing the commingling of biotech crops with traditional varieties).

The *Starlink* case arose from the U.S. release of a biotech variety approved only for use in animal feed (because of its potential allergenicity) into the human food system. EPA’s approval to commercially plant the Starlink™ corn for animal feed was conditioned

on the existence of an effective identity-preservation system. Nevertheless, Starlink™ was found in tacos shells and a range of other foods. After Starlink was found in the human food chain, U.S. EPA required that it be completely eliminated (zero tolerance) in the recall. In addition to paying many hundreds of millions of dollars to actually recall corn and corn-containing food products, Aventis, the parent company that now owns Starlink™ proprietor Aventis Crop Sciences USA, Inc., agreed to pay \$110 million to settle a class action with farmers who claimed the contamination caused a decrease in commodity corn prices. Thousands of farmers shared in the Starlink class-action settlement without having to prove any actual harm other than depressed corn prices.

Other plaintiffs are alleging damages arising from other varieties of biotech crops that lack overseas approval. In *Sample v. Monsanto*, 283 F. Supp. 2d 1088 (E.D. Mo. 2003), farmer plaintiffs added public nuisance and negligence theories to antitrust action claims against Monsanto for GM corn and soybean seeds that caused declines in prices (*i.e.*, economic loss). The court applied the *Starlink* precedent and put plaintiffs to prove the “physical injury” of actual commingling. Since none could be proved, the Court held that the “economic loss” doctrine, which was rejected as a defense in the *Starlink* case, would bar the tort claims as a matter of law. Plaintiffs were deemed to have abandoned certain allegations regarding actual commingling via pollen drift, and even though “potential unnamed class member(s) might live in a state where nuisance claims are actionable even in the absence of physical injury,” *id.*, at 1095, the court dismissed the case. Taking a page from the *Starlink* settlement, Plaintiffs also claimed that Monsanto failed to take the appropriate measures to prevent the GM corn from entering the “grain marketing channel” and that, as a result, the plaintiffs lost significant income in domestic and foreign commodity corn markets.

The *Sample* court rejected plaintiffs' arguments and granted summary judgment on claims alleging economic loss from unapproved-in-EU crops, finding that "no evidence of physical injury to the person or property of the named plaintiffs or any proposed class member was offered by plaintiffs." To allege actual commingling in the chain of grain marketing sufficient to establish the "physical injury" contemplated by the *Starlink* decision may be difficult, given this decision. The court held: "The claims of this tort class are based on commingling, our word 'contamination,' in the U.S. marketing channel, not where the wind blows in Iowa and where and if it blows off the fence of a particular farmer's property." *Id.* at 1091-92. Counsel explained that the term "contamination" did not refer to physical injury to the person or property of the plaintiffs, but to the "U.S. marketing channel." *Id.* Plaintiffs alleged that non-GM farmers lost revenue because the EU rejected Monsanto's genetically modified products and boycotted all American corn and soy as a result. *Id.* (Author's Note: The EU did not ban all U.S. soybeans at any time – just corn).

## CAFO Precedents

Expanding domestic liability for grower operations is also illustrated by numerous cases involving concentrated animal feeding operations (CAFOs). Most of the actions against CAFO's have been brought under state law, alleging that the activity may lead to future economic harm. The theory could also be extended to federal common law on the premise that transboundary damage is at issue. A showing that defendants have suffered actual damage may be unnecessary if it is reasonably certain to occur. For example, in *Nickels v. Burnett*, *Nickels v. Burnett*, 2003 Ill. App. LEXIS 1278, No. 02-MR-175 (Ill. App. Oct. 20, 2003), the court affirmed an injunction on the theory of "anticipatory" nuisance against a proposed CAFO, based on its "substantially certain" anticipatory adverse effect on human health and land values.

Using "best management practices" may fail as a defense. In *Parker v. Barefoot*, 130 N.C. App. 18, 502 S.E.2d 42 (1988), the North Carolina Court of Appeals concluded that the use of state-of-the-art technology could not be considered when deciding *whether* a nuisance exists but *could* be considered in deciding the *magnitude* of the nuisance. As a result, Plaintiffs were entitled to a jury instruction that the Defendant hog farmers' use of the best technology available to control odor is not a defense in a nuisance suit.

The emergence and success of nuisance-related causes of action in CAFO-related environmental liability cases is a clear precedent for biotech crop-related cases. Other theories of liability also have increasing relevance in a zero-tolerance world – one where harm from biotechnology is frequently assumed even though it cannot be proved. The material below provides some insight into what kinds of practices in the biotech "food chain" might provide a basis for grower liability.

## Implications for Agricultural Management after EU Traceability

### *Seed Company Liability Disclaimers*

Grower liability conceivably starts the moment a grower buys the biotechnology-derived seed. Given the potential for an unapproved-in-EU variety of crop to cause significant compensable economic loss (for which the grower would have to pay his neighbor or the grain elevator sustaining the loss), a seed company could be held responsible, under joint and several liability for creating a nuisance. See *Starlink, supra*; see also *Selma Pressure Treating v. Osmose Wood Preserving Co.*, 221 Cal. App. 3d 1601 (1990) (chemical spill led to comparative fault for chemical supplier's failure to warn of improper disposal).

However, as with other kinds of intellectual property-intensive products such as software,

seed buyers are increasingly being asked to sign for bags of seed at purchase with printed “contractual” undertakings printed on the bag. Are they enforceable? State laws in Kansas, Minnesota and Wisconsin limit certain types of agricultural production contracts. Wisconsin has administrative rules against contractual “risk-shifting” in vegetable procurement contracts. Minnesota and Kansas imply “good faith” into agricultural contracts. See generally, J.W. Looney, Anita K. Poole, *Adhesion Contracts, Bad Faith and Economically Faulty Contracts*, 4 DRAKE J. AGRIC. L. 177 (Spring 1999).

Unconscionability has been successful as grounds on which to void or alter a contract. For example in *Langemeier v. National Oats Co.*, 775 F.2d 975 (8th Cir. 1985), the court refused enforcement to a contract of adhesion because a fact that was important to the grower’s commercial success was not disclosed. Notably, the court raised this issue of unconscionability on its own, even though the grower did not plead it. In that case, the defendant National Oats retained a right to reject the crop for defects, including damage due to freezing weather, but the court found the seed contract unconscionable due to defective disclosure that unfairly distorted the bargaining process.

In the case of a biotech crop, *Langemeier* could be relied on by growers who find the disclosures of a biotech seed company inadequate to effectively prevent commingling with conventional or organic crops bound for export. There are many aspects of stewardship involved in maintaining crop integrity from seed to harvest. These should be fully disclosed and explained, and responsibility taken to ensure that provisions can be adhered to. For instance, particular growers may need to know what type of crops are being grown in their vicinity to segregate their crop from their neighbors (who may even be growing biotech crop of a different variety). The failure to communicate particular details could provide

the opening for a viable claim of unconscionability.

### *State Seed Certification Law*

Small quantities of GM crops can turn up in non-GM conventional farms and organic farms as a result of impurities in seeds, cross-pollination between fields, GM plants that grow where they weren’t intentionally planted, and accidental mixing during harvesting, storage, and processing. A trace amount of unintended GM crops is called “adventitious presence.” USDA’s Animal and Plant Health Inspection Service (APHIS) is responsible for generating guidance on crop separation distances and conditions, but its recommendations have changed many times since they were first promulgated. U.S. agricultural interests have to respond to the zero tolerance demands of the market (in the EU and organic business) and the increased risks of some kinds of crops (particularly pharmaceutical ones). APHIS and EPA also recommend specific measures in permit conditions to additionally confine some biotech crops.

At the state level, seed laws after protect farmers using tolerances for varietal mixing and purity. Since these high tolerances exceed the EU’s mixed-in GM content threshold by several orders of magnitude, farmers need more protection in the age of “zero tolerance” for certain biotech crops in world trade. As a result, states are preparing to require seed certification to address this problem. For example, Illinois is developing a new genetics testing laboratory for crop seed. The Trait Lab at the state Agriculture Department in Springfield, Illinois, is intended to “help ensure that export markets remain open to Illinois farmers.” Other states are resuming their role as enforcers of seed purity by testing GM seeds.

In the absence of seed-specific statutes, federal and state regulation of deceptive sales

practices might address some liability issues associated with seed labels. However, under some state statutes, disclaiming implied warranties of merchantability or fitness for a particular purpose is limited to particular conditions.

For instance, the threshold established by the Association of Official Seed Certifying Agencies (AOSCA) is 2 percent in certified soybean seed and 5 percent in certified corn seed. See <http://www.aosca.org/aoscaflash.html> (site visited Dec. 30, 2004). This is a matter of great concern for the seed industry and the food chain. The American Seed Trade Association has noted that:

Preliminary results of testing the level of adventitious GM material found in “non-GM” seed lots suggest an average level of approximately 1%. Accordingly, Canada, United States, Argentina and the International Seed Trade Federation’s (FIS) have argued that anything less than 1% would be not be achievable. . . . To date, many regulatory authorities worldwide have stated that the threshold level for “unapproved” events is zero. The implications of this action will have extreme negative consequences for international seed trade. However, food manufacturers that source ingredients, and food retailers that want to import manufactured foods, from all parts of the world will also be negatively impacted.

Mark S. Condon, American Seed Trade Association, *Know Where It’s Going: Bringing Food To Market in the Age of Genetically Modified Crops*, available at <http://pewagbiotech.org/events/0911/speakers/Condon.pdf> (site visited Dec. 30, 2004).

While disclaimers or adherence to international standards might suffice to protect seed suppliers from liability, they can also be used for creating the “commonality” of legal issues that

bind growers together for class certification. If separation distances or other methods of crop separation are intentionally ignored, or are deemed in hindsight to prove inadequate, a trespass theory could be viable. The common violation of an industry standard could add to the commonality for class certification or “centralization” in one U.S. district court under 28 U.S.C. § 1407. See *Starlink*, 212 F. Supp. at 833.

### *Third Party Certification and Adventitious Presence*

Increased adherence to prescriptive standards by the industry might provide elements of defense, as could certification. Some companies are reportedly looking at international standards such as ISO 9000. However, ISO 9000, an environmental management standard, allows the enterprise subject to certification to set its chosen level of performance to a standard. It does not set the standard (here, a standard of seed purity). Therefore, although ISO 9000 certification will provide a high level of assurance that management procedures are being rigorously applied, it does not provide assurance as to the ultimate level of performance. That is, some seed manufacturers already following ISO 9000 also have 1 percent GM content in their seed.

Since corn, canola and sugar beets are open-pollinated, meaning that their pollen is spread by the wind or insects in order for the plant to bear fruit, producers of those crops are particularly at risk of liability resulting from pollen drift into adjacent fields. Soybeans are self-pollinating, meaning that they do not need other plants to reproduce. However, even some self-pollinating plants can appear in a farmer’s field a year after it was originally planted – at which time the farmer may have planted either a conventional crop or a crop with a different GM trait. The problem for growers is not just that GM traits not intended by the grower might be introduced into organic or non-biotech fields, but

that non-intended GM traits might be introduced by a neighbor into his fields.

As with seed purity standards, there is no policy solution as yet for the adventitious presence (AP) issues. EU legislation allows for a temporary AP in non-GM crops of 0.5 percent (under certain very specific conditions). But this is a very low threshold and unlikely to be met by many growers whose fields lie adjacent to the more prolific open-pollinated crops. USDA has recently increased mandatory minimum separation distances between conventional crops and those intended for "bio-pharming," thus intending to reduce the possibility of unintended cross-pollination of crops intended for pharmaceutical production with crops intended for food use. USDA will also promulgate additional regulations under the Plant Protection Act to deal with the environmental consequences of biotech crops, particularly those relating to noxious weeds and genetically engineered biological control agents. See 69 Fed. Reg. 3271 (Jan. 23, 2004).

However, this does not remove the problem. It is worth noting that, if the EU tolerance for AP of unapproved varieties in the food supply is low, the U.S. tolerance for unapproved varieties is lower, officially at zero (*i.e.*, for pharmaceutical crops, industrial chemical-producing crops, Starlink corn, etc.). A grower who does not meet this standard may be liable under nuisance, negligence, or trespass for compensatory damages to a neighbor whose non-GM crop he has "contaminated."

## Conclusion

It might be easy for some to conclude that while biotechnology has great benefits, it also imposes economic risks that are too great to undertake. This would be a mistake. As the technology evolves, the regulatory systems servicing it are also evolving. The great challenge is to close the gaps in areas such as

grower liability where disincentives to responsible care threaten both the technology and those who use it, and to work with other countries in this process. This is important work that will be carried out over the next few years, and the future of the technology will rest in part on its success.

*Jane Earley, principal of Jane Earley, LLC in Alexandria, Virginia, consults on international environmental and agriculture issues. She can be reached at [jeasley@promarinternational.com](mailto:jeasley@promarinternational.com).*

## AMERICAN BAR ASSOCIATION SECTION OF ENVIRONMENT, ENERGY, AND RESOURCES

### *Calendar of Section Events*

**23rd Annual Water Law Conference**  
Feb. 24-25, 2005  
San Diego

**34th Annual Conference on  
Environmental Law**  
March 10-13, 2005  
Keystone, Colorado

**Wetlands Law and Regulation**  
June 8-10, 2005  
Washington, D.C.  
(Cospponsored with ALI-ABA and ELI, for  
information see [www.ali-aba.org](http://www.ali-aba.org).)

**13th Section Fall Meeting**  
Sept. 21-25, 2005  
Nashville, Tennessee

***For more information, see  
the Section Web site at  
<http://www.abanet.org/environ>  
or contact the Section at  
(312) 988-5724.***

## BIOPHARMING: ITS RECENT PAST AND FORESEEABLE FUTURE

---

**Thomas P. Redick**  
**Alan J. Sachs**

The production of pharmaceuticals and other useful industrial compounds in plants through the use of biotechnology techniques holds considerable promise for industry and society if the risks are managed properly. Such plant-made pharmaceutical (PMP) activities are federally regulated in the United States primarily by the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA). In addition to government oversight, members of the private sector and universities involved in this burgeoning industry have adopted voluntary measures to raise the level of public confidence in the management of PMPs. The public's response to a recent, isolated incident in which PMPs were found outside of their dedicated production channels (in the ProdiGene incident) illustrates the need for a cohesive effort among biotech researchers, companies and growers to continue to examine and implement management practices that eliminate the possibility of commingling insofar as possible. This article reviews recent policy initiatives that promote responsible PMP management standards. The use of internal management systems can assure the public that PMPs are being managed effectively and may help protect manufacturers from costly environmental liability actions or market disruptions.

### **A Primer on Production and the Pipeline**

“Biopharming,” or the development of PMPs, involves the production of pharmaceutical or industrial proteins or other compounds in genetically modified crops. Once extracted from the plant, researchers believe that these compounds may provide the building blocks for drugs targeting a number of debilitating diseases, including cancer, heart disease, HIV, diabetes and Alzheimer's. See BIOTECHNOLOGY INDUS. ORG., PLANT-MADE PHARMACEUTICAL TERMS

(2002), available at [http://www.bio.org/health\\_care/pharmaceutical/pmp/pmpterms.pdf](http://www.bio.org/health_care/pharmaceutical/pmp/pmpterms.pdf) (site visited Dec. 30, 2004).

Currently, pharmaceutical proteins and industrial compounds are produced outside of chemical laboratories and production facilities only in a limited number of crops, including alfalfa, corn, duckweed, rice, safflower and tobacco. Federal law prohibits the presence of any adulterant in food, including potentially harmful levels of prescription pharmaceuticals, which could apply to require recalls after commingling of PMPs in food crops. The production of PMPs is subject to strict oversight by FDA and USDA's Animal and Plant Health Inspection Service (APHIS), under the Biotechnology Regulatory Services (BRS) program. In general, the production of PMPs must meet rigorous federal guidelines that aim to protect humans and the environment from potential adverse effects.

APHIS rules require companies to obtain a permit for field tests and pharmaceutical protein production, and APHIS recently enhanced its permit oversight in an effort to further ensure that commingling with food or export-bound crops does not occur. APHIS is empowered to fine companies for the unauthorized release of genetically engineered PMP crops, and may apply criminal penalties to a company for any knowing violations. Civil penalties can be assessed up to \$250,000 per violation or \$500,000 per adjudication, and permits may be revoked for specified violations. See, Plant Protection Act, 7 U.S.C. §§ 7701-7772 (2000).

### **A Brief History of Biopharming Policy Initiatives**

Over the past few years, several events have transformed the biopharming policy arena:

On May 17, 2002, the Biotechnology Industry Group (BIO), a Washington, D.C.-based industry group for biotechnology and PMP companies, issued a leading reference document that continues to set the standard of care for the

production of PMPs in the United States. See Reference Document for Confinement and Development of Plant-Made-Pharmaceuticals in the U.S., *available at* <http://www.bio.org/healthcare/pharmaceutical/pmp/PMPConfinementPaper.pdf> (site visited Dec. 1, 2004). The document describes a specific PMP confinement process to assist member companies in ensuring the prevention of commingling. This process includes: (1) training growers and others that handle PMPs; (2) contracting with growers to ensure that harvested PMPs are not sold through conventional channels used for food and feed (channeling); (3) selecting and securing sites to avoid unwanted animal or human intruders; (4) establishing procedures for crop production to ensure that seed production, planting and harvesting are all handled without the threat of commingling with food or feed, including the development of systems to identify PMPs in transit, with dedicated containers and transports; (5) developing disposal procedures to ensure that unused plant material is not released into the environment; (6) establishing management processes that ensure compliance for inspectors; and (7) monitoring post-production to ensure that problems do not arise at a production site after the fact (for example, avoiding the use of a PMP corn field for conventional corn production in a subsequent season).

On May 21, 2002, APHIS published a summary of confinement and other mitigation measures for PMPs being field tested in 2002. See, *USDA Risk Mitigation Guidance*, (May 21, 2002) <http://www.aphis.usda.gov/brs/pdf/pharm-2002.pdf>. (Site visited Dec. 1, 2004). The document required a one-mile buffer for seed corn in an effort to prevent drifting of biopharm-pollen to fields containing food crops. Under the APHIS guideline, food/feed corn could be planted within one-quarter mile of the biopharm-corn.

On July 16, 2002, the National Academy of Science's National Research Council (NRC)

issued a multi-stakeholder report expressing concerns regarding the level of surveillance over biotech crops that had entered the marketplace. See COMM. ON ENVTL IMPACTS ASSOCIATED WITH COMMERCIALIZATION OF TRANSGENIC PLANTS, NAT'L RESEARCH COUNCIL, ENVIRONMENTAL EFFECTS OF TRANSGENIC PLANTS: THE SCOPE AND ADEQUACY OF REGULATION 192 (2002), *available at* <http://www.nap.edu/books/0309082633/html> (Site visited Dec. 1, 2004) (stating that pre-commercialization quality *and* post-commercialization testing are necessary and essential). The report recommended improving oversight of PMPs and other crops that should not be commingled with food.

In September 2002, APHIS identified tasseled "volunteer" PMP corn plants growing in a soybean field at a ProdiGene test site in Iowa. APHIS required ProdiGene, a biotech company based in College Station, Texas, to harvest and incinerate 155 acres of corn surrounding the site to ensure that the PMP corn did not reach the food supply.

On Sept. 12, 2002, FDA issued draft guidance related to PMP production. See "Draft Guidance for Industry: Drugs, Biologics, and Medical Devices Derived from Bioengineered Plants for Use in Humans and Animals," *available at* <http://www.fda.gov/OHRMS/DOCKETS/98fr/02d-0324-gdl0001.pdf> and at <http://www.fda.gov/cber/gdlns/bioplant.pdf>. (Sites visited Dec. 1, 2004.) This document provided the PMP industry with instruction on "confinement" under "environmental considerations."

In October 2002, another APHIS compliance inspection identified further permit violations at a ProdiGene field test site in Nebraska. This more serious violation involved conventional soybeans that were harvested with PMP corn and sent to a local grain elevator, where the crop was commingled with additional conventional soybeans. All of the commingled soybeans in the grain elevator were unmarketable, resulting in a loss of several

million dollars to ProdiGene. This incident generated considerable publicity and stoked fears related to the safety of the U.S. food supply. Calls for greater inspection and enforcement from a variety of food industry, environmental and other public interest groups became more frequent. See, e.g., Center for Science in the Public Interest, *CSPI on Possible Permit Violations by ProdiGene* (Nov. 15, 2002), available at: <http://www.cspinet.org/new/200211151.html>; *Black eye for ag-biotech: Texas company under fire for possibly contaminating food crops*, THE SCIENTIST (Nov. 20, 2002), available at: <http://www.biomedcentral.com/news/20021120/03/>.

On Oct. 24, 2002, BIO launched its own stewardship initiative to manage the risks of PMPs. In recognition of the potential for economic losses arising from the commingling of biopharming compounds with food, BIO's initiative imposed a voluntary moratorium on planting PMP corn in Midwestern states in the 2003 planting season. See generally, Biotechnology Industry Organization, *Statement Regarding Plants that Produce Pharmaceutical and Industrial Products*, at <http://www.bio.org/healthcare/pharmaceutical/pmp/statement.asp> (last visited Aug. 12, 2003). BIO urged its members were to cease biopharming plantings only in 2003 and only in those regions where a particular crop, such as corn, was deemed of considerable economic importance, as measured by USDA.

On Nov. 12, 2002, FDA announced that it had ordered ProdiGene to destroy 500,000 bushels of food-grade soybeans because of possible contamination with "volunteer" PMP corn sprouted from unharvested seed from the previous season.

On Nov. 13, 2002, APHIS issued a press release publicizing ProdiGene's compliance violations and the imposition of a \$3.25 million fine (including \$3 million for the unmarketable soybeans). APHIS later issued an interest-free loan to ProdiGene to help it pay the fine.

By December 2002, BIO's moratorium on biopharming in the Corn Belt had become subject to significant political pressure from growers and industry. Press Release, *Grassley Continues Efforts to Support Biotech Crop Production in Iowa: Senator Works with USDA, Iowa State to Ensure Fair Treatment for Iowa Producers* (Nov. 4, 2002), available at <http://www.grassley.senate.gov/releases/2002/p02r11-04.htm> (stating "[BIO] is responding to the demands of special interest, not the demands of science. I'll continue to work to ensure that Iowa is not unjustly left out of corn-based pharmaceutical crop production") (site visited Sept. 15, 2004). BIO withdrew the moratorium on PMPs in the Corn Belt (see Oct. 14, supra) but reassured concerned members of the public that BIO members would still avoid biopharming in the Corn Belt in 2003, pending USDA's adoption of improved segregation procedures.

On Jan. 31, 2003, BIO staff members, in cooperation with various food industry stakeholders, met with federal officials. The group urged Iowa growers to refrain from any biopharming, pending the issuance of new regulations that would provide enhanced federal regulatory oversight.

On Feb. 7, 2003, BIO provided its comments to FDA on the proposed Draft Guidance listed above, stating that BIO members would follow protective measures prescribed by USDA, including physical, temporal and spatial isolation.

On March 10, 2003, National Food Processors Association (NFPA) commented to USDA noting that it is possible for insect pollination to occur beyond the expanded planting distances required in the rule. See NFPA's Comments to Docket No. 03-031-1, *Field Testing of Plants Engineered to Produce Pharmaceuticals and Industrial Compounds* (Mar. 10, 2003) available at: [http://www.nfpa-food.org/content/regulatory/comments\\_view.asp?id=43](http://www.nfpa-food.org/content/regulatory/comments_view.asp?id=43).

On March 11, 2003, APHIS issued permit conditions for the 2003 growing season with tighter regulatory restrictions, including more frequent inspections and a minimum buffer zone of one mile around PMP crops in which food/feed crops could not be grown. See *Field Testing of Plants Engineered to Produce Pharmaceuticals and Industrial Compounds* (proposed at 68 Fed. Reg. 11337 (Mar. 10, 2003) to be codified at 7 CFR 340 *available at*: <http://www.aphis.usda.gov/brs/pdf/7cfr.pdf> (site visited Dec. 30, 2004).

On Oct. 16, 2003, Monsanto, one of the world's leading agricultural biotechnology companies, announced its decision to abandon its PMP program to focus on other lines of its business. The St. Louis-based company stated that its decision was not related to the controversy surrounding PMPs, but was rather simply a part of Monsanto's broader effort to streamline its product pipeline. See *Monsanto Overhauling Businesses, Drops Pharmcrops*, N.Y. TIMES (Oct. 16, 2003).

On Aug. 5, 2004, the disclosure of sites for field trials of PMP crops was required, for the first time, by a federal court in Hawaii. The ruling came in a lawsuit brought by a coalition of environmental and consumer organizations to compel the government to review the environmental impact of PMP crops. *Center for Food Safety v. Veneman*, No. 03-CV-621 (D. Haw. filed Nov. 12, 2003). Field trial locations for pharmaceutical plants are generally kept confidential, and the government and industry both argued that disclosure of site locations could lead to vandalism or theft of confidential intellectual property. The district court judge rejected these arguments, declining to find that the locations of the sites are confidential business information and ordering the four biotech companies that have been granted biopharm permits in Hawaii to disclose their site information to the plaintiffs. The lawsuit remains pending.

## **The Role of Environmental and Quality Management Systems**

It is vital that industry players have adequate internal compliance management systems. BIO, for example, has adopted strict "stewardship" programs to help its members contain PMPs and ensure compliance with environmental regulations. See, e.g., Bradley A. Shurdut, Global Leader, Government and Regulatory Affairs, Dow AgroSciences LLC., *New USDA Guidelines Represent An Informed Approach* (noting zero tolerance and industry risk management measure in place to ensure compliance) and Mary Sophos, Senior Vice President of Government Affairs, Grocery Manufacturers of America, *Pharming Presents Challenges* (calling for "consultations with the FDA on the potential impact on the food supply" to be required and for USDA and FDA to "help ensure consumer confidence in the safety and purity of the U.S. food supply"). (Both articles are available at <http://pewagbiotech.org/buzz/print.php3?StoryID=102> (last visited Dec. 1, 2004)). Given "zero tolerance" for commingling, sound industry stewardship is essential to protecting the U.S. food supply.

While BIO's moratorium may have helped to reassure the marketplace that the U.S. agricultural food supply is safe, BIO may wish to emulate other industry associations that have worked to promote improvement in their members' environmental management systems. For example, the chemical industry has adopted "Responsible Care," the semiconductor industry recently adopted its "Global Care" initiative and the Cotton Council has a program called "Cotton Cares." In addition, general international process-based standards such as ISO 9000 (quality systems) and ISO 14000 (environmental management systems) can help companies better manage the risks of PMPs or industrial biotech crops. A concerted effort along these lines may be advisable for the biopharming industry if it is to avoid a repeat of the negative publicity and impacts of the

ProdiGene incident, and instead earn accolades for sound agricultural management.

*Thomas P. Redick is a partner with the law firm of Gallop, Johnson & Neuman, L.C. in St. Louis, Missouri, and a vice chair of the ABA Section of Environment, Energy, and Resources' Agricultural Management Committee. He can be reached at [tpredick@gjn.com](mailto:tpredick@gjn.com).*

*Alan Sachs is an associate with the law firm of Beveridge & Diamond, P.C. in Washington, D.C., and a vice chair of the ABA Section of Environment, Energy, and Resources' Agricultural Management Committee. He can be reached at [asachs@bdlaw.com](mailto:asachs@bdlaw.com).*

## VISIT US ON THE WEB!

To learn more about the ABA, Section and Committee, please visit:

### **American Bar Association:**

<http://www.abanet.org>

### **Section of Environment, Energy, and Resources:**

<http://www.abanet.org/environ>

### **Agricultural Management Committee:**

<http://www.abanet.org/environ/committees/agricult/home.html>

### **Agricultural Management Committee Newsletter:**

<http://www.abanet.org/environ/committees/agricult/newsletter/>

### **Books from the Section and ABA Publishing:**

<http://www.abanet.org/environ/pubs/books/catalog/home.html>

## HOW BIOTECHNOLOGY-DERIVED CROPS REDUCE THE RUNOFF THAT CREATES "DEAD ZONES"

**Kimball Nill**

The so-called "dead zone" in the Gulf of Mexico has been a controversial topic for many years. Often the discussants have pointed fingers at agriculture – both cropland and concentrated animal feeding operations (CAFOs). In turn, those agriculturalists have noted the runoff resulting from suburban lawns (which tend to be over-fertilized and sprayed with pesticides at rates nine times that of croplands), recreational cabins' inadequate septic systems and other non-point sources. Without getting involved in a finger-pointing exercise, based on farmer experience and research, this article argues that biotechnology-derived crops:

Are enabling U.S. farmers today to greatly reduce the relevant runoff from their croplands, by using "no till" practices that generally employ herbicide-resistant biotech crops, and

Will enable CAFOs in the future to also significantly reduce their relevant runoff.

### **Background: "No Till" or "Low Till" Farming**

Modern agriculture accomplishes control of weeds either through mechanical cultivation or via the application of herbicides. Weed pressure will vary by location, but the maize and soybean farmers who use only mechanical cultivation (e.g., "organic" farmers in America) have to cultivate their fields as many as 14 times per growing season. See *Organic Grower Spends Many Hours On His Tractor*, Soybean Digest, (Mar. 2000) at 38. By contrast, the "no tillage" and "low tillage" crop production methods utilize one, and 2-4 cultivation passes-over-field respectively; which decreases soil erosion (due to wind and water)

by 90 percent or more. See Soybean Digest (Jan. 2000) at 40 and Soybean Digest (Sept. 1999) at 14.

When a farmer switches from intensive mechanical cultivation to “no tillage” or “low tillage” crop production, the population of earthworms subsequently increases in direct proportion to the amount by which mechanical cultivation is avoided. See *Healthy Soil Boosts Yields*, Corn & Soybean Digest (Oct. 2003) at 28-29. As mentioned above, that same switch in crop production methods also helps remove carbon dioxide from the Earth’s atmosphere, because avoidance of over-cultivation allows the natural fungi that grow on plant roots to produce glomalin, a protein that sequesters carbon taken in by plants and keeps it within the soil. Glomalin also helps to improve the fertility of soil by acting as the sort of “glue” to cause soil particles to properly clump together; for subsurface spaces to be created which allow water, oxygen, and plant roots to permeate the soil. Glomalin is one of the primary differences between fertile cropland soil and lifeless desert sand. See *Nutrient Knowledge*, Farm Industry News (Sept./Oct. 1999) at 11.

Another result of that switch to “no till” or “low till” is a reduction in soil compaction, a process in which the soil particles were compressed together. That is both because heavy tillage equipment is no longer driven over the “no till” field, and because the large topsoil particles are no longer ground-down to smaller size via cultivation/abrasion. Again, this benefit of conservation tillage results in the relevant field absorbing more rainfall, with little or no runoff. See *Study Demonstrates Negative Effects Of Soil Compaction On Corn Yields*, Commercial Agriculture (May 2001) at 4.

### **Biotech Crops and Tillage**

The best available agricultural management practices have been improved via biotechnology-derived crops, and will improve even more in the future. For example, biotech

herbicide-resistant varieties will constitute 86 percent of total U.S. soybean acres during 2004 and 40 percent of total U.S. corn acres during 2004. It is foreseeable that these and other tools available to U.S. farmers via their adoption of biotechnology products will help them to reduce any potential liability risks or regulatory violations for causing hypoxia (dead zone) in the Gulf of Mexico to essentially zero. See Rattan Lal, et al., *Managing Soil Carbon*, Science (Apr. 16, 2004) at 393; Drew Kershen, *Legal Liability Issues in Agricultural Biotechnology* (available at <http://www.nationalaglawcenter.org>) (site visited Dec. 30, 2004).

Research published during 2000 showed that “no tillage” methods of crop production reduce modern agriculture’s impact on global warming by approximately 88 percent. See G. Phillip Robertson, et al, *Greenhouse Gases in Intensive Agriculture: Contributions of Individual Gases To The Radiative Forcing Of The Atmosphere*, Science (Sept. 15, 2000) at 1922-1925. The rate of global warming (*i.e.*, the postulated increase in the Earth’s average temperature resulting from activities of mankind) would tend to be increased by activities that place more carbon dioxide (a “greenhouse gas”) in the atmosphere. However, the adoption or increased utilization of “no tillage” and “low tillage” methods of crop production – which is facilitated by the new herbicide-tolerant biotech crops (see Soybean Digest (Jan. 1999) at 42; Farm Chemicals (Aug. 2000) at 22) – removes net carbon dioxide from the atmosphere by sequestering it into the soil of cropland. As more of that carbon is added to the topsoil each year, the cropland is able to absorb increasing amounts of rainfall, with a concomitant reduction in runoff. See *No-Till Uses Less Fuel And Increases Your Profit Potential*, Commercial Agriculture (May 2001) at 4; *The Value Of Carbon In Soil*, Farm Chemicals (August 2000).

A 2003 study by the Cotton Foundation found that 78 percent of U.S. cotton farmers who

adopted conservation tillage practices (*i.e.*, “no tillage” or “low tillage”) since the 1997 introduction of biotech herbicide-resistant cotton varieties had done so specifically because those biotech varieties had made conservation tillage more feasible. See *Biotech Boosts ‘Con Till’*, Progressive Farmer (March 2003).

A 2001 study conducted by the American Soybean Association found that a similar percentage of U.S. soybean farmers had adopted conservation tillage practices since 1997 specifically due to the fact that biotech herbicide-resistant soybean varieties had made it more feasible. During that period, use of conservation tillage in soybean fields approximately doubled – so by 2001, 49 percent of total U.S. soybean acres were “no till” and an additional 33 percent of total U.S. soybean acres were “low till.” *ASA Study Confirms Environmental Benefits Of Biotech Soybeans* (Nov. 12, 2001), available at <http://www.soygrower.org/ctstudy/> (site visited Dec. 30, 2004).

Another environmental benefit to the switch to biotech crops by U.S. farmers is that in general, herbicides are applied to these herbicide-resistant crops in lesser amounts and with fewer adverse environmental impacts than the older herbicide(s) they replace. That is due to their lesser persistence (longevity in the environment), lower toxicity to wildlife, and/or their tendency to adhere so tightly to soil particles that they do not run-off as some of the older herbicides did. See *USDA Agricultural Outlook Summary* (July 20, 2000).

### **Future: Biotech Applications for CAFOs**

Poultry and swine producers in most countries currently add mined and processed phosphate to their feed rations to enable optimal animal growth. That is in addition to the natural phosphate already present in traditional soybean and corn varieties, because the phosphate extant in traditional soybeans and

corn exists in the form of an insoluble phytate (chemically bound with phytic acid).

Monogastric animals such as chickens and pigs lack the phytase enzyme needed for digestion of phytate. Virtually all of the extant corn/soy phytate and part of the added (mined) phosphate is excreted by the animals, which can sometimes cause pollution problems. *Enhanced Animal Feed Good For The Environment*, BioScience News & Advocate (Feb. 27, 2004).

A number of biotechnology companies are currently working to develop corn and soybean varieties with greatly reduced phytate content. When low-phytate soybean meal is mixed with low-phytate corn to make animal feed rations, phosphate emissions in swine and poultry manure are reduced by approximately half. The iron, calcium and protein in the ration are also absorbed more completely by the animal, which thereby reduces both anemia and nitrogen excretion. See *Environmentally Friendly Phosphorous Feeding*, National Hog Farmer (Mar. 15, 2003) at 14-15; *Low-Phytate Grains Cut Phosphorous Excretion*, National Hog Farmer (Dec. 15, 2000) at 14.

*Kimball Nill is the Technical Issues director of the American Soybean Association, based in St. Louis, Missouri. He can be reached at [knill@asaim.soy.org](mailto:knill@asaim.soy.org).*

### **LIKE TO WRITE?**

The Agricultural Management Committee welcomes the participation of members who are interested in preparing this newsletter. If you would like to lend a hand by writing, editing, identifying authors or identifying issues, please contact Thomas P. Redick at (314) 615-6000 or [tpredick@gjn.com](mailto:tpredick@gjn.com).