Revising Seed Purity Laws to Account for the Adventitious Presence of Genetically Modified Varieties: A First Step Towards Coexistence

by

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REVISING SEED PURITY LAWS TO ACCOUNT FOR THE ADVENTITIOUS PRESENCE OF GENETICALLY MODIFIED VARIETIES: A FIRST STEP TOWARDS COEXISTENCE

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Adoption of genetically modified (GM) seed varieties in the United States, Canada, and South America continues to expand, with GM crops comprising almost 76 million hectares and over 93 percent of the total biotech cropland worldwide.[1] As an increasing number of farmers plant GM varieties, the potential for adventitious[2] mixture of genetically modified DNA with products produced via organic and conventional (non-GM) methods also increases. Many consumers of organic and identity-preserved products, however, object to the adventitious presence of genetically modified DNA at even low levels. Accordingly, the ability of farmers to choose between conventional, organic, or GM crop production and achieve required purity levels—commonly referred to as coexistence[3]—is increasingly difficult.

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1. C. Ford Runge & Barry Ryan, The Global Diffusion of Plant Biotechnology: International Adoption and Research in 2004, at 5 (2004), *available at* http://www.apec.umn.edu/faculty/frunge/globalbiotech04.pdf; *see also* Clive James, Preview: Global Status of Commercialized Biotech/Gm Crops: 2004 at 4, *available at* http://www.isaaa.org [hereinafter ISAAA Preview]; Press Release, International Service for the Acquisition of Agri-Biotech Applications (ISAAA), Worldwide Biotech Crops Experience Near Record Growth, Biotech Crop Area Increases 11 Percent In the United States, Jan. 12, 2005, *available at* http://www.isaaa.org/kc/CBTNews/press_release/briefs32/News_release/English.pdf.

2. Also referred to as technically unavoidable or admixture. Graham Brookes et al., Genetically Modified Maize: Pollen Movement and Crop Co-Existence 3 (2004), *available at* http://www.pgeconomics.co.uk/pdf/Maizepollennov2004final.pdf.

3. *See* Commission Recommendation 2003/556, pmbl. (3), 2003 O.J. (L 189) 36.

Potential sources of admixture include pollen drift between neighboring fields, commingling during harvest or post-harvest activities (such as transportation or storage), volunteer plants from previous growing seasons, and seed impurities.[4] Minimizing admixture requires diligence during each step of the global food chain and, prior to the biotech revolution, the agricultural community successfully adopted coexistence production methods for a variety of products.[5] Despite notable and, ultimately, expensive failures,[6] farmers,

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4. *See* BROOKES ET AL., *supra* note 2, at 4; ANNE-KATRIN BOCK ET AL., EUROPEAN COMMISSION, SCENARIOS FOR CO-EXISTENCE OF GENETICALLY MODIFIED, CONVENTIONAL AND ORGANIC CROPS IN EUROPEAN AGRICULTURE 4, Report EUR 20394EN (2002), *available at* ftp://ftp.jrc.es/pub/EURdoc/eur20394en.pdf.

5. *See infra* notes 10-12 and accompanying text.

6. Perhaps the most notable breakdown in the segregation of GM crops was the admixture of StarLink varieties approved only for use as animal feed with corn destined for human consumption. *See generally* D.L. Uchtmann, *StarLink—A Case Study of Agricultural Biotechnology Regulation*, 7 DRAKE J. AGRIC. L. 159 (2002) (providing a comprehensive review of the legal issues surrounding the StarLink controversy). The StarLink commingling spawned several legal claims against the developer, Aventis Crop Science USA, by the nation's corn farmers who suffered a severe drop in the price of their corn. In November 2004, Aventis made payments to over 72,000 plaintiffs in the nationwide class action brought on behalf of corn farmers that did not plant Starlink varieties. Payments were approximately $2.88/acre. *See* D.L. Uchtmann & A. Bryan Endres, *Non-StarLink Farmers Litigation: Accounting to "Share" Landlords and Others with an Interest in the Crop*, AGRIC. L. & TAX'N. BRIEFS, Oct. 29, 2004, *available at* http://www.farmdoc.uiuc.edu/legal/articles/ALTBs/ALTB_04-13/ALTB_04-13.pdf. Although the extent to which remnants of Starlink varieties continue to exist in the food distribution system or seed supply are unknown, in November 2004, two and a half years after the discovery of the product in human food products, the Canadian Food Inspection Agency dropped its negative Starlink testing requirement for all whole grain corn imports from the United States. *See* CANADIAN FOOD INSPECTION AGENCY, *Industry Advisory: Food, Feed and Seed Products Containing U.S. Corn*, Nov. 18, 2004, *at* http://www.inspection.gc.ca/english/fssa/invenq/inform/20041118e.shtml (last visited Mar. 14, 2005).

A second troubling exception involved the commingling of non-regulated soybeans with corn genetically engineered to produce pharmaceuticals. Volunteer corn plants from the field test were harvested, along with soybeans the following year, and commingled with 500,000 bushes of other soybeans. ProdiGene, Inc., the company responsible for the field tests, entered into a consent agreement with the United States Department of Agriculture and the Food and Drug Administration in which it paid a civil penalty of $250,000 and agreed to reimburse the government for its costs in securing approximately 500,000 bushes of soybeans in storage. *See* Press Release, USDA, USDA Announces Actions Regarding Plant Protection Act Violations Involving Prodigene, Inc., *available at* http://www.usda.gov/news/releases/2002/12/0498.htm. The unfortunate events in the Prodigene case prompted the USDA, in an effort to prevent future admixture, to tighten its rules for field tests of agricultural products genetically engineered to produce industrial or pharmaceutical products in an effort to prevent future admixture. *See generally* Field Testing of Plants Engineered to Pro-

grain handlers, and processors have made some progress in implementing on-farm and post-harvest segregation and identity preservation systems to minimize admixture of genetically modified DNA.[7]

Seeds are "the irreducible core of crop production on the farm and the most fundamental agricultural input."[8] Therefore, the undisputed starting point for a successful identity preservation system is ensuring seed purity. Existing seed laws at both the federal and state level, however, do not address directly the adventitious presence of genetically modified organisms (GMOs) in seed labeled as conventional. Recent scientific studies, as well as anecdotal evidence, strongly suggest that GMOs are present at low levels in seed marketed to farmers as conventional.[9] Studies also indicate that as the area under GM production increases, the adventitious presence of GM seeds grows along with a corresponding increase in the difficulty of obtaining purity thresholds.[10]

The adventitious presence of genetically modified DNA in products marketed as conventional or organic could have serious economic consequences for farmers and processors.[11] Therefore,

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duce Pharmaceutical and Industrial Compounds, 68 Fed. Reg. 11,337-340 (Mar. 10, 2003) (to be codified at 7 C.F.R. pt. 340).

7. Too often, however, regulatory action is taken only in response to admixture events rather than on a proactive basis. One example is the StarLink situation in which, despite objections, commercial production of the genetically engineered corn was approved for use as feed, but not as food. *See* Rebecca M. Bratspies, *Consuming (F)ears of Corn: Public Health and Biopharming*, 30 Am. J.L. & Med. 371, 373-76 (2004) (describing dangers of producing pharmaceuticals within a commodity-type food crop). The U.S. Environmental Protection Agency [EPA] has since revised its procedures to require approval for use as food *and* feed before introduction in the commodity production system. *See* Uchtmann, *supra* note 6, at 205 (describing EPA's policy change).

8. Jack R. Kloppenburg, Jr., First the Seed: The Political Economy of Plant Biotechnology 4 (1988) ("Nothing is more fundamental to agriculture and our food supply than seeds. Whether eaten directly or processed through animals, seeds are the ultimate source of human nutrition. The variety, abundance, and safety of foods are all dependent on the availability and quality of seeds."); Margaret Mellon & Jane Rissler, Gone to Seed: Transgenic Contaminants in the Traditional Seed Supply 1 (2004), *available at* http://www.ucsusa.org/food_and_environment/biotechnology/seedreport_fullreport.pdf.

9. *See* Mellon & Rissler, *supra* note 8, at 12.

10. European Commission, Health and Consumer Protection Directorate-General, Opinion of the Scientific Committee on Plants concerning the adventitious presence of GM seeds in conventional seeds, SCP/GMO-SEED-CONT/002-Final (2001), *available at* http://europa.eu.int/comm/food/fs/sc/scp/out93_gmo_en.pdf [hereinafter Opinion of Scientific Committee on Plants].

11. Graham Brookes, *Co-existence of GM and non GM Crops: economic and market perspectives* 3-4, *available at* http://www.pgeconomics.co.uk/pdf/coexistence_paper_01.

farmers seeking price premiums from identity-preserved harvests for domestic consumption or the European export market must implement on-farm and post-harvest measures to ensure their product meets the required purity standards. If seeds contain significant quantities of genetically modified DNA, however, even the most comprehensive post-planting controls for admixture may fail to preserve the expected premiums for the farmer.

This article examines the critical role played by federal and state seed purity laws in the achievement of coexistence in the United States and the preservation of commodity agricultural exports to the European Union (E.U.). As background, Part I of this article discusses informal farm-level management practices and developing laws that impact coexistence. A comparison is made between rules in the United States, a leader in the adoption of agricultural biotechnology, and the E.U., which has proceeded along a more cautious (some may say hostile) route in approving genetically engineered food and feed products. Because the E.U.'s position with respect to the import of GM products has engendered significant controversy, Part I also briefly outlines the traceability and labeling requirements for GM products imported into the Member States of the E.U. Part II examines the E.U.'s legal efforts to ensure a level of seed purity sufficient to achieve its formal coexistence goals. Part III focuses on attaining seed purity in the United States, including the extent of adventitious GM presence in the domestic seed stocks[12] and how the Federal Seed Act and corresponding state seed laws address the challenges presented by GM seed. In Part IV, this article concludes that existing domestic seed laws should be revised to account for the widespread adoption of GM varieties. Although the adventitious presence of genetically modified DNA in seed marketed as conventional or organic probably cannot be eliminated entirely, it could be minimized and tolerances that are practically and economically feasible should be established within the context of existing seed laws. The European approach, which directly addresses the question of adventitious presence of genetically

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pdf ("The economic implications of co-existence for GM and non-GM crops have two main elements: the costs involved in meeting tolerances for the adventitious presence of unwanted material . . . and/or; the economic consequences of not meeting tolerances.").

12. On occasion the author uses the term "contamination" to refer to the presence of genetically modified DNA in conventional or organic seeds and products. The term by "contamination" is not intended to have a negative connotation other than the sense that the object is undesirable in its present location or state of existence. *See, e.g.*, MELLON & RISSLER, *supra* note 8, at 7.

modified DNA in conventional seed stocks, may provide a helpful benchmark for revising domestic seed laws.

I. The Evolution of Laws and Informal, Farm-Level Management Practices that Foster Coexistence

Farmers have long practiced variations of modern segregation and identity preservation. For example, for centuries subsistence farmers have engaged in selective breeding to improve yields with successful results perpetuated and traded among neighbors.[13] More recently, commercial agriculture has adopted successful coexistence strategies in a variety of production situations: waxy and non-waxy corn; white, blue, and other specialty corns; and high- and zero-erucic acid oilseed rape.[14] In the United States, informal methods have evolved in the absence of a formal legal regime supporting coexistence. In contrast, the E.U. has taken initial steps to delineate responsibilities for obtaining coexistence.[15] The following two sections examine the evolution of coexistence measures in the United States and E.U.

A. Coexistence in the United States

1. The Costs of Segregation: Private Solutions

Formal legal rules to determine whether conventional or GM producers must bear the cost of in-field segregation and setback measures to achieve coexistence do not exist in the United States. Further, no reported case has assessed liability for the farm-to-farm admixture of genetically modified DNA via pollen drift, shared farm machinery, or other sources.[16] In the absence of legal rules seed and

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13. Kloppenburg, *supra* note 8, at 1-2.

14. *See* Bock et al., *supra* note 4, at 5; International Seed Federation, Position Paper: Coexistence of Genetically Modified, Conventional and Organic Crop Production (2003), *available at* http://www.worldseed.org/pdf/PosPaperCoexistence.pdf [hereinafter International Seed Federation]; Peter W.B. Phillips, *Traceability and Trade of Genetically Modified Food*, *in* Biotechnology: Science and Society at a Crossroad 141, 150 (National Agricultural Biotechnology Council 2003), *available at* http://www.habc.cals.cornell.edu/pubs/nabc_15/chapters/Phillips.pdf.

15. For a comprehensive case study of how informal societal norms in agricultural communities may supplant formal legal rules, *see generally* Robert C. Ellickson, Order Without Law: How Neighbors Settle Disputes (1991) (examining open and closed range regimes in California and how traditional farm practices incorporate informal social norms and discount legal rules).

16. Farmers in Canada, however, have filed a number of high profile court actions against seed developers to recover costs related to coexistence efforts. The most famous case, *Monsanto Canada Inc. v. Schmeiser*, [2004] 1 S.C.R. 902, included allegations

specialty crop producers (including organic producers) have historically borne all of the costs necessary to achieve desired purity standards.[17] Specific costs may include setback and crop rotation requirements, as well as segregation measures. For example, the National Organic Program (NOP) requires organic farms to have "dis-

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that GM pollen from neighboring fields blew onto defendant Schmeiser's field or that GM seeds spilled from a truck traveling down a road adjacent to Schmeiser's field and contaminated the defendant's canola crop. The courts did not directly address coexistence responsibilities but instead looked at whether the defendant violated Monsanto's patent rights by saving and planting seed containing the patented DNA. *See id.* at ¶ 92-97; *see also* Carlos Scott Lopez, *Intellectual Property Reform for Genetically Modified Crops: A Legal Imperative*, 20 J. CONTEMP. HEALTH L. & POL'Y 367, 408-411 (2004) (discussing Monsanto Can. Inc. v. Schmeiser). The defendant's wife later filed a separate court action against Monsanto for the alleged contamination of Mrs. Schmeiser's organic vegetable garden with genetically modified DNA and her attendant clean up costs. *See* A.B. Hansen, *Mrs. Schmeiser Sues Monsanto for $140*, COMMON GROUND, Dec. 2004, *available at* http://www.commonground.ca/iss/0412161/cg161_MrsSchmeiser.shtml. In addition, a class action suit (class not yet certified by the trial court) by certified organic farmers in Saskatchewan against Monsanto and Bayer Crop Sciences alleges that farmers are no longer able to grow certified organic canola in Saskatchewan and that GM canola from neighboring fields increasingly appears as weeds or volunteers in certified organic fields with the costs of removing the GM plants unnecessarily borne by the organic farmer. *See* Press Release, Organic Consumers Association, Organic Class Action Against Monsanto Moves Forward in Canada (Nov. 8, 2004), *available at* http://www.organicconsumers.com/OFGU/canada111204.cfm; *see also* ORGANIC AGRICULTURE PROTECTION FUND, *The Class Action*, *available at* http://www.saskorganic.com/oapf/legal.html (providing a copy of the Amended Statement of Claim).

17. *See, e.g.*, Association of Official Seed Certifying Agencies, *About AOSCA*, *at* http://www.aosca.orga/about.html (last visited Apr. 13, 2005) (explaining that a major purpose of AOSCA is "[t]o establish minimum standards for genetic purity and identity and recommend minimum standards for seed quality for the classes of certified seed"); Organic Production and Handling Requirements, 7 C.F.R. § 205.202 (2004) (detailing setback requirements); 7 C.F.R. § 205.201(a)(5) (2004) (providing requirement to describe management practices and physical barriers to prevent commingling with non-organic products and contact with prohibited substances, which includes GMOs organisms); 7 C.F.R. § 205.204 (2004) (providing organic seed requirement where commercially available). Because of the site-specific nature of organic production, the United States Department of Agriculture (USDA) did not include specific setback and segregation requirements in the national regulations but delegated the responsibility to individual certifying agents to review and evaluate each farm's segregation plan. 7 C.F.R. § 205.200 (2004). In addition, certification organizations may impose standards beyond those required by the NOP in order to satisfy third-country import requirements. *See* Letter from A.J. Yates, Administrator, USDA Agricultural Marketing Service, to Jose Sousa Uva, European Commission (Sept. 6, 2002), *available at* http://www.ams.usda.gov/nop/NOP/TradeIssues/EuropeanCommission.pdf (noting that NOP expressly permits U.S. certifiers to certify to standards for exports).

tinct, defined boundaries and buffer zones . . . to prevent . . . contact with a prohibited substance applied to adjoining land that is not under organic management."[18] Similarly, the Association of Official Seed Certifying Agencies (AOSCA), an umbrella organization for agencies responsible for seed certification, has promulgated minimum production requirements designed to maintain genetic purity and varietal identity.[19] Under AOSCA rules, seed corn may not be grown on land that grew corn of another color or endosperm type during the preceding season, and there must be a minimum distance from other corn and/or border rows to trap potential pollen drift.[20]

In an effort to minimize segregation requirements, and thereby costs at the individual farm level, some large-scale seed producers have adopted a strategy of contracting with contiguous blocks of farmers in a particular region.[21] As a result, only operators on the edge (i.e., fields that do not share a common border with fellow contractors on all sides) must sacrifice a portion of their fields as a setback. Interior farms can extend plantings to their respective fence lines without fear of contamination from neighbors. A variation of this concept is the establishment of GM-free zones where conventional and organic farmers do not have to plant border rows to "catch" drifting GM pollen. California appears to be the leader in this movement, with several counties recently passing referendums prohibiting the cultivation of crops with genetically modified DNA.[22] Conversely, a locality with a

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18. *See* 7 C.F.R. § 205.202 (2004) (setting forth land requirements).

19. *See* AOSCA, *Seed Certification*, *at* www.aosca.org/seed%20certification.htm (last visited Apr. 2, 2005).

20. *See id.*

21. Conversation with Donald N. Duvick, Affiliate Professor, Iowa State University, in Ames, IA (Nov. 6, 2004) [hereinafter Conversation with Duvick]. In the alternative, a corn breeder could arrange to only contract with farmers whose adjacent neighbors' intend to plant soybeans (or provide an incentive to those neighbors to forego corn in favor of soybeans). A related concept is the development of "fence-in laws" for livestock (only those farmers with livestock need to bear the cost of fencing). Individuals engaging in production practices with the potential to harm their neighbors' crops traditionally have had the responsibility to confine their animals within the boundaries of their own property. In some localities, however, particularly where livestock producers outnumbered row crop farmers, the farmer, as opposed to the rancher, had the responsibility to fence out the potentially harmful animals. These "fence-in" or "fence-out" districts, allow the predominant agricultural practice in the locality to shift individual production costs to the minority producer.

22. *See* Greg Lucas, *Genetically Altered Crops: 2 Counties Rejecting Ban, Not Marin*, S.F. CHRON., Nov. 3, 2004, at B10 (noting passage of voter referendum in Marin County, California that prohibits the cultivation of GM crops, and similar ordinances in Mendocino and Trinity counties); Thomas P. Redick & Michael J. Adrian, *Do European Non-Tariff Barriers Create Economic Nuisances in the US?*, 1 J. FOOD L. & POL'Y 87 (2004).

particularly high concentration of producers planting GM crops theoretically could create a "GM-only" or "GM-preferred" agricultural zone and thereby minimize possible liability exposure from pollen drifting into neighbors' fields.[23]

In addition to direct costs of establishing and maintaining coexistence, non-GM farmers face the risk that their systems for coexistence will fail.[24] For example, despite a producer's efforts to comply with organic certification standards, organically produced grains tainted with genetically modified DNA from an unknown origin may be rejected at the point of initial sale. In that case, the producer is forced to forgo the expected organic price premium and sell the product as commodity grade grain.[25] Although no reported case exists where an

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Minimizing on-farm coexistence costs may not be the only purpose of these laws, as general opposition to genetic engineering probably is driving adoption of these rules. *Id.*

23. *See also* Redick & Adrian, *supra* note 22, at 103-04 (discussing grower districts in Idaho and Washington formed to isolate industrial rapeseed from edible rapeseed (canola oil) because pollen from the plant my travel as far as three kilometers).

24. Not all risk of failure is borne by the organic or specialty crop producer. For example, the risk of damage from pesticide drift from applications on neighboring farms is borne by the applicator. *See* A. Bryan Endres, *GMO: Genetically Modified Organism or Gigantic Monetary Obligation? The Liability Schemes for GMO Damage in the United States and European Union*, 22 Loy. L.A. Int'l & Comp. L. Rev. 453, 490-91 (2000) (discussing damages resulting from pesticide drift). At least one commentator has suggested that if the economic/market consequences are high, which would likely happen if there is a large price premium for non-GM supplies, then farmers are likely to minimize this risk via insurance (assuming it is available). *See* Brookes, *supra* note 11, at 8.

25. Rejections and thus economic losses may arise later in the food supply chain. For example, Terra Prima, a producer of organic tortilla chips, recalled and destroyed 85,000-95,000 bags of certified organic chips from Europe because of the presence of GM corn. *See* Erica Walz, Organic Farming Research Foundation, Final Results of the Fourth National Organic Farmers' Survey: Sustaining Organic Farms in a Changing Organic Marketplace 22, 73, 87, *available at* http://www.ofrf.org/publications/survey/Final.Results.Fourth.NOF.Survey.FastView.pdf (noting that two percent of survey respondents indicated they lost sales due to perceived or actual contamination of their organic crop by GMOs, twenty-seven percent of respondents indicated that some outside entity has requested testing of some portion of the farm's seeds, inputs or products for the presence of GMOs, and nine respondents indicated they were unable to grow organic corn in their region because of pollen drift); Andrew Pollack, *Can Biotech Crops be Good Neighbors?*, N.Y. Times, Sept. 26, 2004, at A12 (describing concerns of organic producers of contamination from genetically modified DNA). If the harvested seed was contaminated with genetically modified DNA during pollination, the GM seed may be multiplied over several years and contaminate future harvests. *See* Catherine L. Moyes & Philip J. Dale, Organic Farming and Gene Transfer from Genetically Modified Crops § 4.5 (1999), *available at* http://www.gmissues.org/organic%20report.htm.

organic farmer has pursued relief from the courts by way of a direct action against another farmer or seed manufacturer for this economic injury, the potential for such lawsuits exists.[26]

2. Efforts by Seed Companies to Facilitate Coexistence

Current seed stewardship guidelines from the seed breeder and regulating agencies require non-GM reserves only for the purpose of preventing and/or slowing resistance.[27] Unfortunately, measures designed to slow resistance may not prevent admixture. Guidelines for planting corn genetically engineered to produce the toxin Bacillus thuringiensis (Bt) provide an excellent illustration. Because Bt is an important insecticide for organic producers, the developer of Bt technology in corn plants, as well as regulating agencies, have expressed concern regarding development of resistance to the toxin. Accordingly, Monsanto requires growers to certify that they have read and understand the Technology Use Guide that accompanies the sale of their YieldGuard Rootworm corn. To slow resistance, growers are instructed to plant twenty percent of their field with a non-Bt variety. The hope is that insects with a mutation allowing them to survive exposure to Bt will mate with insects in the refuge and produce offspring without a tolerance for Bt. From a coexistence perspective, the refuge probably should border the genetically engineered corn to minimize pollen drift.[28] The location of this reserve, however, is left

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26. *See* Endres, *supra* note 24, at 482-94 (discussing potential tort causes of action available to an organic farmer to recover damages resulting from pollen drift); Hansen, *supra* note 16 (noting Mrs. Schmeiser's suit against Monsanto in Canada).

27. In addition to on-field stewardship guidelines, Monsanto requires farmers to complete a "Market Choices" form when planting GM varieties that are not approved for export. *See* Monsanto Company, 2004 Grain Marketing Communication Plan, *available at* http://www.monsanto.com/monsanto/us_ag/content/stewardship/marketchoices/mc_market_plan2004.pdf. The purpose of the form is to ensure that farmers growing such products do not direct the harvested commodities into the export market. In completing the form, the farmer must specify where the grain was used or marketed, e.g., on-farm feeding, domestic feed lots, elevators agreeing to accept non-export grain, or other approved domestic market uses. *See* David R. Moeller & Michael Sligh, Farmers' Guide to GMOs 13-14, *available at* http://www.nationalaglawcenter.org/assetts/articles/moeller_gmos.pdf.

28. Border rows of non-GM corn may serve as a "fence" by catching drifting pollen from the GM varieties. The corn planted in the refuge will then produce a grain containing genetically modified DNA and should be harvested and treated as a GM product. Graham Brookes & Peter Barfoot, Co-Existence in North American Agriculture: Can GM Crops be Grown with Conventional and Organic Crops 11, *available at* http://www.pgeconomics.co.uk/pdf/coexistencereportNAmericafinaljune2004.pdf. However, anecdotal evidence suggests that farmers will occasionally harvest, and attempt to market, corn planted in the refuge as conventional. *Id.*

to the sole discretion of the farmer. The refuge may be planted on one side of the field, in a neighboring (even if not adjacent) field, or as alternate rows within the same field,[29] thereby squandering its value as a coexistence tool.

3. State Delegation of Responsibility for Coexistence

In the absence of legal rules fashioning coexistence standards, some state legislators continue to propose, without success, statutes mandating notification of surrounding farmers of an intention to plant GM crops.[30] Such bills are shortsighted, however, because a notification requirement may inadvertently impose the burden of in-field segregation on the non-GM farmer. That is, by providing notice of intent to plant GM crops, the GM farmer may be deemed to have satisfied all duties owed to neighbors to restrain pollen or otherwise prevent admixture of the GM product. So warned, a conventional or organic farmer could then be held responsible for implementing setbacks and border rows to catch drifting genetically modified DNA.[31]

In an effort to build consensus for a more comprehensive coexistence scheme, North Dakota State University formed the Coexistence Working Group with grant assistance from the Northern Plains Sustainable Agriculture Society.[32] Group membership included representatives from the biotechnology, conventional, identity-preserved and organic farming sectors, organic certification groups, the North Dakota Agriculture Department, and various organizations within the

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29. *See* MONSANTO, 2005 TECHNOLOGY USE GUIDE 6, *at* http://www.monsanto.com/Monsanto/us_ag/content/stewardship/tug/tug2005.pdf (last visited Apr. 2, 2005). The Technology Use Guide illustrates additional refuge options with little coexistence value. *Id.*

30. *See, e.g.*, A.B. 115, 228th Leg. Sess., 2005-2006 Reg. Sess. § 31-0303(1) (N.Y. 2005) (requiring anyone who "uses, grows or produces GMO seed . . . [to] inform any landowner located within two miles . . . or such distance as the pollen of such GMO seed species is determined by the Commissioner to travel, whichever is greater"); H.B. 150, 2001 Sess. (Minn. 2001) (requiring seed manufacturer to mail a notification to neighboring farmers that identifies the person intending to grow GM seed); H.B. 1024, 23rd Leg. (Haw. 2005) (requiring public disclosure of locations of each crop field and testing site containing GMO crops); *cf.* Genetically Modified Organism Liability Act § 142-C, H.B. 1022, 23rd Leg. (Haw. 2005) (imposing tort liability for drift of GMO pollen to neighboring organic farms).

31. *See* ORGANIC TRADE ASSOCIATION, AMERICAN ORGANIC STANDARDS 29, n. 38 (2003), *available at* http://www.ota.com/pics/documents/AOS032003.pdf (stating that the burden for avoiding contamination for GMOs should not be placed entirely on the organic producer) [hereinafter ORGANIC TRADE ASSOCIATION].

32. *See* COEXISTENCE WORKING GROUP, SUGGESTED BEST MANAGEMENT PRACTICES FOR THE COEXISTENCE OF ORGANIC, BIOTECH AND CONVENTIONAL CROP PRODUCTION SYSTEMS 1 (2004), *available at* www.ag.ndsu.nodak.edu/coexistence/a1275.pdf.

University.[33] The Group reached consensus (and near unanimity) on a variety of "best management practices" to foster coexistence,[34] including: (1) product stewardship education is the responsibility of the party marketing the GM seed; (2) growers and handlers should be aware of the requirements and risks of contracts they enter into and the impact of those requirements on their operating procedures; (3) stakeholders should review insurance coverage with respect to damages from the adventitious presence of GMOs; (4) producers should take steps to maximize crop purity and segregation; (5) transportation devices should be carefully cleaned and inspected; (6) tolerance levels should be set by the market and not the government; (7) the process for public input for seed certification standards should be publicized; (8) if GM admixture is suspected in the seed, the purchaser should pre-plant test the seed; (9) seed stock breeders should test for adventitious presence in breeder and foundation seeds; (10) growers should communicate production intentions to neighbors; and (11) consumers should have unbiased information on the various food production systems to enable an educated choice.[35]

Unfortunately, after initial voting on the proposed best management practices, five members of the group withdrew their support and discontinued participation in the project.[36] One of their primary objections was the passage by a nine-to-eight vote of the "recommendation" that states not set seed certification standards for the adventitious presence of genetically modified DNA in otherwise non-GM seed.[37] The objectors noted that "[s]eed standards are a recognized system of identity preservation and segregation. Without standards, there is not segregation. Without a strict segregation system in place, there will be no coexistence."[38] Although the process broke down before the Group could obtain a consensus on a comprehensive set of best management practices, the process served as a valuable starting point for future debate and elevated the issue of coexistence to state level consideration.

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33. *See id.*

34. The working group specifically noted that the best management practices developed during the process were "not intended to advocate the development or implementation of legislative or regulatory policies." *Id.* at 2.

35. *See generally id.* (listing approved BMPs and vote totals).

36. Letter of Resignation Addressed to the Coexistence Working Group, February 7, 2004 (on file with the author) [hereinafter Letter of Resignation]. One other best management practice passed on a controversial votes of 9 in favor to 8 against: compliance with regulatory minimum standards in an important factor in determining liability. *See* COEXISTENCE WORKING GROUP, *supra* note 32, at 2.

37. *See* Letter of Resignation, *supra* note 36.

38. *See id.*

Because the United States has adopted a policy of voluntary labeling for GM food and feed, coexistence is of immediate importance to those producers attempting to access the identity-preserved, organic, export, or other specialty markets.[39] As discussed in Section B, producers seeking admittance to European, and to a lesser extent Asian,[40] export markets must meet stringent non-GM purity standards. So long as European consumers and, therefore, food processors and distributors, continue to reject products containing or produced from GMOs,[41] conventional crop producers in the United States must implement coexistence measures to ensure their harvest does not exceed the E,U.'s threshold for labeling the product as "genetically modified."[42]

Organic farmers face similar market-based coexistence concerns.[43] Although federal organic rules acknowledge and allow for the adventitious presence of GMOs in organic products, the government has not established a specific, numeric federal tolerance level.[44] The National Organic Program (NOP) established certification stan-

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39. *See* Nicholas Kalaitzandonakes, *Regulating Biotechnology: GM Food Labels*, *in* BIOTECHNOLOGY: SCIENCE AND SOCIETY AT A CROSSROAD 125-27 (National Agricultural Biotechnology Council 2003); BROOKES & BARFOOT, *supra* note 28, at 14.

40. *See* BROOKES ET AL., *supra* note 2, at 4 (noting less onerous labeling thresholds for the adventitious presence of GMOs for export to Japan and Korea (five percent and three percent, respectively) compared to the European Union (0.9 percent)).

41. GEORGE GASKELL ET AL., EUROPEANS AND BIOTECHNOLOGY IN 2002 at 36-40 (Eurobarometer 58.0, 2d ed. 2003), *available at* http://europa.eu.int/comm/public_opinion/archives/ebs/eb_177_en.pdf (finding continued resistance to GM food in contrast to acceptance of biotechnology for medical purposes).

42. *See* BROOKES ET AL., *supra* note 2, at 4 (discussing labeling threshold of 0.9 percent in the European Union).

43. *See* Catherine Greene & Carolyn Dimitri, *Organic Agriculture: Gaining Ground*, AMBER WAVES, Feb. 2003, *available at* http://ers.usda.gov/AmberWaves/Feb03/Findings/OrganicAgriculture.htm. Although relatively small in relation to conventional and GM production methods, the organic market is one of the fastest growing sectors in domestic agriculture, with a sustained twenty percent increase in sales since the 1990s. *Id.*

44. National Organic Program, 65 Fed. Reg. 80,548 (Dec. 21, 2000) (to be codified at 7 C.F.R. pt. 205) (clarification of "genetic drift" issues). USDA noted that organic standards are "process based" and certification is granted according to the ability of organic operators to follow a set of production standards and processes. *Id.*

> The presence of a detectable residue of a product of excluded methods [e.g., genetically modified organisms] alone does not necessarily constitute a violation of this regulation. As long as an organic operation has not used excluded methods and takes reasonable steps to avoid contact with the products of excluded methods . . . the unintentional presence of the products of excluded methods should not affect the status of the an organic producer or operation. *Id.* at 80,556.

dards based on a "process" or "production method" rather than an end-product guarantee.[45] Some advocate that the lack of clear international standards for the adventitious presence of genetically modified DNA has "disrupted the flow of trade in seed, agricultural commodities and food."[46] Accordingly, the government should adopt a "science-based policy on adventitious presence . . . and persuade other countries to adopt similar measures" to prevent arbitrary restrictions on exports.[47] On the other hand, IFOAM and the Organic Trade Association oppose establishing a *de minimis* tolerance because

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"Reasonable steps to avoid contact" with GMOs could include tracing back at least one step in the biological chain all processing aids and other inputs into the organic production system to verify that the product was not derived from genetic engineering and prohibiting use of GMOs on farms with split production systems (i.e., the farm produces both organic and non-organic products). *See* INTERNATIONAL FEDERATION OF ORGANIC AGRICULTURE MOVEMENTS (IFOAM), IFOAM BASIC STANDARDS FOR ORGANIC PRODUCTION AND PROCESSING 11-12 (2002), *available at* http://www.ifoam.org/standard/norms/ibs.pdf. Although specifically noting that the burden for avoiding contamination from GMOs should not be placed entirely on the organic producer, the Organic Trade Association requires additional measures for certified producers including: "establishment of physical barriers, diversion of runoff, notification of neighbors, posting of borders, buffer zones of no less than 25 feet, or other means as approved by the certification agent to prevent the application or drift of a prohibited substance to land on which organically produced crops are grown." ORGANIC TRADE ASSOCIATION, *supra* note 31, at 28-29.

45. 65 Fed. Reg. 80,548 (Dec. 21, 2000) (to be codified at 7 C.F.R. pt. 205) (referring to clarification of "genetic drift" issues). *See also* IFOAM, *Position on Genetic Engineering and Genetically Modified Organisms*, *available at* http://www.ifoam.org/pospap/ge_position.html [hereinafter IFOAM GMO Position].

> The potential of GMO contamination does not alter the traditional approach of certifying organic as a "production method" rather than an end-product guarantee. Organic producers are not defined or certified as being "free" of unwanted pollution. Just as organic farmers cannot guarantee zero contamination from pesticides they do not use themselves, there is no way for them to guarantee that organic products will not be polluted by traces of GMOs. *Id.*

IFOAM, however, does require organic producers and operators to "take all reasonable measures to minimize and manage the risk of contamination." *Id.*

46. Biotechnology Industry Organization, *Issues in Brief: Standards Need to be Developed for Adventitious Presence of Biotech Products*, *available at* http://www.bio.org/foodag/background/adventitious.asp.

47. *Id.*; *see also* The Pew Initiative on Food and Biotechnology, *Biotech and Organic: Reaching Détente* (paraphrasing Leon Corzine of the Biotechnology Working Group of the National Corn Growers Association as advocating tolerances for organic foods in order to ensure organic and biotech farming methods remain viable options), *available at* http://pewagbiotech.org/buzz/print.php3?StoryID=62; National Corn Growers Association, *NCGA Position: Biotechnology* 1-2 (supporting "development of internationally accepted, science-based tolerance standards" for the adventitious presence of GM material and development of "merchandising and process verification standards for

it might require testing for all producers who otherwise follow organic principles and experience contamination from circumstances beyond their control.[48] As the tolerance debate continues, organic certifying organizations, in response to consumer demand, have imposed their own tolerance standards; as a result, grain elevators and processors routinely refuse to accept otherwise organically certified shipments that contain adventitious amounts of genetically modified DNA.[49]

B. The European Union's Approach to Coexistence

1. Specific Measures Aimed at Coexistence

While conventional and organic farmers in the United States must rely on *ad hoc* informal norms, the E.U. has proposed formal principles of coexistence[50] and is in the process of developing formal rules and accompanying best management practices.[51] In July 2003,

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goods that do not contain biotech corn"), *available at* http://www.ncga.com/biotechnology/pdfs/BIOTECHNOLOGYPOSITIONPAPERS.pdf.

48. *See* IFOAM GMO Position, *supra* note 45, at 4; *see also* COEXISTENCE WORKING GROUP, *supra* note 32, at 6 ("The marketplace, represented by the purchasing entity, will determine the acceptable level (tolerances) of unintended presence."); INTERNATIONAL SEED FEDERATION, *supra* note 14, at 2 (opposing adoption of specific thresholds for the adventitious presence of GM material in organic products and, if such thresholds are adopted, arguing that "responsibility to reach and guarantee them must rest with organic producers and the burden of their decision should not be transferred to the farming community at large"); Organic Trade Association, *Summary of OTA Positions on GMOs* (2003), *available at* http://www.ota.com/pp/otaposition/geos.html.

> [The E.U.] has a tolerance level of 1 [percent], but OTA does not support setting a tolerance level . . .OTA stresses that organic production is a process guarantee, and notes that just as there are trace amounts of persistent synthetic pesticides in much of our food, so there may be background levels of GMOs in North American food, due to the high percentage of GM crops grown here. *Id.*

49. *See* The Pew Initiative on Food and Biotechnology, *Organic Farmers Sing Biotech Blues* (noting that even the "slightest bit of biotech contamination can cut the value of the crop by a third or more" and "food companies and livestock producers are increasingly forcing farmers and grain elevators to test organic commodities to detect any traces of biotech material"), *available at* http://pewagbiotech.org/newsroom/summaries/display.php3?NewsID=458. Some farmers, however, purchase non-GMO seed due to personal preference, cost concerns or simply because the traits genetically engineered into the plant offer no benefit. For example, a farmer is unlikely to purchase corn genetically modified to resist the corn borer or rootworm if the farmer does not experience yield pressure from those plant pests. *Id.*

50. *See generally* Commission Recommendation 2003/556, 2003 O.J. (L 189) 36.

51. Commission Recommendation 2003/556, art. 2.1.2, 2003 O.J. (L 189) at 41. Best management practices (BMPs) should reflect "the best available scientific evidence," and "should take into account the differences between crop species, crop

the European Commission issued guidelines to its Member States for the development of national coexistence strategies and best management practices for coexistence.[52] Under the new guidelines, Member States must strive to ensure that farmers have the ability to "make a practical choice between conventional, organic and GM crop production, in compliance with the legal obligations for labeling and/or purity standards."[53] Among the key implementation principles is the requirement that farmers introducing a new production type in a region (presumably GM crop production) must bear the responsibility for implementing the farm management measures necessary to limit admixture.[54] In addition, Member States should establish mechanisms to favor coordination and voluntary arrangements among neighbors and, in crafting rules, rely on the best available scientific evidence regarding the probability and sources of admixture.[55]

These proposed rules present a stark contrast to the adoption of GM production methods by farmers in the United States, where the absence of regulatory rules supporting coexistence subsidize the adoption of GM production as producers are free to disregard production practices on neighboring farms and pass segregation costs onto the non-GM farmer. In contrast, European producers will likely see the cost of switching to GM production rise in response to implementation of the European rule. As a result, the adoption of GM technology in the E.U. may be further slowed.[56] In addition to on-farm management costs, European GM producers may face liability for admixture because the Commission recommended that Member States "examine their civil liability laws to find out whether existing national

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varieties and product type (e.g., crop or seed production) . . . [d]ifferences in regional aspects (e.g., climatic conditions, topography, cropping patterns, and crop rotation systems, farm structures, crop-specific GMO share in a region) that may influence the degree of admixture." Commission Recommendation 2003/556, art. 2.1.6, 2003 O.J. (L 189) at 41.

52. Commission Recommendation 2003/556, art. 2.1.6, 2003 O.J. (L 189) at 41.

53. Commission Recommendation 2003/556, art. 1.1, 2003 O.J. (L 189) at 39.

54. Commission Recommendation 2003/556, art. 2.1.2, 2003 O.J. (L 189) at 41.

55. Commission Recommendation 2003/556, art. 2.1.2, 2003 O.J. (L 189) at 41. An additional interesting recommendation is the requirement for farmers planting GM seeds to notify neighboring farms. Commission Recommendation 2003/556, art. 2.1.7, 2003 O.J. (L 189) at 41.

56. In addition to on-farm management costs, some Member States have imposed further costs on the farmer adopting GM production methods such as payment into an indemnity fund for damage resulting from GMOs. *See* Benoit & Wassener, *infra* note 57 (discussing indemnity funds & damage from GMOs).

laws offer sufficient and equal possibilities" in the event of economic damage resulting from admixture.[57]

The Commission's guidelines place emphasis on farm specific management measures (e.g., setbacks, segregation protocols, coordination among neighboring farms) over region wide coexistence measures such as GM-free growing zones.[58] Measures of regional dimension "should only be considered if sufficient levels of purity cannot be achieved by other means . . . and will need to be justified for each crop and product type (e.g., seed versus crop production) separately."[59] Despite this stated priority, several Member States have imposed region wide bans on GM crop production or "opt-out" clauses in national legislation that empower regional governments to declare themselves "biotech-free."[60]

2. Approval and Marketing of GM Products in the E.U.

In addition to specific measures directed to obtaining coexistence, the E.U. has adopted a robust approval and post-market regulatory system for genetically modified organisms (GMOs) and products produced from GMOs.[61] Included in this scheme are comprehensive

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57. *See* Commission Recommendation 2003/556, art. 2.1.9, 2003 O.J. (L 189) 36. In November 2004 the lower house of the German Parliament passed a revised civil liability measure addressing economic damage from admixture. The law places the risk of liability on the producer adopting production methods that employ genetically modified DNA. *See* Bertrand Benoit & Bettina Wassener, *German Bill Lays Down Strict Rules for "Genetic" Crops*, FINANCIAL TIMES, Nov. 26, 2004, at 8.

58. *See* Commission Recommendation 2003/556, art. 2.1.5, 2003 O.J. (L 189) 36.

59. *See* Commission Recommendation 2003/556, art. 2.1.5, 2003 O.J. (L 189) 36.

60. *Europe Reflects Italian Battle over Biotech Coexistence*, ANSA ENGLISH MEDIA SERVICE, Oct. 13, 2004 (available on Lexis) [hereinafter ANSA]. Region wide bans on GM production have also garnered increasing attention in the United States, especially in California. *See supra* note 22 and accompanying text. As an alternative to an outright ban on GM cultivation (a violation of E.U. rules), Denmark established "extremely tough penalties for biotech farmers who contaminate conventional crops . . . and face a special 'GMO tax,' amounting to 13.50 euros per hectare" to finance a compensation fund for farmers damaged by admixture with GMOs. ANSA, *supra* note 60; *see also* Jeremy Smith, Reuters, *Lawmaking on Genetic(GMO) Food is Minefield for EU*, Feb. 28, 2005, *available at* http://www.usatoday.com/tech/news/techpolicy/2005-02-28-biotech-eu_x.htm.

61. *See* Council Directive 90/219, 1990 O.J. (L 117) 1 (outlining the approval process for research and other use of genetically engineered DNA within containment systems); Parliament and Council Directive 2001/18, 2001 O.J. (L 106) 1 (explaining approval process for field testing and marketing of GMOs); *see also* Margaret Rosso Grossman, *Traceability and Labeling of GM Crops, Food, and Feed in the European Union*, 1 J. FOOD L. & POL'Y 43, 53-65 (parts II. A-C) (2005); Margaret Rosso Grossman & A. Bryan Endres, *Regulation of Genetically Modified Organisms in the European Union*, 44 AM.

rules for traceability and labeling of GMOs, some of which impact coexistence. Regulation 1829/2003 established procedures for the approval and labeling of GM food and feed.[62] Regulation 1830/2003, adopted concurrently with Regulation 1829/2003, created an operational framework for the traceability of products consisting of or containing GMOs, as well as food and feed produced from GMOs.[63] The purpose of the two regulations is to facilitate accurate labeling of products, monitoring of environmental and health effects, and implementing necessary risk management measures, including the possible withdrawal of products from the market.

The operator, when first placing products "consisting of" or "containing GMOs," on the market, and at all subsequent stages of marketing, must notify the receiving operator in writing that the products contain or consist of GMOs, as well as the unique identifier(s) assigned to each GMO present in the shipment.[64] Products containing or consisting of *mixtures* of GMOs intended to be used directly as food or feed or for further processing may be accompanied by a declaration from the operator that lists all GMOs used to constitute the mixture as well as the unique identifiers.[65] Operators must retain this transaction information for a period of five years.[66] At the consumer level, labels on prepackaged products (or on the display for nonprepackaged products) must state "[t]his product contains genetically modified organisms" or "[t]his product contains genetically modified [name of organism]."[67] Similarly, labels on animal feed composed of a feed that contains or consists of GMOs must state "genetically modi-

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BEHAV. SCI. 378 (2000) (describing the European Union's regulatory approval process for GMOs).

62. Parliament and Council Regulation 1829/2003, 2003 O.J. (L 268) 1.

63. Parliament and Council Regulation 1830/2003, 2003 O.J. (L 268) 24.

64. Regulation 1830/2003, art. 4(A), 2003 O.J. (L 268) at 26. Similar rules apply to products "produced from" GMOs. *See* Regulation 1829/2003, art. 13, 25(2)(b), 2003 O.J. (L 268) at 11-12, 17; Regulation 1830/2003, art. 5, 2003 O.J. (L 268) at 27. The traceability and labeling rules, however, do not apply to food or feed "produced *with*" GMOs. An example of a product produced "with" GMOs would be an animal fed GM grain or treated with a GM medicinal product. *See* Regulation 1829/2003, pmbl. (16), 2003 O.J. (L 268) at 2-3.

65. Regulation 1830/2003, art. 4(A), 2003 O.J. (L 268) at 26.

66. Regulation 1830/2003, art. 4(A), 2003 O.J. (L 268) at 26.

67. Regulation 1830/2003, art. 4(B), 2003 O.J. (L 268) at 26. In addition, Article 13 of Regulation 1829/2003 requires that food products intended for the final consumer that contain or consist of GMOs must indicate on the ingredients list "genetically modified [name of organism]" or, where there is no list of ingredients, indicate the same somewhere clearly on the label.

fied [name of organism]" in parentheses immediately following the name of the feed or in a footnote to the list of feed.[68]

The traceability and labeling rules, however, do not apply to food or feed that meet a preset tolerance level. Food or feed containing material which contains, consists of, or is produced from GMOs in a proportion no higher than 0.9 percent of the food ingredients considered individually (or food consisting of one ingredient) may be marketed in the E.U. without a label indicating the presence of GMOs, provided that the presence is adventitious or technically unavoidable.[69] To qualify for the exemption, operators must be able to demonstrate that appropriate steps were taken to avoid the presence of GMOs in the product.[70] The adventitious presence rules, however, only apply to GMOs approved for use in the European Union. There is no tolerance level for GMOs rejected or otherwise not yet approved for release.[71]

Like the United States, organic certification rules in the E.U. acknowledge that GMOs may be present in organically produced products. The E.U. has not yet established a *de minimis* threshold for unavoidable contamination, but has signaled that it will in the future.[72] Absent specific rules, the general traceability and labeling standards (0.9 percent for approved GMOs) probably apply to organic products.[73] Organic certification bodies, as well as processors, may impose a more stringent threshold of 0.1 percent.

II. European Union Seed Laws: A Work in Progress

As a starting point in the achievement of its agricultural purity standards, the E.U. enacted a series of statutory measures regulating the production, labeling and sale of agricultural seeds to "minimize genetic contamination and maximize varietal purity."[74] Directive

68. Regulation 1829/2003, art. 25(2)(a), 2003 O.J. (L 268) at 17.

69. Regulation 1829/2003, art. 12, 24, 2003 O.J. (L 268) at 11, 16-17; Regulation 1830/2003, art. 4(c) & 5, 2003 O.J. (L 268) at 26-27.

70. Regulation 1829/2003, art. 12, 2003 O.J. (L 268) at 11.

71. Regulation 1829/2003, art. 47(1), 2003 O.J. (L 268) at 22. In addition to the zero tolerance level for unapproved GMOs, Regulation 1829/2003 carves out a limited exception for GMOs with a favorable risk evaluation completed before November 7, 2003, but not yet approved for use. The adventitious presence for this limited category of GMOs is limited to 0.5 percent. *See also* Commission Regulation 641/2004, 2004 O.J. (L 102) 14.

72. Council Regulation 1804/1999, 1999 O.J. (L 222) 1. In contrast, the United States process based organic standards have a "reasonable efforts" requirement to avoid contamination from GMOs. *See supra* note 44 and accompanying text.

73. *See* Commission Recommendation 2003/556, 2003 O.J. (L 189) 36.

74. Bock et al., *supra* note 4, at 15.

2002/53/EC[75] codified earlier legislation that established a common catalog of each variety of agricultural plant species accepted for certification and marketing in the Member States of the E.U.[76] Once listed in the common catalog, seed varieties are freely marketable within the Member States.[77] Separate Directives establish specific certification standards for marketing each type of seed and plant propagating material.[78]

Genetically modified varieties may be included in the common catalog only after approval in accordance with Regulation 1829/2003,[79] the regulation authorizing the placing on the market of products consisting of, containing, or produced from GMOs.[80] Moreover, the catalog listing must clearly indicate that the variety is genetically modified,[81] and individual labels must accompany each seed lot.[82] Current seed certification and marketing directives, however, do not establish a tolerance level for the adventitious presence of GM seeds

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75. Council Directive 2002/53, 2002 O.J. (L 193) 1 (regarding the common catalog of varieties of agricultural plant species).

76. *See* Council Directive 70/458, 1970 O.J. SPEC. ED. 674 (regulating the marketing of vegetable seed).

77. Council Directive 2002/53, pmbl. (11), 2002 O.J. (L 193) 1.

78. *See* Directive 66/401, 1965-1966 O.J. SPEC. ED. 132 (regarding fodder plant seed); Council Directive 66/402, 1965-1966 O.J. SPEC. ED. 143 (regarding cereal seed, including maize); Council Directive 68/193, 1967-1968 O.J. SPEC. ED. 93 (regarding wine and table grapes); Council Directive 92/33, 1992 O.J. (L 157) 1 (regarding plant propagating material other than seed); Council Directive 92/34, 1992 O.J. (L 157) 10 (regarding fruit plants); Council Directive 2002/54, 2002 O.J. (L 193) 12 (regarding beet seed); Council Directive 2002/55, 2002 O.J. (L 193) 33 (regarding vegetable seed); Council Directive 2002/56, 2002 O.J. (L 193) 60 (regarding seed potatoes); Council Directive 2002/57, 2002 O.J. (L 193) 74 (regarding oil and fiber plant seeds, including soybeans).

79. *See* Regulation 1829/2003, pmbl. 34, 2003 O.J. (L 268) at 4. For example, on September 8, 2004, the European Commission approved the inscription of seventeen varieties of GM corn into the common catalog. All of the varieties were derived from Monsanto's MON810 maize sold under the trade name YieldGuard. Press Release, European Commission, Inscription of MON 810 GM maize varieties in the Common EU Catalogue of Varieties (IP/04/1083, Sept. 8, 2004).

80. Regulation 1829/2003, art. 4(2), 2003 O.J. (L 268) at 7. Approval under Regulation 1829/2003 assumes prior approval for the release under Directive 2001/18.

81. Council Directive 2002/53, art. 9.5, 2002 O.J. (L 193) at 5.

82. *See, e.g.*, Council Directive 98/95, 1999 O.J. (L 25) 1 (amending, in respect to the consolidation of the internal market, GM plant varieties and plant genetic resources, Council Directives 66/400, 66/401, 66/402, 66/403, 69/208, 70/457 and 70/458 on the marketing of beet seed, fodder plant seed, cereal seed, seed potatoes, seed of oil and fibre plants and vegetable seed, and on the common catalogue of varieties of agricultural plant species, and amending, *inter alia*, labeling requirements required under art. 11a of Directive 66/402).

that are otherwise approved for marketing in the E.U. Accordingly, agricultural seeds are subject to the generic 0.9 percent labeling and traceability threshold applicable to all GMOs.[83] However, a farmer planting conventional seed with an adventitious GM presence of 0.9 percent is unlikely to harvest a final crop with only 0.9 percent genetically modified DNA due to a variety of potential admixture events, including: cross-pollination, volunteer plants, harvesting, transportation, and storage.[84] Accordingly, the European Commission is considering legislation that would establish labeling thresholds for the adventitious presence of GM seed at a level low enough to ensure the harvested crop could satisfy the 0.9 percent threshold for traceability and labeling.[85]

The Scientific Committee on Plants of the European Commission acknowledged that a zero level of adventitious GM seed is unobtainable in practice given the nature of field experiments and the fact that unapproved GM varieties may have received some level of regulatory approval in third countries.[86] Instead, the Committee recommended thresholds of 0.3 percent for cross-pollinating crops and 0.5 percent for self-pollinating vegetatively propagated crops.[87] An October 13, 2003 Commission Staff Working Paper recommended thresholds of 0.3 percent for rape (canola), 0.5 percent for maize and 0.7 percent for soybeans. The required thresholds were calculated to produce an end-product with a GM presence of approximately 0.8 percent, leaving a margin *vis a vis* the 0.9 percent labeling threshold for final products.[88]

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83. *See* Commission Recommendation 2003/556, art. 2.1.4, 2003 O.J. (L 189) 36.

84. One study has estimated post-planting admixture from these sources to be 0.81 percent for oilseed rape and 0.57 percent for maize. Opinion of Scientific Committee on Plants, *supra* note 10, at 8.

85. *See* Commission Recommendation 2003/556, art. 2.1.4, 2003 O.J. (L 189) 36. Factors to consider in setting seed purity thresholds include whether the species is self or open pollinated and the difficulty of controlling volunteers. Opinion of Scientific Committee on Plants, *supra* note 10, at 7. Of course, this assumes the farmer would practice adequate farm level and post-harvest segregation measures. *See supra* notes 4 and 80 and accompanying text (describing possible factors influencing admixture) and *infra* notes 100-07 and accompanying text (noting possible prevention measures).

86. Opinion of Scientific Committee on Plants, *supra* note 10, at 16. Analytical sensitivity is currently at 0.1 percent. Moreover, an international database of DNA sequences and analytical procedures is necessary to be able to detect unauthorized GM material. *Id.* at 7; International Seed Foundation, Access to Relevant Technology to Test the Adventitious Presence of GM Material in non-GM Seed, *available at* http://www.worldseed.org/Position_papers/Acc_rel_tech.htm.

87. Opinion of Scientific Committee on Plants, *supra* note 10, at 7.

88. Commission Staff Working Paper, SEC (2003) 1131 (on file with author). A 2004 Draft Commission Decision would establish tolerances of 0.3 percent for canola

Of course, any Europe-wide labeling requirement would not *a priori* guarantee acceptance of the harvested crop as non-GM. Farmers would have to practice adequate farm level and post-harvest segregation measures to preserve genetic purity. The ability to purchase properly labeled non-GM seeds with an adventitious presence significantly below the 0.9 percent threshold, however, does provide a reasonable starting point toward obtaining coexistence.

III. GM to the Exclusion of All Others: How Domestic Seed Laws Fail to Curtail the Adventitious Presence of Genetically Modified DNA in the Seed Supply

As the undisputed leader in the development and adoption of agricultural biotechnology,[89] the United States' agricultural production system has served as the "guinea pig" for coexistence. Accordingly, an evaluation of the efficacy of its interlocking system of agency oversight[90] provides a baseline for development of regulatory models abroad. Unfortunately, the initial rollout of biotechnology advances in agriculture did not anticipate resistance by trading partners[91] (such as the E.U.) and the potential consequences of the adventitious presence of genetically modified DNA in the domestic seed production system.[92] This section discusses the extent of the adventitious presence of genetically modified DNA in the nation's seed supply and how federal and state seed purity laws currently address GM seeds.

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and maize and 0.5 percent for sugar and fodder beet, potato and cotton. In addition to seed purity standards, achievement of the labeling thresholds would require good farm level and post-harvest management practices. Factors influencing local levels of contamination other than seed purity include the relative proportion of the species in the agricultural landscape, the relative size of the fields (pollen emitter and receptor), the field pattern and the process of collecting, drying, transporting and storing the harvested product. Bock et al., *supra* note 4, at 65. An increase in isolation distances (buffer zones) and coordination of pollination times for GM and non-GM varieties are additional, complementary farm level measures to reduce adventitious admixture. *Id.* A recent review of the scientific literature of cross-pollination of maize crops concluded that four buffer rows of non-GM maize or, in the alternative, a separation distance of six meters, is likely to prove effective for coexistence purposes. Brookes et al., *supra* note 2, at 18.

89. *See* ISAA Preview, *supra* note 1.

90. *See, e.g.*, U.S. Regulatory Agencies Unified Biotechnology Website, Welcome, *at* http://usbiotechreg.nbii.gov (last visited June 8, 2005) (describing the coordinated framework for the regulation of biotechnology by USDA, FDA and EPA).

91. Andrew Pollack, *We Can Engineer Nature, But Should We?*, N.Y. Times, Feb. 6, 2000, at 16 (noting that "[s]ome executives at bio-engineered seed companies say their mistake was to regard the farmer and not the consumer as the customer. With no apparent benefit, it is easy to shun even a miniscule risk, just to be safe").

92. Mellon & Rissler, *supra* note 8, at 9.

A. The Infiltration of Genetically Modified DNA in the Domestic Seed Supply

The scientific community and the American public have become increasingly concerned about the potential environmental dangers presented by cultivation of GM crops.[93] Typical concerns include the elimination of the ability to grow non-GM varieties, the contamination of wild relatives and landraces,[94] and the development of "super" weeds and bugs resistant to existing pesticides.[95] Assuming released GM crops are safe (i.e., have been approved or deregulated by the appropriate agency), coexistence is concerned with the economic viability of sustaining different farming practices, as opposed to the environmental or health consequences of GM production methods.[96] Unlike environmental concerns, the economic consequences of unwanted genetically modified DNA are not theoretical dangers to farmers but are here and potentially catastrophic to the sustained viability of the conventional and organic farming community.

The adventitious presence of genetically modified DNA in the domestic seed supply greatly hampers coexistence efforts. Each potentially contaminated seed produces multiple offspring and, once in foundation seed stocks, will reintroduce the genetic sequences during each use.[97] Unfortunately, there are increasing reports of genetically modified DNA within seed marketed as conventional or organic. North Dakota State University's Foundation Seedstocks Program reported the adventitious presence of GM soybeans in its natto variety

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93. *See, e.g.*, Pollack, *supra* note 25; Andrew Pollack, *Genes From Engineered Grass Spread for Miles, Study Finds*, N.Y. TIMES, Sept. 21, 2004, at A1; Alex Pulaski, *A Growing Controversy*, THE SUNDAY OREGONIAN, Sept. 12, 2004, at D1; Gregory M. Lamb, *Seeds of Concern: Genetically Altered Material Turning Up*, THE SEATTLE TIMES, Mar. 22, 2004, *available at* http://seattletimes.nwsource.com/html/nationworld/2001885053_genfood22.html; Susanne Quick & Kimm Groshong, *Modified Crops Could Erase Wild Counterparts*, MILWAUKEE JOURNAL SENTINEL, July 25, 2003, *available at* http://www.jsonline.com/alive/news/jul03/157588.asp.

94. COMMISSION FOR ENVIRONMENTAL COOPERATION OF NORTH AMERICA, MAIZE AND BIODIVERSITY: THE EFFECT OF TRANSGENIC MAIZE IN MEXICO 10-13 (2004), *available at* http://www.cec.org/files/PDF//Maize-and-Biodiversity_en.pdf.

95. Pulaski, *A Growing Controversy*, *supra* note 93, at D1; PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, ISSUES IN THE REGULATION OF GENETICALLY ENGINEERED PLANTS AND ANIMALS 39-40 (2004), *available at* http://pewagbiotech.org/research/regulation/Regulation.pdf.

96. BROOKES & BARFOOT, *supra* note 28, at 6; INTERNATIONAL SEED FEDERATION, *supra* note 14, at 1.

97. *See* IFOAM GMO POSITION, *supra* note 45, at 4; MELLON & RISSLER, *supra* note 8, at 10.

bean for the 2001 and 2002 seed supplies.[98] Foundation seed programs in Virginia, Missouri, and Michigan have also acknowledged the adventitious presence of GMOs in foundation soybean seeds.[99] In a pilot study to assess the extent of adventitious presence of genetically modified DNA in conventional seed supplies, the Union of Concerned Scientists found conventional varieties of corn, soybeans, and canola "pervasively contaminated with low levels of genetic sequences originating in transgenic varieties."[100] Although the pilot study was too limited to support quantitative estimates of overall levels of GM presence in conventional crop varieties, expected contamination levels were estimated to be between 0.05 percent and 1.0 percent of conventionally labeled seed.[101]

The scarcity of non-GM seeds already poses a major challenge to organic producers and is likely to only increase as GM use continues to expand.[102] Based upon a two-year field test of wind transport of GM corn pollen, Professors John Jemison and Michael Vayda con-

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98. Mikkel Pates, *Agriculture: Seed Raises Control Issues*, AGWEEK, Nov. 12, 2002, *available at* http://www.grandforks.com/mld/grandforksherald/4498432.htm.

99. MELLON & RISSLER, *supra* note 8, at 10 (citing THE NON-GMO SOURCE, Vol. 3, No. 6, pp. 1-2 June 2003).

100. *Id.* at 12. *See also* Lyle F. Friesen et al., *Evidence of Contamination of Pedigreed Canola (Brassica Napus) Seedlots in Western Canada with Genetically Engineered Herbicide Resistance Traits*, 95 AGRONOMY J. 1342, 1345 (2003) (reporting finding of a high level of genetically modified DNA in foundation, registered and certified canola seed with thirty-two of thirty-three seedlots recording the presence of genetically modified DNA and fourteen of those seedlots with contamination levels above purity guidelines for certified seed).

101. MELLON & RISSLER, *supra* note 8, at 26-27. Six varieties of each species (corn, soybean and canola) were tested at two independent laboratories. Laboratory 1 (GeneScan USA, Inc.) found genetically modified DNA in fifty percent of the corn and soybean samples and 100 percent of the canola samples. Laboratory 2 (Biogenetic Services, Inc.) found genetically modified DNA in eighty-three percent of the corn, soybean and canola samples. *Id.*

102. *See id.* at 11 ("Organic growers . . . are finding it increasingly difficult to obtain non-engineered seed"); In 2000, the USDA acknowledged the problem of ensuring genetic identity of seeds used for organic production, but declined to take affirmative steps to address the problem. *See* National Organic Program, 65 Fed. Reg. 80,548, 80,556 (Dec. 21, 2000) (to be codified at 7 C.F.R. pt. 205). As a general rule, organic producers "must use organically grown seeds, annual seedlings, and planting stock." 7 C.F.R. § 205.204(a) (2004). In recognition of the problem of acquiring organically produced seeds, producers are exempted from the requirement if an organically produced variety is not commercially available. *Id.* at § 205.204(a)(1)-(2). The difficulty in obtaining organic seed is a major concern to organic trade groups, and IFOAM recently sponsored an international conference on this issue. *See generally*, IFOAM, FIRST WORLD CONFERENCE ON ORGANIC SEED: CHALLENGES AND OPPORTUNITIES FOR THE ORGANIC AGRICULTURE AND THE SEED INDUSTRY (2004) (on file with the author).

cluded that it is increasingly important for organic producers to carefully consider what seed to purchase and perhaps to independently test seed stocks before planting.[103] Other recommended alternatives include growing open-pollinated corn varieties or purchasing certified seed. IFOAM, the leading international non-governmental organization for organic producers, echoes these concerns[104] and recommends that organic producers make "special efforts . . . to ensure that the seeds they use are not contaminated."[105] The organization further directed organic certification bodies to ensure that producers implement precautionary measures regarding seed contamination and requested that organic trade associations assist producers in their efforts to obtain uncontaminated seed.[106] Not surprisingly, in a recent survey of organic farmers, forty-eight percent of the respondents indicated that they believe contaminated seed stocks presents the greatest risk of GMO contamination to their farms, followed by pollen drift at forty-two percent.[107]

As discussed below, however, neither the federal nor state governments have openly considered the consequences of low levels of genetically modified DNA in the context of their seed purity laws. Moreover, the International Seed Federation, in response to the problems of adventitious presence in seed supplies, drafted for its members a "Model for Conditions of Sale Applicable to Seed Lots" foreswearing liability arising from the adventitious presence of GM material.[108] As a result of inadequate labeling laws and non-negotia-

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103. John M. Jemison, Jr. & Michael E. Vayda, *Cross Pollination From Genetically Engineered Corn: Wind Transport and Seed Source*, 4(2) AgBioForum 87, 91 (2001), *available at* http://www.agbioforum.org/v4n2/v4n2a02-jemison.pdf; *see also* Coexistence Working Group, *supra* note 32, at 6 (noting one of the recommended best management practices from the Coexistence Working Group is to conduct a pre-planting test of suspect seed) (on file with author).

104. IFOAM GMO Position, *supra* note 45, at 4 (noting that minimization of the adventitious presence of genetically modified DNA "is especially important for seed, because if the seeds used by organic producers are contaminated it has an impact on future production").

105. *Id.*

106. *Id.*

107. Erica Walz, Final Results of the Fourth National Organic Farmers' Survey: Sustaining Organic Farms in a Changing Organic Marketplace, *available at* http://www.ofrf.org/ publications/survey/Final.Results.Fourth.NOF.Survey.FastView.pdf.

108. *See* International Seed Federation, *Model Conditions of Sale Disclaimer*, *available at* http://www.worldseed.org/Position_papers/cond_sale.htm. The recommended disclaimer states:

> Seeds supplied to you are from a variety bred from parent components that have not been genetically modified. The methods used in the development

ble contract provisions in seed sales that foreclose compensation, farmers attempting to produce conventional or organic products face substantial economic risk before the first seed is planted.

B. Federal and State Seed Laws Have Failed to Protect the Conventional and Domestic Seed Market from Contamination from Genetically Modified DNA

Although genetically modified DNA may be present at low levels throughout the conventional seed supply, the contamination can be reduced substantially, even if complete reversal is not possible.[109] Initial steps should include a full-scale investigation by the USDA to determine the extent, cause, and impact of the contamination with a view toward recommending the most efficient methods of reestablishing genetic purity.[110] Moreover, some commentators recommend creation of a reservoir of non-GM seeds at the lowest achievable amount of contamination to enable the agricultural community to shift from GM production methods, if required, as the long-term impacts of the technology are realized.[111] In the interim, private seed companies should test their seed stocks for the presence of undesired genetically modified DNA and publicize the results to enable farmers to make informed choices.[112]

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and maintenance of that variety are aimed at avoiding the presence of off-types, including genetically modified material, as defined by the applicable laws or regulations.

Seed production has been carried out in accordance with production rules including stipulated isolation distances. However, in open fields there is free circulation of pollen. As it cannot be excluded that in seed multiplication areas the growing of approved GM plants takes place, it is not possible to totally prevent the adventitious presence of GM material and to guarantee that the seed lots comprising this delivery are free from any traces derived from GM plants.

(Company name) has undertaken due diligence to avoid adventitious presence of GM material in this seed lot. However, (company name) gives no guarantee that the seed is GM free and can accept no liability arising from the adventitious presence of GM material. *Id.*

109. MELLON & RISSLER, *supra* note 8, at 3.
110. *Id.* at 52.
111. *Id.* at 54.
112. *Id.* at 56.

1. The Federal Seed Act

Enacted to ensure "truth-in-labeling,"[113] federal and state seed laws currently do not require disclosure of low levels of adventitious presence of GM seeds. Under federal law, product labels must accompany all seeds transported or delivered for transportation in interstate commerce.[114] Labels must include, *inter alia*, the name of the kind[115] or variety[116] of seed present in excess of five percent of the whole,[117] the percentage of each kind or variety,[118] and for each variety included on the label, the percentage of germination, the percentage of hard seed, and the date the test was completed to determine the respective percentages.[119] Accordingly, labels need not include information regarding adventitious presence of GM seeds so long as they are present below the five percent threshold.[120]

Although the Federal Seed Act does not explicitly address GM seeds, in practice it is implied that seed is not of a GM variety unless

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113. *See* Enforcement of the Varietal Labeling Provisions of the Federal Seed Act, 67 Fed. Reg. 59,769 (Sept. 24, 2002) (to be codified at 7 C.F.R. pt. 201). A secondary purpose of most seed laws is to prevent the entry of noxious weeds into the respective geographical region. Accordingly, the Federal Seed Act, 7 U.S.C. §§ 1551-1611 (2005), prohibits the presence of certain weeds. *See* 7 U.S.C. § 1561(9)(A)-(B). In addition, each state seed act or implementing regulation generally includes provisions banning additional weeds. *See, e.g.*, 8 ILL. ADMIN. CODE §§ 230.20, 230.30 (1987) (listing prohibited and restricted weed seeds in Illinois). The USDA maintains a list of all noxious weed seed by state. *See* UNITED STATES DEP'T OF AGRIC., STATE NOXIOUS-WEED SEED REQUIREMENTS RECOGNIZED IN THE ADMINISTRATION OF THE FEDERAL SEED ACT, *available at* http://www.ams.usda.gov/lsg/seed/2004noxiousweed.pdf.

114. 7 U.S.C. § 1571(a).

115. The Federal Seed Act defines the term "kind" as "one or more related species or subspecies which singly or collectively is known by one common name, for example, soybean, flax, carrot, radish, cabbage, cauliflower, and so forth." 7 U.S.C. § 1561(11).

116. The term "variety" is a "subdivision of a kind which is characterized by growth, plant, fruit, seed, or other characteristics by which it can be differentiated from other sorts of the same kind, for example, Marquis wheat, Flat Dutch cabbage, Manchu soybeans, Oxheart carrot, and so forth." 7 U.S.C. § 1561(12).

117. 7 U.S.C. § 1571(a)(1).

118. 7 U.S.C. § 1571(b)(3)(A).

119. 7 U.S.C. § 1571(b)(3)(C).

120. Seed companies, however, have the option of including on the label the percentage by weight of other agricultural seeds that comprise less than five percent of the whole. 7 U.S.C. § 1571(a)(8). If the seed company chooses to indicate the presence of such seeds, the label must also include the percentage of germination and hard seed, as well as the date of the test to determine the respective percentages. 7 U.S.C. § 1571(a)(8).

labeled accordingly.[121] GM seed is considered the "variety" of its broader "kind" of seed. On the label, the kind and variety designation will be the conventional kind and variety name (e.g., field corn 4513), with Bt or similar designation added to the end of the variety name to indicate that it is genetically modified (e.g., field corn 4513Bt).[122] Failure to include the Bt (or other appropriate designation) implies that the seed is conventional and probably would constitute a "mislabeling" violation.[123] With respect to adventitious presence in seeds marketed as conventional, GM seeds would fall into the "other crop" or "other variety" category. Therefore, if the GM variety is present in less than five percent of the whole, designation on the label is not required.[124] On the other hand, if GM seed constitutes more than five percent of the whole, it must be designated on the label.[125]

Enforcement of the Federal Seed Act's requirements is through cooperative agreements with state governments.[126] States are responsible for collecting and testing seed samples for compliance with the Federal Seed Act, as well as applicable state laws.[127] Subject to broad federal guidelines, state seed agencies have the discretion to test however they see fit.[128] For example, states may choose to test a certain amount of each type of seed, or they may choose to test particular companies that have mislabeled seed in the past. Violations are reported to the Federal Seed Regulatory & Testing Branch of the USDA.[129] Depending upon the circumstances of each violation, the USDA may issue a cease and desist order, impose a monetary fine, commence a civil suit, or file criminal charges.[130] However, no private right of action exists under the Act.[131]

Enforcement is tempered further by a statutory-based "safe-harbor" provision. No violation of the Federal Seed Act's labeling requirements occurs if kinds or varieties of seeds present above the five

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121. Telephone interview by Brenda Menard with Richard Payne, Chief, USDA Seed Regulatory and Testing Branch, Livestock and Seed Program, Beltsville, Md. (June 8, 2004) [hereinafter Payne interview].

122. *Id.*

123. *Id.*

124. 7 U.S.C. § 1571(a)(1).

125. 7 U.S.C. § 1571(a)(1).

126. *See* 67 Fed. Reg. at 59,769.

127. *See generally* 67 Fed. Reg. at 59, 769.

128. *See* 7 C.F.R. § 201.37 (2005).

129. *See* 67 Fed. Reg. at 59,769.

130. *See* 67 Fed. Reg. at 59,769-770 (Sept. 24, 2002) (outlining range of USDA enforcement options and policy of use).

131. *See* Ren-Dan Farms, Inc. v. Monsanto Co., 952 F. Supp. 370, 374 (W.D. La. 1997).

percent threshold[132] are not identified and, therefore, not included on the label "because of their indistinguishability in appearance from the seeds intended to be transported or delivered for transportation in interstate commerce."[133] In order to qualify for the safe-harbor, the entity charged with labeling the seeds must prove that it has taken "reasonable precautions to insure the identity of the seeds to be that stated" on the label.[134]

At this time, the scope of the "indistinguishable in appearance" exception is unclear as it relates to the adventitious presence of GM seed. Detecting the presence of genetically modified DNA from current commercially marketed varieties requires sophisticated laboratory analysis, such as polymerase chain reaction (PCR) testing.[135] PCR testing, however, requires "primers" that locate and replicate the targeted DNA within the sample. In other words, PCR testing will find and measure known contaminants but will not identify genetically modified DNA for which a primer is not available.[136] Accordingly, GM material that has not received regulatory approval "is unlikely to be detected because the DNA sequence data is probably not available" for comparison with the sample.[137] If DNA sequence data is unavaila-

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132. 7 U.S.C. § 1571(a)(1) (2005).

133. 7 U.S.C. § 1573(d).

134. 7 U.S.C. § 1573(d).

135. MELLON & RISSLER, *supra* note 8, at 18-19. Another common testing method is the Immunoassay (ELISA) "dipstick" test. *See* Steven Sonka et al., *Transportation, Handling, and Logistical Implications of Bioengineered Grains and Oilseeds: A Prospective Analysis* 22, 23 (USDA, Nov. 2000), *available at* http://www.ams.usda.gov/tmd/lats/latsbiotech.pdf. The ELISA "dipstick" methods works similarly to a home pregnancy testing kit. "[a] sample of grain is ground and added to a tube filled with liquid. The dipstick is then inserted in the tube and, within 5 minutes, a positive or negative result is indicated by a change of color." *Id.* at 23.

136. MELLON & RISSLER, *supra* note 8, at 18-21 (describing process of PCR testing). For example, a test that is designed to detect the presence of genetically modified DNA from Liberty Link corn (Liberty brand herbicide tolerant) would not detect the presence of Roundup Ready corn (glyphosate tolerant corn). A separate test is required to detect each genetic modification. *See* Sonka et al., *supra* note 135, at 23.

137. Opinion of Scientific Committee on Plants, *supra* note 10, at 16. Because detection of undesired genetically modified DNA in a sample requires the investigator to have an analytical method in place that is capable of "routine use, with appropriate sampling procedures and confidence limits," the Committee recommends the establishment of "an international database of DNA sequences and analytical procedures to be able to detect unauthorized GM material." *Id.* This position is echoed by the International Seed Federation. *See* International Seed Federation, *Access to Relevant Technology to Test the Adventitious Presence of GM Material in Non-GM Seed* (2002), *available at* http://www.worldseed.org/Position_papers/Acc_rel_tech.htm (stating "it is essential that seed companies have at their disposal for internal use the necessary technology to test the seed they are producing").

ble for a particular transgene, a variety containing that DNA probably falls within the Act's safe-harbor provision. The outward appearances of most genetically modified seeds are indistinguishable from their conventional counterparts. The question, therefore, is whether the agency would require PCR or other sophisticated DNA testing of seeds to distinguish their "internal appearance" and eliminate the safe-harbor for companies marketing seeds with an adventitious presence of genetically modified DNA above the five percent threshold.

2. State Seed Laws

Most state seed laws closely track the federal version and, unfortunately, do not offer conventional and organic farmers any additional protection from the adventitious presence of genetically modified DNA in seeds. For example, the only significant difference between the Federal Seed Act and the Illinois Seed Law[138] is the listing of additional noxious weed seeds.[139] As the enforcing agency for both the federal and state seed acts in Illinois, the Illinois Department of Agriculture (IDOA) promulgates specific rules governing the labeling, sampling, inspecting, analyzing, testing, and examining of seeds, and establishes state requirements for, *inter alia*, seed purity and germination.[140]

In addition, IDOA tests official samples of seeds offered for sale in Illinois, including GM seeds, to ensure the seeds possess the advertised traits.[141] IDOA occasionally tests official samples of conventionally labeled seed for the unintended presence of GM traits as well. In such tests, GM traits usually account for less than one percent of the total weight.[142] IDOA will also test nonofficial seed samples for the presence of GM traits on a fee basis.[143] Anecdotal evidence suggests that seed companies generally do not request testing for the presence

138. 505 ILL. COMP. STAT. 110/1 *et seq.* (Thomson/West 2004).

139. *Compare* 7 C.F.R. § 201.16 (2005) *with* 8 ILL. ADMIN. CODE §§ 230.20 and 230.30 (2005).

140. *See* 505 ILL. COMP. STAT. 110/3 (2004).

141. If mislabeling with respect to a GM trait is discovered in testing (*i.e.*, greater than the five percent threshold), IDOA will generally send a letter to the offending company. Historically, there has been very little problem in Illinois because few companies label incorrectly. Telephone interview by Brenda Menard with Mike Simpson, State Seed Analyst, IDOA, Certified Seed Analyst/Association of Official Seed Analysts (June 29, 2004 and July 16, 2004).

142. Telephone interview by Brenda Menard with Mike Simpson, State Seed Analyst, IDOA, Certified Seed Analyst/Association of Official Seed Analysts (July 23, 2004) [hereinafter Interview with Mike Simpson].

143. *See* 8 ILL. ADMIN. CODE § 230.80 (2005).

of GM seeds in conventional seeds.[144] Farmers, however, have requested such tests with results varying from 0.5 percent up to 5 percent of the total weight.[145]

A few states have modified their respective seed laws to account for the advent of GMOs. Vermont House Bill 777, effective October 1, 2004, amended Vermont's seed laws to require "identification of seeds that have been genetically engineered."[146] Labels accompanying seeds containing GM material must specify the identity and relevant traits of the seed, requirements for safe handling, transport and use, and the contact point for further information.[147] It is unclear as of this writing whether the state will set a tolerance level for the adventitious presence of GM seed. In its current form, a literal reading of the statute appears to impose a zero tolerance (or at least the detectable limit of 0.1 percent) for labeling. If the standard holds, the Vermont law will be the first of its kind in the United States to require labeling for adventitious presence below the 5 percent threshold.[148]

State seed purity enforcement agencies in two other states, Kentucky and Mississippi, have taken first steps in dealing with GM seed. In Kentucky, the Division of Regulatory Services is testing old samples of conventional seed to determine the level of adventitious presence of GM seed as time and money permits.[149] Initial reports indicate "not a significant amount" of adventitious GM presence in the old samples.[150] In 2000, Mississippi amended its Pure Seed Law to include "transgenic seeds" in its definition of "agricultural seeds."[151] Transgenic seeds are also mentioned specifically in the seed law as something that the Commissioner of Agriculture and Commerce

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144. Perhaps this is because many large seed companies conduct testing in-house and other companies may not want to alert regulatory authorities to potential problems.

145. *See* Telephone Interview with Mike Simpson, *supra* note 142.

146. VT. STAT. ANN. tit. 6, § 611(c) (supp. 2004).

147. VT. STAT. ANN. tit. 6, § 644(a)(4) (supp. 2004).

148. Maine also modified its seed labeling laws to require seed dealers selling GM seed to include instructions on how to reduce the chances of contaminating non-GM crops. *See* ME. REV. STAT. ANN. tit. 7, § 1052 (1964). The statute, however, does not mandate that the farmer follow the instructions or require implementation of methods to reduce the chance of adventitious presence. Moreover, there is no labeling requirement for adventitious presence below the five percent threshold.

149. Telephone interview by Brenda Menard with David Buckingham, Coordinator, Seed Regulatory Program, Kentucky Division of Regulatory Services (July 12, 2004).

150. *Id.* Interestingly, Kentucky informally considers Roundup Ready soybeans a "trait" of a variety and not an independent variety that would trigger labeling requirements. *Id.*

151. MISS. CODE ANN. § 69-3-1 (1972).

should sample, test, and analyze.[152] Within the Mississippi Department of Agriculture and Commerce, the Bureau of Plant Industry is responsible for seed purity and conducts tests for the presence of Roundup Ready seeds (soybean and cotton) on request and, occasionally, on official samples.[153] As of mid-September 2004, there were no violations of the seed purity laws in Mississippi as a result of adventitious presence of GM seed.[154] Violations, however, are only instances in which adventitious presence exceeds five percent—well above the thresholds required for export to the E.U.

In sum, a few states have taken small steps regarding adventitious presence and seed labeling. Other states have proposed legislation designed to reduce admixture but not necessarily seed labeling.[155] It remains to be seen whether the Vermont approach will have a significant effect on seed labeling practices in other states.

IV. Recommended Changes to Domestic Seed Laws to Ensure Coexistence

Absent a consensus on labeling and tolerance levels (0.9 percent in the European Union versus 5 percent in the United States), the domestic agricultural community will face continued uncertainty and will have to navigate a patchwork of questionably effective regulations. Producers wishing to market products to traditional trading partners such as the European Union will have to comply with the higher end-product standards while using inputs (i.e., seeds) with less stringent tolerance levels.[156] For the most part, federal decision makers have

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152. Miss. Code Ann. § 69-3-19 (1972).

153. Telephone interview by Brenda Menard with Lee Daughtry, Director of Seed Division, Mississippi Department of Agriculture and Commerce (Sept. 10, 2004).

154. *Id.*

155. *See, e.g.*, Me. Rev. Stat. Ann. tit. 7, § 1052 (discussing Maine's labeling requirements); S. & Assem. B. 2761, 226th Ann. Leg. Sess. (N.Y. 2003) (requiring seed dealer to provide written instructions to farmer on how to prevent cross-pollination of GM seed and imposing strict liability on the farmer for failing to follow the instructions); S. & Assem. 10094, 227th Ann. Leg. Sess. (N.Y. 2003) (requiring anyone who "uses, grows or produces GMO seed . . . [to] inform any landowner located within two miles . . . or such distance as the pollen of such GMO seed species is determined by the commissioner to travel, whichever is greater"); H.R.B. 150, 82d Leg. Sess. (Minn. 2001) (requiring seller of GM seed to provide purchaser with written instructions to prevent cross-pollination with conventional seeds and requiring seed manufacturer to mail a notification to neighboring farmers of the purchaser's intent to grow GM seed); H.B. 1415, 92d Gen. Assem., 2d Reg. Sess. (Mo. 2004) (requiring manufacturer or seed dealer to provide instructions on how to avoid "cross contamination").

156. *See* Peter W.B. Phillips, *Traceability and Trade of Genetically Modified Foods*, in Nat'l Agricultural Biotechnology Council, Biotechnology: Science & Society

done little to address this problem; instead these agencies have been focusing their efforts on opposing, without success, trading partners' labeling rules.[157] A federal bill introduced in 2003 garnered little attention but represented an important first step in addressing adventitious presence of genetically modified DNA.[158] The bill would require sellers of seeds to provide instructions on measures to avoid "cross-contamination" for crops considered "outcrossed pollinators."[159] More importantly, the law would prevent the labeling of seed as non-GM if samples of seed contained genetically modified DNA.[160] Although Vermont's new seed purity law incorporated this concept, it remains to be seen whether other state legislatures will follow Vermont's proactive approach and enact similar seed labeling laws. In the interim, the National Corn Growers Association requested that "seed companies make available the percent of transgenic purity of seed labeled, promoted, and sold as non-genetically modified."[161]

In conjunction with voluntary labeling by seed sellers, a more complete study of the extent of adventitious presence should be undertaken to assess the nature and scope of the problem. Assuming a full study confirms the preliminary results of the Union of Concerned Scientists' investigation[162] and the domestic seed supply is contaminated with low levels of genetically modified DNA, federal and state lawmakers and seed regulatory agencies should take affirmative steps to restore the integrity of the seed production system and revise existing labeling laws to provide conventional and organic farmers accurate information.

Although adventitious presence thresholds below one percent may be difficult to achieve without an increase in costs to the seed breeders[163] (and, therefore, the end user), it is essential to have clear labeling standards to allow farmers to purchase seed with the potential to yield a harvested crop that will meet the import standards of

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AT A CROSSROAD 141, 146 (2003), *available at* http://nabc.cals.cornell.edu/pubs/nabc_15/chapters/Phillips.pdf.

157. *See generally*, Redick & Adrian, *supra* note 22 (discussing whether European traceability and labeling restrictions are unlawful trade barriers and the United States' WTO challenge to the European Union's rules).

158. *See* H.R. 2918, 108th Congress (2003).

159. *See* H.R. 2918.

160. *See* H.R. 2918.

161. National Corn Growers Association, *supra* note 47, at 2; *see also* MELLON & RISSLER, *supra* note 8, at 56.

162. *See supra* notes 100-101 and accompanying text.

163. *See* International Seed Federation, *Motion on Adventitious Presence of GM Material in non-GM Seeds* (2001).

major trading partners and the purity demanded by consumers of identity-preserved and organic products. Seed purity standards should be set according to sound science and at a level that considers the degree of potential post-planting admixture. Proposed standards developed by the E.U.'s Scientific Committee on Plants of 0.3 percent for corn and 0.5 percent for soybeans provides a starting point for discussion and further evaluation.[164]

In order to meet the requirements of any new labeling rules, however, seed companies and testing agencies must have the necessary technology (e.g., primers for PCR analysis) to test for the adventitious presence of genetically modified DNA.[165] An international database of genetically modified DNA and testing procedures (including testing material for genetic engineering events that have not yet received final regulatory approval)[166] should be compiled, and maintained in a manner that preserves the intellectual property and trade secrets of the seed developers.[167]

Another helpful revision at the federal level would be elimination of the safe-harbor provision with respect to GM varieties. Elimination of the safe-harbor, however, would not *a priori* ensure coexistence but could provide at least a limited incentive for seed companies to test for the adventitious presence of genetically modified DNA in their seed inventory.

Finally, the agricultural production system has faced similar challenges in the past and crafted workable solutions. Coexistence is possible to obtain and will require similar creativity on the part of the world's farmers and policymakers. A new look at seed laws is a logical, and necessary, first step.

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164. *See supra* notes 85-90 and accompanying text (discussing recommended seed purity thresholds).

165. *See supra* notes 137-139 and accompanying text (describing difficulties of conducting testing for DNA originating from genetic engineering).

166. *See* Opinion of Scientific Committee on Plants, *supra* note 10, at 16.

167. *See* International Seed Federation, *supra* note 137.