Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004
T +1 202 637 5600
F +1 202 637 5910
www.hoganlovells.com

MEMORANDUM

To: ASTA Legislative and Legal Concerns Committee

From: Gary Jay Kushner
Maile Gradison Hermida
Veronica Colas

Date: June 10, 2014

Re: **Legal Developments Update**

The rights and responsibilities of participants in the seed industry continue to be litigated and debated around the world, particularly with regard to seed derived through modern biotechnology ("biotech seed"). Throughout the past six months, we have seen federal and state courts consider the impacts of biotech seeds, states pass legislation to require labeling for products containing ingredients derived through modern biotechnology, regulatory agencies review the usage of biotech seed, and the international community review and debate biotech seed approval and regulation. Like previous *Legal Developments Updates*, this edition summarizes selected recent developments of which we have become aware that should be of interest to the industry.

LITIGATION AND RELATED DEVELOPMENTS

Supreme Court Addresses Fee Recovery for Patent Cases

On April 29, 2014, the U.S. Supreme Court issued a unanimous opinion that addresses when prevailing parties can recover attorney's fees in patent cases. 1/ The Court's ruling provides broad discretion to federal district courts to determine when fees are appropriate, restricting the ability of the U.S. Court of Appeals for the Federal Circuit to second-guess the trial court's determination.

At issue in the case was application of Section 285 of the Patent Act, which states: "The court in exceptional cases may award reasonable attorney fees to the prevailing party." Under existing precedent, a case may be deemed "exceptional" either (1) "when there has been some material inappropriate conduct," or (2) when it is both "brought in subjective bad faith" and is

1/ *Highmark Inc. v. Allcare Health Management System, Inc.*, 572 U.S. ___ (2014).

"objectively baseless." The legal question before the Supreme Court was whether an appellate court should accord deference to a district court's determination that litigation is "objectively baseless."

The case resulted from a lawsuit brought by a health insurance company, Highmark Inc., that sought a court determination that a patent owned by Allcare Health Management System, Inc. was invalid and, therefore, that Highmark was not infringing it. The District Court ruled in favor of Highmark and granted their motion for fees on the basis that Allcare engaged in a pattern of "vexatious" and "deceitful" conduct throughout the litigation. On appeal, the U.S. Court of Appeals for the Federal Circuit reversed the award of attorney fees, finding that none of Allcare's conduct warranted an award of fees. In reversing the District Court, the Federal Circuit reviewed the lower court's decision *de novo*—meaning that the appellate court considered the issue anew, without consideration of the legal conclusions reached by the lower court.

Relying in part on another opinion issued the same day, the Supreme Court ruled that the Federal Circuit erred in considering the award of attorney fees under the *de novo* standard of review and, instead, should have reviewed the lower court's decision for "abuse of discretion." The Court determined that a district court is in the best position to determine whether a lawsuit is objectively baseless and, as such, is entitled to deference upon appeal.

This case is important to ASTA members because obtaining attorney fees awards in patent cases can offer some financial recourse for parties dragged into non-meritorious litigation, which often can occur in suits initiated by "patent trolls." Further, there have been complaints that the Federal Circuit has been too quick to overturn district court fee awards, rather than providing substantial deference to the trial court's judgment. This holding directs the Federal Circuit to give the trial courts more deference.

Suit Seeks to Block Kauai Ordinance

In January, DuPont Pioneer, BASF, Syngenta, and Agrigenetics Inc. filed suit in federal court challenging Kauai County's recently enacted ordinance restricting the planting of biotech crops and the use of pesticides. 2/ The law, Ordinance 960 (formerly known as Bill 2491), was enacted in November 2013 by the Kauai County Council through an override of the mayor's veto. The ordinance imposes 500 foot pesticide buffer zones near medical facilities, schools, homes, roads, and public waterways. It also requires major seed and biotech companies with operations in Kauai to disclose which restricted-use pesticides they are applying to their crops, post warning signs, and issue pre-application notices. The companies also must disclose the type and location of any biotech crops grown on Kauai.

The suit challenges the law on jurisdictional and constitutional grounds and seeks an injunction to bar its enforcement when it takes effect in August 2014. In particular, the lawsuit alleges the County has no jurisdiction to regulate pesticide usage and biotech organisms, which are regulated by state and federal laws. The suit also claims the law violates the plaintiffs' rights to equal protection and due process, and constitutes an unconstitutional taking.

In April, the court allowed four non-profit groups to join Kauai County to defend the law. These groups are the Center for Food Safety, the Pesticide Action Network North America, the

2/ *Syngenta Seeds v. County of Kauai*, Case No. 1:14-cv-00014 (D. Haw.).

Surfrider Foundation, and Ka Makani Hoopono. Several motions currently are pending before the court, including cross-motions for summary judgment. A hearing on the motions is scheduled for July.

Judge Blocks Biotech Registration Law

In March, a Hawaii circuit court judge granted an anonymous farmer's request for a temporary restraining order that blocks Hawaii County from requiring farmers growing biotech crops to register with the county. 3/ Under the law, which took effect two days before the court order, "all persons engaged in any form of cultivation, propagation, development, or indoor testing of genetically engineered crops or plants of any kind shall register annually beginning on or before March 5, and shall pay an annual registration fee of $100 per location, payable to the director of finance." Penalties for violating the law include a fine of up to $1,000 for each day the violation is committed or continued. The plaintiff argued that there was an urgent need to put enforcement of the law on hold because of the "imminent threat" of vandalism and other harm if the confidential, private, and proprietary information is disclosed to the public.

USDA Sued Over Biotech Alfalfa

In March, the Center for Food Safety (CFS) filed a lawsuit against the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (USDA) that seeks, under the Freedom of Information Act (FOIA), to compel disclosure of documents about APHIS's approval of "Roundup Ready" (RR) alfalfa. 4/ CFS alleges that APHIS violated FOIA by: (1) failing to disclose the requested documents, instead unlawfully withholding the requested information; and (2) failing to adequately respond to CFS's appeal within the statutorily prescribed time limit.

This is the latest in a long series of cases involving biotech alfalfa, which include a decision by the U.S. Supreme Court in 2010. Shortly after APHIS issued its January 2011 decision to grant unrestricted approval to RR alfalfa, CFS filed a FOIA request seeking all documents related to the decision and all documents relating to the final Environmental Impact Statement. When APHIS responded in April 2012, CFS was dissatisfied with the agency's explanation for why certain documents were withheld. CFS appealed the denial, but argued that APHIS has yet to issue a final response or an estimated timeline for completing review of the appeal.

CFS asks the court to declare APHIS's withholding of certain documents as unlawful, order APHIS to produce all records requested by CFS and challenged in its FOIA appeal, closely supervise APHIS as it processes the appeal, and award all costs and reasonable attorney fees. The case is currently pending.

3/ *Doe v. County of Hawai'i*, Case No. 14-1-0094 (Circuit Court for the Third Circuit, State of Hawai'i).

4/ *Center for Food Safety v. Animal and Plant Health Inspection* Service, Case No. 1:14-cv-398 (D.D.C.).

Biotech Wheat Litigation Undergoing Mediation

Several consolidated lawsuits against Monsanto involving the unapproved release of biotech wheat are currently stayed to allow the parties to engage in mediation to resolve the case. The lawsuits were filed in 2013 after unapproved biotech wheat was found in Oregon. The lawsuits previously were consolidated before U.S. District Judge Kathryn Vratil in the District of Kansas. 5/ Judge Vratil's order granting the stay noted that even if the mediation is not entirely successful, it should assist the parties in identifying and narrowing the issues in dispute.

Farmer Sued for Saving Seed

In February, Monsanto filed a lawsuit in federal court against a farmer alleged to have knowingly and intentionally used and planted seed derived from Monsanto's patented cotton seed without authorization. The complaint alleges that the defendants, Christopher Ponder and Chris Ponder Farms, LLC, sought out from a local gin specific varieties of seed known to be infringing. Further, defendants are alleged to have sold and transferred saved and delinted seed to other farmers. Monsanto seeks an injunction, interest, costs, and treble damages. The case is pending in the U.S. District Court for the Middle District of Georgia. 6/

LEGISLATIVE DEVELOPMENTS – FEDERAL

Biotech Labeling Bill Introduced in Congress

In April, legislation was introduced in the U.S. House of Representatives that would establish uniform, national standards for labeling foods containing, or claiming not to contain, biotech ingredients. The law would be preemptive, meaning that it would trump any inconsistent state biotech labeling laws (including the biotech labeling law recently passed by the Vermont legislature, discussed below). Therefore, it would eliminate the potential of a 50-state patchwork of biotech labeling requirements. The bill would:

- Establish federal labeling standards for foods with biotech ingredients, giving sole authority to the Food and Drug Administration (FDA) to require labeling on such foods if they are ever found to be unsafe or materially different from foods produced without biotech ingredients (with such labeling addressing the safety issue or material difference, not stating the food contains biotech ingredients);
- Revamp the agency's framework for reviewing biotech traits before they are marketed, setting up a new "premarket biotechnology notification program" (intended to provide consumer confidence that biotech foods are safe). Under the proposed program, technology developers must notify FDA 210 days before introducing a new biotech trait into the marketplace;

5/ *In Re: Monsanto Company Genetically-Engineered Wheat Litigation*, Case No. 2:13-md-02473 (D. Kan.).

6/ *Monsanto v. Ponder*, Case No. 7:14-cv-00013 (M.D. Ga.).

- Allow food products to be labeled that they do not contain biotech ingredients, even if such ingredients are present inadvertently, provided certain supply chain traceability-related criteria are met; and
- Require the FDA to create a definition of the term "natural," which also would have a preemptive effect.

The legislation, the Safe and Accurate Food Labeling Act (H.R. 4432), was introduced by Rep. Mike Pompeo (R-Kan.) and the lead Democratic co-sponsor is Rep. G.K. Butterfield (D-N.C.). The bill currently has a total of four co-sponsors, two Democrats and two Republicans. Although it could take some time before Congress fully considers such legislation, this bill could lay the groundwork for federal legislative action in this area.

Bill Introduced to Provide Federal Civil Cause of Action for Trade Secret Theft

In April, a bill was introduced in the U.S. Senate that would provide a federal civil private right of action for trade secret misappropriation. Currently, a federal criminal remedy exists for trade secret theft, but the U.S. Department of Justice (DOJ) does not have the resources to prosecute all such cases. State civil trade secret laws exist but are not well suited to remedying interstate theft. The bill seeks to address these issues by providing a federal cause of action that allows for equitable and legal remedies, including *ex parte* injunctions, damages to compensate for loss and unjust enrichment, and exemplary damages for willful or malicious misappropriation. The bill, the Defend Trade Secrets Act (S. 2267), was introduced by Sen. Christopher A. Coons (D-Del.).

Congress Considers Patent Litigation Reform

This term, Congress has considered two pieces of legislation that would reform the patent litigation system. In December 2013, the House passed the Innovation Act (H.R. 3309) by a vote of 325 to 91. At a high level, the bill would enhance the pleading requirements for patent infringement cases and require very detailed information in complaints. The legislation also would impose enhanced disclosure requirements upon filing a patent infringement case, place restrictions on discovery, establish a cost and fee shifting provision, and provide protections for end users of the allegedly infringing product or service.

A companion bill, the Patent Transparency and Improvements Act (S. 1720), was introduced in the Senate in November 2013. This legislation would:

- Establish disclosure requirements for patentees who file a patent infringement suit;
- Require the Federal Trade Commission (FTC) to exercise enforcement authority with respect to so-called "bad-faith demand letters" (defined as widespread written communications with false or misleading information stating that the intended recipients or affiliated persons are infringing or have infringed a patent and bear liability or owe compensation); and
- Provide protections for end users.

The Senate bill was withdrawn from the Senate Judiciary Committee agenda in May by Sen. Patrick Leahy (D-Vt.) based upon a lack of support. In his press release, Senator Leahy noted, "We have heard repeated concerns that the House-passed bill went beyond the scope of addressing

patent trolls, and would have severe unintended consequences on legitimate patent holders." The withdrawal of the bill from the Committee agenda means it is less likely that Congress will pass patent reform legislation this year. ASTA is monitoring legislation in this area closely.

Invasive Species Legislation Introduced in Congress

Legislation was introduced in the House in February that would require the Secretary of the Interior and the Secretary of Agriculture to carry out activities on federal lands managed by each respective Department that would control and manage invasive species to inhibit or reduce their populations and effectuate restoration or reclamation efforts. The legislation is titled the Federal Lands Invasive Species Control, Prevention, and Management Act (H.R. 3994), and would require development and implementation of a strategic plan that aims to achieve an annual 5 percent net reduction of invasive species populations on the lands managed by each Secretary. The control and management activities would need to include on-the-ground efforts, such as authorized pesticides, biological control agents, and re-vegetation. In selecting the method(s) to control or manage an invasive species, the Secretaries would be required to use "the least costly options necessary" to perform effectively, based on sound scientific data and other commonly used cost-effective benchmarks. The bill was introduced by Rep. Rob Bishop (R-Ut.). After being referred to the House Agriculture and Natural Resources Committee in February, there has been no further action on the legislation.

LEGISLATIVE DEVELOPMENTS – STATE AND LOCAL

Vermont Enacts Biotech Labeling Bill

In early May, the state of Vermont enacted a bill, H. 112, which mandates special labeling of foods containing ingredients produced with biotechnology and prohibits the use of "natural" claims on such foods. The law, styled as a "Right to Know" law, marks the first state biotech labeling law that takes effect without any preconditions. The labeling requirements in the Vermont law become effective July 1, 2016.

After California's Proposition 37 was defeated during the 2012 elections, Maine and Connecticut each passed their own biotech labeling laws—but those laws will take effect only if enough nearby states also pass similar laws. The Vermont law will count toward the number of states needed to trigger the Connecticut and Maine laws, but passage of the Vermont law is insufficient on its own to trigger them.

The Vermont law requires that any food offered for sale by a retailer in the state of Vermont that was produced partially or entirely with biotechnology be labeled to declare the use of biotechnology. The law provides for different methods of labeling for processed foods and raw agricultural commodities:

- *Processed food.* The manufacturer must label the package with one of the following phrases:
    - "partially produced with genetic engineering";
    - "may be produced with genetic engineering"; or

- "produced with genetic engineering."
- *Raw agricultural commodities not separately packaged.* The retailer must post a sign on the shelf or bin stating "produced with genetic engineering."
- *Packaged raw agricultural commodities.* The manufacturer must include on the package's label the statement "produced with genetic engineering."

The law does not specify where on the package the statement must appear, but it does clarify that the biotech statement is not required to be included in the ingredient statement or as part of the common or usual name or "primary product descriptor" of the food. The legislation also prohibits describing a food produced entirely or in part from biotechnology as "natural," or by similar terms.

The law contains several exceptions from both the biotech labeling requirement and the "all natural" labeling prohibition. This includes an exception for small amounts, which covers foods containing materials produced with biotechnology that cumulatively do not account for more than 0.9% of the total weight of the product.

The Grocery Manufacturers Association (GMA) has announced its intent to file suit in federal court against the state of Vermont to overturn the law, on the basis that the government has no compelling interest in warning consumers about foods containing biotech ingredients.

Beyond the three states that have passed bills requiring labeling of foods produced with biotech ingredients—Vermont, Maine, and Connecticut—at least 25 additional states are considering mandatory or voluntary labeling measures this year. In particular, a bill introduced in the New York Assembly has been approved by two committees and likely will proceed to a vote in the Assembly by the end of the legislative session, which ends June 19.

Oregon's Jackson County Bans Planting of Biotech Crops

In May, voters in Oregon's Jackson County passed a ballot initiative to ban the planting of biotech crops within the county, which is a popular area for growing biotech sugarbeets. The measure, titled 15-119 *Ordinance to Ban Growing of Some "Genetically-Engineered" (defined) Plants*, was approved by a vote of 66 to 34 percent. The ordinance states that all existing biotech plants must be harvested, destroyed, or removed from Jackson County within 12 months of enactment. It also provides a private right of action for enforcement. 7/ Among the findings in the ordinance is the recognition that "genetic drift … can create significant economic harm" to farmers who choose to grow non-biotech crops.

Oregon's Josephine County also approved in May a ban on growing biotech crops by a vote of 58 to 42 percent, but that measure likely is illegal under recently enacted state legislation. As previously reported in the *Legal Developments Update*, Oregon passed legislation in 2013 that prevents local governments from imposing any laws or regulations that would regulate farm practices, including restrictions on the planting of biotech crops. The law provided an exemption for Jackson County, which had already scheduled the Spring 2014 vote to ban the growing of biotech crops, but did not include a similar exemption for Josephine County.

7/ The full text of the ordinance is available at http://www.co.jackson.or.us/Files/JACK%2015-1%20Full%20Ordinance.pdf.

REGULATORY DEVELOPMENTS

Update on FSMA Proposed Rules and Comments

The FDA currently is in the process of implementing the FDA Food Safety Modernization Act (FSMA), which is the most broad-reaching overhaul of the country's food safety laws since 1938. Although it primarily is directed at food manufacturers, some aspects of the law could affect the seed industry. In particular, FDA's proposed rule regarding preventive controls for animal food would regulate most FDA-registered seed facilities that divert broken or otherwise unusable seeds for animal consumption as "animal food" manufacturers. 8/ Such facilities would have to implement food animal food-oriented good manufacturing practices and food safety plans (analogous to Hazard Analysis and Critical Control Point (HACCP) plans). ASTA filed detailed comments in March that oppose this requirement and also held multiple meetings with FDA about the issue.

In April, FDA announced plans to make changes to the animal food preventive controls proposed rule, scaling back the scope of its requirements. Mike Taylor, FDA's Deputy Commissioner for Foods and Veterinary Medicine, posted a blog that addresses the impact of the animal food preventive controls proposed rule on companies, such as seed manufacturers, that send their edible byproducts to farmers or feed manufacturers for animal feed uses. 9/ Mr. Taylor acknowledged that sending byproducts to animal feed "contributes substantially to the efficiency and sustainability of our food system and is thus a good thing." He said that FDA has "no intention to discourage or disrupt" this practice and never intended to suggest this was the purpose of the proposed rule. He explained, however, that such materials need to be subject to some level of regulation, such as good manufacturing practices, to keep hazards from being introduced inadvertently.

FDA plans to issue a revised proposed rule on animal food preventive controls this summer that will include changes consistent with the announcement in this blog post. It is expected that FDA will propose that byproduct materials must be produced under certain tailored GMPs, but do not require food safety plans. FDA's reproposal will be open for public comment.

Appropriators Question USDA on Biotech Crop Application Backlog

In April, several members of the House Agriculture Appropriations subcommittee questioned Kevin Shea, Administrator of APHIS, regarding the backlog of new biotech crop applications awaiting agency review. Mr. Shea testified that the agency has streamlined its review process and reduced the backlog from 22 to 16 applications, but that the speed of the process is limited because the agency does not want its reviews to be vulnerable to legal challenge. The Administrator cited the example of the litigation over RR alfalfa, for which APHIS' environmental impact study was challenged as insufficient. The Administrator also stated the agency's intent to reduce the backlog of deregulation petitions under review from 16 to 12 or 13 by next year and to reduce the average time of review from an average of 3 years to about 13 to 16 months.

8/ 78 Fed. Reg. 64736 (Oct. 29, 2013).

9/ The blog posting is available at: http://blogs.fda.gov/fdavoice/index.php/2014/04/getting-it-right-on-spent-grains.

APHIS Actions on Biotech Plant Petitions

As reported in prior editions of this report, APHIS has been working to speed the deregulation process by publishing deregulation petitions in the *Federal Register* for comment as soon as the agency determines the applications are complete, rather than waiting until it has completed an environmental assessment. 10/ Under this process, in the last six months the agency:

- Made a determination to deregulate herbicide-resistant soybean (BASF Plant Sciences); 11/
- Made a preliminary determination of nonregulated status for insect-resistant soybean (Dow AgroSciences); 12/ and
- Made available for public comment petitions seeking determinations of nonregulated status for:
    - Herbicide-resistant cotton (Dow AgroSciences); 13/ and
    - Maize that has been genetically engineered for protection against corn rootworm and resistance to glyphosate (Monsanto). 14/

Selected AMS Enforcement Actions

Throughout the past six months, USDA's Agricultural Marketing Service (AMS) has announced that thirty-three companies agreed to pay fines to settle alleged violations of the Federal Seed Act. The companies paid fines ranging from $350 to $6,500 to settle cases involving interstate shipments of seed. The violations alleged in these matters included the following:

- False labeling of pure seed and other crop seed percentages;
- False labeling as to presence of noxious-weed seed;
- False labeling or failure to label as to variety name;
- False labeling as to germination and hard seed percentages;
- Failure to test for germination percentage within five months of interstate shipment; and
- Failure to keep or supply complete records of the seed.

NOSB Subcommittee Decides Not to Propose Seed Purity Standard

As reported in previous editions of this report, the National Organic Standards Board (NOSB) established an ad-hoc subcommittee in 2012 to consider whether a seed purity standard or protocol is necessary to avoid the inadvertent presence of transgenes from biotech crops. In February, the subcommittee issued its final discussion document summarizing comments the panel received on its initial discussion documents, and concluding that it will not propose a new standard on seed purity. The subcommittee determined there is not enough data to establish contamination limits for seeds, but noted that in the future it will become increasingly difficult to find non-contaminated seed upon

10/ 77 Fed. Reg. 13258 (Mar. 6, 2012).
11/ 79 Fed. Reg. 15095 (Mar. 18, 2014).
12/ 79 Fed. Reg. 11790 (Mar. 3, 2014)
13/ 79 Fed. Reg. 15096 (Mar. 18, 2014).
14/ 79 Fed. Reg. 13035 (Mar. 7, 2014).

which to base a testing program. Interestingly, the subcommittee said it believes "costs of contamination should be borne by the [biotech] seed patent holders." In contrast, the 2012 report of the USDA Advisory Committee on Biotechnology and 21st Century Agriculture (AC21) recommended that USDA implement a compensation mechanism under which organic producers purchase insurance to cover any economic losses due to contamination.

USDA Issues Report on Bee Deaths

In May, USDA and the "Bee Informed Partnership" issued a report of preliminary results on managed honey bee colony losses in the U.S. 15/ The report found that surveyed beekeepers suffered average hive losses of 23 percent over the winter of 2013-2014. The losses for this year were an improvement compared to the 30.5 percent loss in 2012-2013 but worse than the 21.9 percent in 2011-2012. The responses represented 21.7 percent of the country's 2.6 million colonies. The report follows regulatory actions in the European Union (EU) and Oregon in 2013, banning and temporarily restricting, respectively, the use of neonicotinoid-containing pesticides.

GMA Files Citizen Petition with FDA on "Natural" Labeling for Biotech Foods

GMA has requested that FDA issue a regulation authorizing statements such as "natural" on foods that are or contain foods derived from biotechnology. Specifically, GMA filed a citizen petition with FDA asking the agency to amend the "common or usual name for nonstandardized foods" regulations and the general regulations for standardized foods to allow "natural" and similar terms to accompany the name of a food or appear elsewhere on the label or in labeling. GMA also requests that these regulations state that a food shall not be deemed to be misbranded solely because it is or contains a food derived from biotechnology. The citizen petition contends that this amendment will bring much needed uniformity and consistency to the contentious issue of "natural" labeling by expressly preempting non-identical state and local requirements.

SELECTED INTERNATIONAL DEVELOPMENTS

France Approves Ban on Biotech Corn

In early May, the French Parliament approved a standing ban on Monsanto's MON810 biotech corn variety. The law bans the cultivation of all biotech maize, even though the EU has cleared the Monsanto trait, citing risk to the environment and the precautionary principle. The ban also would apply to strains adopted at the EU level in the future. The formalized ban follows a decree issued by the French Ministry of Agriculture in March to stop the planting of MON810 while the government sought a longer-term ban. In May, France's Conseil d'Etat, the country's highest administrative court, rejected a procedure initiated by French growers to annul the March decree. This is in contrast to the same court's previous decisions annulling the country's 2008 and 2012 bans on MON810 as in violation of EU law.

15/ Bee Informed Project, Colony Loss 2013-2014, Results: Winter Loss Survey (May 15, 2014), available at http://beeinformed.org/2014/05/colony-loss-2013-2014/.

EU Considers Overhaul of Biotech Cultivation Rules

The EU's Environment Council is considering a proposed overhaul of the EU legal framework for biotech planting applications. Under the proposal, member states could opt out of EU-wide approvals on grounds other than food safety and environmental or health risks, which would remain the domain of the European Food Safety Authority (EFSA). In opting out of an approval, countries could cite socioeconomic, ethical, land management, or co-existence concerns. France has put forward an alternate proposal, whereby member states would make a decision as to whether to approve or ban each biotech trait from a list specified at the EU level. The Greek Presidency of the Environment Council is seeking an agreement within the Council by June, with the ultimate goal of finalizing the revisions with the European Parliament by the end of 2014.

European Parliament Rejects Draft Seed Regulation

In March, the European Parliament rejected the European Commission's proposal to modernize the EU's plant reproductive material law or "seed law." 16/ The draft text was rejected by a vote of 650 to 15, based on concerns that it would not provide sufficient flexibility to EU member states to tailor the rules to their individual needs. Following Parliament's rejection, the Commission declined to withdraw the draft rules, so Parliament formally concluded its first reading of the proposal and sent its position to the Council. The Council can either support the rejection, in which case the legislative process will end, or amend the Commission's original proposal.

China Continues to Reject U.S. Biotech Corn Imports

As previously reported, in November 2013 China began rejecting imports of U.S. corn containing Syngenta's MIR 162 because the trait is not yet approved in China. Since then, China has rejected an estimated 1.45 million metric tons of the corn, and has given no indication of whether or when it will approve the crop.

Australian Court Rules Against Plaintiff in Biotech Contamination Case

The Supreme Court of Western Australia ruled in late May against an organic farmer who brought suit against a neighboring farmer, alleging that drift of Monsanto's RR canola contaminated his wheat fields and caused him to lose his organic grower certification. The judge held that the farmer of the biotech crops did not breach any duty of reasonable care, that no physical harm to the property had been shown, and that, therefore, no damages were owed. The judgment also opined that Australia's organic certification body's decision to decertify the plaintiff appeared to be a "gross overreaction." Unlike the U.S. and EU, which permit the adventitious presence of trace levels of biotech traits in organic foods, Australia has a zero tolerance standard. The case was closely watched internationally and viewed as a test case for biotech contamination litigation.

16/ A Question and Answer document on the proposal is available at http://ec.europa.eu/food/plant/plant_propagation_material/review_eu_rules/docs/faq_regulation_proposal_en.pdf.

Canada Reviews Crop Variety Registration System

The Canadian government, as part of its effort to modernize Canada's agricultural policy and reduce unnecessary regulatory burdens, is in the process of reviewing the country's crop variety registration (VR) system and its effects on the development and adoption of new crop varieties. The review was initiated in 2013 by Agriculture and Agri-Food Canada (AAFC), the Canadian Food Inspection Agency (CFIA), and the Canadian Grain Commission (CGC). The agencies have outlined four potential options for modernizing and streamlining the system, and solicited stakeholder input. 17/ A plurality of commenters supported Option 1 – "Allow the flexibility inherent in the current VR system to emerge." A majority of respondents supported some type of reform, with varying levels of support for the remaining proposed Options: (2) Streamline the regulatory process by requiring that all crops meet a minimum registration requirement with the option for some crops to have a merit assessment through an independent assessment process; (3) Streamline the regulatory process by maintaining a minimum level of federal government oversight, and eliminate any merit assessment or performance data under the VR system; and (4) Withdraw federal government oversight in VR, allowing industry or third parties to assume these functions. The agencies now are in the process of considering revisions to the system.

Indian Panel Approves Field Trials of Biotech Crops

In March, India's Genetic Engineering Appraisal Committee (GEAC) reached a decision to allow field trials of eleven varieties of biotech crops. The varieties include maize, rice, sorghum, wheat, and cotton. Each of the varieties was previously approved but the earlier permits lapsed when not approved by the States. In order to be finalized, the revalidations would still need to be approved by the Union Environment and Forests Minister, as well as the individual States.

Taiwan Enacts Biotech Labeling Law

The Taiwanese government passed a law in March to require labeling for food containing biotech ingredients. Such foods will be required to carry a label if they contain more than 0.9% biotech content, an approach similar to that taken in the EU. Regulations currently are being developed by the Taiwan Food and Drug Administration and are expected to require biotech labeling for foods sold in restaurants and fresh markets.

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Please do not hesitate to contact us if you have any questions. In addition, as always, please inform us of developments that come to your attention so that we may summarize them and alert the membership accordingly.

17/ The findings from the initial review are available at http://tinyurl.com/ppzv8y6 and the summary of public comments is available at http://www.agr.gc.ca/eng/what-we-heard-crop-variety-registration-in-canada-options-for-the-future/?id=1397505428575.