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Rubber-Stamped Regulation: The Inadequate Oversight of Genetically Engineered Plants and Animals in the United States

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The Inadequate Oversight of Genetically Engineered Plants and Animals in the United States

*By Genna Reed**

Introduction

The U.S. Department of Agriculture first approved genetically engineered ("GE") crops in the United States in the 1990s,[1] and since then the country has been the biggest global adopter of this technology. GE crops were supposed to improve yields, lower costs for farmers, and reduce agriculture's environmental impact. Yet nearly twenty years after their introduction, genetically engineered crops have not provided the benefits promised by the companies that patented them.

Additionally, the patchwork of federal agencies that regulates genetically engineered crops and animals in the United States has failed to adequately oversee and monitor GE products. Three U.S. federal agencies — the Food & Drug Administration ("FDA"), the U.S. Department of Agriculture ("USDA"), and the Environmental Protection Agency ("EPA") — each have some responsibility over these products but have largely failed to create any overarching regulatory structure to protect public health and the environment. Lax enforcement, uncoordinated agency oversight, inadequate review of GE foods, a failure to track post-market problems, and a failure to require labeling of these foods have allowed unregulated and unstudied GE plants and animals to slip through the regulatory cracks.

The potential long-term risks of eating genetically engineered food are unknown. GE corn and soybeans are the building blocks of the industrialized food supply, ending up in products ranging from livestock feed to hydrogenated vegetable oils to high-fructose corn syrup. Companies submit their own safety testing data, and independent research on GE foods is limited because biotechnology companies prohibit cultivation for research purposes in the restrictive licensing agreements that control the use of these patented seeds.[2]

The Rise of GE Crops

Biotechnology involves manipulating the genetic makeup of plants or animals to create new organisms. Proponents of the technology contend that these alterations are improvements because they add new desirable traits, yet this manipulation may have considerable unintended consequences. Genetic engineering uses recombinant DNA technology to transfer genetic material from one organism to another to produce plants, animals, enzymes, drugs, and vaccines.[3] GE crops became commercially available in the United States in 1996 and now constitute the vast majority of corn, cotton, and soybean crops grown in the country.[4] More recently, biotechnology firms have developed genetically engineered animals, including food animals such as hogs and salmon that would eventually be sold for human consumption.[5]

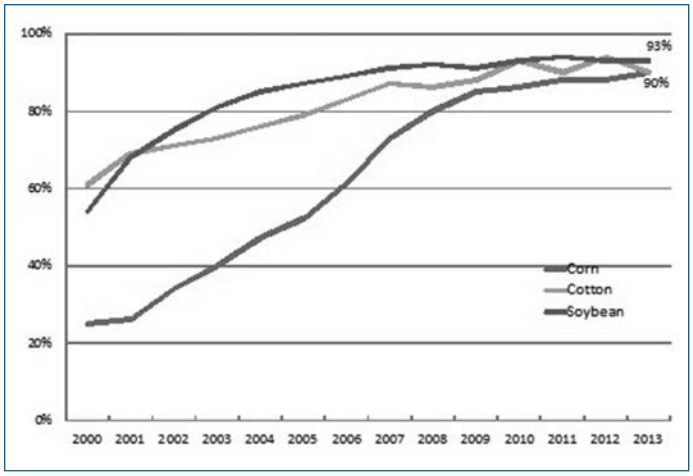

Figure 1. Biotechnology Share of U.S. Cultivation. Source: *Data Set: Genetically Engineered Varieties of Corn, Upland Cotton, and Soybeans, by State and for the United States, 2000-13*, U.S. Dep't Agric. Econ. Research Serv. (July 8, 2013) (excel file on file with author), *available at* http://ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us.aspx#.U20wc_ldXkd.

Genetic engineering modifies the genetic material of crops to display specific traits.[6] Biotechnology companies develop most GE crops to be either herbicide tolerant, allowing herbicides to kill weeds without harming crops; or insect resistant, allowing plants to produce their own pesticide to repel pests.[7] After nearly twenty years, the USDA has only approved one high-yield GE seed in an effort to boost soybean productivity.[8]

In 2011, more than 420 million acres of GE crops were cultivated in twenty-eight countries.[9] The United States is the world leader in GE crop production, with 172 million acres, or nearly half of global production.[10] U.S. GE cultivation grew rapidly from only 7% of soybean acres and 1% of corn acres in 1996, to 93% of soybean and 90% of corn acres in 2013.[11]

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U.S. federal regulators approve most applications for GE field trials because there is no testing requirement before field trials, and regulators have never rejected any crops for commercial cultivation.[12] Federal regulators approve most GE crops despite widespread concerns[13] about the risk to consumers and the environment.[14] Nonetheless, the biotechnology industry has pressed for even lighter regulatory oversight. Between 1999 and 2009, the top agricultural biotechnology firms spent more than $547 million on lobbying and campaign contributions to ease GE regulatory oversight, push for GE approvals, and prevent mandatory GE labeling.[15]

The agencies responsible for regulating and approving biotechnology include the FDA, the USDA, and the EPA. Although the missions of these agencies overlap in some areas, it is the responsibility of the USDA to ensure that GE crops are safe to grow, the EPA to ensure that GE products will not harm public health or the environment, and the FDA to ensure that GE food is safe to eat.

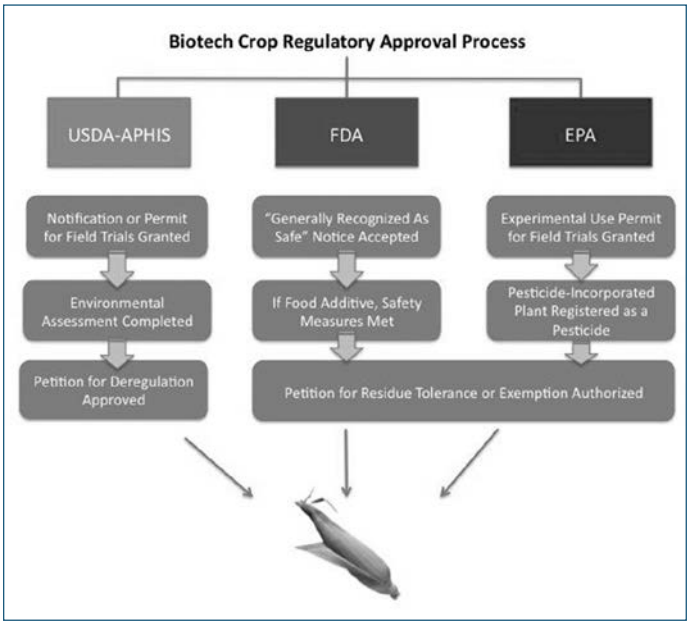

Figure 2. Biotechnology Crop Regulatory Approval Process Flowchart. Source: Food & Water Watch, Genetically Engineered Food: An Overview 9 (May 2012)

Safe to Grow?

The USDA is responsible for protecting crops and the environment from agricultural pests, diseases, and weeds, including biotechnology and conventional crops.[37] The Animal and Plant Health Inspection Service ("APHIS") oversees the entire GE crop approval process, including field-testing, restrictions on imports and interstate shipping, commercial cultivation, and monitoring of approved GE crops.[38]

The USDA is accelerating its approval process for GE crops even as the seed companies rush the new, untested varieties to market. In November 2011, the USDA unveiled its new streamlined process for GE crop approvals, which shortens approval timelines by thirteen to fifteen months.[39]

Biotechnology Regulatory Timeline

1930: The Plant Patent Act of 1930 provided seventeen-year patent protection for plant varieties, including hybrids.[16]

1952: The Patent Act of 1952 extended broader patent rights to agricultural developments to "any new and useful […] composition of matter" including chemicals and processes.[17]

1961: The International Convention for the Protection of New Varieties of Plants established an intergovernmental organization, of which the United States is a member and which provided intellectual property rights to the breeders of new plant varieties.[18]

1970: The Plant Variety Protection Act of 1970 provided plant variety breeders with exclusive patent rights for eighteen years.[19] It included a "farmer's exemption" that allowed farmers to save seed and to sell saved seeds to other farmers.[20]

1980: The U.S. Supreme Court decision in *Diamond v. Chakrabarty* extended patent rights to genetically engineered oil-eating bacteria.[21] The Court ruled that laboratory-created living things were not "products of nature" under the 1952 Patent Act and were thus patentable. This watershed decision bestowed patent protection on GE plants, animals and bacteria.

1981: The first transgenic[22] mice were produced for tissue manipulation and experimentation.[23]

1985-88: A series of rulings by the U.S. Patent and Trademark Office awarded patent protection to plants and nonhuman animals.[24]

1985: The first transgenic sheep and pigs were modified to display accelerated growth.[25]

1986: The Reagan White House determined that no new laws were necessary to regulate biotechnology since it did not pose any special or unique risks.[26]

1986: The Technology Transfer Act allowed the USDA to share publicly financed research and technology with private businesses.[27]

1987: The USDA authorized field trials of GE plants.[28]

1992: The USDA approved the first GE crop commercial cultivation, Calgene's Flavr Savr tomato.[29]

1994: The United States ratified the International Convention for the Protection of New Varieties of Plants, which extended plant patents to twenty years for most crops and prohibited farmers from selling saved patented seed without the patent owner's permission.[30]

1995: The EPA registered the first pesticide-incorporated plant, Monsanto's NewLeaf potato.[31]

1996: The U.S government approved commercial cultivation of GE soybeans and insect-resistant *Bt*[32] corn.[33]

2000: GE StarLink™ corn, approved solely for use in animal feed, unintentionally contaminated the human food system before being approved for human consumption.[34]

2001: FDA released guidance allowing food companies to voluntarily label GE or non-GE foods, provided that the labels are not false or misleading.[35]

2009: FDA announces that GE animals would be regulated as veterinary drugs instead of food (in a document known as Guidance 187) and defined transgenic animals as veterinary drugs under the Federal Food, Drug and Cosmetics Act.[36]

Biotechnology companies must either enter a "notification" or "permit" process before GE field trials can begin.[40] Under the streamlined notification process, companies submit data showing that the new GE plant will not harm agriculture, the environment, or non-target organisms and then the USDA either approves or denies the field-testing application within one month.[41] If the USDA denies the notification application, the company can re-apply under the more involved permit process.[42] The notification process does not require either an environmental assessment ("EA") or an environmental impact statement ("EIS") under the National Environmental Policy Act[43] ("NEPA") for GE crops that are neither new species nor new modifications.[44]

Under the more rigorous permit application process, the USDA determines if the GE field trial poses significant environmental impact before issuing a permit.[45] The USDA reviews scientific submissions for four months before granting or denying the field test permit request.[46] If approved, the permit imposes restrictions on planting or transportation to prevent the GE plant material from escaping and posing risks to human health or the environment.[47] The applicant is required to submit field-trial data to the USDA within six months of the test, demonstrating that the crop did not pose any harm to plants, non-target organisms, or the environment.[48] If the applicant violates the permit, the USDA can withdraw it.[49] The USDA has approved the vast majority—92%—of the applications for biotechnology field releases between 1987 and 2005.[50]

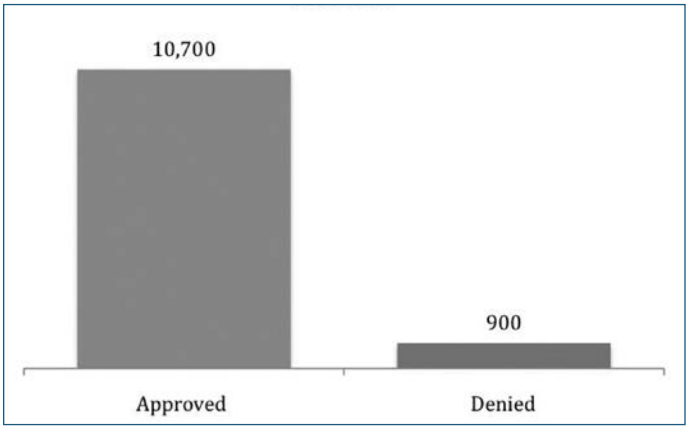

Figure 3. USDA GE Field Test Determinations: 1987-2005. Source: Jorge Fernandez-Cornejo & Margriet Caswell, USDA-ERS, The First Decade of Genetically Engineered Crops in the United States 3 (April 2006).

The USDA must complete an EA and potentially an EIS before approving any new crop release (including biotechnology crops) that will affect the environment under NEPA.[51] The EA determines whether the GE crop will pose significant risks to human health or the environment if cultivated.[52] If there is no significant risk, the USDA issues a "finding of no significant impact" ("FONSI").[53] But if the USDA finds more significant environmental implications, it must also perform a more thorough EIS.[54]

If a field trial does not reveal significant risks, the company can petition for nonregulated status, which allows the crop to be cultivated and sold commercially without further oversight.[55] The USDA solicits public comments on the deregulation for sixty days.[56] After reviewing available data, the USDA makes a final decision within six months.[57] By 2008, the USDA had approved nearly 65% (73 of 113) of new GE crop deregulation petitions, according to the U.S. Government Accountability Office.[58]

After the USDA approves the GE crops, it performs almost no post-release oversight and has no program for monitoring approved GE plants.[59] Instead, the USDA's primary post-market role with GE crops is through the Agricultural Marketing Service ("AMS"), which helps facilitate the export of transgenic crops by verifying their genetic identity.[60] The AMS does not test for GE presence in grains; it only works with interested shippers who participate in a voluntary verification program.[61]

Safe for the Environment?

The EPA regulates pesticides and herbicides, including GE crops designed to be insect resistant.[62] EPA defines a pesticide as a substance that "prevents, destroys, repels or mitigates a pest."[63] The EPA also sets allowable levels of pesticide residues in food, including GE insect-resistant crops. Between 1995 and 2008, the EPA registered twenty-nine GE pesticides engineered into corn, cotton, and potatoes.[64]

EPA regulates bioengineered pesticides under the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), first enacted in 1947.[65] New pesticides—including those designed for insect-resistant GE crops—must demonstrate that they do not cause "unreasonable adverse effects on the environment," including polluting ecosystems and posing environmental and public health risks.[66] Just as with conventional pesticides, the EPA must approve and register new GE insect-resistant crop traits.[67] To obtain registration with EPA, biotechnology companies must apply to field test new insect-resistant GE crop traits, establish permissible pesticide trait residue levels for food, and register the pesticide trait for commercial production.[68]

Pesticide residue standards: The EPA establishes allowable pesticide residue limits for food or feed crops and is required to meet all food and feed safety standards enforced by the FDA.[69] These "tolerance levels," or safe levels of pesticide residues, are based both on immediate exposure risks and on the potential accumulated risk from consuming pesticide residues over time.[70]

The EPA pesticide tolerances are extremely generous. A 2010 National Institutes of Health cancer risk study reported criticism by environmental health professionals and advocates that agribusiness influence at EPA deterred the agency from establishing sufficiently strong pesticide limits.[71] The EPA can even exempt pesticides from the need to establish tolerance levels if it finds a low probability of risk to public health.[72] Theoretically, such tolerance exemptions would allow food to contain *any* amount of pesticide residue.[73] Further, in developing its tolerance levels, the EPA relies solely on self-reported testing of new products. Despite these potential harms, the FDA and USDA's monitoring programs do not test for residue of glyphosate, a popular herbicide, on food or crops.[74]

Facing pressure from agribusiness lobbies, the EPA has even amended its tolerance levels when repeat applications of pesticides lead to higher pesticide levels in food. As farmers applied more Roundup® to cope with glyphosate-resistant weeds, the herbicide residues increased—but the EPA merely hiked up the permitted residue levels, with the result that glyphosate-resistant crops did not exceed the new allowable tolerance levels.

Field trials and final approval: The EPA considers any substance that "prevents, destroys, repels or mitigates a pest" a pesticide, including insect-resistant crops which the agency terms "plant incorporated protectants."[75] Companies must register all new pesticides, including plant incorporated protectants with the EPA.[76] Additionally, the EPA reviews and grants experimental use permits for field tests of unregistered pesticides or of registered pesticides tested for an unregistered use.[77] Biotechnology companies must apply for an experimental use permit for insect-resistant GE crops if they are grown on more than ten acres of land.[78] Experimental use permits typically limit field trials to one year.[79] Those companies seeking permits must submit all test data detailing a plant's toxicity and environmental risk to the EPA within six months of the field trial's completion.[80] If the test demonstrates that the crop poses acceptable risks, the company can apply to register the new crop for commercial distribution. The EPA may solicit expert scientific input as well as public comment on pending applications.[81]

Applications for permit registration must include management plans that describe any limitation on cultivating the new insect-resistant GE crops.[82] The management plans often require the designation of a non-insect-resistant seed buffer refuge along the border of the GE crop.[83] This "refuge" is intended to give pests access to non-pesticidal plants so that a pest does not develop resistance to the pesticide.[84] Biotechnology seed companies are responsible for ensuring that farmers follow these management plans. In 2010, the EPA imposed a $2.5 million fine on Monsanto for selling GE seed between 2002 and 2007 without informing Texas farmers about EPA-mandated planting restrictions.[85]

Occasionally a GE crop approved for a specific or restricted use appears in the wrong place. In 1998, the EPA approved restricted cultivation of Aventis' insect-resistant StarLink™ corn, but only for domestic animal feed and industrial purposes because the corn had not been tested for human allergenicity.[86] However, in 2000, StarLink™ traces were found in taco shells in U.S. supermarkets.[87] The EPA granted Aventis's request to cancel StarLink™'s registration, helping to remove the GE corn from the food supply.[88] The StarLink™ episode is a cautionary tale of the failure of the regulatory system to keep unapproved GE crops out of the human food supply.

Safe to Eat?

The FDA is responsible for the safety of both conventional and GE food, animal feed, and medicines. The agency regulates GE foods under the Food, Drug and Cosmetics Act, which also gives the FDA authority over the genetic manipulation of animals or products intended to affect animals.[89] Like traditional, non-GE foods, GE foods can pose risks to consumers from potential allergens and toxins.[90] The FDA does not, however, determine the safety of proposed GE foods; instead, it evaluates whether the GE product is similar to comparable non-GE products.[91]

In 1992, the FDA issued guidance that the biotechnology industry would be responsible for ensuring that new GE foods are safe and compliant with the Food, Drug and Cosmetics Act.[92] In 2001, the FDA proposed a rule requiring companies to submit data and information on new biotechnology-derived foods 120 days before commercialization.[93] As of 2014, the decade-old rule still had not been finalized and the industry data submissions remained voluntary.[94]

In effect, the biotechnology industry self-regulates when it comes to the safety of GE foods. For whole foods (intact foods such as a whole apple or potato), safety determinations are made by the producer, and no FDA premarket approval is necessary.[95] However, the FDA classifies substances added to food like biotechnology traits as "generally recognized as safe" ("GRAS") or as food additives.[96] A company may voluntarily submit a GRAS notification and scientific documentation to the FDA, but it is not a requirement.[97]

The FDA grants GRAS determinations to GE-derived foods considered equivalent in structure, function, or composition to food currently considered safe.[98] If the FDA determines that the GE food or ingredient is GRAS, it is not required to make a premarket safety determination to approve the substance the way it would for a food additive.[99]

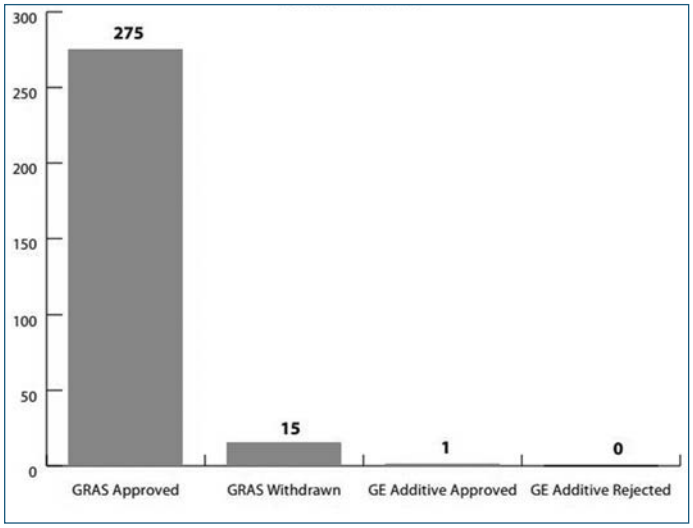

Figure 4. FDA Food Determinations: 1998-2010. Source: Food & Water Watch, Genetically Engineered Food: An Overview 11 (Jan. 2014), *available at* http://documents.foodandwaterwatch.org/doc/Genetically_Engineered_Food_2014.pdf (depicting GRAS approved foods).

By contrast, the FDA pre-approves food additives before they are sold. Yet the FDA trusts biotechnology companies to certify that their new GE foods and traits are the same as foods currently on the market. The company may send information on the source of the genetic traits (i.e., which plants or organisms are being combined) and on the digestibility and nutritional and compositional profile of the food, as well as documentation

that demonstrates the similarity of the new GE substance to a comparable conventional food.[100] The FDA evaluates company-submitted data, and does not do any independent safety testing of its own.[101] The agency then may approve the GE substance, establish certain regulatory conditions (such as setting tolerance levels), or prohibit or discontinue the use of the additive entirely.[102] The FDA evaluates the safety of all additives, but thus far it has evaluated only one GE crop trait as an additive: the first commercialized GE crop, Flavr Savr tomatoes.[103]

Once a GE food product has been approved and is on the market (either by GRAS designation or as a food additive), the FDA is responsible for its safety. Until recently, the agency could ask companies to recall dangerous food products only voluntarily; however, the FDA Food Safety Modernization Act of 2011 granted the FDA mandatory recall authority.[104] Generally, the FDA has awaited outbreaks of foodborne illness before taking action, rather than vigorously monitoring and inspecting food manufacturers.[105] This reactive approach has been ineffective in preventing foodborne illnesses.[106] On one unique occasion the FDA did pressure a company to recall a GE food product—StarLink™ corn, which was not approved for human consumption—when it entered the food supply.[107] The FDA's lack of post-market monitoring thus exposes the public to unapproved GE traits in the food supply.

When Monsanto commercialized its Roundup Ready® crops, the company's marketing campaign described glyphosate as being "less toxic to rats than table salt."[108] Company-submitted safety studies highlighted the benign quality of glyphosate, but some of the independent, peer-reviewed research done on glyphosate-tolerant crops has revealed troubling health implications including deterioration of liver and kidney function and impaired embryonic development in rats fed GE feed.[109]

A 2009 *International Journal of Biological Sciences* study found that rats that consumed Roundup Ready® corn for ninety days developed a deterioration of liver and kidney functioning.[110] Another study found irregularities in the livers of rats, suggesting higher metabolic rates resulting from a Roundup Ready® soybean diet.[111] Different research on mouse embryos showed that mice fed Roundup Ready® soybeans had impaired embryonic development.[112]

Even GE livestock feed may have unknown down-the-line consequences for consumers of animal products. In 2006, Italian researchers discovered biotechnology genes in the milk produced from dairy cows fed a GE diet, suggesting the ability of transgenes to survive pasteurization.[113] Later, a 2012 *Journal of Applied Toxicology* study revealed that *Bt*[114] toxins present in GE foods might affect human tissue at the cellular level, especially when combined with pesticides associated with GE crops, such as Roundup®.[115]

Corn and soybeans, the two 2,4-D-tolerant crops in the pipeline, could also be dangerous to eat because independent tests have shown that a metabolite of 2,4-D (2,4-Dichlorophenol or "DCP") causes skin sores, liver damage, and sometimes death in animals.[116] Because of the risks of this byproduct, scientists from the French National Institute for Agricultural Research suggest that crops treated with 2,4-D "may not be acceptable for human consumption."[117] A 2012 study found that individuals with 2,4-DCP present in their urine were more likely to have a diminished tolerance to food and environmental allergens.[118]

Under the current U.S. regulatory system, the FDA has no effective way to track adverse health effects in people consuming GE foods. And because there is no labeling requirement for food containing GE ingredients,[119] consumers do not know when they are eating these ingredients.

GE Animals: The FDA also regulates genetically engineered animals as veterinary medicines. In 2009, the agency interpreted the Food, Drug and Cosmetics Act definition of veterinary drugs as substances "intended to affect the structure of any function of the body of man or other animals" as including genetically altered animals.[120] This allows the FDA's Center for Veterinary Medicine to approve GE animals under a procedure that is wholly unsuited for the necessarily complex interactions of transgenic animals with other livestock and the environment. This regulatory interpretation (known as Guidance 187) was released in the same year that many companies publicly announced their intentions to bring transgenic food animals to market.[121] As of early 2014, GE salmon is under consideration for commercial approval, but no transgenic animals have yet been approved to enter the food supply.[122]

The FDA must approve a New Animal Drug application before a GE animal can be commercially produced. The application must demonstrate the GE animals' safety and efficacy, as well as contain methods for detecting residues in food-producing animals, a description of manufacturing practices, and any proposed tolerance levels.[123] However, veterinary drug manufacturers that are introducing their products for investigational use are exempt from new animal drug approval requirements.[124]

Once the FDA approves the production of experimental GE animals, the USDA must consider if and under what restrictions these animals can be slaughtered, processed, and entered into the food supply.[125] The biotechnology company must also prepare an EA for investigational GE animals.[126] In 2009, the FDA used the investigational use process to approve the first commercial biologic from a GE animal: the anticlotting agent ATryn produced with transgenic goat's milk.[127] Many of the FDA's approval processes involving drugs are exempt from disclosure, making it difficult for the public to participate fully in regulatory decisions concerning GE animals.[128]

It seems unlikely that the USDA will keep meat products derived from GE livestock out of the food supply, based on the FDA's tacit approval of food from cloned livestock. In 2008, the FDA determined that there are no risks associated with eating meat from cloned livestock or meat from the offspring of clones.[129] The USDA then asked producers of cloned animals, of which several hundred were currently on the market at the time, to abide by a voluntary moratorium on selling meat or milk from cloned animals.[130] The moratorium was supposed to allow time for a proposed USDA study on the potential economic impacts of cloned animals on U.S. agriculture and international trade.[131] As of early 2014, that study has yet to be completed, and there

are no known FDA efforts to ensure that owners of cloned animals are complying with the voluntary moratorium on sales of meat or milk from cloned animals.

Insufficient Labeling: The FDA governs the proper labeling of U.S. food products. But because the agency views GE foods as indistinct from conventional foods, the FDA does not require the labeling of GE food products as such. The FDA does permit voluntary GE labeling as long as the information is not false or misleading.[132] Food manufacturers can either affirmatively label GE food or indicate that the food item does not contain GE ingredients (known as "absence labeling"). Virtually no companies disclose that they are using GE ingredients under this voluntary scheme. Most consumers in the United States blindly consume foods that contain GE ingredients.[133]

For consumers to have the opportunity to make informed choices about their food, all GE foods should be labeled. A 2013 *New York Times* poll found that 93% of respondents were in favor of a mandatory label for genetically engineered food.[134] A 2010 Consumers Union poll found that 95% of U.S. consumers favor mandatory labeling of meat and milk from GE animals.[135] Yet despite this overwhelming support, the FDA will likely not require labeling of food that comes from genetically modified animals such as the AquaAdvantage salmon.[136] Consequently, in 2013 over twenty-five states introduced legislation to label GE foods, but only two—in Connecticut and Maine—passed.[137]

Juxtaposing the EU's Precautionary Approach with U.S. GE Regulation

Biotechnology regulation in the European Union ("EU") is far stricter than in the United States and operates under the "precautionary principle," assessing each food's safety before approving its commercialization.[138] In 1994, the United Nations Conference on the Human Environment in Rio de Janeiro declared the "precautionary approach" as one of twenty-seven principles designed to protect the environment.[139] The EU has approved more than thirty GE products for sale in the region, mostly GE soy and corn (maize) in animal feed.[140] Only two GE crops have been approved for cultivation in the EU: Monsanto's insect-resistant corn and BASF's high-starch potato.[141] Moreover, domestic GE production is very limited in Europe, which grows less than one-tenth of a percent of the global genetically engineered cropland.[142]

Despite having separate regulation for "novel" food, EU biotechnology regulation still allows some GE products to fall through the cracks. EU law requires that all foods and feeds with any GE content bear labels, including those with more than 0.9% accidental biotechnology content. But GE products considered "processing aids," like GE enzymes used to make cheese, are exempt from the labeling process.[143] In this way, the majority of GE use, including imported soy and corn, is hidden from consumers in unlabeled meat and milk from GE-fed livestock. European consumers, who have widely opposed GE foods, have been duped into believing that these products have been withdrawn from the food chain when consumers are in fact unwittingly supporting the GE industry via imported animal feed.[144]

European consumers are generally skeptical of the safety of GE foods. A 2010 biotechnology survey performed by the European Commission reported that 59% of Europeans think that GE food is unsafe for their health and that of their families, and 61% do not think that the development of GE food should be encouraged.[145] These opinions are reflected in the nearly one-quarter of EU member countries that maintain bans on GE products despite agribusiness and World Trade Organization pressure.[146] Under the EU's Deliberate Release Directive which regulates GE crops that go to market, a "safeguard clause" allows member countries to restrict or prohibit GE use or sales, provided there is evidence that the crop poses significant risks.[147]

Global Repercussions of U.S. Policies

Although the United States has readily approved GE crops and products, many countries, including key export markets, have not done so. Three-quarters of consumers in Japan, Italy, Germany, and France are skeptical of the safety of GE foods.[148] Europe has been restrictive in its approval of biotechnology foods because of uncertainty about the safety of the products for human consumption.[149]

Six EU countries currently ban GE cultivation altogether: Austria, France, Germany, Greece, Hungary, and Luxembourg.[150] Countries that ban GE foods typically impose strict rules to prevent unauthorized GE imports, which block or limit U.S. exports of corn and soybeans, which are primarily GE crops. Japan does not grow GE crops and requires mandatory labeling of all GE foods.[151]

Despite the advanced grain-handling system in the United States, GE grains have contaminated non-GE shipments and devastated U.S. exports. The U.S. Government Accountability Office ("GAO") identified six known unauthorized releases of GE crops between 2000 and 2008.[152] In 2000, Japan discovered GE StarLink™ corn, not approved for human consumption, in 70% of tested samples, even though StarLink™ represented less than 1% of total U.S. corn cultivation.[153] After the StarLink™ discovery, Europe banned all U.S. corn imports, costing U.S. farmers $300 million.[154] In August 2006, unapproved GE Liberty Link® rice was found to have contaminated conventional rice stocks.[155] Japan halted all U.S. rice imports and Europe imposed heavy restrictions, costing the U.S. rice industry $1.2 billion.[156] In 2007, Ireland impounded imported U.S. livestock feed that tested positive for GE.[157]

The United States is aggressively seeking to force its trading partners to overturn their GE prohibitions. The U.S. Trade Representative is lobbying trading partners to remove "unjustified import bans and restrictions to U.S. biotechnology products" and is even pressing countries to eliminate GE labeling requirements.[158] The diplomatic push by U.S. biotechnology interests extends to developing countries as well; in recent years, the U.S. State Department has pressured governments all over the world to lift GE restrictions.[159]

Recommendations

To ensure that GE food and crops are safe for the environment and human consumption, the author recommends the following reformations to the U.S. GE food and crop policy:

- **Enact a moratorium on new U.S. approvals of genetically engineered plants and animals:** The federal government should enact a moratorium on new GE plant and animal approvals until adequate scientific study presents avenues for their safe use.
- **Require mandatory labeling of GE foods:** An affirmative label should be present on all GE foods, ingredients, and animal products.
- **Institute the precautionary principle for GE foods:** Currently in the United States, most GE foods, donor organisms, and host organisms are generally considered safe for consumption and the environment until proven otherwise.[160] The United States should enact policy that would more rigorously evaluate the potentially harmful effects of GE crops before their commercialization to ensure public safety.
- **Develop new regulatory framework for biotechnology foods:** Congress should establish legislation specifically suited to GE foods instead of allowing a piecemeal regulatory scheme ill-suited to address this complex technology.
- **Improve agency coordination and increase post-market regulation:** The EPA, USDA and FDA should create mechanisms for coordinating information and policy decisions to correct major regulatory deficiencies highlighted by the GAO.[161] Additionally, the agencies should adequately monitor the post-market status of GE plants, animals, and food, which would be aided by a requirement that all GE food be labeled.

Conclusion

New technologies—like genetic engineering—create uncertainties and risk that should first be carefully evaluated before being rapidly pushed into the market. The existing regulatory framework for GE foods simply does not protect consumers, markets, and international trade relationships. The U.S. regulatory system; comprised of piecemeal oversight by the Department of Agriculture, the Environmental Protection Agency, and the Food and Drug Administration; has failed to protect the environment, the food system, or public health from the uncertainties and negative consequences of GE foods. It is time for a new approach to biotechnology in the U.S. food system.

Endnotes: Rubber-Stamped Regulation: The Inadequate Oversight of Genetically Engineered Plants and Animals in the United States

1 *Adoption of Genetically Engineered Crops in the U.S.*, Econ. Research Serv., U.S. Dept. of Agric., http://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us/documentation.aspx#.UyeXLvldUQk (last updated July 8, 2013) [hereinafter USDA-ERS] (stating genetically engineered crops have been widely adopted since they were introduced commercially in 1996 and that soy, cotton, and corn are the most widely adopted genetically engineered crops in the United States).

2 *See* Johan Diels et al., *Association of Financial or Professional Conflict of Interest to Research Outcomes on Health Risks or Nutritional Assessment Studies of Genetically Modified Products*, 36 Food Policy 197 (2011) (noting that technology agreements essentially allow a company to limit, or even prohibit any research conducted by the independent researchers on their products without its explicit authorization, even after the product has been approved and marketed).

3 Pew Initiative on Food & Biotechnology, Guide to U.S. Regulation of Genetically Modified Food & Agricultural Biotechnology Products i (2001) [hereinafter Pew Initiative]; Donna U. Vogt & Mickey Parish, U.S. Dept. of State, Food Biotechnology in the United States: Science, Regulation, and Issues 2 (1999).

4 USDA-ERS, *supra* note 1.

5 Enviropig™, http://www.uoguelph.ca/enviropig/ (last visited March 3, 2011); AquaBounty Tech., www.aquabounty.com/PressRoom/ (last visited Feb. 8, 2011).

6 Jorge Fernandez-Cornejo & Margriet Caswell, USDA-ERS, The First Decade of Genetically Engineered Crops in the United States 1 (2006) (explaining that genetic engineering techniques allow for targeting and precise alteration of a single trait of an organism, allowing a company to create a product that is more effective than a similar conventional product).

7 Robbin Shoemaker, USDA-ERS, Economic Issues in Agricultural Biotechnology 9 (2001).

8 *Petitions for Determination of Nonregulated Status,* USDA Animal & Plant Health Investigation Serv., http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml (last visited Feb. 12, 2014); USDA Animal & Plant Health Inspection Serv., Monsanto Petition (11-202-01p) for Determination of Nonregulated Status of Event: MON 87712-4 Soybean: Environmental Assessment (2013).

9 *ISAAA Brief 44-2012: Executive Summary Global Status of Commercialized Biotech/GM Crops: 2012*, Int'l Serv. for Acquisition of Agri-Biotech Applications, http://www.isaaa.org/resources/publications/briefs/44/executivesummary/default.asp.

10 *Id.* at Table 1.

11 USDA Office of Inspector General, Audit Report: USDA's Role in the Export of Genetically Engineered Agricultural Commodities 7 (2009); USDA-ERS, *supra* note 1.

12 USDA APHIS Biotechnology Regulatory Services, Permit User's Guide With Special Guidance for ePermits 10 (2012); USDA APHIS, *supra* note 8.

13 See *infra* Safe to Grow? Section and Safe to Eat? Section.

14 USDA-APHIS Biotechnology Regulatory Services, *supra* note 12 at 10.

15 Food & Water Watch analysis of Center for Responsive Politics data (unpublished analysis) (on file with author); *See* Food & Water Watch, Food & Agriculture Biotechnology Industry Spends More Than Half a Billion Dollars to Influence Congress 1 (2010) (explaining that the fifty largest agricultural and food patent-holding companies and two of the largest agrochemical and biotechnology trade associations have spent more than $572 million in campaign contributions and lobbying expenditures by hiring at least thirteen former Congress members and over 300 former Congressional and White House staffers to promote GE food and agricultural products).

16 Jorge Fernandez-Cornejo, The Seed Industry in U.S. Agriculture: An Exploration of Data and Information on Crop Seed Markets, Regulation, Industry Structure, and Research and Development 19 (2004) (explaining that the Plant Patent Act of 1930 was specifically enacted to address issues of plant breeding and provides patent protection over sexually or vegetatively reproduced plant varieties).

17 *Id.* (stating that the Plant Patent Act of 1952 extends patent rights under a more general category that includes machines and processes used in creating GE products, and that expanding the definition of what can be patented created

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for sub-Saharan Africa from 2015-2020; US $108 billion in IQ-based lost economic productivity due to children's exposures to lead in Africa, Latin America, and South East Asia; and US$ 634 million per year in lost productivity of commercial fisheries in China due to acute water pollution. *See Cost of Inaction Initiative*, UNEP, http://www.unep.org/hazardoussubstances/UNEPsWork/Mainstreaming/CostsofInactionInitiative/tabid/56397/Default.aspx (last visited Apr. 10, 2014).

[94] OECD, *supra* note 1, at 150; Oslo Manual, *supra* note 2, at 78.

[95] Andreas Kortenkamp et. al, State of the Art Assessment of Endocrine Disruptors 97 (2012), *available at* http://ec.europa.eu/environment/chemicals/endocrine/pdf/sota_edc_final_report.pdf (report comissioned by the Directorate-General for the Environment of the European Commission).

[96] REACH Innovation Report, *supra* note 41, at 77.

[97] REACH Innovation Report, *supra* note 41, at 66.

[98] REACH Innovation Report, *supra* note 41, at 19.

[99] REACH Innovation Report, *supra* note 41, at 36.

[100] Ashford & Heaton, *supra* note 37, at 136-37 (citing several studies from the 1970s).

[101] Ashford & Heaton, *supra* note 37, at 138.

[102] REACH Innovation Report, *supra* note 41, at 33.

[103] REACH Innovation Report, *supra* note 41, at 72.

[104] *See* REACH Innovation Report, *supra* note 41, at 71-75 (emphasis added).

[105] *See* REACH Innovation Report, *supra* note 41, at 76, 81.

[106] *See* REACH Innovation Report, *supra* note 41, at 16, 70.

[107] *See* REACH Innovation Report, *supra* note 41, at 36.

[108] *See* REACH Innovation Report, *supra* note 41, at 10.

[109] Our patent landscape study showed that from 1972-2011, most inventions went beyond the scope of laws to restrict the use of phthalates, including coating, paints, and resins, as well as polyvinyl chloride (PVC) and plastics generally.

Endnotes: The Minamata Convention on Mercury: Past, Present, and Future Environmental Health

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have lost their livelihoods. *Minamata Disease Archives: Pathway of Methylmercury from Factory to Human*, Japan Ministry of Env't (2014), http://www.nimd.go.jp/archives/english/tenji/a_corner/a06.html.

[8] *See generally* Nat'l Research Council, Toxicological Effects of Methylmercury 4-7 (2000), *available at* http://www.nap.edu/openbook.php?record_id=9899&page=R1.

[9] Normile, *supra* note 4, at 1447.

[10] Normile, *supra* note 4, at 1447.The Japanese government has recognized 2,265 victims of methylmercury poisoning; however, many people who suffered from smaller exposures to the toxin or have lesser health effects still go unrecognized. *Id.*

[11] Normile, *supra* note 4, at 1446.

[12] *See* Normile, *supra* note 4, at 1446. *Compare Minamata Disease Related Sights*, Japan Guide, http://www.japan-guide.com/e/e4527.html (last visited Feb 18, 2013) *with Minamata Disease Archives Factsheet*, Japan Ministry of Env't (2014), *available at* http://www.nimd.go.jp/archives/english/outline/leaflet_jyoho.pdf.

[13] Joseph DiGangi, *Opinion: A Call for Action in Minamata*, Environmental Health News (Oct. 10, 2013), http://www.environmentalhealthnews.org/ehs/news/2013/a-call-for-action-in-minamata.

[14] Minamata Convention on Mercury, Nov. 6, 2013, UNEP(DTIE)/Hg/INC.5/7*, *available at* http://www.mercuryconvention.org/Portals/11/documents/conventionText/Minamata%20Convention%20on%20Mercury_e.pdf.

[15] Naomi Lubick & David Malakoff, *With Pact's Completion, The Real Work Begins*, 341 Science 1443, 1443 (2013).

[16] *Id.*

[17] *Id.* at 1443-44.

[18] Krabbenhoft & Sunderland, *supra* note 7, 1458.

[19] *See* Minamata Convention on Mercury, *supra* note 14, at art. 21 (outlining Parties' reporting requirements).

[20] Lubik & Malakoff, *supra* note 15, at 1443.

[21] Krabbenhoff & Sunderland, *supra* note 7, at 1458.

[22] *See* Lubick & Malakoff, *supra* note 15, at 1445 (explaining that Parties to the Mercury Convention could develop a coordinated database, similar to that developed under the 2001 Stockholm Convention on Persistent Organic Pollutants, to record biomonitoring and infrastructure data for mercury).

[23] Lubick & Malakoff, *supra* note 15, at 1445.

[24] Lubick & Malakoff, *supra* note 15, at 1443.

[25] *See* Lubick & Malakoff, *supra* note 15, at 1445.

[26] Lubick & Malakoff, *supra* note 15, at 1445.

[27] Lubick & Malakoff, *supra* note 15, at 1445.

[28] Lubick & Malakoff, *supra* note 15, at 1445; *see also* Minamata Convention on Mercury, *supra* note 14, at art. 13 (outlining the Convention's mechanism for sharing financial resources).

[29] Lubick & Malakoff, *supra* note 15, at 1445 ("Countries still need to work out what kinds of data to collect . . . .").

[30] Lubick & Malakoff, *supra* note 15, at 1445.

[31] *See supra* notes 19, 23 and accompanying text.

[32] Lubick & Malakoff, *supra* note 15, at 1445.

[33] Lubick & Malakoff, *supra* note 15, at 1445.

[34] For example, unlike measuring ozone depletion, utilizing a variety of different methods or sample sources used to measure mercury may skew results. Lubick & Malakoff, *supra* note 15, at 1445 ("An alternative [to blood samples] might be gathering hair or urine samples, but recent research has shown that each might accumulate a different record of mercury exposure, potentially skewing results.").

Endnotes: Rubber-Stamped Regulation: The Inadequate Oversight of Genetically Engineered Plants and Animals in the United States

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an important opening for covering innovations in biotechnology and genetic engineering); 35 U.S.C. § 101 (2011).

[18] Fernandez-Cornejo, *supra* note 16, at 19 (explaining the act established the International Union for the Protection of New Varieties of Plants to ensure that breeders of new varieties of plants were provided with the appropriate intellectual property rights).

[19] 7 U.S.C. § 2483 (2010); USDA, Plant Variety Protection Act and Regulations and Rules of Practice 14 (2006).

[20] 7 U.S.C. § 2543 (2011); USDA, *supra* note 19, at 19.

[21] Diamond v. Chakrabarty, 447 U.S. 303 (1980) (deciding to extend patent rights to genetically engineered microorganisms, which are important tools and products of biotechnology, and strengthen the rights of breeders).

[22] The USDA defines "transgenic organism" as an "organism resulting from the insertion of genetic material from another organism using recombinant DNA techniques." *Glossary of Agricultural Biotechnology Terms*, U.S. Dep't of Agric. http://www.usda.gov/wps/portal/usda/usdahome?navid=BIOTECH_GLOSS&navtype=RT&parentnav=BIOTECH (last updated Feb. 27, 2014).

[23] Franklin Costantini & Elizabeth Lacy, *Introduction of a Rabbit B-globin Gene into the Mouse Germ Line,* 294 Nature 92, 92-94 (1981).

[24] Fernandez-Cornejo, *supra* note 16, at 19 (noting that several rulings by the U.S. Patent Office extended intellectual property rights to a wide range of new biotechnology products such as seeds, plants, plant parts, genes, traits, and biotechnology processes).

[25] Robert Hammer, et al. *Production of Transgenic Rabbits, Sheep and Pigs by Microinjection,* 315 Nature 680, 680 (June 1985).

[26] 51 Fed. Reg. 23302. (June 26, 1986).

[27] Shoemaker, *supra* note 7, at 9.

[28] *History of Biotechnology and Regulatory Services*, USDA APHIS, http://www.aphis.usda.gov/wps/portal/banner/help?1dmy&urile=wcm%3apath%3a/

aphis_content_library/sa_our_focus/sa_biotechnology/sa_program_overview/ct_about_history (last updated Jan. 2014).

[29] *Id.*; Shoemaker, *supra* note 7 at 21.

[30] Fernandez-Cornejo, *supra* note 16, at 19 (stating that the 1994 amendment to the Plant Variety Protection Act brought the Act into conformity with the international standards established by the International Union for the Protection of New Varieties of Plants and extended the protection provided by Certificates of Protection from eighteen years to twenty years for most crops); Shoemaker, *supra* note 7, at 9.

[31] USDA APHIS, *supra* note 28.

[32] The USDA defines Bt crops as, "crops that are genetically engineered to carry a gene from the soil bacterium Bacillus thuringiensis (Bt). The bacterium produces proteins that are toxic to some pests but non-toxic to humans and other mammals. Crops containing the Bt gene are able to produce this toxin, thereby providing protection for the plant. Bt corn and Bt cotton are examples of commercially available Bt crops." *Glossary of Agricultural Biotechnology Terms, supra* note 22.

[33] Doug Gurian-Sherman, Failure to Yield: Evaluating the Performance of Genetically Engineered Crops 15 (2009) (stating the Glyphosate-tolerant soybeans now constitute over 90% of all soybeans planted in the United States and represent the biggest proportion among GE crops).

[34] U.S. Envtl. Prot. Agency, Concerning Dietary Exposure to CRY9C Protein Produced by Starlink™ Corn and the Potential Risks Associated with Such Exposure, Draft White Paper, 1 (2007) [hereinafter EPA] (finding that residues from Starlink were detected in taco shells).

[35] U.S. Food and Drug Admin., Guidance for Industry: Voluntary labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering, Draft Guidance (last updated Feb. 21, 2014), *available at* http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/labelingnutrition/ucm059098.htm.

[36] U.S. Food & Drug Admin., Guidance for Industry 187 – Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs, Final Guidance 5 (2009).

[37] Biotechnology Regulatory Serv., APHIS Biotechnology: Permitting Progress Into Tomorrow 1 (2006), *available at* https://scholarworks.iupui.edu/bitstream/handle/1805/819/Permitting%20progress%20into%20tomorrow%20-%20BRS%20factsheet.pdf?sequence=1.

[38] 7 U.S.C. § 7701(3) (2000). *See also id.*at 1-4.

[39] *APHIS Unveils Customer-Driven Improvements and Solutions–Changes Could Achieve Reductions in Processing Times Ranging from 20 to 76 Percent*, U. S. Dep't of Agric. (Nov. 10, 2011), http://www.aphis.usda.gov/wps/portal/aphis/newsroom/news/sa_federal_register_posts?1dmy&urile=wcm%3Apath%3A%2FAPHIS_Content_Library%2FSA_Newsroom%2FSA_News%2FSA_By_Date%2FSA_2011%2FSA_11%2FCT_Customer_driven (claiming that improvements will achieve reductions in various agency processing times ranging from 20–77% and anticipates being able to reduce its veterinary biologics licensing processes by potentially 100 days).

[40] 7 C.F.R. § 340.3(a) & (b) (2012).

[41] 7 C.F.R. § 340.3(b), (c) & (e)(4) (2012). *See also* Pew Initiative, *supra* note 3, at 11.

[42] 7 C.F.R. § 340.3(e)(5) (2012). *See also* Pew Initiative, *supra* note 3, at 11.

[43] 42 U.S.C. § 4321 et seq.

[44] 7 C.F.R. § 340.3 (2012); 7 C.F.R. 372.5 (c) & (d) (1995). *See also* Pew Initiative, issues In The Regulation of Genetically Engineered Plants and Animals 33 (2004).

[45] 7 C.F.R. §340.4(b) (2012). *See also* Pew Initiative, *supra* note 3, at 10 (noting that obtaining a permit for field testing, or making a notification that testing will take place, is a typical step in the development of a commercial product).

[46] 7 C.F.R. § 340.4(b) (2012); Biotechnology Regulatory Serv., *supra* note 37, at 3.

[47] 7 C.F.R. § 340.4(f)(2012). *See also* Biotechnology Regulatory Serv., *supra* note 37, at 2.

[48] 7 C.F.R. § 340.4(f)(9) (2012).

[49] 7 C.F.R. § 340.4(g) (2012).

[50] Fernandez-Cornejo & Caswell, *supra* note 6, at 3 (noting that significant numbers of applications were approved for varieties with improved product quality, viral resistance, and enhanced agronomic properties such as drought resistance and fungal resistance).

[51] 7 C.F.R. § 372.5(b)(3) (2002).

[52] Biotechnology Regulatory Serv., National Environmental Policy Act and Its Role in USDA's Regulation of Biotechnology 2 (2006), *available at* http://permanent.access.gpo.gov/gpo9876/BRS_FS_NEPA_02-06.pdf (noting that the EA preparation process includes: consultation and coordination with other Federal, Tribal, State/Local agencies; public scoping; Federal Register Notices; public comments; public meetings; publication of a final EA; and supplements to a previous EA).

[53] 7 C.F.R. § 372.9(a) (2010). *See also id.* at 2.

[54] 7 C.F.R. § 372.8(b)(1) (2010) (involving a more in-depth inquiry into the proposal and any reasonable alternatives to it).

[55] 7 C.F.R. § 340.6(a) (2011). *See also* Pew Initiative on Food and Biotechnology, *supra* note 3, at 11-12.

[56] 7 C.F.R. § 340.6(d)(2) (2011) (allowing any interested person to submit written comments regarding the filed petition to the Administrator, which will become part of the petition file).

[57] 7 C.F.R. § 340.6(d)(3) (2011) (indicating either approval or denial of petition).

[58] U.S. Gov't Accountability Office, Genetically Engineered Crops: Agencies are Proposing Changes to Improve Oversight, But Could Take Additional Steps to Enhance Coordination and Monitoring 11 (2008) [hereinafter GAO].

[59] Michael R. Taylor & Jody S. Tick, Pew Initiative on Food and Biotechnology, Post-Market Oversight of Biotech Foods: Is The System Prepared? 19 (2003), *available at* http://www.pewtrusts.org/uploadedFiles/wwwpewtrusts-org/Reports/Food_and_Biotechnology/hhs_biotech_exec_0403.pdf (noting that these crops are not subject to regulatory control under the PPA unless and until APHIS finds them to be a plant pest or noxious weed on the basis of new data or analysis).

[60] *Grain, Rice & Pulses: Biotechnology*, U.S. Dep't of Agric. http://www.gipsa.usda.gov/GIPSA/webapp?area=home&subject=grpi&topic=rd-bi (last visited Feb. 9, 2011).

[61] Facilitating the Marketing of the U.S. Agricultural Products With New Testing and Process Verification Services, 67 Fed. Reg. 50853-50854. (Aug. 6, 2002).

[62] 7 U.S.C. § 136(u)(1) (2006). *See also* 40 C.F.R. § 174.3 (2011) (defining "plant-incorporated protectant").

[63] 7 U.S.C. § 136(u)(1) (2006).

[64] GAO, *supra* note 58, at 11 (adding that five of which have since been cancelled).

[65] Federal Insecticide, Fungicide, Rodenticide Act, 7. U.S.C. prec. § 121 (2012). *See also EPA History: FIFRA Amendments of 1988,* U.S. Envt'l Prot. Agency (Oct. 26, 1988), http://www2.epa.gov/aboutepa/epa-history-fifra-amendments-1988.

[66] 7 U.S.C. § 136a(c)(5) (2013).

[67] 40 C.F.R. § 152.1(a) (2013).

[68] 40 C.F.R. § 172.3(a) (2013). *See also* 40 C.F.R. § 180 (1997); 40 C.F.R. §152.1(a) (2008); Pew Initiative, *supra* note 3, at 13-14.

[69] 21 U.S.C. § 346a(c)(2)(A) (2011). *See also* Pew Initiative, *supra* note 3, at 13.

[70] 21 U.S.C. § 346a(b)(2)(ii) (2011).

[71] *See* Suzanne H. Reuben, U.S. Dep't of Health and Human Serv., Reducing Environmental Cancer Risk: What We Can Do Now 46 (2010).

[72] 21 U.S.C. § 346a(c)(2)(A) (2013). *See also* Pew Initiative, *supra* note 3, at 14.

[73] EPA, *supra* note 34, at 7.

[74] National Pesticide Information Center, Glyphosate Technical Fact Sheet 9 (2010).

[75] 7 U.S.C. § 136(u)(1) (2013); 40 C.F.R. § 174.3 (defining "plant-incorporated protectant").

[76] Pew Initiative, *supra* note 44, at 39.

[77] 40 C.F.R. § 172.2(a) (2013); Pew Initiative, *supra* note 3, at 12.

[78] 40 C.F.R. § 172.3(a), (c) (2013).

[79] 40 C.F.R. § 172.5(b) (2013).

[80] 40 C.F.R. § 172.8 (2013).

[81] U.S. Gov't Accountability Office, Genetically Modified Foods: Experts View Regimen of Safety Tests as Adequate, but FDA's Evaluation Process Could Be Enhanced 7 (2002).

[82] U.S. Envt'l Protection Agency, Biopesticides Registration Action Document: Bacillus Thuringiensis (Bt) Plant-Incorporated Protectants 17-18 (2001).

[83] *Insect Resistance Management Fact Sheet for Bacillus thuringiensis (Bt) Corn Products*, U.S. Envt'l Protection Agency (Feb. 2011) http://www.epa.gov/oppbppd1/biopesticides/pips/bt_cotton_refuge_2006.htm (providing requirements for growers of Bt cotton).

[84] U.S. Envt'l Protection Agency, *supra* note 82, at 17.

[85] *EPA Fines Monsanto for Distributing Genetically Engineered Pesticide*, U.S. Envt'l Protection Agency (July 8, 2010), http://yosemite.epa.gov/opa/admpress.nsf/0/6754B55AAEC2AEE18525775A0061F90B (describing the EPA fining Monsanto for misbranding related to the sale of cotton seeds that contained genetically engineered pesticides).

[86] *Id*.

[87] *Id*.

[88] *Id*.

[89] 21 U.S.C. § 301 (2013); Pew Initiative, *supra* note 3, at 15.

[90] *See* U.S. Gov't Accountability Office, *supra* note 81, at 9.

[91] 21 C.F.R. § 170.35(c)(1)(iii) (2013); Pew Initiative, *supra* note 3, at 20-21.

[92] Foods Derived from New Plant Varieties, 57 Fed Reg. 22984 (May 29, 1992).

[93] Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706 (Jan. 18, 2001).

[94] As of the publication of this article, FDA has still not finalized this rule.

[95] Pew Initiative, *supra* note 3, at 19-20.

[96] *See* Pew Initiative, *supra* note 3, at 20.

[97] 21 C.F.R. § 170.35(c)(4), (c)(5) (2013). *See also* Pew Initiative, *supra* note 3, at 20.

[98] HHA Eligibility for Recognition as Generally Recognized as Safe, 21 C.F.R. § 170.30 (2012) (outlining the types of food to be recognized as GRAS); Pew Initiative, *supra* note 3, at 21 (describing the Flavr Savr tomato as triggering the food additive process).

[99] Geoffrey S. Becker & Tadlock Cowan, Biotechnology in Animal Agriculture: Status & Current Issues 6 (2009); *GRAS Notice Inventory,* U.S. Food & Drug Admin., http://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices (last visited April 28, 2011). The FDA has awarded "generally recognized as safe" status to almost all—95%—of the GRAS applications submitted for food since 1998.

[100] U.S. Gov't Accountability Office, *supra* note 81, at 11-12.

[101] FDA Food Additives Petitions, 21 C.F.R. § 171.1(c) (2013).

[102] FDA Food for Human Consumption, 21 C.F.R. § 170.38(c) (2013).

[103] 66 Fed. Reg. §4708. (Jan. 18, 2001); Pew Initiative, *supra* note 3, at 21.

[104] FDA Recalls (Including Product Corrections)–Guidance on Policy, Procedures and Industry Responsibilities, 21 C.F.R. § 7.4(c) (2012); An Act to Amend the Federal Food, Drug and Cosmetic Act with Respect to Safety of Food Supply, H.R. 2751, 111th Cong. (2011), *available at* http://www.gpo.gov/fdsys/pkg/PLAW-111publ353/pdf/PLAW-111publ353.pdf (amending the act to include a mandatory recall authority).

[105] U.S. Gov't Accountability Office, Federal Oversight of Food Safety: FDA Has Provided Few Details on the Resources and Strategies Needed to Implement its Food Protection Plan (2008) (statement of Lisa Shames, Director, Natural Resources and Environment) (explaining congressional oversight of the FDA).

[106] *See* U.S. Gov't Accountability Office, Food Safety: USDA and FDA Need to Better Ensure Prompt and Complete Recalls of Potentially Unsafe Food 1 (2004) (describing the process through which food companies recall food that has been discovered contaminated).

[107] EPA, *supra* note 34, at 9.

[108] Assurance of Discontinuance Pursuant to Executive Law § 63(15) at 3, In the Matter of Monsanto Company (Nov. 25, 1996), *available at* http://big.assets.huffingtonpost.com/fraud.pdf (offering proof that "Glyphosate is less toxic to rats than table salt following acute oral ingestion").

[109] Joel Spiroux de Vendomois et al., *A Comparison of the Effects of Three GM Corn Varieties on Mammalian Health*, 5 Int'l. J. of Biological Sci. 707, 716-18 (delineating the effect of GM corn on rats); Manuela Malatesta et al., *Ultrastructural Morphometrical and Immunocytochemical Analyses of Hepatocyte Nuclei from Mice Fed on Genetically Modified Soybean,* 2 Cell Structure & Function Abstract (2002) (showing the lack of evidence that GM foods have a negative impact on health); Barbara Cisterna et al., *Can a Genetically-Modified Organism-Containing Diet Influence Embryo Development? A Preliminary Study on Pre-implantation Mouse Embryos.* Eur. J. Histochemistry 263 (2008); Antonella Agodi et al., *Detection of Genetically Modified DNA Sequences in Milk From the Italian Market.* Int'l. J. Hygiene & Envtl. Health Abstract (2006); R. Mesnag et al., *Cytotoxicity on Human Cells of Cry1Ab and Cry1Ac Bt Insecticidal Toxins Alone or With a Glyphosate-Based Herbicide,* J. Applied Toxicology Abstract (2012) (describing the toxicology issues posed by the effects of pesticides).

[110] de Vendomois et al., *supra* note 109, at 716-18 (concluding the effects of GM crop/food require a case-by-case evaluation).

[111] Malatesta et al., *supra* note 109, at Abstract (outlining the impact of Roundup Ready® soy on animal organs).

[112] Cisterna et al., *supra* note 109, at 263.

[113] Agodi et al., *supra* note 109, at Abstract.

[114] *See* note 32.

[115] Mesnage et al., *supra* note 109, at Abstract.

[116] François Laurent et al., *Metabolism of [^{14}C]-2,4-dichlorophenol in Edible Plant*s. 62 Pest Mgmt. Sci. 558 (2006) (explaining the test results of corn and soy on animals).

[117] *Id.*

[118] Elina Jerschow, *Dichlorophenol-containing Pesticides and Allergies: Results from the US National Health and Nutrition Examination Survey 2005–2006*, 109 Annals of Allergy Asthma Immunology, 420, 422 (2012).

[119] Fernandez-Cornejo & Caswell, *supra* note 6, at 3.

[120] U.S. Food & Drug Admin., *supra* note 36, at 4-5.

[121] Genetically Engineered Animals Frequently Asked Questions, Biotechnology Industry Org. 4 (Sept., 2010), *available at* http://www.bio.org/sites/default/files/FAQs_GEAns_0908_0.pdf (enumerating the purpose of Guidance for Industry 187).

[122] *Id.* at 2-4.

[123] 21 U.S.C. § 360b(b)(1) (2002) (regulating the application process for "new animal drugs").

[124] 21 C.F.R. § 511.1 (2013); 21 U.S.C. § 360b(1) (2002).

[125] U.S. Food & Drug Admin., *supra* note 36, at 11.

[126] 21 C.F.R. § 25.20 (m) (2012).

[127] *FDA Approves Orphan Drug ATryn to Treat Rare Clotting Disorder,* U.S. Food & Drug Admin. (Feb. 6, 2009), http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm109074.htm; Becker, *supra* note 99, at 2.

[128] 21 C.F.R. § 25.50 (b) (2012).

[129] U.S. Food & Drug Admin., Guidance for Industry 179: Use of Animal Close and Clone Progeny for Human Food and Animal Feed (Jan. 15, 2008), *available at* http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052469.pdf (explaining the Risk Assessment process and its implication on SCNT).

[130] Bruce I. Knight, Advisory Comm. On Biotechnology & 21st Century Agric., Animal Cloning: Transitioning from the Lab to the Market 3 (Mar. 5, 2008) (providing the regulatory guidance on the market for clones animal products).

[131] *Id*. at 2.

[132] U.S. Food & Drug Admin., *supra* note 36, at 2.

[133] Fernandez-Cornejo & Caswell, *supra* note 6, at 1.

[134] Allison Kopicki, *Strong Support for Labeling Modified Foods*, N.Y. Times, July 27, 2013, http://www.nytimes.com/2013/07/28/science/strong-support-for-labeling-modified-foods.html?_r=0.

[135] Press Release, Consumers Union, FDA Will Not Require Labeling of Meat or Fish from Genetically Engineered Animals (Jan. 15, 2009) (on file with author).

[136] *Id*.; U.S. Food & Drug Admin., *supra* note 36, at 24.

[137] Benjamin Senauer, Considering the Mandatory Labeling of Genetically-Engineered (GE) Foods in the U.S. 1 (Issue Brief 2013); Alanna Durkin, *Maine Advances Genetically Modified Food Labels*, BusinessWeek, June 12, 2013; National Cotton Council, *Connecticut Approves Labeling GE Foods*, Western Farm Press, June 10, 2013.

[138] Directive 2001/18/EC, of the European Parliament and of the Council of 12 March 2001 on the Deliberate Release into the Environment of Genetically Modified Organisms and Repealing Council Directive 90/220/EEC, 2001 O.J (L106) 8.

[139] Rio Declaration on Environment and Development, G.A. Res. 151/26, U.N. Doc. A/RES/151/26, Principle 15 (June 3 to 14, 1992).

[140] *EU Register of Authorized GMOs,* Eur. Comm. Health &Consumers, http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

[141] *Id*.

[142] Eur. Comm'n Agric. & Dev., EU Register of Genetically Modified Food and Feed 43, 381 (2011), *available at* http://ec.europa.eu/agriculture/agrista/2010/table_en/2010enfinal.pdf.

[143] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on Genetically Modified Food and Feed, 2003 O.J. (L268) at Article 12.2.

[144] Pew Res. Ctr. Global Attitudes Project, Broad Opposition to Genetically Modified Foods (2003).

[145] Eur. Comm'n, Special Eurobarometer 341/Wave 73.1 Biotechnology Report 18 (Oct. 2010), *available at* http://ec.europa.eu/public_opinion/archives/ebs/ebs_341_en.pdf.
[146] *Rules on GMOs in the EU–Ban on GMOs cultivation*, Eur. Comm'n, http://ec.europa.eu/food/food/biotechnology/gmo_ban_cultivation_en.htm; Irina Ivanova, *Bulgaria Parliament Bans GMO Crops to Soothe Fears*, Reuters (Mar. 18, 2010), http://www.reuters.com/article/2010/03/18/us-bulgaria-gmo-idUSTRE62H3EJ20100318; Svetlana Kovalyova, *Italy Regions Push Minister for Official GM Ban*, Reuters (Sept. 30, 2010), http://www.reuters.com/article/2010/09/30/italy-gmo-idUSLDE68T1RX20100930.
[147] Directive 2001/18/EC, *supra* note 138, at art. 23.
[148] The Pew Global Attitudes Project, Views of a Changing World 90-91 (2003).
[149] Regulation 1829/2003, *supra* note 143, at art. 6.4, L268/8.
[150] *Which EU Countries Ban the Cultivation of GMOs?* Eur. Comm. , http://ec.europa.eu/food/food/biotechnology/qanda/d4_en.htm#d (last visited Mar. 9, 2011).
[151] Suguro Sato, Japan Biotechnology Annual Report 2008 3 (2008).
[152] GAO, *supra* note 58, at 14.
[153] U.S. Envt'l Prot. Agency, *supra* note 34; Sato, *supra* note 151, at 3; GAO *supra* note 58, at 16; *Is USDA Accounting For Costs To Farmers Caused By Contamination From Genetically Engineered Plants? Before the Domestic Policy Subcomm. of the U.S. House Oversight & Gov.t Reform Comm.*, 110th Cong. 2 (Mar. 13, 2008). (Statement of Colin A. Carter, Professor, Department of Agricultural and Resource Economics, University of California, Davis).
[154] *Is USDA Accounting For Costs To Farmers Caused By Contamination From Genetically Engineered Plants? Before the Domestic Policy Subcomm. of the U.S. House Oversight & Gov't Reform Comm.*, 110th Cong. 2 (Mar. 13, 2008) (Statement of Todd Leake, Conventional and GE grain grower, Dakota Resource Council).
[155] *Is USDA Accounting For Costs To Farmers Caused By Contamination From Genetically Engineered Plants? Before the Domestic Policy Subcomm. of the U.S. House Oversight & Gov't Reform Comm.*, 110th Cong. 1 (Mar. 13, 2008) (Statement of Harvey Howington, Vice President U.S. Rice Producers Association).
[156] *Id*. at 3.
[157] Sean McConnell, *Animal Feed Containing Illegal GM Maize Impounded*, Irish Times, http://www.friendsoftheirishenvironment.org/papers-today/13-biodiversity/9772. Because Ireland has not approved that particular GE trait, it was not allowed into the country.
[158] U.S. Trade Representative, 2010 Report on Sanitary and Phytosanitary Measures 20 (2010).
[159] U.S. Dep't of State, Cable No. 07STATE160639 (Nov. 27, 2007); U.S. Dep't of State, Cable No. 08STATE129940, FY 2009 Biotechnology Outreach Strategy & Dep't Resources (Dec. 10, 2008); U.S. Dep't of State, Cable No. 09STATE122732, FY 2010 Biotechnology Outreach Strategy & Dep't Resources (Dec. 1, 2009).
[160] Pew Initiative, *supra* note 3, at 20-21.
[161] GAO , *supra* note 58, at 4.

Endnotes: The Gold War of Romania: Sustainable Development or Irreversible Damage? *continued from page 34*

[7] Eric Reguly, *Gabriel Threatens Romania with Billion-Dollar Lawsuit*, The Globe & Mail (Sept. 11, 2013), http://www.theglobeandmail.com/report-on-business/international-business/european-business/gabriel-resources-ceo-vows-to-sue-if-romania-kills-europes-biggest-gold-mine/article14240950/.
[8] *See generally* Bates, *supra* note 6.
[9] The World Fact Book: Romania, Central Intelligence Agency, https://www.cia.gov/library/publications/the-world-factbook/geos/ro.html; Romania, *Travel and Tourism Information,* http://www.romaniatourism.com/ [hereinafter *Romania Travel and Tourism Information*].
[10] *See generally Romania Travel and Tourism Information*, *supra* note 9.
[11] Council on Foreign Relations, *The Relationship between Democracy and Development: Implications for Policy* (Mar. 19, 2003), http://www.cfr.org/democratization/relationship-between-democracy-development-implications-policy/p5778.
[12] Friedmann Mueller & Philip Mueller, *The Essentials of Good Governance*, Harvard Univ. Belfer Ctr. (Dec. 10, 2012), http://belfercenter.ksg.harvard.edu/publication/2706/essentials_of_good_governance.html.
[13] *Democracy and Development – The Missing Link*, Int'l Inst. for Democracy & Electoral Assistance (Jun. 17, 2008), http://www.idea.int/dem_and_dev_missing_link.cfm.
[14] John Scot, *Democracy is Not Enough*, Foreign Affairs, http://www.foreignaffairs.com/articles/134000/john-scott/democracy-is-not-enough (last visited Feb. 25, 2014).
[15] Francis N. Botchway, *Good Governance: The Old, The New, The Principles and The Elements*, 13 Fla. J. Int'l L. 159, 161 (2001).
[16] *See generally* The World Bank, Sub-Saharan Africa: From Crisis to Sustainable Growth (1989), *available at* http://www-wds.worldbank.org/external/default/WDSContentServer/WDSP/IB/1999/12/02/000178830_98101901364149/Rendered/PDF/multi0page.pdf.
[17] Presentation by Nayana Renukumar, Centre for Good Governance, *Good Governance: Concepts and Components*.
[18] *Id*.
[19] United Nations Development Programme, Good Governance and Sustainable Human Development 3 (1994), *available at* http://mirror.undp.org/magnet/policy/chapter1.htm.
[20] *See* United Nations Economic and Social Commission for Asia and the Pacific (ESCAP), *What is Good Governance*, *available at* http://www.unescap.org/sites/default/files/good-governance.pdf (last visited Apr. 25, 2014).
[21] Kabir Tahir Hamid, Promoting Good Public Governance and Transparency 2 (Dec. 31, 2008) (unpublished paper prepared for Two-Day Sensitization Workshop for the Commemoration of the International Day against Corruption), *available at* http://www.academia.edu/1920609/Promoting_Good_Public_Governance_and_Transparency.
[22] *Id*.
[23] *The Rosia Montana Project's Confidential Documents*, Save Rosia Montana, *available at* http://saverosiamontana.net/2013/10/the-rosia-montana-projects-confidential-documents/ (last visited Mar. 17, 2014) [hereinafter Save Rosia Montana].
[24] *Id*.
[25] See generally *id*.
[26] Law No. 182/2002 on Protection of Classified Information, Art. 15(b), Apr. 12, 2002, *available at* http://www.orniss.ro/ro/182.html.
[27] Save Rosia Montana, *supra* note 23.
[28] Salvati Rosia Montana, *All about Rosia Montana Mining Project*, http://rosiamontana.org/en/argumente/all-about-rosia-montana-mining-project (last visited Mar. 13, 2014).
[29] *Id*.
[30] Bates, *supra* note 6.
[31] Andrew Wilson & David Matingly, Statement of Significance: Rosia Montana, Carnic Massif (September 2010 with additional summary July 2011), *available at* http://users.ox.ac.uk/~corp0057/Raport-Oxford-Rosia-Montana-MD1.pdf.
[32] Raluca Besliu, *Rosia Montana: Alternative Development Paths,* Harvard Int'l Review (Jan. 14, 2014), *available at* http://hir.harvard.edu/blog/visitor/rosia-montana-alternative-development-paths.
[33] *See generally* Robert E. Moran, Review of the Rosia Montana Environmental Impact Assessment Report with a Focus on Water and Water Quality-Related Issues, *available at* http://www.rosiamontana.ro/img_upload/472936e3bca2bc61045730fbb1869240/2.raport_Moran_final.pdf.
[34] Nicolae Stefanuta, *The People vs. Gold: How Legal Action Can Rid Romania of a Bad Deal*, Georgetown Pub. Pol'y Review (Oct. 17, 2013), http://gppreview.com/2013/10/17/the-people-vs-gold-how-legal-action-can-rid-romania-of-a-bad-deal/.
[35] *Romania's Mineral Resources Agency Denies Extraction Prospects of Other Minerals than Gold, Silver at Rosia Montana*, Romania Insider (Sept. 25, 2013), http://www.romania-insider.com/romanias-mineral-resources-agency-denies-extraction-prospects-of-other-minerals-that-gold-silver-at-rosia-montana/107005/ (describing how Romania's mineral resource agency denies extraction prospects of other minerals at Rosia Montana).
[36] Law 85/2003, Art. 1, *available at* http://lege5.ro/Gratuit/gq3danjx/legea-minelor-nr-85-2003.