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Toward Rational Regulation of Genetically Modified Food

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TOWARD RATIONAL REGULATION OF GENETICALLY MODIFIED FOOD*

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I. CURRENT REGULATION OF GENETICALLY MODIFIED PLANTS AND ANIMALS

A. The Coordinated Framework

As the biotechnology industry developed in the early 1980s, it was recognized that regulation was necessary to protect human health and the environment from the potential deleterious effects of transgenic products. This recognition culminated in the promulgation of the federal government's Coordinated Framework for Regulation of Biotechnology by the White House Office of Science and Technology Policy in 1986.[1] The Coordinated Framework instituted a "comprehensive federal regulatory policy for ... biotechnology research and products."[2] It specified that bioengineered products generally would be regulated under what was the then-existing statutory and regulatory structure.[3] The foundation for this decision was a determination that the process of biotechnology was not inherently risky, and therefore, only the products of biotechnology, not the process itself, required

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[1] Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (June 26, 1986).

[2] *Id.* at 23,302.

[3] *Id.* at 23,302-08, 23,309, 23,313-14, 23,336.

oversight. On this basis, the Coordinated Framework established that existing laws and regulations were sufficient to handle the products of biotechnology.[4] This decision was based in part on a desire not to impose regulations that could hamper the development of a promising and fledgling industry.[5]

As a result of the Coordinated Framework, genetically modified products are regulated by three administrative agencies: the FDA, the EPA, and the USDA. These three administrative agencies are involved in the regulation of the genetically modified products discussed in this paper: The Food and Drug Administration (FDA) is responsible for food safety issues for transgenic crop and food-animal varieties, in addition to drug safety issues for modified pharmaceutical-producing plants or animals; the Environmental Protection Agency (EPA) handles health and environmental effects of pest-protected plants; and the United States Department of Agriculture (USDA) regulates the effect of genetically modified plants on other plants and animals in both agricultural and nonagricultural environments.[6] Because the Coordinated Framework would result in multiple agencies acting in closely related areas, two basic principles were delineated in order to guide regulatory policy. First, "[a]gencies should seek to adopt consistent definitions of those genetically engineered organisms subject to review to the extent permitted by their respective statutory authorities."[7]

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[4] *Id.* at 23,302-03; *see* NAT'L RESEARCH COUNCIL, GENETICALLY MODIFIED PEST-PROTECTED PLANTS: SCIENCE AND REGULATION 25-26 (2000) [hereinafter NRC 2000 REPORT].

[5] Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23,302-03.

[6] *See* Nat'l Research Council, Environmental Effects of Transgenic Plants 19 (2002) [hereinafter NRC 2002 Report].

[7] Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23,303.

Second, the "agencies should utilize scientific reviews of comparable rigor."[8] With the Coordinated Framework in place, the regulation of biotechnology was left to the administrative agencies.

B. The Food and Drug Administration

The FDA is responsible for insuring that all food products on the market in the United States, other than meat and poultry, are safe. In furtherance of this goal, the FDA provides voluntary premarket consultations with food companies, seed companies, and plant developers regarding the safety of transgenic foods.

The FDA's statutory authority is the Federal Food, Drug, and Cosmetics Act (FFDCA), enacted in 1938.[9] No statutory provisions or FDA regulations expressly cover genetically modified foods. Pursuant to FDA regulations, plants modified through modern rDNA techniques are not treated any differently from conventionally modified plants.[10]

Section 402(a)(1) of the FFDCA authorizes the FDA to regulate "adulterated foods," which is food that "bears or contains any poisonous or deleterious substance which may render it injurious to health."[11] In addition, section 409 of the FFDCA provides for the regulation of "food additives," which are substances that are intended for use in food, that may reasonably be expected to become a component of food, or that otherwise may affect the

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[8] *Id.*

[9] *See* Federal Food, Drug, and Cosmetics Act, 21 U.S.C. §§ 301-399 (2003).

[10] Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984 (May 29, 1992).

[11] 21 U.S.C. § 342(a)(1) (1994). "Food" is defined as "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." *Id.* § 321(f). This includes human food, animal food, pet food, and substances migrating to food from food-contact articles. 21 C.F.R. § 170.3(m) (2003).

characteristics of food.[12] A food additive must be approved by the FDA prior to being used in a food product. [13] Manufacturers, however, do not need approval for a food additive if such substance is generally recognized as safe (GRAS) by experts.[14]

Thus, both the inserted gene of a transgenic plant and the product that it expresses are food additives, unless they are GRAS.[15] With respect to genetically modified foods, the FDA has determined that "[i]n most cases, the substances expected to become components of food as a result of genetic modification of a plant will be the same as or substantially similar to substances commonly found in food, such as proteins, fats and oils, and carbohydrates," and therefore will be GRAS.[16]

The food additive manufacturer, not the FDA, determines whether a food additive is GRAS.[17] A manufacturer does not need to report to the FDA that it has made a GRAS determination, but it may do so and may receive from the FDA an affirmation that the particular substance is GRAS.[18] Thus, the FDA's regulatory requirements with respect to genetically modified food are primarily voluntary. This decision was explicitly made by the FDA based on its determination that "[a]ny genetic modification technique has the

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[12] 21 U.S.C. §§ 321(s), 348 (1994).

[13] *Id.* § 348.
[14] *Id.* § 321(s).

[15] Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. at 22,990.

[16] *Id.* at 22,985. The primary exceptions, where foods would require special review, would be where the gene transfer produces unexpected genetic results, may cause allergic reactions, significantly increases the level of toxicants, or changes the nutrient composition of the food. *Id.* at 22,993 fig.1.

[17] *Id.* at 22,989.

[18] 21 C.F.R. § 170.35 (2003). Such a determination will protect the product from enforcement actions. *Id.*

potential to alter the composition of food in a manner relevant to food safety, although, based on experience, the likelihood of a safety hazard is typically very low."[19] In 1995, the FDA conducted a safety review of the first genetically modified food product to be commercialized, the Flavr Savr tomato.[20] This review was conducted at the request of the manufacturer, who was attempting to build public confidence.[21] Since that time, the FDA has not conducted a safety review of any of the scores of other genetically modified food products that have been commercialized; however, the FDA believes that manufacturers have voluntarily consulted with it regarding each of these products.[22]

The FDA does not require that genetically modified foods be labeled as such. The basis for this determination is the FDA's conclusion that

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[19] Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. at 22,986. A challenge to the FDA's decision not to regulate genetically modified food differently from conventional food was dismissed. Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166 (D.D.C. 2000).
On January 18, 2001, the FDA published proposed revised regulations for genetically engineered food. Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706 (Jan. 18, 2001) (to be codified at 21 C.F.R. pts. 192, 592). These regulations would require manufacturers and importers to provide the FDA with premarket notification of their intent to market genetically modified foods that have not been subject to a previous premarket notification. *Id*. at 4707. These proposals, promulgated days before President George W. Bush took office, have not been finalized or acted upon since that time.

[20] *See* John Henkel, *Genetic Engineering: Fast Forwarding to Future Foods*, FDA Consumer, April 1995, *available at* http://www.fda.gov/bbs/topics/CONSUMER/geneng.html.

[21] *Id.*

[22] Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. at 4708; NRC 2000 Report, *supra* note 2, at 29; Press Release, U.S. Dep't of Health and Human Servs., FDA To Strengthen Premarket Review of Bioengineered Foods (May 3, 2000), *available at* http://www.fda.gov/bbs/topics/NEWS/NEW00726.html. The FDA has been consulted on more than fifty bioengineered plants. Office of Food Additive Safety, FDA List of Completed Consultations on Bioengineered Foods, http://www.cfsan.fda.gov/~lrd/biocon.html (last visited Sept. 18, 2005). The FDA has not required any of the transgenic plants, or their expression products, to be reviewed as food additives. NRC 2000 Report, *supra* note 4, at 29.

genetically modified products do not differ materially from, or create greater safety concerns than, their conventional counterparts.[23] To the extent that there are significant safety concerns or usage issues, such as substantial changes in composition or nutritive value, the FDA requires labeling.[24]

The FDA explicitly has waived its regulatory authority over genetically modified pest-protected plants, so long as the plants have not also been modified to express other nonpesticidal proteins.[25] These plants are regulated by the EPA as pesticides, and are discussed below.[26]

The FDA asserts regulatory authority over genetically modified fish and other animals pursuant to the "new animal drug" provisions of the FFDCA.[27] These provisions allow the FDA to evaluate the new animal drug's safety with "reference to the health of man or animal,"[28] which is interpreted to include environmental effects that impact the health of humans

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[23] Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. at 22,991.

[24] *Id.* In *Alliance for Bio-Integrity v. Shalala*, 116 F. Supp. 2d 166 (D.D.C. 2000), the court upheld the FDA's decision not to require labeling based on consumer interest. *Id.* at 181. Proponents of genetically modified food labeling point out an apparent inconsistency in FDA regulations, as the FDA *does* require labeling based on processing differences and consumer interest in certain other areas. Examples include labeling requirements for juice made from concentrate and for food that has been frozen. *See* 21 C.F.R. § 102.33 (2003) (labeling requirements for juice from concentrate); 9 C.F.R. § 381.129 (2003) (labeling requirements for previously frozen poultry).

[25] Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. at 23,005.

[26] *See infra* Part I.C; Exemption from the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Residues Derived Through Conventional Breeding from Sexually Compatible Plants of Plant-Incorporated Protectants (Formerly Plant-Pesticides), 66 Fed. Reg. 37,830, 37,835 (July 19, 2001) (to be codified at 40 C.F.R. pt. 174); *see also* Regulations Under the Federal Insecticide, Fungicide, and Rodenticide Act for Plant-Incorporated Protectants (Formerly Plant-Pesticides), 66 Fed. Reg. 37,772, 37,775 (July 19, 2001) (to be codified at 40 C.F.R. pts. 152, 174) (EPA regulations for pest-protected plants).

[27] *See supra* notes 11-13 and accompanying text.

[28] 21 U.S.C. § 321(u) (1994).

or animals other than those intended to receive the new drug.[29]

The FDA has regulatory authority over pharmaceuticals grown in genetically modified plants that are intended for use in humans pursuant to the Public Health Service Act[30] and the FFDCA. A full discussion of FDA regulations governing the approval of pharmaceuticals for human use is beyond the scope of these comments. It is sufficient to note that FDA regulations are similar to those governing transgenic plants used for food. In both cases, the FDA regulates the use of plants that might express an allergenic or toxic compound in the pharmaceutical, and protects against the introduction of nonfood material into food or feed.[31] The FDA regulations governing human drugs, biologics, and animal drugs do not specifically address biotechnology.[32] The USDA shares regulatory authority over the growth of the genetically engineered pharmaceutical-producing plants, as discussed below.[33]

C. The Environmental Protection Agency

The EPA regulates genetically modified products through its authority to regulate pesticide use and pesticide residue in food products. All pesticides must be registered with the EPA prior to their distribution, sale, or use, pursuant to the Federal Insecticide, Fungicide, and the Rodenticide Act

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[29] Council on Envtl. Quality & Office of Sci. & Tech. Policy, Case Study No. I: Growth-Enhanced Salmon 14 (2001) [hereinafter Case Study No. I: Growth-Enhanced Salmon], *available at* http://www.ostp.gov/html/ceq_ostp_ study2.pdf.

[30] 42 U.S.C. § 262-262(a) (2003).

[31] *See* Ctr. for Biologics Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep't of Health and Human Servs., FDA Guidance for Industry: Drugs, Biologics, and Medical Devices Derived from Bioengineered Plants for Use in Humans and Animals (Draft Guidance) (2002), *available at* http://www.fda.gov/cber/gdlns/bioplant.htm.

[32] *See* Nat'l Research Council, Animal Biotechnology: Science-Based Concerns 164 (2002) [hereinafter Animal Biotechnology].

[33] *See infra* Part I.D.

(FIFRA) of 1947.[34] "Pesticide" is defined under FIFRA to include any substance "intended for preventing, destroying, repelling, or mitigating any pest."[35] To register a pesticide, one must demonstrate that the pesticide will not cause "unreasonable adverse risk to man or to the environment."[36] The EPA has authority to exempt pesticides from registration requirements if it determines them "to be of a character which is unnecessary to be subject to [FIFRA] in order to carry out the purposes of [FIFRA]."[37]

FIFRA was enacted to regulate chemical substances, not biotechnological products (it was enacted prior to Watson and Crick's discovery of the DNA molecule). Based on FIFRA's statutory definition of "pesticide," however, the EPA regulates the genetic material inserted into transgenic plants to express pesticidal products, as well as the expression

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[34] 7 U.S.C. § 136-136(a) (1994). The EPA has the authority to regulate chemical substances under the TSCA, 15 U.S.C. §§ 2601-2629 (1994), but has determined that transgenic plants are not chemical substances. Statement of Policy, Microbial Products Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Toxic Substances Control Act, 51 Fed. Reg. 23,313, 23,324 (June 26, 1986). The EPA regulates genetically modified microorganisms pursuant to TSCA, defining microorganisms as chemical substances. 40 C.F.R. § 725.8(c)(1) (2001).

[35] 7 U.S.C. § 136(u) (1994).

[36] *Id.* § 136(a)(c)(8).

[37] *Id.* § 136(w)(b). The EPA will exempt pesticides where there is "a low probability of risk to the environment, and [it] is not likely to cause unreasonable adverse effects [on] the environment even in the absence of regulatory oversight under FIFRA." Regulations Under the Federal Insecticide, Fungicide, and Rodenticide Act for Plant-Incorporated Protectants (Formerly Plant-Pesticides), 66 Fed. Reg. 37,773 (July 19, 2001) (to be codified at 40 C.F.R. pts. 152, 174). The EPA has exempted pest-protected plants that are derived through conventional breeding processes from pesticide registration requirements. Exemption from the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Residues Derived Through Conventional Breeding from Sexually Compatible Plants of Plant-Incorporated Protectants (Formerly Plant-Pesticides), 66 Fed. Reg. 37,835 (July 19, 2001) (to be codified at 40 C.F.R. pt. 174). The EPA also has used this exemption process to exempt from the FFDCA tolerance requirements "residues of nucleic acids that are part of a plant-incorporated protectant." Exemption from the Requirement for a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Residues of Nucleic Acids That are Part of Plant-Incorporated

products themselves, as pesticides.[38] Thus, manufacturers of transgenic pest-protected plants must receive registration of the plants from the EPA prior to commercialization. Certain congressional members and professional societies have contended that the EPA does not have authority to regulate transgenic pest-protected plants as pesticides under FIFRA, but the regulations have not been challenged in court.[39]

In 1988, just prior to the widespread development of genetically engineered pest-protected plants, the EPA exempted plants and microorganisms with pesticidal properties from the requirements of FIFRA.[40] This exemption was intended for plants, such as chrysanthemums, that are naturally pest-protected.[41] Due to these regulations, the EPA does not regulate any plants themselves, including genetically modified ones.[42] As discussed above, the EPA does regulate the inserted genetic material and the products it expresses.

The EPA is responsible for regulating both the environmental and human health impacts of plants genetically modified to produce their own

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Protectants (Formerly Plant-Pesticides), 66 Fed. Reg. 37,817, 37,820 (July 19, 2001).

[38] Regulations Under the Federal Insecticide, Fungicide, and Rodenticide Act for Plant-Incorporated Protectants (Formerly Plant-Pesticides), 66 Fed. Reg. at 37,772-73.

[39] NRC 2000 Report, *supra* note 4, at 38. In addition, they have raised concerns that the EPA regulation lacks "formal cost-benefit analysis," that it "could damage the [technological] progress ... by overburdening small biotechnology companies and public breeding programs," and could undermine "[public] confidence in the food supply." *Id.* Regarding the first issue, the lack of formal cost-benefit analysis, it is worth noting that the registration decision takes into account the "economic, social, and environmental costs and benefits" of the pesticide. 7 U.S.C. § 136(bb) (1994).

[40] 40 C.F.R. § 152.20a (2001); *see* Pesticide Registration Procedures, Pesticide Data Requirements, 53 Fed. Reg. 15,952, 15,975 (May 4, 1988) (to be codified at 40 C.F.R. pts. 152-53, 156, 158, 162).

[41] NRC 2000 Report, *supra* note 4, at 150.

[42] *See* 40 C.F.R. § 152.20a (2001); Regulations Under the Federal Insecticide, Fungicide, and Rodenticide Act for Plant-Incorporated Protectants (Formerly Plant-Pesticides), 66

pesticides as the FDA has ceded regulatory authority over pest-protected plants to the EPA.[43] Where use of a pesticide will result in any residue being left on food, the pesticide is subject to regulation by the EPA pursuant to the FFDCA. In these instances, the EPA establishes "tolerance" levels for the allowable amount of pesticide residue that can be left on food products.[44] Currently, all FIFRA-registered pest-protected plants are exempt from tolerance level requirements because tests of these transgenic plants have not revealed a human health risk.[45]

The EPA does not regulate genetically engineered plants other than those modified to contain pesticides,[46] and it does not regulate the environmental impacts or potential impacts of genetically engineered animals.

D. The U.S. Department of Agriculture

The USDA is responsible for protecting and promoting American agriculture. Based on the principle that genetically modified plants could pose a risk to agricultural crops, the USDA oversees the agricultural safety of the movement, importation, and field testing of transgenic plants.

In order to grow transgenic plants outside of a laboratory, approval must be obtained from the Animal and Plant Health Inspection Service (APHIS) of the USDA. APHIS's authority to regulate genetically modified plants stems from the Plant Protection Act (PPA).[47] The PPA was enacted in

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Fed. Reg. at 37,774.

[43] *See* 7 U.S.C. § 136(bb) (1994). The registration process requires submission of information on the potential beneficial or adverse effects of the pesticide on human health and the environment. 7 U.S.C. § 136a(c)(2) (1994).

[44] 21 U.S.C. § 346a (1994).
[45] *See* 40 C.F.R. § 180.1155 (2001).

[46] For example, it does not regulate herbicide-resistant or disease-resistant plants.

[47] Plant Protection Act, 7 U.S.C. §§ 7701-7772 (2003).

2000, and thus, at first glance, appears to deviate from the trend of regulating biotechnology under ancient statutes. The PPA, however, essentially consolidated authority from two previous statutes that APHIS had used to regulate genetically modified organisms: the Federal Plant Pest Act (FPPA),[48] enacted in 1957, and the Federal Plant Quarantine Act (PQA),[49] enacted in 1912. Both the FPPA and PQA were originally enacted to regulate the introduction of non-indigenous plant species.[50] APHIS regulations governing genetically modified plants under the PPA are simply those established pursuant to the FPPA and the PQA.[51] No modification to APHIS's regulation of biotechnology products has been made pursuant to the PPA.[52]

In accordance with the PPA, APHIS has primary regulatory authority for all genetically modified plants except pest-protected ones.[53] As APHIS is supposed to carry out its mandate while not impeding the growth of the

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[48] 7 U.S.C. § 150aa-jj (1994).

[49] 7 U.S.C. §§ 151-164, 166-167 (1994).

[50] *See* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,342-43 (June 26, 1986).

[51] *See* Plant Protection Act, Revisions to Authority Citations, 66 Fed. Reg. 21,049 (Apr. 27, 2001) (revising the genetically modified plant regulations to change authority citations to the PPA without substantively changing the regulations); Michael R. Taylor & Jody S. Tick, Post-Market Oversight of Biotech Foods: Is the System Prepared? 25 (2003). The PPA was enacted as part of the Agricultural Risk Protection Act of 2000, pursuant to H.R. 2559. There was no Senate or House debate on the PPA portions of H.R. 2559, and there is little legislative history to indicate what Congress' intent was with respect to genetically modified plants when it passed the PPA.

[52] Where APHIS has promulgated new regulations subsequent to the enactment of the PPA, such regulations have not differed "from what [APHIS] would have proposed under the authority of th[e] applicable provisions of law that were repealed by the Plant Protection Act." Plant Pest Regulations, Update of Current Provisions, 66 Fed. Reg. 51,340 (Oct. 9, 2001); *see* Taylor & Tick, *supra* note 51, at 25.

[53] NRC 2002 Report, *supra* note 6, at 101.

biotechnology industry,[54] critics have contended that an agency charged with promoting agriculture (including the biotechnology industry), "may not be able to objectively assess the safety of new products of agricultural biotechnology."[55]

Under the PPA, anyone seeking to introduce (i.e., import, transport interstate, or release into the environment)[56] a regulated article must receive authorization from APHIS.[57] "Regulated article" includes,

> [a]ny organism which has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent belongs to any genera or taxa designated in § 340.2 [a list of known plant pests] and meets the definition of plant pest, or is an unclassified organism and/or an organism whose classification is unknown, or any product which contains such an organism, or any other organism or product altered or produced through genetic engineering which [APHIS] determines is a plant pest....[58]

A "plant pest" includes a wide variety of organisms "which can directly or indirectly injure or cause disease or damage in or to any plants or parts thereof ...."[59] This definition is very broad; any species that interacts

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[54] *Id.* at 49.

[55] *Id.* at 19.

[56] "Environmental release" is the use of a regulated article outside the physical constraints of a laboratory, contained greenhouse, or other contained structure. 7 C.F.R. § 340.1 (2003).

[57] *Id.* § 340.

[58] *Id.* § 340.1. Note that this definition is explicitly based on the organism's having been developed through genetic engineering; i.e., it regulates based on the process by which the article was produced, not based on the product. One result of the taxonomic list restriction is that vertebrates cannot be considered plant pests. *Id.* § 340.2.

ecologically with a plant could likely be considered to indirectly injure or damage it.[60]

Prior to conducting a field trial of a new transgenic plant, a developer must perform a risk evaluation on the plant to determine whether the plant may be a plant pest. No consideration of any other risks, such as other human health or environmental risks, must be evaluated prior to the field test.[61]

Authorization from APHIS can come via a notification or permitting process, each of which is aimed at ensuring that the transgenic organisms are grown and handled in a manner to prevent their escape into the environment. For most genetically modified plants, under certain conditions, simple notification of APHIS prior to release (without the requirement of receiving a permit) is sufficient.[62] Nearly 99% of all field tests, importations, and interstate movement of genetically engineered plants take place under the notification system.[63]

Permits are required for the movement, importation, and field testing of transgenic plants that do not qualify for notification and for plants denied

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[59] *Id.* § 340.1.

[60] *Id.*

[61] *Id.* § 340.

[62] *Id.* § 340.3. The notification process applies to a specified list of plants and characteristics. Requirements include: confinement; that the plant not be listed as a noxious weed or considered a weed in the area of release; that the inserted gene be stably integrated; that the function of the inserted gene be known; that the inserted gene's expression not result in plant disease; that the inserted gene be derived from human or animal viral pathogens; and that the inserted gene does not cause the production of an infectious entity, encode for substances likely to be toxic to nontarget species or to feed on the plant, or encode for products intended for pharmaceutical use. NRC 2002 Report, *supra* note 6, at 108-09.

The applicant must notify APHIS of its intent to release a regulated article. APHIS staff reviews the notification for qualification and completeness, and then sends a recommendation to state officials for concurrence. The entire process must be completed in ten days for interstate movement, and thirty days otherwise. 7 C.F.R. § 304.3 (2001).

[63] Council on Envtl. Quality & Office of Sci. & Tech. Policy, Case Study No. III: Herbicide-Tolerant Soybean 4 (2001) [hereinafter Case Study No. III: Herbicide-Tolerant Soybean], *available at* http://www.ostp.gov/html/ceq_ostp_study4.pdf.

notification.[64] APHIS uses the permitting process to evaluate potential plant pest risk and to require prevention measures to reduce risk.[65] The primary emphasis of the permitting process is confinement.[66]

An applicant can petition APHIS to determine that a certain genetically modified plant is not a plant pest (essentially that the regulated article is free from the risks outlined above), and therefore should be given "nonregulated status."[67] Plants granted nonregulated status, as well as their progeny, are no longer subject to any APHIS oversight—they may be freely planted, transported, and sold.[68] This process is the sole manner in which transgenic plants can be commercialized, and the primary, though not sole, route through which the products of transgenic plants can be commercialized (e.g., sale of an industrial protein derived from a plant).[69]

APHIS regulates transgenic pharmaceutical-producing plants pursuant to the same authority under which it regulates other transgenic plants, such as "regulated articles" under the PPA.[70] Thus, applicants must acquire a permit prior to the field test of transgenic pharmaceutical-producing plants, as such plants are specifically excluded from the notification

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[64] NRC 2002 Report, *supra* note 6, at 110.

[65] *Id.*

[66] *Id.*

[67] 7 C.F.R. § 340.6 (2001).

[68] *Id.* Prior to receiving nonregulated status, APHIS must conduct an Environmental Assessment pursuant to NEPA. 42 U.S.C. § 4332 (2000); 40 C.F.R. §§ 1500-1508 (2002).

[69] NRC 2002 Report, *supra* note 6, at 111. "[C]ommercial products have also been created from regulated transgenic [plants]." *Id.* at 120. APHIS has deregulated many genetically modified crops. APHIS maintains a list of the deregulated plants, as well as pending deregulation petitions. APHIS, Petitions of Nonregulated Status granted or pending by Aphis, http://www.aphis.usda.gov/brs/not_reg.html (last visited Sept. 18, 2005).

process.[71] Various measures must then be taken to confine the transgenic plants to the field site during the period of release, and to prevent the plants or their offspring from persisting in the environment subsequently.[72]

With respect to biotechnology developments beyond plants, the Food Safety and Inspection Service (FSIS) of the USDA is responsible for the safety of food products prepared from domestic livestock and poultry.[73] The Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) require FSIS to inspect cattle, sheep, swine, goats, equines, poultry, and food products prepared from them, which are intended for use as human food.[74] Pursuant to these acts, the FSIS has regulatory authority over genetically modified domestic livestock and poultry.

APHIS also has regulatory authority over the release of insects for pest management,[75] and presumably would regulate the release of transgenic insects in the same manner. No agency regulates research and commercialization of transgenic insects other than for their intentional release, and no guidelines exist that govern their containment or the potential

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[70] 7 C.F.R. § 340 (2001).

[71] *Id.* § 340.4.

[72] *Id.* § 340.3. Earlier regulations required that the pharmaceutical-producing plants be isolated by a 1320 foot buffer from other plants in order to prevent cross-pollination, a distance twice that used to assure purity of their seeds. Andrew Pollack, *New Ventures Aim to Put Farms in Vanguard of Farm Production*, N.Y. Times, May 14, 2000, at A1; 7 C.F.R. § 201.76 (2003); Regulations proposed by APHIS would increase the buffer zone to one-half to one mile depending on certain factors. Field Testing of Plants Engineered To Produce Pharmaceutical and Industrial Compounds, 68 Fed. Reg. 11,337, 11,338 (Mar. 10, 2003) (to be codified at 7 C.F.R. pt. 340).

Other protective techniques are being developed. These include implanting a gene to turn the pharmaceutical-producing plant a different color and harvesting the pharmaceutical-producing plants before sexual maturity. Pollack, *supra*, at A1.

[73] *See* 9 C.F.R. §§ 300.1, 300.2, 300.3 (2003) (establishing the FSIS within the USDA); 21 U.S.C. §§ 451, 601, 1031 (2003) (granting the FSIS administrator the authority to regulate the safety of domestic livestock, poultry, and poultry products).

[74] 21 U.S.C. §§ 451, 601, 1031 (2003).

ecological risks posed by their release.[76]

As evidenced by the preceding analysis, the statutory structure under which biotechnological products are regulated in the United States is based on legislation enacted decades ago, long before transgenic products were scientifically conceivable. As a result of dated statutes, and decisions made in the Coordinated Framework and thereafter, the regulations governing genetically modified products have been developed in a piecemeal, haphazard manner. Genetically modified plants and animals are now governed by as many as twelve different statutes and five different agencies or services.[77]

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[75] 7 U.S.C. § 7701 (2003); 7 C.F.R. §§ 2.3, 2.22, 2.80(a)(51) (2003).

[76] Animal Biotechnology, *supra* note 32, at 21, 88-89, 114. For a discussion of how certain existing statutes could be applied to transgenic insects, *see* The Pew Initiative on Food & Biotechnology, Bugs in the System?: Issues in the Science and Regulation of Genetically Modified Insects (2004) [hereinafter Bugs in the System], *available at* http://pewagbiotech.org/research/bugs/bugs.pdf.

[77] *See* Table 1 *infra* Part I.D.

Table 1. Regulatory Authority over Transgenic Plants and Animals.[78]

USE	STATUTE	AGENCY
Food and food additives Meat, poultry, egg products Pesticide residues	FFDCA FMIA,[79] PPIA,[80] EPIA[81] FFDCA	FDA FSIS EPA
Production of pharmaceuticals Human drugs Human biologics Animal drugs Animal biologics	 FFDCA PHS Act,[82] FFDCA FFDCA AQL,[83] VSTA[84]	 FDA FDA FDA APHIS
Production of pesticidal substances in plants	FIFRA PPA	EPA APHIS
Production of plant herbicide-tolerance Herbicide usage on plants	PPA FIFRA	APHIS EPA
Biocontrol of plants	PPA FIFRA	APHIS EPA
Biocontrol of plant pests	PPA FIFRA	APHIS EPA
Biomedical research on animals	AWA[85] HREA[86]	APHIS NIH[87]

[78] Animal Biotechnology, *supra* note 32, at 162-64; Council on Envtl. Quality & Office of Sci. & Tech. Policy, CEQ and OSTP Assessment: Case Studies of Environmental Regulations for Biotechnology 6 (2001) [hereinafter CEQ and OSTP Assessment], *available at* http://www.ostp.gov/html/ceq_ostp_study1.pdf. This Table lists the common uses of genetically modified plant and animal products, the statutes under which they are regulated, and the regulating agency under each statute. A careful reader will note that this Table lists only eleven statutes. As discussed elsewhere in these comments, the AHPA (enacted in 2002) may represent the twelfth statutory authority concerning genetically modified plants and animals. *See infra* note 101.

[79] Federal Meat Inspection Act, 21 U.S.C. §§ 601-691 (2003).

[80] Poultry Products Inspection Act, 21 U.S.C. §§ 451-471 (2003).

[81] Egg Products Inspection Act, 21 U.S.C. §§ 1031-1056 (2003).

[82] Public Health Service Act, 42 U.S.C. §§ 262, 264 (2003).

[83] Animal Quarantine Laws, 21 U.S.C. §§ 101-135 (2003).

[84] Virus, Serums, and Toxins Act, 21 U.S.C. §§ 151-159 (2003).

[85] Animal Welfare Act, 7 U.S.C. §§ 2131-2159 (2003).

[86] Health Research Extension Act, 42 U.S.C. §§ 201-300gg-92 (2003).

The multiplicity of statutes and agencies regulating biotechnology has created confusion among the regulated industry and the public, reduced clarity regarding scientific standards and requirements, and has retarded the efficiency of biotechnology development and regulation. Not surprisingly, this fractured approach to regulation has led to numerous problems. These regulatory problems are discussed and categorized in the following section.

II. REGULATORY GAPS, INCONSISTENCIES, INEXPERIENCE, AND OVERLAPS

The statutory and regulatory regime for genetically modified products described in the preceding section only partially reveals how these products are actually regulated in practice. The quality of transgenic product regulation is affected by issues of agency financial and personnel resources, agency priorities, agency decision making structures, the quality of and reliance on in-house and third-party research, agency capture, political pressure, in addition to other factors. This section analyzes deficiencies that exist in the regulation of genetically modified products.

In order to better understand these deficiencies, and to work towards their cure, it is useful to categorize them. The following four categories cover most of the regulatory problems concerning transgenic products identified here: gaps in regulation or regulatory authority; overlaps in regulation or regulatory authority; inconsistencies among agencies in their regulation of similarly situated or identical products; and instances of agencies acting outside their areas of expertise.

Gaps are a problem because of the potential for harm to human health or the environment. Overlaps cause a dead-weight loss on multiple fronts: for the regulated industry which has to fulfill duplicative requirements, for

[87] National Institutes of Health.

government and the taxpayers who pay beyond the necessary cost of regulation, and for society for whom the development and commercialization of transgenic products is inefficiently delayed. Inconsistencies are not only irrational, but they also create a dead-weight loss for industry trying to comply with the regulations and they may delay the development of valuable products. Lastly, instances of agencies acting outside their areas of expertise are inefficient and unreasonably increase the risk posed to society by genetically modified products. Each of these categories of deficiencies is discussed in turn.

A. Regulatory Gaps

1. Gaps in Environmental Review

The most striking incidence of regulatory gaps with regard to genetically modified products is the lack of EPA involvement in the review and approval of numerous products that could have a significant impact on the environment. The most significant risks posed by the introduction of genetically modified fish, for instance, are likely environmental. The EPA, however, has determined that it does not have regulatory authority over these products. The EPA also has no role in the approval or field-testing and widespread planting of genetically modified plants other than those modified to be pest-protected. Thus, the EPA is not evaluating the potential impact of transgenic pharmaceutical-producing, industrial compound-producing, herbicide-tolerant, drought-tolerant, salinity-tolerant, virus-resistant, temperature-tolerant, or disease-resistant plants on the environment.

Since the majority of types of genetically modified plants are not subject to environmental evaluation by the agency charged with protecting the nation's environment, there is the potential for unsafe products permeating the market. APHIS does not conduct environmental assessments

of transgenic plants submitted through the notification process,[88] which is currently the dominant route for the field-testing of new genetically engineered plants.[89]

Perhaps most troubling is the insufficiency of the environmental testing that APHIS engages. The National Research Council recently criticized certain APHIS environmental risk assessments for "lack[ing] scientific rigor, balance, and transparency,"[90] for containing an analysis that was "weak and inconsistent,"[91] for failing to evaluate potential impacts on nontarget organisms, for failing to consider the interactions between multiple transgenic traits, and for failing to utilize all available scientific data and information.[92] APHIS also has been criticized for "relying too heavily on existing scientific literature rather than requiring applicants [for notification] to develop new experimental data" relevant to the risks posed by the pertinent genetically modified plants being reviewed.[93] The EPA, with numerous experts trained in and routinely performing environmental risk

[88] NRC 2002 Report, *supra* note 6, at 123. APHIS assumes genetically modified plants released into the environment pursuant to the notification process to be environmentally safe based upon the notification criteria and efforts required to minimize the chance of escape in the field. *Id.*

[89] *See supra* text accompanying note 63.

[90] NRC 2002 Report, *supra* note 6, at 148.

[91] *Id.* at 149.

[92] *Id.* at 148-53, 160-66, 235. These criticisms were based on concerns that APHIS had ignored certain scientific information it had reviewed, reached contradictory conclusions on related analyses, relied on explanatory information as predictive, assumed that a lack of reported problems was evidence that problems had not occurred, used data inconsistently, failed to consider alternate options, and failed to consider interactions between different traits. *Id.*

[93] John Charles Kunich, *Mother Frankenstein, Doctor Nature, and the Environmental Law of Genetic Engineering*, 74 S. Cal. L. Rev. 807, 840 (2001).

assessments, almost assuredly would not have run into the same difficulties as APHIS.[94]

The concerns raised by the existing gaps in environmental review will be exacerbated with next-generation biotechnology developments. In addition to transgenic fish, the FDA, not EPA, has authority to review the environmental impacts of transgenic farm animals modified to produce human drugs.[95] The EPA also lacks authority over the environmental and ecological impacts of transgenic insects.[96] The FDA and APHIS, not the EPA, are the agencies that review the environmental impacts of pharmaceutical-producing and industrial compound-producing plants.[97] As discussed above, whether APHIS has the capacity to conduct sufficient environmental reviews is questionable. For similar reasons, it is also unclear whether the FDA has the expertise necessary to evaluate adequately the environmental risks posed by biotechnology.[98] The FDA is not an environmental agency and lacks expertise in critical areas concerning

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[94] Nevertheless, the EPA has been criticized for environmental scientific failures of its own. *See* Gregory N. Mandel, *Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals*, 45 Wm. & Mary L. Rev. 2167, 2211-13 (2004); *see also* SAP Report No. 99-06, Report: FIFRA Scientific Advisory Panel Meeting (2000), *available at* http://www.epa.gov/scipoly/sap/1999/december/report.pdf (criticizing the EPA's nontarget insect data requirements for genetically modified pest-protected plants as being inadequate).

[95] Council on Envtl. Quality & Office of Sci. & Tech. Policy, Case Study No. IV: Farm Animal (Goat) That Produces Human Drugs 7 (2001) [hereinafter Case Study No. IV: Farm Animal That Produces Human Drugs], *available at* http://www.ostp.gov/html/ceq_ostp_study5.pdf.

[96] Animal Biotechnology, *supra* note 32, at 21.

[97] Case Study No. III: Herbicide-Tolerant Soybean, *supra* note 63, at 52-53.

[98] Pew Initiative on Food & Biotechnology, Future Fish: Issues in Science and Regulation of Transgenic Fish 54-55 (2003) [hereinafter Future Fish].

environmental impacts such as ecology and evolutionary biology.[99] Even if the FDA's environmental assessments are adequate, it is unclear whether the FDA possesses authority to deny certain applications on the basis of environmental risk.[100] With new biotechnological developments fast approaching, it is imperative that these environmental gaps be closed.

2. Gaps Beyond Environmental Review

Regulatory gaps exist with respect to various agencies' authority beyond the concerns raised by inadequate environmental review:

> · Once APHIS grants a petition for nonregulated status for a transgenic plant, it no longer has any authority over the plant or its progeny. For instance, APHIS is unable to monitor for unexpected impacts.[101]
>
> · There is no requirement that a manufacturer notify the FDA prior to the commercial introduction of a new genetically modified product.[102] The FDA's promulgation two years ago of a proposed regulation that would require notification recognized that this gap was a problem.[103]
>
> · It is unclear whether any agency has regulatory authority over transgenic animals

[99] Animal Biotechnology, *supra* note 32, at 114-15.

[100] Gregory Jaffe, *Coordinated Framework: Structure Needs an Overhaul*, Envtl. F., May/June 2002, at 24.

[101] NRC 2002 Report, *supra* note 6, at 111, 233. In addition, if these progeny are mated conventionally with other nonregulated transgenic plants carrying different transgenes, the offspring also will be considered nonregulated, even though they will contain combinations of transgenes never reviewed. These combinations could have pleiotropic effects. *Id*.

[102] *See infra* Part I.B.

[103] *See* Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706, 4709-12 (Jan. 18, 2001) (to be codified at 21 C.F.R. pts. 192, 592) (proposed rule requiring premarket notification of FDA of new genetically modified products).

not intended for human food or to produce human biologics.[104]

· EPA lacks regulatory authority over the growers of pest-protected plants (its authority only extends to the producers of such plants).[105]

· Many APHIS requirements pertaining to preventing the environmental release of transgenic plants do not cover the release or movement of pollen.[106]

· Some genetically modified plants are not regulated on the basis that their modified trait has been conventionally bred into plants as well; this decision lacks scientific justification as the genetic modification may cause different effects than those caused by conventional breeding.[107]

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[104] Case Study No. IV: Farm Animal That Produces Human Drugs, *supra* note 95, at 14. It is possible that APHIS could exercise authority pursuant to the Animal Health Protection Act (AHPA) of 2002, 7 U.S.C. §§ 8301-8320 (1999 & Supp. 2003), to regulate genetically modified animals, to the extent such animals may affect the health of livestock (in much the same manner as APHIS regulates genetically modified plants based on their plant pest threat). APHIS authority turns on the meaning of "disease" under AHPA, a term to be defined by the Secretary of Agriculture. *Id.* § 8302(3). The Secretary may be able to define disease in such a manner as to include genetic modification of animals, although this would not be consistent with how the Secretary has defined the term previously, so whether such a definition would survive judicial review is not clear. *See, e.g.*, 7 C.F.R. § 319.59-1 (2004) (defining "disease" in another agricultural context to include "its common meaning [and] a disease agent which incites a disease"). In addition, the legislative history of the AHPA is quite sparse and does not indicate that such a broad interpretation was intended.

[105] Taylor & Tick, *supra* note 51, at 35.

[106] NRC 2002 Report, *supra* note 6, at 109; APHIS, User's Guide for Introducing Genetically Engineered Plants and Microorganisms Technical Bulletin 1783 (1997) [hereinafter APHIS, User's Guide], *available at* http://www.aphis.usda.gov/brs/usergd.html.

[107] *See* NRC 2002 Report, *supra* note 6, at 86 (arguing that the failure to regulate crops conventionally bred to contain certain traits does not justify not regulating crops genetically engineered to contain the same trait).

> · APHIS lacks the statutory authority to regulate genetically modified vertebrate plant pests and all organisms free of genetic material from plant pests.[108]

A cross-agency deficiency results from agencies' reliance on the developer's planned use for their transgenic product as the trigger for regulation, as opposed to basing regulation on the actual characteristics of the product. For example, the EPA only regulates a transgenic plant under its pest-protected plant rules if the developer of the plant plans for it to be used for its pesticidal effects. Thus, the EPA does not regulate a transgenic corn variety modified to produce a known pesticide because the developer is developing the corn for purposes other than pest resistance, in this instance for medical diagnostic procedures (is this qualification needed?).[109] Similarly, for purposes of determining whether field-testing of a transgenic plant meets APHIS's notification criteria, a modification is only considered to be for a pharmaceutical use if clinical testing of the product is proposed to the FDA.[110] Thus, the developer of the product, as opposed to APHIS, determines whether these types of transgenic plants may be prohibited from notification approval.

Other gaps exist in APHIS' notification and permitting processes. APHIS regulations state that a transgenic plant is not eligible for testing or commercialization under the notification process if the transgenes "[e]ncode substances that are known or likely to be toxic to nontarget organisms."[111] APHIS, however, defines "toxicity to nontarget species" to apply only to

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[108] Kunich, *supra* note 93, at 840.
[109] NRC 2002 Report, *supra* note 6, at 180.

[110] *See* APHIS, User's Guide, *supra* note 106.

[111] 7 C.F.R. § 340.3(b)(4)(ii) (2003).

species that feed on the plant, not on dispersed plant parts, such as seeds, pollen, or plant residue.[112] Further, allergenicity is not one of the factors considered in approving a notification.[113] As discussed above, under the notification process, there is no limit to the amount of genetically modified product that can be planted or commercialized.[114] It therefore would be possible under the notification process to grow vast quantities of genetically engineered crops that have toxic plant parts or may be allergenic.[115] This scenario appears to have occurred in at least one instance.[116]

Similarly, under APHIS' permit process, APHIS can request additional information from applicants, but cannot require the requested information.[117] This deficiency may become critical as the permit process is expected to be the primary route for the commercial production of pharmaceutical-producing plants.

Regulatory gaps also exist with respect to the failure to properly inform growers regarding the proper manner for use and containment of genetically modified crops. This failure is a root cause of the contamination that occurred in the well-covered StarLink and ProdiGene genetically modified food contamination scares.[118] Critics also have noted it as a

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[112] NRC 2002 Report, *supra* note 6, at 180-81.

[113] *Id.* at 181.

[114] *See id.* at 180-81.

[115] *See id.* at 181.

[116] *See id.* at 180-81. This instance involves transgenic corn that produces the glycoprotein avidin. *Id.* Avidin is potentially toxic to a broad array of organisms, both in the field and after harvest. *Id.* The National Research Council "questions the wisdom of allowing such plants to be grown under the streamlined notification system." *Id.* at 182.

[117] *Id.* at 110; *see also* 7 C.F.R. § 340.4 (2003).

[118] *See* Mandel, *supra* note 94, at 2203-08, 2213-16.

problem with regard to the proper planting of refuge areas so as to reduce the incidence of pesticide resistance.[119] Part of this deficiency stems from a failure of agencies to exercise their full regulatory authority, and part stems from regulators lacking authority over all entities involved in the use of biotechnological products.

The numerous regulatory gaps identified above unnecessarily increase the risk posed by genetically modified products. In addition, they increase the likelihood of future high-profile transgenic product scares that could both reduce public trust in the regulatory system and cause public opinion to coalesce against transgenic products. In either case, this would prevent society from harvesting the optimum benefit of such products.

B. Regulatory Inconsistencies

The Coordinated Framework in 1986 identified two primary priorities: that the agencies regulating genetically modified products "adopt consistent definitions" of genetically modified organisms and that the agencies implement scientific reviews of "comparable rigor" in their regulation of transgenic products.[120] Neither priority has been met.

As a result of constraints created by primary reliance on statutes that predate the advent of biotechnology, each of the three agencies involved in the regulation of genetically modified products define identical regulatory constructs differently. Pest protected plants provide an example of a genetically modified product over which all three agencies have regulatory

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[119] Rebecca Bratspies, *The Illusion of Care: Regulation, Uncertainty, and Genetically Modified Food Crops*, 10 N.Y.U. Envtl. L.J. 297, 343-46 (2002) (discussing farmers' noncompliance with refuge requirements); Gregory Jaffe, Planting Trouble: Are Farmers Squandering Bt Corn Technology? 5-6 (2003), *available at* http://www.cspinet.org/new/pdf/bt_corn_report.pdf (providing data on the number of farms out of compliance with refuge requirements in various states).
[120] Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,303 (June 26, 1986).

authority. As Table 2 shows, each of the agencies identify the regulated product and define the regulated substance differently.

Table 2. *Inconsistent Agency Definitions of Pest-Protected Plants*[121]

	EPA	USDA	FDA
Regulated Product	Plant-Incorporated protectant	Plant pest, regulated article	Food, feed, food additive
Regulated Substance	Pesticidal substance and genetic material necessary for its production	Organism engineered to contain sequences from plant pests	Human food (whole or processed), animal feed

With respect to the second priority, the National Research Council has specifically noted that the data on which the EPA and APHIS base their analyses, and the scientific stringency with which they conduct their analyses, are not comparably rigorous.[122] APHIS's risk assessment model may, in fact, bias it toward a finding of no significant risk.[123] Thus, close to two decades after the Coordinated Framework was established, neither of its priorities, both of which were aimed at consistency, have been achieved.

Other substantial regulatory inconsistencies exist. Genetically engineered pest-protected crops require premarket approval if they are intended to be used for their pest-protection properties, in line with EPA regulations;[124] all other genetically engineered food crops do not require premarket approval, including those crops modified to express a known

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[121] NRC 2000 Report, *supra* note 4, at 159 (the table reproduced above has been modified to reflect changes to agency definitions since the table was originally published). The Coordinated Framework recognized from the outset that achieving consistent definitions would not always be possible because of statutory constraints. *See, e.g.*, Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23,303 (stating that as a result of existing law, some definitions between agencies may seem inconsistent). The failure to achieve this goal, therefore, is not necessarily the result of a lack of effort on the agencies' part. It does, however, demonstrate the difficulty of promulgating consistent regulations based on statutes enacted to handle different products.

[122] *See* NRC 2000 Report, *supra* note 4, at 170-71.

[123] NRC 2002 Report, *supra* note 6, at 98.

[124] *See supra* notes 43-46 and accompanying text.

pesticide, so long as the developer is producing the crop for another purpose, as they are subject to the FDA's voluntary consultation process.[125] This differentiation lacks a sound basis in science, logic, or public policy.

In another example, when APHIS granted nonregulated status to certain genetically modified Bt crops, it did so, on the basis that EPA regulations would adequately prevent Bt resistance from arising in plant pests.[126] APHIS, however, granted nonregulated status prior to the EPA's registration process, and did not follow-up to check that the EPA had promulgated the anticipated regulations.[127] Once APHIS granted nonregulated status, manufacturers and growers had no obligation to track or keep track of the genetically modified product, thereby limiting the EPA's ability to gather data and information on the impacts that APHIS expected the EPA to prevent through regulation in the first instance.[128]

The regulatory inconsistencies identified in this section are irrational and introduce substantial inefficiencies and unreasonable risks into transgenic product regulation.[129]

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[125] *See supra* text accompanying notes 17-19; *see also* 21 C.F.R. § 170.35 (2003).

[126] *See* Bratspies, *supra* note 119, at 324-25.

[127] *See id.* at 325.
[128] *See id.* at 325-26.

[129] Instances in which agencies' regulatory authority overlap, but the agencies have reached different conclusions regarding the regulation of transgenic products, also demonstrate inconsistencies. *See infra* Part II.D.

C. Regulatory Inexperience

The StarLink corn contamination highlights both an example of an agency acting outside of its area of expertise and the potentially disastrous effects of such action. Had the EPA, or likely the FDA, been familiar with the nation's agricultural system, it would have recognized that it was impossible for StarLink corn, unapproved for human consumption, to be kept fully segregated from corn used for human food.[130] This lack of knowledge led to the most infamous transgenic food scare to date.

The numerous instances of agencies other than the EPA bearing responsibility for environmental review also present situations in which agencies are acting outside of their areas of expertise. These examples include: (1) the USDA and the FDA regulating the environmental impact of genetically modified plants other than pest-protected ones,[131] (2) the FDA regulating the environmental impact of transgenic fish and animals,[132] and (3) APHIS likely regulating the environmental impact of transgenic insects.[133]In this regard, for instance, APHIS's analysis of the likelihood of virus-resistant genes spreading from squash to weedy relatives has been criticized for not being well supported by scientific studies and lacking necessary data.[134] In part, these deficiencies were perceived to come about as the result of "inadequate expertise [at APHIS] in population genetics."[135]

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[130] *See* Barnaby J. Feder, *Companies Act To Keep Bioengineered Corn Out of Food*, N.Y. Times, Sept. 27, 2000, at C2; Charles A. Deacon & Emilie K. Paterson, *Emerging Trends in Biotechnology Litigation*, 20 Rev. Litig. 589, 614-15 (2001).

[131] *See supra* notes 25-26, 53 and accompanying text.

[132] *See supra* notes 27-29 and accompanying text.

[133] *See supra* notes 75-76 and accompanying text.

[134] *See* NRC 2002 Report, *supra* note 6, at 134-35; NRC 2000 Report, *supra* note 4, at 122-25.

[135] NRC 2002 Report, *supra* note 6, at 134.

Lack of expertise and experience has led to other problems. In evaluating the risk that certain genetically modified crops posed to the Monarch butterfly, for instance, the EPA failed to fully grasp the potential varied impact of transgenic products, and various assumptions made concerning the threat of transgenic pollen were scientifically unsound.[136]

Perhaps similarly stemming from inexperience, isolation distances required by APHIS for test plots of transgenic crops have been criticized as not being scientifically justifiable.[137] APHIS appears to have derived a required isolation distance, intended to establish a zero tolerance for contamination simply by doubling the isolation distance used by the USDA in another regulatory context in which a contamination level of 0.1% was acceptable.[138] There was no evidence that doubling the isolation distance would reduce the anticipated level of contamination from 0.1% to zero.[139] As discussed above, long distance pollen flow is poorly understood.[140] Pollen does appear to travel at least several kilometers, many times the isolation distance at issue.[141] Some have cited contamination by pollen flow as part of the cause of the StarLink fiasco.[142]

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[136] Mandel, *supra* note 94, at 2212-13.

[137] *See* NRC 2002 Report, *supra* note 6, at 125.

[138] *See id.*

[139] *Id.*

[140] *See id.*, at 66-67; NRC 2000 Report, *supra* note 4, at 80; Martin Teitel & Kimberly A. Wilson, Genetically Engineered Food: Changing the Nature of Nature 38-39 (2001). Organic farmers particularly are concerned about gene flow because the movement of genes from genetically modified plants into organic crops could render such crops non-organic. NRC 2000 Report, *supra* note 4, at 90.

[141] *Compare* 7 C.F.R. § 201.76 (2003) (stating the required isolation distances for various crops), *with* NRC 2000 Report, *supra* note 4, at 91 (discussing a study which found pollen dispersed as far as three kilometers from its source). Currently proposed regulations would increase the buffer zone for corn to between a half mile and one mile,

These problems of regulatory inexperience and agencies acting in areas beyond their expertise not only result in significant inefficiencies, but also dramatically and unnecessarily increase the risk posed by genetically modified products.

D. Regulatory Overlaps

Several types of regulatory overlap exist in the current regulatory structure. The first overlap concerns situations in which different agencies have authority over similar issues. For example, the EPA addresses food safety issues associated with plants genetically modified to produce their own pesticide,[143] whereas the FDA addresses similar food safety issues for all other genetically modified plants.[144] There is no scientific rationale for this distinction. It is the result of the historical accident of transgenic pest-protected plants falling within FIFRA's statutory language.

Similarly, both the EPA and APHIS conduct overlapping reviews regarding the impact of pest-protected plants on nontarget species. The EPA studied the potential impact of Bt corn on butterflies to determine the effect of the pesticide on nontarget species, whereas APHIS studied the potential impact of Bt corn on butterflies to determine whether it would lead to a reduced butterfly population.[145] A reduced butterfly population was

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depending on certain other factors. *See supra* note 72.

[142] *See, e.g.*, Thomas O. McGarity, *Seeds of Distrust: Federal Regulation of Genetically Modified Foods*, 35 U. Mich. J.L. Reform 403, 487 (2002) ("Still others claimed that they had innocently sold elevators StarLink®-contaminated corn when the corn they planted became cross-fertilized by StarLink® corn from neighboring fields.").

[143] *See supra* notes 43-46 and accompanying text.

[144] *See supra* notes 25-26 and accompanying text.

[145] *See* NRC 2002 Report, *supra* note 6, at 72-74; Council on Envtl. Quality & Office of Sci. & Tech. Policy, Case Study No. II: Bt-Maize 32 (2001) [hereinafter Case Study No. II: Bt-Maize], *available at* http://www.ostp.gov/ html/ceq_ostp_study3.pdf (presenting an example of overlap between the EPA and APHIS); NRC 2000 Report, *supra* note 4, at 163-65 (concluding that there is substantial overlap in this area); *see also* Regulations

considered a potential plant pest risk as it could allow greater growth of weeds that the butterflies feed on.[146] In each instance, the result is that regulatory expertise and effort is inefficiently duplicated in multiple agencies.

A second type of regulatory overlap occurs where multiple agencies request the same information about the same biotechnological product, but do not share the information. For instance, though APHIS reviews genetically modified herbicide-tolerant plants and the EPA reviews the herbicide that will be applied, these reviews are not coordinated.[147]

The worst case scenario for overlaps is for agencies to reach different conclusions concerning the same product. Such a result has occurred. Both APHIS and the EPA reviewed the potential for transgenic cotton to cross with wild cotton in parts of the United States. APHIS concluded that "[n]one of the relatives of cotton found in the United States ... show any definite weedy tendencies."[148] EPA, conversely, found that there would be a risk of transgenic cotton crossing with species of wild cotton in southern Florida, southern Arizona, and Hawaii.[149]

Under the Federal Insecticide, Fungicide, and Rodenticide Act for Plant-Incorporated Protectants (Formerly Plant-Pesticides), 66 Fed. Reg. 37,775 (July 19, 2001) (to be codified at 40 C.F.R. pts. 152, 174) (recognizing the potential for duplicative regulation in this area). In certain instances, it has been unclear whether APHIS was acting independently of the EPA, possibly producing differing levels of regulatory scrutiny, or whether APHIS lacked requisite expertise and was relying on the EPA's determinations. *See* NRC 2002 Report, *supra* note 6, at 157.

[146] *See* NRC 2002 Report, *supra* note 6, at 72.

[147] *See* Case Study No. III: Herbicide-Tolerant Soybean, *supra* note 63, at 17-18 (stating that although APHIS and the EPA are working on coordinating efforts, currently, there are no formal exchanges between the two agencies on this subject).

[148] John H. Payne, USDA / APHIS Petition 97-013-01p for Determination of Nonregulated Status for Events 31807 and 31808 Cotton: Environmental Assessment and Finding of No Significant Impact (1997), *available at* http://www.aphis.usda.gov/brs/dec_docs/9701301p_ea.HTM.

Regulatory overlap in the area of genetically modified products has led to inefficient duplicative expertise and review as well as to conflicting conclusions.

III. CURING REGULATORY DEFICIENCIES

The deficiencies identified above point directly to many of the solutions that must be implemented in a new statutory and regulatory structure for regulating genetically modified products. These solutions fall into two broad categories: closing regulatory and statutory gaps, and overhauling the division of regulatory responsibility.

A. Closing Regulatory and Statutory Gaps

Numerous statutory and regulatory gaps must be closed to provide an adequate regulatory structure for genetically modified products. The most critical gaps exist with respect to environmental protection and next-generation biotechnology.[150] The EPA should be given statutory authority to evaluate the environmental risk posed by genetically modified products, with respect to transgenic fish because of the risk that escaped fish pose to native populations.[151] Transgenic insects similarly pose environmental concerns.[152] Although the environmental risk posed by livestock is lower because of the reduced risk of escape,[153] the EPA still should have authority over all genetically modified animals. The EPA also should be able to consider the

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[149] U.S. Envtl. Protection Agency, Bt Plant-Pesticides Biopesticides Registration Action Document IIC9-IIC10 (2000), *available at* http://www.epa.gov/scipoly/sap/2000/october/brad3_enviroassessment.pdf.

[150] *See supra* Part II.A.1.

[151] *See* Mandel, *supra* note 94, at 2208-11.

[152] *See id.*, at 2201.

[153] *See supra* note 95.

environmental impact of transgenic plants other than those modified to be pest protected because of the risks of gene flow and invasiveness.[154] Currently APHIS' review of releases, which focuses on impacts to agriculture, is the only review of the environmental impact of these plants. The vast majority of this review consists of the notification process.[155]

Expanded EPA environmental review does not mean that industry expenses will significantly increase, which could slow or otherwise impede biotechnology growth. First, EPA review will likely indicate that many types of transgenic products are not significant environmental threats and can be handled through some sort of notification process.[156] It should be the EPA that makes this environmental determination, not an agency that lacks environmental expertise or resources. Second, for products of greater concern, EPA expertise should allow it to reach final determinations faster and more predictably than the current arrangement, with concomitant benefits for biotechnology developers.

The second major gap area, concerning next-generation biotechnology, also must be addressed. Regulations governing genetically modified animals for uses other than as human food or to produce human biologics must be encouraged. This is particularly important, as several animals modified to produce animal or veterinary biological products are anticipated in the near future.[157] As discussed above, the AHPA may provide

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[154] Examples of these types of plants would include, for example, pharmaceutical-producing, industrial compound-producing, herbicide-tolerant, drought-tolerant, salinity-tolerant, virus-resistant, temperature-tolerant, and disease-resistant plants.

[155] *See supra* notes 62-69 and accompanying text.

[156] *See, e.g.*, NRC 2002 Report, *supra* note 6, at 83 (stating that most genetic introductions will not pose a threat to the environment).

[157] *See* Case Study No. IV: Farm Animal That Produces Human Drugs, *supra* note 95, at 14.

APHIS with a basis for regulatory authority over such transgenic animals, but such authority is both unclear and has not been asserted.[158] Similarly, statutory authority for and regulations governing the research and commercialization of transgenic insects also needs to be developed. The lack of a clear regulatory structure in these next-generation areas may impede scientific progress.

Additional regulatory gaps must be filled within each of the three agencies. All agencies should regulate based on the potential risks of a given product, not based on how a developer classifies the product. APHIS should be given authority to monitor transgenic plants after they have been granted nonregulated status to provide for postmarket monitoring or oversight in order to be able to detect and correct any unanticipated problems.[159]

The FDA should implement its 2001 proposed regulations to make notification of the commercialization of new genetically modified food products mandatory. Though the FDA believes it has been voluntarily notified of all such products introduced to date,[160] as the role of biotechnology expands, not all developers will necessarily take this step. Absent knowledge of a particular genetic modification, the FDA has no method for monitoring whether food products have been genetically modified or contain any genetically modified component.[161]

Growers of genetically modified pest-protected plants should be made accountable to the EPA for the manner of use and containment of the

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[158] *See supra* note 74.

[159] *See* Taylor & Tick, *supra* note 51, at 44 (stating that the need for postmarket oversight is likely to change with genetic products).

[160] *See supra* note 22 and accompanying text.

[161] *See* Taylor & Tick, *supra* note 51, at 54 (stating that agencies today only respond to specific safety concerns that arise, rather than knowing which products are genetically

transgenic plants. Currently, only product developers are accountable to the EPA, and grower accountability is attempted through contractual agreements between the producer and the grower required by the EPA.[162] The contamination in the StarLink[163] and ProdiGene[164] cases, as well as recent surveys of grower compliance,[165] demonstrate that such informal control is not sufficient.

Most of the other statutory and regulatory gaps identified above have clear fixes and will not be discussed further.[166] A final point with respect to regulatory gaps should be made. Some gaps are not the result of statutory or regulatory deficiencies but result in part from a lack of scientific knowledge. Long-distance pollen flow is a prime example. It is a poorly understood phenomenon, but it has a significant effect on how numerous genetically modified crops and pharmaceutical-producing and industrial compound-producing plants should be handled. One solution in these instances is to create a market for the missing scientific data. If, for instance, agencies began to require data on pollen flow in relation to regulatory approval for planting transgenic plants under certain conditions, understanding of this critical parameter would improve rapidly.[167] Improved scientific understanding will

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modified).

[162] *See id.* at 34-36. The grower is therefore under no legal obligation to the EPA to comply with any planting restrictions. *See id.*

[163] *See* Mandel, *supra* note 94, at 2203-08.

[164] *See id.* at 2213-16.

[165] Jaffe, *supra* note 119, at 5-6 (presenting data on refuge requirement compliance deficiencies on corn farms).

[166] *See supra* Part II.A.

[167] For example, Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) liability and potential liability created a market for data on groundwater chemistry and hydrology. *See* James Salzman, *Valuing Ecosystem Services*, 24 Ecology L.Q. 887, 898 (1997) (reviewing Nature's Services: Societal Dependence on Natural

allow for more finely tuned regulation, which in turn will result in savings for industry as it will not have to comply with regulations that are inefficiently overprotective due to a lack of information.

B. Overhauling the Division of Regulatory Responsibility

In order to maximize the social welfare improvements provided by genetically modified products, instances of regulatory agencies acting outside of their areas of expertise, regulatory overlap, and inconsistent and sometimes conflicting regulation must be remedied. All three of these problems can be substantially ameliorated by shifting the division of regulatory authority over genetically modified products from the current one, based haphazardly on preexisting statutes, to a division based upon each agency's expertise and general mandate. Thus, the FDA should bear responsibility for the human health risks posed by genetically modified plants or animals intended for use as human food or pharmaceuticals; the EPA should take responsibility for evaluating the environmental risks posed by transgenic products; and the USDA should regulate the impact of genetically engineered products on agricultural crops and livestock.

This division of regulatory authority not only is inherently logical, but provides the added benefits of increased efficiency, greater human health and environmental protection, and economic savings. Placing regulatory authority for particular risks in the hands of the agency with the most expertise, experience, and relevant resources will best guarantee that the risk

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Ecosystems (Gretchen C. Daily ed., 1997)). Wetlands regulations created a market for data on wetlands vegetation and hydrology. *Id.* Both of these needs led to a much better understanding of the respective scientific issues.

Requiring industry to provide scientific information raises concerns about potential industry bias in the reporting of data. The experience with hazardous and toxic waste site clean-up, wetlands protection, endangered species surveys, and other types of environmental assessment requirements has demonstrated that regulatory agency review of industry-provided data can help to ensure accuracy and lead to greater scientific knowledge in the long run. *See id.* (discussing the improvement in the understanding of scientific matters due to CERCLA and wetlands regulation).

is properly evaluated and protected against. It will do so as quickly and inexpensively as possible. Such action also will clear up instances of regulatory inconsistency and overlap because a given risk will only be evaluated by a single agency.

One concern with such a solution may be that a single transgenic product could be regulated by multiple agencies if it presents multiple types of risks; that is, there will be certain types of overlap even under the proposed changes to the regulatory system. Because genetically modified products raise varied types of risk, it is inevitable that there will be some overlap in agency responsibility under any regulatory system. The nature of legislation and regulation themselves necessarily create overlaps and gaps, as well as over-regulation and under-regulation. Legislation and regulation require the categorization of problems or concerns in some manner. Inevitably certain issues will arise that do not fit neatly into the regulatory boxes created. Where these issues fall through the cracks, there will be a regulatory gap; where they fall within multiple boxes, there will be regulatory overlap. For efficiency and economic purposes, one goal of regulation should be to minimize these regulatory problems, while still maintaining adequate protection. The proposals provided here seek to minimize regulatory gaps and greatly reduce the existing amount of regulatory overlap.

In addition, the expense of any overlap that results from this proposal can be reduced by requiring the agencies to coordinate their actions; for instance, by designating a lead agency based on the most significant risk and requiring only a single developer submission covering all pertinent information for a given product. Under the existing regulatory system, a lead agency is usually, but not always, designated for transgenic products that fall within multiple agencies' authority. Such designation, however, is not

necessarily based on the type of risk presented and generally has not resulted in coordinated information submission requirements.[168] For instance, both the EPA and the USDA require similar information submissions on pest-protected plants.

The requirements proposed here also would force better communication among the various agencies, a problem that has plagued biotechnology regulation since its inception,[169] with increased efficiency for industry and savings for taxpayers. Most importantly, placing responsibility for a given risk with the agency best equipped to regulate it removes the cost of paying for unnecessary duplicative areas of expertise in multiple agencies, significantly reducing the expense of regulation.

It is worth noting that in most areas of regulation in the United States, the agency that has regulatory authority over a given product is usually the agency with the most expertise in handling the type of risk presented by the product. Genetically modified product regulation, however, is a product of the historical accident of transgenic products being squeezed into statutory definitions not intended for them. Shifting regulatory authority to a risk-based approach will eradicate numerous inefficiencies and minimize risks to consumers and society.

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[168] *See* Wilson Huhn, *Three Legal Frameworks for Regulating Genetic Technology*, 19 J. Contemp. Health L. & Pol'y, 1, 29 (2002) ("Despite its name, the [Coordinated Framework] has often lacked coordination.").

[169] *See, e.g.*, Recommendations and Statement of the Administrative Conference Regarding Administrative Practice and Procedure, 54 Fed. Reg. 53,493 (Dec. 29, 1989) (recommending numerous steps to improve interagency coordination in the regulation of biotechnology); Case Study No. III: Herbicide-Tolerant Soybean, *supra* note 63, at 17-18 (noting that the EPA and APHIS have not coordinated herbicide-tolerant plant review); NRC 2000 Report, *supra* note 4, at 16 (recommending improving interagency coordination in the regulation of biotechnology).