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Fear and Hope over the Third Generation of Agricultural Biotechnology: Analysis of Public Response in the *Federal Register*

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The third generation of agricultural biotechnology looms large as plant-made pharmaceuticals (PMPs) and plant-made industrial products (PMIPs) both promise new, cheaper, and more plentiful pharmaceutical drugs and industrial products, such as plastics, cosmetics, enzymes, and epoxies. At the same time, they threaten the US food supply through adventitious presence (e.g., inadvertent mixing) of PMPs/PMIPs with the traditional food supply—a concern brought home by the StarLink and Prodigene controversies in the past few years. This paper explores the third generation of agricultural biotechnology by looking at the products being developed and field tested and the regulations being implemented to address environmental release of PMPs and PMIPs. We next address the overwhelming public response to *Federal Register* notices concerning field release of PMPs and PMIPs and consider both the unprecedented volume of responses and their content, which reveals public and industry debate in terms of how to define science, governmental trust, and emotional response to the new technologies. We conclude by considering implications for not only PMPs and PMIPs, but also agricultural biotechnology in general.

Key words: agricultural biotechnology, Federal Register, plant-made industrial products (PMIP), plant-made pharmaceuticals (PMP), public opinion, risk

As the new agricultural biotechnology approaches its twentieth year, the much-vaunted technology evidences a mixed record, as the third generation of agricultural biotechnology—plants that produce pharmaceuticals and industrial products—enters the fields. Although the first-generation crops, which were modified for such agronomic purposes as insect resistance and herbicide tolerance, continue to dominate the corn, cotton, and soybean markets in the United States, the future viability of these crops are in doubt, as the European Union and Africa enacted trade restrictions, and the environmental effectiveness of these crops have been reduced through insect and weed adaptations. The second generation of genetically engineered plants—those modified for product quality characteristics such as Calgene's failed experiment with the McGregor Flavr Savr tomato and the much-hyped "golden rice"—have not lived up to expectations.

Furthermore, the US regulatory scheme, the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework) put in place in 1986, has been found wanting. Three incidents since 1999 have cast unfavorable public attention on agricultural biotechnology and its regulators. The first controversy dealt with the monarch butterfly and Bt corn (1999–2001). Here, a lab-based study found that monarch larva were harmed by a type of Bt corn in production agriculture. This finding, in turn, highlighted a gap in the Coordinated Framework: The USDA's Animal and Plant Health Inspection Service (APHIS) does not consider effects on nontarget species in field tests.

The second incident dealt with StarLink Bt corn entering the food supply of the United States and other countries. StarLink was approved by the EPA and FDA only for animal feed use, not for human consumption, but was found in the food supply in 2000, specifically in taco shells and other corn-based products. The incident pointed out the ease in which US food security was breached. It also highlighted the inability of the EPA to enforce regulations concerning what enters into the food stream.

The event most pertinent for this research was Prodigene's plant-made pharmaceutical (PMP) corn almost entering the US food supply in 2002. Here, volunteer corn plants engineered to prevent "traveler's diarrhea" were found in Iowa and Nebraska fields. This mere presence violated APHIS field test conditions. As a result, more than 500,000 bushels of soybean were destroyed and 115 acres of corn were incinerated due to cross-pollination concerns. The event exposed flaws in stringency and enforcement of the APHIS permitting system and led to even higher levels of concern over the

safety of the US food system and the ability of the Federal government to regulate it (Stewart & Knight, in press).

In spite of these incidents and the uproar they aroused, there are still high expectations for the third generation of the new agricultural biotechnology—that of plant-made pharmaceuticals (PMPs) and plant-made industrial products (PMIPs). Their promise is to provide the agricultural sector with new products that would revolutionize how drugs and other industrial products are made, making them cheaper, more diverse, and more plentiful. Examples of pharmaceutical products produced by these plants include avidin (used in medical diagnostics), tripsin (an enzyme used in drug production), hiridin (a human anticoagulant protein), a topically applied antibody that prevents the transmission of herpes, and a potential vaccine for HIV (Jaffe, 2002). Industrial products include enzymes and epoxies for industrial uses, cosmetics, and plastics to replace petroleum-based products.

At the same time, PMPs and PMIPs raise a host of new critiques based upon fears of pharmaceuticals and industrial products entering the food supply, along with the familiar critiques of agricultural biotechnology that express ecological concerns about weediness and genetic drift. This is due mainly to the current regulatory system that is not perceived as advanced enough to address the range of environmental and health concerns raised. Specifically, although the science of agricultural biotechnology and related disciplines has advanced, and the range and extent of genetically crops grown has increased since the Coordinated Framework of Biotechnology was put in place in 1986, regulations continue to be rooted in a regulatory framework stitched together from disparate elements and agencies in response to theoretical risks from limited experimental plantings (Stewart & Knight, in press; Stewart & Sorensen, 2000). Now that pharmaceuticals and industrial products have the potential to be grown outside of greenhouses and controlled conditions on a relatively large scale, with the potential for adventitious presence of PMPs and PMIPs in food crops (Mellon & Rissler, 2004; National Research Council [NRC], 2002; Taylor & Tick, 2004), the flaws and holes in the Coordinated Framework have become highlighted. The mixture of hope and fear can be seen in the debate over regulations as the scope, direction, and tenor of conflict over this third generation of technology has expanded and diversified.

In this paper, we explore the third generation of agricultural biotechnology by looking at the products being developed and field tested, the regulations being implemented to assure environmental and health safety, and public response to these regulations. Specifically, we consider trends in third-generation agricultural biotechnology field testing by analyzing APHIS databases. We next look at USDA APHIS regulations recently promulgated to address environmental release of PMPs and PMIPs. Finally, we address the overwhelming public response to *Federal Register* notices concerning field release of PMPs and PMIPs. We consider both the volume of response, which is unprecedented in terms of agricultural biotechnology, and the content of these responses, which reveals public and biotech industry debate in terms of how to define science, governmental trust, and emotional response to the new technologies.

Field Release Trends

Since 1986, when the Coordinated Framework (which used preexisting regulatory agencies and their regulations and emphasized regulation on the basis of products) was put in place by the Office of Science and Technology Policy (OSTP), biotechnology policy has undergone a series of changes. From its inception, regulations pertaining to the field release of genetically engineered plants have been relaxed, as the agency dealing with these crops, USDA APHIS, gained experience, and the economic importance of these crops, as realized by industry, grew. Table 1 suggests there have been three periods of change prior to current times. The first occurred as the regulatory regime was being put in place in 1986–87. The next period occurred five years later, as an OSTP directive led to deregulation of field release activity. Three years later, the APHIS biotech office reorganized, and field release activity was further deregulated.

The relaxation is reflected in the nearly exponential increase in field release activity, as shown in Figure 1. These data consider both the more expensive and rigorous permit track and the fast-track notification procedure. Although this data does not consider total acreage or experimental plots, it does provide us with insight into research activity involving release into the environment. From the start of field experimentation in 1987 until the most recent data in 2002, the rapid increase in this activity is linked to deregulatory activity by USDA APHIS in 1993 and 1997 (Stewart & Knight, in press).

Further analysis of the USDA APHIS field release data considering PMPs and PMIPs reveals a similar upward trend in field experimentation activity until 2001, when the three agricultural biotechnology controversies (with the Prodigene case likely having the most

Table 1. Federal regulation of field release of agricultural biotechnology.

1986	Office of Science and Technology Policy (OSTP) Coordinated Framework for the Regulation of Biotechnology.
1987	USDA Animal and Plant Health Inspection Service (APHIS) establishes Office of Agricultural Biotechnology (OAB) and Biotechnology, Biologics and Environmental Protection Division (BBEPD).
1987	USDA APHIS "Introduction of organisms and products altered or produced through genetic engineering which are plant pests or which there is reason to believe are plant pests." Start of field release permitting.
1992	OSTP "Exercise of federal oversight within scope of statutory authority: Planned introductions of biotechnology in the environment."
1993	"Genetically engineered organisms and products: Notification procedures for the introduction of certain regulated articles; and petition for non-regulated status." Simplified field release regulations for plants not considered a plant pest risk (corn, cotton, soybean, tobacco, tomato).
1996	BBEPD reorganized.
1997	"Genetically engineered organisms and products: Simplification of requirements and procedures for genetically engineered organisms." Extends nonregulated status to organisms closely related to those already deregulated.
2002	OSTP "Proposal to update field test requirements for biotechnology derived plants and establish early food safety assessments for new proteins produced by such plants." Affects USDA, EPA, and FDA.
2002	APHIS Biotechnology Regulatory Service (BRS) replaces BBEPD to regulate and facilitate biotechnology. 2,600 agricultural quarantine inspectors transferred from APHIS to Department of Homeland Security.
March 10, 2003	USDA APHIS request for comments on "Field testing of plants engineered to produce pharmaceutical and industrial compounds." increases regulatory and reporting requirements.
August 6, 2003	USDA APHIS interim rule and request for comments on "Introductions of plants genetically engineered to produce industrial compounds."

impact) led to greater regulatory scrutiny (Figure 2). This added oversight can be seen as called for, given that of the 413 total field release activities concerning PMPs or PMIPs, 75% (310) used food plants. Corn was used in 242 of these field experiments, soybean in 32, tomato in 12, and rice in 10, amplifying the potential for pharmaceutical and/or industrial product traits to enter the food supply.

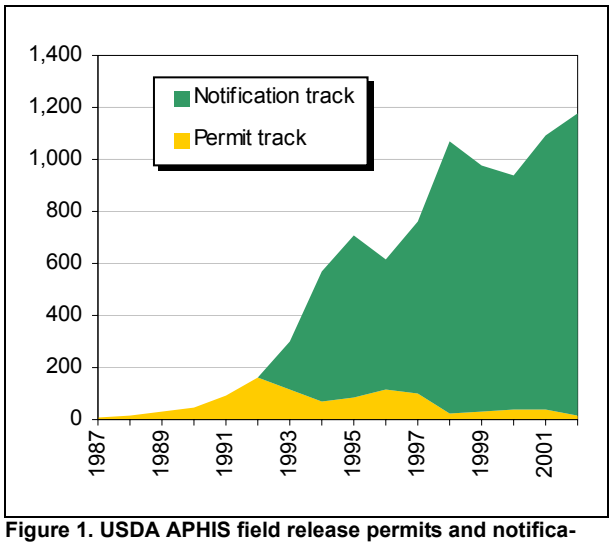

Figure 1. USDA APHIS field release permits and notifications—combined total.
Note. Data from USDA APHIS, compiled by authors.

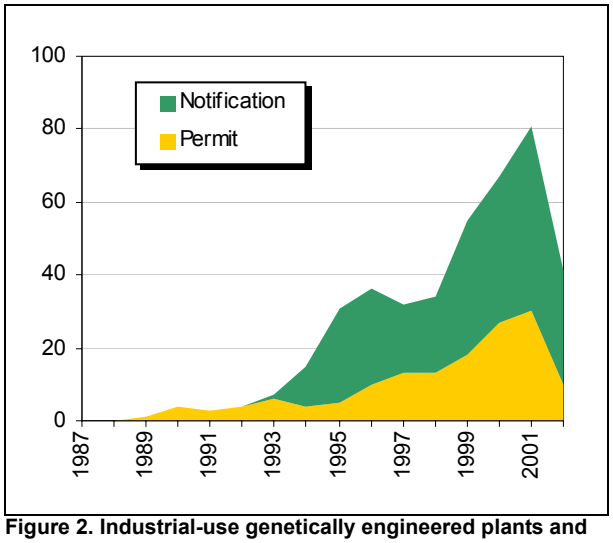

Figure 2. Industrial-use genetically engineered plants and PMPs—total of release types.
Note. Data from USDA APHIS, compiled by authors.

Consideration of trends in PMP/PMIP experimentation in light of overall field experimentation suggests a waning of activity, and presumably optimism, in these third-generation crops. Although it is difficult to pinpoint the exact cause, the flurry of regulatory activity starting in 2002 occurred after the three crises (monarch butterflies and Bt, StarLink corn, and Prodigene corn) discussed earlier. Public concern and resultant regulatory action have come to be focused on the unknown risks from the new PMPs and PMIPs.

Regulating PMPs And PMIPs

The Animal and Plant Health Inspection Service created the Biotechnology Regulatory Services (BRS) presumably to deal with PMPs and PMIPs specifically and genetically engineered organisms generally. Monitoring, auditing, and inspection changes instituted by BRS include training for APHIS inspectors, new technology use, and historical trend analysis (United States Department of Agriculture [USDA], 2003a). To carry out its workload, the 26-member BRS draws on agriculture quarantine inspectors, of which more than 2,600 have been transferred to the Department of Homeland Security (USDA, 2003b) under agreement between USDA APHIS and DHS.

Current regulations, which are undergoing modification, incorporate significant changes in how PMPs and PMIPs are regulated (USDA, 2003b). Using the PMP regulatory changes as a starting point, APHIS took immediate action to remove the notification track option, requiring complete permit track review in their recent (August 6, 2003) interim rule. For all plants genetically engineered to produce pharmaceutical and/or industrial compounds and field tested under permit, APHIS established seven conditions that can be grouped into three categories. The first category considers field test siting, the second the dedication of equipment and facilities to their production, and the third considers procedural matters.

Field test siting regulations proposed by APHIS for PMPs and PMIPs provide perimeter conditions (with special consideration for pharmaceutical corn) in order to prevent inadvertent commingling and inadvertent harvesting of food or animal feed in the following season. The second category concerns the dedication of farm equipment and facilities to the production of such crops, with planters and harvesters dedicated to the test site for the test's duration, and tractors and tillage attachments cleaned according to APHIS rules. Additionally, all equipment and regulated articles must be stored in dedicated facilities for the duration of the field experimentation.

The final requirements from the proposed rules concern submission to APHIS and approval of procedures for seed cleaning and drying. Permittees must also implement an APHIS-approved training program. To ensure that those being regulated comply with APHIS requirements, increased field site inspections that match with critical times for confinement will occur, with APHIS potentially inspecting permitted field test sites up to five times during the growing season, twice after harvest, and more frequently if necessary (Field Testing, 2003).

Response to PMP Regulations

Concerns raised by increased experimentation with PMPs and PMIPs led to APHIS changing rules concerning field testing of these crops in March 2003 (Field Testing, 2003; Introductions of Plants, 2003). Response to the *Federal Register* notice of these changes, in comparison with prior *Federal Register* notices of regulatory change, reflects the changing salience concerning the third generation of genetically engineered plants. Changes to the APHIS regulations in 1993 garnered 84 comments, whereas the more wide-ranging changes in 1997 attracted only 50 comments (NRC, 2002, pp. 104-105). However, the *Federal Register* notice of March 2003 concerning PMP field-testing requirements attracted at least 847 comments (of which 77 were late).

The rationale for the extreme increase in comments received in response to the *Federal Register* notice may be ascribed to a variety of factors. The first is the salience of the topic, as previous regulatory changes dealt with a relatively obscure technology with not easily identified risks in a well-insulated policy subsystem (Stewart & Sorensen, 2000). In this case, risks are easily identified as pharmaceuticals or industrial products and salient on the basis of previous regulatory failures to deal with ecological incidents since 1999. Second, the advent of the electronic docket with greater ease of access to the federal rulemaking process (the *Federal Register*) has expanded public participation. Most obviously, the huge response to the proposed organic standards—over 275,000 comments, with the proposal to define genetically modified crops as part of organically grown generating the most response—may be attributed in part to ease of access through the internet (Nestle, 2003). Here, of the 847 total comments, 70 were mailed in using traditional postal mail, with the remainder using email.

To better understand public response, the contents of the docket were analyzed in their entirety by visiting the APHIS reading room in Washington, DC and obtaining copies of all the comments (emailed and posted). Those weighing in on behalf of the regulations or suggesting minor, incremental modifications were the organizations expected to benefit from maintaining the status quo (or some semblance of existing regulations). Most obviously, biotechnology and bio-related companies and agricultural organizations have the most to lose from radical changes to the regulatory system. However, the

Table 2. Organizations responding to 2003 PMP *Federal Register* notice.

Biotech/biotech-related companies	Martin Marietta Aggregate; Numedloc; Monsanto Protein Technologies; Controlled Pharming Ventures, LLC.; The Dow Chemical Company; Stauffer Seeds, Inc.
Agricultural organizations	Rocky Mountain Farmers Union; North American Millers Association (NAMA); Crop Life America; Iowa Corn Growers Association; National Grain and Feed Association (NGFA) and North American Export Grain Association (NAEGA); American Seed Trade Association; Association of Official Seed Certifying Agencies; Michigan Crop Improvement Association; International Certification Services (Organic)
State government departments	Texas Department of Agriculture; Iowa Department of Agriculture and Land Stewardship; Virginia Department of Agriculture and Consumer Services; Colorado Department of Agriculture
Food production organizations	Grocery Manufacturers of America (GMA); Biscuit and Cracker Manufacturers Association (BCMA); American Bakers Association (ABA); Food Marketing Institute (FMI); Institute of Shortening and Edible Oils (ISEO); International Dairy Foods Association (IDFA); National Confectioners Association (NCA); National Council of Chain Restaurants (NCCR); National Restaurant Association (NRA); National Soft Drink Association (NSDA); Snack Food Association (SFA)
Public interest groups	Center for Science in the Public Interest; Union of Concerned Scientists; Consumer Policy Institute; Friends of the Earth—Genetically Engineered Food Alert; Center for Food Safety
Universities	SpectroTech, Inc./Clemson University; Cornell College of Agriculture and Life Sciences; Mississippi State University—Life Sciences and Biotechnology Institute

level of support given by state departments of agriculture and universities—the representatives of the public interest—suggests a level of comfort with current institutional arrangements.

A high percentage of comments came not from the agricultural biotechnology community (as had been the case with previous comments) but rather from individuals not typically associated with the biotechnology debate. As may be expected, critiques of PMP regulations were raised by individuals who appeared to have ties with the organic movement or with environmental groups such as Greenpeace. A large number of these comments were received via email, with nearly 600 of these cut-and-paste forwards. However, concerns were also raised by other politically powerful groups (see Table 2) with the Grocery Manufacturers of America and affiliated food groups expressing concern over uncontained field release of PMPs and PMIPs, especially in food and feed plants. Interestingly enough, although support for a total ban on PMPs was expressed by a small number of individuals, concern by consumer groups and traditional biotechnology opponents was tempered—likely mitigated by the potential for medical benefits from this new technology.

Analysis of Response to PMP/PMIP Regulations

Analysis of the debate shown in the *Federal Register* docket suggests a sea change of sorts when considering agricultural biotechnology. Whereas past debate focused on the definition of "nature" and "natural" and their juxtaposition with "manmade" (Plein, 1990; Stewart & Sorensen, 2000; Thompson, 1988), the tenor of the current debate, as seen in response to the *Federal Register* notice concerning PMPs, goes beyond the debate over natural and manmade to ask: "Whose science do we use and trust?" Additionally, the responses emphasize the characteristics of risk perceptions for these plants and raises questions of institutional trust. Although these comments were selected on the relatively subjective basis of expert review, they provide insight into the perceived risks of those fearing the third generation of agricultural biotechnology and may be seen as leading to greater understanding of potential fears that may be expressed among the general public.

Table 3 provides a selection of statements concerning science being used. The pro-status-quo science comments give the perspective of those companies with an economic stake in the regulations allowing continued experimentation. In these comments, "sound science" is conflated with "common sense" and the status quo of applying regulations concerning conventional crops to the third generation of agricultural biotechnology. If there are any changes to be made, they are incremental changes to permit conditions.

Those responding critically to the proposed field experimentation conditions likewise used science as a reference point, showing the inadequacy of the decision rules used by USDA APHIS. In this case, respondents suggested that science was not being utilized to change the regulations. Instead, according to them, the politics of corporations and greed was given preeminence. Comments proffered ranged from specific questions concerning how buffer parameters were arrived at, to what may be construed as anger over ignorance of biology and

Table 3. Trans-science debates.[a]

Pro-status-quo science	• "We favor continued evaluation of all rules and embrace changes based on sound scientific data and common sense application." (Stauffer Seeds Inc.; 293) • "Regulatory policies and decisions must continue to be based on sound science to ensure that biotechnology-derived products are being held to the same high standards of health and environmental safety as their conventional counterparts." (Monsanto Protein Technologies; 654) • "We support the efforts of regulatory agencies including APHIS to utilize a science-based coordinated regulatory framework for the proper development and implementation of plant biotechnology derived pharmaceuticals." (The Dow Chemical Company; 660) • ". . . generally workable. Some of the conditions appear to be subjectively derived rather than based on science and existing crop practices." "Permit conditions should be adjusted for future years allowing for application of science that eliminates a pollution concern." (Iowa Biotechnology Association; 753)
Anti-status-quo science	• "Open air testing of this technology is insane. Didn't anybody there study biology?" "This biotechnology initiative pretends to be based on science but it is based only on greed and an arrogantly willful ignoring of basic ecology and of the risks to humanity and the natural world." (750) • "Scientific evidence points to the fact that the proposed regulations will fail to protect our food supply and environment from drug contamination." (625) • "Given generally-accepted science about pollination, it is unwise and imprudent for the USDA APHIS to allow ANY outdoor growing of plants that are genetically engineered to contain pharmaceutical and industrial chemicals." (299) • "Both experience and science-based research tell us that no system for keeping pharmcrops separate will ever be able to contain 100% of every seed kernel, plant pollen and grain kernel generated from crops grown in agricultural fields." (661) • "Where is the science that shows how the different distances for different plants were arrived at?" (669) • "I am befuddled (by the 1 mile buffer). As a mother, wife, and strong supporter of the organic foods movement, I am gravely concerned. . . . Please keep these genetically modified foods in the labs where they belong." (716)

[a] *Numbers in parentheses following individual comments refer to the comment number in the docket.*

ecology as applied to agriculture. This conflict over whose science is "sound science" and whose is, by inference, "junk science" reflects the "trans-scientific" nature of the debate, where the rhetoric of politics meets the uncertainty of science, especially in such a rapidly expanding and poorly understood field as genetic engineering.

In addition to conflict over the application of science, perceptions of the risk(s) posed by PMPs appears to correlate with findings in the psychometric literature concerning the characterization of risk (Slovic, 1992). Specifically, in this literature, two factors define risk perceptions. The first factor, *unknown risk*, is made up of such characteristics as (a) how observable it is, (b) whether it is known to those exposed to it, (c) the immediacy of its effect, (d) how old the risk is, and (e) whether it is known to science. The second factor, *dread risk*, is composed of characterizations of: (a) how controllable the risk is; (b) how much dread (i.e., fear) it raises; (c) how catastrophic, (d) fatal, (e) equitable, or (f) risky to future generations it is; (g) if it is involuntary or (h) easily reduced; and (i) if the risks increase (Slovic, 1992). There is a good deal of overlap in characterization of risk in both factors—overlap that appears in comments concerning plant-made pharmaceuticals (Table 4).

Comments that may be characterized as reflecting the unknown risk factor(s) are obviously those comments that convey concern over knowledge of the consequences of field experimentation with PMPs (and by inference, PMIPs). Other aspects of the unknown risk factor offered in comments concerns how familiar the technology is, with respondents referencing Frankenstein's monster, mother nature's revenge, and playing God while discussing humans' inability to regulate nature.

Dread risk is reflected in respondents' perceived lack of control, perceived potential for catastrophic disaster that increases over time while inequitably affecting future generations, and fear over the effects of PMPs entering the ecosystem and food supply. Those expressing concern over control of PMPs stated that it is "a technology out of control" that is too dangerous to be in the field and that, as a result, the health of Americans is being used for experiments. Linked with the uncontrollable nature of PMPs is the belief that not only do they pose the potential for ecological/scientific disaster, but that this risk will increase to affect future generations inequitably. Likewise, although fear is not a separate construct, it is tied to concerns over the effects of PMPs and reflected in statements of concern, fear, perceptions of danger, and being horrified.

Table 4. Risk perceptions.[a]

Unknown risk factor	**Unknown**	• "UNKNOWN CONSEQUENCES IS TOO GREAT FOR SUCH EXPERIMENTATION TO BE ALLOWED." (712) • "Please respect the Precautionary Principle which dictates common sense and restraint in the face of unknown risks." (648)
	Unnatural	• "[PMPs] an idea worthy of Dr. Frankenstein. My family and I do not want drugs in our food." ". . . cannot regulate nature." (697) • "I know that splicing and dicing of DNA and genes and everything else in all growing this is all the rages these days. . . . Will mother nature not come back with revenge of her own?" (666) • "To me it sounds like the pharmaceutical companies (who are very rich) are playing God. This is very scary business. . . ." (756)
Dread risk factor	**Uncontrolled**	• "GM crop production is a technology clearly out of control." (754) • "Stop experimenting with the health of the American citizens by exposing our food supply to drug contamination." (633) • "Biotechnology [is] far too dangerous for anything other than stringent clean room laboratories." (731)
	Disaster and intergenera-tional equity	• "Everybody knows that pollen, air and 'biopharm'crops are an ecological disaster waiting to happen." (642) • "[PMPs will] lead to a scientific disaster the likes of which we have never seen before" ". . . spread throughout the world's complex and sensitive ecosystem." (629) • ". . . taking chances with untested drug crops that could poison our human and animal food supplies." "Contaminating our food source would be the last step in the ultimate human extinction." (733) • "Do you have the common every day sense to realize that genetically engineered crops pose one hell of a threat to health of future generations?" (649) • "DO YOU KNOW WHAT YOU ARE UNLEASING [*sic*] ON US AND FUTURE GENERATIONS FOREVER?" (689)
	Fear	• "I am horrified that your proposed regulation titled 'Field testing of plants engineered to produce pharmaceutical and industrial compounds' would practically guarantee that food crops will be contaminated by drugs and industrial chemicals." (L-19) • "I am very concerned at the idea of bioengineered crops grown close to crops for human (or animal) consumption." (734) • "I have been studying the issues. . . ." "It is clear there are grave dangers." (735) • "I am worried about genetically engineered agriculture. I am not a technophobe, nor a person who is terrified of new things. However, I fear that without proper testing . . ." (691)

[a] *Numbers in parentheses following individual comments refer to the comment number in the docket. Numbers preceded by the letter L indicate comments that were received late.*

Finally, there is a level of outrage expressed in these comments. Respondents are angry over what they perceive being done to them by large corporations and pharmaceutical companies. The lack of control has understandably given rise to anger. This anger is then focused on federal government agencies responsible for regulation (specifically the USDA) as well as on the government in general. Such anger can be categorized as being over regulatory capture and/or perceived negligence by the government regulators (Table 5).

Regulatory capture, in which the USDA and other government agencies are seen as beholden to the pharmaceutical/biotechnology industry, is perceived by a large number of *Federal Register* respondents. Respondents charge that corporate personnel are in the regulatory agencies, with movement back and forth from government to industry. There is also belief in more obvious and blatant corporate influence on governmental policy making and implementation. Subjects see that regulations may be easily waived, due to the wording of the PMP proposal. Furthermore, concerns were raised over the provision of science by industry and the need for agencies not to take the industry's word regarding findings. In other words, the biotechnology industry is not to be trusted, and any risk or cost should be borne solely by them.

Another prevalent and broad concern raised by respondents was willful negligence by USDA in carrying out their regulatory duties. Concern and anger was expressed by a number of respondents. References were made to US farmers and citizens, as well as those throughout the world, being unwilling subjects in "mad science" and experimentation. In one case, the threat posed by PMPs was seen as greater than that posed by terrorists. Moreover, USDA was seen as siding with the

Table 5. Institutional trust.[a]

Capture	• ". . . recklessness I find inexplicable . . . even given the interpenetration of corporate personnel with that of regulatory agencies." (681) • ". . . PUBLIC TRUST—I do not feel protected by the USDA. . . . Regulations can be waived at request of biotech companies." (698) • "It is clear there are grave dangers." "The USDA should withdraw the proposed rules and explain in a detailed EIS, prepared with the research and knowledge of individuals who are not connected financially with pharmaceutical and chemical companies." (726) • "Ther [*sic*] are too many ugly things going on in agriculture today supposedly in the name of science that have not been studied to the degree they should have been. Just because a major corporation says it has done studies doesn't mean FDA or EPA should take their [*sic*] word for it." (760) • "I am disappointed to learn that important genetic engineering issues will be discussed later this week at a USDA public meeting that is cosponsored by a biotechnology-industry funded group." (732) • "Since private industry is the profit seeker and profit taker . . . the risk and costs should be theirs. . . ." "Be cautious. Be overly conservative. Please do not bend to [industry]." (737)
Negligence	• "PLEASE PEOPLE, WAKE UP!! THIS IS CRAZY." (724) • "I am vehemently and totally opposed!" ". . . much more threatening to our 'Homeland Security' than outside terrorist activity." (736) • "Our ecosystem is not a laboratory!" (635) • "How can you justify killing us slowly?" (759) • "The government supports this mad science against the desires of the people of the world." (644) • "[Regulations show] a stunning disregard for America's farmers and the citizenry dependent on the food they grow." (L-39) • "I have been continually appalled at the USDA's lack of foresight in dealing with genetic engineering." (638) • "USDA must act in public's interest to ensure the safety of our food supply." (639) • "I am disturbed to learn USDA (PMPs) to be grown with such lenient regulations." (729) • "Please take into consideration the views of the little people." (762)

[a] *Numbers in parentheses following individual comments refer to the comment number in the docket. Numbers preceded by the letter L indicate comments that were received late.*

powerful against the little people—those whose interests USDA was to serve.

Conclusions

The new agricultural biotechnology is at a critical nexus. The first generation of its crops—Bt corn, Bt cotton, and RoundUp Ready soybean, which make farming easier—dominate the marketplace without general public awareness of their consumption (Pew Initiative on Food and Biotechnology, 2003; Shanahan, Scheufele, & Lee, 2001). The second and third generations of this technology have not exhibited its value; only the promise of new products can be touted. This lack of perceived benefit, coupled with very public failures of the federal regulatory system in at least three circumstances, has given rise to changes in the regulatory arena and has aroused greater concern than previously had been the case.

Chief among these new agricultural biotechnology products with high levels of perceived benefit and risk are plant-made pharmaceuticals. These PMPs are marketed as providing cheaper, more plentiful, and safer pharmaceuticals by using plants as factories. However, concerns raised by Prodigene's failure to effectively control its field experiment aroused public suspicion and led to tightened regulations. PMIPs likewise raise concerns, although not to the extent PMPs have; potentially due to both, the USDA and EPA, with an eye towards postmarket concerns, are currently considering restructuring how they regulate genetically engineered plants.

Concerned citizen and corporate response to the proposed USDA APHIS regulations gives insight into the extent and types of concerns raised. Although a number of comments received in response to the *Federal Register* notice were cut-and-paste email forwards and may not reflect the depth and breadth of concern, many more enunciated very real concerns. Most obviously, and perhaps most pertinently, issues raised by the food industry over adventitious presence of PMPs and PMIPs in food plants suggest a modicum of concern that very well might sway regulatory activity.

However, in the end, it is public perception that matters most. Public support for the new technologies and confidence in government regulation will establish the likelihood of PMPs and PMIPs (as well as other genetically engineered plants) being grown. Respondents to the *Federal Register* notice show a lack of confidence in the science being used to set current and proposed stan-

dards, stating that the technology pays little attention to basic principles of ecology. Furthermore, stated perceptions of the risk correlate strongly with psychometric theory of risk characterization. Respondents see the risk as unknown and unnatural, perceive it as out of control with disastrous repercussions for future generations, and fear the immediate and long-term ramifications. These risk perceptions are reflected in the absence of institutional trust possessed by respondents who perceive the responsible agencies—especially USDA APHIS—as negligent in their duties to protect the American food supply, and as captured by those companies developing these plants. In most cases, anger is the underlying theme.

Although respondents' concerns may be dismissed as representing fringe interests (in this case, environmentalists and those wishing to preserve access to organic foods), they provide a perspective of risk that may become commonplace if not addressed. Consent for the use of this new technology has not been obtained from the American public; instead, consent has been assumed as food products containing genetically engineered plants have entered the food supply over the past decade. To maintain the support of the American consumers and reap the benefits of new products produced through the new agricultural biotechnology, including (but not limited to) plant-made pharmaceuticals and plant-made industrial products, industry and regulatory agencies must address and assuage concerns such as those brought up in the *Federal Register* notice discussed here.

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