

August 3, 2011

Mr. Tom Vilsack, Secretary
U.S. Department of Agriculture
1400 Independence Ave., S.W.
Washington, DC 20250

Dear Secretary Vilsack,

We, the undersigned, urge you to strengthen USDA oversight of genetically engineered (GE) crops by creating fair regulations to protect US food security, diversity, and importantly – farmer and consumer choice. We support a strong, science-based regulatory system that prioritizes the interests of American farmers and consumers. The principle guiding our recommendations below is that a science-based regulatory system will best serve all growers, whether they choose GE, conventional or organic production systems.

We applaud your recognition of the need to establish protections for conventional and organic farmers and their markets. We also appreciate that powerful political interests favor weakening the already inadequate system. However, it must be clearly understood that such a weakening would undoubtedly cause serious harm to the interests of American agriculture as a whole, as discussed further below.

As you know, USDA's Animal and Plant Health Inspection Service (APHIS) has been at work since 2004 on the first major revision of USDA GE crop regulations since they were established in 1987. A major purpose was to implement additional statutory authority from subsumption of the Plant Pest, Noxious Weed and Plant Quarantine Acts under the Plant Protection Act of 2000. Some of us have closely followed and participated in the rulemaking process. Through 2007, we had hopes that at least somewhat improved regulations would result. These expectations were not met in October of 2008, when the Bush Administration issued a proposed rule that set the stage for wholesale deregulation of GE crops. Under the current rules, any genetically engineered plant that contains DNA from, or is developed with the use of, plant pest organisms must be reviewed for environmental safety by USDA. Virtually every GE plant is covered by this regulatory regime. In 2008, however, USDA proposed that it would eliminate this system and instead review only those engineered plants that are themselves plant pests or noxious weeds. This change would result in the great majority of biotech crops—corn, soybeans, canola, vegetables, trees and grasses—falling outside of USDA's regulatory scope from the very start.¹

We present our detailed recommendations for the final rule in Appendix 1. We emphasize here that it must be altered from the 2008 proposal such that it covers all genetically engineered crops, without exception, as recommended by the National Academy of Sciences (NAS). As the NAS committee explained, use of genetic engineering as the

"trigger" for APHIS regulation is scientifically sound and does not conflict with a GE product-focused regulatory regime.² It is also more transparent than the system recommended in the 2008 proposed rule. Both the American public and foreign nations expect USDA to assess all GE crops. In the case of foreign markets, the proposed rule would set the stage for potential rejection of U.S. agricultural commodities contaminated with GE crops that had not undergone proper review by APHIS. Domestic food companies may also reject such GE-contaminated supplies.

Additionally, USDA should make full use of its noxious weed authority under the Plant Protection Act to forestall harms ensuing from deregulation of GE crops. These include: 1) Economic harms to non-GE markets from the judiciously recognized environmental impact of GE crop gene flow to conventional and organic crops; and 2) Harms to the interests of agriculture and the environment from GE herbicide-resistant crop systems, which include proliferation of noxious resistant weeds and crop damage from herbicide drift.

With regard to drift, there is substantial evidence that emerging, multiple-herbicide resistant crops will lead to dramatic increases in the spraying of volatile herbicides prone to off-target movement, triggering minor to serious damage to crops, trees, and other vegetation in nearby areas. There is no basis in law or regulation to presume that the U.S. EPA will mitigate such damage, since the Agency relies on pesticide registrants to address drift issues through label restrictions and guidance advanced by the registrants and accepted without review or judgments regarding efficacy by the Agency. Under your leadership, USDA has sought to reduce the need for and reliance on litigation in agriculture, especially lawsuits that pit farmers against their neighbors. Unless the USDA and EPA set clear and binding limits on where and how volatile herbicides subject to drift can be used on GE herbicide-resistant crops as a condition of deregulation, the stage will be set for chaos in rural areas.

We address these and other aspects of the final rule below.

Regulation Does Not "Stifle" GE Crop Innovation

Before discussing this further, however, it is important to clear away a widely propagated myth: that GE crop innovation is "stifled" by the current regulatory regime. Not a single promising GE crop has been blocked or hindered by this extremely unprotective system.

Under current rules, any legitimate institution or person wishing to conduct an outdoor field trial ("environmental release") need only submit basic information about the experimental GE crop, the conditions and location of the trial to APHIS. Since the year 2000, 93.7% of GE crop field trial permits have been issued under the streamlined "notification" system introduced in 1993.³ The GE crop developer "notifies" APHIS of its plan to conduct a field trial, and APHIS responds within 30 days with a *pro forma* "acknowledgement."⁴ A single "acknowledgement" confers permission to field test a single crop, but in some cases covers over a dozen different GE varieties of that crop, planted on thousands of acres in a dozen or more different states.⁵ APHIS does not prescribe gene containment protocols for notification field trials; rather, developers merely "self-certify" their compliance with loosely defined "performance standards." APHIS does not require

submission of field trial protocols, and rejected the recommendation of USDA's Inspector General (IG) that it do so for purposes of review and distribution to inspection officers.⁶ The IG also found that many notification field trials went uninspected, and that field trial locations were often not specified.

GE crops that produce pharmaceuticals or have similar traits of special concern (6.3% of field trial permits since 2000) require somewhat more oversight, but only marginally so. Permit field trials can also be thousands of acres,⁷ and 85% of the permits inspected by the IG listed the company's business address as the planting location.⁸ APHIS has not conducted a single environmental assessment of a GE crop field trial in the past four years.⁹

In short, APHIS under its current rules permits dozens of GE crop varieties to be grown on thousands of acres in multiple states, without prior environmental assessment, prescribed gene containment protocols, review of protocols, or (often) on-the-ground inspections. APHIS is frequently unaware of field trial locations. Nothing about this system can be called "stifling." It has been designed to make field-testing GE crops as easy and inexpensive as possible. This is one reason that USDA's regime has failed to contain gene flow from experimental GE to commercial crops, in some cases with extremely serious consequences for farmers, as discussed below.

If GE technology developers have not delivered crops with promised new traits, the reasons have nothing to do with "overregulation." Rather, it is due to serious technical obstacles,¹⁰ which entail a high failure rate¹¹ and thus high costs of development. This should not be surprising. Enormous losses due to an extremely low success rate are well-documented in medical biotechnology,¹² where similar techniques are used, and are common to the early years of most new technologies. Ernst and Young reported that publicly traded biotechnology companies suffered \$45 billion in cumulative losses from 1976 through 2004,¹³ while The Wall Street Journal has likened investments in biotechnology to "the ultimate roulette game."¹⁴ Another important factor is gene patents, which often remove valuable biotechnological traits and tools from the public sphere, necessitating the payment of license fees or the creation of "work-arounds" to avoid these fees.¹⁵ Still another reason is the strong R&D focus on developing crops with tried and true traits, which diverts resources from more high-risk ventures on novel traits. For instance, herbicide-resistance is particularly favored by large and small firms alike as being a well-proven trait and as offering profitable "synergies" between GE seed and herbicide sales.¹⁶ Over half of GE crops pending deregulation decisions (12 of 23) are herbicide-resistant.¹⁷

Those who blame the regulatory system for the failures of this relatively new and thus failure-prone technology do not appear to be basing their opinions on empirical fact, which fails to support this position.

Conventional Crop Growers Victimized by Inadequate GE Crop Regulation

In discussing the tenets of an adequate regulatory regime, it is important to understand that GE crop regulation is of great importance not only to organic, but to conventional growers, who are equally threatened by inadequate regulation.

On July 1st of this year, attorneys for 11,000 American rice farmers announced a \$750 million settlement with Bayer CropScience for damages these conventional growers suffered due to the contamination of their rice harvests with experimental LLRICE601.¹⁸ Prior decisions and settlements totaled about \$200 million (see Appendix 2), bringing compensated damages to near \$1 billion. APHIS could have prevented this. APHIS could and should have required field trial operators to adhere to prescriptive, redundant gene containment protocols, and backed it up with regular inspections and fines for violators. If APHIS had done this, over ten thousand farmers would have been spared the ordeal of substantial income loss, stressful uncertainty over their family's livelihood, and no doubt grueling entanglement in the judicial system. In Appendix 1, we recommend that the final rule stipulate pharma crop-level gene containment protocols for all GE crop field trials, and that the proposed "low-level presence" regulations be rejected.

In the wake of the LLRICE601 episode, Congress ordered APHIS in the 2008 Farm Bill to tighten ship to prevent future contamination episodes.¹⁹ Unfortunately, USDA has failed to fulfill this Congressional mandate within the stipulated 18 months. Three years have now passed. Federal courts have also reversed several USDA deregulation decisions, in part from USDA's failure to address GE crop gene flow.

As you know, StarLink contamination in 2000/2001 caused similar income loss to Midwestern growers of both conventional and fully approved GE varieties of corn. Here too, export markets penalized U.S. farmers for inadequate regulation, which permitted a corn unapproved for human consumption to widely contaminate the food supply. As with LLRICE601, messy and resource-draining legal proceedings filled the gap left by inadequate regulation. The Government Accountability Office (GAO) describes these and four other major GE crop contamination episodes.²⁰ Hundreds of lesser incidents have also occasioned losses to farmers.

One might argue that biotech companies and growers have by now become more responsible and sensitive to the need for gene containment, yet the facts do not support this view. Roundup Ready alfalfa has already been detected contaminating conventional or feral plants on at least 63 occasions (Appendix 3), indicative of much broader, undetected, contamination. During this period, no more than roughly 1% of alfalfa acres was Roundup Ready. More widespread gene flow is undoubtedly occurring now, and will expand in the future, for several reasons. First, RR alfalfa adoption will likely increase substantially beyond 1% (Forage Genetics projects 51% adoption in ten years), and the frequency of GE gene flow events increases with GE crop acreage. Second, most of these episodes occurred after court-ordered stewardship measures were imposed – measures specifically intended to prevent such gene flow. Because those measures lapsed with USDA's unconditional deregulation, RR alfalfa gene flow will be still less constrained going forward. Contractual provisions are extremely unlikely to prevent or mitigate gene flow, due to lack of enforcement stemming from conflict of interest.²¹ In Appendix 1, we recommend a commercial permitting system to give USDA continuing oversight over commercialized GE crops to better prevent such harms.

Lax Regulation Means Loss of Export and Other Market Opportunities for Conventional and Organic Growers

Our competitors among exporting nations do not share the U.S. government's unbalanced approach, which facilitates biotech production at the expense of conventional and organic systems. For instance, the Brazilian government's EMBRAPA is actively promoting cultivation of conventional soybeans to better secure for Brazilian farmers this profitable market, which offers substantial premiums (\$0.57 to \$1.14/bushel) over biotech soybeans.²² EMBRAPA is committing resources to conventional soybean breeding, and conducting "field days" to educate growers about the advantages of non-GE soybeans.²³ Brazil is clearly not "anti-GMO;" the nation's farmers also grow GE soybeans and corn. Rather, Brazilian authorities recognize a profitable market opportunity for their nation's farmers, and are pragmatically assisting them to exploit it.

In the United States, the threat of gene flow and herbicide drift from GE crops is a major constraint inhibiting farmers from growing more conventional and organic crops to take advantage of these high-value markets. An organic and specialty grain handler has "offshored" production of organic corn seed to Argentina, though he would rather employ American farmers, because it is impossible to ensure seeds uncontaminated with GE content.²⁴ As detailed in a previous letter,²⁵ organic growers sometimes have their produce rejected due to GE contamination. This happens even though they have not lost their organic certification status. Some farmers who would rather grow conventional instead adopt Roundup Ready crops to protect themselves against devastating Roundup drift from a neighbor's field.²⁶

USDA ERS researchers note that the domestic supply of several important organic crops (including soybeans and corn) is not sufficient to meet demand, necessitating imports.²⁷ In fact, 38% of organic handlers rely on imports for some or all of their organic products.²⁸ Imports represent lost opportunities for American farmers in this high-value market. It is an unfortunate state of affairs when the world's leading grain producer is unable to produce sufficient quantities of organic soybeans and corn. While there are multiple reasons for shortages of domestic organic supplies, the threat of GE contamination is clearly one important factor. Commercial permits for GE crops that stipulate gene containment and (in the case of HR crops) herbicide drift prevention measures would go a long way towards making organic and non-GE production a more viable option for American farmers.

Other measures are also needed. Soybean breeders in several states report a shortage of conventional soybean seeds due to high demand,²⁹ while 40% of Illinois growers report that they do not have access to high-quality, non-Bt corn hybrids.³⁰ Like EMBRAPA, USDA should stimulate public sector breeding efforts to increase the availability of high-quality conventional and organic seeds for those growers who wish to grow them. Unfortunately, USDA has repeatedly failed to provide even minimal funds for conventional breeding programs, once again despite clear Congressional directives to do so.³¹

Serious Weed and Other Agronomic Problems Ensuing from Inadequate Regulation

Gene flow from biotech to non-GE crops is not the only reason to strengthen oversight of GE crops. Biotech farmers would also benefit from enlightened regulation.

Glyphosate-resistant crop systems have triggered an epidemic of glyphosate-resistant weeds, which constitute one of the most serious challenges facing American farmers. Agronomists have recently sounded the alarm about weeds resistant to multiple herbicides (usually including glyphosate).³² In certain cases, these noxious resistant weeds threaten to put chemical-intensive growers out of business;³³ in others, they are on the verge of making continued cultivation of biotech and conventional soybeans impractical in some Midwestern fields.³⁴ Industry-sponsored stewardship plans have been completely ineffective at forestalling resistant weeds. In some cases, firms have even given farmers self-serving advice that has exacerbated rather than prevented them.³⁵ In Appendix 1, we recommend that USDA institute mandatory weed resistance management programs for herbicide-resistant crops, utilizing its noxious weed authority for prevention rather than reaction. The Environmental Protection Agency has mandatory insect resistance management plans for Bt crops, so there is precedent for this approach. Such rational, pro-farmer regulation would benefit GE crop growers by preventing costly herbicide-resistant weeds and the increased exposure to toxic herbicides that they entail.

Human Health and Environmental Threats From Inadequate Regulation of GE Crops

Meaningful regulation to prevent weed resistance to glyphosate would have obviated the need for new HR crops resistant to older, more toxic herbicides like 2,4-D and dicamba.³⁶ 2,4-D, part of the Agent Orange defoliant used in the Vietnam War, is a probable human carcinogen, endocrine disruptor and neurotoxin.³⁷ Studies show dicamba to be a potential carcinogen and developmental toxin.³⁸ Use of these compounds is projected to increase dramatically with widespread adoption of soybeans resistant to them.³⁹ Far from “preserving glyphosate-resistance technology,” as advertised, these new HR crops signal the broadening failure of glyphosate-resistant crop systems via evolution of glyphosate-resistant weeds. It is questionable whether these new HR crops should be approved at all; if so, only in the context of strong, mandatory weed resistance management and drift prevention programs that emphasize priority use of non-chemical weed control methods. Otherwise, there is virtually no chance of preventing emergence of increasingly unmanageable weeds resistant to multiple herbicides, and a toxic spiral of increasing herbicide use.⁴⁰ USDA’s noxious weed authority could certainly be applied here to prevent or mitigate these adverse outcomes.

Many turfgrasses are non-native invasive plants that in some places are smothering our few remaining remnants of native prairie ecosystems, which are home to threatened and endangered (T&E) species.⁴¹ Glyphosate is considered to be an important tool in prairie restoration efforts. Independent scientists, the U.S. Fish and Wildlife Service, The Nature Conservancy, and others report that introduction of glyphosate-resistant turfgrasses will result in considerable spread of glyphosate-resistance in these grasses and their many sexually-compatible relatives.⁴² The resulting loss of glyphosate for use in prairie

restoration efforts would accelerate loss of native prairies, including T&E species. In fact, the Fish and Wildlife Service (FWS) recently predicted the likely extinction of two endangered species, and adverse effects on two dozen other T&E species, if glyphosate-resistant (GR) bentgrass is deregulated.⁴³ Bluegrass is also invasive,⁴⁴ and so GR bluegrass may have similar impacts. These threats are another reason the final rule should regulate ALL GE crops, and thus close the loophole by which Scotts escaped regulation of GR bluegrass. USDA could also apply its noxious weed authority to prohibit HR turfgrasses.

Another environmental impact is the recent finding that continual use of glyphosate in Roundup Ready crop systems has decimated populations of milkweed in the agricultural fields of Iowa and likely other Midwestern states.⁴⁵ This has contributed (along with other factors) to the 15-year decline in Monarch butterflies that require milkweed as a host plant for larvae (caterpillars).⁴⁶ Sensible restraints on glyphosate-resistant crop systems would reign in the phenomenal usage of this herbicide⁴⁷ and both assist in protection of the Monarch as well as help American farmers plagued by resistant weeds.

Conclusion

Strengthened regulation of GE crops would in no way stifle innovation. It would, however, benefit a broad range of farmers as well as the environment in the numerous ways discussed above. Stronger regulation would also be more scientifically sound. The only remaining obstacle, it would seem, is USDA's mistaken notion that it lacks authority to address the issues raised above via regulation.

First, the original intent of the regulation revision process was to implement additional statutory authority to strengthen, not weaken, GE crop regulation. The Bush Administration's USDA clearly understood that it was well within USDA's statutory authority to do so.

Second, stronger regulation was in fact proposed late in the process in the 2007 draft programmatic Environmental Impact Statement. USDA proposed to subject all GE crops to regulation, as well as make novel uses of its noxious weed authority. The 2008 proposed rule represented a shocking reversal, completely inexplicable on the legal or scientific merits.

Third, as we have argued throughout this letter, sound science and farmer welfare demand stronger, not weaker, regulation.

The proper response to inadequate regulation (the reason for the lawsuits and their success in the first place) would be to strengthen the system, not abdicate authority. Such an approach would benefit farmers and make future litigation unnecessary. We urge you to break with the Bush Administration's radical deregulatory initiative, as embodied in the proposed rule, and issue a strong final rule that adequately regulates GE crops.

We would be happy to discuss these matters further at your convenience.

Sincerely,

Center for Food Safety, *Andrew Kimbrell*

Rural Advancement Foundation International – USA, *Michael Sligh*

Beyond Pesticides, *Jay Feldman*

Clif Bar & Company, *Gary Erickson and Kit Crawford*

Clif Bar Family Foundation, *Thao Pham*

Consumers Union, *Michael Hansen*

CROPP Cooperative/Organic Valley, *George Siemon*

Equal Exchange, *Keith Olcott*

Food and Water Watch, *Wenonah Hauter*

Midwest Organic and Sustainable Education Services, *Faye Jones*

National Cooperative Grocers Association, *Robynn Shrader*

National Family Farm Coalition, *Kathy Ozer*

National Organic Coalition, *Liana Hoodes*

Northeast Organic Dairy Producers Alliance, *Ed Maltby*

Northeast Organic Farming Association –Interstate Council, *Steve Gilman*

Northeast Organic Farming Association -Massachusetts, *Jack Kittredge*

Organic Seed Alliance, *Kristina Hubbard*

Organically Grown Company, *Josh Hinerfeld*

Organic Trade Association, *Laura Batcha*

Pesticide Action Network North America, *Marcia Ishii-Eiteman*

Seed Matters, *Matthew Dillon*

UNFI, *Michael Funk*

cc: Deputy Secretary Kathleen Merrigan

Appendix 1

Recommendations for the Final Rule on "Importation, Interstate Movement, and Release into the Environment of Certain Genetically Engineered Organisms"

Regulate ALL Genetically Engineered Crops

The proposed rule gives biotechnology firms primary responsibility for determining whether APHIS regulations even apply to a new GE crop, based on a narrow and subjective interpretation of whether the GE crop is itself, strictly speaking, a "plant pest" or "noxious weed." This represents a radical departure from the present regime, in which use of "plant pest" material in the development process is employed merely as a trigger to bring (most) GE crops under USDA jurisdiction so that they can be reviewed for a broad range of possible environmental impacts. Sound science demands that USDA utilize genetic engineering as the trigger for regulation, as recommended by the National Academy of Sciences.⁴⁸ This was also USDA's own "preferred alternative" in the 2007 draft Environmental Impact Statement.⁴⁹ The NAS committee also emphasized that use of genetic engineering as the trigger for regulation did not conflict with a commitment to a case-by-case, risk-based approach to regulation of this technology. If USDA goes forward with its proposal, GE crops could be field-tested and grown commercially without any review by, or even the knowledge of, APHIS. This would set the stage for massive rejection of U.S. agricultural commodities contaminated with GE crops that fall completely outside of APHIS's purview.

Sound Science Must Guide USDA Regulation of GE Crops

APHIS must rely on "sound science," as required under the Plant Protection Act and the Obama Administration's Memorandum on Scientific Integrity.⁵⁰ The Memorandum stipulates that "[s]cience and the scientific process must inform and guide decisions of my Administration," with the "highest level of integrity in all aspects of the executive branch's involvement with scientific and technological issues." APHIS has frequently violated the tenants of sound science in its decision-making documents on GE crops in numerous ways: reliance on outdated science and data; excessive reliance on applicants' analysis and views; frequent citation of industry-sponsored misinformation that puts GE crops in a falsely positive light; egregious factual errors biasing decisions in favor of the applicant; among other unscientific practices. In contrast, sound science requires APHIS to undertake its own independent and holistic analysis of the impacts of GE crops; base its decision-making on up-to-date, peer-reviewed scientific literature whenever possible; critically examine applicant claims and analysis rather than uncritically accept them; and call on independent experts from outside the agency for external peer review. In addition, unduly narrow assessments – for example, not assessing impacts from pesticides used in conjunction with herbicide-resistant GE crops – cannot be considered sound science. Sound assessments must also apply the social sciences, for instance, to analyze the economic impacts of transgenic contamination of non-GE crops. Sound science may in some cases demand rejection of, or conditions on the approval of, certain GE crops. The institutional culture at USDA must change to allow for such outcomes.

Broad Use of Noxious Weed Authority

The Plant Protection Act incorporates the former Noxious Weed Act, and thus gives USDA additional statutory authority to regulate GE crops. APHIS's original intent was to utilize

this authority to strengthen regulation, but the Bush Administration's proposed rule undermined those tentative steps. APHIS should fully implement its PPA noxious weed authority to address adverse effects of GE crops on "the interests of agriculture," the environment, and public health in the following three areas:

A. Economic Harms from GE Contamination:

A primary purpose of the PPA is to protect the agricultural economy, yet APHIS has explicitly disavowed authority to prevent adverse economic impacts from GE crop introduction (such as market rejection). In *Geertson vs. USDA*, a federal court ruled that GE crop gene flow to conventional varieties is a direct environmental impact. The National Environmental Policy Act requires consideration of socioeconomic effects that are interrelated with environmental impacts. Since transgenic contamination of commercial food/feed supplies is an environmental impact that often entails substantial economic losses in GE-sensitive agricultural markets, particularly organic and foreign markets, APHIS's final rule must address these economic harms. APHIS cannot simply disregard them as "marketing" problems. Under commercial permitting (addressed below), GE crop developers would share responsibility for preventing GE contamination, and provide compensation when gene containment measures fail and economic harms ensue.

Moreover, the noxious weed authority includes "indirect" harm to agriculture as its own form of potential harm. This means that APHIS must analyze harms from GE crops other than transgenic contamination, including for example harms from pesticide use and drift or the promotion of weed resistance.

B. Herbicide-Resistant Crops, Pesticide Use and Resistant Weeds:

The PPA requires USDA to protect the environment and the interests of agriculture against harms both direct and indirect. The most widely planted class of GE plants – herbicide-resistant (HR) crops – are specifically designed to withstand application of one or more herbicides. HR crops have dramatically altered weed control on American farms, leading to rapid evolution of herbicide-resistant weeds, sharp increases in herbicide use and associated environmental pollution, frequent episodes of herbicide drift that damage neighboring crops, and increased weed control costs for American farmers. Industry-touted "stewardship programs" to slow evolution of herbicide-resistant weeds have failed. Absent sensible, pro-farmer regulation, these adverse impacts and costs will continue to rise, in some cases putting farmers out of business, and in others making it impractical to grow certain crops. USDA must implement its noxious weed authority for prevention of, rather than reaction to, noxious resistant weeds. The U.S. Environmental Protection Agency has established a useful precedent with mandatory insect resistance management plans for Bt crops. USDA should collaborate with EPA in drafting appropriate regulations for HR crops with aim of preventing evolution of weed resistance and damaging off-target herbicide drift. This would provide the "coordination" that is so sorely lacking in the Coordinated Framework. Such regulations would benefit farmers by reducing weed control costs, reducing crop damage from herbicide drift and volatility, and decreasing the need for tillage and hand-weeding to control resistant weeds.

C. Public Health:

The PPA's noxious weed authority requires APHIS to protect public health, yet APHIS explicitly disavows its responsibility to ensure the safety of GE crops. Three compelling

reasons for APHIS to assume this responsibility are: 1) The lack of any mandatory FDA review of GE crops for food or feed safety; 2) The use of GE food crops as “biofactories” for production of potentially harmful experimental pharmaceutical and industrial compounds; and 3) A policy permitting the low level presence of unapproved GE traits in commercial food and feed. APHIS must properly interpret and apply its noxious weed authority to assess and ensure the safety of GE crops for human and animal consumption.

Two-Tiered Permitting System

APHIS should end its practice of unconditionally removing GE crops and their progeny from its oversight through a “determination of non-regulated status.” In the final rule, APHIS should clarify that it retains authority to monitor and regulate GE crops for issues not detected in field trials and for threats that emerge or manifest only after commercial cultivation begins. For instance, herbicide-resistant crop systems should be monitored for their potential to foster resistant weed populations or occasion crop damage through off-target herbicide drift, with appropriate control measures imposed if monitoring reveals a problem. All GE crops require monitoring and control measures to mitigate transgenic contamination of crops grown for GE-sensitive markets. These suggestions comport with recommendations made by the National Academy of Sciences, the National Science and Technology Council, and the Government Accountability Office (GAO).⁵¹

To this end, APHIS should implement a two-tiered permitting process. Permits for field trials of experimental GE crops should only be granted on condition that strict, redundant gene containment protocols are adhered to. Such protocols should be prescriptive, based on the gene flow potential of the crop, and incorporate generous margins of safety to assure gene containment even under less usual conditions (e.g. high winds) that are conducive to long-distance pollen/seed dispersal. Redundant measures – e.g. temporal and spatial isolation – are required to ensure efficacy when one measure fails. Such permit conditions could be modeled on pharma crop gene containment protocols. Commercial permits would allow GE crops to be cultivated commercially, but with continuing APHIS jurisdiction to monitor, collect data to confirm risk assessments and detect unanticipated harms, and impose protective measures when necessary to manage emerging risks. Gene containment measures (though less strict than those for experimental GE crops) would also be required. Provisions for compensation of conventional/organic growers whose crops are contaminated through violation of these requirements should be included in both permit types.

Low-Level Presence

While USDA claims to advocate “co-existence” of biotech, conventional and organic agriculture, its proposed Low Level Presence (LLP) regulations would make co-existence much more difficult. These regulations would allow APHIS to take no recall or similar action when untested, experimental GE crops grown in field trials are found contaminating commercial food, feed or seed. Despite its quantitative appellation, the proposed LLP rules set no upper limit to “low level” presence, and thus in theory sanction unlimited levels of experimental GE crop material in the food supply. Exposure to untested, experimental GE crops contaminating food may in some cases pose health risks, yet the proposed regulations contain no protocols for assessing such potential harms.

LLP would reduce incentives to prevent gene flow, thus making GE contamination and loss

of non-GE markets more likely. This is because in most cases, LLP regulations would make the presence of untested GE crop material in foods “non-actionable” (i.e. not subject to recall). Without the threat of recall and associated liability, GE field trial permit holders have little incentive to prevent gene flow. In the event of litigation, the firm whose negligent practices caused the contamination could argue that LLP regulations essentially sanction GE contamination of conventional/organic crops. While it is true that USDA already has an LLP policy in place, codification of this policy in the Code of Federal Regulations is a far more serious affair. Would rice farmers have obtained just compensation for Bayer’s negligence re: LLRICE601 had the company been able to appeal to LLP regulations as providing legal sanction for contamination?

APHIS should thus eliminate this proposal, which is unscientific because it contains no quantitative definition of “low level,” and it applies indiscriminately to all GE crops, irrespective of trait, including perhaps pharma crops producing experimental drugs. Instead, APHIS should make “zero tolerance” its **management goal** by mandating recalls whenever experimental GM crops contaminate the food, feed or seed supply. One can set zero tolerance as a goal even while recognizing that it will not always be met in practice. The threat of liability for recalls represents a powerful incentive to biotech companies to adhere to strict gene containment protocols. For coexistence to be feasible, the regulations must “establish scientifically valid and proven isolation and containment distances,” as mandated in the 2008 Farm Bill (Sec. 10204(C)(1)(c)) and clarify that it is the responsibility of the developer and the grower of GE crops to establish and maintain appropriate isolation distances and other gene containment measures to minimize the potential for contamination.

Pharmaceutical and Industrial Crops

APHIS should prohibit the outdoor cultivation of plants engineered as biofactories for experimental drug production, and all cultivation of any such food crops. Pharma and industrial crops produce experimental pharmaceuticals or industrial compounds that in some cases may pose risks to human health in the event of inadvertent exposure, yet no risk assessment is required before they are grown out of doors. Public interest groups, the food industry, many scientists and even some in the biotech industry advocate an end to outdoor cultivation of pharma crops, especially food crops,⁵² due to the inevitable contamination of food.

Under the PPA, APHIS has broad authority to restrict the introduction of such plants to protect public health and the economy. APHIS recognized this authority in its draft programmatic EIS, where it proposed alternatives that would either bar outdoor cultivation of ALL pharma crops, or of all pharma food crops.⁵³ Unfortunately, APHIS rejected these sensible alternatives, and in the proposed rule inappropriately lumped pharma crops into the same subjective risk assessment scheme with all other GE crops. Ignoring sound science, APHIS’s current thinking is that concerns about pharma crops are nothing more than “marketing” or “public perception” issues. Yet there is nothing unscientific about regulations designed to keep untested pharmaceuticals out of the food supply. We urge USDA to reconsider this issue and adopt a prohibition on all pharma crops, or at least pharma food crops, in the final rule.

Appendix 2

Legal Settlements and Awards for Bayer Contamination of U.S. Rice

Individual Cases

- 1) December 2009: Federal court awarded \$2 million to Missouri rice farmers: Kenneth Bell and Johnny Hunter⁵⁴
- 2) February 2010: Federal court awarded \$1.5 million to three Arkansas rice farmers: Joe Penn, Jim Penn and Jerry Catt⁵⁵
- 3) March 2010: Woodruff County Circuit Court awards over \$1 million to Arkansas rice farmer Lenny Joe Kyle⁵⁶
- 4) April 2010: Lonoke Circuit Court awards twelve Arkansas rice farmers \$48 million: \$5.9 million in compensation, \$42 million in punitive damages.⁵⁷ The punitive damages were awarded because Bayer knew about the contamination before the 2006 crop was planted, but delayed informing rice farmers.⁵⁸
- 5) June 2010: Bayer agrees to pay Riviana Foods \$5.8 million in a settlement.⁵⁹
- 6) July 2010: Louisiana rice grower Danny Deshotels was awarded \$500,248 by a St. Louis jury. At this time, Bloomberg reported that Bayer faced 500 additional lawsuits in federal and state courts with claims by 6,600 plaintiffs.⁶⁰
- 7) October 2010: Three small Texas rice growers settle with Bayer for \$290,000 in compensation.⁶¹
- 8) March 2011: Arkansas Circuit Court awarded Riceland Foods, a farmer-owned cooperative, \$136.8 million: \$11.8 in compensation and \$125 million in punitive damages.⁶²

In individual cases, 22 farmers who sued Bayer won \$53 million; farmer-owned cooperative Riceland Foods was awarded \$136.8 million; Riviana Foods (rice products) settled with Bayer for \$5.8 million. **Total awards and settlements: \$195.6 million.**

Class Action Settlement

On July 1, 2011, attorneys for about 11,000 rice farmers in Texas, Louisiana, Missouri, Arkansas and Mississippi announced a \$750 million settlement with Bayer CropScience to compensate them for losses suffered due to the negligence of Bayer in conducting field trials of experimental LLRICE601, which contaminated over 30% of U.S. rice land planted to long-grain rice.⁶³

Bottom Line

USDA's abdication of responsibility for overseeing GE crop field trials has once again forced the courts to step in and fill the gap. While these rice farmers won some measure of compensation for their losses, many others will likely not be so lucky in future episodes, which are sure to grow in number if USDA continues its current lax regulatory system for GE crop field trials.

Appendix 3

Roundup Ready Alfalfa Contamination Events

Year [Ref.]	No. of episodes	Testing firm/individual	Description	Notes
2006 [1]	11 seed fields	Dairyland farmers	11 of 16 seed production fields tested by farmers were positive for RR gene: MT (9), ID (1), WY (1). Seed to seed gene flow occurred at distances of 950 feet to 1.5 miles	RR gene levels from 0.2%-0.9%, with 1 "trace"
2008 [1, 2]	6 seed lots (3% of seed lots tested)*	Cal/West	Testing conducted in CA, OR, WA, ID, NV, MT, WY, Canada, Australia. Not specified where contaminated lots found.	Strip tests, no levels given
2008 [1, 2]	6 research seed lots	Cal/West	Woodland, CA, in Yolo County, where there is no commercial alfalfa seed production. All 6 lots tested were positive for RR	RR hay-to-seed gene flow
2008 [3]	9 feral alfalfa populations	Phil Geertson	Feral alfalfa plants in various locations in Twin Falls & Canyon County, ID and Malheur County, OR. 9 of 10 plants tested were positive for the RR gene	PCR testing
2009 [1, 2]	> 24 seed lots (> 12% of > 200 seed lots)	Cal/West	Testing conducted in CA, OR, WA, ID, NV, MT, WY, Canada, Australia. Not specified where contaminated lots found.	Strip tests, no levels given
2009 [1, 2]	3 research seed lots	Cal/West	Woodland, CA, in Yolo County, where there is no commercial alfalfa seed production. 3 of 10 seed lots positive for RR (preliminary results)	RR hay-to-seed gene flow
NR [1]	1 seed field	Cal/West	Foundation seed, California	0.01-0.03% RR
NR [1]	2 seed fields	Cal/West	Washington, 2 of 3 seed fields seeded from the CA foundation seed lot noted directly above.	0.01% RR
NR [1]	1 or more seed fields	Cal/West contractor	"Fields in proximity" cited as source, perhaps RR alfalfa hay fields, though not specified	RR gene levels 0.5%-1.5%
TOTAL	> 63 episodes			

NR = not reported. Sources: [1] Final Environmental Impact Statement on Roundup Ready Alfalfa, USDA APHIS, December 2010, Appendix V, V-64 to V-65; [2] Cal/West Seeds Newsletter, Winter Issue 2010; [3] "Roundup Ready Contamination of Feral Alfalfa," report and affidavit by Phil Geertson, May 28, 2009 (report has description and photographs and GPS coordinates of sites tested, and Genetic ID results of PCR testing of feral alfalfa for the RR gene; * Cal/West reports that 3% of tested seed lots were positive for the RR gene, but does not give the number of seed lots tested. We assume 200, based on the number of lots tested in 2009: 3% of 200 = 6.

Of the 63 detected contamination events, 11 were detected in 2006. ***At least 48 contamination episodes were detected in 2008 and 2009, after court-ordered gene flow mitigation measures were imposed (in 2007).*** With complete deregulation, those measures are no longer in place, thus gene flow is still more likely. Detected GE gene flow events are likely a small fraction of those that actually occurred. Cal/West [2] states: "The significant increase from 2008 to 2009 in seed lots showing the presence of the GMO trait is significant and foreshadowing of what [we] should expect in the future." Furthermore, Cal/West reports that hay-to-seed gene transmission was responsible for the contamination of 9 research seed lots in 2008 and 2009. APHIS, FGI and others who have discounted the potential for hay-to-seed contamination need to reconsider their assessment in light of these real-world data, especially since they were gathered during a period of time when court-ordered gene containment measures were supposed to prevent such gene flow. Cal/West further notes: "It is becoming clear that this gene or any gene can easily spread and that ***we are going to have to take extraordinary measures when producing foundation seed and commercial seed for GMO sensitive markets.***" Complete deregulation falls far short of the "extraordinary measures" that are needed.

Endnotes

¹ USDA APHIS (2009). "Importation, Interstate Movement, and Release Into the Environment of Certain Genetically Engineered Organisms," Proposed Rule, Docket No. APHIS-2008-0023, FR Notice October 9, 2008, pp. 60008-60048, see p. 60015.

² NAS (2002). Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation, Committee on Environmental Impacts Associated with Commercialization of Transgenic Plants," National Research Council, National Academy of Sciences, 2002, pp. 79-84 (hereinafter "NAS Report"). See also CFS (2008). Comments on the draft programmatic environmental impact statement, Docket No. APHIS 2008-0023, Nov. 24, 2008, pp. 5-12.

³ 9,881 notifications "acknowledged" and 666 permits "issued." See <http://www.isb.vt.edu/search-release-data.aspx>.

⁴ USDA-APHIS (2011). "USDA-APHIS Biotechnology Regulatory Services User Guide: Notification," http://www.aphis.usda.gov/biotechnology/downloads/notification_guidance_0311.pdf.

⁵ For instance, acknowledgement #11-019-110n grants permission to DuPont subsidiary Pioneer to test soybeans genetically engineered for 20 different phenotypes (traits) on up to 5,593.93 acres in 22 states. See: <http://www.isb.vt.edu/getRelDetail.aspx?bp=11-019-110n>.

⁶ USDA OIG (2005). "Audit Report: Animal and Plant Health Inspection Service Controls Over Issuance of Genetically Engineered Organism Release Permits," Office of Inspector General, Southwest Region, USDA, Audit 50601-8-Te, December 2005, v-vi. <http://www.usda.gov/oig/webdocs/50601-08-TE.pdf>.

⁷ For instance, permit #10-35-113rm allows Monsanto to grow corn genetically engineered for 17 different phenotypes (traits) on 1,960 acres in eight states. See <http://www.isb.vt.edu/getRelDetail.aspx?bp=10-350-113rm>.

⁸ USDA OIG (2005), op. cit., p. 14.

⁹ Source: APHIS GE crop field trial database, maintained by Virginia Tech, last visited 7/23/11. Go to <http://www.isb.vt.edu/search-release-data.aspx>. Check the box "Show only results with release environmental assessment." Note that the most recent field trial with an EA is permit #06-325-111r, issued 6/27/07. From this date to present, APHIS has apparently not conducted a single EA for any of the 3,159 GE crop field releases it has authorized in this period.

¹⁰ For biotechnology's failure to develop GE crop with increased nitrogen use efficiency, vs. the success of existing methods, see: Gurian-Sherman, D. & N. Gurwick (2009). "No Sure Fix: Prospects for Reducing Nitrogen Fertilizer Pollution through Genetic Engineering," Union of Concerned Scientists, Dec. 2009,

http://www.ucsusa.org/assets/documents/food_and_agriculture/no-sure-fix.pdf. For biotechnology's failure to produce any FDA-approved "plant-made pharmaceuticals," see: Freese, B. (2002). "Manufacturing Drugs and Chemicals in Plants," Friends of the Earth, 2002. www.iatp.org/files/Manufacturing_Drugs_and_Chemicals_in_Crops.doc. To our knowledge, there have been no FDA-approved PMPs introduced since the time of this report nine years ago.

¹¹ One gets a good sense of the high failure rate from GE crop field trial data. USDA lists 316 institutions (93 of them universities/colleges) as having carried out field trials involving over 100 GE species and over 1,000 GE traits. APHIS has authorized 21,669 GE crop field trial releases by phenotype category, meaning that GE crops with this many phenotypes (traits) have been tested in outdoor field trials (many traits are tested repeatedly, so 21,669 does not represent the number of distinct traits, which is on the order of 1,000). Since many field releases are carried out in several states, the number of actual field trial sites is several-fold higher. Despite this enormous investment of time and resources over the past quarter century, commercialized GE crops are limited almost entirely to those with glyphosate-resistance and/or a handful of different insecticidal proteins (Bt crops). If the vast majority of these field trials have failed to lead to a successful GE crop, the reason quite obviously has nothing to do with the extremely accommodating regulatory regime. For 21,669 field trial releases by phenotype category, add figures in "Number of Approved Releases by Phenotype Category" chart at <http://www.isb.vt.edu/release-summary-data.aspx>. For number of institutions that have conducted GE crop field trials, number of different GE species and "traits," check "Institution," "Organism" and "Phenotype" boxes and count listings (some apparent duplicates present) at <http://www.isb.vt.edu/search-release-data.aspx>.

¹² Nightingdale, P & P. Martin (2004). "The myth of the biotech revolution," TRENDS in Biotechnology 22: 564-569.

¹³ Elias, P. (2005). "Biotechnology loses billions a year," The Associated Press, June 1, 2005.

¹⁴ Hamilton, D.P (2004). Biotech's Dismal Bottom Line: More Than \$40 Billion in Losses. As Scientists Search for Cures, They Gobble Investor Cash; A Handful Hit the Jackpot - 'The Ultimate Roulette Game'" Wall Street Journal, May 20, 2004. [http://www.mindfully.org/GE/2004/Biotech-\\$40B-Losses20may04.htm](http://www.mindfully.org/GE/2004/Biotech-$40B-Losses20may04.htm).

¹⁵ Association of Molecular Pathology et al v. U.S. Patent and Trademark Office et al, Opinion, 09 Civ. 4515, March 29, 2010. A decision striking down Myriad Genetics' patents on the BRAC breast cancer genes. <http://www.aclu.org/files/assets/2010-3-29-AMPvUSPTO-Opinion.pdf>.

¹⁶ For large firms, see: Kilman, S. (2010). "Superweed outbreak triggers arms race," Wall Street Journal, June 4, 2010. <http://www.hawaiiseed.org/downloads/articles/GMO-superweeds-herbicides-WSJ-6-4-10.pdf/view>. Biotech start-up Athenix, which developed a gene conferring greatly increased levels of glyphosate resistance for incorporation into crops (which will of course facilitate evolution of still greater resistance in weeds), was bought up by Bayer CropScience in 2009. See: Service, R.F. "A Growing Threat Down on the Farm," Science 316: 1114-1117; for Bayer's acquisition of Athenix: <http://www.bayercropscience.com/bcsweb/cropprotection.nsf/id/99A98B14A7436118C1257662004A754D>.

Cibus, another biotech startup, has partnered with Makhteshim-Agan, an Israeli manufacturer of many toxic, off-patent pesticides such as atrazine, lactofen, imazethapyr, linuron, and trifluralin (see: <http://www.ma-industries.com/products-solutions/crop-protection>). Makhteshim-Agan is investing to own up to 50.1% of Cibus, which will use its non-transgenic biotechnological techniques to develop herbicide-resistant crops for use with Makhteshim-Agan's herbicides. See <http://www.cibus.com/press/press092109.php>. Cibus has also partnered with Rotam, another pesticide producer: <http://www.cibus.com/press/press121410.php>. These are just a few of many examples that demonstrate the pesticide-promoting nature of most biotech R&D, whether conducted by large or small companies.

¹⁷ See http://www.aphis.usda.gov/biotechnology/not_reg.html.

¹⁸ See: <http://www.bloomberg.com/news/2011-07-01/bayer-to-pay-750-million-to-end-lawsuits-over-genetically-modified-rice.html>

¹⁹ Food, Conversation, and Energy Act of 2008, Pub. L. No. 110-246, § 10204, 122 Stat 1651 (June 18, 2008).

²⁰ GAO (2008). "Genetically engineered crops: Agencies are proposing changes to improve oversight, but could take additional steps to enhance coordination and monitoring," Report to the Committee on Agriculture, Nutrition, and Forestry, U.S. Senate, U.S. Government Accountability Office, GAO 09-060, Nov. 2008, Appendix VII, pp. 90-95.

²¹ CFS (2011). Letter to Secretary of Agriculture Tom Vilsack re: Roundup Ready alfalfa from Center for Food Safety, January 24, 2011. <http://www.centerforfoodsafety.org/wp-content/uploads/2011/01/Open-Letter-CFS-to-Vilsack-FINAL-1-24-10-with-CG-list.pdf>.

²² "Conventional Soybeans Maintaining Niche in Brazil," Soybean & Corn Adviser, June 3, 2010.

http://www.soybeansandcorn.com/news/jun3_10-Conventional-Soybeans-Maintaining-Niche-in-Brazil.

²³ "Conventional Soybeans (non-GMO) Promoted by Embrapa," Soybean & Corn Adviser, May 24, 2011.

http://www.soybeansandcorn.com/news/May24_11-Conventional-Soybeans-non-GMO-Promoted-by-Embrapa.

²⁴ Testing Methodologies in Tracing, Segregating and Labeling Foods Derived from Modern Biotechnology: Proceedings, Center for Food and Nutrition Policy, Feb. 25, 2003, p. 54,

http://cfnap.umd.edu/Outreach/Conference%20Proceedings/pdfs/Biotech_Proceedings.pdf.

²⁵ Organic Community Sign-On Letter re: APHIS Docket 2008-0023, copied to Secretary Vilsack and Deputy Secretary Merrigan, June 29, 2009.

²⁶ Baldwin, F.L. (2010). "Herbicide drift damaging rice," Delta Farm Press, June 7, 2010.

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²⁷ Dimitri, C. & Oberholtzer, L. (2008). "Using vertically coordinated relationships to overcome tight supply in the organic market," USDA Economic Research Service, VGS-329-01, Oct. 2008. "One factor contributing to the short supply of these final products [organic meat and milk], is the scarcity of feed and grains, especially corn and soybeans," p. 2. See also Figure 4, p. 7.

²⁸ Greene, C. et al (2009). "Emerging issues in the U.S. organic industry," Economic Information Bulletin No. 55, USDA ERS, June 2009, p. iv.

²⁹ Jones, T. (2008). "Conventional soybeans offer high yields at lower cost," University of Missouri, Sept. 8, 2008.

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Journal of Agricultural and Food Chemistry, Table 2. <http://pubs.acs.org/doi/abs/10.1021/jf102673s>.

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- ⁴⁸ NAS (2002), op. cit.
- ⁴⁹ USDA (2007). "Introduction of Genetically Engineered Organisms: Draft Programmatic Environmental Impact Statement, USDA APHIS, July 2007, p. 168, where APHIS states that it intends to "use genetic transformation as the trigger for regulation."
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- ⁵³ USDA (2007), op. cit., Alternatives 3 and 4, pp. 32-33.
- ⁵⁴ <http://www.dallasfortworthinjurylawyer.com/2009/12/bayer-must-pay-farmers-for-con.html>
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- ⁵⁶ <http://www.hwnn.com/news/103-arkansas-rice-farmers-win-third-case-against-bayer>
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- ⁵⁸ "However, this time the verdict was larger, based on the jury's conclusions that Bayer was both negligent in its handling of Liberty Link rice, and that it acted with malicious intent by not announcing the contamination of the commercial rice-seed pool as soon as the company learned about it. The suit claimed Bayer knew of the contamination well before the 2006 crop was planted, but that farmers were not told until USDA did so shortly before harvest time." <http://www.arkansaricegrowers.com/news/recent-rice-supply-contamination-case-verdict>.
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- ⁶⁰ <http://www.businessweek.com/news/2010-07-14/bayer-loses-fifth-straight-trial-over-u-s-rice-crops.html>
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