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To whom it may concern:

On behalf of the Union of Concerned Scientists (UCS) and the Consumer Federation of America (CFA), we are pleased to submit the following comments on the U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service's (APHIS's) draft programmatic environmental impact statement (EIS) on contemplated revisions of its biotechnology regulations.

UCS, the leading science-based nonprofit working for a healthy environment and a safer world, combines independent scientific research and citizen action to develop innovative, practical solutions and secure responsible changes in government policy, corporate practices, and consumer choices. A major goal of UCS's Food and Environment Program is to strengthen the regulatory system that applies to products of agricultural biotechnology.

Since 1968, CFA, an advocacy, research, education, and service organization, has provided consumers a well-reasoned and articulate voice in decisions that affect their lives. CFA's professional staff gathers facts, analyzes issues, and disseminates information to the public, policymakers, and the rest of the consumer movement.

I. BACKGROUND

APHIS issued the draft EIS and request for public comments in the *Federal Register* on July 17, 2007. The EIS has been prepared by APHIS to inform the preparation of proposed rules the agency is planning for genetically engineered (GE) crops and biological control agents. The rulemaking will implement new, consolidated quarantine authority provided to the USDA in the

Plant Protection Act of 2000.[1] The current rules implement quarantine authorities, primarily the Plant Pest Act, that were repealed as part of the enactment of the Plant Protection Act.

The EIS consists of an analysis of regulatory alternatives on ten issues APHIS has identified as important for the upcoming rulemaking. For each issue, the agency has presented a no-action alternative, essentially the regulations as they currently exist, and one or more action alternatives.

We compliment the agency on providing a well-organized analysis of the 10 selected issues. Below we make several general points about the draft EIS and offer comments on most of the 10 specific issues presented by APHIS.

II. GENERAL COMMENTS ON THE DRAFT EIS

1. The draft EIS lacks substantive analysis of environmental impacts.

The draft EIS is notable in that it is virtually devoid of the substantive analysis of environmental impacts ordinarily found in EISs. Instead, the document contains analyses that are based primarily on principles of regulatory flexibility, burden on industry, and transparency. In many ways the document resembles an advance notice of proposed rulemaking rather than an EIS. Although the policy analysis in the paper is important background for the major overhaul of regulations, such an analysis is beyond the scope of an EIS, which should properly address only the environmental impacts of various policy choices. This document references environmental impacts, but primarily as background information, an approach that does a poor job of informing agency actions in the future.

The proper way to prepare an EIS is to assemble the data on impacts and relate those data to policy choices. For example, if data demonstrated that performance standards for field tests were effective in confining troublesome genes to test plots, one might choose a status quo option. At the same time, if performance standards had been shown to be ineffective, a different approach would be considered.

One problem confronting APHIS is that it often does not have the data needed for such an analysis. On pharmaceutical and industrial (pharma/industrial) crops, for example, the agency has allowed crops to be tested under performance standards for 15 years but has never systematically collected data on their effectiveness. As a result, decisions among options related to pharma/industrial crops are based on unsubstantiated assertions of efficacy and notions of regulatory flexibility. Even on issues where environmental impact data are available, e.g., on the development of herbicide-resistant weeds or non-target effects of Bt crops, few of the data have been included in the document. The result is analyses of regulatory options that are theoretical where they ought to grounded in science.

It is arguable that this EIS is so devoid of data it does not satisfy the requirements of the National Environmental Policy Act (NEPA). But since this EIS is prepared in advance of its proposed rule, APHIS has another chance to remedy any deficiencies in this EIS. The agency should take

[1] The Plant Protection Act of 2000, 7 U.S.C. §§ 7701.

the opportunity and prepare a more specific EIS, based on available data, to accompany the proposed rule. APHIS should take care that future NEPA analyses are grounded in scientific observation, not regulatory principles.

2. The lack of environmental impact data in the draft EIS suggests that APHIS needs new mechanisms to generate risk assessment data and bring scientific input into its decisionmaking processes.

The scientific issues discussed in the greatest depth in the Environmental Consequences section of the draft EIS—insect resistance management, food allergenicity, and virus-resistant plants—are issues involving organisms regulated by the Environmental Protection Agency (EPA). One reason for the relative richness of the scientific assessment in these areas is that the EPA regularly convenes scientific advisory panels to address scientific issues important to regulation.

APHIS should consider establishing a formal scientific advisory mechanism that would allow it to deal with scientific issues in a public forum, especially issues that arise in connection with new applications of genetic engineering.

APHIS should also consider asking the National Research Council of the National Academies of Science to prepare reports on scientific topics related to the oversight of GE organisms and work with Congress to secure more funding for USDA's biotechnology risk assessment program.

Finally, APHIS should consider the ways in which it could use the ongoing field tests of GE organisms to collect risk-related data to inform future decisions.

3. The draft EIS fails to discuss the economic impacts of contamination on farmers serving non-GE markets.

Farmers, including organic farmers and conventional farmers selling into demanding non-GE markets, are finding themselves through no fault of their own *economically* disadvantaged by the contamination of their products with genes and seeds from GE crops. Three rice contamination events this past year are only the latest example of farmers' incurring large financial losses due to the presence of GE contaminants.[2] A recent court decision,[3] which dealt with GE alfalfa and alfalfa farmers, ordered APHIS to evaluate and consider economic impacts of GE contamination along with more conventional environmental impacts, but that has not been done in this draft EIS.

Contamination by GE crops potentially has economic consequences for conventional producers of many crops including corn, rice, wheat, soybeans, and papaya, as well as producers of USDA-certified organic food. Those economic impacts should be addressed in APHIS's draft EIS and other NEPA documents produced by the agency.

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[2] Bennett, D. 2007. GM rice—proposed class action. *Delta Farm Press*, May 28. On line at http://deltafarmpress.com/rice/070528-class-action.

[3] Geertson Seed Farms Inc., et al., v. Mike Johanns, et al. Docket No. 06-01075 CRB (U.S. District Court, Northern District, California, February 14, 2007).

4. The draft EIS discussion of environmental consequences ignores important scientific reports.

The draft EIS generally ignores important scientific reports in the risk assessment literature and as a result presents a one-sided, overly benign view of the risks of GE crops. Some of the most important scientific omissions are discussed below.

Human health risks—food allergenicity

In its analysis of the risks of introducing allergens into the food supply (pp. 88-97), APHIS neglected to include the recent article, "Transgenic expression of bean α- amylase inhibitor in peas results in altered structure and immunogenicity,"[4] by researchers from the Australian Commonwealth Scientific and Industrial Research Organization (CSIRO). This study, which resulted in CSIRO's abandoning a product that had been under development for 10 years, is a seminal paper in this field. Its major finding, *that non-immunogenic crops can be converted into immunogens as a result of genetic engineering*, has implications for every food crop subject to GE technology and should have been discussed by APHIS. The paper also offers an animal test that might be useful to regulators assessing the potential of engineered crops to act as food allergens. This is a major omission in view of the admitted lack of predictive tests for food allergens.

Human health risks—pharma/industrial crops

The section on pharma/industrial crops does not mention the potential health impacts associated with production of orally active drugs or toxins that might be transferred to food. In addition, it fails to address the likelihood of contamination in light of the 2002 ProdiGene pharma corn incident and other non-pharma contamination incidents relevant to contamination by pharma crops. The EIS should also discuss the ongoing investigation into last fall's LibertyLink 601 rice-contamination event,[5] which could shed light on locales and causes of commingling.

Weediness risks—herbicide-resistant crops

The discussion of herbicide-resistant crops (pp. 119-121) is out of date and fails to make clear that herbicide-resistant weeds, as predicted, have emerged and are a significant problem for U.S. agriculture. This section contains primarily references from1998 or earlier. Since herbicide-resistant crops were first introduced in the mid-1990s and not grown on a large scale until the late 1990s, the time period of the EIS references is too early to expect to detect resistant weeds.

The discussion references the *concern* among weed scientists that "overreliance on fewer weed-management strategies will result in the evolution of resistance to the more useful herbicides or population shifts to naturally resistant weed species" (p. 119). But the discussion fails to note that those past concerns have been richly justified by current events. In fact, over the past eight to ten years, farmers in the United States *have* relied heavily on Roundup Ready (glyphosate-resistant) crops, and population shifts to weeds naturally resistant to glyphosate have occurred

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[4] V.E. Prescott, et al. 2005. Transgenic expression of bean α-amylase inhibitor in peas results in altered structure and immunogenicity. *Journal of Agriculture and Food Chemistry* 53:9023-9030.

[5] USDA. 2006. Transcript of Remarks by Agriculture Secretary Mike Johanns and Dr. Robert Brackett, Director of the Food and Drug Administration's Center for Food Safety and Applied Nutrition. USDA Office of Communications Release No. 0308.06, August 18.

and are a growing problem.[6] In 1998, only one state, California, had reported a glyphosate-resistant weed—rigid rye grass.[7] By 2007, about a decade after the first large-scale introduction of Roundup Ready crops, seven additional weeds had been reported in states across the country.[8]

The discussion also ignores the development of difficult-to-control weeds as a result of increased use of herbicide-resistant canola. Volunteer multiple-herbicide-resistant canola weeds have emerged in Canada as a result of gene flow among four different herbicide-resistant canola varieties (three GE and one non-GE).[9]

The emergence of herbicide-resistant weeds has both economic and environmental consequences. Not only are farmers losing a valuable herbicide, but the environment is suffering as farmers are resorting to the more toxic herbicides that glyphosate was supposed to replace. For example, Syngenta, a major biotechnology/pesticide company, recommends paraquat to control glyphosate-resistant weeds.[10] Monsanto, the developer of Roundup Ready crops, suggests a mix of alachlor and atrazine.[11] A North Carolina State University extension weed specialist recommends 2,4-D.[12]

Moreover, with the emergence of glyphosate-resistant weeds, farmers are applying greater quantities of herbicides to Roundup Ready crops. Between 1996 and 2004, farmers used 138 million more pounds of herbicides on GE varieties than on conventional ones.[13]

APHIS should include a response to the problem of emerging herbicide-resistant weeds in its proposed rules.

Weediness risks—GE grasses

In its discussion of the potential for genetic engineering to increase weediness risks, the draft EIS presents a few studies involving GE plants but primarily relies on extrapolation from research on non-GE plants (pp. 68-78). Based on its analysis of these studies, APHIS generally downplays

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[6] See for example, D. Bennett. 2006. What will be the next herbicide-resistant weed? *Delta Farm Press*, January 9. Online at http://deltafarmpress.com/news/060109-herbicide-resistance; D. Bennett. 2006. For some Georgia cotton producers: Glyphosate-resistant pigweed a nightmare. *Southwest Farm Press*, December 21. Online at http://southwestfarmpress.com/mag/farming_georgia_cotton_producers_2; C. Yancy. 2005. Weed scientists develop plan to combat glyphosate resistance. *Southeast Farm Press,* June 3 Online at http://southeastfarmpress.com/news/060305-Glyphosate-resistance.

[7] Weed Science Society of America. 2007. International survey of herbicide resistant weeds. Online at www.weedscience.org/Summary/UspeciesMOA.asp?lstMOAID=12&FmHRACGroup=Go.

[8] Palmer amaranth (AR, GA); common waterhemp (KS, MO); common ragweed (AR, KS, MO); giant ragweed (IN, KS, OH); hairy fleabane, (CA); horseweed (AR, CA, DE, IN, KS, KY, MD, MS, MO, NE, NJ, NC, OH, PA, TN); Italian ryegrass (MS, OR). Source: Weed Science Society of America. 2007. International survey of herbicide resistant weeds. Online at www.weedscience.org/Summary/UspeciesMOA.asp?lstMOAID=12&FmHRACGroup=Go.

[9] Hall, L., et al. 2000. Pollen flow between herbicide-resistant *Brassica napus* is the cause of multiple-resistant *B. napus* volunteers. *Weed Science* 48:688-694.

[10] See www.syngentacropprotection-us.com/media/article.asp?article_id=609.

[11] See www.monsanto.com/monsanto/ag_products/crop_protection/products/lariat.asp.

[12] See www.weedresistancemanagement.com/content/voicefromfield/RRFYorkTipBox.pdf.

[13] Benbrook, C. 2004. Genetically Engineered Crops and Pesticide Use in the United States: the First Nine Years. BioTech InfoNet, Technical Paper Number 7. Online at www.ucsusa.org/food_and_environment/genetic_engineering/genetically-engineered-crops-pesticide-use.html.

concerns over increased weediness. However, the EIS fails to consider recently published studies that should raise concerns about weediness. APHIS ignores two important research papers on GE bentgrass that show the first known establishment of a GE crop in the wild in the United States and the first known transfer in nature of a GE trait to a wild plant.[14] It is surprising that APHIS omitted from its discussion the only GE crop it considered risky enough to require an EIS before making a decision on its release.

Impacts of Bt crops on non-target insects

The draft EIS discussion of the impacts of Bt crops (pp. 98-104) devotes a mere two paragraphs to non-target insects, again neglecting important research. The draft EIS omits, for example, studies on the effects of Bt corn pollen on monarch butterfly larvae, an issue that was the subject of intense scrutiny after a study published in *Nature* in 1999 revealed that Bt pollen could be toxic to monarch larvae.[15] In response to these preliminary results, the USDA and industry pooled funds to sponsor studies to determine the potential impacts of Bt crops on monarchs under field conditions. The results were published in six papers in the *Proceedings of the National Academy of Sciences* in 2001.[16] The draft EIS neglected the opportunity to discuss what is arguably the most comprehensive analysis thus far of any non-target impact of a GE crop.

The draft EIS also failed to mention papers published by ecologist Angelika Hilbeck and her colleagues on Bt crops and non-target insects over the past few years, including her research reports on the effects of Bt corn on green lacewing predators.[17]

In summary, APHIS ignored numerous key studies on the environmental impacts of GE crops, a few of which are listed above. That list is not complete but is long enough to suggest that the

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[14] L.S. Watrud et al. 2004. Evidence for landscape-level, pollen mediated gene flow from genetically modified creeping bentgrass with *CP4 EPSPS* as a marker. *Proceedings of the National Academy of Sciences, USA* 101:14533-145338; J.R. Reichman et al. 2006 Establishment of transgenic herbicide-resistant creeping bentgrass (*Agrostis stolonifera* L.) in nonagronomic habitats. *Molecular Ecology* 15:4243-4255.

[15] Losey, J. E., et al. 1999. Transgenic pollen harms monarch larvae. *Nature* 399:214.

[16] Hellmich, R.L., et al. Monarch larvae sensitivity to *Bacillus thuringiensis*-purified proteins and pollen. *PNAS* 98:11925-11930; Oberhauser, K.S., et al. Temporal and spatial overlap between monarch larvae and corn pollen. *PNAS* 98:11913-11918; Pleasants, J.M., et al. Corn pollen deposition on milkweeds in and near cornfields. *PNAS* 98:11919-11924; Sears, M.K., et al. Impact of Bt corn pollen on monarch butterfly populations: A risk assessment. *PNAS USA* 98:11937-11942; Stanley-Horn, D.E., et al. Assessing the impact of Cry1Ab-expressing corn pollen on monarch butterfly larvae in field studies. *PNAS* 98:11931-11936; Zangerl, A.R., et al. Effects of exposure to event 176 *Bacillus thuringiensis* corn pollen on monarch and black swallowtail caterpillars under field conditions. *PNAS* 98:11908-11912.

[17] 1998. Effects of transgenic *Bacillus thuringiensis* corn–fed prey on mortality and development time of immature *Chrysoperla carnea* (Neuroptera: Chrysopidae). *Environmental Entomology* 27:480-487; 1998. Toxicity of *Bacillus thuringiensis* Cry1Ab toxin to the predator *Chrysoperla carnea* (Neuroptera: Chrysopidae). *Environmental Entomology* 27:1255–1263; 1999. Prey-mediated effects of Cry1Ab toxin and protoxin and Cry2A protoxin on the predator *Chrysoperla carnea*. *Entomologia Experimentalis et Applicata* 91:305–316; 2001. Implications of transgenic, insecticidal plants for insect and plant biodiversity. *Perspectives in Plant Ecology, Evolution, and Systematics* 4: 43-61; 2002. Transgenic host plant resistance and non-target effects. *In* D. Letourneau and B. Burrows (eds.), *Genetically Engineered Organisms: Assessing Environmental and Human Health Effects.* CRC Press, pp. 167–185; 2004. Science-based risk assessment for nontarget effects of transgenic crops. *BioScience* 54:637-649; 2006. Another view on Bt proteins – How specific are they and what else might they do? *Biopesticides International* 2(1):1-50.

agency should undertake a major effort to thoroughly update its analysis of research reports before it issues proposed rules on GE crops.

As APHIS updates its evaluation of environmental impacts, we urge the agency to include an analysis of a paper published this summer. A meta-analysis of Bt crop field studies showed that the crops caused less reduction in arthropod biodiversity than conventional varieties treated with chemical insecticides, but greater reductions in biodiversity compared to crops grown without insecticides (as may occur with organically grown crops).[18] This paper also demonstrated the importance of using several relevant types of controls in assessing the risks from GE crops.

Finally, there is no discussion of GE insects or other invertebrates that might be used as biocontrol agents, perhaps because the current planned rulemaking is confined to GE plants. APHIS should compile and present the emerging literature on GE insects and other biocontrol agents in advance of any rulemaking establishing a program overseeing the regulation of GE biocontrol agents.

5. APHIS's espousal of the virtues of transparency in the draft EIS are at odds with its current practices involving FOIA requests, CBI, and field inspection reports.

Throughout the draft EIS, APHIS refers to the openness of its current oversight program and its desire to increase even further the level of transparency. That commitment is at odds with UCS's experience, particularly with the agency's oversight of pharma/industrial crops, in three areas: Freedom of Information Act (FOIA) requests, confidential business information (CBI), and field inspection reports.

FOIA

APHIS requires citizens to request documents through its incredibly slow FOIA process. For example, in February 2007, UCS submitted four FOIA requests for pharma crop permit applications that APHIS was in the process of considering for approval. Subsequently the agency issued draft environmental assessments for public comment and then approved the permits. Yet, seven months after our FOIA requests, APHIS has not released any documents. Without access to permit applications, the public cannot participate meaningfully in agency risk assessments or decisionmaking.

CBI

APHIS's CBI policies also inhibit public involvement. The agency allows companies to withhold too much risk-related information on CBI grounds. As an example, in a recent permit review, APHIS allowed a company to withhold the proposed acreage of production sites as well as the procedures and safeguards it promised to implement to confine the pharma crop and genes to the production sites.[19] In a recent APHIS assessment of a non-pharma permit, even the names of the transgenes were withheld, substantially interfering with the public's ability to fully evaluate and

[18] Marvier, M., et al. 2007. A meta-analysis of effects of Bt cotton and maize on nontarget invertebrates. *Science* 316:1475-1477.

[19] See UCS comments to APHIS on an environmental assessments for a permit for Ventria to grow pharma rice in Kansas. Online at www.ucsusa.org/food_and_environment/genetic_engineering/pharma-rice-comments.html.

comment on the APHIS review.[20] As an example of the how the withholding of risk data can impede public review, the National Research Council (NRC), in a report evaluating APHIS's oversight of GE crops, commented that the amount of data held as CBI impeded its analyses. The NRC also noted that "the extent of confidential business information (CBI) in registrant documents sent to APHIS hampers external review and transparency of the decision-making process."[21] As a result, even if APHIS were to release relevant documents in a timely fashion, its permissive CBI policies would likely severely limit the amount of risk data available for public consideration.

Field inspection reports

Finally, by withholding field inspection reports, APHIS limits the public's ability to monitor its enforcement of confinement requirements, which are intended to protect the food supply from pharma/industrial crop contamination. According to the agency, government inspections are key to ensuring company compliance with permit conditions.[22] Without these reports, however, the public is unable to hold the agency accountable for confinement lapses. Since releasing one set of inspection reports in 2006, the agency has refused to divulge any additional ones, despite our subsequent FOIA requests.

As it promulgates new rules, APHIS should consider reforming its procedures for handling FOIA requests, CBI, and inspection reports in light of agency commitments to openness and transparency in its draft EIS.

III. COMMENTS ON SPECIFIC ISSUES IDENTIFIED BY APHIS

ISSUE 1: APHIS is considering the broadening of its regulatory scope beyond genetically engineered organisms that may pose a plant pest risk to include genetically engineered plants that may pose a noxious weed risk and genetically engineered organisms that may be used as biological control agents. Do regulatory requirements for these organisms need to be established?

APHIS prefers a combination of alternatives 2 and 4:
2—Expand the scope of what is regulated by adding considerations of noxious weed risk and regulating GE biological control organisms in addition to evaluating plant pest risks, and use genetic transformation as the trigger for regulation. Continue to regulate event-by-event.
4—Exclude specific classes of highly familiar organisms and highly domesticated, nonweedy crop plants and also create a mechanism to exclude additional organisms from the definition of regulated article after a safety review.

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[20] See UCS comments to APHIS on an environmental assessment for genetically engineered eucalyptus. Online at www.ucsusa.org/food_and_environment/genetic_engineering/ucs-comments-to-usda-on-eucalyptus.html.
[21] National Research Council. 2002. *Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation.* National Academy Press, Washington, DC, see p. 11-12.
[22] USDA APHIS. No date. Compliance and the site inspection process. Online at www.aphis.usda.gov/biotechnology/compinsp_process.shtml; USDA APHIS. 2006. Permitting genetically engineered plants that produce pharmaceutical compounds. Biotechnology Regulatory Services Fact Sheet. Online at www.aphis.usda.gov/publications/biotechnology/content/printable_version/BRS_FS_pharmaceutical_02-06.pdf.

UCS and CFA disagree with APHIS's preference for a combination of alternatives 2 and 4 and support solely alternative 2.

APHIS definitely should broaden the scope of its regulatory program beyond plant pests to include both noxious weeds and biological control agents. As discussed below, the broader scope would for the first time put the agency's biotechnology regulatory system on a sound legal and scientific footing, permit the agency to oversee a much wider set of GE organisms than it currently oversees, and allow the agency to prevent or remedy a wider range of harms than under the Plant Pest Act. If vigorously implemented, a new program based on the expanded authority would be far more protective of the environment and public health than the existing program.

A. Broadening the scope of oversight beyond plant pests.

1. Broadening the scope of oversight would put APHIS's regulatory program on a sound legal and scientific footing.

APHIS's original regulatory program for GE crops was based on quarantine statutes, primarily the now-repealed Plant Pest Act. USDA chose to use quarantine statutes because administration-wide policy adopted in the mid-1980s ruled out the enactment of new legislation specifically targeted to the products of genetic engineering and directed regulatory agencies instead to adopt existing statutes to cover the new products of genetic engineering.[23] The quarantine statutes were the most suitable vehicles on which to base a program under which the agency could review GE crops before they went into the fields or on the market. The major advantage of such statutes was that they contained requirements for permits for movement of pests that could be adapted to the needs of premarket review.

But the Plant Pest Act and other quarantine statutes had major downsides as the basis for a premarket review system. From a scientific standpoint, very few GE crops can be considered plant pests because, generally speaking, they are the targets of plants pests not pests themselves.[24] From a legal standpoint, the plant pest program was vulnerable because most crops did not meet the statutory definition of a plants pest as an organisms which "can directly or indirectly injure or cause disease or damage in any *plants or parts thereof, of any processed, manufactured, or other products of plants* (emphasis added)."[25] Except for relatively rare parasitic plants, which would be covered under the definition, most crops do not "directly or indirectly injure … plants" and thus do not meet the legal definition of a plant pest.

In addition, since virtually no one intends to introduce a plant pest into agriculture, the use of these statutes for pre-release and premarket approval of GE crops severely contorted the purpose of these statutes and undermined their credibility in the United States and around the world.

[23] Office of Science and Technology Policy. 1986. Coordinated framework for regulation of biotechnology. *Federal Register* 51:23302-23393, June 26.
[24] Plant pests, like cotton bollworms, potato beetles, and root-rotting fungi pose threats *to* crops.
[25] 7 U.S.C. § 150aa(c) (repealed)

Basing the new regulation on the Plant Protection Act of 2000 could remedy many of those problems. The new legislation includes a new category, noxious weeds, that comfortably captures crops and other plants. Basing its oversight on this new broader scope puts the APHIS program on a sound legal and scientific footing.

2. ***By providing clear authority to regulate both noxious weeds and biological control agents, the Plant Protection Act extends the number and kind of GE organisms overseen by APHIS.***

The Plant Protection Act also explicitly provides authority for the agency to cover organisms introduced into the environment as biological control agents. While some biological control agents might have met the definition of plant pests, not all would have, so the additional authority to oversee GE versions of biological control organisms as such is welcome. We look forward to APHIS's establishment of a program implementing this authority.

3. ***By defining noxious weeds to include plants that "cause damage to … the public health or the environment," the Plant Protection Act gives APHIS the needed authority to prevent or mitigate a broad set of environmental harms.***

The now-repealed Plant Pest Act was not an environmental statute. Its purpose was to prevent economic damage to plants. As long as APHIS's oversight of GE crops rested on that statute, the agency arguably could only act in instances where GE crops caused harm economically to important plants. Yet GE plants could potentially damage public health or the environment in many other ways. The Plant Protection Act substantially expands APHIS's authority by defining noxious weeds broadly to include those which damage the public health or the environment.[26] That new authority is essential to an adequately protective program.[27]

In sum, UCS and CFA agree with APHIS's preferred alternative 2 of expanding the scope of its regulation to include noxious weed risks. We also agree that organisms should be regulated "event by event" because each transformation event has the potential to cause different harms. Finally, we agree that APHIS should use the authority in the Plant Protection Act to regulate GE biological control agents and look forward to the establishment of a program to oversee such organisms.

B. Exclusions from the definitions of noxious weeds and plant pests

UCS and CFA, however, do not agree that APHIS should adopt alternative 4 to establish a mechanism to "[e]xclude specific classes of highly familiar organisms and highly domesticated, nonweedy crop plants and also create a mechanism to exclude additional organisms from the definition of a regulated article after a safety review" (p. 169).

[26] 7 U.S.C. § 7702(10).

[27] The Plant Protection Act authority remains somewhat unsatisfactory as the basis for a permit system, in that it is awkward to "approve" the use of noxious weeds, but this is a minor deficiency that can be overlooked in view of other advantages of the statute.

APHIS should not exclude any class of GE organisms from the definition of noxious weeds or plant pests. Such an exclusion would effectively put the organisms beyond the ready reach of regulators in terms of monitoring and adverse event reporting and would make it difficult or impossible to respond in case the organism subsequently was shown to be risky.

As we will discuss more thoroughly under issue 3, we urge APHIS to move to a system that issues permits for all field trials and commercial uses of GE organisms.

ISSUE 2: APHIS is considering revisions to the regulations to increase transparency and to address advances in technology that may create new products and concerns. Should a new system of risk based categories be designed to deal with new products and new concern? If so, what criteria should be used to establish the risk-based categories?

APHIS prefers alternative 4—Establish a tiered permitting system for plants based on newly devised criteria and evaluate permit applications for field tests of nonplant organisms on a case-by-case basis.

UCS and CFA agree with APHIS's preference for alternative 4.

A tiered regulatory system represents an efficient, scientifically sound approach that would help APHIS group organisms by apparent risk and take into account the experience the agency gains as it reviews similar organisms. We agree with the general outlines of the tiers described in the draft EIS, but the details of the tier definitions will have important consequences for the protectiveness of the system. The definition of the tiers should be arrived at only after gaining input from all stakeholders in the regulatory system and should be subject to periodic review. This would a good issue on which to convene an outside scientific advisory panel.

As discussed under issues 1 and 3, however, no GE crops should be exempt from the jurisdiction of APHIS's program.

ISSUE 3: APHIS is considering ways to provide regulatory flexibility for future decisions by accommodating commercialization of certain genetically engineered organisms while continuing, in some cases, to regulate the organisms based on minor unresolved risks. Other regulated articles could be treated as they have been under the current system, in which all regulatory restrictions are removed. What environmental factors should be considered in distinguishing between these kinds of decisions?

APHIS prefers alternative 2—Develop appropriate safety criteria and procedures through which plants can be either (1) fully removed from agency oversight or (2) retained under some degree of oversight as necessary to mitigate any minor risks

UCS and CFA do not agree with either APHIS's preferred alternative 2 or the no-action alternative. We fundamentally disagree with the regulatory premise apparently underlying the issue.

UCS and CFA disagree with the regulatory premise apparently underlying APHIS's approach to this issue: that organisms cannot be commercialized if they are still regulated. This view appears to rest on the approach developed by the agency under the Plant Pest Act under which a so-called "deregulation" became a legal surrogate for a commercial approval.

In brief, APHIS reviewed "regulated articles" to determine whether they posed risks as plant pests. If not (and as noted under issue 1, it was scientifically highly unlikely that any crop would pose plant pest risks), the GE crop fell outside of the jurisdiction of the statute and as a result could be used without restriction. In general, the determination that GE crops were not plant pests was made after the completion of field trials, prior to commercialization. Thus the deregulation of a plant became the equivalent of a commercial approval.

Most field trials were conducted after notification to APHIS of the intent to plant a GE crop, except for a few categories, for example, pharma crops, that required permits from the agency. Regulated articles that required permits for field tests could be commercialized without being "deregulated."

UCS and CFA recommend that APHIS abandon this scientifically unsatisfactory and confusing regulatory approach and set up a straightforward system that requires field trial or commercial permits for all regulated articles. The system would treat all GE organisms that meet the definition of plant pests, noxious weeds, or biological control agents, as regulated articles and issue permits for both field testing and commercial use. Each GE organism would be reviewed under a tiered system that takes into account the familiarity and history of use. (See our comments on issue 2).

All GE organisms that pass appropriate safety reviews would be granted permits, conditioned as appropriate to the degree of perceived risk. While many familiar organisms may have reduced, or even no, data requirement, and virtually no restrictions on use, all permits would contain a condition that organisms would be subject to further review and action if new data of substantial risks come to light. No GE organism would be ever be declared to be completely outside of APHIS's regulatory system.

The permit system described above would position the agency to respond in a timely and effective way to the discovery of new environmental or health harms associated with GE organisms. Bringing organisms back under the jurisdiction of a statute after they have been excluded is far more difficult to accomplish than simply rescinding a permit. Having the ability to act swiftly with few legal impediments is essential for an effective regulatory system. It is not unreasonable to expect that harms to public health or the environment might not emerge until long after crops are first commercialized. Ecologists have recognized that field trials are not extensive enough to reliably detect many possible harms that could emerge after commercialization. The creation of new weeds or herbicide-resistant weeds, or gene flow to crop wild relatives, for example, could reasonably take years.[28]

[28] Haygood, R., et al. 2004. Population genetics of transgene containment. *Ecology Letters* 7(3):213-220

At bottom, APHIS should not be overly confident in its ability to discern the environmental risks of even familiar crops. This is especially true since the agency does not monitor crops after approval and has never scientifically validated the accuracy of its risks assessments. It is far too early to declare whole classes of organisms to be so safe they can be released completely from regulatory oversight. Instead, APHIS should consider the recommendations of the Ecological Society of America to monitor the environmental impacts of GE crops after commercialization.[29]

In sum, UCS and CFA are adamantly opposed to a system that uses deregulation as a surrogate for commercial permits. We strongly believe that all regulated articles ought to be permitted for field tests and commercial use and that permits should carry conditions commensurate with assessments of risks. We further believe that the intensity of reviews should take into account familiarity and experience with GE organisms and that many regulated crops could be permitted with minimally burdensome conditions.

ISSUE 4: Are there changes that should be considered relative to environmental review of, and permit conditions for, genetically engineered plants that produce pharmaceutical and industrial compounds?

APHIS prefers alternative 2—Continue to allow food and feed crops to be used for the production of pharmaceutical and industrial compounds. The agency would impose confinement requirements, as appropriate, based on the risk posed by the organism and would consider food safety in setting conditions.

UCS and CFA disagree with APHIS's preference for alternative 2 and support alternative 4, which would "[a]llow field testing only if the crop has no food or feed uses."[30]

1. ***APHIS should reject alternative 2 in favor of alternative 4, which would in essence ban the outdoor cultivation of food and feed crops engineered to produce pharma/ industrial compounds.***

UCS and CFA do not agree with APHIS's preferred alternative 2 of continuing its status quo oversight of GE pharma/industrial crops with some ill-defined consideration of food safety in setting standards. Continuation of the existing program is demonstrably insufficient to protect the public health, the environment, and the economic interests of farmers, food companies, and commodity exporters.

APHIS should adopt alternative 4, which would ban the outdoor use of food and feed crops genetically engineered for pharma/industrial purposes. This option would allow companies to engineer non-food crops to produce drugs and industrial chemicals outdoors but without an unacceptable threat of the contamination of exports and retail food and feed products.

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[29] Snow, A.A., et al. 2005. Genetically engineered organisms and the environment: current status and recommendations. *Ecological Applications* 15(2):377–404.

[30] For a more detailed discussion of UCS's recommendation for a ban on the outdoor use of pharma and industrial food crops, see our position paper at www.ucsusa.org/food_and_environment/genetic_engineering/ucs-position-paper.html.

The idea that adding some sort of food safety review to the current system would make the inevitable contamination event more palatable to the public is illusory. The notion that "safe drugs" will be acceptable in breakfast flakes or exports is naïve. Consumers whether here or elsewhere in the world will react negatively to the presence of drugs or plastics in retail or commodity foods. The availability of a food safety review for the drug will not dampen the outrage.

Moreover, it is not clear which agency, APHIS or FDA, would conduct the food safety reviews, but both agencies have drawbacks. APHIS has neither experience nor expertise in doing food safety reviews. FDA has experience but its reviews are voluntary and opaque (because confidential business information is withheld from the public). In view of FDA's failure to establish a strong, mandatory approval system for GE food, UCS is pleased to see APHIS contemplating adding food safety capacity. But to inspire public confidence, the agency will need to acquire new expertise. APHIS's failure to even mention the seminal Australian pea study referred to above on page 3 suggests that the agency may not be up to the challenge.

APHIS's preference for alternative 2 is based on an unsubstantiated and overly optimistic assessment of its current program. According to the EIS (p. 170), "[b]ased on previous experience in field testing of plants producing [pharmaceutical and industrial] compounds, the use of highly stringent confinement measures can be used effectively to protect the environment from significant impact." But APHIS presents no data demonstrating that its confinement measures for pharma/industrial crops are working. The agency does not systematically monitor for the movement of genes off test sites either in pollen or seeds. Nor does APHIS test the seed supply to determine the level of contamination with approved or unapproved GE elements. The agency may expect or hope that performance standards are working, but it has no data demonstrating that they are.

Meanwhile, a number of high profile contamination incidents, resulting from tests done not by APHIS but by export customers and others have shown that transgenes and seeds of GE varieties are not confined to their test plots. Such incidents give rise to serious doubts about the efficacy of agency standards, including the more stringent measures that apply to pharma/industrial crops.

At a minimum, before the agency asserts that the system is sufficiently stringent, it should wait for the results of its investigations into the contamination of commodity rice with unapproved LibertyLink 601 traits last year.[31] While the traits were non-pharma crop traits, the origin of the contamination could illuminate the full range of activities that could contaminate commodity crops and should be taken into account by APHIS in making decisions about pharma/industrial crops.

2. ***Completely protecting the food and feed supply in the absence of a ban would require APHIS to develop and implement a new and complex oversight system.***

[31] USDA. 2006. Transcript of Remarks by Agriculture Secretary Mike Johanns.

As shown in UCS's 2004 report, *A Growing Concern*,[32] there are numerous points at which contamination of the food and feed supply can occur if food and feed crops engineered to produce pharma/industrial compounds are used outdoors. These include not only pollen flow, but seed production and post-harvest transport. To block all of the points of transfer requires a system far more comprehensive than APHIS's, which focuses too narrowly on pollen flow. But, in addition, it requires a system that will be immensely complex, requiring numerous inspections, complicated recordkeeping, and orchestration of both federal and state entities.

Failure of such a complicated system is almost assured and could easily result in an incident with serious environmental or public health consequences as well as devastating economic costs for commodity traders or retail food purveyors or the biotechnology industry itself.

The better option by far is simply to ban the outdoor use of food and feed crops—such as corn, soybeans, canola, safflower—for the production of substances never intended to be in food or feed.

3. *APHIS is unable to successfully implement the complex oversight system that would be required to meet the complete-protection standard.*

UCS and CFA have concluded that APHIS is unable to develop and successfully execute a system to completely protect the food and feed supply. We have come to this conclusion because of the agency's failure to adequately implement its current regulatory scheme—a relatively simple system compared to the one that would be needed.

Two recent incidents illustrate our concern. Less than two years ago, the USDA's Office of Inspector General (OIG) released a report[33] detailing significant deficiencies in APHIS's oversight of GE crop field tests, including trials of pharma/industrial crops. Among other deficiencies, the OIG found that APHIS had failed to inspect pharma/industrial crop fields as often as promised and to ensure proper and timely disposal of the crops after harvest.

UCS's analysis[34] of documents received in response to a 2006 FOIA request indicate that those and other serious deficiencies persist. Our analysis revealed that the agency conducted only three of five required inspections of pharma rice grown in North Carolina in 2005. In addition, the records showed no contact between the agency and company producing pharma rice in the aftermath of Hurricane Ophelia, which passed close by the site in September 2005, a few weeks before harvest. Despite the reasonable possibility that heavy wind and rain could have spread pharma rice seeds into a nearby government-run rice-breeding plot, APHIS evinced no interest in

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[32] Andow, D.A., et al. 2004. *A Growing Concern: Protecting the Food Supply in an Era of Pharmaceutical and Industrial Crops*. Union of Concerned Scientists: Cambridge, MA, 125 pp. Online at www.ucsusa.org/food_and_environment/genetic_engineering/pharmaceutical-and-industrial-crops-a-growing-concern.html.

[33] USDA, Office of Inspector General, Southwest Region. 2005. Audit report: Animal and Plant Health Inspection Service controls over issuance of genetically engineered organism release permits. Audit 50601-8-Te, December. Online at www.usda.gov/oig/webdocs/50601-08-TE.pdf.

[34] For more information, including documents released by USDA, see the following UCS web page: UCS uncovers lax USDA oversight of pharma crops. Online at www.ucsusa.org/food_and_environment/genetic_engineering/usda-ventria-oversight.html.

the impact of Hurricane Ophelia until nearly a year after the event, and then only in response to UCS's inquiry on the matter. Yet, this pharma rice was the most controversial pharma crop grown in 2005.

ISSUE: 5: The definition of noxious weed in the PPA includes not only plants, but also plant products. Based on that authority, APHIS is considering the regulation of nonviable plant material. Is the regulation of nonviable material appropriate and, if so, in what cases should we regulate?

APHIS prefers alternative 2—Regulate nonviable GE plant material in certain circumstances, based on the risks posed.

UCS and CFA agree with APHIS's preference for alternative 2.

ISSUE 6: APHIS is considering establishing a new mechanism involving APHIS, the States, and the producer for commercial production of plants not intended for food or feed in cases where the producer would prefer to develop and extract pharmaceutical and industrial compounds under confinement conditions with governmental oversight, rather than grant nonregulated status. What should be the characteristics of this mechanism?

APHIS prefers alternative 2—Allow for special multi-year permits, with ongoing oversight. The new system would maintain these crops under regulation, but APHIS oversight would be exercised in a different manner than under the current system of permits.

UCS and CFA disagree with APHIS's preference for alternative 2 and support alternative 1, under which the agency would "continue to authorize field tests of crops not intended for food or feed use under permit" and would "[r]equire application and review of these permits on an annual basis."

As discussed above, in our view all GE organisms should be under permit at all times with the conditions of the permits varying with what APHIS believes to be the risk associated with the organisms.

It may make sense in some cases to issue multi-year permits for some products. But of all the kinds of organisms for which the agency might consider granting multi-year permits, pharma/industrial crops seem the least likely. In general, it is difficult to see the advantages of the multi-year permits if the inspections and auditing would go on as usual. UCS and CFA are concerned that such permits would allow the companies to vastly increase the acreage of the pharma/industrial crops without notifying the agency or the public. These concerns were exacerbated this past spring by APHIS's failure to tell the public whether the pharma rice plantings approved for 2007 in Kansas were for 100 or 3200 acres.[35]

[35] UCS. 2007. UCS comments to USDA on Kansas pharma rice. Online at www.ucsusa.org/food_and_environment/genetic_engineering/pharma-rice-comments.html.

If the agency decides to adopt alternative 4 (a ban on outdoor growth of the use of food crops as pharma and industrial crops) on issue 4, issue 6 would be moot for food and feed crops.

As an aside, the assurance that any permitted field trials would be performed at appropriate isolation distances "to maintain confinement and minimize gene flow" suggests that APHIS might believe that gene flow by pollen is the most likely or most important route by which contamination of the food supply or commodity crops might occur. While it is important, it is not the only route of contamination and blocking only that route will not safeguard the food supply.

Moreover, the agency's performance standards require a good deal more than merely "minimizing gene flow." The language on permit conditions requires compliance with conditions "necessary *to prevent the dissemination and establishment* of plant pests" (emphasis added).[36]

ISSUE 7: The current regulations have no provision for the low-level presence of regulated articles in commercial crops, food, feed, or seed of GE plant material that has not completed the required regulatory processes. Should low-level occurrence of a regulated article be exempted from regulation?

APHIS prefers alternative 3—Establish criteria under which occurrence of regulated articles would be allowable, that is, considered not-actionable by APHIS. Allow field testing and impose confinement strategies based on whether a plant meets the criteria.

UCS and CFA disagree with APHIS's preference for alternative 3 and believe instead that alternative 4, the establishment of new stringent criteria for field tests, is the better option.

Criteria sufficiently stringent to effectively confine the movement of GE seeds or transgenes would protect the public health, the environment, the interests of conventional and organic farmers, and promote overall confidence in U.S. agricultural products. APHIS should not assume that the pharma/industrial crop standards are sufficiently stringent without, as discussed above on issue 4, validating the effectiveness of the performance standards.
We reject alternatives 2 and 3 because they rest on two faulty assumptions: i) the level of contamination is known and relatively low and ii) APHIS can differentiate risky from non-risky products.

APHIS has virtually no data to support these assumptions.

First, the agency does not survey U.S. commodities for contamination by elements derived from unapproved GE organisms, and therefore it cannot assume that the level is low. In fact, APHIS does not have access to the molecular tools, known as primers, needed to detect such elements. Its understanding of the levels of contamination is based on the occasional discovery of

[36] 7 CFR 340.4(f) *Permit conditions*. A person who is issued a permit and his/her employees or agents shall comply with the following conditions, and any supplemental conditions which shall be listed on the permit, as deemed by the Administrator to be necessary to prevent the dissemination and establishment of plant pests.

contamination, usually by export customers. These discoveries surely under represent the true levels of contamination, but it is difficult to know by how much.

It should be noted that field tests now have been underway for 20 years. This means that movement of genes and seeds from these tests into the U.S. commodity seed and grain supply is highly likely.[37] Because APHIS has never tested for the presence of unapproved GE varieties, the agency has no idea of the extent of contamination this long, loosely controlled planting of GE crops has produced.

Second, the agency cannot differentiate between safe and unsafe GE organisms with enough confidence to allow low levels of some crops to be considered safe or non-actionable. The potential harms of GE crops range broadly and include environmental, public health, and food safety concerns. The risk assessment of GE crops remains challenging across all those dimensions. One reason is that APHIS does not monitor crops after they have been deregulated and does not know whether its safety assessments are valid.

Another more fundamental reason is that APHIS only has long-term experience with two GE traits, Bt and herbicide-resistance That experience is not definitive proof of safety because different gene-crop combinations present different spectra of risks. Experience with two traits, even if favorable, does not translate to new, different genes, traits, crops, and constructs.

The soundest approach then is to confine GE genes and elements as completely as possible until they have been assessed and evaluated. Approaches similar to those described in alternatives 2 and 3 might be possible in the future, but only after the agency has a strong handle on the levels of contamination, has a system in place to monitor contamination, and has evidence of the efficacy of confinement systems in practice.

Until then, alternative four is the best option.

A note on primers: Primers are molecular tools that allow the detection of GE genes and elements. One of the most important steps APHIS could take to protect the food supply, consumers, and farmers, and expedite enforcement of agency regulations would be to gain access to primers for all events that are field tested in the United States. UCS and CFA recommend that APHIS address this issue in its final EIS and include a provision in its proposed regulations requiring companies, as a condition of approval of field testing, to provide primers for their GE crops. APHIS should also investigate the feasibility of having companies that have field tested engineered crops in the past provide the agency primers for their products. Once APHIS has primers in its possession it would be in a position to monitor and respond to changing levels of unapproved transgenes and GE elements in the U.S. supply of grains, fruits, vegetables, and grasses.

Active monitoring of field trials would provide needed data about contamination and gene flow that are currently largely unavailable. It may also detect contamination before it becomes widespread and causes economic (and possibly other) harm, as occurred with LibertyLink 601 rice.

[37] Andow, D.A., et al. 2004. A Growing Concern.

ISSUE 9: Currently, genetically engineered *Arabidopsis* spp. are exempt from interstate movement restrictions under 7 CFR 340.2 because they are well understood and extensively used in research. Should the movement of genetically engineered *Arabidopsis* spp. or other GE organisms be exempted from movement restriction?

APHIS prefers alternative 2—"Exempt a class of GE plants or organisms that are well-studied and present little or not environmental risk from permit requirements for interstate movement as is currently done for Arabidopsis.

UCS and CFA agree with APHIS's preference for alternative 2, provided organisms are added to the exempt class based on criteria developed with the full participation of stakeholders.

ISSUE 10: What environmental considerations should be evaluated if APHIS were to move from prescriptive container requirements for shipment of GE organisms to performance-based container requirements, supplemented with guidance on ways to meet the performance standards?

APHIS prefers alternative 2—Switch to performance-based standards for all shipping containers.

UCS and CFA agree with APHIS's preference for alternative 2.

Thank you for your consideration of our comments.

Sincerely,

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