



# Union of Concerned Scientists

Citizens and Scientists for Environmental Solutions

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Regulatory Analysis and Development  
USDA APHIS PPD  
Station 3A-03.8  
4700 River Road, Unit 118  
Riverdale, MD 20737-1238

Submitted via Federal eRulemaking Portal: Docket No. APHIS-2008-0023

Re: USDA APHIS proposed rule regulating genetically engineered organisms

To whom it may concern:

On behalf of the Union of Concerned Scientists (UCS), we are pleased to submit the following comments on the U.S. Department of Agriculture Animal and Plant Health Inspection Service's (APHIS's) proposed rule on the regulation of genetically engineered (GE) organisms.

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.

## BACKGROUND

APHIS issued the proposed rule and request for public comment in the *Federal Register* on October 9, 2008, with the comment period ending on November 29, 2008.<sup>1</sup> Since then, the agency reopened the comment period on January 16, 2009,<sup>2</sup> extended the reopened comment period on March 11, 2009,<sup>3</sup> and held two public meetings—one on March 13, 2009, and one on April 29 and 30, 2009.<sup>4</sup> The rulemaking, one of the first actions of the Obama administration on cutting-edge agricultural technologies, will shape the course of crop genetic engineering in the 21<sup>st</sup> century.

At the April public meeting, APHIS distributed brief issue papers<sup>5</sup> on five of the most controversial topics raised in comments on the proposed rule: the scope of the proposed rule, incorporating noxious weed authority, eliminating notifications and establishing a category-

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<sup>1</sup> 73 Fed. Reg. 60008-48.

<sup>2</sup> 74 Fed. Reg. 2907-2909.

<sup>3</sup> 74 Fed. Reg. 10517-10518.

<sup>4</sup> 74 Fed. Reg. 10517 and 74 Fed. Reg. 16797-16798.

<sup>5</sup> USDA APHIS Biotechnology Regulatory Services (BRS). 2009. Public meeting on proposed rule for biotechnology regulations: meeting issue papers. Available online at [www.aphis.usda.gov/biotechnology/meetings\\_340april09\\_issuepapers.shtml](http://www.aphis.usda.gov/biotechnology/meetings_340april09_issuepapers.shtml).

based permitting system, regulating pharma crops,<sup>6</sup> and remediating low-level contamination. Each issue paper describes comments APHIS has received, summarizes the agency's current thinking on the topic, and lists questions for discussion at the public meeting.

According to agency staff, once it has considered comments received by the June 29 deadline, APHIS intends to prepare a final rule that it will release along with the final EIS. The agency has not informed the public of its timetable for completing the rulemaking.

UCS submitted comments on the proposed rule on November 29, 2008.

The rulemaking that was the subject of our November comments and the comments below is intended to align biotechnology regulations with the Plant Protection Act (PPA) of 2000,<sup>7</sup> which consolidated a number of plant health laws including the Noxious Weed Act and the Federal Plant Pest Act (FPPA). Current biotechnology regulations implement primarily the FPPA and other quarantine authorities that were repealed as part of the enactment of the PPA.

To inform the preparation of the proposed rule, APHIS published a draft environmental impact statement (EIS) and request for public comment in the *Federal Register* on July 17, 2007.<sup>8</sup> The EIS consisted of an analysis of regulatory alternatives on ten issues APHIS identified as important for the rulemaking. The agency has said that its final EIS will summarize and address the comments on the draft EIS.

The new rule proposed by APHIS solidifies and extends the legal authority the agency relies on for the regulation of GE crops, trees, and invertebrates. The current system is based on the FPPA and a number of other quarantine statutes intended to protect agriculture against plant pests, not to protect the environment broadly. These authorities have always been a legal stretch because crops only rarely act as pests on other plants. Nevertheless, the agency was able to use them to establish a comprehensive system for pre-market review of GE products developed for outdoor use. The system, which applies to virtually all GE crops and trees, requires permits or notifications for introduction into the environment and offers determinations that the plants were deregulated as a surrogate for commercial permits.

The range of scientific concerns about GE organisms has always been broad and includes potential threats to the public health through accumulation of heavy metals; threats to charismatic insects like the monarch butterfly; disruption of ecosystems by, for example, enabling salt-tolerant rice to invade aquatic ecosystems; and threats to centers of diversity of important crops like corn and squash. Under the current system based on plant pest authority, APHIS has considered such issues, but only in the context of reviews under the National Environmental Policy Act (NEPA).

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<sup>6</sup> The term pharma crops covers GE crops whose products are intended to be used as pharmaceuticals or industrial compounds.

<sup>7</sup> The Plant Protection Act of 2000, 7 U.S.C. 7701 *et seq.*

<sup>8</sup> 72 Fed. Reg. 39021-25.

The PPA expands APHIS's authority in two ways. It provides broad authority to regulate noxious weeds, a category that more comfortably encompasses GE crops than plant pests, and it expands the definition of noxious weeds beyond a narrow focus on the protection of agriculture and infrastructure of the United States to include plants that directly or indirectly injure the environment and public health.

While quarantine statutes are inherently challenging as jurisdictional authority for a pre-market review system, with proper implementation this system could work well. The PPA represents a broad grant of authority under which the agency has leeway to construct a regulatory regime for the biotechnology products of the 21<sup>st</sup> century that is comprehensive, rational, and protective. However, the proposed rule fails to use the opportunity and instead has proposed a confusing rule that drastically weakens the regulation of GE crops and other organisms even compared to the weak existing system.

## **SUMMARY OF UCS CONCLUSIONS**

UCS's overall view is that the proposed rule, while based on sounder legal foundation than its predecessor, markedly weakens oversight of the agricultural biotechnology industry. The proposed rule has five major defects. First, the scope provisions are confusing and constructed so that over time the rule will cover fewer and fewer GE products, leaving APHIS in the dark about the activities of the biotechnology industry. Second, the potential harms the rule intends to regulate do not include most of the concerns scientists have raised about the impacts of GE crops. Third, the severity of the injury required to merit consideration as a noxious weed under the rule is extremely high and would allow products that cause substantial environmental disruption to escape regulation. Fourth, the rule fails to protect the food supply from pharmaceutical and industrial crops. Fifth, the proposed rule allows GE organisms to be removed from the agency's legal jurisdiction through a petition process. In addition to these defects, the process for disclosing the environmental consequences of proposed regulatory options fails to adhere to NEPA requirements.

Below we provide detailed comments and a summary of recommendations on six major issues raised by the proposed rule: scope, implementation of noxious weed authority, pharma crop regulation, conditional exemptions from permit requirements, the petition process to establish nonregulatory status, and compliance with NEPA.

In addition to reiterating the views we expressed in our November 2008 comments, we also respond to some of the points made by APHIS in issue papers released by the agency in April in which it summarizes its current thinking on the comments it had received up to that point.<sup>9</sup>

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<sup>9</sup> USDA APHIS BRS. 2009. Public meeting.

## UCS COMMENTS

### **I. The scope of the proposed rule is convoluted, does not subject all GE plants to oversight, gives too much power to the regulated industry, and over time diminishes the agency's oversight of the industry.**

There are three major flaws in the proposed scope of the rule: failure to cover all GE crops, allowing industry to determine what products are subject to oversight, and giving up the capacity over time to oversee and monitor the biotechnology industry.

In our November 2008 comments, UCS urged the agency to establish a scope—the description of those products or organisms the agency intends to review—that would cover all GE plants, non-vertebrates, and non-plants. To capture a product or organism for review does not mean it is not safe, only that it is worth a look by the government. Indeed, most reviewed products are expected to be safe. The agency determines which products are not safe enough to go on the market after reviewing data presented by developers.

Our earlier comments applauded the fact that the scope of the proposed rule covers only GE organisms<sup>10</sup> (and thus is process-based). But the scope does not cover *all* GE organisms. With regard to plants,<sup>11</sup> the criteria for determining scope in the proposed rule apply only to those GE plants: i) that are derived from an unmodified plant that is itself a plant pest or noxious weed, ii) whose potential to become a noxious weed has been enhanced by the genetic engineering, iii) whose risk as either a plant pest or noxious weed is unknown, or iv) if the administrator determines that the GE plant poses a plant pest or noxious weed risk.<sup>12</sup>

APHIS's position in its April issue paper acknowledges concern about the scope<sup>13</sup> but does not embrace the sensible course of simply covering all GE crops as potential noxious weeds. The agency's indicates only that the scope criteria “may need to be refined and clarified” and that “[m]ore lucid scope criteria will also reduce the number of GE organisms whose regulatory status may be ambiguous or unknown ....”<sup>14</sup>

Minor adjustments of the overly complex scope definition will not solve its problems. The agency has designed a scope that is defined in terms of the harms the regulation is intended to prevent. It appears that APHIS adopted this approach in order to be able to say that “[t]he mere act of genetic engineering does not trigger regulatory oversight,”<sup>15</sup> and instead GE plants must pose risks to be regulated.<sup>16</sup> But the result is circular reasoning: the organisms the agency will

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<sup>10</sup> 73 Fed. Reg. 60011.

<sup>11</sup> Similar scope provisions that apply to non-vertebrate, non-plants raise similar concerns, but will not be discussed in these comments.

<sup>12</sup> 73 Fed. Reg. 60011.

<sup>13</sup> USDA APHIS BRS. 2009. Issue 1: Scope of the proposed Part 340 regulations and which GE organisms should be regulated. Available online at [www.aphis.usda.gov/biotechnology/340/340\\_downloads/apr09pubmtg\\_issuepaper\\_scope.pdf](http://www.aphis.usda.gov/biotechnology/340/340_downloads/apr09pubmtg_issuepaper_scope.pdf).

<sup>14</sup> USDA APHIS BRS. 2009. Issue 1.

<sup>15</sup> 73 Fed. Reg. 60012.

<sup>16</sup> 73 Fed. Reg. 60012.

review to determine whether they are plant pests or noxious weeds are those that are plant pests or noxious weeds.

The element in the scope capturing GE plants whose plant pest or noxious weed risks are unknown is a way for the agency to get out of this bind.<sup>17</sup> Since plant pest and noxious weed are legal terms of art, it would be rare that a producer would know for sure whether a product was or was not a plant pest or noxious weed. Including products whose risks are unknown enlarges the scope to potentially capture most GE plants.

A plant pest risk could be “known” if APHIS were familiar with the crops or genes. But, how much information the agency needs to consider risks known is a matter of judgment. Much rides on the decision: if the plant is familiar and the risk can be considered known, the plant is not subject to regulation of any sort.

A sensible policy would bring all GE crops to the agency for review and adjust the burden of the review to reflect the likelihood of risks. Such an approach would put APHIS in a position to provide assurances to the public and our trading partners that the technology is being overseen. APHIS needs to craft a simple definition of scope that will accomplish this purpose.

UCS’s second major area of concern is the grant of considerable power to the regulated industry to decide what products will be subject to the regulations. The proposed rule gives developers extraordinary authority through a “responsible person” to decide whether the scope criteria apply to their products.<sup>18</sup> Under this approach, it will be a challenge for companies or scientists to know whether their products need to be submitted to the agency and virtually impossible for the public to know the extent to which GE plants are being overseen.

In addition, where a company or developer is uncertain about scope it *may choose to consult* with APHIS, but it need not.<sup>19</sup> If a company chooses to consult, the agency will provide a written rationale of its scope determination and post it on the web.<sup>20</sup>

According to the April issue papers, the rule’s ambiguity in this matter drew considerable comment from both proponents and critics of the technology.<sup>21</sup> In response, the agency notes: “It must be made clear to the public that what falls under the jurisdiction and scope of the regulations is determined solely by APHIS.”<sup>22</sup> We applaud this statement and look forward to the elimination of the “responsible person” provision and the establishment of clear criteria that can be understood and followed by all.

The third major flaw in the scope is that the range of covered products and organisms will decrease over time under the proposed regime.<sup>23</sup> Our concern here is that, as time passes, an increasing number of organisms will not even come to the agency for review. If this scenario

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<sup>17</sup> 73 Fed. Reg. 60012.

<sup>18</sup> 73 Fed. Reg. 60011.

<sup>19</sup> 73 Fed. Reg. 60012.

<sup>20</sup> 73 Fed. Reg. 60012.

<sup>21</sup> USDA APHIS BRS. 2009. Issue 1.

<sup>22</sup> USDA APHIS BRS. 2009. Issue 1.

<sup>23</sup> 73 Fed. Reg. 60012.

plays out, APHIS will have no idea of how many GE organisms there will be in the field or in commerce and will have little opportunity to oversee or monitor much of the biotechnology industry.

The agency asked for the best way to provide “administrative guidance to the public on the issue of which GE organisms are within the scope of the regulations.”<sup>24</sup> UCS’s response is that under the program it has devised, most of the information on what products have been developed but are not being regulated will remain with the industry. The agency’s problem is not how to share such information, but how to obtain it in the first place.

We urge APHIS to eliminate the “responsible person” provision and to clearly state that the agency will be the sole arbiter of jurisdictional decisions. To correct the other two flaws, UCS recommends that APHIS redraft the scope of the proposed rule to essentially cover all GE plants and non-vertebrate, non-plant GE organisms not previously deregulated by the agency.

## **II. APHIS’s interpretation of the PPA’s noxious weed authority fails to protect public health and the environment and prevent economic harm to agricultural interests by potentially allowing the release and propagation of harmful GE plants.**

The proposed rule is based on robust new authority to regulate noxious weeds, which are defined in an expansive way to include “[a]ny plant or plant product that can directly or indirectly injure or cause damage to crops (including nursery stock or plant products), livestock, poultry, or other interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment.”<sup>25</sup> With the addition of the terms public health and the environment, this definition of noxious weeds constitutes a generous grant of authority that allows the agency to protect against the broad range of scientific concerns that have been raised about GE organisms, including the enhanced weediness of the existing crops, creation of new weeds through the flow of genes to wild relatives, and protection of charismatic species like the monarch butterfly.

In addition, the inclusion of the phrase “other interests of agriculture” in the list of protected interests broadens the definition to allow the agency to consider the potential harm to organic farmers, the food industry, exporters, and others resulting from contamination by GE crops and transgenic elements.

In order to protect the environment and public health and enhance the commercial acceptance of the technology, the agency must use the full range of its grant of authority. APHIS has failed to use that authority in three ways, discussed below.

### ***A. The agency proposes to use an overly narrow definition of noxious weeds.***

In our November 2008 comments, we criticized APHIS’s intention to interpret its authority very narrowly by adopting a definition of noxious weeds that is based on the kinds of plants currently

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<sup>24</sup> 73 Fed. Reg. 60012.

<sup>25</sup> 73 Fed. Reg. 60039, Proposed rule at 7 CFR 340.1

listed as noxious weeds.<sup>26 27</sup> Such an interpretation suggests that the agency intends to regulate only the plants that cause harm of the same magnitude as the selected examples, most of which cause extreme harm.

The issue paper on noxious weed authority indicates that APHIS has not wavered from that position.<sup>28</sup> According to the paper, the agency received contrasting comments on the matter, with industry generally calling for a narrow interpretation of the noxious weed definition and public interest groups and individual citizens calling for a more expansive interpretation.<sup>29</sup> The agency responded with a reaffirmation of the proposed rule's approach, that is, to oversee GE plants under the same narrow interpretation of noxious weed risks that it currently applies to non-GE plants.<sup>30</sup>

APHIS is reluctant to regulate GE organisms more strictly than non-GE organisms. In its words, it "must consistently apply its PPA noxious weed authority and thus its noxious weed assessment of GE plants under the proposed regulations must be similar to and consistent with the way that APHIS has in the past and continues to evaluate the noxious weed risk of non-GE plants. It is not justifiable either from a regulatory or a scientific perspective to hold GE plants to a different standard than non-GE plants for risks regulated under the same statutory authority by the very same agency."<sup>31</sup>

APHIS's assertions are without justification and belied by its past actions. For over twenty years, the agency has inconsistently applied the Plant Pest Act, holding GE plants to a different standard and much higher level of scrutiny than non-engineered plant pests. Just as APHIS exercised its discretion in developing a different assessment process and different standards for pests regulated under the Plant Pest Act, it can do so for both pests and noxious weeds under the PPA.

Given that the agency's current thinking is to proceed with incorporating noxious weed authority in the same manner as laid out in the proposed rule, we reiterate our November 2008 comments objecting to that approach.

In its introduction to the proposed regulations, the agency presents a table of the examples of impacts caused by federally listed noxious weeds<sup>32</sup> and says that these examples illustrate the "...types of effects APHIS will be looking for when evaluating whether GE crops reviewed under part 340 have any potential noxious weed traits."<sup>33</sup>

The weeds in this table are dominated by examples like serrated tussock that significantly reduce the productivity of pasture lands and hydrilla, which can substantially reduce water flow and

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<sup>26</sup> 73 Fed. Reg. 60012-14.

<sup>27</sup> The current list of noxious weeds is available online at <http://plants.usda.gov/java/noxious>.

<sup>28</sup> USDA APHIS BRS. 2009. Issue 2.

<sup>29</sup> USDA APHIS BRS. 2009. Issue 2.

<sup>30</sup> USDA APHIS BRS. 2009. Issue 2.

<sup>31</sup> USDA APHIS BRS. 2009. Issue 2.

<sup>32</sup> 73 Fed. Reg. 60013-14, Table 1.

<sup>33</sup> 73 Fed. Reg. 60013.

impact irrigation, flood control, and water treatment plant intake.<sup>34</sup> These and the other species on the list are described as “...*dramatically* reducing [crop] yields,” “...leaving [infested areas] *completely* incapable of supporting livestock,” “...*completely* dominating the landscape” or, for aquatic noxious plants, as “...vegetation resulting in a *complete* ecological shift of the habitat” and that “...can alter aquatic ecosystems so drastically that native plants are *entirely* eliminated” (emphasis added).<sup>35</sup> GE plants may cause substantial environmental harm, but still not rise to the level of damage caused by these examples. Requiring that GE plants meet this level of adverse impact to be restricted or regulated under the PPA would leave many harmful GE plants without controls.<sup>36</sup>

Interpreting the definition of noxious weeds in the PPA to apply only to the “worst of the worst” weeds is an unnecessarily restrictive interpretation that will leave uncontrolled many GE plant species that could cause substantial harm to public health, the environment, and agricultural interests. In our view, effects that are less severe than those cited as examples by APHIS, should be potentially controlled under the PPA.<sup>37</sup> In fact, regulating the characteristic risks of GE crops and other organisms appears to be the purpose of expanding the authority beyond the old definition of noxious weeds.

In addition, the proposed rule too narrowly considers potential economic impacts when determining whether a GE plant is a noxious weed. APHIS states that it “does not consider significant economic effects alone that are not linked to physical damage to be sufficient to determine a plant is a noxious weed” and that “[t]he economic loss is never simply the result of market preference to have commodities free of certain noxious weed seeds in and of itself, in the absence of any potential physical damage or harm.”<sup>38</sup> This restricted view excludes consideration of economic harm to agricultural interests such as organic growers and grain exporters as a result of contamination of their products by GE crops.

In summary, APHIS should set a reasonable bar for the regulation of GE crops, well below the extremely severe impacts listed in the introductory discussion to the proposed rule and broader than the current narrow view of economic harm.

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<sup>34</sup> 73 Fed. Reg. 60013.

<sup>35</sup> 73 Fed. Reg. 60013-14.

<sup>36</sup> APHIS admits that the noxious weed definition could exclude many harmful weeds and GE plants by drawing the following distinction between ‘weeds’ and noxious weeds: “In a narrower sense, weeds are invasive, often non-native, plants which impact natural and managed ecosystems, often with significant negative consequences due to lost yields, changes in management practices, altered herbicide use, etc. Only a fraction of these problematic weeds are considered to be so invasive, so harmful, and so difficult to control that Federal regulatory intervention to prevent their introduction or dissemination is justified....” (73 Fed. Reg. 60013)

<sup>37</sup> The current noxious weed list includes only about 100 terrestrial and aquatic species (<http://plants.usda.gov/java/noxious>) leaving out hundreds of important agricultural and environmental weeds that collectively cause tremendous losses, either directly or through control costs. Among the weeds not on the APHIS noxious weeds list are ones considered to be among the world’s worst, such as Johnson grass (*Sorghum halepense*).

<sup>38</sup> 73 Fed. Reg. 60014.

***B. APHIS categories for classifying field trial permits consider too few harms to adequately regulate the full range of adverse risks posed by GE crops.***

UCS applauds APHIS's proposal to eliminate the use of notifications to oversee field trials, and instead to require permits for all field trials. Notifications rely on general performance standards and allow applicants to determine how to meet those standards with insufficient oversight from the agency. This has placed too much of the regulatory responsibility in the hands of GE crop producers who may not have adequate risk assessment expertise and have a vested interest in conducting field trials as expeditiously as possible. Permits require greater involvement by APHIS and will result in specific conditions tailored to individual crop/gene combinations.

As part of its process to determine potential field trial risk, APHIS proposes to initially sort applications for GE plant release permits into four increasingly risky environmental release categories, also referred to as administrative permit categories.<sup>39</sup> The agency notes that these administrative categories are only preliminary risk-sorting criteria, and that a final risk determination and subsequent field trial permit conditions would be established only after further evaluation. The agency makes clear, however, that the preliminary risk categorization would heavily influence its final evaluation of the proposed field trial risk.<sup>40</sup>

The two main risk factors that APHIS will consider to sort field trials into categories are the persistence of the unmodified recipient crop in the environment and the potential harm of the engineered trait.<sup>41</sup>

The specific list of harms the agency will consider in applying the sorting categories is very limited and includes only: toxicity to vertebrates or humans,<sup>42</sup> potential to create mechanical injury or damage, herbicide resistance, creation of an infectious entity, or increased susceptibility to disease.<sup>43</sup> The severity of these traits increases from low through severe through the permit categories from A to D.<sup>44</sup>

An important failing of the proposed regulation is that the above list of harms comprises only a small subset of the harms that may be caused by GE plants. For example, increased weediness may occur due to habitat expansion by a plant engineered for increased biotic or abiotic stress, like drought tolerance, without causing damage or mechanical harm to plants in the environment. GE plants may harm biodiversity, without being toxic to vertebrates by altering habitats or soil or by harming invertebrate animals or microbes. And vertebrates can be negatively impacted

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<sup>39</sup> 73 Fed. Reg. 60017-19.

<sup>40</sup> APHIS states that "*In most cases the initial groupings would also result in a similar level of oversight of the release and conditions attached to the permit – but any final determination of the permit category, oversight and permit conditions would depend on the results of the APHIS evaluation*" (emphasis added). (73 Fed. Reg. 60018)

<sup>41</sup> "The two primary factors APHIS identified as most relevant to define its sorting system for environmental release permits were the 1) ability of the unmodified recipient plant species to persist in the wild and 2) potential of the engineered trait to cause harm, injury, or damage, as described in the definitions of plant pest and noxious weed." (73 Fed. Reg. 60018)

<sup>42</sup> The lowest-risk category, "A," also includes a prohibition against "serious harm" upon consumption or contact with the GE plant by invertebrates, but this prohibition is not included in other potential harm categories.

<sup>43</sup> 73 Fed. Reg. 60018.

<sup>44</sup> 73 Fed. Reg. 60041-42, PR at 340.2(d)(1)(i)(B).

without harming them *per se*, for example, by reductions in habitat or in invertebrate- or plant-based food sources. APHIS's list also fails to include the impact of increased fitness of wild relatives that may result from the flow of a stress-tolerance gene from a GE plant. These are the kinds of environmental impacts that seriously concern scientists.<sup>45</sup>

In addition, the list of potential harms ignores the economic harm that GE plants can cause to organic growers, exporters, food processors, and others in the food chain as a result of contamination either by biological pollen flow or physical mixture of seeds.

UCS recommends that APHIS revise its list of potential harms of GE crops to include, among others, increased weediness in plants or in wild relatives of plants, threats to biodiversity, increased invasiveness due to enhanced ability to withstand abiotic stress, and economic damage as a result of contamination.

***C. APHIS fails to seriously consider the importance of gene flow and seed mixing in evaluating the risks of GE organisms.***

Despite the fact that many field-grown GE crops pose risks resulting from the movement of transgenic seeds, genes, or genetic elements into other crops or wild relatives, APHIS barely mentions the topics in its discussion of risks.

Genes that confer resistance to abiotic stress like cold, salt, or drought could equip wild and weedy plants with traits that could give them a competitive edge (increased fitness) in an unmanaged environment. The National Research Council (NRC) of the National Academy of Sciences recognizes that genes for stress tolerance may increase fitness and weediness.<sup>46</sup> Wild relatives with enhanced fitness obtained through gene flow from GE crops may persist and spread in the environment even if gene flow occurs at very low levels. As noted by the NRC, “[g]enerally, if an allele confers a fitness advantage - once introduced into a population - it is expected to increase in frequency, even if it is introduced only once.”<sup>47</sup> Preliminary research with a Cry1 gene in wild sunflower suggests that this gene may increase the fitness of the plants in the presence of seed-feeding moths, which may lead to persistence and spread of the gene.<sup>48</sup>

In the past, APHIS has imposed gene-flow-related permit conditions that have not succeeded in preventing gene flow. For example, gene flow occurred from a large field trial of GE creeping

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<sup>45</sup> For example, Pilson and Prendeville note that some Lepidopteran species with a narrow host range that depend on wild sunflowers as a sole food source may be threatened if a transgene like Cry1Ab, which APHIS considers to be of only “moderate” risk, spreads through wild sunflower. (Pilson, D. and H.R. Prendeville. 2004. Ecological effects of transgenic crops and the escape of transgenes into wild populations. *Annual Review of Ecology, Evolution, and Systematics* 35:149–74.)

<sup>46</sup> National Research Council. 2004. *Biological Confinement of Genetically Engineered Organisms*. Washington, D.C.: National Academies Press, p. 49. The NRC writes that it could not generalize about fitness implications of all classes of transgenes, but that “[o]ne could imagine that genes engineered to confer pest resistance *or otherwise increase fitness* (such as herbicide resistance or tolerance to abiotic stresses) could contribute to the evolution of increased weediness...” (emphasis added)

<sup>47</sup> National Research Council, 2004, p. 48.

<sup>48</sup> Snow, A.A., et al. 2003. A Bt transgene reduces herbivory and enhances fecundity of wild sunflowers. *Ecological Applications* 13(2):279–86.

bentgrass over a distance of at least 13 miles<sup>49</sup> despite compliance with APHIS confinement guidance based on isolation distance. In other cases, research on gene flow with various plant species has shown that permit conditions accepted by APHIS, for example, seed agency isolation distances, may not prevent gene flow.<sup>50</sup> Instances where biotechnology products have escaped from test plots and established themselves in the field have already occurred.<sup>51</sup>

While the record suggests that APHIS should take the effects of gene flow and seed mixing on the risks of GE crops seriously, the agency barely touches upon the issues in the discussion of risks preceding the proposed rule.

The agency should compile information on the history and impacts of contamination in its final EIS on this rule and use the information to devise programs to minimize that contamination. In conjunction with ecologists and other scientists, the program should also institute ongoing efforts to monitor and analyze the impacts of gene flow and seed mixing on the environment and our economy.

### **III. APHIS's proposed rule further weakens the already lax oversight of pharma crops, at a time when stronger, much stronger, oversight is needed.**

APHIS's issue paper on pharma crop regulation notes that this topic drew more comments than any other on both the proposed rule and draft EIS.<sup>52</sup> Also, according to the paper, commenters were overwhelmingly opposed to the outdoor use of GE food crops to produce drugs and industrial compounds, citing "concerns about the potential for serious public health, environmental consequences, or—absent any health or environmental consequences—that serious market disruptions could occur."<sup>53</sup>

The agency's response to this remarkable level of opposition from a broad spectrum of stakeholders—the food industry, environmental and consumer organizations, and thousands of individual citizens—is to dismiss their concerns as merely "marketing and public perception concerns." By labeling legitimate public health, environmental, and economic concerns in this way, the agency apparently believes it can avoid responsibility for protecting against the risks of pharma crops because "the PPA does not provide authority for regulating an organism based solely upon such issues or factors."<sup>54</sup>

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<sup>49</sup> Watrud, L.S., et al. 2003. Evidence for landscape-level, pollen-mediated gene flow from genetically modified creeping bentgrass with CP4 EPSPS as a marker. *Proceedings National Academy of Sciences* online at [www.pnas.org/cgi/doi/10.1073/pnas.0405154101](http://www.pnas.org/cgi/doi/10.1073/pnas.0405154101).

<sup>50</sup> Gurian-Sherman, D. 2006. Contaminating the wild? Gene flow from experimental field trials of genetically engineered crops to related wild plants. Washington, D.C.: Center for Food Safety. Online at [www.centerforfoodsafety.org/pubs/contaminating\\_the\\_wild\\_report.pdf](http://www.centerforfoodsafety.org/pubs/contaminating_the_wild_report.pdf). See Appendix A for case studies.

<sup>51</sup> Reichman, J.R., et al. 2006. Establishment of transgenic herbicide-resistant creeping bentgrass (*Agrostis stolonifera* L.) in nonagronomic habitats. *Molecular Ecology* 15:4243-55.

<sup>52</sup> USDA APHIS BRS. 2009. Issue 4: Environmental release permit categories and regulation of genetically engineered crops that produce pharmaceutical and industrial compounds. Available online at [www.aphis.usda.gov/biotechnology/340/340\\_downloads/apr09pubmtg\\_issuepaper\\_pharma.pdf](http://www.aphis.usda.gov/biotechnology/340/340_downloads/apr09pubmtg_issuepaper_pharma.pdf).

<sup>53</sup> USDA APHIS BRS. 2009. Issue 4.

<sup>54</sup> USDA APHIS BRS. 2009. Issue 4.

In fact, the concerns about pharma crops as discussed below, involve far more than marketing and perception. They are based on the inevitability of gene flow and seed mixing so far ignored by the agency in its NEPA documentation and its development of this rule.

We are disappointed that APHIS, in the face of overwhelming support for a ban on the outdoor use of pharma food crops, refuses to use the authority and discretion granted under the PPA to implement such a ban as the surest way to protect the food supply against contamination by drugs and industrial compounds.

Under the proposed rule, APHIS rejects not only a ban but any strengthening of pharma crop oversight. In fact, the agency moves in the opposite direction—and weakens its already inadequate regulations.<sup>55</sup>

Below we discuss three major areas where the effect of the proposed rule is to weaken pharma crop oversight.

***A. The proposed rule no longer treats pharma crops as a high-risk category of products and instead intends to regulate them case-by-case in a system that gives the agency wide leeway.***

The proposed rule does not explicitly address pharma crops or any other subset of GE organisms. Rather the rules set up administrative categories A, B, C, and D to which all GE organisms will be assigned at the beginning of the review process. The categories, discussed above, establish increasing levels of control that reflect rough determinations of potential risk. The categories are not determinative. Products that are assigned to one category might end up with controls associated with another category.

While much about the operation of the new administrative categories is vague, this much is clear. In the proposed rule, APHIS has abandoned its previous view that all pharma crops belong in a high-risk category. In the words of the agency, “[w]e have not see evidence suggesting that [pharma crops] present unique or uncontrollable risks, or risks higher than those that may be associated with many other uses for GE plants.”<sup>56</sup>

By eliminating the class status of pharma crops, APHIS is no longer required to subject all pharma crops to stringent regulatory oversight. Instead pharma crops will be evaluated under a case-by-case process based on the administrative categories mentioned above.

Clues to what that means for pharma crops can be found in the way APHIS discusses the operation of the administrative categories. In one of its few references to pharma crops, the agency says that “[b]ased upon APHIS experience to date, *many* releases of GE plants producing pharmaceutical or industrial substances.... would carry the same level of oversight (Category C) as current permits for [plants making pharmaceutical and industrial compounds]” (emphasis

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<sup>55</sup> See UCS’s position paper at [www.ucsus.org/food\\_and\\_agriculture/solutions/sensible\\_pharma\\_crops/ucs-position-paper-on-pharma.html](http://www.ucsus.org/food_and_agriculture/solutions/sensible_pharma_crops/ucs-position-paper-on-pharma.html), which evaluates the current pharma crop regulatory approach and recommends a ban on outdoor production of pharma food crops.

<sup>56</sup> 73 Fed. Reg. 60031.

added).<sup>57</sup> The use of the word "many" suggests that APHIS intends to place at least some pharma crops into lower risk categories, A or B.

Even for pharma crops placed in category C—the category APHIS considers equivalent to the existing regime for pharma crops—the proposed rule might not require the same stringency in permit conditions imposed by the current program. The agency would assign regulatory controls case-by-case commensurate with the level of risks,<sup>58</sup> apparently eliminating the standard specific regulatory controls now imposed on pharma crops such as confinement conditions, company reporting requirements, and frequency of APHIS inspections.

***B. Under the proposed rule, APHIS could declare that low-level contamination of the food supply with pharma crops is acceptable.***

The proposed rule lays out criteria for GE crops that have not been approved for human consumption, which, if met, would allow so-called “low levels” of those unapproved crops to contaminate the food supply.<sup>59</sup> These criteria include similarity of the GE-crop contaminants to existing nonregulated GE crops and lack of sexually compatible, wild relatives in the United States. These criteria do not reflect the major concerns about pharma and industrial crops, which, in many cases, for example, do not have wild relatives, but threaten the food supply through crop-to-crop gene transmission.

Thus, many pharma crops could well meet the non-actionable criteria, but still constitute a threat to the public, the environment, or valuable food brands. Nevertheless, under the proposed rule, APHIS would allow low levels of these crops in the food supply.

***C. The proposed provisions governing nonregulated status could allow pharma crops to be commercialized without regulatory controls.***

While the proposed rule does not directly address the relationship between a newly established nonregulatory status and commercialization, it is possible that some pharma crops would be eligible for nonregulated status provisions<sup>60</sup> under the rule. If so, pharma crops could be grown commercially without any regulatory controls. Under the existing system, pharma crops have not been eligible for similar status (in that case deregulation) that would relieve them of regulatory controls. In all cases, pharma crops continued to be subject to controls even during commercial production. Granting nonregulated status to pharma crops under the proposed rule would virtually ensure that the food supply would become contaminated with drugs and industrial chemicals.

UCS continues to recommend that APHIS abandon its proposed oversight of pharma crops and adopt a ban on the outdoor production of pharma food crops.

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<sup>57</sup> 73 Fed. Reg. 60020.

<sup>58</sup> 73 Fed. Reg. 60020, PR at 340.2(d)(1).

<sup>59</sup> 73 Fed. Reg. 60047-48340, PR at 340.7(g)(2).

<sup>60</sup> 73 Fed. Reg. 60046-47, PR at 340.6.

We have called for a ban in the past because we believed that pharma crops constitute a class of products that presents higher risks to public health, the environment, trade, and food brands than other products.

Most pharma crops are engineered to produce compounds, often at high levels, that are not normally found in food, for example, hormones, vaccines, and plastics. Many of the foreign chemicals are drugs designed to be active in humans, some at very low doses. These drugs are intended ultimately to treat only a small subset of consumers for a particular medical condition and could prove dangerous to people not suffering from these conditions if accidentally ingested. Plant-produced industrial chemicals like plastics and lubricants, dietary substances like the sweetener brazzein, or accumulated heavy metals may also be harmful if they are consumed in contaminated food. Some may be toxic or allergenic;<sup>61</sup> others may cause neurological, hormonal, or other harmful effects.

Even if certain pharma crops turn out not be dangerous, UCS believes they should be appropriately treated as a high-risk class, if for no other reason because the public will treat them as a class. Drugs in corn flakes will be a trade and food brand issue even if the drug itself is subsequently determined to be safe.

Processors, millers, retailers, exporters, and others in the food chain have expressed concern about potentially adverse effects of pharma crop contamination on their products, brands, and markets. These concerns have been validated by a series of incidents involving the accidental mixing of unapproved GE crops, including pharma crops, with commodity versions of the same crops. The StarLink episode in 2000, for example, involved a nationwide recall of products that led to huge economic losses, estimated to have run into the hundreds of millions of dollars, for food processors and retailers, farmers, traders, and others in the food supply chains.<sup>62</sup> Future contamination of food crops by pharma crops may cause similar disruptions and losses.

Contamination can occur as a result of cross pollination with food versions of the same crops or accidental mixing of pharma crop seeds with food crop seeds at any number of points in the production chain.<sup>63</sup> This contamination, in turn, could threaten public health as well as the economic well being of the industries that make up the food chain.

UCS has concluded on the basis of thorough analysis that APHIS's current program is not up to the task of protecting the food supply from contamination by pharma food crops grown in the field.<sup>64</sup> The proposed rule makes it even more likely that the food supply will become contaminated.

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<sup>61</sup> Prescott, V.E., et al. 2005. Transgenic expression of bean  $\alpha$ -amylase inhibitor in peas results in altered structure and immunogenicity. *Journal of Agricultural and Food Chemistry* 53:9023-30; van Ree, R., et al. 2000.  $\beta$ (1,2)-xylose and  $\alpha$ (1,3)-fucose residues have a strong contribution in IgE binding to plant glycoallergens. *Journal of Biological Chemistry* 275(15):11451-58.

<sup>62</sup> Lambrecht, B. 2001. *Dinner at the New Gene Café*. New York: St. Martin's Press, pp. 52–55.

<sup>63</sup> For more detail, see Andow, D.A., et al. 2004. A Growing Concern: Protecting the Food Supply in an Era of Pharmaceutical and Industrial Crops. Cambridge: UCS. Available online at [www.ucsusa.org/food\\_and\\_agriculture/science\\_and\\_impacts/impacts\\_genetic\\_engineering/a-growing-concern-protecting.html](http://www.ucsusa.org/food_and_agriculture/science_and_impacts/impacts_genetic_engineering/a-growing-concern-protecting.html).

<sup>64</sup> See Andow, D.A., et al., 2004, for more detail.

In summary, pharma food crops grown outdoors pose serious threats to the food supply, public health, and food industries. In our view, only a ban can achieve the necessary standard of complete protection of the food supply.

UCS is deeply disappointed at the failure of APHIS to treat pharma crops seriously despite the outpouring of comments from varied sectors of society. We reiterate our call for the only scientifically sound way to keep drugs and industrial chemicals out of our food supply—a ban on the outdoor production of pharma food crops.

In addition to protecting the food supply, a positive effect of a ban would be to encourage the pharma crop industry to move to non-food pharma crops and systems based on plant cells, fungi, bacteria, or algae that could be grown in contained facilities. Such alternatives exist, and, unlike pharma crops, have already been used to produce FDA-approved pharmaceuticals.<sup>65</sup>

**IV. Conditional exemptions from permit requirements are reasonable provided APHIS issues them only where risks are negligible, imposes appropriate conditions, and establishes them through notice-and-comment rulemaking.**

It is reasonable for the proposed rules to establish a method for exempting product classes that pose negligible risks from permit requirements. The exemptions from requirements for permits under the existing program for interstate movement of organisms like *Arabidopsis* and certain strains of *E. coli* and other microbes are examples of appropriate uses of such authority.<sup>66</sup>

UCS is concerned, however, that APHIS is planning to use the authority to exempt major activities like the import of GE commodities intended for food, feed, or processing or perhaps large categories of GE organisms intended for commerce.

In the case of imports, we are not persuaded that having received all of the necessary regulatory approvals in their country of origin is a sufficient assurance that such shipments pose negligible risks. In any case, we believe that major activities should be regulated through a permit process.

In addition, especially because it appears that the agency intends to apply the exemptions to large categories of products and activities, we believe that the exemptions should be granted only pursuant to notice-and-comment rulemaking.

UCS recommends that conditional exemptions from permit requirements be granted only to products and activities that pose minimal risk and that such exemptions be granted only pursuant to notice-and-comment rulemaking.

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<sup>65</sup> For additional information on alternative systems, see Freese, B. 2002. Alternatives to open-air biopharming. In *Manufacturing Drugs and Chemicals in Crops*. Friends of the Earth and Genetically Engineered Food Alert. Online at [www.foe.org/camps/comm/safefood/biopharm/biopharm\\_report.pdf](http://www.foe.org/camps/comm/safefood/biopharm/biopharm_report.pdf).

<sup>66</sup> These exemptions were conditioned on factors such as the species of GE organism, types of genetic modifications, and manner of shipping.

**V. APHIS’s proposed petitions for nonregulated status will allow unrestricted production of GE organisms, some of which may threaten public health and the environment.**

Under the proposed regulation, APHIS will offer developers the option of petitioning for nonregulated status based on a determination that GE organisms are not plant pests or noxious weeds. If a petition is granted, the product or organism would no longer be subject to the regulations in Part 340. By definition, under such a status there could be no conditions on the release, transport, or importation of such products. A provision in the proposed rule would allow APHIS to revoke the nonregulated status of a GE organism based on new information that the organism is likely to be a plant pest or noxious weed,<sup>67</sup> but there is no information on the quality of the information that would be needed for revocation or the length of time the process would take.

The petitions for nonregulated status would be available for GE plants, non-vertebrates and non-plants subject to the regulations. There is no explicit linkage of petitions for nonregulated status and commercialization. Companies apparently may commercialize their products after obtaining a declaration of nonregulated status. Or they may choose to commercialize without petitioning for such status, in which case the products would still be governed by whatever conditions obtain in the permits for environmental release. In addition, there are no criteria for the kinds of products for which nonregulated status can be sought. It is possible, as discussed below, that pharma crop developers could petition for nonregulated status for their products.

UCS strongly disagrees with the agency’s approach of removing organisms from its legal jurisdiction through a determination of nonregulatory status. Even with a procedure in place to revoke the approval of such a status, there is no assurance that APHIS would be in a position to respond quickly if new public health or environmental risks of a nonregulated GE crop were discovered. Nonregulated status also makes it impossible to establish programs that would monitor post-commercial environmental impacts of GE products.

APHIS should instead adopt a system that would require all GE organisms that meet the definition of plant pests, noxious weeds, or biological control agents to obtain permits for field testing and commercial use. All permits would be conditioned commensurate with the degree of perceived risk. While many familiar organisms may have reduced, or even no, data requirements, and virtually no restrictions on use, all permits would contain a condition that organisms would be subject to further review if new information of substantial risks emerged. No GE organism would ever be completely outside APHIS’s regulatory system.

UCS recommends that APHIS abandon the “nonregulatory” petition process in favor of a system that requires permits for all environmental releases, including field testing and commercial production, of all GE organisms.

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<sup>67</sup> 73 Fed. Reg. 60047, PR at 340.6(d).

## **VI. The APHIS rulemaking is following an irregular process that does not comply with NEPA.**

The rulemaking on the new APHIS regulations is following an irregular process that does not comply with NEPA. That act requires that agencies prepare documents that disclose the environmental impacts of major federal actions, including regulatory actions. The intent of the statute is to improve decision making by focusing an agency's attention on environmental consequences while there is still time for the agency to make modifications or change course.

The draft EIS issued July 17, 2007, lacked any substantive analysis of environmental impacts ordinarily found in EISs. Instead, the analyses in the document were based primarily on considerations 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 considerations are important background for a major overhaul of regulations, they do not constitute an EIS.

The proposed rule does nothing to remedy the deficiency in the draft EIS. It does not assemble the data on environmental impacts and relate those data to policy choices. In addition, it does not respond to the scientific and legal comments APHIS received in response to the draft EIS.

The misdirected pharma crop policy might have been avoided if the agency had followed NEPA and developed its policy options on the basis of scientific analysis. Such an analysis would demonstrate that APHIS has allowed crops to be tested under performance standards for 15 years but has never systematically collected data on their effectiveness. An appreciation and acknowledgement of how little the agency understands about the level of contamination of the food supply by pharma genes would likely result in a more conservative, protective rule.

At this point, APHIS has yet to publish a document that would meet the requirements of NEPA. The agency could have prepared a proper EIS, based on available scientific data, to accompany this proposed rule, but it did not. The agency has indicated that it will respond to the comments on the draft EIS at the same time that it publishes the final rule. Apparently, APHIS intends to go forward without an analysis of the environmental consequences of its actions. In addition to inviting litigation on the rule, such a course makes a mockery of NEPA.

UCS recommends that APHIS stop now and prepare a substantive analysis of environmental impacts of its regulatory options, and not issue a final rule under the final EIS, until those options, including the pharma crop ban, have been analyzed and considered.

Among the impacts that should be considered in an EIS are 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.<sup>68</sup> A

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<sup>68</sup> Bennett, D. 2007. GM rice—proposed class action. *Delta Farm Press*, May 28. Online at <http://deltafarmpress.com/rice/070528-class-action>.

recent court decision,<sup>69</sup> 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. APHIS should address the economic impacts for conventional and organic producers of GE crop contamination in the final EIS and other NEPA documents produced by the agency.

## **UCS RECOMMENDATIONS**

### **I. Scope**

APHIS should redraft the scope of the proposed rule to essentially cover all GE plants and non-vertebrate, non-plant GE organisms not previously deregulated by the agency.

### **II. Interpretation of Plant Protection Act noxious weed authority**

The agency should set a reasonable bar for the regulation of GE crops, well below the extremely severe impacts listed in the introductory discussion to the proposed rule.

APHIS should revise its list of potential harms of GE crops to include, among others, increased weediness in plants or in wild relatives of plants, threats to biodiversity, increased invasiveness due to enhanced ability to withstand abiotic stress, and economic damage to organic growers and others whose products are contaminated by GE crops.

The agency should give serious regard to gene flow and seed mixing in assessing the risks of GE crops.

### **III. Pharma and industrial crop oversight**

APHIS should abandon its proposed weak oversight of pharma and industrial crops and adopt a ban on the outdoor production of pharma food crops.

### **IV. Conditional exemptions from permit requirements**

The agency should grant conditional exemptions from permit requirements only to products and activities that pose minimal risk and such exemptions should be granted only pursuant to notice-and-comment rulemaking.

### **V. Nonregulatory petition process**

APHIS should abandon the proposed petition process for nonregulatory status in favor of a system that requires permits for all environmental releases, including field testing and commercial production, of all GE organisms.

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<sup>69</sup> 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).

## VI. NEPA process

APHIS should stop now and prepare a substantive analysis of environmental impacts of its regulatory options under NEPA, and not issue a final rule under the final EIS until those options, including the pharma crop ban, have been analyzed and considered.

The agency should address the economic impacts for conventional and organic producers of GE crop contamination in the final EIS and other NEPA documents.

This rulemaking will be one of, if not the first, major action of the Obama administration on the regulation of GE crops. The regulation will influence the course of agricultural biotechnology in the 21<sup>st</sup> century and set precedents for other novel technologies like nanotechnology and synthetic biology. As such, the right balance between regulatory protection and burden is critical.

The proposed rule is extraordinarily weak and will leave the agricultural biotechnology industry with very little effective oversight as it moves into an era of ever more complicated and consequential products. Such a rule is not good for the industry, consumers, or the environment. Strengthening this rule should be a major priority of the Obama administration.

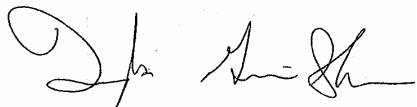
Sincerely,



Margaret Mellon, Ph.D., J.D., Director  
Food and Environment Program



Jane Rissler, Ph.D., Deputy Director/Senior Scientist  
Food and Environment Program



Doug Gurian-Sherman, Ph.D., Senior Scientist  
Food and Environment Program