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Regulatory Analysis and Development
USDA APHIS PPD
Station 3A-03.8
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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, 2008.¹ The rulemaking is intended to align biotechnology regulations with the Plant Protection Act (PPA) of 2000,² 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 Current biotechnology regulations implement primarily the FPPA and other quarantine authorities that were repealed as part of the enactment of the PPA.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, 2007.³ The EIS consisted of an analysis of regulatory alternatives on ten issues APHIS identified as important for the rulemaking.

¹ 73 Fed. Reg. 60008-48.

² The Plant Protection Act of 2000, 7 U.S.C. §§ 7701. [UNFINISHED]

³ 72 Fed. Reg. 39021-25.

APHIS plans to publish a final rule before the end of the current administration. Concurrent with the final rule, the agency said it would issue a final EIS that summarizes and addresses 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 cluster 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 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).

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

While quarantine authority is always something of a difficult fit for a pre-market review system, with proper implementation this system could work well. Unfortunately, this proposed rule goes in the opposite direction and drastically weakens the regulation of GE crops and other organisms even compared to the weak existing system.

Below we provide comments and recommendations on six major issues raised by the proposed rule: scope, interpretation of PPA authority, conditional exemptions from permit requirements, nonregulatory petition process, pharma crop⁴ oversight, and the NEPA process.

SUMMARY OF UCS CONCLUSIONS

UCS's overall view is that the proposed rule, while based on sounder legal foundation than its predecessor, will in practice provide exceptionally weak oversight of the agricultural biotechnology industry. The proposed rule has five major regulatory defects. First, the scope provisions are set up so that over time the rule will cover fewer and fewer GE products, leaving APHIS in the dark about the activities of biotechnology companies. Second, the list of harms considered worthy of regulation ignores most of the concerns scientists have raised about the

⁴ The term pharma crops covers GE crops whose products are intended to be used as pharmaceuticals or industrial compounds.

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 proposed rule allows GE organisms to be removed from the agency's legal jurisdiction through a nonregulatory petition process. Fifth, the rule fails to protect the food supply from pharmaceutical and industrial crops.

In addition to these defects, the process for disclosing the environmental consequences of proposed regulatory options fails to adhere to NEPA requirements.

Like many other rules favoring industry over the public interest, this rule is being rushed to completion just as the Bush administration is leaving office, depriving the Obama administration of the opportunity to put its stamp on the direction of biotechnology regulation.

In our view, proper compliance with NEPA would result in the process extending beyond the end of the Bush Administration and we recommend such a course. Even if the agency were to choose not to provide that process, UCS recommends that APHIS not finalize the rule until after January 20. This proposed rule represents a major weakening of the regulation of biotechnology and the Obama administration should have an opportunity to review it. If the final rule is in effect when the Obama administration takes up the reins, UCS recommends that its revocation, revision, and strengthening become a top priority of the new administration.

Our detailed comments and summary of recommendations follow below.

UCS COMMENTS

I. The scope of the proposed rule is convoluted and gives far too much power to the regulated industry.

The straightforward approach to establishing scope—the description of those products or organisms the agency intends to review—is to cover all GE plants, non-vertebrates and non-plants. To capture a product or organism for review does not mean that 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 screens out the products that are not safe after reviewing data presented by developers.

APHIS did not adopt this approach. Instead, the agency has designed a convoluted scope that gives developers extraordinary authority to determine whether their products will be reviewed at all. Under this scope, it will be difficult 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.

The scope of the proposed rule covers only GE organisms⁵ (and thus is process-based), but not *all* GE organisms. With regard to plants,⁶ the proposed rule applies only to GE plants: i) that are derived from an unmodified plant that is itself a plant pest or noxious weed, ii) whose potential

⁵ 73 Fed. Reg. 60011.

⁶ Similar scope provisions that apply to non-vertebrate, non-plants (cite) raise similar concerns, but will not be discussed in these comments.

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.⁷

The difficulty is that the scope of this regulation 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,”⁸ and instead GE plants must pose risks to be regulated.⁹ But the result is circular reasoning: the organisms the agency will review to determine whether they are plant pests are those that are plant pests.

The element in the scope capturing GE plants whose plant pest or noxious weed risks are unknown is a way to get out of this bind.¹⁰ 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.

While potentially broad in theory, APHIS plans to reduce the scope in practice by inviting the developers through a “responsible person” to decide whether the criteria apply to their products.¹¹ A plant pest risk could be “known” if APHIS were familiar with the crops or genes. 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.

Situations where crops are somewhat familiar to APHIS are likely to encompass most commercial applications of crop biotechnology. That means for most products, the industry will be able to make its own decision about whether its products need to be reviewed.

Where a company or developer is uncertain about scope it *may choose to* consult with APHIS, but it need not.¹² If a company chooses to consult, the agency will provide a written rationale of its scope determination and post it on the web.¹³

APHIS expects the range of covered products and organisms to decrease with time under the proposed regime.¹⁴ Thus, as time passes, an increasing number of organisms will not even come to the agency for review. If this scenario 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.

⁷ 73 Fed. Reg. 60011.

⁸ 73 Fed. Reg. 60012.

⁹ 73 Fed. Reg. 60012.

¹⁰ 73 Fed. Reg. 60012.

¹¹ 73 Fed. Reg. 60011.

¹² 73 Fed. Reg. 60012.

¹³ 73 Fed. Reg. 60012.

¹⁴ 73 Fed. Reg. 60012.

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.”¹⁵ UCS’s response is that under the program it has devised, most of the information on what is not being regulated will have to come from industry. The agency’s problem will not be how to share such information, but how to obtain it in the first place.

The proposed system is a serious abdication of APHIS’s responsibility to regulate agricultural biotechnology in such a manner to assure both the markets and the public that GE crops are being developed safely.

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. In that way, APHIS, not the industry, decides which plants are overseen. In addition, the agency would be able to keep a complete record of the GE products that have been released into the environment or introduced into commerce.

II. APHIS’s interpretation of its Plant Protection Act authority fails to protect public health and the environment by potentially allowing the release and propagation of harmful GE plants.

The proposed rule is based on 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*” (emphasis added).¹⁶ With the addition of the terms public health and the environment, this definition of noxious weeds becomes 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.

But in order to protect the environment and public health, 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 appears poised to use an overly narrow definition of noxious weeds.

The introductory discussion on the proposed rule indicates that APHIS intends to interpret its authority very narrowly by adopting a definition of noxious weeds is that based loosely on the kinds of plants currently listed as noxious weeds.¹⁷ ¹⁸ 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.

¹⁵ 73 Fed. Reg. 60012.

¹⁶ 73 Fed. Reg. 60039, Proposed rule at 7 CFR 340.1 (hereinafter PR at 340.1)

¹⁷ 73 Fed. Reg. 60012-14.

¹⁸ The current list of noxious weeds is available on line at <http://plants.usda.gov/java/noxious>.

In its introduction to the proposed regulations, the agency presented a table of the examples of impacts caused by federally listed noxious weeds¹⁹ 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.”²⁰

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 impact irrigation, flood control, and water treatment plant intake.²¹ 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).²² 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.²³

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 or the environment. In our view, effects that are less than noxious, as currently interpreted by APHIS, should be potentially controlled under the PPA.²⁴ In fact, that appears to be the purpose of expanding the authority beyond the old definition of noxious weeds.

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.

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

¹⁹ 73 Fed. Reg. 60013-14, Table 1.

²⁰ 73 Fed. Reg. 60013.

²¹ 73 Fed. Reg. 60013.

²² 73 Fed. Reg. 60013-14.

²³ 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).

²⁴ The current noxious weed list includes only about a 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*).

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.²⁵ 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.²⁶

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.²⁷

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,²⁸ potential to create mechanical injury or damage, herbicide resistance, creation of an infectious entity, or increased susceptibility to disease.²⁹ The severity of these traits increases from low through severe through the permit categories from A to D.³⁰

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 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 about which scientists are concerned.³¹

²⁵ 73 Fed. Reg. 60017-19.

²⁶ 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)

²⁷ "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)

²⁸ 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

²⁹ 73 Fed. Reg. 60018.

³⁰ 73 Fed. Reg. 60041-42, PR at 340.2(d)(1)(i)(B).

³¹ 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

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 protection of charismatic species like the monarch butterfly.

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.³² 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.”³³ 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.³⁴

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 bentgrass over a distance of at least 13 miles³⁵ 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.³⁶ Instances where biotechnology products have escaped from test plots and established themselves in the field have already occurred.³⁷

of transgenic crops and the escape of transgenes into wild populations. *Annual Review of Ecology, Evolution, and Systematics* 35:149–74)

³² 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).

³³ National Research Council, 2004, p. 48.

³⁴ Snow, A.A., et al. 2003. A Bt transgene reduces herbivory and enhances fecundity of wild sunflowers. *Ecological Applications* 13(2):279–86.

³⁵ 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* on line at www.pnas.org/cgi/doi/10.1073/pnas.0405154101.

³⁶ 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. On line at www.centerforfoodsafety.org/pubs/contaminating_the_wild_report.pdf. See Appendix A for case studies.

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

III. 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.³⁸

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 apparently 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.

IV. 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

³⁷ Reichman, J.R., et al. 2006. Establishment of transgenic herbicide-resistant creeping bentgrass (*Agrostis stolonifera* L.) in nonagronomic habitats. *Molecular Ecology* 15:4243-55.

³⁸ These exemptions were conditioned on factors such as the species of GE organism, types of genetic modifications, and manner of shipping.

organism is likely to be a plant pest or noxious weed,³⁹ 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.

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

In response to APHIS's draft EIS, food companies, the Grocery Manufacturers Association, NGOs, and thousands of individual citizens called on the agency to adopt a ban on the outdoor production of pharma food crops as the surest way to protect the food supply against contamination by drugs and industrial chemicals.

The agency not only rejected a ban to strengthen pharma crop oversight but has moved in the opposite direction with the proposed rule, that undermines APHIS's already inadequate pharma crop regulations.⁴⁰ Below we discuss three major areas where the effect of the proposed rule is to weaken pharma crop oversight.

³⁹ 73 Fed. Reg. 60047, PR at 340.6(d).

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.”⁴¹

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 added).⁴² 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 that might be 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,⁴³ apparently eliminating the standard specific regulatory controls now imposed on pharma crops such as confinement conditions, company reporting requirements, and frequency of APHIS inspections.

⁴⁰ See UCS’s position paper at 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.

⁴¹ 73 Fed. Reg. 60031.

⁴² 73 Fed. Reg. 60020.

⁴³ 73 Fed. Reg. 60020, PR at 340.2(d)(1).

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.⁴⁴ 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.

Some 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 could 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 nonregulatory status and commercialization, it is possible that some pharma crops would be eligible for nonregulated status provisions⁴⁵ 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 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 would virtually ensure that the food supply would become contaminated with drugs and industrial chemicals.

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

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;⁴⁶ others may cause neurological, hormonal, or other harmful effects.

⁴⁴ 73 Fed. Reg. 60047-48340, PR at 340.7(g)(2).

⁴⁵ 73 Fed. Reg. 60046-47, PR at 340.6.

⁴⁶ Prescott, V.E., et al. 2005. Transgenic expression of bean α -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. β (1,2)-

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 genetically engineered 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.⁴⁷ 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.⁴⁸ 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.⁴⁹ The proposed rule makes it even more likely that the food supply will become contaminated.

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.⁵⁰

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.

⁴⁷ Lambrecht, B. 2001. *Dinner at the New Gene Café*. New York: St. Martin's Press, pp. 52-55.

⁴⁸ See Andow, D.A., et al., 2004, for more detail.

⁴⁹ See Andow, D.A., et al., 2004, for more detail.

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 analyzed its policy options on the basis of scientific facts, for example, that the agency has allowed crops to be tested under performance standards for 15 years but has never systematically collected data on their effectiveness. A full analysis of how little the agency understands about the level of contamination of the food supply by pharma genes might have resulted 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 data, to accompany this proposed rule, but it did not. The agency has indicated only that will respond to the comments on the draft EIS when it publishes the final rule. Apparently APHIS intends to go forward without an analysis of the environmental consequences of its actions. 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

⁵⁰ 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.

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.⁵¹ A recent court decision,⁵² 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 authority

- A. 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.
- B. 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 protection of charismatic species like the monarch butterfly.
- C. The agency should give serious regard to gene flow and seed mixing in assessing the risks of GE crops.

III. Conditional exemptions from permit requirements

APHIS 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.

IV. Nonregulatory petition process

The agency should 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.

V. Pharma crop oversight

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

⁵¹ Bennett, D. 2007. GM rice—proposed class action. *Delta Farm Press*, May 28. On line at <http://deltafarmpress.com/rice/070528-class-action>.

⁵² *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

The agency 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.

If APHIS chooses to continue with its irregular NEPA process and finalize the rule before the end of the Bush administration, UCS recommends that the rule's revocation, revision, and strengthening become a top priority of the Obama administration.

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

Thank you for considering our comments.

Sincerely,

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