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By Regular and Electronic Mail

Docket No. 03-031-2

Regulatory Analysis and Development

PPD, APHIS

Station 3C71

4700 River Road, Unit 118

Riverdale, MD 20737-1238

Re: Comments to Docket No. 03-031-2 Regarding Federal Register Notice dated January 23, 2004 (69 FR 3271).

The Center for Science in the Public Interest (“CSPI”)¹ hereby submits the following comments to the Animal and Plant Health Inspection Service (“APHIS”) regarding the issues raised in its Federal Register notice dated January 23, 2004 (69 FR 3271). CSPI commends APHIS for announcing that it is considering amendments to its current regulatory system for genetically engineered (“GE”) crops. In addition, CSPI applauds APHIS’ decision to conduct an environmental impact statement on the impact of any proposed regulatory changes. If those two actions proposed by APHIS are carried out in a fair and transparent manner, the result could be a strengthened regulatory system that increases consumer confidence in the safety of GE crops.

Although the current regulations set forth in 7 CFR 340 have regulated the movement and release into the environment of thousands of GE crops, those regulations have been criticized as inadequate by numerous reputable organizations and are in desperate need of revision. For example, the current regulations do not take advantage of the full range of legal authorities in the Plant Protection Act that could pertain to GE crops. They do not provide comprehensive regulation for all GE crops nor do they ensure that each crop gets a thorough environmental assessment before it is released in the environment. Also, the current regulations have not be updated to address new applications of the technology (such as crops engineered to produce

¹ CSPI is a nonprofit education and advocacy organization that focuses on improving the safety and nutritional quality of our food supply and on reducing the damage caused by alcoholic beverages. CSPI seeks to promote health through educating the public about nutrition and alcohol; it represents citizens’ interests before legislative, regulatory, and judicial bodies; and it works to ensure advances in science are used for the public good. CSPI is supported by the 800,000 member-subscribers to its Nutrition Action Healthletter and by foundation grants. CSPI receives no funding from industry or the federal government.

pharmaceuticals) nor have they been amended to provide for public participation in the approval process. Therefore, CSPI hopes that the process APHIS is embarking upon will lead to a new regulatory system for GE crops that comprehensively regulates those GE crops to ensure their safe introduction into the environment and the marketplace.

To help guide APHIS in evaluating its current regulations and any proposed changes to those regulations, CSPI provides the following specific comments on the questions and issues raised in the federal register notice:

I. APHIS Should Strengthen Its Regulatory System by Taking Advantage of All Authorities in the Plant Protection Act.

When the Plant Protection Act was passed in 2000, Congress expected USDA would eventually revise regulations promulgated under statutes that were superceded by that Act (such as the Plant Pest Act) using its new authorities. APHIS's announcement that it intends to conduct an Environmental Impact Statement (EIS) in connections with potential changes to its regulatory system is an opportune time to take advantage of all legal authorities in the Plant Protection Act that could be used to thoroughly regulate all GE crops. In particular, APHIS should increase the robustness of its regulatory system by doing the following:

1. The current regulatory system for GE crops relies solely on the "plant pest" status of a crop. Thus, only GE crops that could be considered a plant pest are regulated. Using the Plant Protection Act, APHIS should change its regulatory system to ensure that ALL genetically engineered crops are covered. If this can be achieved by including noxious weeds and biological control agents under the regulatory system, then APHIS should broaden its regulatory scope to include such organisms.
2. The current regulatory system for GE crops has limited legal authority to address environmental risks posed by particular crops, especially if those risks don't also pose a plant pest problem. APHIS should invoke authorities granted to regulate noxious weeds to ensure that each GE crop receives a thorough environmental evaluation before it is released into the environment. Any new regulations should provide APHIS with the explicit authority to deny an application if the environmental risks posed by an application cannot be eliminated or adequately mitigated.

II. It Should Not Be the Responsibility of APHIS to Ensure the Food-Safety of GE Crops or To Safeguard the Food Supply from Such Crops.

In the Federal Food, Drug, and Cosmetic Act, Congress determined that the Food and Drug Administration is responsible for ensuring the safety of our food supply. It is the responsibility of FDA to determine whether GE crops pose any food-safety risks.

Although the noxious weed provisions of the Plant Protection Act may allow USDA to assess and address how noxious weeds might affect humans, those provisions should not be interpreted so broadly as to provide APHIS with the legal responsibility or authority to determine the food-safety of GE crops or to prevent engineered crops from entering the food supply. When Congress passed the Plant Protection Act and eliminated the Noxious Weed Act, Congress did not intend that APHIS would use its legal authorities to address food-safety issues surrounding GE crops. Thus, the federal government should not use the Plant Protection Act to plug gaps in FDA's current legal authority over GE crops. APHIS only should review and approve each GE crop's release into the environment to ensure that the release will not pose any risks to agriculture interests or to the environment.

APHIS's regulatory system for GE crops should not determine the safety of eating those crops, regulate non-viable materials from those crops that are eaten by humans or animals, or require permit conditions that have the primary purpose of preventing those crops from entering the food supply. APHIS does not have the legal authority or the scientific expertise to conduct its own food-safety assessments of GE crops intended for food or non-food use and it should not review and analyze food-safety risk assessments conducted by an applicant. In addition, the noxious weed provisions do not provide APHIS with the legal authority to require that an applicant submit a food-safety evaluation on a GE crop to FDA and obtain FDA's opinion on that assessment as a necessary condition to obtaining a Plant Protection Act release permit. APHIS also does not have the authority to deny a permit solely because FDA has not opined on the food-safety of a particular crop. Finally, APHIS should not use legal authority granted by the Plant Protection Act to indirectly impose release conditions on GE crops when the primary purpose of those conditions is to safeguard the food supply. Permit conditions should be imposed to safeguard the environment and agricultural interests from the release of the GE crop.

III. Public Participation Should be an Integral Part of the APHIS Regulatory Process

APHIS' current regulatory system provides little opportunity for the public to provide input before individual regulatory decisions are made. Public comment only occurs before the agency decides on a request from a company to grant an engineered crop non-regulated status. In those instances, the public is provided information about the crop and its potential plant-pest and environmental risks and then allowed to comment before the agency's decision. For all APHIS permitting decisions for field trials and commercial products, however, there is no opportunity for public participation. The effect of the current policy is that for some crops, such as crops engineered to produce pharmaceuticals, there is no opportunity for the public to comment prior to the decision to release those crops into the environment for experimental or commercial purposes.²

² APHIS has said publicly that petitions for non-regulated status will not be granted for crops engineered to produce pharmaceuticals or industrial compounds. Thus, those crops go through the same permitting process irrespective of whether the release is for a field test or to harvest the crop and then sell a commercial product.

APHIS should amend its regulatory system to allow a formal opportunity for the public to comment on permit applications before the agency's decision. That public comment opportunity should be allowed for any engineered crop that currently requires a permit prior to release into the environment (i.e. anything that cannot proceed through the current notification process). Under such a system, the public would have the opportunity to comment on controversial or risky applications (such as crops engineered to produce pharmaceuticals) while safer applications that qualify for notification would continue to be released without public comment. The public comment requirement could be met by providing the public with a 30-day period of time in which to comment following the release of the company's application (redacted for authentic confidential business information).

IV. APHIS Should Increase the Transparency Surrounding its Decisions on Individual GE Crops.

Although APHIS has improved the transparency of its rulemaking and guidance-setting procedures, the APHIS regulatory process for authorizing the release of an individual GE crop into the environment is not transparent and needs significant improvement. Notifications submitted to APHIS, permit applications, and the permits that are issued from those applications currently are not accessible to the public in a timely fashion. Thus, APHIS should amend its regulations to allow the public immediate access to documents submitted by the applicant and permits issued by the agency.

To provide for timely access to documents submitted to APHIS in the notification and permitting process, APHIS should require individuals and companies submitting notifications or permit applications do the following: (1) submit two copies of their documents, one with and one without confidential business information ("CBI"); and (2) provide support and justification for each individual piece of CBI contained in their submission. The documents submitted without the CBI should be immediately placed in a public docket and also made available on the USDA website. At the same time, the confidentiality claims should be adjudicated in an expeditious manner and any information deemed not to be confidential should be placed in the docket and on the website. For the final permits and any government documents that support those permit decisions, APHIS should place those documents immediately in a public docket and post them on the USDA website. In writing the permits, APHIS should minimize its use of information that has determined to be "authentic" CBI. Any CBI that must included in the permit or agency documents supporting the permit should be placed in an appendix. That will allow the remainder of the document to be easily provided to the public.

V. If APHIS Decides to Review Field Trial Applications Differently Depending on the Introduced Gene, Those Categories Should be Based on Objective Scientific Risk-Based Criteria, Not the Intended Use of the Product.

In any approval process, the amount of information requested, the degree of scrutiny of the application by the agency, and the conditions imposed on the approved action should be

directly proportionate to the risk of the particular product. Products that are riskier or raise novel issues should receive more scrutiny and regulatory review than products that pose little risk or that are similar to other products already determined safe. Thus, it is appropriate for APHIS to consider revising its regulations to set forth specific risk-based categories that would determine the regulatory process for a particular field test or commercial release decision.

If different categories will determine the regulatory process for particular GE crops, those categories should be based on objective, scientific, risk-based criteria. Those categories should not be defined by specific types of products, such as all “pharmaceutical or industrial crops not intended for food or feed.” Placing all plant producing pharmaceuticals in the same category is not a scientific, risk-based decision since not all crops engineered to produce pharmaceuticals have the same risks. For example, growing a pharmaceutical in tobacco raises very different risk issues than growing that same pharmaceutical in corn and those two crops may not deserve the same regulatory treatment. Therefore, different regulatory review and approval procedures may be appropriate for GE crops with different types of risks but the criteria for differentiating among products should be based on scientific criteria, not the intended use of the product.

VI. Petitions for Non-Regulated Status Should be Eliminated and Commercial Permits Should be Issued Instead.

When a GE crop developer wants to sell its crop commercially, the developer usually petitions the agency to grant the crop non-regulated status, which means the crop is no longer regulated by APHIS. Those petitions have been granted for all GE crops that are commercially available today. Thus, in the current regulatory system, when a GE crop is commercialized, it is no longer regulated by APHIS. This prevents, among other things, the imposition of labeling requirements on GE seeds, the imposition of post-commercialization monitoring for environmental and agricultural effects, and the collection of data to address unresolved risks. It also greatly limits the actions that can be taken by APHIS if a commercial GE crop is later found to be harmful to agricultural interests or the environment.

To rectify those problems, APHIS should eliminate its petition process and instead implement a two-tiered permitting process, with experimental permits for field trials and commercial permits for GE crops that are to be sold in commerce. Such an administrative change would allow APHIS to keep jurisdiction over all GE crops planted in the U.S. and actively regulate commercialization of certain GE crops that warrant continued oversight as commercialized crops. In the commercial permits, APHIS could tailor any specific obligations for the planting of a particular crop to the results of the environmental assessment conducted on that crop. For some crops with significant unresolved risks, the result might be a commercial permit with numerous obligations that might restrict where and how the plant is grown and what type of monitoring is required. For other crops with minimal risks, however, the permit might contain only a set of standard post-commercialization obligations, such as general monitoring, reporting, and renewal requirements. Thus, adding a commercial permitting process to the current regulatory system and eliminating the petition process would provide APHIS with the

legal authority to regulate all GE crops released into the environment and the flexibility to impose any obligations needed to address unresolved risks posed by commercial plantings.

VII. Current Scientific Knowledge About GE Crops Does Not Support Exempting Any Releases Into the Environment from the APHIS Regulatory System At This Time.

The Federal Register notice states that APHIS is considering exempting from permitting requirements certain “low-risk categories” of GE crops. Although APHIS has been regulating GE crops for over fifteen years and there have been more than 9,000 field releases, agricultural biotechnology is still in its infancy. The scientific community has generated very little data that allows a thorough assessment of the potential environmental risks of those crops. Thus, it is premature to consider completely exempting from regulatory oversight any releases of such crops into the environment. APHIS should not only be notified of every field release of an experimental GE crop but should approve each release. Also, APHIS should conduct post-approval oversight (through inspections and other compliance measures) to ensure that those trials comply with government-imposed confinement and containment conditions.

VIII. The Approval of a GE Crop in Another Country Should Not Be a Factor Determining the Level of Review for That Crop by APHIS.

The Federal Register notice states that APHIS is considering an expedited review for certain low-risk GE commodities intended for importation but not intended for propagation in the U.S. Although it may be appropriate to grant such applications an expedited review if the risks posed are negligible, it is not appropriate to base that expedited review on the fact that the imported product received regulatory approval in its country of origin. Some countries may have extensive regulatory systems that would adequately ensure that the release of that product into the U.S. would not have a detrimental effect on agriculture or the environment. In other countries, however, the regulatory system may only provide a cursory review of relevant risk issues or may not address issues particularly relevant to the U.S. (e.g. may not address wild relatives because there are none present in that country). Thus, any expedited review process should be based on objective scientific risk-based criteria and should not rely on regulatory determinations from other countries as a proxy for safe introduction into the U.S.

IX. APHIS Environmental Assessments Should Address the Full Range of Environmental Issues.

In the past several years, the National Research Council (“NRC”) has issued several reports addressing the APHIS regulatory process for GE crops. In those reports, the NRC determined that APHIS has not assessed the full range of potential environmental issues and risks that might be posed by a particular engineered crop’s release into the environment. For example, the NRC’s 2004 report entitled “Biological Confinement of Genetically Engineered Organisms” stated that “regulators should consider the potential effects that a failure of a genetically engineered organism confinement could have on other nations....” Similarly, in its 2002 report

entitled “Environmental Effects of Transgenic Plants,” the NRC recommended that “APHIS should include any potential impacts of transgenic plants on regional farming practices or systems in its deregulation assessments.” Therefore, APHIS should amend its regulations to broaden the range of environmental issues that are to be assessed prior to an approval of an engineered crop’s release into the environment. Scientific data and analysis should be required from the applicant on the full range of environmental concerns, including effects on other nations and regional considerations in the U.S.

X. The Regulatory System Should Establish Mechanisms for Post-Commercialization Monitoring.

Under the current regulatory system at APHIS, once a petition for non-regulated status is granted for a GE food crop, there is no oversight of that crop’s release into the environment. In particular, there is no monitoring of that crop’s effect on the environment nor any testing or collection of data to validate the assumptions and predictions made in the crop’s environmental risk assessments. In “Environmental Effect of Transgenic Plants, the NRC stated that “post-commercialization validation testing be used to assess the adequacy of precommercialization environmental testing.” Therefore, APHIS should amend its regulations to establish post-commercialization monitoring requirements for applicants seeking commercial release of a GE crop.

CSPI appreciates the opportunity to submit comments on the issues raised in the Federal Register notice. If USDA would like additional information about these comments, I would be happy to meet with you at your convenience.

Sincerely,

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