



CENTER FOR
Science IN THE
Public Interest

*The nonprofit publisher of
Nutrition Action Healthletter*

November 24, 2008

By Electronic Submission

Docket No. APHIS-2008-0023
Regulatory, Analysis and Development
PPD, APHIS
Station 3A-03.8
4700 River Road Unit 118
Riverside, MD 20737-1238

Re: Comments to Docket No. APHIS-2008-0023.

The Center for Science in the Public Interest (“CSPI”)¹ hereby submits the following comments to the Animal and Plant Health Inspection Service (“APHIS”) on the proposed regulations discussed in the Federal Register notice dated October 9, 2008 (73 FR 60008). CSPI commends APHIS for considering amendments to its current regulatory system for genetically engineered (“GE”) crops. CSPI believes the proposed regulatory changes, if adopted, will be an overall improvement over the current regulations.

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 and are in desperate need of revision. The proposed regulations improve the current regulations in a number of important ways. First, they take advantage of additional legal authorities in the Plant Protection Act, in particular the authority to regulate “noxious weeds.” Second, the regulations set forth a tiered system for assessing the potential risk of GE crops, which provides a scientific risk-based

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 900,000 member-subscribers to its Nutrition Action Healthletter and by foundation grants. CSPI receives no funding from industry or the federal government.

system. Under that system, GE crops with greater potential for risks require more data in their submissions, go through a more thorough review by the government, and obtain permits with the more stringent planting restrictions and additional recordkeeping obligations. Finally CSPI commends APHIS for providing the public with key documents and the opportunity to comment before it grants a petition for nonregulated status or allows a conditional exemption. Regulatory decisions in those areas will be improved because of the transparency and public participation requirements that are contemplated in those provisions of the proposed rule.

While the proposed rule has many improvements over the current regulations, it falls short of establishing a comprehensive regulatory system for GE crops that is transparent, participatory, and will ensure safety. Therefore, CSPI provides the following specific comments on the proposed rule and hopes APHIS will revise the proposal to address these concerns:

I. The Public Should Have the Opportunity to Comment Before All Major APHIS Decisions on Individual GE Crops

A public comment period before major APHIS decisions on how it will regulate a specific a GE crop will allow the public to raise new issues or provide new scientific data not in the application. Public comment on those areas can lead to a better regulatory decision. APHIS clearly understands the value of public involvement as the proposed rule provides the public with a comment opportunity before a decision is made on a petition for nonregulated status and requests for conditional exemptions. While public participation in those two areas is important, it is also important for other APHIS regulatory decisions. In particular, all permits decisions for the release of a GE crop that fall within permit categories B-D should provide for public comment before the permit is issued.

Under the current regulatory system, there is no opportunity to comment under the notification process and only limited opportunity for GE crops that require permits for their environmental release. The GE crops that have required permits include many crops engineered to produce a pharmaceutical or industrial compound as well as other GE crops that have greater potential risks. For a small subset of GE crops that file permit applications, APHIS develops an environmental assessment and provide the public an opportunity to comment on it before it makes its permit decision. Under the proposed rule, it is unclear whether this procedure will continue. There is no discussion in the proposed rule about conducting environmental assessments for GE permit applications nor about providing the public an opportunity to comment before GE crop permits are issued (as opposed to other parts of the rule that specifically state that public comments will be part of the regulatory process).

In the revised regulations, APHIS needs to state that the public will be provided with the opportunity to comment on permit applications for the release of a GE crop that fall within administrative permit categories B-D. Under such a system, the public would

have the opportunity to comment on the more risky applications (such as crops engineered to produce pharmaceuticals), while safer applications in category A could be issued without a public comment process. 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 redacted permit application. This would result in better decisionmaking by APHIS and a more transparent and participatory regulatory system for GE crops.

II. To Achieve the Goal of Increasing Transparency, APHIS Needs to State in the Proposed Regulations that All Key Regulatory Decisions on Individual GE Crops Will be Made Available to the Public.

All documents that memorialize the key decisions by APHIS in the regulation of individual GE crops need to be provided to the public in order to establish a truly transparent regulatory system that instills public confidence. The documents that should be made public include: (1) the redacted permit applications, (2) the permits issued by APHIS, (3) the petitions for nonregulated status, (4) the determination by APHIS on the petitions, (5) any requests for conditional exemptions, (6) the APHIS decisions on conditional exemptions, (7) audit and inspection reports, and (8) the final disposition of any enforcement actions. With computers, scanning, the internet, and electronic filings for permits, APHIS should be able to allow the public electronic access to all the identified documents on a publicly accessible website without great expense or time. In addition, APHIS should establish a registry that lists each GE crop and its regulatory history (field trial permits, petition for nonregulated status, etc...).

III. APHIS Should Ensure that the Proposed Regulations Provide All Necessary Enforcement and Compliance Tools.

The proposed regulations provide APHIS with a number of important enforcement and compliance tools, including inspection authority, recordkeeping and document retention requirements, and the ability to conduct or require a developer to conduct remedial action. However, additional enforcement and compliance tools would help APHIS protect agriculture and the environment, such as (1) the ability to collect samples of plants and seeds and (2) requirements that applicants submit test protocols and retain representative samples. Adding additional provisions that cover those areas would greatly improve the proposed rule.

Section 340.7 of the proposed rule provides inspectors access to any place where the regulated articles (the GE crops under permit) might be. Those provisions also allow the inspector to audit and review all records required under the proposed regulations. Nowhere in the regulations, however, is the inspector given the power to collect samples of GE plants, GE seeds, or non-GE crops in the same location. That power, however, is important to ensure that permit conditions are being met and GE crops are not persisting in the environment after a field trial is completed. Therefore, the proposed regulations should be modified to add language giving inspectors the right to collect samples of plants and seeds found at any place involved in the permitted activity. If the current law does not allow for such authority, APHIS should approach Congress and request that they

amend the Plant Protection Act to give APHIS that power.

The proposed regulations should also require the applicant to retain in their records gene-specific testing procedures needed to identify regulated articles in the event of an unauthorized release and representative samples of any regulated article, including GE seed. Both of these proposed requirements are found in the USDA document entitled “Lessons Learned and Revisions under Consideration for APHIS’s Biotechnology Framework.” In that document, APHIS stated that adding those requirements would “enhance the regulatory framework” and correct some of the problems that were encountered by APHIS when it investigated the LibertyLink Rice Incident. Therefore, the proposed regulations should add those two requirements, both to implement the suggestions from APHIS’s own report on improving its regulatory framework² and to provide APHIS with the necessary tools to allow it to carry out its compliance and enforcement responsibilities.

IV. Petitions for Non-Regulated Status Should be Eliminated and Commercial Permits Should be Issued For All GE Crops.

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 many GE products 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, the imposition of conditions to address minor risks that could be easily mitigated, and the collection of data to confirm assumptions made in the risk assessment process. 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.

The proposed rule continues the current petition process with all its weaknesses. The proposed rule does provide a formal mechanism for revoking a previous approval of nonregulated status but it establishes a high burden for APHIS to meet to re-regulate a GE crop. Under the proposal, the Administrator may revoke an approval “if the Administrator receives information subsequent to approving the nonregulated status and makes a determination based upon this information that the circumstances have changed such that the GE organism *is likely to be* a plant pest or noxious weed.”(emphasis added). Such a provision puts the burden on APHIS to collect enough evidence so that it can prove that the GE organism “is likely to be” a plant pest or noxious weed. Without any

² In fact, the Federal Register notice specifically states that APHIS is proposing certain changes to address the considerations from the Lessons Learned report. It is unclear why the two recommendations identified here are not included in the proposed rules. Without the samples and testing procedures, APHIS was clearly hampered from conducting past compliance and enforcement investigations. Requiring the retention of this information would prevent those problems in the future.

obligation by a developer to keep records on problems that may arise from their nonregulated GE organism (there is no legal authority for USDA to require adverse incident reporting requirements from GE crops that are found not to be plant pests or noxious weeds), it will be very difficult and expensive for USDA to meet its burden under the new requirement. In addition, in the time that it would take APHIS to develop a case proving that the GE organism needs to be regulated, the GE crop could establish itself in the environment and cause significant damage to agricultural interests

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. The permit would allow the free planting of the crop anywhere in the US but might contain a set of standard post-commercialization obligations, such as general monitoring, reporting, and renewal requirements.

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 problems that might arise after commercial planting of the GE crop. It also would reduce the confusion that currently exists with the public in the U.S. and internationally about the petition process and what it means for a GE crop to have “nonregulated status.”³ Finally, commercial permits would be the best method for APHIS to meet its mandate of safeguarding agricultural interests and the environment.

V. The Scope of the Regulations Needs to be as Clear as Possible so That its Application is Obvious to All Responsible Persons.

CSPI supports the broadening of the scope in the proposed rules (such as the inclusion of noxious weed issues) but believes that the proposed rule needs to be clear so all developers know how to apply it to their specific GE crops. The language in the Federal Register notice explaining the proposed rule, however, acknowledges that in some situations, “it may not be readily apparent to the responsible person for a GE organism whether or not the organism falls within the scope of Section 340.0 and is

³ The “petition for nonregulated status” process is extremely confusing to the public. The public understands the need to get a permit or license to produce a product but they don’t understand the government regulating a product for years and then deciding it no longer needs regulation. Replacing the petition process with a commercial permit process would significantly reduce that confusion. It would be a much simpler regulatory system if all GE organisms needed a commercial permit (or license) to be grown commercially, not just GE crops that produce pharmaceuticals or industrial compounds.

regulated.” (73 FR 60012). It then states that the person may consult with APHIS to determine applicability. While it is important to have a consultation option in those cases, CSPI believes that consultation should be mandatory, not voluntary. If there is any question about applicability of a particular GE organism, that determination should be made by APHIS, not the responsible person.

CSPI also supports the provisions in the Federal Register notice that state that those consultation determinations will be made public. (73 FR 60012). Making this information public will help future developers determine applicability and also inform the public about the types of GE organisms under regulation. Therefore, each consultation should be documented and then made public on the APHIS internet site.

VI. Additional Clarity Around Regulatory Procedures in the Proposed Rule Should be Retained.

There are a number of provisions in the proposed rule that clarify for the regulated community and the public the procedures that will be used to regulate GE crops. For example, there are explicit procedures for amendment, transfer of responsibility, and revocation of permits in section 340.2 as well as formal acknowledgement of the current policy to allow state and tribal review before a permit is issued. In sections 340.2 and 340.6, the appeal procedures are spelled out for permits or petitions that have been denied. Section 340.8 sets forth the requirements for requesting confidential treatment of business information. Those and other provisions provide useful information to the public about the regulatory process and should be retained in the final rule. The more details the rule can provide about how APHIS will regulate GE crops, the greater the transparency of the process, and the more confidence the public will have in what APHIS is trying to do.

CSPI appreciates the opportunity to submit comments on the APHIS proposed rule. If APHIS would like more information about any of these comments, we would be happy to meet with you at your convenience.

Sincerely,



Gregory Jaffe
Director, Biotechnology Project
The Center for Science in the Public Interest
202-332-9110, Ext. 369