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April 12, 2004

Docket No. 03-031-2
Regulatory Analysis and Development, PPD
APHIS Station 3C71
4700 River Rd., Unit 118
Riverdale, MD 20737-1238

DELIVERED BY EMAIL AND COURIER

Re: Notice of intent to prepare an environmental impact statement (EIS) on regulation of certain genetically engineered organisms

Dear Sir/Madam:

Thank you for the opportunity to comment on the above-referenced docket. The International Center for Technology Assessment (CTA) is a non-profit, public interest, advocacy organization. CTA is devoted to fully exploring the economic, ethical, social, environmental and political impacts that can result from the applications of technology, including the genetic engineering of plants and animals.

During the APHIS stakeholder session on Jan. 26, Peter Jenkins delivered much of these comments orally on behalf of CTA and its sister organization, the Center for Food Safety (CFS). But, these written comments provide more detail on those oral points as well as addressing some other topics. CFS is submitting separate written comments, authored by Doug Gurian-Sherman, Ph.D., that CTA supports and endorses.

1. PEIS. We here reiterate that we support the general notion of revising the APHIS regulations on GE plants that may be plant pests or weeds, and on preparing a Programmatic EIS (PEIS) on the revision. So long as the PEIS is prepared with objective, independent analysis informed by comments from the public and outside experts, while carefully following the Council on Environmental Quality's NEPA regulations on how to do a PEIS, it should be a productive undertaking.

2. Alternatives. The key is that APHIS must clearly articulate its proposed programmatic action (or set of actions) and must articulate clear alternative actions that are well thought-out, distinct, and comparable in scope to the Proposed Action. Only then will the PEIS provide meaningful analysis of separate regulatory alternatives and thereby provide the ultimate decisionmaker with real choices.

Preparing a PEIS with a "mishmash" of vaguely distinguished alternatives, or just one obviously-favored Proposed Action and one "no action" alternative, would be a waste of time and effort and could be challenged as inadequate.

3. Biopharmaceutical and industrial crops. We suggest that the regulatory sub-actions analyzed include, at a minimum, some meaningful alternative approaches to regulating GE biopharmaceutical and industrial crops that provides an assessment of "real world" impacts, rather than vague or highly general impacts. This could include a detailed discussion of alternative regulatory approaches such as: 1) only allowing indoor/underground plantings of such crops; 2) only allowing non-food platform crops to be used; and 3) regulating such plantings geographically by state or region so as to effectively eliminate risks of contamination of food crops. Such a PEIS should assess the actual types of biopharmaceutical and industrial crops that are being proposed or are foreseeable and discuss foreseeable impacts on human health, animal health, and the environment. While such analysis would necessarily be somewhat general, it should include scientific discussion of the pharmacological, toxicological, and environmental impacts that foreseeably could result if such crops were broadly commercialized under the different programmatic alternatives. In other words, the PEIS needs to look far enough into the future, (at least five to ten years) and look at broad enough alternatives, while looking at real potential impacts, to provide a useful guide to future decision makers (and to the public) in choosing the best regulatory alternative.

5. Weed authority. On the issue of using APHIS's authority over noxious weeds as the agency regulates GE crops, CTA supports broadening the base of your regulatory authority. However, you should not do so in a way that would preclude any noxious weed listing petition from being sent to the APHIS weed program merely because it relates to a GE plant. It is foreseeable that as more and more GE crops of various kinds are planted, GE weeds can and will develop. As you know, CTA and CFS have petitioned APHIS's weed division seeking a determination that GE glyphosate tolerant creeping bentgrass and Kentucky bluegrass already qualify as Federal Noxious Weeds. In short, we recommend that you not seek to prevent the type of petitions that CTA and CFS filed on these GE varieties. Doing so would violate the weed listing petition provisions of the Plant Protection Act. It also would reduce the diversity of viewpoints within APHIS that would be applied by taking the agency's weed specialists out of the primary regulatory role.

6. Post-approval authority. Further, the PEIS should assess the option of regulating risky crops, including but not limited to, the biopharm crops and glyphosate tolerant turfgrasses, through the imposition of enforceable stewardship, monitoring, reporting, and similar conditions. The current system of deregulating crops without even having the regulatory option of imposing conditions that a deregulated party must comply with, such as in the area of resistance management for pesticidal/herbicidal crops, marketing and sales restrictions, and preventing genetic contamination of other crops, will not serve the public interest in the future as more novel and risky phenotypes are proposed. Regulators in other areas routinely impose comparable enforceable conditions on approvals; APHIS should have that power too. Regulatory reform should include provisions

allowing prompt and reliable recalls by APHIS of GE products that later turn out to cause unanticipated damage or pose other unwanted risks.

7. Categorical exclusion reform. Further, we reiterate the need for a regulatory system that would apply careful environmental impact analysis more reliably and earlier in the process. The first need is to drop the system of virtually automatic Categorical Exclusions under NEPA, which has lead to APHIS failing to do even an Environmental Assessment (EA) on any field test of any GE crop since 1998. As we stated before in various comments to you and in a Dec. 16, 2002, petition on biopharm crops sent under the name of the Genetically Engineered Food Alert (GEFA), APHIS should amend its NEPA regulations on Categorical Exclusions, at 7 C.F.R. §372.5, which are a confusing mess. Classifying outdoor plantings as "confined" just makes no sense; the Prodigene contamination incidents made that very clear. Biopharm crops and fertile outcrossing turfgrasses obviously should not qualify for Categorical Exclusions because of the risks they pose (see the National Academy Sciences reports on these points, which we cited and discussed in the GEFA petition and in our comment to you, dated Mar. 4, 2004, on the Monsanto/Scotts GE creeping bentgrass deregulation petition.)

8. Commercialization. No one should be allowed to sell commercial quantities of GE plant-derived compounds under the field test regime. If they are allowed to do so, given APHIS's excessive use of Categorical Exclusions, they may commercialize a GE product without ever conducting even an EA, not to mention an EIS. This is what Prodigene accomplished for some biopharm substances, such as aprotinin. The PEIS could assess regulatory alternative such as a maximum acreage threshold for novel crops above which the presumption should be that commercialization is occurring (absent a clear showing otherwise) and a full EIS is required. Alternatively, the regulatory approach could put the burden on companies doing any field tests to certify that they will not commercialize the GE plant-derived substance or the plant itself without obtaining additional regulatory approval, which latter step would have a very clear NEPA compliance requirement, again with the presumption being that a full EIS is required, absent a clear showing otherwise.

9. GE trees and perennial grasses. On further regulatory alternatives, you should propose and assess the alternative of separate regulatory provisions for field testing and possible commercialization of GE trees and GE perennial turf and pasture grasses. Both classes are distinct from traditional GE annual crops and should be regulated distinctly. They possess features like long life spans, invasiveness, wide presence in natural habitats, numerous wild relatives, widely dispersing pollen, and use in major non-agricultural markets. APHIS has recognized this by conducting or sponsoring separate workshops for GE trees and GE grasses. As with the biopharm and industrial crops, separate regulatory provisions tailored to those classes of GE crops are needed. The transparent process of proposing and finalizing such a regulation would provide you with valuable outside comments from the public and from experts on those topics. They would help to identify the state of the science in these areas and highlight the priority regulatory concerns.

10. CBI. On other related matters, we have urged you to reform APHIS's confidential business information (CBI) provisions in your clearly out-of-date 1985 CBI policy applicable to biotechnology (Policy Statement on the Protection of Privileged or Confidential Business Information, 50 Fed. Reg. 38561 [Sept. 23, 1985]). The four main CBI pitfalls we have identified that hamper transparency and reduce public confidence in APHIS's regulation of GE crops are:

- a) Allowing "stale" claims to proliferate in APHIS's field test database and in response to FOIA requests and other document requests; these are CBI claims for compounds and other information that have already been publicized by the companies in other contexts (such as patent applications, websites, and press releases), or otherwise don't still qualify as CBI, but are still wrongly labeled by APHIS as CBI and kept secret from the public.

- b) Allowing repeated opportunities for companies to claim CBI. This acts to prevent any timely response to FOIA requests as the "foot dragging" companies (who are motivated to keep everything secret that they possibly can) and APHIS's terribly backlogged FOIA office combine to render a typical response time for any document in this area to around **two years or more**. That is unacceptable and renders the FOIA process largely worthless because any information produced is so dated and redacted - often with little justification - to be of little value. APHIS should revise its CBI policies and regulations to conform with EPA's modern and state-of-the-art approach adopted very recently for CBI in the context of GE Plant Incorporated Protectant crops (40 CFR § 174.9). This regulation requires any companies claiming CBI to do so at the first opportunity and to provide complete justifications at the time the claim is asserted, otherwise a claim is waived. Absent unusual circumstances, no need exists to provide the companies a "second chance" to claim CBI (and thereby terribly delay records production) as APHIS does now.

- c). The lack of an emergency exemption allowing release of CBI to the public in cases of containment violations that potentially could threaten public health, cause environmental damage, or contaminate other crops. The Prodigene violations potentially posed contamination of the environment, neighboring property, other crops, and the food supply. Nevertheless, the Acting BRS Director stated that, due to the CBI protections, she had no legal ability to publicly release the identity of the contaminating GEPPV, thus she refused to do so despite a direct request (C. Smith, pers. comm.). This is unacceptable.

Ms. Smith apparently based her refusal on the outdated 1985 APHIS Policy that addressed CBI and biotechnology long before GEPPVs had ever been field-tested or even considered. This 1985 Policy flat-out restricts public CBI disclosure, failing to consider possible cases of containment violations that may harm public health and the environment if the CBI is <u>not</u> disclosed.

APHIS has discretion to change its CBI policy and it should promptly exercise this discretion on behalf of the public interest. APHIS should note that the EPA's regulations allow disclosure of CBI to potentially exposed people in emergencies involving releases of potentially toxic chemicals.

Specifically, 40 C.F.R. § 2.306(k), on CBI obtained by EPA under the Toxic Substances Control Act, allows public disclosure under circumscribed procedures "when necessary to protect health or the environment against an unreasonable risk of injury." See also the EPA provisions at 7 CFR § 136h(d) allowing similar disclosures of pesticide information under the Federal Insecticide, Fungicide, and Rodenticide Act. APHIS should adopt a parallel regulation allowing disclosure of CBI when containment violations occur and similar "risks of injury" are present.

- d) Withholding field test locations for GE crops under "anti-vandalism" justifications is not the same as CBI. Therefore, the recent APHIS practice of "allowing" companies that are worried about vandalism to claim the test locations as CBI is a fiction, unauthorized under the Trade Secrets Act, which is the source of Federal CBI protection. Different policy concerns are involved in any "anti-vandalism" approach and they cannot be masked under the CBI policy. APHIS must stop this practice and reveal field test locations in response to FOIA and other record requests, absent clear new legal authority to withhold it.

11. Information/outreach. As a method to further increase transparency, you should reform your State and local (or tribal) level public information and outreach efforts to provide better advance notification of precisely what field tests are proposed and where. The current field test database maintained by Virginia Tech is utterly inadequate. It lists many field tests as occurring in multiple states and with multiple genes, and with cumulative acreage, if the acreage is even given at all. Thus, often there is no indication of which new gene is being proposed for which particular state and in what amount of acreage. This information needs to be disaggregated and listed by the gene and acreage proposed for each state and for each county therein. Further, where multiple plantings are proposed under one field test for a given county, that needs to be clearly indicated.

12. State and local notification. Most importantly, your new regulations should require some mechanism for clear and timely notification at the State and local (or tribal) levels of each new proposed field test. Your PEIS should consider alternative approaches, such as specific publications, email lists to interested stakeholders, or a program to certify that states and counties where field tests are proposed have adequate public notification programs in place before a field test can be approved in those locations. Relying on the Virginia Tech database as a means of public notification is too passive and ineffective.

13. ESA compliance. You need to clarify how the Endangered Species Act (ESA) Section 7 consultation requirements are satisfied for each field test, and you need to make that information available to the public before a final decision on a proposed field test. Making this ESA information available would be acheived through the State and local level public notification processes discussed in the previous paragraph of this comment. An example of an apparently adequate ESA consultation approach is found in your recent Environmental Assessment (EA) prepared for the proposed confined release of a GE strain of the bacterium *Erwinia amylovora*, the causal agent of fire blight disease (announced at 69 FR 13280-13281). That EA, at sections V.5 and Appendix 1 discusses

ESA concerns in a transparent manner that should be duplicated for every other proposed field test.

We look forward to your written responses to each of these comments individually, and to further participating in the PEIS process. For further information on this comment, please contact me.

Sincerely,

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