

June 29, 2009

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")<sup>1</sup> submitted comments on November 24, 2008, 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). On January 16, 2009, USDA reopened the public comment period for its proposed rules and asked that additional comments consider addressing certain key areas in the proposal. CSPI now supplements its original comments with the following comments on the proposed rule and the issues raised by USDA in its announcement.

## I. <u>The Scope of the APHIS Regulations Should Encompass GE Plants and non-vertebrate, non-plant Organisms.</u>

CSPI supports explicit inclusion of all GE plants and other relevant organisms in the scope of the proposed regulations. APHIS should establish as broad a scope as possible to make sure that APHIS can regulate any GE plant that may raise potential safety concerns.

CSPI is a nonprofit education and advocacy organization that focuses on improving the safety and nutritional quality of our food supply. CSPI seeks to promote health through educating the public about nutrition; 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.

Once APHIS has determined that it can regulate all GE plants under its authority from the Plant Protection Act, CSPI supports proportionate scientific risk-based regulations for those products. The regulations should include procedures to exempt individual GE plants or categories of GE plants from some or all regulatory obligations if they pose no potential risk. The regulations should also provide streamlined procedures for low risk GE plants and additional safeguards for high risk GE plants. Thus, a system should be established where all GE plants are covered by the regulations but, depending on the potential risks posed by the plant, the requirements for complying with the regulations will vary from extensive data submissions and permits with stringent confinement conditions to minimal data requirements and minimal permit obligations, if any.

## II. The Proposed Rules Should Incorporate the Noxious Weed Provisions of the Plant Protection Act.

As mentioned briefly in our previous comments submitted on November 24, 2008, CSPI supports the broadening of the scope of the APHIS regulation of GE crops to include noxious weed concerns. APHIS should use all the potential regulatory authorities it has been given by Congress to ensure that GE crops do not harm the environment and agricultural interests. By incorporating the noxious weed provisions of the Plant Protection Act into its new regulations for GE plants and other organisms, APHIS will broaden the range of potential issues, risks, and concerns it can assess and address when regulating those organisms. CSPI finds no reason not to use this additional authority to regulate GE crops.

## III. Permits Should be Issued for All GE Crop Plantings and Both "Notification" and "Petitions for Non-Regulated Status" Should be Eliminated.

In most countries around the world, when a developer wants to plant a GE crop outdoors (as a field trial or a commercial crop), they apply to a regulatory agency which approves the application and issues a permit. Under the current APHIS regulatory system, some experimental GE crops can be planted under a notification process while others require a permit. When a developer wants to produce a commercial product, they can continue to use the notification or permitting process (whichever applies) or they can petition the agency to make a determination that the GE crop no longer needs regulation (a petition for non-regulated status). Those three different regulatory procedures are confusing to developers, the American public, and the international community because it is not always clear how a particular GE crop will be regulated nor whether two similar products will have the same regulatory pathway. The regulations also prevent the imposition of post-commercialization conditions on most GE crops. Finally, those procedures are not always transparent nor do they provide the opportunity for public comment for the vast majority of GE crop plantings.

In its new regulations, APHIS should take this opportunity to simplify its regulatory procedures by eliminating both petitions for non-regulated status and the

notification procedure. Instead, APHIS should promulgate one all-encompassing permitting system that covers all stages of GE crop development. Under a new permitting system, there could be permits for field experiments and different permits for GE crops planted for commercial purposes (i.e. to be harvested as food, feed, energy, or for the extraction of pharmaceuticals or industrial compounds). The field trial permitting process could provide a streamlined process for GE crops that previously qualified for the notification process, so that the regulatory burden for those low risk crops does not change from the current regulatory system. For GE crops that currently need permits, those crops could continue to require permits with confinement obligations. For any risky GE crop field trials (including all GE crops engineered to produce pharmaceuticals or industrial compounds), the permitting process should become more transparent and participatory by first releasing the applications and agency analysis to the public and then allowing for public comment before any permit is issued.

For the commercial permits, most issued permits would act as a license, allowing the developer to sell the GE crop to farmers to plant and harvest. The commercial permit would provide APHIS with a mechanism to impose on the developer, if scientifically warranted, post-commercialization obligations, such as monitoring for environmental and agricultural effects or the collection of data to confirm assumptions made in the risk assessment process. For some commercial permits, such as permits for GE crops that produce pharmaceuticals, the permits might look very similar to field trial permits with stringent confinement obligations. In all cases, applications for commercial permits would be made public and there would be an opportunity for public comment before the permit is issued. Such a system would alert the public to all commercial GE crops (information that is not currently available under the current system) and keep all GE crops regulated in case risks arise at a later time that need government oversight.

## IV. <u>APHIS Should Strictly Regulate All GE Crops That Produce Pharmaceuticals or Industrial Compounds</u>.

While CSPI supports USDA's scientific risk-based and proportionate approach to regulating GE plants, GE crops that produce pharmaceutical or industrial compounds pose potential risks that require special regulatory requirements and procedures. All GE crops that produce pharmaceuticals or industrial compounds should be required to obtain a permit for any outdoor plantings, including both field trial experiments and plantings that result in the production of a commercial product. Those permits should require strict confinement obligations, especially for pharmaceutical or industrial compound production in food or feed crops. In addition, no GE crop that produces a pharmaceutical or industrial compound should be allowed to submit a petition for non-regulated status. Those crops should only be planted under permits that impose stringent confinement obligations and require significant oversight by USDA.

As APHIS establishes its regulatory requirements for GE crops that produce pharmaceutical or industrial compounds, the following requirements should be included to provide appropriate protection from the risks posed by those crops:

- The permitting process for GE crops that produce pharmaceutical or industrial compounds needs to be transparent and allow for public participation. APHIS should make the application for each permit available to the public (reacted for confidential business information only) and then allow a public comment period before any decision is made to grant or deny the permit. In addition, any issued permits should be published on the APHIS website.
- Before any permit is issued, APHIS should conduct a thorough environmental assessment of any potential risks from growing the crop outdoors.
- Any permits should require stringent confinement obligations, including, but not limited to, biological confinement measures (e.g. male sterility, chloroplast transformation, etc...), physical confinement measures (e.g. fences, netting, etc...), and geographic restrictions (e.g. no pharma corn in corn belt states).
- Any permits should require conditions to ensure compliance, including, but not limited to, training of farmers, certification of farmers, documentation of compliance, and the hiring of third party auditors to inspect, test, review documents and submit compliance reports to APHIS.
- APHIS should agree to inspect locations planting those crops numerous times during the year. APHIS also should inspect neighboring fields and take samples to confirm that confinement has been achieved.

CSPI believes that if APHIS imposes the conditions above on GE crops that produce pharmaceuticals or industrial compounds, the regulatory system will be moving in the direction of providing protection based upon risk.

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

Sincerely,

Gregory Jaffe

Director, Biotechnology Project

The Center for Science in the Public Interest

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