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Docket No. APHIS-2006-0112
Regulatory Analysis and Development
PPD, APHIS, Station 3A-03.8
4700 River Road Unit 118
Riverdale, Maryland 20737-0112

Re: Introduction of Genetically Engineered Organisms, Draft Programmatic Environmental Impact Statement – July 2007

This letter is being submitted in response to the public release of the Draft Environmental Impact Statement (DEIS) prepared by the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (USDA) on July 17, 2007. The DEIS was prepared to assess the impacts of changes APHIS is considering regarding how genetically engineered plants are regulated under 7 CFR Part 340. Regulation of such plants is important to the business of our company, Edenspace Systems Corporation (Edenspace).

Edenspace is a leader in the development and use of plants for energy and environmental applications. The company's focus is on developing improved crop feedstocks for production of low-cost cellulosic ethanol. Significant technical advances are needed in order to achieve the national goal of producing cost-effective cellulosic ethanol on a large scale basis, including the development of enhanced, genetically-engineered crops. In addition to its development of crops for renewable fuels, Edenspace is a leader in the use of non-transgenic plants to remove serious environmental hazards such as arsenic and lead from contaminated soil and water, and is also a leader in developing transgenic plants as "bioindicators" to signal the presence of environmental hazards. Its current and past environmental customers include the U.S. Environmental Protection Agency (EPA), the U.S. Army Corps of Engineers, and numerous government, industrial and municipal clients. Through innovative uses of living plants, since its founding in 1998 Edenspace has demonstrated a sustained commitment to protection of human health and the environment.

Edenspace first notes that APHIS has been regulating the introduction of transgenic plants into the environment for twenty years and in that time has evaluated and approved over 15,000 field releases of transgenic organisms. Both USDA, through its Biotechnology Risk Assessment Grant Program, and the Environmental Protection Agency have studied the potential and actual impacts of transgenic organisms. The fact that none of these releases of transgenic organisms has led to a significant negative impact on the environment or human health suggests that transgenic technology is not necessarily a risky technology and that APHIS has been effectively regulating these products. As APHIS states in its DEIS, however, emerging technologies might not be adequately assessed under its current regulatory process under the Plant Protection Act. In addition, new transgenic plant technologies offer the potential of lower-cost

pharmaceuticals, nutrition and renewable fuels, for which rapid, efficient assessment of actual risk is essential if health and environmental benefits to large numbers of people are to be realized. Edenspace therefore believes that the DEIS is timely and that the recommendations proposed by APHIS will benefit both applicants in creating a more transparent risk based assessment process and APHIS personnel, by streamlining the evaluation process for familiar low risk applications. At the same time, these recommendations will still maintain adequate review of novel products. Edenspace would therefore like to provide the following comments on specific issues that APHIS evaluated for its DEIS for which Edenspace has experience or expertise.

Issue 1: Scope of Regulatory Oversight (Authority over Noxious Weeds and Biological Control Organisms)

APHIS has preliminarily selected a combination of Alternatives 2 and 4: "Expand the scope of what is regulated by adding considerations of noxious weed risk and regulating biological control organisms in addition to evaluating plant pest risks, and use genetic transformation as the trigger for regulation. Continue to regulate event-by-event." "Exclude specific classes of highly familiar organisms and highly domesticated, non-weedy crop plants and also create a mechanism to exclude additional organisms from the definition of regulated article after a safety review." Edenspace supports APHIS's recommendations for the most part. Emerging technologies may lead to transgenic products produced via methods that will not trigger review under APHIS's current regulations, so broadening APHIS's regulatory authority by considering products as a noxious weed risk will allow for more complete regulatory coverage. Edenspace also feels it is appropriate to define classes of organisms that will be exempt from regulation, as many products do not pose any risk to human health or the environment and their planting over many years supports this.

However, Edenspace strongly recommends that APHIS reconsider continuing to regulate all transgenic products on an event-by-event basis. A report by the National Research Council in 2002 stated that the focus of regulatory assessment of transgenic organisms should be on the phenotype (i.e. trait) of the product, and not the method by which it was produced. Trait based regulation would be more consistent with the NRC recommendations, so Edenspace recommends that APHIS generally regulate products on a trait-by-species basis, reserving the right to regulate organisms with a high foreseeable risk on an event-by-event basis. This would allow applicants to more readily evaluate multiple lines containing the same transgene, while conserving APHIS's resources for greater scrutiny of higher risk products (i.e. tier 3 or 4 products).

Issue 2: Risk-based Categories (Expanded Tiered Permitting System)

APHIS is considering defining different classes for transgenic products based on the potential risk of the transgene and the plant and has selected Alternative 4: "Establish a tiered permitting system for plants based on newly devised criteria and evaluate permit applications for introductions of non-plant organisms on a case-by-case basis" as its preliminary recommendation. Edenspace strongly believes in a science-based approach

to assess transgenic products, and supports APHIS's decision to establish tiers based on scientific criteria. While a great deal of work will be necessary to define these different tiers, Edenspace would like to make a few general suggestions on the characteristics of the tiers.

- Products should be assigned to the tiers based on characteristics of the trait-species combination rather than the function of the product (e.g. PMP or PMIP) in order to avoid inconsistent regulation. For example, a plant engineered to express a cell wall hydrolyzing enzyme to produce fermentable sugars might be considered an industrial product, while the same plant used to increase the feed value of a crop by increasing digestability would be considered an agronomic product. If APHIS chooses to establish tiers similar to the ones described in the DEIS, an industrial product would automatically be assigned to a higher risk tier than the plant modified for agronomic use. It is the likely risk posed by the trait-species combination, rather than any single factor such as the intended use of the product, that should determine how biotechnology-derived products are regulated. Edenspace would therefore recommend establishing tiers based on trait-plant combination (e.g. weediness potential, food or feed crop, wild relatives) including the transgene product (e.g. toxicity, potential allergenicity, source of the transgene). The intended use of the plant is certainly a factor to consider in a risk-based evaluation, but often will be a rather unimportant factor.

- Higher levels of scrutiny should involve more thorough cost/benefit analysis of the product in which foreseeable collateral benefits (e.g., reduced use of herbicides) and risks (e.g., spread of glyphosate resistance in weeds) are included.

- As APHIS has suggested in the DEIS, there should be a method in place to allow a product to move to a lower tier once APHIS has gained familiarity with it, or conversely to move to a higher tier if new data indicates the product has a higher level of risk than originally thought.

Many new varieties of transgenic plants are expected to be developed in the near future, and assessing each one at the existing level of detail will likely produce a significant burden on APHIS's staff and unnecessarily delay the introduction of products that benefit public health and the environment. The establishment of clear, risk-based tiers will simplify the process of identifying products that necessitate increased scrutiny and regulation and help best utilize APHIS's limited resources by streamlining the assessment process for most low risk products.

Issue 3: <u>Regulatory Flexibility at Commercial Scale (Retention of Regulatory Oversight for Commercialized Products)</u>

APHIS has examined the possibility of continued regulatory oversight of transgenic products after commercialization and selected Alternative 2 as its preferred action: "Develop appropriate safety criteria and procedures through which plants can be

either (1) fully removed from Agency oversight or (2) retained under some degree of oversight as necessary to mitigate any minor risks." Currently transgenic plants that become commercialized have been given deregulated status by APHIS, removing them from all regulatory oversight, and this approach should be appropriate for the majority of future products. The development and introduction of novel types of products containing traits not previously expressed in plants or present in the environment will necessarily produce uncertainty as to the long term impact of the transgenic product. The ability of APHIS to continue to retain regulatory oversight over certain transgenic products could better serve the public interest in protecting human health and the environment. Specific characteristics of transgenic plants that may trigger the need for continued regulatory oversight could be the presence of weedy wild relatives or if the introduced transgene produces a product demonstrated to be toxic to non-target organisms or humans.

Issue 4: PMP/PMIP Regulation (Permit Conditions for Plants Producing Pharmaceutical and Industrial Compounds)

Issue 4 addresses the development of emerging transgenic plants expressing pharmaceutical (PMP) or industrial (PMIP) compounds, and APHIS has selected Alternative 2: "Continue to allow food and feed crops to be used for the production of pharmaceutical and industrial compounds. The agency would impose confinement requirements, as appropriate, based on risk posed by the organism and would consider food safety in setting conditions." Edenspace agrees with this recommendation to evaluate each product on its trait characteristics, as it fits with the concept of a science-based assessment system. As we have stated earlier in our discussion of Issue 2, APHIS should strive to develop a true risk-based system for assessment that does not broadly categorize products based on their intended function. Defining assessment tiers based on the function of the product will allow for inconsistent regulation, as numerous transgenic products could conceivable be used either as an industrial product (and be classified in a high risk tier), or an improved food or feed (and be classified in a low risk tier).

Historically hundreds, if not thousands of plants or plant products have been used for medicinal purposes, including some that are still currently consumed by humans such as cocoa beans (*Theobroma cacao*) and turmeric (*Curcuma longa*). The fact that a pharmaceutical or industrial use protein is produced in a food or feed crop does not necessarily mean there is increased risk compared to food or feed crops expressing other types of traits.

Issue 5: Regulation of Nonviable Plant Material

APHIS currently regulates the viable material of transgenic products such as seeds and the living organism. With the development of products that contain active proteins that can be hazardous to human health or the environment, it is conceivable that non-viable material such as leaves and stems could be a concern. To address this issue, APHIS is considering Alternative 2 as its preferred alternative: "Regulate nonviable GE plant material in certain circumstances, based on the risks posed."

While Edenspace recognizes that there are conceivable products for which non-viable material could pose a threat to human health or the environment, we have questions with APHIS's recommendation to regulate nonviable GE plant material in certain circumstances. As has been observed with cases involving adventitious presence of regulated transgenic material, it is very difficult to ensure complete containment of material, though as recognized in this DEIS low level presence of regulated material often does not present any risk. Similarly, if non-viable material would become regulated, it also seems difficult to ensure complete containment of the leaves or stems produced during a field study, leading to violation of the release permit and likely significant consequences to the applicant. Accordingly, if APHIS chooses to regulate non-viable materials Edenspace would recommend that it do under a risk-based approach, such that low-level presence of low-risk, non-viable regulated material be non-actionable as described in Issue 7.

Edenspace has extensive experience with existing regulation of non-viable plant material. Transport, storage and disposal of phytoremediation plant material that accumulates contaminants such as arsenic, lead, mercury and uranium is regulated by the EPA under a risk-based approach. Under this approach, the hazard posed by each contaminant is evaluated in establishing proper procedures, with higher levels of contaminant in the harvested plants leading to higher levels of care in handling and disposal. In all cases, plants containing low levels of hazardous contaminants are exempt from regulatory requirements. Importantly, in every case the EPA's science-based regulatory restrictions apply only to plants containing materials that are already known to be hazardous.

Given the existing body of regulation on nonviable plant material, Edenspace therefore recommends that APHIS coordinate with the other Federal departments and agencies that have experience in this area to ensure that all regulations are consistent.

Issue 6: <u>Multi-Year Permits for Commercialization of Plants</u>

APHIS has acknowledged that certain applicants may prefer to grow certain crops engineered to produce pharmaceutical products on small acreage and not wish to go through the extensive deregulation process. To address this issue APHIS has selected Alternative 2 as its preferred alternative: "Allow for special multi-year permits, with ongoing oversight." Edenspace agrees with APHIS's recommendation, as this will provide greater regulatory flexibility and benefit both applicants and APHIS staff in reducing the regulatory burden. Edenspace would also suggest that APHIS consider allowing the option for multi-year permits for any product, not just PMP or PMIP products. This approach would be more appropriate for a science-based assessment system that evaluates all products based on the risk of the trait-crop combination, not the intended function, and would also be very beneficial for developers of transgenic perennial plants (e.g. grasses or trees modified for biofuel production) for which multi-year field studies are necessary.

Issue 7: <u>Low-Level Presence of Regulated Biotechnology Materials</u>

While there have been no significant negative impacts from biotechnology products that have gone through regulatory evaluation by APHIS and commercialized, there have been a number of incidents where regulated material has been detected at low levels in the environment or food supply. In none of these cases of adventitious presence were any harmful impacts on the environment or on human health detected or foreseeable, nor would harmful effects be expected for low level presence of the vast majority of biotechnology products. Nonetheless, these incidents required regulatory action which clearly was disproportionate to the actual science-based risk of the product. To address this issue, APHIS has selected Alternative 2: "Establish criteria under which occurrence of regulated articles would be allowable, that is, considered non-actionable by APHIS. Allow field testing and impose confinement strategies based on whether a plant meets the criteria." Edenspace strongly supports this recommendation, as it still retains the product as a regulated item, but acknowledges that action does not necessarily need to be taken unless justified by actual risk. Applicants will still be obligated and should strive to contain regulated material, but as tolerances have already been developed to allow low levels in food of actual hazards such as rodent feces, pesticide residues, mycotoxins, and heavy metals, it seems reasonable that biotechnology products presenting no known or foreseeable hazard should also be allowed reasonable tolerances. Edenspace feels that criteria described in the DEIS for types of products for which low-level presence would be non-actionable (i.e. Tier 1 plants) is reasonable and supports APHIS's decision.

Issue 9: <u>Expanded Scope of Exemption for Interstate Movement of Low-risk Research Organisms</u>

As APHIS has noted in the DEIS, the transport of transgenic products is a low risk activity, and certain organisms such as *Arabidopsis thaliana* are currently exempt from movement permits. Consequently, in assessing this issue APHIS has selected Alternative 2: "Exempt a class of GE plants or organisms that are well-studied and present little or not environmental risk from permit requirements for interstate movement as is currently done for *Arabidopsis*. " Edenspace agrees that the interstate transport of transgenic products presents little risk, believes this to be the preferable alternative, and recommends that APHIS consider exempting products that meet the criteria for Tier 1 and 2. Researchers would still be obligated to transport the material in secure shipping containers as appropriate and to keep records of all interstate movements of regulated products. While APHIS could request to review these records, researchers would not ordinarily need to submit the records to APHIS, reducing the regulatory burden for both parties.

Edenspace appreciates the significant effort expended by APHIS in preparing the DEIS and the opportunity to submit comments regarding APHIS's proposed changes to its regulatory process. The recommendations put forth by APHIS are likely to increase transparency in the regulation of GE organisms, allowing for better review of emerging technologies and encouraging the development of new and important biotechnology

products. Edenspace would like to emphasize the importance of matching the level of regulatory scrutiny with the level of expected risk of the product and looks forward to additional opportunities to work with APHIS in the development of revised regulations for GE products.

Sincerely,

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