NEPA Decision Summary for Permit #14-348-101r

Planton LLC has requested a permit for confined field release of genetically engineered (GE) potato (*Solanum tuberosum*) for a single release site of limited acreage for one year in Calhoun County, Iowa. The introduced genetic material is designed to confer production of a pharmaceutical protein and to confer expression of two marker genes. Over a thousand GE potato field releases have been previously authorized by APHIS BRS. This is a renewal request of a previously approved application with the same construct, #13-347-104r-a1. Based on a review of the permit, the following determinations were made:

1. Under this permit, Planton LLC intends to conduct a confined field release of potato lines that have been genetically engineered (GE) with a single construct to confer production of a pharmaceutical protein and the expression of two marker genes. The introduced genetic material is derived from plant, bacterial, mammalian and non-coding, regulatory plant viral DNA sequences. GE crops containing the same genetic components and associated gene donors have been approved for field release previously by APHIS BRS. The non-coding regulatory regions of the constructs come from organisms that are well-tested for their safety and have been in use for several years to genetically engineer crop plants. The small-scale experimental field release, familiarity of gene donors, and well-tested functionality of genes do not raise any new issues about the field release of GE potato plants. The genes and non-coding regions regulating their expression are not likely to pose a plant pest risk. The potato lines described in the permit have not been evaluated for food or feed safety by the FDA. None of the potatoes from the field release will be used as food or feed in the United States. The company intends to conduct the pharmaceutical product development activities, including clinical trials, in Germany.

2. Based on the methods of transformation, the genetic material is stably integrated into the plant genome and no plant pest vector sequences that can cause plant disease will be associated with the transformed potato lines as a result of this process. The method of transformation is commonly used and is familiar to APHIS BRS. The gene sequences inserted into the plants do not have any inherent plant pest characteristics and are not likely to pose a plant pest risk. The introduced DNA will not lead to the expression of a toxin or other substance that is known or likely to be toxic to or cause disease in non-target organisms.

3. Both the applicant and APHIS BRS staff are familiar with potato biology and ecology. Over 1000 field tests have been performed with GE potato plants under APHIS BRS authority. The following confinement measures will be used and determined to be adequate to prevent mechanical commingling and to prevent pollen-mediated gene flow between adjacent plots:

- Modern potato cultivars are vegetatively reproduced through the use of seed potatoes, small tuber pieces with ‘eyes’. Based on greenhouse studies, the

applicant has reported that tuber formation (amount and morphology) in genetically-engineered potato is similar to the parent cultivar Desiree. Based on the known functions of the introduced genes, they are unlikely to increase the ability of the regulated potato to outcross with non-regulated potato. True potato seeds are generally not planted because potato seed does not breed true to type. Potato seed exhibit high variability and low vigor. Potato plants have variable fertility; however the parent cultivar for the regulated potato lines, Desiree, is known to be highly fertile (Lawson, 1984). Potato pollination is primarily by bumblebees that "buzz pollinate" the crop as they collect pollen; potato flowers produce no nectar. While bumblebees might transport pollen beyond 1 km, field research has shown that potato pollen dispersal is negligible beyond 10 m (McPartlan and Dale, 1994).

- Cultivated potato is sexually compatible with two diploid tuber-bearing *Solanum* spp. that occur in the US. However, these wild potatoes are geographically limited to the southwestern US and are not found in Iowa (Hijmans and Spooner, 2001). Therefore, there is no possibility of gene flow to any sexually-compatible wild relatives.

- The proposed field trial will be managed in a manner consistent with the production of potato tubers. To ensure reproductive confinement, the applicant will maintain a 1 mile separation distance to other cultivated potato plants. The applicant will also employ a 50 foot fallow buffer zone to prevent commingling of GE potato propagules with other crops. During the course of the field release, the regulated field site will be inspected weekly. Therefore, gene flow to non-regulated potato, or commingling of propagules with other crops, is extremely unlikely. Furthermore, cultivated potato is vegetatively propagated. In the unlikely event of gene flow to another potato plant, the resulting seed would not be harvested or further propagated.

- Final trial destruction (termination) will be accomplished by harvesting all tubers and disking any remaining vegetative material into the soil.

- Following termination of the field trial, the applicant will monitor the field release site and the 50 foot buffer zone for volunteer potato monthly for 2 years. The field site will be treated quarterly with glyphosate. All encountered volunteers will be destroyed by digging them up, burning them on site and then burying the residue on site. If volunteers are encountered in the final 6 months of monitoring prior to the first frost, then monitoring will be continued for an additional year. No food or feed crops will be produced on this site throughout the duration of post-harvest monitoring period.

- The applicant has submitted a training program and standard operating procedures (SOPs) which will be enforced through permit conditions to ensure that procedures are carried out in a manner to prevent escape or commingling of the regulated article with other non-regulated material and that appropriate records

are kept and required reports are submitted. All field operations personnel are trained related to their specific job responsibilities according to the SOPs. No field equipment that would retain reproductive tissues will be used. All equipment will be cleaned and inspected by APHIS prior to leaving the field test site. Facilities, vehicles, and containers used to store or transport the tubers will be cleaned before return to general use, or destroyed.

- The distribution of the regulated article will occur only between the personnel mentioned in the permit application as approved by APHIS. All regulated potato materials mentioned in the application are only for experimental purposes and no sale of the material produced or transported while under the permit will occur.

4. There is 1 fish, the Topeka shiner (*Notropis Topeka)* and 2 plant species, Prairie bush-clover (*Lespedeza leptostachya*) and Western Prairie Fringed Orchid (*Platanthera praeclara*) that are listed as threatened or endangered. There is 1 mammal, the northern long-eared Bat (*Myotis septentrionalis*), that is listed as proposed endangered in Calhoun County, Iowa. (http://ecos.fws.gov/tess_public/countySearch!speciesByCountyReport.action?fips=19025, accessed 01/27/2015). Of the species listed as threatened or endangered, only the Topeka Shiner has designated critical habitat within Calhoun County; however none of this critical habitat is located in Greenfield Township where the proposed field release will occur. The closest critical habitat is more than 5 miles from the proposed release site. The ranges and feeding habits of the listed species in Calhoun County, Iowa, are not known to overlap with the proposed field release site described in this permit. The proposed release site is on managed agricultural land, and the action area of the release site is not located within designated critical habitat or habitat proposed for designation for any of the listed species.

5. APHIS BRS's analysis of the location of the proposed field trial indicates that it is occurring on agricultural land, indicating that there is no change in land usage. Potato is not sexually compatible with any other listed or proposed threatened or endangered species, and the genetic constructs do not result in the production, or increase the production, of a toxin, natural toxicant, allelochemical, pheromone, hormone, etc. that could directly or indirectly result in killing or interfering with the normal growth, development, or behavior of a federally listed threatened or endangered species or species proposed for listing. Therefore, movement and release under this permit will have no effect on federally listed threatened or endangered species, species proposed for listing, designated critical habitat, or habitat proposed for designation.

6. The only impacts from the proposed release are related to typical agricultural production practices. The proposed environmental release is at a single location of limited acreage in Calhoun County, Iowa for one year. The proposed field site has been managed for row crop production for over 20 years. The small experimental plot size and the short duration of the proposed trial are not expected to

significantly alter the agro ecosystem of the release area. The only past, present, and reasonably foreseeable actions associated with the location for the proposed release are those related to agricultural production. APHIS does not expect there to be a change in the baseline in the type or magnitude of effects related to agricultural production as a result of the proposed field release. APHIS has determined that the incremental impact of the proposed action will not aggregate with effects from past, present, or reasonably foreseeable actions to create cumulative impacts or reduce the long-term productivity or sustainability of any of the resources (soil, water, ecosystem quality, biodiversity, etc.) associated with the release site or the ecosystem in which it is situated. No resources will be significantly impacted due to cumulative impacts resulting from the proposed action.

For the above reasons, and those documented on the NEPA/ESA decision worksheet, APHIS has determined that this permit involves a confined field trial of genetically engineered organisms or products that do not involve a new species or organism or novel modification that raises new issues. Issuance of this permit qualifies for categorical exclusion status under 7 CFR § 372.5(c)(3)(ii), and none of the exceptions for categorically excluded actions under 7 CFR § 372.5(d) apply to this action because APHIS has determined that all environmental impacts resulting from the issuance of this permit will be insignificant. APHIS has determined that this action does not have the potential to significantly affect the quality of the human environment, and neither an environmental assessment nor an environmental impact statement is required.

References

Hijmans RJ, Spooner DM (2001) Geographic distribution of wild potato species. American Journal of Botany 88:2102-2112.

Lawson HM (1983) True potato seeds as arable weeds. Potato Research 26:237-246.

McPartlan HC, Dale PJ (1994) An assessment of gene transfer by pollen from field-grown transgenic potatoes to non-transgenic potatoes and related species. Transgenic Research 3:216-225.

Signed: _____/s/_____
Christina Vieglais
Acting Branch Chief, Plant Branch
Biotechnology Regulatory Services

Date: _____01/28/2015
KLR_/s/_