NEPA Decision Summary for Permit #11-074-103rm

Planet Biotechnology Inc. has requested a permit for a small-scale confined field release of genetically engineered tobacco (*Nicotiana tabacum*) at a site in Fayette County, Kentucky.

Based on a review of Permit **#11-074-103rm**, the following determinations were made:

1. The gene constructs proposed for the confined field release are expected to result in the production of an immunoadhesin against protective antigen of *Bacillus anthracis*, an antibody against botulinum neurotoxin, or an immunoadhesin against human major group rhinoviruses in tobacco. The gene constructs contains regulatory sequences derived from plant pests. The genes encoding the recombinant proteins do not have any inherent plant pest characteristics and are not likely to pose a plant pest risk.

2. Based on the method of transformation, disarmed *Agrobacterium*-mediated transformation, only the genetic constructs that are designed to be expressed in the genetically engineered tobacco lines are expected to be efficiently inserted into the tobacco genome. No plant pests are expected to be associated with the transformed tobacco lines as a result of the transformation process.

3. Over fifty field trials have been performed with transgenic tobacco plants under APHIS authority, and APHIS is familiar with tobacco biology and methods to manage confined tobacco field trials. Of these releases, at least 14 have been for the production of pharmaceuticals. An EA was prepared and a FONSI published for tobacco producing an antibody against dental caries in response to permit 05-354-03r submitted by Planet Biotechnologies, Inc. The date of the FONSI is 2/4/2008**.**

4. Fertile *Nicotiana tabacum* plants will be topped prior to pollen production to assure that no pollen or seed is produced. *Nicotiana tabacum* hybrids are expected to be male sterile and produce no pollen. Plants from these hybrids will be allowed flower and monitored daily for the production of pollen. Thus, gene flow to any compatible species including commercial tobacco is highly unlikely.

5. This field release is intended to provide measurements of product accumulation in the roots, stems and leaves of the regulated articles. The products are several different recombinant proteins encoded by genes that have been genetically engineered into *Nicotiana tabacum* Cultivar Wisconsin 38 and sterile *Nicotiana tabacum* hybrids.

6. The proposed field site is located in Kentucky in Fayette County. The distance between the field site will be at least, ¼ mile to commercial (non-research) tobacco crop, ½ mile to flowering research tobacco and 1 mile to commercial tobacco used for seed production. Tobacco between the 1,320 feet and 2,640 feet distance will be topped and will not be used for seed production. The field site is surrounded by a fifty-foot wide fallow zone. This distance is sufficient to reduce outcrossing to insignificant levels even if flowering were to occur.

7. Plant debris, not containing seeds, will be devitalized by incorporation into the soil. Seed will be devitalized using heat. The field will be monitored for volunteers monthly for 12 months following planting. All volunteer tobacco plants found will be removed manually or using an appropriate herbicide.

8. According to the Fish and Wildlife Service http://ecos.fws.gov/tess_public/countySearch!speciesByCountyReport.action?fips=21067 Accessed on April 11, 2001). One flowering plant and one mammal were listed or proposed threatened and endangered species in the Fayette County, KY. The animal is not known to forage on tobacco or live in agricultural fields and the plant does not cross with tobacco. There is no critical habitat in Fayette County, KY where the field site is listed (http://crithab.fws.gov/, accessed 4/11/2011). The only animal known to forage on tobacco is skunk. Most of the farm is fenced and the entrances are gated. These gates are locked during non-work hours. The only known animal that forages on tobacco is skunk. Due to the presence of nicotine in the tobacco plant, few organisms consume tobacco. In the unlikely event of accidental consumption, the pharmaceutical proteins produced during this field trial are non-toxic and are not expected to harm animals feeding on these plants. Therefore, these field trials should have no effect on threatened or endangered species.

9. Any plant material left after harvest, containing only insignificant amounts of the proteins, will be plowed under the soil surface. The proteins have no known or foreseeable toxic effects, so this method of disposal should have no negative impacts on the environment.

10. The gene products proposed for these field trials do not have characteristics of known toxins or allergens. No foreseeable effects on other organisms are expected.

11. The proposed field trial is 2.5 acres. Trials of such size are easily monitored and will be confined to permitted areas, under environmental mitigation measures similar to those specified in the permit application and in the standard and supplemental permit conditions.

12. Tobacco is not observed to be capable of establishment in unmanaged environments: it is reliant on continuous human intervention for its survival. In previous field tests and applications, seed dormancy in tobacco has not been observed. Furthermore, flowers will be removed to eliminate seed production.

13. There are no sexually-compatible relatives of tobacco known to exist in the area where the trial will be performed.

14. Regulated materials in this field trial are not intended for food and/or feed. Any use of these products for food or feed must be in compliance with the guidelines published in the Federal Register by the United States Food and Drug Administration [57 FR 22984, May 29, 1992].

For the above reasons, and those documented on the NEPA-ESA decision worksheet, APHIS has determined that permit application **11-074-103rm** involves a confined field trial of genetically engineered organisms or products that do NOT involve a new species or organism or novel modifications that raise new issues. APHIS has determined that the actions authorized under this permit do NOT have the potential to significantly affect the quality of the human environment. Therefore, approval of this permit is properly categorically excluded from the need to prepare an EA (or EIS) pursuant to 7 CFR 372.5., and none of the exceptions to this categorical exclusion apply.