

NEPA Decision Summary for Permit #10-182-103r

Dr. Kristi Snell, the Director of Plant Sciences for Metabolix, Inc., has requested a permit for a small confined field release of genetically engineered *Camelina sativa* (Camelina, Gold-of-Pleasure False Flax) plants at a site in Tom Green County, Texas.

Camelina has been approved on multiple occasions for the field release of genetically engineered plants (08-154-102r, 08-293-101r, 07-352-103r, and 07-256-101r) and the current proposed field release does not raise any new issues. The exact same phenotype/genotype combinations were approved for an earlier filed release (09-317-105r)

Based on a review of Permit #10-182-103r, the following determinations were made:

1. The gene constructs proposed for the confined field release are expected to result in Camelina that produces poly-beta-hydroxybutyrate (PHB), a biodegradable polymer that can be produced through the expression of bacterial genes. The construct consists of several bacterially derived genes involved directly or indirectly in the synthesis or modification of PHB that are claimed as Confidential Business Information (CBI). The inserted genetic constructs also include genes that encode products involved in the regulation of the expression of the PHB and those that encode the production of a common visual marker, presumably for the purposes of tracking gene expression. The applicant is also applying to release plants containing a construct with only the visual marker. Gene and regulatory sequences are derived from a variety of donor organisms including plant and mammalian viruses, animals, fungi, bacteria, and plants. The constructs were introduced using disarmed *Agrobacterium* transformation. Constructs containing similar genes have been approved previously from this and other applicants and the marker gene has also been approved previously on multiple occasions and in multiple plant species. None of the genes encoding the desired traits or the selectable marker, nor the regulatory elements controlling their expression, have any inherent plant pest characteristics, and they are not likely to pose a plant pest risk.

2. Using disarmed *Agrobacterium tumefaciens* for the purpose of plant transformation, it is expected that only the genetic construct that is designed to be expressed in the genetically engineered Camelina plant lines is stably inserted into the Camelina genome. No plant pest vectors are expected to be associated with the transformed Camelina lines as a result of the transformation process.

3. The intent of this field release is to produce plant materials containing PHB as part of a pilot study and to study the agronomic properties of the various Camelina lines. Seeds from this field trial will either be collected for destructive analysis or destroyed directly. All plant material produced in this field study will be destroyed with the exception of small lots of seeds to be kept for additional planting which has yet to be determined and would not be authorized under this permit.

4. PHB is a biopolymer which is present in all living organisms (Das, et al., 2002. *Biochemistry*, 41:5307-5312). PHB is biodegradable (Kim and Rhee, 2003. *Applied Microbiology and Biotechnology* 61:300-308; Jendrossek and Handrick, 2002. *Annual Review of Microbiology*, 56:403-432). PHB is considered non-toxic and not found to have genotoxicity (Ali, et al., 2008 *Toxicology in Vitro*, 22:57-67). While Camelina is not considered a toxic plant, it is not typically grown for feed and food purposes and does not have any established pest species that feed on the plants or diseases within the United States. The applicant will monitor the plants for the presence of both vertebrate and invertebrate pests.

5. Both the applicant and BRS staff are familiar with Camelina biology and ecology. However, being a new and lesser known crop, there is less information about the gene flow potential of Camelina compared to more commonly grown crop species. Camelina generally sets seed via self-pollination, yet it can outcross based on the type and frequency of insect visitation. The AOSCA isolation distance established for the production of foundation seed of Camelina is only 50 ft. There is a minimal likelihood of gene flow to surrounding plants for several reasons. *Camelina sativa* is not listed as a noxious weed in the states where the field trials will take place. It is not found on the Federal Noxious Weed List (<http://www.aphis.usda.gov/ppq/weeds/weedlist2006.pdf>). There are four wild species/subspecies of *Camelina* (*C. microcarpa*, *C. rumelica*, *C. sativa* ssp. *sativa*, *C. sativa* ssp. *alyssum*) distributed across the United States (<http://plants.usda.gov/>). The field release is going to take place in Tom Green County, Texas where no sexually compatible relatives of camelina are known to exist. Additionally, the field cooperators at the release site will scout around the release site and remove any plants found within 300 meters. The applicant has confirmed that there are no commercial fields of Camelina within 10 miles. The field site is approximately five miles from any commercial beehives. The entire planted area and surrounding area will be monitored for volunteer plants once per month for a period of two years or until three consecutive months of no volunteer plants are observed during conditions that favor germination and growth. Any volunteer plants found will be destroyed by cultivation or herbicide treatment before flowering. The confinement measures described in the application and supplemental permit conditions are sufficient to prevent any unplanned releases of the transgenic plant material or transgenic seed; or the persistence of the transgenic material or its progeny in the environment.

6. There is designated critical habitat for a Threatened or Endangered Species (TES) within Tom Green County, Texas for the Concho Water Snake (*Nerodia paucimaculata*) (<http://criticalhabitat.fws.gov/> - crithab portal accessed 8/26/10) which has also been proposed for delisting (<http://ecos.fws.gov/speciesProfile/profile/speciesProfile.action?spscode=C04E>). The Critical Habitat within Tom Green County is along/including the portion of the Concho River that exits the county to the northwest and is more than 10 miles from the release location. Therefore there is no effect associated with designated critical habitat that could result from this release.

All other TES species within Tom Green County are birds except one plant. (http://ecos.fws.gov/tess_public/countySearch!speciesByCountyReport.action?fips=48451)

There is no reason for an interaction of the camelina release location with any TES bird species. None of the TES bird species in the county are known or expected to feed on Camelina seed, and there is no toxicity associated with the camelina plants or seed, so there will be no impacts associated with direct or indirect feeding on the camelina plants in the unlikely event that such were to occur.

The TES plant is the endangered slender rush-pea (*Hoffmannseggia tenella*), which is not sexually compatible with camelina (belonging to a completely different plant family). According to the 50 Federal Register 45615, the rush-pea is found interspersed with native grasses or on hard clay soil of creek banks. It is a component of disturbed prairie. The most serious threat to the plant is habitat alteration. No critical habitat has been designated because of take concerns (collectors). As the proposed field trial of camelina is a confined field release that does not involved the introduction of an invasive grass species or uncontrolled release of any material for that matter, and as there will be no change in land usage associated with the approval or implementation of the pending permit, it is determined that there will be no effect on the slender rush-pea.

APHIS' analysis of the location of the proposed field trial indicates that it is occurring on an agricultural land, so there is no change in land usage. Furthermore, Camelina is not sexually compatible with any 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 TES species or species proposed for listing. It is determined that there will be no effect on any species resulting from the proposed field release trial of Camelina.

7. Regulated materials in this field trial are not intended for, nor will they be used 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. In addition to the confinement measures described above, there will be no mixing of regulated plant material with other food, feed, or seed as a result of the trial. After the trial, any GE material left in the field will be destroyed by herbicide application or harvest and burning. The applicant has protocols in place for the identification and cleaning of the equipment that will be used. The applicant has provided documentation that demonstrates that all handlers of regulated material will be given training, and there are Standard Operating Procedures in place for the use and cleaning of equipment on regulated material (see attached Checklist for APHIS Review and Approval or SOPs submitted with Industrial Permits – 10-182-103r_psc.doc). Post-harvest planting restrictions will prevent mixing of transgenic Camelina with food or feed crops following harvest of the crop.

8. The distribution of the regulated article will occur only between personnel mentioned in the permit application and approved by APHIS. All regulated *Camelina* materials mentioned in the application are only for experimental purposes and no sale of the materials will occur.

9. The small experimental plot and the short duration of the proposed trial are not expected to significantly alter the agroecosystem 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 document, 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 state is required.

Signed: smk /s/ _____
Susan Koehler
Branch Chief, Plants
Biotechnology Regulatory Services

Date: _____ 8/31/10
JS _____/s/ _____