NEPA Decision Summary for Permit #11-036-101r

Professor Thomas Clemente of the University of Nebraska at Lincoln has requested a permit for a small confined field release of up to 0.5 acres of genetically engineered *Camelina sativa* (Camelina, Gold-of-Pleasure False Flax) plants at a site in Lincoln County, Nebraska for a year or less. Camelina has been approved on multiple occasions for the field release of genetically engineered plants and the current proposed field release does not raise any new issues.

Based on a review of Permit #11-036-101r, the following determinations were made:

1. The genetic constructs proposed for the confined field release are expected to result in Camelina with two different phenotypes, those that produce wax esters in their seeds and those that have high oleic acid oil in their seeds. These genetic constructs are derived from other plant species. Two constructs contain a beta-ketoacyl-CoA synthase gene from either *Simmondia chinensis* (common name, jojoba) or from *Lunaria annua* cv. *Alba* (common name, Lunaria) and genes for fatty acyl-CoA reductase and wax synthase, both from *S. chinensis,* that are designed to result in the production of C20, C22, and C24 long chain fatty acids and fatty alchohols, and their wax esters, respectively. The production of wax esters in transgenic plants by expression of these genes from these plants has been previously described (Lassner et al. 1999). A third construct includes portions of the *Arabidopsis thaliana* delta 12 desaturase and fatty acid elongase genes in sense and antisense orientations, along with an intron, that are designed to silence similar endogenous genes and result in higher levels of oleic acid. These genes are under the control of regulatory regions (promoters and terminators) of seed storage protein genes from other plant species that have been demonstrated to drive seed-specific expression. The inserted genetic constructs also include genes that encode the production of a common visual marker, a common herbicide resistance marker for selection, and genetic components that regulate the expression of these genes. The marker genes and regulatory sequences are derived from a variety of donor organisms including bacteria, marine invertebrate, and plant virus (non-coding plant virus regulatory sequences only). The constructs were introduced using disarmed *Agrobacterium* transformation. 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 Camelina with wax esters and high oleic oils produced in the seeds. The applicant has indicated that the intent of synthesis of the wax esters is for an industrial application of biolubricant production. Seeds from this field trial will either be collected for destructive analysis or destroyed directly.

4. The wax esters expected to be produced as a result of the inserted genetic material are expected to be similar to those produced by the jojoba plant. While jojoba seeds are considered toxic when consumed as a sole source of food (due to simmondsins, Booth et al 1974), the source of the toxicity is not derived from the seed oil or wax esters. The wax esters are not digestable, and while this may cause some adverse reactions if consumed, they are not considered toxic. (see MSDS - http://www.purcelljojoba.com/JojobaTechInfo/JojobaDataSheets/JojobaOilMsds.aspx and EPA Fact Sheet - http://www.epa.gov/oppbppd1/biopesticides/ingredients/factsheets/factsheet_067200.htm - accessed 3/10/2011). While Camelina is not considered a toxic plant, it is not typically grown for feed and food purposes (see http://www.hort.purdue.edu/newcrop/ncnu07/pdfs/pilgeram129-131.pdf, Accessed 3/10/2011) and does not have any established pest species that feed on the plants or novel diseases within the United States.

5. Both the applicant and BRS staff are familiar with Camelina biology and ecology. The invasion potential and competitive ability of *Camelina sativa* in rangeland ecosystems is the subject of a recent dissertation (P. B. Davis, 2010) and a Plant Biology Document is under preparation by the Canadian Food Inspection Agency (2011). 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. 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/). As summarized by CFIA (2011), there is potential for crossing, and therefore gene introgression, from *C. sativa* into its congeners. *Camelina sativa* and *C. alyssum* (as *C. macrocarpa*) have been reported as completely interfertile (Tedin 1922). Recent experimental crosses performed by Séguin-Swartz et al. (2010) confirmed Tedin's report as well as demonstrated the ability of *C. sativa* and *C. microcarpa* to successfully hybridize. The transfer of genetic information from *C. sativa* into the fourth North American *Camelina* species, *C. rumelica*, is highly unlikely as seed obtained from experimental crosses between the progeny of *C. sativa* and *C. rumelica* was mostly shrivelled and non-viable (Séguin-Swartz et al. 2010). No information was found to suggest that several other species within the Camelinaeae tribe (*Arabidopsis lyrata, A. thaliana, Capsella bursa-pastoris, Ersimum* spp., *Neslia paniculata* and *Turritis glabra*) are capable of crossing with *C. sativa*, and several crosses between *C. sativa* and several *Brassica* spp. (*B. juncea, B. nigra, B. napus, B. rapa*, members of the Brassicaceae family outside of the Camelineae tribe) were unsuccessful (Table 1 in CFIA 2011). *Camelina sativa* is not listed as a noxious weed in the state where the field trials will take place. It is not found on the Federal Noxious Weed List (http://plants.usda.gov/java/noxiousDriver, Accessed 3/11/2011)). The field release is going to take place in Lincoln County, Nebraska where sexually compatible relatives of Camelina may exist (http://plants.usda.gov/java/profile?symbol=CAMEL, Accessed 3/11/2011). Documentation exists for *C. microcarpa* in Lincoln County, and for *C. sativa*

and *C. sativa* ssp. *sativa* in a neighboring county. The applicant has field tested Camelina before at this location.

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. The field cooperator at the release site will scout around the release site and remove any plants of *Camelina* species or subspecies found within 300 meters. The applicant has confirmed that there are no commercial fields of Camelina within at least a mile. The field site is at least 1320 feet from any commercial beehives. The entire planted area and surrounding area will be monitored for volunteer plants once per month for a year and then every other month for another year. Based on reported dormancy, germination, and maturation characteristics (summarized in CFIA 2011), this frequency and duration of monitoring should be sufficient to devitalize volunteers from seedlings before they can flower or set mature seed. Although some of the transgenic Camelina are engineered for resistance to glufosinate herbicide, other herbicides can be used to control Camelina (CFIA 2011). Any volunteer plants found will be destroyed. 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 no designated critical habitat for a Threatened or Endangered Species (TES) within Lincoln County, Nebraska according to the Fish and Wildlife Critical Habitat portal (http://criticalhabitat.fws.gov/ - accessed 3/07/11).
According to the FWS field office that covers the state of Nebraska (http://www.fws.gov/mountain-prairie/endspp/countylists/nebraska.pdf, accessed 3/10/2011) there are 8 threatened or endangered species listed in the county of Lincoln, Nebraska. This includes two mammals (black-footed ferret and gray wolf), three birds (Interior least tern, Piping plover, and Whooping crane), and an insect (American burying beetle) none of which are known or likely to feed on Camelina, nor to be typically found on agricultural crop land. Although the Whooping crane can use agricultural land as habitat, it usually includes habitat with wetlands, and Camelina is not indicated as a food. Furthermore, the genetic constructs in the transgenic Camelina 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 associated with direct or indirect feeding on the Camelina plants in the unlikely event that such were to occur. The two plant species are *Penstemon hydenii* and *Platanthera praeclara*, and they are not sexually compatible with Camelina, nor is it likely that these plants would be found on the land proposed for release, as they show a strong preference for other habitats. (NatureServe accounts were examined for all species except the *Penstemon haydenii* plant, in which case the US FWS species profile was examined: http://ecos.fws.gov/speciesProfile/profile/speciesProfile.action?spcode=Q2EX.) All land proposed for use to grow regulated Camelina have been in agricultural use for many years and there will be no substantial change in land usage, nor in the agricultural

practices that occur at the release site location. Therefore, the proposed release will have no effect on any TES species.

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 – 11-036-101r_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.

References:

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Lassner, M.W, Lardizabal, K., Metz, J.G. 1999. Producing wax esters in transgenic plants by expression of genes derived from jojoba. In: *Perspectives on New Crops and New Uses.* J. Janick (ed.), ASHS Press, Alexandria, VA. pp.220-224.

Signed: _ _____
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