

NEPA Decision Summary

Based on a review of Permit 08-058-105r, the following determinations were made:

- Over fifty field trials have been performed with transgenic barley plants under APHIS authority, and APHIS is familiar with barley biology and methods to manage confined barley field trials.
- Barley is 99% self-pollinated, and is not generally pollinated by insects. Association of Official Seed Certifying Agencies (AOSCA) isolation distances for certification of foundation, registered or certified nonhybrid barley seed is zero feet. Therefore a 50 foot fallow zone and a distance of 600 feet from any other barley as proposed by the applicant should be more than adequate to prevent unintended release of the transgenic barley into adjacent fields. This distance is sufficient to reduce outcrossing to insignificant levels.
- The permittee will also impose a temporal isolation of 10 days between the barley in this permit and any other barley in the area of the field test further insuring no outcrossing with any neighboring barley.
- Barley does not hybridize with any other species growing in the United States. Therefore there is no risk of gene flow to wild and weedy species.
- Human lactoferrin and lysozyme are abundant proteins in saliva and human milk. They have no known toxic effects. Bovine lactoferrin and egg white lysozyme have been granted GRAS status by the FDA.
- The transgenic barley will be planted and seeds harvested by hand. Therefore there is no chance that seeds will be dispersed via mechanical equipment. Harvested seeds will be threshed and processed inside a designated laboratory using a small dedicated laboratory thresher. Therefore, viable seeds will not have the potential to be dispersed into the area outside of the test site during processing.
- The processing area for this barley is kept separate from any other barley processing activities.
- The size of the proposed field test is very small, only 0.90 acres. Consequently environmental exposure will be negligible. Trials of such small size are and have been easily monitored and confined to permitted areas, under environmental mitigation measures similar to those specified in the permit application and in the standard and supplemental permit conditions.
- Seed dormancy has not been demonstrated with this barley cultivar; therefore, emergence of volunteers will be limited to the following season.

- Cultivated barley does not have the ability to establish itself permanently in natural plant communities. Any accidental movement of seeds will not result in plants from this test becoming established outside of the field test area.
- 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 (See EAs prepared for Ventria rice plantings containing lysozyme and lactoferrin - permits 05-117-02r, 06-278-01, 05-117-01r and 06-285-02r.).
- There are two TES plant species listed in Whitman County <http://www.fws.gov/easternwashington/documents/Whitman%20Cty%204-15-08.pdf> and there is critical habitat listed for Steelhead trout in the county <http://criticalhabitat.fws.gov/> (accessed 11/10/08). There are two plants: *Silene spaldingii* (Spalding's campion) and *Spiranthes diluvialis* (Ute ladies' tresses). Neither of these plants are sexually compatible with barley. Spalding's campion is restricted to Palouse Prairies, sometimes extending into areas where the grasslands are intermingled with ponderosa pine (*Pinus ponderosa*) woodlands. The Ute ladies' tresses orchid occurs along riparian edges, gravel bars, old oxbows, high flow channels, and moist to wet meadows along perennial streams. It typically occurs in stable wetland and seepy areas associated with old landscape features within historical floodplains of major rivers, as well as in wetlands and seeps near freshwater lakes or springs. Neither plant would find the area of the field test as suitable habitat. The critical habitat for the Steelhead trout is found in the Snake River basin which is over 11 miles away from the test site. No federally listed threatened or endangered species or species proposed for listing are likely to be found at the release site. The habitat is either not suitable or does not contain constituent elements required by the species. Field activities will result in no changes to the habitat used by any listed species. The site is not within or near designated critical habitat or habitat proposed for designation. Therefore, the action will have no effect on listed species or species proposed for listing and would not affect designated critical habitat or habitat proposed for designation.
- 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 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 affect significantly the quality of the human environment, and neither an environmental assessment nor an environmental impact statement is required.

Signed: _____/s/ _____

Michael Watson

Director of Regulatory Programs (acting)

Date: ____12-7-08_____