NEPA Decision Summary for Permit #10-047-102r

The National Environmental Policy Act of 1969 (NEPA) is the mandate of any federal agency or department for the protection of the environment. NEPA requires all federal agencies to consider the values of environmental preservation for all significant actions and prescribes procedural measures to ensure that those values are in fact fully respected.

The Council on Environmental Quality (CEQ) developed the categorical exclusion process to reduce the amount of unnecessary paperwork and delay associated with NEPA compliance.

The categorically excluded actions for APHIS Biotechnology Regulatory Service (BRS) processes are listed in 7 CFR 372.5(c)(2)(ii):

> "Permitting, or acknowledgment of notifications for, confined field releases of genetically engineered organisms and products"

However, the CEQ acknowledged that, from time to time, exceptions to a categorical exclusion may arise. As a result, the CEQ requires all agencies to develop procedures to determine whether a normally excluded action may have a significant environmental effect. Exceptions to categorically excluded actions for APHIS BRS are determined by the following criteria found in 7 CFR 372.5(d)(4):

> "When a confined field release of genetically engineered organisms or products involves new species or organisms or novel modifications that raise new issues."

Washington State University has requested a permit to plant up to 1 acre of genetically engineered barley in one site in Whitman County, Washington (WA). The genes inserted to produce lysozyme and lactoferrin to be isolated from the GE grain for further study.

APHIS BRS has reviewed the permit application and has set permit conditions for the activities to be authorized under this permit. These conditions can be found in the e-permits file associated with this application. APHIS BRS has concluded that issuing Permit number 10-047-102r is categorically excluded action under section 7 CFR 372.5(c)(ii) because it is a confined field release of genetically engineered organisms.

An EA was prepared for barley permit 93-320-01r. EAs were prepared for lysozyme in rice for permit 05-117-02r and for lactoferrin in rice for permit 05-117-01r. There are FDA GRAS (Generally Recognized As Safe) notices for bovine lactoferrin (GRN 000077) and for egg white lysozyme (GRN 000064). The prior EAs produced by USDA APHIS are still applicable to both the crop (barley) and genes (lactoferrin and lysozyme).

The field release is confined for the following reasons:

1) The proposed field release site is for up to 1 acre, in one location(s). There will be 1 planting. The small experimental plot with limited plant numbers decrease the pollination potential (pollen pool) of the field site to other plants not involved in the study. Studies have suggested large field sites and therefore, large pollen pools increase the potential for pollination and gene escape.[1]
2) The experimental plot will be planted in Whitman County, WA. There will be no commercial barley production plants within 600 feet of the experimental plots and sexually compatible wild relatives do not exist in the area. A 50 ft fallow zone will also be around the release site. This prevents escape of the genetic traits via pollination.
3) Seed dormancy has not been demonstrated with this barley cultivar; therefore, emergence of volunteers will be limited to the following season. Short dormancy ensures that rogue volunteer plants will not appear after the experiment has terminated and the volunteer monitoring period has ended.
4) Waste or plant material generated by sample processing or handling will be destroyed by tilling or herbicide application. Destruction prevents inadvertent plant material escape.
5) The regulated area will be monitored monthly for a year after termination of the trial. If regrowth is found, it will be destroyed immediately. Should regrowth be found during the last monitoring month (month 12) of the year, monitoring will continue and APHIS BRS Compliance will be notified.

APHIS has determined that the exception for categorically excluded actions (7 CFR 372.5(d)(4)) Do not apply to this action for the following reasons:

1) This GE barley is not a new species to APHIS. 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.
2) The introduced traits do not raise new issues because lysozyme and lactoferrin are ubiquitous in nature and part of human and animal diet.
3) APHIS BRS has issued prior permits for GE barley with lysozyme and lactoferrin and have found no significant impacts to the human environment.

In addition to determining that the field trial is confined and that the exclusions do not apply to this action, APHIS has also concluded that there are unlikely to be any significant impacts from the authorization of this field trial because:

1) The field release is limited in time and space. The plants will be in the field for less than one year in an area equal to or less than 1 acre.
2) The genes do not code for toxins or any other substance that is likely to harm any animals or humans that may encounter the plants. 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.

[1] USDA APHIS (2004). Workshop on the Confinement of Genetically Engineered Crops during Field Testing, September 13-15, 2004. Washington, D.C.

3) The GE plants do not encode any substances that will persist in the soil, water or air. Most of the genes alter the expression levels of naturally occurring compounds. The marker gene codes for a protein that will degrade in the environment like other proteins native to the plant.
4) The genetically engineered GE barley will not be used for food or feed.
5) 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.
6) 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.

APHIS analyzed the potential for effects to federally-listed threatened or endangered species and their critical habitat. Based on the analysis below APHIS has determined that there is no effect to any of these species or that the activities authorized in this permit would result in the alteration of any designated critical habitat.

Applicant and APHIS searched the US FWS web site (http://crithab.fws.gov) and relevant Federal Register Notices relating to listed endangered and threatened species. The release site and action area are not within designated critical habitat for a listed threatened or endangered species or within habitat proposed for designation. None of these animals are traditionally found in or around GE barley or use GE barley as a primary food source.

This GE barley field trial will occur on land that has been cultivated for agricultural purposes for over 50 years and therefore will not eliminate habitat that may contain a threatened, endangered or candidate species.

Signed: _____/s/_____
John M. Cordts, M.S.
Chief, Plant Pests and Protectants Branch
Environmental Risk Analysis Division
Biotechnology Regulatory Services

Date: ____3/10/10_____