

Worksheet for Determining Whether Field Trials are Categorically Excluded from NEPA

Permit #	04-090-01r
Institution	Applied PhytoGenetics
Organism	Eastern Cottonwood trees
Category	phytoremediation
Transgene	organomercury lyase
1. Confinement	
Confinement and mitigation conditions have been reviewed and determined to be adequate	X
2. Threatened or Endangered Species or its habitat	
Resident or migratory in counties and harm to threatened or endangered species or habitat is likely	
Resident or migratory in counties and harm to threatened or endangered species is unlikely	X
None observed in area (no harm to threatened and endangered species)	
New or Novel	
3. New or Novel Crop	
Never used in a field trial	
Not new but no prior EA	X
Not new and prior EA	
4. New or Novel Trait (gene product)	
Never used in a field trial	
Not new but no prior EA	X
Not new and prior EA	
5. Cumulative Effects	
Cumulative effects likely	
Cumulative effects possible	
Cumulative effects unlikely	X
6. Plant Pollination	
Primarily bee or insect pollinated crop	
Primarily wind pollinated food or feed crop	
Primarily self fertilized food or feed crop	
Non-food or feed crop	X
7. Effects on Food/Feed Supply	
Known allergen, antinutritive, oral toxicant	
Food safety not established	X
GRAS status or approved food additive for native protein	
GRAS status or approved food additive for plant produced protein	
8. Isolation Distance	
AOSCA standard for crop	None
Proposed isolation distance	*see comment below
9. Scale	
>100 acres/trait/crop/company/year	
50-99 acres/trait/crop/company/year	
10-49 acres/trait/crop/company/year	
<10 acres/trait/crop/company/year	X
10. Effects (positive or negative) on other species	
Significant effects expected/observed	
Minimal, non-cumulative effects expected/observed	
No effects expected/observed	X
11. Sexually Compatible Relatives	
Relatives within dispersal distance	X*
Relatives not within dispersal distance	
12. Seed Dormancy	
>3 years	
3 years	
2 years	
<2 years	X
13. Persistence in environment	
Crop can naturalize	X
Crop can persist 3-5 years without human intervention	
Crop does not persist without intervention	
14. Comments	
*Eastern cottonwood trees used in trial will not be allowed to flower therefore there will be no pollen shed and no seeds formed.	

Worksheet for Determining Whether Field Trials are Categorically Excluded from NEPA

Permit #	04-090-01r
Institution	Applied Phylogenetics
Organism	Eastern Cottonwood trees
Category	phytoremediation
Transgene	mercuric ion reductase
1. Confinement	
Confinement and mitigation conditions have been reviewed and determined to be adequate	X
2. Threatened or Endangered Species or its habitat	
Resident or migratory in counties and harm to threatened or endangered species or habitat is likely	
Resident or migratory in counties and harm to threatened or endangered species is unlikely	X
None observed in area (no harm to threatened and endangered species)	
New or Novel	
3. New or Novel Crop	
Never used in a field trial	
Not new but no prior EA	X
Not new and prior EA	
4. New or Novel Trait (gene product)	
Never used in a field trial	
Not new but no prior EA	X
Not new and prior EA	
Raises new issues	
5. Cumulative Effects	
Cumulative effects likely	
Cumulative effects possible	
Cumulative effects unlikely	X
6. Plant Pollination	
Primarily bee or insect pollinated crop	
Primarily wind pollinated food or feed crop	
Primarily self fertilized food or feed crop	
Non-food or feed crop	X
7. Effects on Food/Feed Supply	
Known allergen, antinutritive, oral toxicant	
Food safety not established	X
GRAS status or approved food additive for native protein	
GRAS status or approved food additive for plant produced protein	
8. Isolation Distance	
AOSCA standard for crop	None
Proposed isolation distance	*see comment below
9. Scale	
>100 acres/trait/crop/company/year	
50-99 acres/trait/crop/company/year	
10-49 acres/trait/crop/company/year	
<10 acres/trait/crop/company/year	X
10. Effects (positive or negative) on other species	
Significant effects expected/observed	
Minimal, non-cumulative effects expected/observed	
No effects expected/observed	X
11. Sexually Compatible Relatives	
Relatives within dispersal distance	X*
Relatives not within dispersal distance	
12. Seed Dormancy	
>3 years	
3 years	
2 years	
<2 years	X
13. Persistence in environment	
Crop can naturalize	X
Crop can persist 3-5 years without human intervention	
Crop does not persist without intervention	
14. Comments	
*Eastern cottonwood trees used in trial will not be allowed to flower therefore there will be no pollen shed and no seeds formed.	

NEPA Decision Summary

Based on a review of Permit 04-090-01r, the following determinations were made:

- The threatened or endangered species known to be present in the counties where these field trials will occur are not known to inhabit or forage on Eastern cottonwood trees and the gene products at issue in the proposed field trials have no known toxic effects on wildlife. Uptake of mercury compounds by these trees at the planting sites could affect organisms that would feed on these trees but three items make this unlikely: 1) Some of the trees have been shown to not accumulate mercury, 2) Site security is in place to minimize the likelihood of site intrusion, and 3) Periodic sampling of the trees for mercury accumulation and reporting to APHIS. If significant mercury is found in trees, additional measures will be imposed to prevent continued exposure of non-target organisms and/or the trial will be terminated. Therefore these field trials will not harm or have adverse or other significant effects on non-target, threatened or endangered species.
- Field trials have been performed with transgenic cottonwood trees under APHIS authority and APHIS is familiar with cottonwood biology and methods to manage confined cottonwood field trials.
- These trees typically do not flower until 4-7 years after planting. Flowering status of these trees will be monitored and these trees will not be allowed to produce viable pollen or seeds. If the trees do mature and show signs of flowering, they will be pruned to remove flowers and/or entire trees will be coppiced (cut at ground level and allowed to sprout from the base of the stumps).
- Because the gene products are expressed at low levels and have no known toxic effects on wildlife, there will be no foreseeable cumulative impacts resulting from multi-year field trials of these transgenic lines. If plant material is found to contain significant levels of mercury, it will be handled appropriately based on EPA requirements.
- The gene products proposed for these field trials have no sequence similarity to any known toxin or allergen and have no demonstrable toxic or allergenic effects. No foreseeable effects on other organisms are expected.
- The proposed field trials are all less than 10 acres. 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.
- Eastern cottonwood is capable of establishment in the wild, however, when the trials are concluded, the trees will be destroyed and not allowed to persist. Disposal will follow APHIS and other possible regulatory requirements (EPA or the individual state) if plants are found to contain significant levels of mercury.

For the above reasons, APHIS has determined that (1) pursuant to 7 C.F.R. §372, the field trials proposed under permit #04-090-01r will not significantly affect the physical environment and (2) there are no applicable, extraordinary, or other reasonably foreseeable circumstances under which significant environmental effects could occur despite the protective and ameliorative measures specified above. Therefore, this field test is deemed confined within the meaning of 7 C.F.R. §372.5.

Signed: _____

Neil E. Hoffman
Director of Regulatory Programs

Date: ____7.19.04_____