Worksheet for Determining Whether Field Trials are Categorically Excluded from NEPA

Permit #	04-040-01r
Company	ProdiGene
Organism	Corn
Transgene	Trypsinogen
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	
Not new and prior EA	X
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	X
Primarily Self fertilized food or feed crop	
Non-food or feed crop	
7. Effects on Food/Feed Supply	
Known allergen, antinutrative, oral toxicant	
food Safety not established	
GRAS status or approved food additive for native protein	X
GRAS status or approved food additive for plant produced protein	
8. Isolation Distance	
AOSCA standard for crop	660 feet
Proposed isolation distance	5280 feet
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	
no relatives within dispersal distance	X
12. Seed Dormancy	
>3 years	
3 years	
2 years	
<2 years	X
13. Persistence in environment	
Crop can naturalize	
Crop can persist 3-5 years without human intervention	
Crop does not persist without intervention	X
14. Comments	

Additional supporting documentation is found in the summary risk assessment completed on 4.06.04

Worksheet for Determining Whether Field Trials are Categorically Excluded from NEPA

Permit #	04-040-01r
Company	ProdiGene
Organism	Corn
Transgene	aprotinin
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	
Not new and prior EA	X
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	X
Primarily Self fertilized food or feed crop	
Non-food or feed crop	
7. Effects on Food/Feed Supply	
Known allergen, antinutrative, 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	660 feet
Proposed isolation distance	5280 feet
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	X
No effects expected/observed	
11. Sexually Compatible Relatives	
relatives within dispersal distance	
no relatives within dispersal distance	X
12. Seed Dormancy	
>3 years	
3 years	
2 years	
<2 years	X
13. Persistence in environment	
Crop can naturalize	
Crop can persist 3-5 years without human intervention	
Crop does not persist without intervention	X
14. Comments	

Additional supporting documentation is found in the summary risk assessment completed on 4.06.04

James White
Branch Chief Risk Assessment
Biotechnology Regulatory Programs
Animal Plant and Health Inspection Service

Worksheet for Determining Whether Field Trials are Categorically Excluded from NEPA

Permit #	04-040-01r
Company	ProdiGene
Organism	Corn
Category	Pharmaceutical Intent-Vaccine
Transgene	5 & 6
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	
Not new and prior EA	X
4. New or Novel Trait (gene product)	
Never used in a field trial	X
Not new but no prior EA	
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	X
Primarily Self fertilized food or feed crop	
Non-food or feed crop	
7. Effects on Food/Feed Supply	
Known allergen, antinutrative, 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	660 feet
Proposed isolation distance	5280 feet
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	
no relatives within dispersal distance	X
12. Seed Dormancy	
>3 years	
3 years	
2 years	
<2 years	X
13. Persistence in environment	
Crop can naturalize	
Crop can persist 3-5 years without human intervention	
Crop does not persist without intervention	X
14. Comments	

Additional supporting documentation is found in the summary risk assessment completed on 4.06.04

Worksheet for Determining Whether Field Trials are Categorically Excluded from NEPA

Permit #	04-040-01r
Company	ProdiGene
Crop	Corn
Category	pharmaceutical intent-vaccine
Transgene	#7
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	
Not new and prior EA	X
4. New or Novel Trait (gene product)	
Never used in a field trial	X
Not new but no prior EA	
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	X
Primarily Self fertilized food or feed crop	
Non-food or feed crop	
7. Effects on Food/Feed Supply	
Known allergen, antinutrative, 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	660 feet
Proposed isolation distance	5280 feet
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	
no relatives within dispersal distance	X
12. Seed Dormancy	
>3 years	
3 years	
2 years	
<2 years	X
13. Persistence in environment	
Crop can naturalize	
Crop can persist 3-5 years without human intervention	
Crop does not persist without intervention	X
14. Comments	

Additional supporting documentation is found in the summary risk assessment completed on 4.06.04

Worksheet for Determining Whether Field Trials are Categorically Excluded from NEPA

Permit #	04-040-01r
Company	ProdiGene
Crop	Corn
Category	pharmaceutical intent
Transgene	#8,9, 10
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	
Not new and prior EA	X
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	X
Primarily Self fertilized food or feed crop	
Non-food or feed crop	
7. Effects on Food/Feed Supply	
Known allergen, antinutrative, oral toxicant	
food Safety not established	
GRAS status or approved food additive for native protein	X
GRAS status or approved food additive for plant produced protein	
8. Isolation Distance	
AOSCA standard for crop	660 feet
Proposed isolation distance	5280 feet
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	
no relatives within dispersal distance	X
12. Seed Dormancy	
>3 years	
3 years	
2 years	
<2 years	X
13. Persistence in environment	
Crop can naturalize	
Crop can persist 3-5 years without human intervention	
Crop does not persist without intervention	X
14. Comments	

Additional supporting documentation is found in the summary risk assessment completed on 4.06.04

Worksheet for Determining Whether Field Trials are Categorically Excluded from NEPA

Permit #	04-040-01r
Company	ProdiGene
Crop	Corn
Category	Value added protein for human consumption
Transgene	brazzein
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	
Not new and prior EA	X
4. New or Novel Trait (gene product)	
Never used in a field trial	X
Not new but no prior EA	
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	X
Primarily Self fertilized food or feed crop	
Non-food or feed crop	
7. Effects on Food/Feed Supply	
Known allergen, antinutrative, 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	660 feet
Proposed isolation distance	5280 feet
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	
no relatives within dispersal distance	X
12. Seed Dormancy	
>3 years	
3 years	
2 years	
<2 years	X
13. Persistence in environment	
Crop can naturalize	
Crop can persist 3-5 years without human intervention	
Crop does not persist without intervention	X
14. Comments	

Additional supporting documentation is found in the summary risk assessment completed on 4.06.04

Worksheet for Determining Whether Field Trials are Categorically Excluded from NEPA

Permit #	04-040-01r
Company	ProdiGene
Crop	Corn
Category	pharmaceutical intent-vaccine (oral swine)
Transgene	transmissible gastroenteritis (TGE) viral protein
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	
Not new and prior EA	X
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	X
Primarily Self fertilized food or feed crop	
Non-food or feed crop	
7. Effects on Food/Feed Supply	
Known allergen, antinutrative, 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	660 feet
Proposed isolation distance	5280 feet
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	
no relatives within dispersal distance	X
12. Seed Dormancy	
>3 years	
3 years	
2 years	
<2 years	X
13. Persistence in environment	
Crop can naturalize	
Crop can persist 3-5 years without human intervention	
Crop does not persist without intervention	X
14. Comments	

Additional supporting documentation is found in the summary risk assessment completed on 4.06.04

NEPA Decision Summary

Based on a review of Permit 04-040-01r, the following determinations were made:

- The only threatened or endangered species known to be present in the county where the field trial will occur, the whooping crane, prefers habitat near a major source of water, and the proposed test site is 15 miles from a major water body. The gene products at issue in the proposed field trials have no known toxic effects on wildlife. In the unlikely event that whooping cranes visit the test site and consume corn seeds, consumption will not harm or have adverse or other significant effects on the cranes.
- Hundreds of field trials have been performed with transgenic corn plants under APHIS authority, and APHIS is familiar with corn biology and methods to manage confined corn field trials.
- Corn is wind pollinated, and is not generally pollinated by bees and several studies have indicated that 660 feet separation distance between corn fields is sufficient to reduce outcrossing to insignificant levels. This is the distance recommended by the Association of Official Seed Certifying Agencies (AOSCA) for the production of the foundation class of certified seed. The applicant proposes separation distances of 5280 feet, eight times the AOSCA distance.
- Almost all of the proteins produced by the transgenes will be concentrated in the seed, and the seed will be removed from the site at harvest. 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.
- The gene products proposed for these field trials have either been granted GRAS status by the FDA and/or they do not have characteristics of known toxins or allergens. No foreseeable effects on other organisms are expected.
- The proposed field trials are all smaller 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.
- Corn is not observed to be capable of establishment in unmanaged environments: it is reliant on continuous human intervention for its survival. In previous field tests and applications, seed dormancy in corn has not been observed.
- There are no sexually-compatible relatives of corn known to exist in the area where the trials will be performed.

For the above reasons, APHIS has determined that (1) pursuant to 7 C.F.R. §372, the field trials proposed under permit #04-040-01r 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 given 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_____