	04.040.04
Permit #	04-040-01r
Company Organism	ProdiGene Corn
Transgene	Trypsinogen
•	ттурыноден
Confinement Confinement and mitigation conditions have been reviewed and determined to be adequate	Х
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 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	I
Not new but no prior EA	Х
Not new and prior EA	
Raises new issues	
5. Cumulative Effects	
Cumulative Effects likely	
Cumulative Effects possible	
Cumulative effects unlikely	Х
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	2006
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	
10. Effects (positive or negative) on other species	X
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	T
3 years	†
2 years	1
<2 years	X
13. Persistence in environment	
Crop can naturalize	
Crop can persist 3-5 years without human intervention	1
Crop does not persist without intervention	Х
14. Comments	

D	04.040.04
Permit #	04-040-01r
Company	ProdiGene
Organism Transpage	Corn
Transgene	aprotinin
1. Confinement	
Confinement and mitigation conditions have been reviewed and determined to be adequate	Х
2. Threatened or Endangered Species or its habitat	
resident or migratory in counties and harm to threatened or endangered species or habitat is likely	V
resident or migratory in counties and harm to threatened or endangered species is unlikely	Х
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	A
Primarily Bee or insect pollinated crop	T
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

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	Х
6. Plant Pollination	
Primarily Bee or insect pollinated crop	
Primarily Wind pollinated food or feed crop	Х
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	Х
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	1
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	T
Crop can persist 3-5 years without human intervention	
Crop does not persist without intervention	X
14. Comments	
L	

Company Critical Crit		
Com Category Transgene 17 1-Confidential Confidential Co	Permit #	04-040-01r
Category Transgene 1. Confinement Confinement and mitigation conditions have been reviewed and determined to be adequate 2. Investment and mitigation conditions have been reviewed and determined to be adequate 2. Investment of Endangered Species or its Heitits resident or migratory in counties and harm to threatened or endangered species is unlikely resident or migratory in counties and harm to threatened or endangered species is unlikely Review of Novel Crop Rever used in a field trial Rever used in		
Transgene ### ### ### ### ### ### ### ### ###	·	
1. Confinement and miligation conditions have been reviewed and determined to be adequate 2. Threatened of Endangered Species of 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 resident or migratory in counties and harm to threatened or endangered species is unlikely X resident or migratory in counties and harm to threatened or endangered species is unlikely X resident or migratory in counties and harm to threatened or endangered species is unlikely X resident or migratory in counties and harm to threatened or endangered species is unlikely X resident or migratory in counties and harm to threatened or endangered species is unlikely X Rev or Novel Crop Nove or Novel Grop Not new or Novel Trait (gene product) Not new but no prior EA Not new Novel Trait (gene product) Not new but no prior EA Not new but no prior EA Not new but no prior EA Raises new Issues 5. Cumulative Effects likely Cumulative Effects likely Cumulative Effects likely Cumulative Effects likely X Cumulative Effects likely X Cumulative Millor (and the counties) X Replace or insect pollinated crop Primarily Wind pollinated food or feed crop Non-food or feed crop X Primarily Self efficiated dood or feed crop Non-food or feed crop X Ceffects on FoodFeed Supply Known allergen, antinutrative, oral toxicant to dood saletive for plant produced protein S Rosalstance S Rosalstance S Rosals and S Rosalstance S Rosalstance S Rosalstance S Rosalstance S Rosalstance S Rosalstance 100 across/rail(crop)companylyear 101 across/rail(crop)companylyear 102 across/rail(crop)companylyear 103 across/rail(crop)companylyear 104 across/rail(crop)companylyear 105 across/rail(crop)companylyear 106 across/rail(crop)companylyear 107 across/rail(crop)companylyear 108 across/rail(crop)companylyear 109 across/rail(crop)companylyear 109 across/rail(crop)companylyear	· ·	
Confinement and miligation conditions have been reviewed and determined to be adequate X 2. Threatened or Endengred 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 in control and harm to threatened and endangered species is unlikely in control and harm to threatened and endangered species is unlikely in control and harm to threatened and endangered species is unlikely in the control of the	·	#7
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 New or Novel The county of the counties and harm to threatened or endangered species is unlikely New or Novel Service of Novel Service or Novel Crop Never used in a fled trial Not new but no prior EA Not new and prior EA Not n		
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 none observed in area (no harm to threatened and endangered species)		X
resident or migratory in counties and harm to threatened or endangered species is unlikely none observed in area (no harm to threatened and endangered species) New or Novel S. New or Novel S. New or Novel Crop Not new but no prior EA Not new and prior EA Relies new Issues S. Comulative Effects (Included Included		<u> </u>
none observed in area (no harm to threatened and endangered species) New or Novel Crop Never used in a field that Not new but no prior EA Rose novel Trait (gene product) Never used in a field trial X Not new but no prior EA Rose new tested in a field trial X Not new but no prior EA Roses new tested in a field trial X Not new but no prior EA Roses new tested in a field trial X Not new but no prior EA Roses new tested in a field trial X Not new but no prior EA Roses new tested in a field trial X Not new but no prior EA Roses new tested in a field trial X Selection of the sel		
New or Novel 3. New or Novel Crop Never used in a field trial Not new but no prior EA X 4. New or Novel Trait (gene product) Never used in a field trial Not new and prior EA X 5. Not new and prior EA X Not new but no prior EA X Not new and prior EA Raises new issues S. Cumulative Effects Cumulative Effects (likely Cumulative Effects unlikely X X Commulative Effects unlikely X Commulative Effects unlikely X X X X X X X X X X X X X X X X X X X	· , , ,	X
3. New or Novel Crop Nover used in a field trial Not new but no prior EA Not new and prior EA Not new and prior EA Not new to prior EA Not new but no prior EA Rose now listed trial Not new but no prior EA Not new and prior EA Reises now issues 5. Cumulative Effects likely Cumulative Effects possible Cumulative effects Cumul	none observed in area (no harm to threatened and endangered species)	
Never used in a field trial Not new but no prior EA Not new and prior EA Not new but no prior EA Not new and prior EA Ralses new Issues S. Cumulative Effects likely Cumulative effects possible Cumulative effects possible Cumulative effects unlikely X 6. Plant Pollination Primarily Bear on insect pollinated crop Primarily Wind pollinated food or feed crop Primarily Wind pollinated food or feed crop Non-food and the stabilished X GRAS status or approved food additive for native protein GRAS status or approved food additive for plant produced protein S. Isolation Status S. Isolation Status S. Isolation distance ADSCA standard for crop S. Scale S. Isolation distance S. Scale S. Scale S. Scale S. Status or approved food additive for plant produced protein Minimal, non-cumulative effects expected/observed Minimal, non-cumu	New or Novel	
Not new but no prior EA Not new and prior EA Not new and prior EA Newer voew I trait (gene product) Never used in a field trial X Not new but no prior EA Not new but no prior EA Not new but no prior EA Roll new and prio	•	
Not new and prior EA A New or Novel Trait (gene product) Never used in a field trial X Not new but no prior EA Not new but no prior EA Raises new issues 5. Cumulative Effects likely Cumulative Effects likely Cumulative effects possible Cumulative effects unlikely A Raises new issues 5. Cumulative effects unlikely K 6. Plant Pollination Primarily Bee or insect pollinated crop Primarily Wind pollinated food or feed crop Primarily Self fertilized food or feed crop Primarily Self fertilized food or feed crop Non-lood or feed drop 7. Effects on Food/Feed Supply Known allerge antinutrative, oral toxicant food safety not established GRAS status or approved food additive for native protein GRAS status or approved food additive for plant produced protein 8. Isolation Distance >100 acres/trait/crop/company/year >100 acres/trait/crop/company/year >100 acres/trait/crop/company/year 10 acres/trait/crop/company/year 10 acres/trait/crop/company/year 10 acres/trait/crop/company/year 10 acres/trait/crop/company/year 11. Sevally Compatible Relatives relatives within dispersal distance no relatives within dispersal distance 12. Seed Dormany 22. years 23. years 24. years 25. years 35. Persistence in environment Crop can naturalize Crop can persist 3-5 years without human intervention X Summer of the company of t	Never used in a field trial	
A. New or Novel Trait (gene product) Never used in a field trial X Not new but no prior EA Raises new Issues 5. Cumulative Effects (Section 1997) Cumulative Effects possible Cumulative Effects unlikely A. Plant Pollination Primarily Bee or insect pollinated crop Primarily Wind pollinated food or feed crop Primarily Wind pollinated food or feed crop Non-food of teed crop Non-food of teed crop Non-food of ede crop RAS status or approved food additive for plant produced protein GRAS status or approved food additive for plant produced protein Saloation Distance AOSCA standard for crop 9. Scale 100 acres/trait/crop/company/year 10-49 acres/trait/crop/company/year 10-49 acres/trait/crop/company/year 10-49 acres/trait/crop/company/year 10-49 acres/trait/crop/company/year 10-50-99 acres/trait/crop/company/year 10-10 Effects (possitive or negative) on other species Significant effects expected/observed No effects expected/observed No effects expected/observed X 11. Effects (possitive or negative) on other species Significant effects expected/observed No effects expected/observed X 2 1-2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	Not new but no prior EA	
Never used in a field trial X Not new but no prior EA Not new and prior EA Raises new issues 5. Cumulative Effects likely Cumulative effects possible Cumulative effects possible Cumulative effects unlikely X Primarily Bet or insect pollinated crop Primarily Wind pollinated food or feed crop Primarily Wind pollinated food or feed crop Primarily Wind pollinated 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 GRAS status or approved food additive for plant produced protein 8. Isolation Distance AOSCA standard for crop 9. 660 feet Proposed isolation distance \$ 5280 feet \$ 50-99 acres/trait/crop/company/year 10-49 acres/trait/crop/company/year 10-49 acres/trait/crop/company/year 10-49 acres/trait/crop/company/year 10-10 Effects (possitive or negative) on other species Significant effects expected/observed No effects expected/observed X 11. Sexually Compatible Relatives relatives within dispersal distance no relatives within dispersal distance 12. Eversitience in environment Crop can naturalize Crop can persist 3-5 years without human intervention X 2	Not new and prior EA	X
Not new but no prior EA Not new and prior EA Raises new Issues 5. Cumulative Effects Cumulative Effects (Effects) Cumulative Effects (Effects) Cumulative effects possible Cumulative effects unlikely 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 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 GRAS status or approved food additive for plant produced protein 8. Isolation Distance AOSCA standard for crop Proposed isolation distance 9. Scale 100 acres/trait/crop/company/year 10-49 acres/trait/crop/company/year 10-49 acres/trait/crop/company/year 10-40 acres/trait/crop/company/year 10-10 acres/trait/crop/company/year 11. Sexually Compatible Relatives No effects expected/observed No effects expected/ob	4. New or Novel Trait (gene product)	
Not new and prior EA Rails's new issues 5. Cumulative Effects likely Cumulative Effects possible Cop paris distance X Cop can naturatize Crop can neturatize Crop can netrialize possible with unitervention Crop does not persist without intervention X X X 10. Possible possible effects possible possibl	Never used in a field trial	X
Raless new Issues Cumulative Effects likely Cumulative Effects possible Cumulative Effects unlikely 6. Plant Pollination Primarily Wind pollinated crop Primarily Self fertilized food or feed crop X Primarily Self fertilized 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 7. Effects or Self-status or approved food additive for plant produced protein 8. Isolation Distance 4. OSCA standard for crop 9. 660 feet Proposed isolation distance 5.280 feet 9. Scale 50.9 acres/trait/crop/company/year 1099 acres/trait/crop/company/year 1099 acres/trait/crop/company/year 1099 acres/trait/crop/company/year 11. Sexually company the septicum of the septicum	Not new but no prior EA	
Raless new Issues Cumulative Effects likely Cumulative Effects possible Cumulative Effects unlikely 6. Plant Pollination Primarily Wind pollinated crop Primarily Self fertilized food or feed crop X Primarily Self fertilized 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 7. Effects or Self-status or approved food additive for plant produced protein 8. Isolation Distance 4. OSCA standard for crop 9. 660 feet Proposed isolation distance 5.280 feet 9. Scale 50.9 acres/trait/crop/company/year 1099 acres/trait/crop/company/year 1099 acres/trait/crop/company/year 1099 acres/trait/crop/company/year 11. Sexually company the septicum of the septicum	Not new and prior EA	
5. Cumulative Effects (Cumulative Effects possible Cumulative Effects possible Cumulative Effects possible (Cumulative Effects possible (Cumulative) (Raises new issues	
Cumulative Effects likely Cumulative effects possible Cumulative effects unlikely A 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 ACSCA standard for crop 9. Scale 9. Scale 9. Scale 100 acres/trait/crop/company/year 10-49 acres/trait/crop/company/year 10-49 acres/trait/crop/company/year 10-8 acres/trait/crop/company/year 10 Effects (positive or negative) on other species Significant effects expected/observed Minimal, non-cumulative effects expected/observed Minimal, non-cumulative effects expected/observed Minimal, non-cumulative effects expected/observed No effects expected/observed Minimal, non-cumulative effects expected/observed No effects expected/observed X 11. Sexually Compatible Relatives relatives within dispersal distance no effects expected/observed X 12. Seed Dormancy -3 years -3 years -4 years -4 years -4 years -4 years without intervention -4 Crop can persist 3-5 years without human intervention -5 Crop does not persist without intervention -5 Crop can persist sithout intervention	5. Cumulative Effects	
Cumulative effects possible Cumulative effects unlikely Cumulative effects unlikely Significant effects expected/observed Minimal, non-cumulative effects expected/observed Significant effects expected/observed No effects expected/observed Significant effects expected/observed No effects expected/observed Significant effects expected/observed No effects expec		
Cumulative effects unlikely X 6. Plant Pollination Primarily Bee or insect pollinated crop Primarily Self fertilized food or feed crop Non-food or feed cr		
6. Plant Pollination Primarily Bee or insect pollinated crop Primarily More pollinated food or feed crop Non-food additive for plant produced protein Statistic or approved food additive for plant produced protein No Statistic or approved food additive for plant produced protein No Statistic or approved food additive for plant produced protein No Statistic or food additive for plant produced protein No Statistic or food in the food of the feed of the food of feet or food in the feet feet feet feet feet feet feet		X
Primarily Bee or insect pollinated crop Primarily Wind pollinated 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 9. Scale >100 acres/trait/crop/company/year 50-99 acres/trait/crop/company/year 40 acres/trait/crop/company/year 410.49 acres/trait/crop/company/year 410.49 acres/trait/crop/company/year 410.Effects (positive or negative) on other species Significant effects expected/observed Monimal, non-cumulative effects expected/observed No effects expected/observed No effects expected/observed X 11. Sexually Compatible Relatives relatives within dispersal distance no relatives within dispersal distance x y years 3 years 2 years 3 years 2 years 2 years 2 years 3 years 13. Persistence in environment Crop can naturalize Crop can persist 3-5 years without human intervention Crop does not persist without intervention X	,	
Primarily Wind pollinated food or feed crop Primarily Self Iertilized 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 AOSCA standard for crop 660 feet Proposed isolation distance 9. Scale 100 acres/trait/crop/company/year 50-99 acres/trait/crop/company/year 40 acres/trait/crop/company/year 410 acres/trait/crop/company/year 410. 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 12. Seed Dormancy 3 years 3 years 2 years 2 years 2 years 2 years 2 years 13. Persistence in environment Crop can persist 3-5 years without human intervention Crop does not persist without intervention X 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 GRAS status or approved food additive for plant produced protein 8. Isolation Distance AOSCA standard for crop Proposed isolation distance 9. Scale 9. Scale 9. Scale 9. Soale 9. Ox acres/trait/crop/company/year 10. 49 acres/trait/crop/company/year 10. 49 acres/trait/crop/company/year 10. Effects (positive or negative) on other species Significant effects expected/observed Minimal, non-cumulative effects expected/observed Mo effects expected/observed M1. Sexually Compatible Relatives relatives within dispersal distance no relatives within dispersal distance 12. Seed Dormancy 9. years 12. years 12. years 13. Persistence in environment Crop can naturalize Crop does not persist without intervention Crop does not persist without intervention X		×
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 GRAS status or approved food additive for plant produced protein 8. Isolation Distance AOSCA standard for crop 660 feet Proposed isolation distance 9. Scale >100 acres/trait/crop/company/year 10-49 acres/trait/crop/company/year 40.0 acres/trait/crop/company/year 10-49 acres/trait/crop/company/year 10. Effects (positive or negative) on other species Significant effects expected/observed Minimal, non-cumulative effects expected/observed Minimal, non-cumulative effects expected/observed X11. Sexually Compatible Relatives relatives within dispersal distance no relatives within dispersal distance 10. 2 years 2 years 3 years 3 years 2 years 4 X 13. Persistence in environment Crop can naturalize Crop can persist 3-5 years without human intervention Crop does not persist without intervention Crop does not persist without intervention		^
7. Effects on Food/Feed Supply Known allergen, antinutrative, oral toxicant food Safety not established 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 AOSCA standard for crop Froposed isolation distance 9. Scale 9. Scale 9. Scale 9. Scale 10. 49 acres/trait/crop/company/year 10. 49 acres/trait/crop/company/year 10. 49 acres/trait/crop/company/year 10. Effects (positive or negative) on other species Significant effects expected/observed Minimal, non-cumulative effects expected/observed Minimal, non-cumulative effects expected/observed 11. Sexually Compatible Relatives relatives within dispersal distance no relatives within dispersal distance no relatives within dispersal distance 12. Seed Dormancy 23 years 3 years 2 years 4 X 13. Persistence in environment Crop can persist 3-5 years without human intervention Crop does not persist without intervention X	, ,	
Known allergen, antinutrative, oral toxicant food Safety not established 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 9. Scale >100 acres/trait/crop/company/year 50-99 acres/trait/crop/company/year 40 acres/trait/crop/company/year 410 acres/trait/crop/company/year 42 acres/trait/crop/company/year 43 acres/trait/crop/company/year 44 acres/trait/crop/company/year 45 acres/trait/crop/company/year 46 acres/trait/crop/company/year 47 acres/trait/crop/company/year 48 type-defects expected/observed Minimal, non-cumulative effects expected/observed No effects expected/observed No effects expected/observed No effects expected/observed X1. Sexually Compatible Relatives relatives within dispersal distance no relatives within dispersal distance no relatives within dispersal distance no relatives within dispersal distance 3 years 3 years 3 years 2 years 3 years 4 X 13. Persistence in environment Crop can persist 3-5 years without human intervention Crop does not persist without intervention X		
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 10-49 acres/trait/crop/company/year 10 acres/trait/crop/company/year	.,,,	
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		Y
GRAS status or approved food additive for plant produced protein 8. Isolation Distance AOSCA standard for crop 6660 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 410 acres/trait/crop/company/year 4210 acres/trait/crop/company/year 430 acres/trait/crop/company/year 450 acres/trait/crop/company/year 4710. 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 4 2 years 4 2 years 4 2. Persistence in environment Crop can naturalize Crop can persist 3-5 years without human intervention Crop does not persist without intervention X	•	
8. Isolation Distance AOSCA standard for crop 6660 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 4.10 acres/trait/crop/company/year 4.10 acres/trait/crop/company/year 50-99 acres/trait/crop/company/ear 50-99 acres/trait/crop/company/ear 50-99 acres/trait/crop/company/ear 50-99 acres/trait/crop/company/ear 50-99		
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 <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 No effects expected/observed X 11. Sexually Compatible Relatives relatives within dispersal distance no relatives within dispersal distance 12. Seed Dormancy >3 years 3 years 2 years 4		
Proposed isolation distance 5280 feet		CCO foot
9. Scale >100 acres/trait/crop/company/year 50-99 acres/trait/crop/company/year 10-49 acres/trait/crop/company/year 10-49 acres/trait/crop/company/year 10		
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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 12. Seed Dormancy 3 years 3 years 2 years 4 years 13. Persistence in environment Crop can naturalize Crop can persist 3-5 years without human intervention Crop does not persist without intervention X X X X X X X X X X X X X		
<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		
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		
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 X 13. Persistence in environment Crop can persist 3-5 years without human intervention Crop does not persist without intervention X		X
Minimal, non-cumulative effects expected/observed X 11. Sexually Compatible Relatives X relatives within dispersal distance X no relatives within dispersal distance X 12. Seed Dormancy X 3 years 3 years 2 years X 13. Persistence in environment X Crop can naturalize Crop can persist 3-5 years without human intervention X Crop does not persist without intervention X	" , , , , , , , , , , , , , , , , , , ,	
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11. Sexually Compatible Relatives relatives within dispersal distance X 12. Seed Dormancy >3 years 3 years 2 years <2 years	·	
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X 12. Seed Dormancy X 12. Seed Dormancy X 13. Persistence X X 14. Seed Dormancy X X X X X X X X X	, , , , , , , , , , , , , , , , , , ,	
12. Seed Dormancy >3 years 3 years 2 years <2 years	relatives within dispersal distance	
>3 years 3 years 2 years <2 years	no relatives within dispersal distance	X
3 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	12. Seed Dormancy	
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	>3 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	3 years	
13. Persistence in environment Crop can naturalize Crop can persist 3-5 years without human intervention Crop does not persist without intervention X	2 years	
13. Persistence in environment Crop can naturalize Crop can persist 3-5 years without human intervention Crop does not persist without intervention X	<2 years	X
Crop can persist 3-5 years without human intervention Crop does not persist without intervention X	13. Persistence in environment	·
Crop can persist 3-5 years without human intervention Crop does not persist without intervention X	Crop can naturalize	
Crop does not persist without intervention X	•	
	Crop does not persist without intervention	X
	,	<u> </u>

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	

	04.040.04
Permit #	04-040-01r
Company	ProdiGene
Стор	Corn
Category	Value added protein for human consumption
Transgene	brazzein
1. Confinement	
Confinement and mitigation conditions have been reviewed and determined to be adequate 2. Threatened or Endangered Species or its habitat	X
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 or habitat is likely	V
	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 inkely Cumulative effects possible	
	v
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	0200 1000
>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	

Darmit #	04 040 04*
Permit #	04-040-01r
Company	ProdiGene
Сгор	Corn
	pharmaceutical intent-vaccine
Category	(oral swine)
_	transmissible gastroenteritis
Transgene	(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	
10.44	
food Safety not established	X
food Safety not established GRAS status or approved food additive for native protein	X
·	X
GRAS status or approved food additive for native protein	X
GRAS status or approved food additive for native protein GRAS status or approved food additive for plant produced protein	660 feet
GRAS status or approved food additive for native protein GRAS status or approved food additive for plant produced protein 8. Isolation Distance	
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
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 Proposed isolation distance	660 feet
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 Proposed isolation distance 9. Scale	660 feet
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 Proposed isolation distance 9. Scale >100 acres/trait/crop/company/year	660 feet
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 Proposed isolation distance 9. Scale >100 acres/trait/crop/company/year 50-99 acres/trait/crop/company/year	660 feet
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 Proposed isolation distance 9. Scale >100 acres/trait/crop/company/year 50-99 acres/trait/crop/company/year 10-49 acres/trait/crop/company/year	660 feet 5280 feet
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 Proposed isolation distance 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	660 feet 5280 feet
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 Proposed isolation distance 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 10. Effects (positive or negative) on other species	660 feet 5280 feet
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 Proposed isolation distance 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 10. Effects (positive or negative) on other species Significant effects expected/observed	660 feet 5280 feet
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 Proposed isolation distance 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 <10 acres/trait/crop/company/year <10 Effects (positive or negative) on other species Significant effects expected/observed Minimal, non-cumulative effects expected/observed	660 feet 5280 feet 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 Proposed isolation distance 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 10. Effects (positive or negative) on other species Significant effects expected/observed Minimal, non-cumulative effects expected/observed No effects expected/observed	660 feet 5280 feet 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 Proposed isolation distance 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 10. Effects (positive or negative) on other species Significant effects expected/observed Minimal, non-cumulative effects expected/observed No effects expected/observed 11. Sexually Compatible Relatives	660 feet 5280 feet 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 Proposed isolation distance 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 10 acres/trait/crop/company/year Significant effects expected/observed Minimal, non-cumulative effects expected/observed No effects expected/observed 11. Sexually Compatible Relatives relatives within dispersal distance	660 feet 5280 feet 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 Proposed isolation distance 9. Scale >100 acres/trait/crop/company/year 50-99 acres/trait/crop/company/year 10-49 acres/trait/crop/company/year -10 acres/strait/crop/company/year -10 acres/strait/crop/company/year -10 acres/strait/crop/company/year -10 acres/strait/crop/company/year -10 acres/strait/crop/company/year -10 acres/strait/crop/company/year -110 effects (positive or negative) on other species Significant effects expected/observed Minimal, non-cumulative effects expected/observed No effects expected/observed 11. Sexually Compatible Relatives relatives within dispersal distance no relatives within dispersal distance	660 feet 5280 feet 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 Proposed isolation distance 9. Scale >100 acres/trait/crop/company/year 50-99 acres/trait/crop/company/year 10-49 acres/trait/crop/company/year 10-49 acres/trait/crop/company/year 10 acres/trait/crop/company/year 10 Effects (positive or negative) on other species Significant effects expected/observed Minimal, non-cumulative effects expected/observed No effects expected/observed 11. Sexually Compatible Relatives relatives within dispersal distance no relatives within dispersal distance 12. Seed Dormancy	660 feet 5280 feet 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 Proposed isolation distance 9. Scale >100 acres/trait/crop/company/year 50-99 acres/trait/crop/company/year 10-49 acres/trait/crop/company/year 10-10 acres/trait/crop/company/year 10. Effects (positive or negative) on other species Significant effects expected/observed Minimal, non-cumulative effects expected/observed No effects expected/observed 11. Sexually Compatible Relatives relatives within dispersal distance no relatives within dispersal distance 12. Seed Dormancy >3 years	660 feet 5280 feet 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 Proposed isolation distance 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 -10 acres/trait/crop/company/year -10 Effects (positive or negative) on other species Significant effects expected/observed Minimal, non-cumulative effects expected/observed No effects expected/observed 11. Sexually Compatible Relatives relatives within dispersal distance no relatives within dispersal distance 12. Seed Dormancy >3 years	660 feet 5280 feet 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 Proposed isolation distance 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 10. Effects (positive or negative) on other species Significant effects expected/observed Minimal, non-cumulative effects expected/observed No effects expected/observed 11. Sexually Compatible Relatives relatives within dispersal distance no relatives within dispersal distance 12. Seed Dormancy 3 years 3 years	X 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 Proposed isolation distance 9. Scale >100 acres/trait/crop/company/year 50-99 acres/trait/crop/company/year 10-49 acres/trait/crop/company/year 10. Effects (positive or negative) on other species Significant effects expected/observed Minimal, non-cumulative effects expected/observed No effects expected/observed 11. Sexually Compatible Relatives relatives within dispersal distance no relatives within dispersal distance 12. Seed Dormancy >3 years 3 years 2 years	X X 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 Proposed isolation distance 9. Scale >100 acres/trait/crop/company/year 50-99 acres/trait/crop/company/year 10-49 acres/trait/crop/company/year 10-49 acres/trait/crop/company/year 10 acres/trait/crop/company/year 10 Effects (positive or negative) on other species Significant effects expected/observed Minimal, non-cumulative effects expected/observed No effects expected/observed 11. Sexually Compatible Relatives relatives within dispersal distance no relatives within dispersal distance 12. Seed Dormancy >3 years 3 years 2 years <2 years	X X 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 Proposed isolation distance 9. Scale >100 acres/trait/crop/company/year 50-99 acres/trait/crop/company/year 10-49 acres/trait/crop/company/year 10-49 acres/trait/crop/company/year 10 acres/trait/crop/company/year 10 Effects (positive or negative) on other species Significant effects expected/observed Minimal, non-cumulative effects expected/observed No effects expected/observed 11. Sexually Compatible Relatives relatives within dispersal distance no relatives within dispersal distance no relatives within dispersal distance 12. Seed Dormancy >3 years 3 years 2 years 22 years 13. Persistence in environment Crop can naturalize	X 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 Proposed isolation distance 9. Scale >100 acres/trait/crop/company/year 50-99 acres/trait/crop/company/year 10-49 acres/trait/crop/company/year 10-10 acres/trait/crop/company/year 10. Effects (positive or negative) on other species Significant effects expected/observed Minimal, non-cumulative effects expected/observed No effects expected/observed 11. Sexually Compatible Relatives relatives within dispersal distance no relatives within dispersal distance 12. Seed Dormancy >3 years 3 years 2 years 13. Persistence in environment Crop can persist 3-5 years without human intervention	X X X 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 Proposed isolation distance 9. Scale >100 acres/trait/crop/company/year 50-99 acres/trait/crop/company/year 10-49 acres/trait/crop/company/year 10-agres/trait/crop/company/year 10. Effects (positive or negative) on other species Significant effects expected/observed Minimal, non-cumulative effects expected/observed No effects expected/observed 11. Sexually Compatible Relatives relatives within dispersal distance no relatives within dispersal distance 12. Seed Dormancy >3 years 3 years 2 years 13. Persistence in environment Crop can persist 3-5 years without human intervention Crop does not persist without intervention	X X X 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 Proposed isolation distance 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 10. Effects (positive or negative) on other species Significant effects expected/observed Minimal, non-cumulative effects expected/observed No effects expected/observed 11. Sexually Compatible Relatives relatives within dispersal distance no relatives within dispersal distance 12. Seed Dormancy >3 years 3 years 2 years 13. Persistence in environment Crop can persist 3-5 years without human intervention Crop does not persist without intervention	X X X X

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.

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Ü	Neil E. Hoffman
	Director of Regulatory Programs
Date:	7.19.04