Permit #	04-114-01r
Company	Chlorogen Inc.
Organism	tobacco
Category	pharmaceutical intent
Transgene	Human serum albumin
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	
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	Х
4. New or Novel Trait (gene product)	
Never used in a field trial	
Not new but no prior EA	
Not new and prior EA	Х
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	
Primarily Self fertilized food or feed crop	
Non-food or feed crop	Х
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	1/4 mile
Proposed isolation distance	1/4 mile
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	Х
10. Effects (positive or negative) on other species	
Significant effects expected/observed	
Minimal, non-cumulative effects expected/observed	
No effects expected/observed	Х
11. Sexually Compatible Relatives	
relatives within dispersal distance	
relatives not within dispersal distance	Х
12. Seed Dormancy	•
>3 years	
3 years	
2 years	
<2 years	Х
13. Persistence in environment	
Crop can naturalize	
Crop can persist 3-5 years without human intervention	
Crop does not persist without intervention	Х
14. Comments	
^{8, 11, 12} Method of transformation minimizes transgene flow through poller	
Plants in the field will have flowers removed.	

Permit #	04-114-01r
Company	Chlorogen Inc.
Organism	tobacco
Category	pharmaceutical intent
Transgene	insulin-like growth factor
1. Confinement	<u>.</u>
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	
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	х
4. New or Novel Trait (gene product)	
Never used in a field trial	
Not new but no prior EA	
Not new and prior EA	Х
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	
Primarily self fertilized food or feed crop	
Non-food or feed crop	Х
	^
7. Effects on Food/Feed Supply Known allergen, antinutritive, 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	4/4
AOSCA standard for crop	1/4 mile
Proposed isolation distance	1/4 mile
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	Х
10. Effects (positive or negative) on other species	
Significant effects expected/observed	
Minimal, non-cumulative effects expected/observed	
No effects expected/observed	Х
11. Sexually Compatible Relatives	
Relatives within dispersal distance	
Relatives within dispersal distance	Х
	X
Relatives not within dispersal distance	X
Relatives not within dispersal distance 12. Seed Dormancy	X
Relatives not within dispersal distance 12. Seed Dormancy >3 years	X
Relatives not within dispersal distance 12. Seed Dormancy >3 years 3 years	x
Relatives not within dispersal distance 12. Seed Dormancy 3 years 3 years 2 years	
Relatives not within dispersal distance 12. Seed Dormancy 3 years 3 years 2 years < 2 years	
Relatives not within dispersal distance 12. Seed Dormancy 3 years 3 years 2 years 2 years 13. Persistence in environment	
Relatives not within dispersal distance 12. Seed Dormancy >3 years 3 years 2 years -2 years 13. Persistence in environment Crop can naturalize Crop can persist 3-5 years without human intervention	X
Relatives not within dispersal distance 12. Seed Dormancy >3 years 3 years 2 years -2 years 13. Persistence in environment Crop can naturalize Crop can persist 3-5 years without human intervention Crop does not persist without intervention	
Relatives not within dispersal distance 12. Seed Dormancy >3 years 3 years 2 years <2 years	X
Relatives not within dispersal distance 12. Seed Dormancy >3 years 3 years 2 years -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

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

Permit #	04-114-01r
Company	Chlorogen Inc.
Organism	tobacco
Category	pharmaceutical intent
Transgene	interferon
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	×
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	Х
4. New or Novel Trait (gene product)	· ·
Never used in a field trial	
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	
Primarily self fertilized food or feed crop	
Non-food or feed crop	Х
7. Effects on Food/Feed Supply	~
Known allergen, antinutritive, oral toxicant	
Food safety not established	Х
GRAS status or approved food additive for native protein	Λ
GRAS status or approved food additive for plant produced protein	
8. Isolation Distance	
AOSCA standard for crop	1/4 mile
Proposed isolation distance	1/4 mile
9. Scale	1/4 11116
>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	~
Relatives not within dispersal distance	X
12. Seed Dormancy	
>3 years	
3 years	
2 years	
<2 years	Х
13. Persistence in environment	
Crop can naturalize	
Crop can persist 3-5 years without human intervention	
Crop does not persist without intervention	Х
14. Comments	
^{8, 11, 12} Method of transformation minimizes transgene flow through pollen	
^{8, 11, 12} Method of transformation minimizes transgene flow through pollen Plants in the field will have flowers removed.	

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

5.06.04

Permail # 04-114-01r Organism Chilorogon Inc. Organism tobacco Stepport pharmacoultari interim Continement A Continement and mingation conditions have been reviewed and determined to be adequate X Continement X Readent or migratory in counties and harm to threatened or endangered species is unlikely X Nore or board X Nore or board or point EA X Nore or board or point EA X Nore or board or point EA X Commative effects loganalia X	- · · ·	
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New or Novel 3. New or Novel Topi 3. New or Sovel		
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Raises new issues	-	^
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Cumulative effects likely		
Cumulative effects possible X Cumulative effects unikely X Plant Pollination ************************************		
Cumulative effects unlikely X 6. Plant Pollination ************************************		
6. Plant Pollination Primarily bee or insect pollinated crop Primarily self tertilized food or feed crop Non-food or feed crop X 7. Effects on Food/Feed Supply X Known allergen, antinutritive, oral toxicant X Food safety not established X GRAS status or approved food additive for native protein S B solation Distance 1/4 mile Proposed isolation distance 1/4 mile Proposed isolation distance 1/4 mile Solate or negative/or negative/ or negati	·	
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Primarily self fertilized food or feed crop X Non-food of feed crop X 7. Effects on Food/Feed Supply X Known allergen, antinutritive, oral toxicant X Food safety not established X GRAS status or approved food additive for native protein X GRAS status or approved food additive for plant produced protein X B. Isolation Distance 1/4 mile Proposed isolation distance 1/4 mile 9. Scale 1/4 mile >10.0 acres/trait/crop/company/year X >10.9 acres/trait/crop/company/year X 10.49 acres/trait/crop/company/year X 10.49 acres/trait/crop/company/year X 10.50 acres/trait/crop/company/year X 10.49 acres/trait/crop/company/year X 10.51 (Set expected/observed X 10.51 (Set expected/observed X 11.5 (Set expected/observed X 11.6 (Set expected/observed X 11.6 (Set expected/observed X 12.5 (Set Ormancy X 2.5 (Set Ormancy X 2.5 (Set Ormancy X 3.5 (Set	• • •	
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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 1/4 mile AOSCA standard for crop 1/4 mile 9. Scale 1/4 mile 9. Scale 2 >100 acres/trait/crop/company/year 50-99 acres/trait/crop/company/year >10.49 acres/trait/crop/company/year X 10.49 acres/trait/crop/company/year X 10.49 acres/trait/crop/company/year X 10 acres/trait/crop/company/year X 11.5 Executed/observed X 11.5 Executed/observed X 11.5 Executed/cobserved X 11.5 Executed/cobserved X 12.5 Seed Dormancy X 3 years X 2 years X 2 years X		
Known allergen, antinutritive, oral toxicant X Food safety not established X GRAS status or approved food additive for plant produced protein X B. Isolation Distance 1/4 mile AOSCA standard for crop 1/4 mile Proposed isolation distance 1/4 mile Scale 1/4 mile >100 acres/trait/crop/company/year 1/4 mile >10-49 acres/trait/crop/company/year 10.49 acres/trait/crop/company/year X 10.5 Effects (positive or negative) on other species Significant effects expected/observed Minimal, non-cumulative effects expected/observed X 11. Sexually Compative Relatives X 12. Seed Dormancy X 3 years X 2 years X 13. Persistence in environment X Crop can naturalize X Crop can persist 3-5 years without intervention X Crop does not persist without intervention X		Х
Food safety not established X GRAS status or approved food additive for native protein Image: Constraint of the status of approved food additive for plant produced protein Alsolation Distance 1/4 mile AOSCA standard for crop 1/4 mile Proposed isolation distance 1/4 mile 9. Scale 1/4 mile >100 acres/trait/crop/company/year 1/4 <104 acres/trait/crop/company/year		
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8. Isolation Distance 1/4 mile AOSCA standard for crop 1/4 mile Proposed isolation distance 1/4 mile 9. Scale 10 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 X 10.49 acres/trait/crop/company/year X 10.49 acres/trait/crop/company/year X 10.49 acres/trait/crop/company/year X 10.50 fiftects (positive or negative) on other species Significant effects expected/observed Minimal, non-cumulative effects expected/observed N No effects expected/observed X 11.5 exually Compatible Relatives X Relatives within dispersal distance X 12.5 eed Dormancy X 3 years Signars 2 years X 13.Persistence in environment X Crop can neturalize Crop can neturalize Crop can persist 3-5 years without human intervention X 41.4 comments X	GRAS status or approved food additive for native protein	
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>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	Proposed isolation distance	1/4 mile
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<10 acres/trait/crop/company/year	50-99 acres/trait/crop/company/year	
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^{8, 11, 12} Method of transformation minimizes transgene flow through pollen		X
Plants in the field will have flowers removed.		
	Plants in the field will have flowers removed.	

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

Based on a review of Permit 04-114-01r, 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 in tobacco fields. Additionally, the gene products at issue in the proposed field trials have no known toxic effects on wildlife. Therefore these field trials will not harm or have adverse or other significant effects on threatened or endangered species.
- Numerous field trials have been performed with transgenic tobacco plants under APHIS authority and APHIS is familiar with tobacco biology and methods to manage confined field trials.
- The technology of the transformation used on these plants prevents dissemination of the gene by pollen movement. Additionally, the plants will be manually topped throughout the trial period to remove flower buds prior to any pollen release. AOSCA standards for seed production of tobacco of ¹/₄ mile will be maintained, nonetheless.
- Any plant material left after harvest, containing only insignificant amounts of the proteins, will be plowed under the soil surface. This method of disposal should have no negative impacts on the environment.
- The proteins being expressed in these field trials do not have characteristics of known toxins or allergens. Given that tobacco is not used for food or feed and that beneficial species are unlikely to be feeding on these plants, issues with toxic and allergenic effects are unlikely.
- 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.
- Tobacco is not observed to be capable of establishment in wild environments. It is reliant on continuous human intervention for its survival. In previous field tests and applications, seed dormancy has not been observed. There are no sexually-compatible relatives 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 #04-114-01r 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_____