

July 19, 2001

**Public Comment on USDA APHIS, Biotechnology Permits Branch,  
Environmental Assessment of June 21, 2001, on the proposal by  
USDA APHIS, Plant Protection Center, for Confined Field Study of a  
Transgenic Pink Bollworm; includes 60 Day Notice of Intent to Sue  
under the Endangered Species Act**

Docket No. 01-024 01  
Regulatory Analysis and Development, PPD  
USDA APHIS, Suite 3C03  
4700 River Rd., Unit 118  
Riverdale, MD 20737-1238

Re: USDA APHIS Environmental Assessment (EA) on the proposal by  
USDA APHIS for a Confined Field Study of a Transgenic Pink Bollworm,  
*Pectinophora gossypiella* (Lepidoptera: Gelechiidae)

Dear Sir/Madam:

The Center for Food Safety (CFS), International Center for Technology Assessment, American Lands, Pesticide Action Network of North America, and Department of the Planet Earth, Inc., all national, non-profit, public interest groups, are pleased to submit this public comment on the above-referenced EA.

CFS was established to use science and the law to address increasing concerns over the impacts of the U.S. agricultural system on human health, animal welfare, and the environment. **International Center for Technology Assessment** is devoted to fully exploring the economic, ethical, social, environmental and political impacts that can result from the applications of technology. **American Lands'** mission is to protect forest, grassland, and aquatic ecosystems; preserve biological diversity; restore landscape and watershed integrity; and promote environmental justice in connection with those goals. **Pesticide Action Network of North America** campaigns to replace pesticides with ecologically sound alternatives. It links over 100 affiliated health, consumer, labor, environment, and progressive agriculture and public interest groups in North America. **Department of the Planet Earth, Inc.**, focuses on a wide range of toxic, environmental, and life quality issues domestically, across the US-Canada border, and globally.

**General comments:**

First, let us reassure you that we are not blind to the potential positive aspects of this proposal. It is: 1) publicly-funded and reasonably transparent (unlike many GE animal proposals); 2) aimed at a serious public problem, i.e., a non-native pest (unlike many GE animal proposals); and 3) clearly subject to Federal permitting authority (again unlike many proposals).

Nevertheless, these potential positives are completely outweighed by your failure to conduct the required "hard look" at the potential impacts, indeed, your failure to comply with even the most basic National Environmental Policy Act requirements for even-handed analysis. We request that you revisit NEPA, the key interpreting cases, the Council on Environmental Quality's (CEQ) implementing regulations, and other CEQ guidance documents. It is contrary to Federal law for APHIS to "rubberstamp" its own projects in the way done here. NEPA's procedures are both required and useful for structuring the analysis necessary to determine whether potentially significant impacts exist to the environment and to the public. Perhaps most mystifying is your failure to comply with published assurances made by APHIS biotechnology officials as to how transgenic arthropod proposals would be regulated and analyzed (Young, Ingebritsen, and Foudin 1999).

Your failure to comply with standard NEPA formatting and analysis and failure to use the best scientific information mean that the EA is inadequate. You are proposing an integral step in the first major unconfined release of a human-engineered, undomesticated, potentially invasive insect, and treating it as if it were a small agricultural research project for which a sloppy, argumentative, environmental document will suffice.

**Specific comments (APHIS's written response is requested to each of these):**

**Comment 1 - Overall Failure:** The EA as a whole is not a "hard look" decision document, as required by NEPA. USDA APHIS prepared the EA on its own very controversial proposal and unfortunately this conflict of interest resulted in the entire document manifesting a clear predetermination in favor of granting the permit. More unfortunate still, APHIS's eagerness to grant itself the permit resulted in its failure to comply with basic NEPA regulations and guidelines applicable to all EAs. **Requested change:** A strong need exists in this high-profile situation for an independent outside consultant, rather than internal analysis. Independent NEPA analysis is very common for Federal proposals and very appropriate here to conduct a complete re-scoping and re-writing, and to avoid the temptation to cheerlead for and rubberstamp APHIS's own project, which this EA amply demonstrates.

**Comment 2 - Lack of Independent Evaluation:** The EA is inadequate because it demonstrates no independent review of the potential impacts of the proposal beyond the opinions put forth by the project proponents themselves. This violates the CEQ NEPA regulations, 40 CFR § 1506.5(a) and -5(b), which provide, in pertinent part:

*(a) Information. ....The agency shall independently evaluate the information submitted and shall be responsible for its accuracy. If the agency chooses to use the information submitted by the applicant in the environmental impact statement, either directly or by reference, then the names of the person responsible shall be included in the list of preparers..... (b) Environmental assessments. If an agency permits an applicant to prepare an environmental assessment, the agency, besides fulfilling the requirements of paragraph (a) of this section, shall make its own evaluation of the environmental issues.....*

Four of the five preparers listed in the EA are the project proponents themselves, that is, the applicants and their collaborators. The only APHIS NEPA analyst in the List of Preparers is not indicated as having been responsible for independent evaluation of the applicant's information, contrary to the regulation, and the EA does not evidence that he undertook this. Indeed, the APHIS NEPA analyst flatly refused to seek review of the information in the EA by the pre-existing (and award-winning) APHIS expert Transgenic Arthropod Team (the "TAT") (R. Rose, APHIS, pers. comm.). This rejection of TAT involvement - which had been created for this very purpose - directly contravened past APHIS practice and contravened published assurances by APHIS officials Young, Ingebritsen, and Foudin (1999, at p. 377). Further, it is simply bad NEPA practice to purposefully disregard readily available independent advice on entomology, genetics, arthropod ecology, and other disciplines.

**Requested change:** Environmental documents for this proposal must incorporate independent review by scientists (not closely allied with the project) with expertise in appropriate disciplines, such as the TAT. Clear evidence of independent evaluation of the project proponent's assertions must be included, in compliance with 40 CFR § 1506.5(b).

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Comments number 3 through 8, below, address your failure to include the legally required elements of an EA under the CEQ NEPA regulations, 40 CFR § 1501 et seq. Specifically, § 1508.9 defines "*Environmental assessment*" in pertinent part (emphasis added) as:

*(b) Shall include brief discussions of the **need** for the **proposal**, of **alternatives** as required by section 102(2)(E),*

*of the **environmental impacts** of the proposed action and alternatives, and a **listing of agencies and persons consulted.***

Taking these required formal elements of an EA one by one:

**Comment 3 - Absence of a "Need" Section:** The EA lacks a "Need for the Proposal" section, which is required by the above regulation and standard in every EA. Instead, this EA repeatedly injects unsupported arguments about purported project benefits throughout the Impact analysis section. This is not a semantic issue, because the EA lacks basic information as to whose needs and precisely what needs are driving the proposal.

**Requested change:** Subsequent environmental document should include a simple, non-argumentative "need" section, identifying whose needs are involved and more about the "why" for the project.

**Comment 4 - Inadequate "Proposal and Alternatives" Sections:** The proposal and alternatives are not adequately described, as required by the CEQ NEPA regulation definition:

*40 CFR § 1508.23 - Proposal. Proposal exists at that stage in the development of an action when an agency subject to the Act has a goal and is actively preparing to make a decision on one or more alternative means of accomplishing that goal and the effects can be meaningfully evaluated.*

Here, APHIS made the crucial mistake of treating issuance of the permit, rather than the project itself, as the "proposal." Due to this confusion, under the "Alternatives" section in the EA, the action alternatives are "Deny" or "Issuance of" the permit. This misconceives what APHIS's true proposal and goal are here, that is, **to improve pink bollworm biological control, not to issue a permit**; and thus fails to evaluate "one or more alternative means of accomplishing the goal."

Further, the EA's "Deny the Permit Alternative" is not the same as a No Action Alternative, which is standard in virtually every EA, but somehow missing here! The Deny the Permit Alternative description in the EA fails to intelligently lay out what No Action really means, and instead launches into an unsupported trashing of two possible, but unexplained, alternative action approaches. (See CEQ's guidance document, the 40 Most Asked NEPA Questions, at Question 3, which instructs you how to analyze the No Action Alternative.) The EA should have treated these other potential action approaches as formal Action Alternatives, then fully described, and "meaningfully evaluated" them, as required by the regulation above.

**Requested change:** Subsequent environmental documents should include a standard Proposal and Alternatives section that objectively lays out: a) the Proposed Action (See Young, Ingebritsen, and Foudin, [1999], at p. 372, emphasis added: "The EA document outlines for the APHIS decisionmaker the potential impact of the **introduction** on the environment....") ; b) the standard No Action Alternative; and c) two suitable Action alternatives that might conceivably accomplish APHIS's goals.

**Comment 5 - Inadequate Proposal Description Section:** What is included about the proposal is inadequate. It fails to give the most basic parameters, such as: 1) actual location of the confined releases, 2) the dates and duration of the project, 3) who will have access to it, 4) the nature of the equipment necessary to construct it, and 5) any proposed mitigation for both mechanical and biological impacts at or near the project site. Absent these details, it cannot be "meaningfully evaluated" as required by § 1508.23, above. For example, there is no discussion at all of on-site impacts such as soil disturbance, dust, glare, and noise. These are the most rudimentary sorts of impacts that virtually **all** project EA's treat.

**Requested change:** Provide information on all basic project parameters. If you refuse to give the actual location, you must give a detailed justification for doing so and at least provide a more detailed description of the surroundings so that the decision makers and the public are not left to guess about the fundamental environmental conditions.

**Comment 6 - Lack of Basic Environmental Impact Analysis for the Affected Environment:** The "Potential Impacts" discussion of the alternatives is completely inadequate. First, it can't be adequate because the alternatives were misconceived, as outlined in Comment 4, above. Second, you gave no description of the "Affected Environment" and you gave no information at all on the climate conditions (temperatures, rainfall, high winds, probability of severe weather events, etc.). It is known that severe thunder and windstorms occasionally strike the Phoenix area, including flash flooding and power outages; the decisionmaker needs to know the likelihood these will contribute to possible failure of the various safety measures, in combination with Phoenix's extreme heat. Your enthusiasm for the project allowed you to miss the most basic NEPA lesson of all: don't analyze just the "best case," consider foreseeable "bad cases" also.

**Requested change:** Describe the Affected Environment, including information about the climate conditions for the various seasons the project would exist, including the probability of severe events that could breach the containment.

**Comment 7 - Lack of Description and Impact Analysis for the Affected Cotton and Other Flora:** The lack of any description

whatsoever of the cotton types or other flora in or around the enclosures is inexcusable. It is scientifically documented that pink bollworms develop and mate differently ("developmental asynchrony") on GE and non-GE cotton (Liu et al. 1999). Nevertheless, the EA completely ignores this parameter, making it of no help in predicting likely transgenic pink bollworm behavior elsewhere in the future. Logically, the releases should take place on both GE and non-GE cotton. Further, the EA makes no mention of the differing susceptibility of GE and non-GE cotton to pink bollworm damage, which clearly affects the overall need for the proposed action.

The EA mentions that alternate hosts for the pink bollworm are known - okra, kenaf, and hibiscus. But, have any other potential hosts been identified? Could they include weeds present in or around the fields? Have the GE pink bollworms been tested on those weeds? The earlier EA section "Description of Research" includes the suggestion - without any citation to evidence - that actually the pink bollworm will **not** use the neighboring hibiscus plants. This assertion belongs in the Impacts section, not in Description of the Research. (This sort of analytical clumsiness pervades the EA.) However, the second page of the EA includes the statement that the pink bollworm **will** use hibiscus as a host. Why this contradiction and why should the reader believe your "non-host switching" assertion when the species has a documented history of using alternate hosts? As one of the aims of the project is to assess performance of the GE species for possible release elsewhere, the failure to describe the flora within the enclosures, on top of the lack of basic "affected environment" information, reduces the usefulness of the project as far as "scaling-up" the lessons learned for applicability to the planned releases in the San Joaquin Valley.

**Requested change:** Provide a detailed description of the cotton type and the surrounding flora, including weeds within or near the enclosures. Identify the presence of all potential alternate hosts. Document whether the GE pink bollworm has actually been tested on the alternate hosts, and the results of such tests. For any assertions about the pink bollworm's behavior that deviate from its documented natural history, provide citations to evidence, not conclusory opinions. Identify in detail the known differences in behavior of pink bollworms on GE and non-GE cotton.

**Comment 8 - No List of Agencies and Persons Consulted Section:**

The EA fails to list the "agencies and persons consulted," as required by 40 CFR § 1508.9. This illegally leaves the reader and decisionmaker guessing about who was involved. CFS has information suggesting, for example, that both Arizona and California agricultural agencies and private interests had input, but where is that reflected in the EA? The reader is entitled to know.

**Requested change:** Provide a detailed list of all agencies and persons consulted. This is standard NEPA practice.

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The following comments address other substantive and legal problems with the EA:

**Comment 9 - Inadequate Endangered Species Consulting and Analysis:** The EA fails to even list the Federally listed or proposed threatened or endangered (T/E) plants or animals in the confined field release vicinity, or their designated or proposed critical habitats. The EA indicates you failed to consult with the U.S. Fish and Wildlife Service (FWS), thus failed to conduct rudimentary Endangered Species Act (ESA) compliance (contrary to Young, Ingebritsen, and Foudin, [1999], at p. 376). The Phoenix area where the fields are - whose precise location you failed to identify - includes designated or proposed critical habitat for species such as the southwestern willow flycatcher, the cactus ferruginous pygmy owl, and others. Further, the San Joaquin Valley pink bollworm SIT project area in California is believed to provide habitat for numerous T/E species, including insects and plants that may be affected; the EA fails to mention, list, or provide evidence of consultation or conferring with the FWS on any of them.

**Requested change:** Provide a detailed description of the listed or proposed T/E species, including designated or proposed critical habitat, and analyze any potential impacts, after first consulting and/or conferring with FWS Section 7 scientists, who must be identified in the list of agencies or persons consulted.

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## **60 DAY NOTICE OF INTENT TO SUE**

**In the event that USDA APHIS and the US Fish and Wildlife Service fail to provide written evidence of the required, scientifically accurate, fully adequate consultation under Section 7 of the ESA, for both this full GE pink bollworm SIT project and for the entire APHIS program of promoting, releasing, and permitting use of GE arthropods, this will serve as notice under 16 U.S.C. § 1540(g) of our intent to sue them for failure to comply with the ESA.**

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**Comment 10 - Lack of Scientific Support:** The EA lacks citation to any scientific literature at all to support its arguments that no unexpected genetic or environmental impacts will occur, with the exception of one non peer reviewed study by the project proponents themselves. This

conclusory approach fails to inform the reader and violates the basic NEPA requirement of using the best information available. It is shocking to see this lack of scientific rigor in a proposal aimed at the first major release of a human-engineered, undomesticated, potentially invasive pest in history. The EA's approach conflicts with the recent Statement on Genetically Modified Organisms from the widely-respected professional ecologists organization, the Ecological Society of America. The Chair of the committee that drafted the Statement noted the need for more "peer-reviewed research on the potential environmental effects of GMOs" (June 1, 2001, press release, online at <http://esa.sdsc.edu/pr060100.htm>; Statement at <http://esa.sdsc.edu/statement0601.htm>).

**Requested change:** For all key conclusions regarding impacts, cite to appropriate published, peer-reviewed scientific literature where available (see APHIS's own website for a lengthy bibliography compiled by the TAT); or if unavailable, then cite to gray literature, unpublished but accessible data, or personal communications with identified experts.

**Comment 11 - Defective Scoping of Impact Analysis:** The EA includes a scope of impact analysis that gyrates wildly, showing a huge bias for purported long-term benefits and massive disregard of potential long-term impacts. **The EA completely fails to discuss and compare any of the impact topics under the "Deny the Permit" alternative or any other alternative besides the "Issuance of the Permit" alternative, rendering the entire Potential Impact discussion unbalanced and essentially useless.** This violates the CEQ NEPA regulations which require "substantially similar" treatment of the alternatives in a NEPA compliance document, 40 CFR 1508.9(b) and -1502.14, (see CEQ's 40 Most Asked NEPA Questions, numbers 36a and 5b).

Further, the EA repeatedly tries to justify this project by focusing on the benefits of long-term release in the San Joaquin Valley in California - improved biocontrol, fewer pesticides, increased cotton production, and so on - **but the EA does not even describe the affected environment there or provide even superficial discussion of any potential long-term negative impacts in the San Joaquin Valley.** This is most obvious in the impact discussion sections, "Effects on chemical load..." and "Risks to Nontarget Plants....." - they tout long-term benefits in the San Joaquin Valley almost exclusively.

The CEQ's Most Asked NEPA Questions, number 13, approves the use of scoping for EAs. This EA desperately suffers from lack of scoping, i.e., not keeping the scale of the benefits/impacts analysis consistent in time and space.

**Requested change:** Prior to doing revised NEPA compliance - which should be in the form of a full EIS - conduct a formal scoping process as outlined by the CEQ regulations to ensure a professional and consistent



document, such that the decisionmaker is not unfairly lured by touted long-term benefits and ignorant of potential long-term impacts. Evenly compare the impacts - using comparable time and geographic frameworks - under each of the newly-scoped impact topics for the Proposed Action, the No Action Alternative, and one or two Action Alternatives as described in Comment 4, above.

**Comment 12 - Failure to Follow APHIS's Analytical Protocols:** The EA fails to follow prescribed protocols for impact analysis, as set forth by Young, Ingebritsen, and Foudin (1999, at pp.s 371-75), all of whom work or worked for APHIS in biotechnology permitting. First, it fails to provide the detailed information outlined therein, in the sections entitled "20.3.4 - Evaluation of the Nontransgenic Form Proposed for Introduction" and "20.3.5 Evaluation of the Transgenic Form." Further, the EA fails to provide the bulk of the information needed for confined releases (with the exceptions of elements 3 and 7), specifically:

- 1. History of introductions of the nontransgenic form*
- 2. Life table/history attributes of the transgenic form*
- 3. Nature/function of the genetic alteration, e.g., mode of inheritance, stability, degree of expression*
- 4. Behavior of the trait in caged or mesocosm situations*
- 5. Mathematical modeling of released populations, to include probability of establishment*
- 6. Consequences of inadvertent escape and establishment*
- 7. Methods for monitoring and control.*

**Requested change:** Follow the analytical protocols prescribed by Young, Ingebritsen, and Foudin (1999), and specifically provide the missing information for confined releases, i.e., elements 1, 2, 4, 5, and 6.

**Comment 13 - Failure to Follow Expert Analytical Approaches:** The EA ignored the leading independent commentator in this field, Hoy (1999, at p. 348), who described an expert-developed decision making protocol, involving 22 separate questions to be answered prior to releasing transgenic arthropods into experimental field plots. Further, the EA lacks the sort of structured objective assessment of potential benefits and costs advocated by many scientists, e.g., Crawley (1999) and as mentioned in Hoy (1999, at p. 360), where she also notes "almost no funding has been allocated to fundamental research on risk assessments of transgenic arthropods."

**Requested change:** In revising the NEPA documentation for the proposal, follow the most advanced analytical approaches, ensure that a balanced assessment of costs and benefits is transparently documented, and do the fundamental risk assessment research called for by Hoy first. These are all consistent with NEPA's aims. If APHIS lacks funds to carry out the

needed research, then it should not undertake field releases. Comment 14 - Inconsistency with Federal Law. The "impact analysis" section in the EA called "Consistency of Proposal with Other Environmental Requirements" shows an unprofessional disregard for Federal law. It merely says you "believe" the proposal is consistent with other laws and makes some self-congratulatory conclusions, without even discussing what those other environmental requirements are, such as avoiding introduction of a plant pest under the Plant Protection Act, avoiding harm to native species and their habitats under the ESA, and complying with Executive Order 13112 on Invasive Species.

Hoy (1999) and others have identified the potential invasiveness of GE arthropods as a risk of key concern due to potential impacts on native species and other values. An important duty rests on Federal agencies to take careful steps to avoid the introduction of harmful invasive species (whether GE or non-GE), under EO 13112 of February 3, 1999. **The EA here addresses a well-known invasive pest, the pink bollworm, proposed for deliberate introduction.** The EO, still in effect, provides in pertinent part:

*Section 2. Federal Agency Duties.*

*(a) Each Federal agency whose actions may affect the status of invasive species shall, to the extent practicable and permitted by law,*

- (1) identify such actions;*
- (2) subject to the availability of appropriations, and within Administration budgetary limits, use relevant programs and authorities to: (i) prevent the introduction of invasive species;....*
- (3) not authorize, fund, or carry out actions that it believes are likely to cause or promote the introduction or spread of invasive species in the United States or elsewhere unless, pursuant to guidelines that it has prescribed, the agency has determined and made public its determination that the benefits of such actions clearly outweigh the potential harm caused by invasive species; and that all feasible and prudent measures to minimize risk of harm will be taken in conjunction with the actions. Because APHIS here intends to "authorize, fund, or carry out actions" that "may affect the status*

*of invasive species" (the pink bollworm), it must adopt appropriate guidelines addressing the benefits and harms and ways to minimize the risks. Requested change: With Office of General Counsel assistance, document the applicable Federal laws and indicate how the various alternatives may or may not be consistent with them, including the "guidelines" requirements of EO 13112. The latter should be drafted in consultation with the national Invasive Species Council, created by the EO.*

**Comment 15 - Unanalyzed Genetic, Quality Control, and**

**Management Risks:** The EA fails to address known genetic stability and quality control risks in the use of GE insects in the SIT technique, such as the potential to "impact negatively on important life traits, e.g., longevity, irrespective of whether the transgene is expressed or not" and other impacts, per Robinson and Franz (1999, at p. 309-10). Further, the EA fails to address the potential impact of the proposal on the availability of space in mass-rearing facilities for GE insects or on the need "to drastically improve quarantine precautions" for rearing facilities, per Robinson and Franz (1999, at pp. 315-16).

**Requested change:** Include a full analysis of the potential impacts mentioned by Robinson and Franz, above.

**Comment 16 - Unanalyzed Potentially Devastating Risks of Gene**

**Mobilization:** The EA mentions *piggyBac* in relation to Baculovirus, but fails to fully analyze the likelihood that the virus will rescue the inserted transposon and mobilize it for transfer to cotton, other plants, and animals, such as mammals (including humans). As stated in the previously-submitted comment on the EA by Professor Joe Cummins of the Univ. of Western Ontario and Dr. Mae-Wan Ho of the Institute of Science in Society, "adequate laboratory studies must be done prior to the field release of potentially dangerous organisms." That comment provides scientific information illustrating the "potential for significant impacts," - of a horrific and devastating nature - such that preparation of a full EIS is required under NEPA. The commenters show the potential inability of the proposed action to actually "contain" the foreseeable genetic interactions. They also provide evidence that *piggyBac* transposon vectors carrying transgenes are unstable and can undergo secondary mobilization to transfer horizontally. Conducting a release in which these potentially significant impacts could occur, as Drs. Cummins and Ho indicate, would be flagrantly irresponsible. The EIS process is ideally suited to analyzing this sort of risk prior to APHIS undertaking the proposed action.

**Requested change:** Provide a detailed analysis in a full EIS based on

**published, peer-reviewed, studies in the laboratory** of the potential for the various proposed, planned, and foreseeable genetic transformations of the pink bollworm to cause harmful genetic changes in cotton, other plants, and animals.

**Comment 17 - A Full EIS is Required For the Entire Transgenic Pink Bollworm SIT Project:** NEPA forbids "piecemealing" of an integrated project, that is, breaking it up into several pieces, each of which alone may not pose potentially significant impacts, but which would if considered as an integrated whole. The proposed field release is not an independent stand-alone project; it is frankly admitted by APHIS to be integral to the larger project of incorporating a much riskier transformation- inserting a "terminator gene" for females - into the current pink bollworm SIT release program (see Briggs [2001], quoting project proponent Thomas Miller on the proposed field releases: "Our ultimate plans are to insert conditional lethal genes..."; and Robinson and Franz [1999, pp. 313-14], indicating that genetic marking is integral to, and does not stand apart from, transgenic SIT programs). Indeed, the EA enthusiastically and repeatedly touts the long-term benefits that will derive from the whole, integrated transgenic SIT project. For example, in the Potential Impacts discussion, under the sections "Potential impacts on humans," "Effects on chemical load on the environment," and "Risks to nontarget plants and animals," the EA says:

*The proposed actions are not expected to adversely affect any of these [minorities and low income] groups and may benefit them by contributing to the reduction of pesticide exposure from habitation near cotton fields and occupational pesticide exposure of cotton workers....The use of the EGFP marker gene to facilitate the pink bollworm SIT program contributes to lowering the pesticide load on the environment....Endangered or threatened species would be at much higher risks due to pesticides used on cotton than by the nature of these experiments that evaluate EGFP marking of pink bollworms to facilitate the SIT program.*

As discussed above in the scoping context, it is unfair and violates NEPA requirements to weigh the long-term benefits of transgenic pink bollworms in the SIT program, without even assessing whether potential long-term negative impacts may occur from using transgenic pink bollworms in the SIT program, which the EA utterly fails to do. The EA does not even describe anything about the area where the SIT program occurs or what the whole SIT program is, other than to tout its benefits. NEPA compliance must address the whole project, not just piece by piece, and a full EIS is clearly the vehicle to address something of the scope and

magnitude as releasing novel, untested, transgenic insects across the entire San Joaquin Valley. APHIS has not mentioned any pre-existing NEPA compliance document for that San Joaquin Valley SIT effort off of which the present project could "tier" (see 40 CFR 1508.28); CFS is informed that none exists. Indeed, all prior suggestions in this comment regarding defects in the site-specific analysis in the EA must be "scaled-up" to address the San Joaquin Valley transgenic SIT project. APHIS plainly has committed substantial resources to this project already, which in itself violates NEPA. This fact counsels for, not against, a full EIS now on the entire transgenic SIT project. The project involves potentially precedent-setting releases with high scientific uncertainty regarding long-term and cumulative impacts; all of these factors indicate strongly against a Finding of No Significant Impact (FONSI).

We note for perspective that past APHIS EAs have been wrong. They grossly underestimated the potential weediness of GM herbicide-resistant canola, the massive potential for StarLink Cry9C corn to affect non-GM corn and the human food supply, and the potential lethality of Bt corn pollen to lepidopterans, such as the monarch butterfly. In each of these cases, APHIS prepared an EA and FONSI, failing to foresee the potentially significant impacts for which a full EIS should have been done (and still should be done). APHIS should avoid further adding to its unreassuring record.

Our call for an EIS now is further supported by respected commenters who urge that major potential long term impacts of GE insect proposals need to be considered earlier, rather than later:

*The scientist developing a new agent must make an honest, imaginative leap into the future and try to predict any possible dangerous consequences - the responsibility for risk assessment must be shouldered by the scientist, together with the regulatory agencies. Because the safety questions are numerous, those of the greatest potential significance, both in the short term and in the long term, should be examined first. (Beard et al. 1998)*

This is entirely consistent with the NEPA requirement that agencies conduct a hard look at potentially significant impacts **prior** to committing resources to any course of action.

APHIS has failed in this regard. APHIS is well aware that the history of biological control projects includes occasionally unexpected negative impacts, such as introducing the voracious mongoose to control rats in Hawaii, which caused far more harm than good. Due to poor planning, poor science, or unforeseen events, even some modern biocontrol agents have switched their attack to native species, in a very few cases

endangering them (Louda et al. 1997; Follet and Duan 2000). USDA has a bad history of introducing well-intended, but extremely harmful, invasive species, such as kudzu and multiflora rose (U.S. Congress, OTA 1993). The present EA provides no analysis of these potential long-term risks, either in the immediate project area or scaled-up to the full San Joaquin Valley SIT program.

**Requested change:** Commit to preparing a full EIS for the entire transgenic pink bollworm SIT Project including its proposed use in the San Joaquin Valley, which addresses all potentially significant impacts, including direct and indirect effects, cumulative impacts, the potential for gene jumping, host-switching, long-term invasiveness, and so on.

**Comment 18 - Lack of Prior NEPA Compliance for APHIS's**

**Transgenic Arthropod Program:** The EA is premature and inadequate because it must be preceded by programmatic NEPA compliance for APHIS's GE arthropods program, of which the proposed action in the EA is a part. A programmatic EIS is required under the CEQ NEPA regulation, 40 CFR § 1508.18b, which defines a "Federal action" to include:

*(3) Adoption of programs, such as a group of concerted actions to implement a specific policy or plan; systematic and connected agency decisions allocating agency resources to implement a specific statutory program or executive directive.*

Further, under the 40 CFR § 1508.23 definition of Proposal:

*A proposal may exist in fact as well as by agency declaration that one exists.*

(See also CEQ 40 Most Asked NEPA Questions, number 24a, on the need for programmatic EISs.)

- APHIS plainly has undertaken new and concerted actions in the area of GE arthropods, including, but not limited to, the following policy decisions, each of which pose potential significant environmental impacts by way of potentially allowing harmful releases.
- APHIS's own development and promotion of GE arthropods such as the pink bollworm (the present project), codling moth, medfly, and other proposed future projects (R. Rose, APHIS, pers. comm.);

- APHIS's conducting of NEPA analysis and permitting of its own proposals internally, given the plain institutional conflict of interest within the agency;
- APHIS's recent elimination of the prior program of providing Regulatory Assessments and courtesy permits to prospective GE arthropod developers for whom regulatory requirements may be unclear, and the recent elimination of its formerly very informative transgenic arthropod webpages, <http://www.aphis.usda.gov/biotech/arthropod/>, now just a barebones directory.
- APHIS's rejection of the former (and award-winning) TAT's role in reviewing EAs, thus foregoing much-needed expert advice;
- APHIS's refusal to follow prescribed analytical steps or to issue guidelines or regulations to improve the coverage for GE arthropods, contrary to prior practice and assurances by its own biotechnology officials Young, Ingebritsen, and Foudin (1999);
- APHIS's abstention from fundamental research on risk issues as called for by many experts (e.g., Hoy, 1999, at p. 361);
- APHIS's deliberate abstention from analyzing and regulating genetically engineered arthropod vectors of animal diseases (GEAVADs) and genetically engineered arthropod vectors of human diseases, many of which also fall under APHIS's jurisdiction as plant or animal pests, particularly in view of the failure of other agencies to take up the regulatory burden for these potentially risky species; and
- APHIS's adherence to its current NEPA regulation, at 7 CFR 372.5(b)(4), which provides that an EA will normally be considered adequate for permitting releases of GE organisms, creating a presumption that an EA and FONSI will suffice instead of an EIS to analyze the novel and precedent-setting introduction of GE arthropods (noting also that APHIS has rigidly followed this presumption for GE plants, having yet to require even one EIS as it has permitted the planting of tens of millions of hectares of GE crops).

These actions and policies as a combined whole constitute a major Federal foray into laissez-faire promotion of transgenic arthropods, with potentially significant impacts on broad parameters of the natural and human-built environments, including long-term genetic impacts. APHIS has not formally declared that these concerted actions constitute a proposal

or a program, but actions speak louder than words, as stated in § 1508.23, above. A full EIS is required prior to proceeding with individual parts of the foray, yet APHIS has done no NEPA documentation for this program area at all. Further, APHIS has an ongoing, but as yet unfulfilled, obligation to comply with EO 13112 on Invasive Species, discussed above in Comment 14. APHIS needs to adopt and publish its guidelines addressing the benefits and harms, and ways to minimize the risks as it "authorizes, funds, or carries out actions" that "may affect the status of invasive species," obviously including release of GE plant pests like the transgenic pink bollworm and GEAVADs. When it issues these guidelines APHIS also will need to comply with NEPA.

The existence of APHIS's concerted program became distressing clear when reading the pink bollworm EA. Rather than analyzing the proposal it advocates for it, thereby undercutting any appearance of objectivity. The "regulatory" efforts of APHIS here must be considered part and parcel of APHIS's overall promotion program for GE arthropods and cannot proceed until the program is analyzed under NEPA. Even a full EIS limited to this project or to the San Joaquin Valley SIT project would be inadequate until APHIS's whole program is assessed. To quote a key case:

*In many ways, a programmatic EIS is superior to a limited, contract specific EIS because it examines an entire policy initiative rather than performing a piecemeal analysis within the structure of a single agency action. (Assoc. of Public Agency Customers, Inc. v. BPA et al., 126 F.3d 1158, 1184).*

**Requested change:** Conduct programmatic NEPA compliance in the form of a full EIS on APHIS's entire current program of developing, promoting, and regulating (or abstaining from regulating) GE arthropods, and on the guidelines required by EO 13112, prior to proceeding with the proposed action.

The above comments establish that potentially significant environmental impacts exist related to this precedent-setting transgenic SIT project, and the broader USDA APHIS program from which it sprang, such that full EISs on both the project and the program are required. We request that you commission an independent environmental consultant to embark on preparation of these EISs immediately. Alternatively, if you are unwilling to apply the highest standards of environmental review in this area, we request that you terminate both this project and your broader program of developing, promoting, and permitting the use of GE arthropods.



Thank you for the opportunity to submit these comments; we look forward to your written responses to each of them separately. In closing, if you seek to go ahead with the proposal by issuing a FONSI on the present record without accomplishing the requested compliance with NEPA and other applicable laws, we anticipate filing a lawsuit challenging such a decision as arbitrary, capricious, an abuse of discretion, and contrary to law. For further information regarding this comment, please contact Peter T. Jenkins, Attorney/Policy Analyst, Tel: 202.547.9359 ext. 13; email: [peterjenkins@icta.org](mailto:peterjenkins@icta.org) . Please notify him immediately of any future decisions related to APHIS's proposal.

Sincerely,

Joseph Mendelson III, Legal Director

Peter T. Jenkins, Attorney/Policy Analyst

cc: Secretary of Interior Gale Norton, with 60 Day Notice of Intent to Sue  
Acting USFWS Director, with 60 Day Notice of Intent to Sue  
Secretary of Agriculture Ann Veneman  
USDA APHIS Administrator Craig Reed  
Shirley Ingebritsen, USDA APHIS  
Arnold Foudin, USDA APHIS  
All Members of the USDA Advisory Committee on Agricultural  
Biotechnology

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