CITIZEN PETITION TO ACTING ADMINISTRATOR, UNITED STATES DEPARTMENT OF AGRICULTURE, ANIMAL AND PLANT HEALTH INSPECTION SERVICE

Petition on Genetically Engineered Arthropods

Submitted by: Center for Food Safety and the International Center for Technology Assessment

Date: September 26, 2001

EXECUTIVE SUMMARY

This Citizen Petition seeks comprehensive improvements in the way the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) regulates and analyzes genetically engineered (GE) arthropods. The Petition builds to a large extent on prior APHIS policy initiatives and assurances that have not borne fruit. The Requested Actions include:

- Promulgate robust, state-of-the-art regulations on the development and release of GE arthropods that are pests of animals, including arthropod vectors of animal diseases;

- Formally re-affirm and broadly communicate APHIS' previous policy statement that permission to conduct limited field trials or unlimited releases of such GE arthropods will not be granted until the necessary regulations are in place;

- Cooperate with the Public Health Service to draft parallel, coordinated regulations covering the development and release of GE arthropod vectors of human diseases, such as mosquitos, which in many cases also vector animal diseases;
- Markedly improve compliance with the National Environmental Policy Act, the Endangered Species Act, and other applicable laws, both for individual GE arthropod release projects, such as APHIS' own proposed GE pink bollworm project, and for APHIS's GE arthropod program as a whole; and

- Maintain the highest standards of expertise and public openness in APHIS's approach.

If APHIS continues its *laissez-faire* approach and fails to regulate comprehensively and effectively in this area, the potential for unfortunate mistakes by incautious investigators in the development and release of GE arthropods will be unacceptably high. **Indeed, lack of Federal oversight in this area translates into lack of knowledge to differentiate who is conducting legitimate research and who may be conducting experiments that pose potential "bioterror" threats in the form of more deadly vectors of animal and human diseases.** The public safety, environmental, and economic interests involved argue strongly for a prompt, positive response. Further, remarkable support exists among the potentially regulated scientific community and among the agency's own scientists for the bulk of the changes requested herein.

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PETITIONERS

Petitioners are the *Center for Food Safety* (CFS) and the *International Center for Technology Assessment* (ICTA) and their undersigned individual members and officers. CFS and ICTA are non-profit, membership organizations located at 660 Pennsylvania Ave. SE, Suite 302, Washington, DC 20003. Petitioner CFS was established to address the increasing concerns about the impacts of our food production system on human health, animal welfare, and the environment. Petitioner ICTA is devoted to fully exploring the economic, ethical, social, environmental and political impacts that can result from the applications of technology.

Petitioners, together with their several thousand active members, have diverse economic, recreational, health, conservation, scientific, and aesthetic interests related to arthropods and their habitats that may be negatively impacted if mistakes occur or unforeseen consequences result from the development and release of GE arthropods.

Petitioners have filed this Petition on an urgent basis due to the pendency of APHIS' decision regarding the proposed field release of the GE pink bollworm, discussed herein. Petitioners anticipate future co-sponsors, who will be identified to APHIS subsequently.

BACKGROUND

Pursuant to the Right to Petition Government Clause in the First Amendment to the United States Constitution,[(1)] the right to petition for new or amended regulations under the Administrative Procedure Act,[(2)] and the USDA's implementing regulations,[(3)] the Petitioners respectfully submit this Petition to the Acting Administrator of APHIS seeking

dramatic improvements in its regulations and programs related to GE arthropods.[4]

Arthropods predominate as the most abundant group of multicellular organisms on earth - one of the oldest and most diverse, with more than one million classified species.[5] Arthropods are a leading cause of disease transmission to humans, domesticated and wild animals, and domesticated and wild plants. They cause massive crop and livestock damage, either directly themselves or by acting as vectors for plant and animal pathogens. However, they also are critical to many natural processes, such as decomposition of organic matter, providing free ecosystem services of incalculable value. Some, such as honeybees and other pollinators, are essential for agriculture. Native arthropods also provide immense scientific, aesthetic, and recreational benefits. At least 54 U.S. arthropods are listed as threatened or endangered under the Endangered Species Act.[6] Many others are proposed or likely candidates for listing in the future.

Much current genetic engineering research focuses on altering harmful arthropods, especially mosquitos, to protect human health from diseases, such as malaria; other research seeks ways to protect domesticated plants and animals from damage caused directly by arthropods or by the pathogens that they vector.[7] While these enterprises have laudable goals, they also are fraught with many dangers. Altering fundamental traits in free-ranging insects such as fecundity, sex ratio, habitat preference, pesticide resistance, temperature tolerance, and vector competence may raise unforeseen, unintended, and undesirable secondary risks. Fully analyzing such risks may require consideration of lengthy time periods - perhaps hundreds of arthropod generations during which evolutionary selection may occur - projected across a vast array of ecosystem and genetic contexts. In the words of a leading arthropod biotechnology researcher (emphasis added):

Many questions need to be answered before we can safely release transgenic arthropods into the environment...What is the probability that the transgenic insects (released into the environment) will create future environmental problems? Will transgenes inserted into insects somehow be transferred horizontally through known or currently unknown mechanisms to other species to create new pests? Can we develop mitigation methods or techniques for retrieving transgenic insects from the environment after their release should they perform in unexpected ways? The issues surrounding potential risks will **require both researchers and regulatory agencies to accept new responsibilities**....

APHIS cannot deny the serious risks involved. Appendix A to this Petition, a document obtained from agency files, is a draft hierarchy of the

potential risks, focused on GE animal disease vectors. The risk categories include, for example: "direct human impact," "spread of the engineered characteristics to species other than the target vector," and "alteration of ecological community." Appendix B, also from APHIS' files, dispels any notion that these concerns are isolated or theoretical. Entitled "Arthropods for which Transgenic Research has been Reported," Appendix B lists 32 individual species or larger taxa reported as of 1999. These include15 direct plant pests, 4 indirect plant pests, 5 animal pests, 6 disease vectors, and 2 miscellaneous pests. Undoubtedly more development has occurred in the two years since APHIS compiled this list.

This Petition addresses a topic of intense public interest. The real prospect of deliberate or accidental releases of novel engineered animals in a laissez-faire regulatory climate raises highly symbolic as well as practical issues. **Lack of Federal oversight has led to unnecessary ignorance regarding experiments that could even pose potential "bioterror" threats, such as mosquitos genetically modified to be more, rather than less, effective vectors of animal and human diseases.** (The transformations required likely are similar.) Major newspapers - the Wall Street Journal, USA Today, and the Washington Post - have published well-researched feature stories on the regulatory gaps detailed below.[(9)] In those articles, several scientists - who themselves are developing GE arthropods - went on record criticizing the lack of scrutiny by the Federal government.

Nothing can justify or excuse a failure to apply the highest standards of scientific scrutiny to novel arthropod development and release projects, which may affect not only public health, safety, and economic interests, but also may alter basic ecosystem processes, indeed, may alter the course of millions of years of evolution. In endeavors of this potential magnitude, no responsible agency can tolerate the current piecemeal regulatory scheme. For these reasons, **Petitioners request APHIS to promptly undertake the following five remedial actions**, each of which is reasonable, necessary, and carefully tailored to the problem.

FIVE REQUESTED ACTIONS

1. Adopt Robust Regulations for Genetic Engineering of Arthropods that are Potential Animal Pests, including Vectors of Animal Diseases; Cooperate with the Public Health Service on Coordinated Regulations for GE Arthropod Vectors of Human Diseases; and Improve APHIS's GE Arthropod Program.

A. Statutory Authority

APHIS has general statutory authority over pests of animals, including vectors of animal diseases. (Appendix C is APHIS's own website compilation further describing its applicable legal authority.)

21 USC § 111. Regulations to prevent contagious disease

The Secretary of Agriculture shall have authority to make such regulations and take such measures as he may deem proper to prevent the introduction or dissemination of the contagion of any contagious, infectious, or communicable disease of animals from a foreign country into the United States or from one State or Territory of the United States or the District of Columbia to another, and to seize, quarantine, and dispose of any hay, straw, forage, or similar material, or any meats, hides, or other animal products coming from an infected foreign country to the United States, or from one State or Territory or the District of Columbia in transit to another State or Territory or the District of Columbia whenever in his judgment such action is advisable in order to guard against the introduction or spread of such contagion.

B. Argument: Promulgate Regulations Under APHIS' Statutory Authority, in Coordination with the Public Health Service

APHIS has failed to regulate under its statutory authority in the manner clearly called for both by agency scientists and numerous outside experts, that is, to: 1) issue appropriate regulations on the development and release of GE arthropods that are potential animal pests, including GE arthropod vectors of animal diseases (GEAVADs); and 2) cooperate with the Public Health Service (PHS) on closely coordinated regulations for GE arthropod vectors of human diseases (GEAVHDs), which also may be GEAVADS. No APHIS regulation mentions GE animal pests, GEAVADs, or GEAVHDs. Yet, APHIS already has received requests for guidance on developing and moving GE mosquitos, which are both GEAVADs and GEAVHDs. Put simply, the Secretary of Agriculture has failed to take the steps necessary under 21 USC § 111 to prevent GEAVAD experiments from "backfiring" (or being carried out with malicious intent) and creating potentially worse animal disease problems or other environmental or health problems.

APHIS currently exercises regulatory oversight for GE arthropods that are potential plant pests.[(10)] It has the statutory responsibility to promulgate similar regulations on GE arthropods that are potential animal pests, including GEAVADs. Yet, the agency has no formal evaluation or permitting process in place. Developers of such GE arthropods have no clear guidance as to what they are required to do. And the public, law enforcement officials, and the scientific community have no trustworthy way to be informed about what is happening in the field. They are

deprived of knowledge required to differentiate who is conducting legitimate research and who may be conducting experiments that pose serious animal or human disease threats. APHIS is fully aware that more projects are expected aimed at widespread releases. The agency cannot reasonably refrain from regulating this new technology.

Many emerging, infectious, arthropod-vectored diseases, such as West Nile virus, affect both animals and people. But, none of the agencies that investigate, provide funding, or give guidance on vector-borne human diseases have adopted specific regulations that would govern the release of all GEAVHDs. In particular, the PHS has regulatory authority over arthropod vectors of human diseases.[(11)] However, the PHS has promulgated no broadly applicable regulations addressing development and release of their GE forms. State authorities and academic Institutional Biosafety Committees reportedly are seeking formal regulatory guidance from the Federal government and are not receiving it.

Petitioners plan to submit a separate petition to the PHS seeking issuance of new parallel regulations and other related actions for GEAVHDs. These changes must occur in coordination with the APHIS actions petitioned for here, as in many cases they will need to address the identical GE arthropods and the same potential public safety, environmental, and economic risks.[(12)] If APHIS approves release of a GEAVAD, it may also be a GEAVHD that by all logic should also have PHS approval, and vice versa.[(13)]

APHIS should not start from scratch. APHIS already has indicated support for a regulatory approach for GE arthropod animal pests, emphasizing GEAVADs. This has been summarized on APHIS's website since at least 1999 (see Appendix C). This originated from APHIS's former award-winning arthropod biotechnology program, which, plainly and unfortunately, has lost its momentum.[(14)] APHIS also has made previous, but unsuccessful, attempts to cooperate with PHS and other agencies on regulating GEAVHDs. Petitioners support the direction APHIS previously embarked on. The journey needs to be completed by undertaking the specific Requested Actions in this Petition.

Failure to adopt regulations for GE arthropod animal pests would contravene assurances made not only on the agency's website, but also in an APHIS-approved chapter in the seminal book in the field, authored by biotechnology officials Young, Ingebritsen, and Foudin.[(15)] Further, in early 1999, Dr. Foudin was quoted in the national press: "The kind of experimentation some people are talking about doing will require considerable oversight."[(16)] Yet, two and one-half years later, investigators are doing the experiments and moving their creations around the nation and the promised oversight remains absent.

Responsible members of the potentially regulated scientific community have been on record for several years supporting the need for a well thought-out APHIS regulatory scheme, coordinated with PHS. The first U.S. scientist to field test a GE arthropod, Dr. Marjorie Hoy of the Univ. of Florida, has stated that the APHIS regulations are insufficient and there are "gaps" in the system.(17) Researcher Dr. David O'Brachta of the Biotechnology Institute at the Univ. of Maryland, who sought to ship GE mosquitos across the country, stated:

It's time for the federal government to give us guidance, but no agency is willing to claim authority.(18)

Dr. Charles Beard of the Center for Disease Control and his collaborators, who are developing GE and paratransgenic vectors of human diseases, wrote in 1998 (emphasis added):

[T]he 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 appropriate regulatory agencies....As the tools and methods that allow broader applications of this approach are developed, and actual products arrive at the point of field testing, **permitting and regulation will be required**. (19)

Further, a resolution of the American Mosquito Control Association (AMCA), the leading organization of academic and regulatory mosquito experts, supports proactive APHIS involvement. The resolution notes that GE mosquitos "may alter [disease] transmission dynamics in ways that are unanticipated and unpredictable."(20) The AMCA urges APHIS to develop guidelines for their release.

Dr. Hoy eloquently stated the biological need for tighter Federal oversight:

At this stage, people are more focused on how to transform the genomes than they are on assessing the risks. The issues of concern have to do with the unknown properties of the organisms and the genes. The release of transgenic arthropods is risky unless we know more about the basic biology, ecology, and behavior than we know today. What are the long-term effects? What are the effects on non-target insects? How will beneficial or endangered species be affected?(21)

The responsible scientific community fears the public and media perception that proposed GE arthropod releases lack governmental review and approval. They also fear this gap could lead to poorly-conceived releases by short-sighted or incautious investigators, ultimately resulting

in backlashes against future releases in the form of litigation or drastic legislative reaction. Add to this the admission of a key APHIS official:

[T]he perception that APHIS was exercising no oversight could be very damaging to our image and negatively affect subsequent agency actions.[22]

Based on all of the above points, little doubt exists that APHIS must promptly act. Given that the Secretary of Agriculture has the statutory duty to issue protective regulations, her failure to do so here would be arbitrary and capricious and constitute an abuse of discretion, in violation of the Administrative Procedure Act.[23]

Finally, APHIS already is on record as stating (from Appendix C; emphasis added):

Permits to conduct limited field trials or unlimited releases into the environment of GEAVADs typically **will not be issued until specific regulations are in place** and the appropriate assessments can be conducted.

This policy statement amounts to a clear de facto moratorium on field trials or releases pending issuance of the regulations sought here. Petitioners support this moratorium and ask that it be formalized.

C. Argument: Re-establish the Positive Aspects of APHIS' GE Arthropod Program Immediately

APHIS' most recent activity in the arthropod biotechnology area is releasing the Environmental Assessment (EA) for the GE pink bollworm, a plant pest.[24] Unfortunately, this document deviated from previous commitments made by APHIS officials regarding the expertise deployed and the public openness of the GE arthropod program. APHIS previously had a well-respected program in place including the award-winning Technical Advisory Team, which was ignored in the EA for the pink bollworm. Further, it is simply bad practice to fail to demonstrate consideration of readily available advice on entomology, genetics, arthropod ecology, and other disciplines.

Also, APHIS has eliminated its prior policy of providing Regulatory Assessments and Courtesy Permits to prospective GE arthropod developers for organisms that may not fall directly under APHIS's jurisdiction. Eliminating this has reduced the information available to the public and the scientific community regarding developments in this field. Also, APHIS's GE arthropod website used to be very informative, but it has not been updated and kept to high standards since 1999.[25] (Other

broader, more long-term, fixes to problems with APHIS' GE arthropod and connected programs are discussed in the following sections of this Petition.)

The worst thing APHIS can do now is to regress, become secretive, and fail to conduct adequate public outreach or provide public information about developments in this field. Such an approach would guarantee unnecessary conflict and contravene advice from virtually all the GE arthropod experts cited herein. New regulations are not necessary to at least return to the program's former award-winning ways immediately, but these ways ultimately should be formalized and made more solid in the new regulations.

Requested Action:

i. Adoptcomprehensive regulations for the development and release of GE arthropod animal pests, including GEAVADs. The new regulations should mandate a permit process incorporating state-of-the-art environmental, economic, and health impact analyses, and be subject to public notice and comment prior to permit decisions.

ii. Formally reaffirm and broadly communicate APHIS' previously announced de facto moratorium, which stated that permission to conduct limited field trials or unlimited releases into the environment of GEAVADs will not be granted until specific regulations are in place.

iii. Work with PHS on closely coordinated, parallel regulations for GEAVHDs.

iv. Immediately re-establish the Regulatory Assessment and Courtesy Permit process APHIS formerly conducted; re-establish and demonstrate consideration of input from the Technical Advisory Team, expanding it to provide expert advice to APHIS on all GE plant pest, GE animal pest, and GEAVHD proposals.[(26)] Then, formalize the review processes in the requested new regulations.

v. Update and maintain the former GE arthropod website consistent with its former high standards. Exhibit a high degree of public openness, including extensive outreach and information efforts, both for projects that APHIS conducts itself and for those over which it has regulatory authority.

2. Improve National Environmental Policy Act Compliance for GE Arthropod Projects.[(27)]

The National Environmental Policy Act (NEPA) is the cross-cutting statute that requires environmental impact assessment for all discretionary,

non excluded Federal agency actions.[28] All Federal agencies are required to prepare a "detailed statement" (or EIS) regarding all "major federal actions significantly affecting the quality of the human environment . . .."[29] To determine whether an EIS is required, Federal agencies generally must first prepare an Environmental Assessment (EA), that provides sufficient evidence and analysis to support the agency's determination on whether the impacts are potentially significant. The Council on Environmental Quality (CEQ), which oversees NEPA implementation by Federal agencies, has adopted regulations listing factors for determining the "significance" of an action. Those factors most applicable to novel GE arthropod proposals include:

- the degree to which the proposed action affects public health or safety,

- the degree to which the effects on the quality of the human environment are likely to be highly controversial,

- the degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks,

- the degree to which the action may establish a precedent for future actions with significant effects or represents a decision in principle about a future consideration. [30]

According to Court decisions, the "presence of one or more of these factors should result in an agency decision to prepare an EIS."[31] For permitting releases of all GE organisms, APHIS's current NEPA implementing regulation, 7 CFR § 372.5(b)(4) (b), provides (emphasis added):

Sec. 372.5 Classification of actions....(b) Actions normally requiring environmental assessments but not necessarily environmental impact statements. This class of APHIS actions may involve the agency as a whole or an entire program, but generally is related to a more discrete program component and is characterized by its limited scope (particular sites, species, or activities) and potential effect (impacting relatively few environmental values or systems)....Actions in this class include:....(4) Approvals and issuance of permits for proposals involving **genetically engineered** or nonindigenous species, except for actions that are categorically excluded, as provided in paragraph (c) of this section.

The presumption that an EA normally will suffice rather than a full EIS means that APHIS presumes the impacts of GE organism releases are not "significant" and that a Finding of No Significant Impact (FONSI) will result. This laissez-faire presumption contravenes the purpose of NEPA and contravenes the CEQ regulations by minimizing the required analysis

for controversial, precedent-setting arthropod introductions that may pose uncertain, unique, and potentially significant impacts, as outlined in the Background section of this Petition.[32]

The problem with this unbalanced regulatory presumption manifested itself in APHIS' EA on its own proposal for a confined field study of the GE pink bollworm. APHIS failed to take the "hard look" at the full scope of the potential impacts required by NEPA.[33] The EA demonstrated no independent review of the impacts beyond the opinions put forth by the project proponents themselves. As Petitioners showed in their earlier comment submitted on this EA (referenced in fn. 24,above), APHIS did not adequately determine whether the impacts were "significant" such that an EIS would have been required. Petitioners were not alone in their criticism; a separate very critical comment regarding the adequacy of APHIS's scientific risk analysis was submitted by a leading GE arthropod researcher, Dr. David O'Brachta of the University of Maryland Biotechnology Institute.[34]

APHIS has never prepared a full EIS, neither on its dozens of prior approvals for broad releases of crops and other GE products, now covering tens of millions of hectares, nor on the cumulative effects of APHIS' decisions. In sum, the NEPA regulation needs amendment to eliminate the presumption that an EIS is unnecessary for novel GE releases and APHIS generally needs to take NEPA more seriously.

Further, in the GE pink bollworm EA, APHIS did not follow its own prescribed analytical protocol for confined field releases of GE arthropods, contrary to prior practice and to published assurances by APHIS biotechnology officials.[35] The protocol represents common-sense questions to answer in order to minimize potential environmental impacts. The protocol has been posted on APHIS's transgenic arthropod website apparently since1995; nevertheless, the pink bollworm EA simply ignored many of the questions.[36]

Finally, a strong need exists in the cases **when APHIS itself is the project developer** for the agency to commission an outside NEPA consultant, instead of doing the analysis internally. An obvious conflict of interest exists. Contracted NEPA analysis is common for Federal agency proposals and very appropriate to avoid the temptation toward rubberstamping, which the pink bollworm EA amply demonstrated.

Requested Action:

i. Promulgate a new implementing regulation revising 7 CFR § 372.5 to eliminate the presumption that an EA normally will suffice rather than a full EIS in order to analyze the release of a GE product.

ii. Whether preparing EAs or EISs, commit by way of a formal policy directive and ultimately by regulation to following the analytical protocol for GE arthropods already published by APHIS officials Young, Ingebritsen, and Foudin and posted on the APHIS website.

iii. For USDA's internally developed GE arthropod projects, commit by way of a formal policy directive and ultimately by regulation to using an outside consultant to prepare the NEPA documentation

iv. Petitioners hereby incorporate into this Petition the arguments and Requested Actions contained in their previous comment to APHIS on the GE pink bollworm EA, and further request APHIS to consider its decisions on that project in light of the points in this Petition, that is, to consider this Petition as an additional comment on that EA.

3. Conduct National Environmental Policy Act Compliance at the Programmatic Level.

In addition taking a "hard look" at the impacts of particular project-related actions, APHIS also is required under NEPA to look at the broader impacts of its programmatic actions involving GE arthropods, and to consider alternative approaches. A programmatic EIS is called for under the CEQ NEPA regulations. Specifically, 40 CFR § 1508.18(b)(3), defines a "Federal action" very broadly to include:

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.

APHIS has undertaken new, systematic, and concerted Federal actions in its GE arthropod program, including the following policy decisions (each of which was discussed above):

Action 1 - Most importantly, the development and promotion of GE arthropods such as the pink bollworm, medfly, and other proposed future projects, requiring substantial allocation of APHIS resources.

Action 2 - The refusal in the GE pink bollworm EA to follow its own analytical protocol, contrary to prior policy and to assurances by its own biotechnology officials Young, Ingebritsen, and Foudin and contrary to assurances on APHIS' own website.

Action 3 - Lack of explicit consideration of advice from APHIS' own Technical Advisory Team's in preparing the GE pink bollworm EA, elimination of the prior policy of providing Regulatory Assessments and

Courtesy Permits to GE arthropod developers, and APHIS's failure to maintain its formerly informative GE arthropod website to prior standards since 1999.

Action 4 - Refusal to issue necessary regulations on GE animal pests, including GEAVADs, notwithstanding years of internal development of a proposed regulatory approach by its own lead scientists, and failure in recent years to urge PHS to adopt parallel regulations on GEAVHDs, despite clear support for both of these needs from the potentially regulated scientific community.

Action 5 - Conducting the NEPA analysis for its own GE arthropod proposals internally, rather than using an independent consultant, given the institutional conflict of interest.

Action 6 - Adherence to APHIS' current NEPA regulation, at 7 CFR 372.5(b)(4), providing that an EA will normally be considered an adequate basis for permitting releases of novel GE arthropods, creating a unbalanced presumption that a EA/FONSI process will suffice, instead of an EIS.

These six actions taken as a whole constitute a major Federal foray into promotion of minimally-regulated GE arthropods, posing potentially significant environmental and health impacts by increasing the likelihood of harmful releases. APHIS has not formally announced that these concerted actions constitute a "proposal" or a "program." For NEPA purposes, however, actions speak louder than words, as provided in the 40 CFR § 1508.23 definition of Proposal:

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

Indeed, APHIS has prepared no NEPA compliance at all on its GE arthropod policies since it began implementing them. Programmatic compliance that looks at the cumulative impacts of an agency's policies is both required and useful. A key NEPA court case is instructive:

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.[(37)]

Requested change: Using an independent consultant, conduct programmatic NEPA compliance in the form of a full EIS on APHIS's entire program of developing, promoting, analyzing, and regulating (or abstaining from regulating[(38)]) GE arthropods. Reasonable alternative

programmatic approaches must be fairly assessed. This should occur either before or in direct conjunction with the issuance of the new regulations and formal policy directives called for in the other sections of this Petition.

4. Commit to Formal Project and Programmatic Endangered Species Act Compliance.

Under the Endangered Species Act (ESA), all Federal agencies have the duty to avoid actions that may jeopardize native species of wildlife.[(39)] Sec. 7 of the ESA provides, in pertinent part:

Interagency cooperation.

(a) Federal agency actions and consultations.... (2) Each Federal agency shall, in consultation with and with the assistance of the Secretary, insure that any action authorized, funded, or carried out by such agency (hereinafter in this section referred to as an "agency action") is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of habitat of such species which is determined by the Secretary, after consultation as appropriate with affected States, to be critical.... In fulfilling the requirements of this paragraph each agency shall use the best scientific and commercial data available. (3)... a Federal agency shall consult with the Secretary on any prospective agency action at the request of, and in cooperation with, the prospective permit or license applicant if the applicant has reason to believe that an endangered species or a threatened species may be present in the area affected by his project and that implementation of such action will likely affect such species. (4) Each Federal agency shall confer with the Secretary on any agency action which is likely to jeopardize the continued existence of any species proposed to be listed under section 1533 of this title or result in the destruction or adverse modification of critical habitat proposed to be designated for such species....

Parallel to the duty to comply with NEPA, APHIS has a duty to consult and confer with the U.S. Fish and Wildlife Service (USFWS) under Sec. 7 with respect to threatened and endangered (T/E) species that applies not only to individual projects that it may carry out or approve, but also to the programmatic actions discussed above under Requested Action 3 of this Petition.[(40)]

If an APHIS action may affect listed T/E species or their critical habitats, then the agency must engage in a formal consultation and obtain a biological opinion, typically from the USFWS.[(41)] To adequately review the effects of the action, APHIS must first provide the USFWS with "the best scientific and commercial data available" regarding which, if any, T/E

species may be impacted.[42] The USFWS must review this information, evaluate the status of impacted species, determine the direct, indirect, and cumulative effects of the action. If the APHIS action is likely to jeopardize a T/E species or adversely modify designated critical habitat, then the USFWS biological opinion must seek to identify reasonable and prudent alternatives.[43] In the case of the EA for the GE pink bollworm, no evidence exists that APHIS consulted with the USFWS at all, omitting even rudimentary Endangered Species Act compliance.[44]

Petitioners note again that at least 54 native arthropods are listed already as T/E species, or are proposed or likely candidates for future listing. Further, more than 500 U.S. animals and more than 735 U.S. plants are listed T/E species.[45] As a general matter, arthropods play vital roles in the habitats upon which these T/E species depend. APHIS must take the duty to consult seriously for each GE project it conducts or approves, and provide evidence that it has done so. A commitment by APHIS to undertake formal Sec. 7 consultation for all of its regulatory and programmatic actions with respect to GE arthropods will greatly increase the confidence of the scientific and conservation communities that APHIS has not overlooked potential T/E species impacts.

Requested change: Issue a policy directive committing APHIS to consult formally with USFWS under ESA Sec. 7 regarding the potential effect on listed T/E species and their designated critical habitats for each

individual APHIS action and for APHIS's overall program for GE arthropods.[46] Commit similarly to confer with the USFWS under ESA Sec. 7 on the potential effect on proposed (but unlisted) T/E species and proposed (but undesignated) critical habitats for each individual APHIS action and for APHIS's overall program.

5. Comply with Executive Order 13112 on Invasive Species.

Hoy and others have identified the potential invasiveness of GE arthropods released from confinement as a key risk due to potential impacts on native species and ecosystem processes.[47] 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 Executive Order (EO)13112 of February 3, 1999, on Invasive Species. This EO, still in effect, provides in pertinent part:

Sec. 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 various APHIS divisions "authorize, fund, or carry out actions" that may create new GE invasive species or "may affect the status" of existing invasive pests, such as the pink bollworm, APHIS must adopt appropriate guidelines under Sec. 2(a)(3) addressing the benefits and harms and ways to minimize the risks of its actions. Virtually by definition, all GE plant pests, GE animal pests, and GEAVHDs must be invasive to accomplish their designed purpose, whether it is invading crop fields for biological control of a plant pest, or invading an area with an existing population of a disease vector, such as a mosquito, to reduce its competence. Formal guidelines are legally required and will help prevent mistakes.[(48)]

Requested Action: Comply with Sec. 2 of EO 13112 by adopting appropriate guidelines addressing the benefits and harms, and ways to minimize the risks, for all APHIS actions that "authorize, fund, or carry out actions" that may create new invasive pests or that "may affect the status" of existing invasive pests.

In closing, we observe that this issue is remarkable for the general consensus among outside observers, the potentially regulated scientific community, and the agency's own scientists that APHIS needs to make progress on regulatory and program improvements. We look forward to your earliest formal responses to each Requested Action in this Petition, and we ask for the opportunity to meet with you to discuss these issues personally.

Please promptly publish notice of this Petition in the Federal Register and create a formal open docket for it, or otherwise assign a petition identification number to it and communicate that to us, as we anticipate submitting future endorsements and supporting comments from other

organizations and individuals. For further information, please contact Peter T. Jenkins, CFS/ICTA Attorney/Policy Analyst, at (202) 547-9359 ext. 13, or email: peterjenkins@icta.org.

Respectfully submitted,

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APPENDICES - KEY DOCUMENTS FROM APHIS FILES AND WEBSITE

Appendix A - Hierarchy of Risks Associated with Release into the Environment of Genetically Engineered Animal Disease Vectors

Appendix B - Arthropods for which Transgenic Research has been Reported

Appendix C - Discussion of the Permitting Process for Genetically Engineered Arthropod Vectors of Animal Diseases

1. "Congress shall make no law ... abridging ... the right of the people ... to petition Government for a redress of grievances." U.S. Const., amend. I. The right to petition for redress of grievances is among the most precious of the liberties safeguarded by the Bill of Rights. United Mine Workers of America, Dist. 12 v. Illinois State Bar Ass'n, 389 U.S. 217, 222 (1967). The Supreme Court has recognized that the right to petition is logically implicit in, and fundamental to, a republican form of government. United States v. Cruikshank, 92 U.S. (2 Otto) 542, 552 (1875).

Note that the original filed copy of this Petition has attached copies of pertinent publications and other documents cited in the footnotes herein, exclusive of regulations, statutes, and case law opinions.

2. 5 USC § 553(e).

3. 7 CFR § 1.28.

4. Arthropods are invertebrate animals, such as insects, with jointed limbs and a segmented body with an exoskeleton made of chitin.

5. Marshall, A. 1998. The insects are coming. Nature Biotechnology 16:530-33.

6. Listed at 50 CFR § 17.11; for totals, see USFWS. 2001. Endangered Species Bulletin vol. XXVI, no.1, p. 40.

7. See generally, Handler, A.M., and A.A. James (ed.s). 1999. Insect Transgenesis - Methods and Applications, CRC Press, Boca Raton, FL.

8. Hoy, M.A. 1999. Deploying transgenic arthropods in pest management programs: Risks and realities. In A.M. Handler and A.A. James, ed.s, Insect Transgenesis - Methods and Applications, CRC Press, Boca Raton, FL, at pp. 336-37.

9. Kilman, S. 2001. Buzz bomb: Bioengineered bugs stir scientific dreams, but will they fly? Wall Street Journal, Jan. 26, p. A1; Yaukey, J. 1999. Designer insects could boost (or sting) research. USA Today, Feb. 1, p. 6D; Kaufman, M. 2001. A glowing achievement, or a can of worms? Proposed field test of gene-altered cotton pest debated, Washington Post, Apr. 25, p. A1.

10. 7 CFR § 340 - "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pest or Which There is Reason To Believe Are Plant Pests." A separate future petition is planned to address the deficiencies of this regulation and APHIS's implementation of it.

11. 42 USC § 264 et seq.

12. Petitioners also are submitting a courtesy copy of this Petition to the Assistant Secretary for Health/Surgeon General, who has authority to issue protective regulations under 42 USC § 264(a).

13. The need for coordination is highlighted by the fact that some National Institute of Health (NIH) officials appear to assume that APHIS is regulating proposed releases of GEAVHDS, when in fact APHIS is not. This is evident in internal documents obtained from NIH, discussed in detail in the accompanying Petition to PHS.

14. In 1997, the program's Transgenic Arthropod Team received the National Performance Review - Hammer Award for its standard of excellence "in efforts to make government work better and cost less."

15. Young, O.P., S.P. Ingebritsen, and A.S. Foudin. 1999. Regulation of transgenic arthropods and other invertebrates in the United States. In A.M. Handler and A.A. James, ed.s, Insect Transgenesis - Methods and Applications, CRC Press, Boca Raton, FL, at p. 376.

16. Quoted in J. Yaukey. 1999. USA Today article cited above.

17. Quoted in M. Kaufman. 2001. Washington Post article cited above.

18. Quoted in S. Kilman. 2001. Wall Street Journal article cited above.

19. Beard, C.B., R.V. Durvasula, and F.F. Richards. 1998. Bacterial symbiosis in arthropods and the control of disease transmission. Emerging Infectious Diseases, vol. 4, No. 4, Oct. - Dec., pp. 581-88.

20. Letter and attached resolution from Robert Graham, AMCA Executive Director, dated July 16, 1996.

21. Hoy interview of Feb. 12, 2001, with Eli Sarnat of CFS.

22. O.P. Young, APHIS, email on animal disease vectors to Craig A. Reed, Administrator, APHIS, dated April 1, 1999, obtained from APHIS files.

23.5 USC § 551 et seq; on the enforceability of the duty of Federal agencies to adopt appropriate protective regulations, see American Horse Protection Association, Inc. v Lyng, 812 F.2d 1 (DC Cir. 1987).

24. See the detailed public comment, online at http://www.centerforfoodsafety.org/li/geinsects.htm submitted by CFS and

ICTA, and endorsed by several other consumer and environmental organizations, on the proposal by the APHIS Plant Protection Center for a Confined Field Study of a Transgenic Pink Bollworm.

25. The Regulation of Transgenic Arthropods, http://www.aphis.usda.gov/biotech/arthropod/.

26. See Young, O.P., S.P. Ingebritsen, and A.S. Foudin. 1999, cited above, at p. 377, for a list of other positive features of the program that APHIS should maintain and expand for GE animal pests and GEAVHDs.

27. Note that the remainder of this Petition is not limited to GE animal pests, GEAVADS, or GEVHDS; it applies to all GE arthropod Projects, including GE plant pests.

28. 42 USC § 4321 et seq.

29. 42 USC § 4332(C).

30. 40 CFR § 1508.27(b)(2)(4)(5)(6)(9). The Supreme Court has held that the CEQ regulations are entitled to substantial deference. Andrus v. Sierra Club, 442 U.S. 347, 348 (1979); Marsh v. Oregon Natural Resources Council, 490 U.S. 360, 372 (1989).

31.Public Service Co. of Colo. v. A ndrus, 825 F. Supp. 1483, 1495 (D. Idaho 1993); See Friends of the Earth, Inc. v. U.S. Army Corp of Eng'rs, 2000 U.S. Dist. LEXIS 11755 (D.D.C. 2000).

32. Petitioners also note that the presumption in 7 CFR § 372.5(b)(4) (b) that an EA is adequate for "nonindigenous species introductions" also appears grossly underprotective. For examples of very harmful intentional introductions, including many carried out by USDA, see U.S. Congress, Office of Technology Assessment. 1993. Harmful Non-Indigenous Species in the United States. U.S. Government Printing Office; Washington, DC. Online at: www.wws.princeton.edu/~ota/disk1/1993/932.

33.Kleppe v Sierra Club , 427 US 390, 410 n.21 (1976).

34. O'Brachta comment dated July 12, 2001, in APHIS Docket No. 01-024 1.

35. Young, O.P., S.P. Ingebritsen, and A.S. Foudin. 1999, cited above, at pp.371 75. The EA failed to provide the detailed information Young et al. called for in the sections entitled "20.3.4 - Evaluation of the Nontransgenic Form Proposed for Introduction" and "20.3.5 Evaluation of the Transgenic

Form." The EA failed 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 establishmen

7. Methods for monitoring and control."

36. Discussion of the Review and Evaluation Procedures Associated With the Permitting Process for a Proposed Introduction of a Transgenic Arthropod, dated 18 September 1995, online at http://www.aphis.usda.gov/biotech/arthropod/tgendisc.html as of September 10, 2001.

37.Assoc. of Public Agency Customers, Inc. v. BPA et al. , 126 F.3d 1158, 1184 (9th Cir. 1997)

38. The EIS also should address regulatory overlaps, ambiguities, and gaps that may affect APHIS's regulatory program. APHIS, the Environmental Protection Agency, the Public Health Service, the Food and Drug Administration, and other agencies must clearly define their areas of regulatory jurisdiction that may affect the development and release of GE arthropods.

39. 16 USC § 1531 et seq. A separate petition will be submitted to the Director, US Fish and Wildlife Service, asking for formal consultation under Sec. 7 on all GE invertebrate projects and programs of other Federal agencies. Petitioners will send APHIS a courtesy copy of that petition.

40. On the duty to conduct programmatic Sec. 7 compliance, see Pacific Rivers Council v. Thomas, 30 F.3rd 1050 (9th Cir. 1994).

41. 16 USC § 1536(b).

42. 50 CFR § 402.14(d).

43. 16 USC § 1536(b)(3)(A).

44. This omission appears contrary to assurances by APHIS officials Young, Ingebritsen, and Foudin. 1999, cited above, at p. 376.

45. USFWS. 2001. Endangered Species Bulletin vol. XXVI, no.1, p. 40.

46. This should occur in conjunction with the programmatic NEPA compliance called for in the previous section of this Petition.

47. Hoy, M.A. 1999, cited above, at pp. 351-52;

U.S. Congress, Office of Technology Assessment. 1993, cited above.

48. An EO adopted pursuant to statutory or constitutional authority, as EO 13112 was (see Preamble section therein for statutory authority) has the force and effect of law for Federal agencies. Legal Aid Society of Alameda County vs. Brenner, 381 FS 125 (DC Cal. 1975).