

A short note on the final Environmental Impact Statement–October 2008: Use of genetically engineered fruit fly and pink bollworm in APHIS plant pest control programs

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This introduction concerns the reasons why an Environmental Impact Statement (EIS) is conducted and how it is done in the USA. Over 100 countries have laws similar to the USA National Environmental Policy Act (NEPA) that require environmental documentation comparable to an EIS.

Environmental Impact Statement is a term used in the USA, which is similar to Environmental Impact Assessment, Environmental Statement, or related terms used in more than 100 other countries under their respective laws. The EIS is required under the USA National Environmental Policy Act of 1969, 42 U.S.C. 4321 et seq. This law requires Federal agencies to do an assessment of the environmental effects of their proposed actions prior to making decisions. Two major purposes of the environmental review process are better-informed decisions and citizen involvement.

Private individuals or companies are often involved in the NEPA process as technical consultants and contract technical writers when the federal agency needs an environmental analysis for a decision regarding issuing of a permit. Federal agencies remain responsible for the scope and accuracy of the analysis.

Purpose of the EIS. The EIS is used by US Federal agencies to plan actions and make decisions with public stakeholder participation. It provides full and unbiased discussion of significant environmental impacts and informs decision makers and the public of the reasonable alternatives to avoid or minimize adverse impacts on the environment including the human environment. The EIS must be written in language that non-scientists can understand and be supported by evidence that the agency has made the necessary environmental analyses.

With a few exceptions, all Federal agencies have to comply with NEPA before they make final decisions about federal actions that could have environmental effects. NEPA applies to a wide range of actions that include Federal approvals of certain licenses and permits. NEPA requires Federal agencies to consider environmental effects that include, among others, impacts on social, cultural, and economic resources, as well as natural resources including endangered and threatened species.

The Regulations for Implementing the Provisions of the National Environmental Policy Act may be found with the USA Council on Environmental Quality (2009). The Global Development Research Center (2009) describes EIAs as have legal and educational roles. The legal role is to insure there are minimal impacts on the environment and to educate everyone involved, including the public, of the potential environmental impacts of the proposed project, program, or action.

Compliance with the regulations for doing an EIS or other analogous environmental documentation required by law also serves to strengthen the legal process for governmental decision-making against frivolous law suits by special interest adversary groups.

The EIS as a Public/Stakeholder Participation Process. The EIS process begins with publication of a public Notice of Intent (NOI), stating the agency's intent to prepare an EIS. In the USA, the NOI is published in the Federal Register. It provides basic information on the proposed action in preparation for the public scoping process. The NOI provides a brief description of the proposed action and possible alternatives. It also describes the agency's proposed scoping process that includes public meetings and hearings and other ways the public can become involved. Scoping is when issues are identified, points of contact determined, project schedules established, and recommendations from the public are received. Scoping includes the following:

- Identify people or organizations interested in the proposed action;
- Identify the significant issues to be analyzed in the EIS;
- Identify and eliminate from detailed review those issues that will not be significant or those that have been adequately covered in prior environmental review(s);
- Identify any related EAs (Environmental Assessments) or EISs; and
- Identify gaps in data and information needs;

As part of the EIS process, agencies are required to identify and invite the participation of interested persons.

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The agency should choose whatever communications methods are most suitable for involvement of people and communities, whether local, regional, or national, that are interested in the proposed action. Video conferencing, public meetings, conference calls, formal hearings, or informal workshops are among the methods used for scoping.

Draft EIS. The next stage in the EIS process that provides opportunity for public input is publication of a draft EIS for public comment. A Notice of Availability is published in the Federal Register informing the public that the draft is available for comment. Based on the communication plan established by the agency, websites, local papers, or other means of public notice are used. The public comment period is at least 45 days. During this time, the agency may conduct public meetings or hearings as a further way to solicit comments. Comments are also requested from other Federal, State, Tribal, and local agencies that may have jurisdiction or interest in the matter.

Statement of Purpose and Need. A necessary element of a draft EIS is the statement of the underlying purpose and need, which describes what is to be achieved. The purpose and need statement explains to the reader why an action is necessary.

Alternatives. The identification and evaluation of alternative ways of meeting the purpose and need of the proposed action is necessary for an EIS. An agency must objectively evaluate all reasonable alternatives, and for alternatives, which were eliminated from detailed study, the reasons for their having been eliminated must be discussed. Reasonable alternatives are those that substantially meet the agency's purpose and need. If the agency is considering an application for a permit or other federal approval, the agency must still consider all reasonable alternatives. All reasonable alternatives or a range of reasonable alternatives must be described in enough detail so that a reader can compare and contrast them.

No Action Alternative. Agencies must always describe and analyze a "no action alternative." The no action alternative is what would happen if the agency did not act upon the proposal for action. The no action alternative may simply be continuation of a current program.

Preferred Alternative or Action. If an agency has a preferred alternative when it publishes a draft EIS, the draft must identify which alternative is preferred. A preferred alternative must be identified in the final EIS.

Environmental Effects/Impacts (a form of objective risk/benefit analysis). The agency must analyze the full range of direct, indirect, and cumulative effects of the preferred alternative, if any, and of the reasonable alternatives identified in the draft EIS. For purposes of NEPA, "effects"

and "impacts" have the same meaning. Effects include ecological (such as the effects on natural resources and on the components, structures, and functioning of affected ecosystems), aesthetic, historic, cultural, economic, social, or health impacts, whether direct, indirect, or cumulative. Effects may also include those resulting from actions, which may have both beneficial and detrimental effects, even if on balance the effect is considered to be beneficial. The phrase "human environment" is used to clarify that human beings are part of the environment. Direct effects are those caused by the action and occur at the same time and place. Indirect effects are those caused by the action and may occur later in time or farther removed in distance, but are still reasonably foreseeable.

Affected Environment. In addition to the purpose and need, identification of reasonable alternatives, and the environmental effects of the alternatives, the draft EIS must contain a description of the environment that would be affected by the various alternatives.

Final EIS. When the draft EIS public comment period is over, the agency analyzes comments, conducts further analysis as necessary, and prepares the final EIS. In the final EIS, the agency must respond to substantive comments received from other government agencies and from the public. The response can be in the form of changes in the final EIS, factual corrections, modifications to the analyses of the alternatives, new alternatives considered, or an explanation of why a comment does not require the agency's response or action. A copy or a summary of substantive public comments and the response to them must be included in the final EIS. The final EIS is also published with a Notice of Availability in the Federal Register. This Notice of Availability marks the start of a 30-day waiting period, which must pass before the agency can make a decision on its proposed action. This provides time for the agency decision makers to consider the purpose and need, weigh the alternatives, balance their objectives, and make a decision.

Record of Decision (ROD). The ROD is the final step in the EIS process. The ROD is a document that states what the decision is, identifies the alternatives considered, including the environmentally preferred alternative, and discusses mitigation plans, including any enforcement and monitoring commitments. In the ROD, the agency discusses all the factors, including any considerations of national policy that were contemplated when it reached its decision on whether to and how to proceed with the proposed action. The ROD also discusses if all practical means to avoid or minimize environmental harm have been adopted, and if not, why they were not. The ROD is also publicly available.

Sources.

- (1) Executive Office of the President of the United States (2007)
- (2) Executive Office of the President of the United States

(1982)

(3) Senate and House of Representatives of the United States of America in Congress (1982)

(4) USA Council on Environmental Quality (2009).

All of the above requirements for an EIS have been completed for the EIS on Use of Genetically Engineered Fruit Fly and Pink Bollworm in APHIS Plant Pest Control Programs.

The Record of Decision (ROD) for the final EIS on Use of Genetically Engineered Fruit Fly and Pink Bollworm in APHIS Plant Pest Control Programs was published in the USA Federal Register (2009). This ROD authorizes the development and use of genetically engineered insects in sterile insect technique applications for USDA APHIS plant pest control programs. The ROD states that the alternative that involves integration of genetically engineered insects into programs is also the environmentally preferred alternative because the potential environmental impacts of this alternative are minimized by the resulting program improvements and reduced to the extent that genetically engineered insects are incorporated.

The following paragraphs contain the Executive Summary of the EIS titled: Use of Genetically Engineered Fruit Fly and Pink Bollworm in APHIS Plant Pest Control Programs, Final Environmental Impact Statement of October 2008 (USDA 2008)

The U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), in cooperation with several States and foreign countries, is proposing further development of genetically engineered fruit fly species and pink bollworm for use in various applications of the sterile insect technique (SIT) applied to agency invasive plant pest control programs. There have been laboratory and confined field studies to test the efficacy of certain genetic engineering applications that could provide benefits to these programs, but these techniques have not been applied in agency eradication actions or preventive release program (PRP) strategies.

The plant pests selected for inclusion in this environmental impact statement (EIS) are the pink bollworm (Lepidoptera: Gelechiidae) and three species of tephritid fruit flies (Mediterranean, Mexican, and Oriental). These species were selected based upon their ongoing threat to U.S. agriculture and the basic research already conducted to develop genetically engineered strains that can be adapted for use in SIT applications for APHIS' control programs. Although APHIS has existing eradication and PRPs that utilize radiation-sterilized insects for two of these species, the use of genetically engineered insects under consideration applies traits that would provide improved production and quality assurance for separation of sterile insects from wild-type insects through the use of genetic markers for field and facility monitoring, reducing the quantity of insect production through male-only fruit fly mass-rearing, and inducing sterility in released insects without the need for exposure to radiation, which damages insects and reduces the mat-

ing ability and sexual competitiveness of the insects being released. The actions being considered in the preferred alternative of this EIS provide APHIS plant pest programs with new and potentially more cost-effective methods for SIT. These methods can result in substantial reductions in operating costs and improved efficiency for the ongoing fruit fly and pink bollworm control programs. This would also benefit APHIS by making more effective use of the limited personnel and limited space available at insect rearing facilities for these programs.

The area impacted by the program actions associated with this EIS is limited to those sites within the host ranges of the pest species. The release of sterile insects in this program would diminish the risk of adverse effects to American agriculture from these species. Although the host plants of the pink bollworm are limited to cotton and okra and only in the dry climates of the Southwest, some of the fruit flies have more than 200 susceptible host plants and agricultural crops that occur in both humid and dry climatic areas. The eradication of pink bollworm has progressed to the point where most program applications are likely to be limited to Arizona, California, and Mexico; however, maintenance of a sterile insect colony for potential use in new introductions or mass releases to prevent infestations (PRPs) is desirable. Most fruit fly outbreaks are expected to occur in California, Florida, and Texas where the most immediate advantages of applications of genetically engineered SIT are anticipated. Nevertheless, future applications for potential oriental and Mediterranean fruit fly eradication efforts in Hawaii and ongoing cooperative control efforts in several foreign countries would also benefit from the use of this technology. The biological fitness of genetically engineered fruit flies and pink bollworm designed for SIT applications in these diverse geographic locations is an important aspect of the successful and environmentally safe use of these insects, and their performance-fitness factors will be assessed for each individual genetic construct or genetically engineered strain before release is considered.

APHIS has an extensive history of using radiation-induced SIT to aid in the timely control and eradication of pest outbreaks. The use of genetic engineering to improve the effectiveness of SIT as a control measure and to minimize program impacts to the environment is a strategic decision that takes advantage of this new technology. Genetically engineered fruit flies and pink bollworm can augment SIT in present control programs by producing: (1) mass-rearing of either male and female or only male fruit flies with a marker gene and are sterilized by radiation exposure and produce practically no offspring, (2) genetically sterilized male-only fruit flies that have a marker gene and that compete more effectively for mates than radiation-sterilized fruit flies, (3) fruit flies that produce only male offspring which carry a heritable sterility gene resulting in only male and no female offspring in the field, thus controlling pest fruit flies through rapid population reduction, (4) mass-rearing of male and female pink bollworm that have a marker gene and are sterilized by radiation before field release, and

(5) mass-rearing of male and female pink bollworms that are genetically sterile without radiation exposure and with males that are more competitive in mating with wild female bollworms than radiation sterilized male bollworms.

The issues regarding the application of this new technology to SIT by APHIS were scoped through a public comment process cited in our notice of intent to prepare this EIS in the Federal Register (71 Federal Register (FR) 20068-20069, Docket No. APHIS-2006-0 166) on December 19, 2006. Comments and information on potential alternatives and substantive issues were provided by the general public, industry, academic, regulatory, and public interest groups. In addition, comments were received during the public comment period on the draft EIS announced by the U.S. Environmental Protection Agency on May 30, 2008 (73 FR 31115, Docket No. ER-FRL-6699-3). This EIS addresses public comments in appendix E and within the text covering the given issue or alternative.

There are three alternatives and their associated components analyzed comprehensively in this EIS. These alternatives are broad in scope and reflect the need of the program to objectively address potential control and eradication of damaging fruit fly species and the pink bollworm. The alternatives for the use of genetically engineered insects in SIT of APHIS' pest control programs include: (1) no action, (2) expansion of existing programs, and (3) integration of genetically engineered insects into programs (the preferred alternative). The alternatives are presented in a manner that explains the environmental issues and the choices to be made regarding the inclusion or exclusion of insects with specific traits in APHIS' SIT programs. This programmatic EIS is also designed to establish criteria for future decisions regarding use of the genetic engineering technology and to identify the potential impacts to address when documenting these decisions.

The potential consequences from each of the three alternatives have some environmental impacts of concern. The greatest potential impacts occur with the no action alternative, in that potential pest risks are not static and continue to increase with expanding trade and travel. Expansion of existing programs could occur to accommodate the growth in trade and travel, but this expansion is not the most effective or most efficient means to improve control program performance. Although the types of actions in the expansion of existing programs alternative do not differ from those under the no action alternative, their context and magnitude would be expected to increase the species, locations, and size of programs. The preferred alternative of this EIS, integration of genetically engineered insects into programs, incorporates potential impacts of the other two alternatives to the extent that the technology of genetic engineering is not applied independent of other available control methods. The other environmental impacts may also be modified by the degree to which the use of genetically engineered insects:

(1) decrease the need for actions involving insecticide applications.

(2) decrease the need to produce both male and female insects for use in SIT releases,

(3) increase production of males that are more competitive in mating than radiation-sterilized males, and

(4) eliminate the need to use, operate, and maintain strong gamma radiation sources.

Many of the issues of concern from the public comments are also issues of concern to the program, in that genetically engineered traits of insect strains must be maintained and restricted to the mass-reared insects used in SIT to ensure their ongoing effective use in control programs. This requires attention to issues such as the biosecurity of facilities, establishment and adherence to facility containment requirements, comprehensive testing of performance-fitness factors of the reared insects, establishment of effective filters to maintain the desired genetic phenotype within rearing colonies, and monitoring of the facilities and the SIT release practices for quality assurance. Just as certain measures are already built into our present programs, APHIS will be establishing standard operating procedures and mitigation measures for application of genetic engineering technology to SIT in specific control programs to ensure that potential applications are not compromised. This will require extensive monitoring of strain effectiveness, particularly for new strains that have not been used previously in SIT releases. Incorporation of this new technology into program operations will require an extended commitment by the agency and its cooperators to ensure that pest control expectations are fulfilled.

Review of the pertinent environmental laws and statutes is presented in this EIS on a programmatic basis. Although the findings related to the requirements cover the most likely issues of concern, the application specific environmental assessments that tier to this programmatic EIS should revisit the issues discussed and any new effect that results from applications or extensions of this technology. The environmental issues of concern are likely to change over time. For example, this EIS arrives at a no effect determination concerning threatened and endangered species and their critical habitat in its assessment completed for compliance with the Endangered Species Act. However, new species of plants and animals are being proposed and added to the lists, so the biological determination will need to be updated to cover any changes. Likewise, other laws, statutes, and executive orders are subject to confirmation that conditions have not changed, and any new issues of concern will need to be addressed.

The rationale to support the preferred alternative relates to the expected potential benefit to the programs and American agriculture from application of this new technology. In particular, its applications to SIT, as described in this programmatic EIS, provide potential for increased program effectiveness with low potential for adverse environmental impacts. Selection of the preferred alternative does not necessarily allow control programs to immediately employ the new technology, but does provide a basis for

future decisions about potential environmental impacts for specific uses of genetically engineered strains in SIT that can be tiered to the findings from this EIS. This alternative will assist in facilitating implementation of the technology by providing procedures for application-specific evaluations of genetically engineered plant pests used to improve SIT release programs.

REFERENCES

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