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Enclosure #1

FS-PIAP PROPOSALS
ELIGIBILITY AND SELECTION CRITERIA

Eligible Studies

Proposals should improve knowledge of the benefits and risks of pesticide registered by US-EPA for use in forestry and related programs. New forestry uses for registered pesticides, or non-chemical treatments may be tested as alternatives to a registered forestry pesticide in FQPA review (refer to Enclosure 2).

Proposals that develop new technologies and field operation methods to improve the ability of field specialists in restoring or protecting America's forests are not considered for FS-PIAP. Refer to the Request for Proposals for the STDP program (http://www.stdpweb.fs.fed.us/stdp/), also administered by FS-WO-FHTET for proposals that develop or modify application or residue detection methodology

National priorities are identified in Enclosure 2. National priorities are data gaps and missing information needed by more than one locality or region of the Forest Service. Study proposals involving other pesticides registered for forestry and related uses may be submitted, with support of Forest Service Region, Station or Area managers. Explain the relevance and scope of the proposed study in the justification section of the proposal.

Proposals for FY 2009 should generally emphasize short-term work, which can be completed within one year, but two-year studies will be considered. Two-year studies must have identifiable yearly accomplishments and budgets.

Funding for all project proposals is considered only on a year to year basis. Funding for multiyear projects is approved for one year. Subsequent years are funded based upon continued available funding, and submission of a satisfactory progress report by November 19.

Proposal Selection Criteria:

All proposals will be evaluated by a technical review committee of representatives of USDA Forest Service and cooperating USDA agencies. The review committee will recommend proposals for funding based on its evaluation of:

1. Priority of study subject (see Enclosure 2) and the objectives of the proposal.

2. Technical quality of proposal.

3. Cost effectiveness of the proposal, including financial contributions from other funding sources.

Region and Area FS-PIAP Coordinators will be notified of proposal selections upon approval of funding recommendations.

Enclosure #2

FS-PIAP NATIONAL PRIORITIES
PESTICIDE DATA GAPS--2008

INTRODUCTION

National priorities are data gaps and missing information needed by more than one locality or region of the Forest Service. They are derived from national FHP steering committee recommendations; Forest Service Pesticide Risk Assessments and Pesticide Use Reports **(available at: http://www.fs.fed.us/foresthealth/pesticide/)**; public comment and appeals of pesticide application projects; review of FQPA pesticide re-registration priorities, and coordination with FS research, resource managers, and USDA Office of Pest Management Policy.
Study proposals involving other pesticides registered for forestry and related sites may be submitted, with support of Forest Service Region, Station or Area managers. Explain the relevance and scope of the proposed study in the justification section of the proposal.

HERBICIDES

Priority Herbicides

All herbicides for which a Forest Service Risk Assessment has been prepared **(available at: http://www.fs.fed.us/foresthealth/pesticide/risk.shtml)**

Herbicides registered for aquatic invasive plant control

Other herbicides registered for forestry or forest nursery, or for related sites (e.g. rangeland, non-crop) where applicable to control of invasive plants (noxious weeds) in natural wildland environments.

Priority Data Needs for Priority Herbicides

Human Health Effects

Exposure (deposition), absorption, and urinary excretion data to refine EPA dose predictions for workers in forestry applications of priority herbicides. NOTE: Enclosure #5 must be completed and coordination with US-EPA Human Studies Review Panel must be documented.

Residues in forest plants and fungi consumed by humans (e.g. huckleberries, mushrooms, ramps, etc)

Environmental Fate

Soil metabolites and their effects

Effects on "soil health" fauna, flora, and processes

Effectiveness of Best Management Practices in preventing contamination of surface waters as a result of priority herbicide application: runoff, sediment transport, drift

Ecological Effects

Efficacy of priority herbicides in Integrated Pest Management strategies for control of invasive, nonnative plant species (noxious weeds)

Toxicity to nontarget wildland organisms, especially Threatened, Endangered and Sensitive species, including developmental and behavioral changes affecting survival and reproduction

Estrogenic effects in wildland organisms

Effects on plant and/or animal communities and biological diversity

2. INSECTICIDES

FS-PIAP priorities focus on producing data needed to support forestry registrations of insecticides in re-registration review by US-EPA.

Additional FS-PIAP priorities are:

Bacillus thuringiensis, var. *kurstaki*

"Safer" insecticides: soaps, plant derivatives, and semiochemicals registered for forest insect control

Registered pheromones for forest insect pests

Priority Data Needs

Public and worker exposures to registered organophosphate and carbamate insecticides in typical forestry application scenarios, and/or alternative IPM strategies using registered pesticides

Studies of alternative registered pesticides in IPM systems to substitute for organophosphates, carbamates, and other insecticides with restricted or

canceled registrations

B.t.k. effects on nontarget organisms (refer to FS Risk Assessment for identification of data gaps)

3. FUNGICIDES

FS-PIAP priorities focus on producing data needed to support forestry registrations of fungicides in Food Quality Protection Act (FQPA) re-registration review by US-EPA.

Priority Data Needs

Worker exposures to FQPA priority fungicides in typical forestry application scenarios, and/or with IPM strategies using registered alternative pesticides.

Efficacy or effects studies of registered alternatives in IPM systems to substitute for fungicides in US-EPA review, and/or to provide alternatives to minimize pathogen resistance through fungicide rotation.

4. ANIMAL DAMAGE CONTROL

Rodenticides and Piscicides

Environmental fate and nontarget effects

Enclosure #3

FS-PIAP PROPOSAL FORMAT

NOTES:

The proposal (excluding budget and attachments) should generally not exceed ten pages. Forest Service units who receive FS-PIAP grants for selected proposals will be required to submit a detailed study plan within sixty days after notification by WO-FHP. The study plan should follow the proposal format, review relevant literature, and describe in detail the specific experimental design, methods, and protocols to be used. Alternatively, Forest Service units may submit the detailed study plan in lieu of a proposal; however, this level of detail is not required by the FS-PIAP Review Committee.

1. Title:

Should be brief, clear, and specific. The title must be limited to 100 spaces (letters, punctuation, and spaces between words). Use the identical title on all reports and correspondence. This will prevent misplacement of records.

2. Contacts:

List name, affiliation, mailing and e-mail addresses, telephone and FAX numbers for Principal Investigator and for Forest Service sponsor.

3. Abstract:

Summarize the project, its objectives, and procedures for accomplishing the objectives, not to exceed 1,000 characters or spaces in length.

4. Objectives:

A concise, complete, clear, logically arranged, and numbered series of statements defining the specific objectives of the project.

5. Background/Justification Statement:

Provide brief statements that justify the proposed study. Outline the essential methods and procedures that will be employed in attaining each objective. The procedure statement should demonstrate that the proposed work would provide relevant data and information toward accomplishing the objectives.

From Enclosure #2, FS-PIAP National Priorities, identify which information needs will be addressed by the study. Studies which do not address national priorities require a justification statement from Forest Service Region or Area FHP FS-PIAP Coordinators

(Enclosure #7).

Identify the scope and program applicability of study findings. Briefly evaluate existing data that are relevant to the proposed studies and explain why additional studies are needed.

6. Expected accomplishments:

Describe in bullet form the mission of your research; what the study will accomplish (use numbered sentences).

7. Research approach:

Provide a brief description of experimental procedures. Where appropriate, specify location of proposed experiments. Exclude detailed explanation of exact methodology but provide succinct statements of how experimental results (data) will be obtained and how they will be evaluated (statistically, economically, other).

Cooperation with other departments, other experiment stations, and other agencies is encouraged, and should be displayed. Be sure to identify financial contributions from sources other than FS-PIAP on Budget Form (Enclosure #4).

Study proposals must comply with the Good Laboratory Practice (GLP) regulatory requirements. Refer to Forest Service Handbook 4090.13, 11 (Enclosure #6) for guidance on when and how to apply GLP regulations to pesticide-related studies performed or supported by the Forest Service. Note that some types of studies supported by FS-PIAP do not require compliance with GLP if not intended for submission to EPA. Proposals must state whether the study will be conducted in compliance with GLP, and provide a rationale where GLP compliance is not required.

8. Research timetable:

The chronology of the research procedures, expected timeframe of the proposed experiments.

9. Technology transfer plan:

Proposals must plan for submission of the study plan and all report in both printed and electronic media. The electronic version must be delivered in html format for installation on Forest Service web site. List planned submissions to professional journals, conferences, etc. that will be based on results of the FS-PIAP study.

10. Required Signatures:

Proposals must have signatures of approval by investigators, their supervisors, and/or other appropriate officials, including a Forest Service contact person for non-Forest

Service proposals. **NOTE: Unsigned applications will not be accepted.**

ATTACHMENTS:

A1. Budget Form (Enclosure #4):

Include personnel cost, supplies, travel necessary to conduct experiments, attendance at scientific meetings to present research outcomes, publishing of research results, and other appropriate items. If they are major components of the total proposed amount of monies, provide cost estimates of items such as computer use, or chemical application, or chemical analyses.

Show indirect costs and contributed funds where applicable. Two-year proposals should show budget for each year.

Overhead may not exceed 15 percent of project cost.

Generally, salaries and benefits for principal investigators and other permanent staff shall not be requested from FS-PIAP. Exceptions may be granted where the investigator or staff is financed on “soft” money, or policies prevent the person(s) from working on the study using their source of permanent financing. A request for an exception must be justified in the proposal budget description.

A2. Studies in Human Subjects (Enclosure #5):

When humans are monitored in pesticide exposure experiments, the human subject certification should be submitted along with the project proposal.

A3. Qualifications:

A brief resume (three pages maximum) of each principal investigator should be attached. Additional items such as reprints, reports of previous or current research, etc., may also be attached.

Enclosure #4

BUDGET FORM
Estimated Costs

Date covered by this estimate: From _____ To _____

Salaries and Wages (Name and title or title only)	Estimated Time	Estimated Salary Rate	Fringe Benefit Cost	Total Direct Salary/Wage Cost
_____				
_____				
_____				
_____				

Total Salaries and Wages _____

Permanent Equipment

_____
_____
_____

Total Permanent Equipment _____

Expendable Supplies and Equipment

_____
_____
_____

Total Expendable Supplies and Equipment _____

Travel

_____
_____
_____

Total Travel Cost _____

Publication Cost

_____
_____

Total Publication Cost _____

Other Costs (Computer, analytical service, etc.)

_____
_____
_____

Total Other Costs _____

Total Project Cost Requested from FS-PIAP_____

Other Contributions (Identify source, amount, and describe) _____
(i.e. PI salary, materials, overhead, etc.)

Enclosure #5

HUMAN SUBJECT CERTIFICATION

Assurance is given that any activity involving human subjects to be conducted under the proposed project will be carried out in accordance with applicable Department of Health, Education, and Welfare rules and regulations, and that our Institutional Review Board, constituted and operating in conformity with applicable Department of Health, Education, and Welfare rules and regulations, has, or will have, reviewed and approved the protocol prior to commencing the activity involving human subjects. Any such activity has been coordinated with the U.S. Environmental Protection Agency Human Study Review Panel.

Name of Institution

Signature & Title of Authorized Official

Date

Enclosure #6

4090.13,10

FSH 4090.13 - GOOD LABORATORY PRACTICES HANDBOOK WO AMENDMENT 4090.13-93-1

CHAPTER 10 - COMPLIANCE WITH GOOD LABORATORY PRACTICES

11 - APPLICABILITY OF GOOD LABORATORY PRACTICES. (Sec. 01, ex. 01; 40 CFR 160.1, 160.10, and 160.135). Good Laboratory Practices (GLPs) specify how to collect, store, and present data to regulatory agencies in a standardized manner that allows effective auditing and evaluation. Good Laboratory Practices do not regulate the experimental design of a study or address issues of worker safety. For direction on worker safety, see:

1. The Health and Safety Code Handbook, FSH 6709.11;

2. Section 55.21 of this Handbook for direction on writing safety-related Standard Operating Procedures; and

3. Other related documents, such as Station or Regional Safety Plans.

11.1 - Types of Studies Requiring Good Laboratory Practices. Any Forest Service study on pesticides that is performed with the intention of submitting the data to the U.S. Environmental Protection Agency in support of a research or marketing permit must be conducted under Good Laboratory Practice (GLP) standards. This includes research on microbial pesticides used for biological control, and pesticide-related laboratory and field studies concerned with any of the following:

1. Health effects.

2. Environmental effects.

3. Chemical fate.

4. Chemical and physical properties.

5. Residue chemistry.

6. Epidemiology.

11.2 - Types of Studies Not Requiring Good Laboratory Practices.

11.21 - Studies Not Submitted to the U.S. Environmental Protection Agency. Pesticide-related studies that are not intended to be submitted to the U.S. Environmental

Protection Agency (EPA) do not need to be conducted under Good Laboratory Practice (GLP) standards. A disclaimer should be added to the study plans or to the project record stating:

This study/project involves the use of pesticides, but the findings are not intended to be submitted to the U.S. Environmental Protection Agency in support of a research or marketing permit. This research is therefore not covered by the Federal Insecticide, Fungicide, and Rodenticide Act Good Laboratory Practices regulations.

The results of such a study may not be accepted by the EPA if the study is submitted to EPA at a later date.

11.22 - Development of New Pesticides and Testing Procedures. The initial phases of research, including pesticide development and establishment of testing methodology, do not fall under Good Laboratory Practices (GLPs). Such basic exploratory studies are not subject to GLP regulations unless the data generated during the study would be submitted to the U.S. Environmental Protection Agency in support of a research or marketing permit.

11.23 - Efficacy Tests. Most efficacy tests, which comprise the bulk of Forest Service pesticide studies, are designed to compare a number of registered chemicals to determine which ones are best for a given forest management situation. Efficacy testing does not currently require Good Laboratory Practice (GLP) compliance if the study is not intended for submission to the U.S. Environmental Protection Agency (EPA). However, efficacy tests must conform to GLP standards if test results are to be submitted to the EPA in support of registration or re-registration. If a study is eventually submitted to the EPA, a compliance statement must be included, even if GLPs were not required or followed when the study was conducted (sec. 12.2).

11.3 - Types of Studies That Allow More Relaxed Good Laboratory Practice Standards. Certain types of studies can be conducted using more relaxed Good Laboratory Practice standards (sec. 01, ex. 01; 40 CFR 160.135; and 40 CFR 792.232) when studies involve:

1. Physical and chemical characterizations of a compound.

2. Pest management alternatives with pesticide-like materials or techniques. These include the use of pest baits, parasites, and predators; the monitoring of traps or trap crops; and the release of sterile male pests.

12 - ASPECTS OF COMPLIANCE.

12.1 - Applicability. (Sec. 01, ex. 01; 40 CFR 160.10). Conduct all studies under Good Laboratory Practices (GLPs) that are intended for submission to the U.S. Environmental Protection Agency (EPA) in support of research or marketing permits. Ensure that any study, or portion of a study, intended for submission to the EPA that is performed under contract by independent consulting laboratories, contractors, or grantees is conducted in compliance with GLP standards.

12.2 - Statement of Compliance. (Sec. 01, ex. 01; 40 CFR 160.12). Include one of the following statements of compliance with each study submitted to the U.S. Environmental Protection Agency (EPA):

1. The study was conducted in accordance with Good Laboratory Practice (GLP) regulations with no deviations from the protocol.

2. The study was conducted in accordance with GLP regulations, but with deviations. Describe in detail all of the differences between the practices used in the study and those required by the GLP regulations.

3. The person was not a sponsor, did not conduct the study, and does not know whether the study was conducted in compliance with GLP regulations. Such a submission may result in rejection of the study.

The applicant, the sponsor, and the Study Director are each responsible for signing the compliance statement. Signing a statement of compliance must be taken very seriously. The EPA officials can prosecute anyone under Title 18, United States Code, section 1001 for knowingly and willfully falsifying information in the compliance statement (sec. 12.4).

12.3 - Inspections. (Sec. 01, ex. 01; 40 CFR 160.15). Allow authorized representatives of the U.S. Environmental Protection Agency (EPA) to inspect field unit facilities (sec. 93). These inspections are conducted to determine whether Good Laboratory Practices and other Federal Insecticide, Fungicide, and Rodenticide Act regulations are being properly followed and that data are available to support the study.

Allow inspectors access to the facility and to all records and materials required to be maintained for the study (sec. 72); otherwise, the EPA may not consider the data reliable for purposes of supporting an application for a research or marketing permit. Refusing an EPA inspection can invalidate a study and may result in cancellation, suspension, or modification of a research or marketing permit (sec. 93.1).

12.4 - Effects of Noncompliance. (Sec. 01, ex. 01; 40 CFR 160.17). The U.S. Environmental Protection Agency (EPA) may invalidate or refuse to consider any study submitted to them that does not follow Good Laboratory Practice (GLP) regulations.

The deliberate falsification of data, records, and reports, or the refusal to maintain or submit required records can lead to the imposition of civil penalties or criminal prosecution. In addition, the applicant, sponsor, and Study Director who fraudulently sign the compliance statement can be civilly liable.

To avoid penalties, accurately and completely list all non-GLP portions of a study in the compliance statement. Penalties are not assessed for submitting non-GLP studies to the EPA; but penalties can be assessed for affirming that studies follow GLP regulations when they do not.

Enclosure #7

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