Forest Health Protection
Forest Service Pesticide Impact Assessment Program

FY 2021 Proposal Instructions and Program Guidelines
Request for Fiscal Year 2021 FS-PIAP Proposals

We are requesting pesticide-related study proposals for the Forest Service Pesticide Impact Assessment Program (FS-PIAP). FS-PIAP projects generate data and findings in support of continued registration of pesticide forestry uses by the U.S. Environmental Protection Agency (EPA) within a framework of integrated pest management (IPM). Refer to Enclosure #1 for proposal eligibility and selection criteria. Refer to Enclosure #2 for specific FS-PIAP priorities. [NOTE: “Pesticide” is defined under FIFRA (7 U.S.C. Sect. 136, et seq.) and includes “biopesticides.” Proposals concerning “biocontrol agents” (ex. predatory insects) are considered under FHP BCIFP program.]

In FY 2020, the FS-PIAP program funded five new projects (sub-total $105,018) and five continuing projects (sub-total $118,490) that had been selected in previous year.

Guidance and forms for preparing FS-PIAP proposals, continuing, and final reports may be found on the Forest Health Protection Grants web page.

Please distribute this set of instructions and guidelines to colleagues who might wish to submit proposals.

Proposal Submittal Instructions for Fiscal Year 2021 FS-PIAP

Both Forest Service units and qualified non-Forest Service organizations and investigators may submit proposals that respond to FS-PIAP priorities. Proposals, Progress Reports and Final Reports must be submitted on the FY2021 “fillable pdf” (Forest Health Protection Grants web page). Download the blank form, enter the appropriate information, and submit the saved document to the appropriate Region Coordinator. Please note: if you plan to enter information via “cut and paste”, your source must be Plain Text. The easiest way to achieve this is to use Word or another word processing program for initial editing, cut and paste the test into Notepad (or any other program that results in a *.txt document), and then cut and paste this Plain Text directly into the Proposal fillable form. Proposals should address data availability if the Project involves the use of external data. For best results, please use Adobe Acrobat Reader DC when filling out the forms on either PC or Mac machines.

Proposals for FY2021 must be submitted by October 16, 2020. to Regional FSPIAP Coordinators. (Enclosure #6 lists current Region FS-PIAP Coordinators.) Proposals sent directly to the FSPIAP National Program Coordinator by investigators will not be accepted. New proposals, and continuing project progress or final reports, must be submitted electronically (using the FS-PIAP forms found on the Forest Health Protection Grants web page) by Principal Investigator or Forest Service sponsor to the cognizant FS-PIAP Region Coordinator. All proposals and reports approved at the Region/IITF level will then be submitted electronically by the Region FS-PIAP Coordinator to the National FS-PIAP Coordinator.

Regional FS-PIAP Coordinators should review proposals to ensure that they meet the requirements and priorities of FS-PIAP before submitting them to the National Coordinator. Submittal of a FS-PIAP study proposal signifies the unit’s endorsement of the need for the study and commitment to ensure the study is successfully completed on schedule, if awarded FS-PIAP funds.

Following Region review and endorsement, proposals for FY21 will be submitted electronically by the Regional FS-PIAP Coordinator to Steve Covell, National FS-PIAP Program Coordinator, no later than close of business November 30, 2020. All proposals must be complete with any requisite forms in order to receive consideration.

Proposals are scheduled to be evaluated in January 2021 by a technical review Committee. Forest Service units that sponsor successful proposals will be notified shortly thereafter.

Please contact Steve Covell, National FS-PIAP Coordinator concerning proposals or related FS-PIAP matters at (571) 255-0818; or via email at stephen.covell@usda.gov.
ENCLOSURE # 1 - FS-PIAP PROPOSALS ELIGIBILITY AND SELECTION CRITERIA

ELIGIBLE PROJECTS

Proposals should be designed to improve knowledge of the benefits and risks of pesticides registered by US-EPA for use in field-based applications supporting forestry and related programs of USFS and cooperators. New forestry uses for registered pesticides, or non-chemical treatments may be evaluated as alternatives to a registered forestry pesticide in EPA/FQPA review (refer to Enclosure #2).

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 or Station managers. Explain the relevance and scope of the proposed study in the justification section of the proposal.

Proposals for FY 2021 should generally emphasize short-term work, which can be completed within one year, but two-year projects will be considered. Two-year projects must have identifiable yearly accomplishments and budgets. Funding for all project proposals is considered only on a year-to-year basis. Funding for multi-year projects is approved for one year. Subsequent years are funded based upon availability of continued funding, and timely submission of a satisfactory progress report to the cognizant Regional FS-PIAP Coordinator (for FY20 projects requesting to continue into FY21, by October 16, 2020).

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:

- Priority of study subject (see Enclosure #2) and the objectives of the proposal. Reviewers will consider how proposal aligns with FSPIAP priorities and need to fill data gaps.

- Technical quality of proposal. Reviewers will consider the likelihood of the proposed project to produce useful results.

- Cost effectiveness of the proposal, including financial contributions from other funding sources. Reviewers will consider advantageous leveraging and matching of funds for best value.

Region FS-PIAP Coordinators will be notified of proposal selections upon approval of funding recommendations. Note: Funding recommendation summary may be available to the investigators from local FSPIAP Regional Coordinator after the evaluation panel has concluded their review.
Enclosure #2 - FS-PI AP National Priorities – Pesticide Data Gaps

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: 1) national FHP steering committee recommendations; 2) Forest Service Pesticide Risk Assessments; public comment and appeals of pesticide application projects; 3) EPA review of pesticide re-registration priorities under the Food Quality Protection Act (FQPA), and 4) coordination with FS research, resource managers, and USDA Office of Pest Management Policy (USDA/OPMP).

Study proposals involving other pesticides registered for forestry and related sites may be submitted, with support of Forest Service Region or Station managers. Explain the relevance and scope of the proposed study in the justification section of the proposal.

For fiscal year (FY) 2021, FS-PIAP particularly encourages:

- Proposals that address data needs for consultation with other Federal agencies on the effects of Forest Service (and other Federal land management agencies) pesticide projects on species listed under the Endangered Species Act. These include focused toxicological and exposure projects to support forest pesticide risk assessments for endangered and threatened species.
- Proposals that include registered alternatives and Integrated Pest Management strategies.
- Advancement in proper use of pesticides (efficacy, efficiency, safety, etc.), because it is Forest Service policy to base actual and recommended uses of pesticides on analysis of effectiveness, specificity, environmental impacts, economic efficiency, and human exposure.
- Proposals that address the efficacy and benefits of new uses of pesticides being considered for management of invasive and native forest pest insects, diseases, and plants.

HERBICIDES

Priority Herbicides

- All herbicides for which a Forest Service Risk Assessment has been prepared. A list of these can be found on the Forest Health Protection Pesticide-Use Risk Assessments web page.
- Herbicides registered for aquatic invasive plant control.
- Other herbicides registered for forestry or forest nursery, or for related sites (e.g. rangeland, non-crop) for control of invasive plants (noxious weeds) in natural wildland environments.

Priority Data Needs for Herbicides

- Human Health Effects and Exposure (deposition, absorption, and urinary excretion data to refine EPA dose predictions for workers in forestry applications of priority herbicides).
- Environmental toxicity, fate; soil mobility and uptake/metabolism, with emphasis on priority herbicides in conjunction with adjuvants (particularly polyethoxylated tallow amines). Species of interest include amphibians, salmonids, and invertebrates including hymenopteran pollinators. 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, and drift.
Ecological Effects
- Efficacy of priority herbicides in Integrated Pest Management strategies for control of invasive, nonnative plant species (noxious weeds). Toxicity to non-target wildland organisms, especially Threatened, Endangered and Sensitive species, including developmental and behavioral changes affecting survival and reproduction. Endocrine disruption effects in wildland organisms. Effects on plant and/or animal communities and biological diversity.

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 and reduced risk insecticides, soaps, plant derivatives, and semiochemicals registered for forest insect control. Registered pheromones for forest insect pests.

Priority Insecticides
- All insecticides for which a Forest Service Risk Assessment has been prepared. A list of these can be found on the Forest Health Protection Pesticide-Use Risk Assessments web page.

Priority Data Needs for Insecticides
- Determination of efficacy of alternative new and registered pesticides in IPM systems to substitute for organophosphates, carbamates, and other insecticides with restricted or canceled registrations. Effects of chemical and biological insecticides on non-target organisms including pollinator species (refer to FS Risk Assessments for identification of data gaps).

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 Fungicides
- All fungicides for which a Forest Service Risk Assessment has been prepared. A list of these can be found on the Forest Health Protection Pesticide-Use Risk Assessments web page.

Priority Data Needs
- Worker exposures to FQPA priority fungicides in typical forestry application scenarios, and/or with IPM strategies using registered alternative pesticides. Determination of efficacy or effects 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.

SYSTEMIC FOREST USE INSECTICIDES AND FUNGICIDES
Physical transport and disposition of priority systemic insecticides and fungicides* with potential application via trunk- and/or soil injection to trees of current interest (i.e. oak, ash, and maple species, redbay, lodgepole and ponderosa pines, hemlock species, Douglas-fir, and select ornamental and fruit-bearing species). Other species will be considered as well.

*pesticides of current interest include imidacloprid, dinotefuran, and emamectin benzoate. These projects are encouraged to be incorporated into investigations of pest control efficacy and will be very valuable in risk assessment development and risk management decisions. Pest species of interest include: polyphagous shothole borer, goldspotted oak borer, Asian longhorned beetle, and hemlock wooly adelgid.

ANIMAL DAMAGE CONTROL
Rodenticides and Piscicides: Environmental fate and non-target effects
Enclosure #3 - FS -PIAP Proposal Guidance

NOTE: Each proposal must be submitted on the designated electronic form and include the study plan purpose and objectives, cite relevant literature, and describe in detail any specific experimental design, methods, and protocols to be used, and technology transfer to be accomplished. Proposal forms must be completed and submitted on schedule in order to receive consideration.

Proposal Title

Should be brief, clear, and specific. The title must be limited to 150 characters (letters, punctuation, and spaces between words). Use the identical title on all reports and correspondence. This will prevent misplacement of records.

Project Summary

Summarize the project, its objectives, and procedures for accomplishing the objectives.

Background, Justification, and Research Basis

Provide brief statements that justify the proposed study. Outline 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. Projects which do not address national priorities require a justification statement from the Forest Service Region FHP FS-PIAP Coordinator (Enclosure #6). Identify the scope and program applicability of study findings. Briefly evaluate existing data that are relevant to the proposed projects and explain why additional projects are needed.

Provide overview of proposed project

A concise, complete, clear, logically arranged, and numbered series of statements defining the specific project objectives, expected accomplishments (use numbered sentences), and advantages to be gained. Provide a brief description of study procedures. Where appropriate, specify location of proposed trials. Exclude detailed explanation here of exact methodology but provide concise statements of how trial 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 in Budget.

As appropriate, study proposals must comply with the Good Laboratory Practice (GLP) regulatory requirements. Refer to Forest Service Handbook 4090.13, 11 (see Enclosure #5) for guidance on when and how to apply GLP regulations to pesticide-related projects performed or supported by the Forest Service. Note that some types of projects supported by FS-PIAP do not require compliance with GLP if not intended for submission to EPA or FDA. Proposals must state whether the study will be conducted in compliance with GLP, and provide a rationale where GLP compliance is not required.

Methods

Identify how results will be obtained, any trials to be conducted, and techniques by which outcomes will be evaluated. Specify any special equipment or supplies to be employed. If statistical analysis of data will be conducted, briefly explain the methods of analysis to be employed.

Describe proposed technology transfer and the expected impacts to Forest Health/Forest Management

Describe why the proposed project is needed, and specifically how results will inform/enable improved Forest Health/Forest Management. Proposals must plan for submission of the study plan and all reports in both printed and electronic media. List planned submissions to professional journals, conferences, etc. that will be based on results of the FS-PIAP study.
Products/Measures of Success

Provide chronology of project progression, expected timeframe of any proposed trials, and identify resultant deliverable products and corresponding delivery target dates.

Citations of Relevant Research

Provide bibliographic listing of key journal articles and published and unpublished studies and reports that support the proposed project need and approach. Provide succinct explanatory annotations describing the relevance of each citation.

Budget Information

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. 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.

Contacts

List name, affiliation, mailing and e-mail addresses, telephone, and FAX numbers for Principal Investigator(s), Forest Service sponsor, and USFS Region Coordinator.

Attachments

List, as appropriate, supplemental documents provided, such as:

Human Subject Certification (see Enclosure #4): When humans are to be monitored in pesticide exposure experiments, the human subject certification must be submitted along with the project proposal. If study will not study human exposure to pesticide, please so note in proposal.

Good Laboratory Practices statement or disclaimer (see Enclosure #5).

Keywords

List project-descriptive terms and phrases, separated by commas that will facilitate search and categorization efforts.
Enclosure #4 - Human Subject Certification

Note: Human Subject Certification is only required if the project proposes to study human exposure to pesticide. If study will not study human exposure to pesticide, please so note in proposal.

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 #5 “Good Laboratory Practices”

FSH 4090.13,10 [excerpts]

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:

2. Section 55.21 of this Handbook for direction on writing safety-related Standard Operating Procedures;
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 #6 - USDA-Forest Service FS-PIAP Regional Coordinators

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