PR. NO.: 5205
DATE: RECEIVED

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IR-4/PIAP

1. PROJECT TITLE::

Clethodim: Magnitude of the Residue on Beans (Snap)

2. JUSTIFICATION AND OBJECTIVES:

IR-4 has received a request for the minor use of clethodim on beans (snap) for control of annual and/or perennial grass weeds. To establish this tolerance, it is required that the magnitude of the residue in or on the commodity be determined as per EPA Guidelines 171-4 and Subdivision O. The purpose of this study is to collect and analyze treated and untreated residue samples from appropriate field sites according to the application parameters requested to provide the sponsor with residue chemistry data to support a pesticide tolerance. To determine the magnitude of residues of total clethodim in or on beans (snap), this protocol will be employed using appropriate SOP's and conducted under provisions outlined in 40 *CFR* Part 160 (IN ACCORDANCE WITH EPA's GOOD LABORATORY PRACTICE STANDARDS).

3. SPONSOR/TESTING FACILITY NAME, ADDRESS AND PHONE:

IR-4 Project Headquarters, Cook College, Rutgers University, New Brunswick, NJ 08903-0231 (908) 932-9575, FAX# (908) 932-8481.

4. STUDY DIRECTOR:

Dr. Daniel L. Kunkel, IR-4 Project Headquarters, New Brunswick, NJ 08903-0231 (908) 932-9575, FAX# 908-932-8481.

5. GOOD LABORATORY PRACTICE COMPLIANCE:

The appropriate cooperative testing facility (field and laboratory) will be responsible for certifying that its portion of the study will be conducted in accordance with EPA's Good Laboratory Practice (GLP) Standards, 40 CFR 160, amended and effective Oct. 16, 1989. A statement of compliance, together with any GLP deviations will be signed and submitted by the appropriate Research Directors in their report.

6. QUALITY ASSURANCE:

The Quality Assurance Unit (QAU) shall review this protocol prior to any audit or inspection. In addition, the QAU personnel should conduct a testing facility inspection, an in-life inspection of the research, an audit of the raw data and final report, and prepare written reports of the findings, including corrective actions. These findings will be sent to the Study Director with the final field and analytical reports. Findings that exhibit non-compliance with GLP (see *Operational Handbook of IR-4*) will be sent immediately to the Study Director with a copy to the Headquarters (HQ) QAU. IR-4 HQ QAU will direct findings to the Testing Facility's Management and appropriate individuals for a response. In addition to the findings, a quality assurance statement form is to be signed and submitted by the QAU. The statement should be included with or attached to the final field or analytical report.

7. PROPOSED DATES:

Experimental Start: 06/92
Experimental Termination: 03/96

8. PROPOSED TEST SITES:

Field sites: TN, FL, WI, OR
Laboratory: WA*

WHEN INITIALED AND DATED HERE _____ THIS PROTOCOL ON COLORED PAPER (_____ PAGES) IS AN EXACT COPY OF THE ORIGINAL

9. AMENDMENT AUTHORIZATION:

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Sponsor Representative Date

Redacted for Privacy

Study Director Date

Received by:

Redacted for Privacy

IR-4 Headquarters QAU Date

10. TEST SYSTEM/CROP:

Beans (snap) - Use a commercial variety and report: variety/source, lot number, etc. Field trials will be conducted at the appropriate sites to support the establishment of a national residue tolerance.

11. TEST/CONTROL SUBSTANCE:

Use SELECT (0.94 EC) formulation of clethodim (EPA Reg. No. 59639-3, CAS# 99129-21-2) that has been characterized to meet GLP standards. IR-4 Personnel will arrange procurement of the test substance. Upon receipt, document the lot/batch number. A copy of the characterization report (including identity, strength, purity, stability, composition) or certification of characterization and documentation of archival location will be sent to IR-4 HQ. Store the test substance in a secure, clean, dry area at temperature ranges noted in the product label. EPA regulations require that test substance container(s) must be maintained until the final study report (Pesticide Tolerance Petition) is completed. The Sponsor will notify Field Research Director of completion of final study report or if a waiver from EPA permits proper disposal. Alternatively, some registrants will archive the test substance container(s). See shipping documents for directions or, if none are given, contact the registrant representative: Dr. Jerry Hulbert, Valent USA, 407-682-3553, FAX# 407-862-7167. The registrants will archive a retention sample of the test substance. Control substances are not relevant to this study.

12. TEST SYSTEM DESIGN and STATISTICAL METHOD:

Each test site will consist of one untreated and one treated (2x) plot. The individual plots will be large enough to permit accurate application of the test substance in a manner that represents the major application technique that will be used commercially and to provide sufficient plant material for residue sampling (Part 17 & 18). Buffer zones will be employed between the plots to prevent encroachment of test substance on neighboring plots. Mark plots with identifiable markers containing at minimum the Field ID No., treatment and rate that will persist for the duration of the field research trial or that can be readily replaced. This study is not designed for statistical evaluation of data.

13. TEST SITE PREPARATION:

Prepare a test site following good local agricultural practices for the production of beans (snap) including fertilization, irrigation, if necessary and available, and other practices that ensure good crop production. If practical, the test site should have a known pesticide and crop treatment history of a minimum of 1 year and preferably 3 years.

14. TEST SUBSTANCE APPLICATION:

Apply broadcast with ground equipment in sufficient water and pressure for uniform coverage of the plant surface. Tank mix with a non-phytotoxic crop oil concentrate (petroleum based) at 1 qt/A equivalent. Calibrate test application equipment prior to treatment to ensure accurate delivery (within 10%). Record calibration data. Agitate mixture before and if practical, during application.

15. APPLICATION TREATMENTS AND TIMING:

Trt#	Treatment	Application Rate	Application Type
01	Untreated		
02	2x Treated	0.25 lb.ai/A	Postemergence

Make 2 post-plant applications approximately 14 days apart with the second application 21 days (plus or minus 1 day) prior to harvest.

16. SUPPLEMENTAL CROP TREATMENTS:

The integrity of the study should be protected by managing pests causing significant damage to the test crop. Only EPA-registered maintenance pesticides should be used at labeled rates. **Document all supplemental crop treatments.** DO NOT USE pesticides which are similar to the test substance or other chemicals that might interfere with analysis of the test substance. If unsure, contact the Residue Research Director (see Section 24) or the registrant representative for guidance (see Section 11).

17. RESIDUE SAMPLE COLLECTION:

Divide each plot (2x and control) into 4 subplots with suitable markers (stakes or flagging tape). Twenty-one days (± 1 days) after the last application, starting with the untreated samples first, collect beans with pods from approximately 12 randomly selected areas of each subplot. Avoid sampling from the plot edges. Each sample should weigh approximately 4 lbs. **Utilize procedures that minimize sample degradation; i.e., placing sample bags in a cooler immediately after collection.** If practical, complete harvest and sample preparation for one subplot before proceeding to the next. Place all samples in plastic-lined cloth bags. Bags may be obtained from the Field Research Coordinator (Section 24). Identify each sample bag with correct Field ID Number, name of Field Research Director, subplot number, location treatment dosage, application dates, type of study (i.e. Magnitude of Residue) and harvest/sampling dates. **Follow proper handling practices with clean hands and tools to prevent transfer of pesticide residue from one sample item to another.**

18. FIELD RESIDUE SAMPLE INVENTORY:

TRT	DAYS AFTER LAST APPL.	NO. OF SAMPLES (ONE/SUBPLOT)	APPROXIMATE WGT. OF BEANS/SUBPLOT
Untreated	NA	4	4 lbs.
2x Treated	21(± 1)	4	4 lbs.
	TOTAL	8	

19. RESIDUE SAMPLE HANDLING AND SHIPMENT:

Freeze samples as soon as possible after collection, within four hours. Maintain samples at temperatures less than +0 degrees F (-18 C) until shipped. If possible, ship samples within 14 days of harvest. Contact the designated person (noted below) from the analytical laboratory prior to shipment of samples for specific instructions. Ship by freezer truck (such as ACDS), overnight air express, or by any other carrier that maintains frozen sample integrity. All storage temperatures are to be monitored and documented.

Send samples to: Ms. Kathryn Moreford,USDA-ARS, Yakima Agricultural Res. Lab., 3706 West Nob Hill Blvd., Yakima, WA 98902 (509) 575-5973, FAX# 509-454-5645.

20. FIELD DOCUMENTATION AND RECORD KEEPING:

All operations, data and observations, appropriate to this study should be recorded directly and promptly into the IR-4 FIELD DATA BOOK or equivalent raw data notebook. At a minimum, collect and maintain the following raw data:

- Name of personnel conducting specific research functions
- Deviations from protocol and standard operating procedures
- Test site information
  - Test substance receipt, use and disposition records
  - Test substance storage conditions
  - Information regarding calibration, and use of application equipment
  - Treatment application data
  - Residue sample collection, storage conditions and handling
  - Meteorological/Irrigation records
  - Other data requested in the IR-4 FIELD DATA BOOK which is appropriate

This trial requires collection of RESIDUE and CROP PHYTOTOXICITY DATA. If possible, also collect EFFICACY and YIELD DATA.

21. PROTOCOL/SOP MODIFICATIONS:

Consult with the Regional/ARS Field Research Coordinator regarding desired changes in the protocol prior to occurrence. If appropriate, an amendment will be issued. Any unauthorized changes to the protocol will require the appropriate Research Director to complete a written report outlining the changes and the potential effects of the alterations on the outcome of the study. This should be provided to the Study Director promptly (e.g. within 14 days of occurrence). All modifications of SOP's also require documentation and approval by the Study Director.

22. FIELD RESEARCH REPORT/ARCHIVING:

The Field Research Director will maintain a complete certified true copy of the IR-4 FIELD DATA BOOK and other raw data and will forward the completed originals of this to the Regional/ARS Field Research Coordinator promptly after the shipment of residue samples. The originals will be forwarded to IR-4 HQ for archiving.

23. ID NO.: FIELD: 5205.93-OR05
LAB: 5205.93-YAR08

24. PERSONNEL FOR THIS FIELD SITE :

FIELD RESEARCH DIRECTOR/TESTING FACILITY:
Mr. Robert McReynolds, NWREC, Oregon State University, 15210 N.E. Miley Rd., Aurora, OR 97002-9543, (503) 678-1264.

RESIDUE RESEARCH DIRECTOR/TESTING FACILITY:
Mr. C. Ron Sell, USDA-ARS, Yakima Agricultural Res. Lab., 3706 West Nob Hill Blvd., Yakima, WA 98902 (509) 575-5877, FAX# 509-454-5645.

REGIONAL/ARS FIELD RESEARCH COORDINATOR:
Mr. Rick Melnicoe, IR-4/PIAP, Dept. of Environmental Tox., Univ. of California, Davis, CA 95616-8588, (916) 752-7633, FAX# 916-~~756-9281~~. 752-2866 MR, 6.1.93 Change in fax #

25. ESTIMATED RESEARCH DATES FOR THIS FIELD SITE:

First Application of Test Pesticide:	7-20-93
Residue Samples Collected:	9-15-93
Samples Transferred to Analytical Laboratory:	10-1-93
Field Report Signed by Field Research Director:	12-30-93

26. ACKNOWLEDGMENTS (FIELD PHASE):

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Mr. Robert R. Libby (Date)
IR-4 Coordinator

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Mr. Rick Melnicoe (Date)
Field Research Coordinator

27. GLP CERTIFICATION(FIELD PHASE):

I acknowledge that I have reviewed, understand, and am responsible for the material contained in pages 1, 2, 3, 4 and 5(D) of this IR-4 Protocol. The field research will be conducted in accordance with this protocol which reflects EPA's Good Laboratory Practice Standards. I further acknowledge that written documentation of research procedures (Standard Operating Procedures, that are equivalent to IR-4 generic SOP's) are available for the appropriate research and that I will cooperate with the independent Quality Assurance Unit.

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Mr. Robert McReynolds (DATE)
Field Research Director*

***RETURN THIS PAGE TO THE FIELD RESEARCH COORDINATOR WITHIN 5 DAYS OF COMPLETION AND PRIOR TO INITIATION OF RESEARCH.**