I. OVERVIEW

Negotiated Rulemaking. Negotiated rulemaking is a tool the legislature has authorized for use in agency rulemaking (Ch. 120.54(2)(d) F.S.). The Department is the third state agency to actively consider its use. This tool has been successfully used by other states and by federal agencies as a cost-effective approach to rule development which requires the voluntary participation of the affected interests. As defined in Chapter 120, "negotiated rulemaking is a process that uses a committee of designated representatives to draft a mutually acceptable proposed rule."

Feasibility Assessment. In February 2002, the Department of Agriculture and Consumer Services (DACS) asked the Florida Conflict Resolution Consortium (CRC), based at Florida State University, to conduct a feasibility assessment for utilizing negotiated rulemaking as a means for rule development pursuant to the Chapter 487, F.S. In particular, the Department asked the CRC to explore with affected interests the feasibility of a negotiated rulemaking to implement provisions in a 2001 amendment requiring rulemaking to establish efficacy and performance standards for registering termiticides for use as a preventative treatment on new construction pursuant to §487.041 F.S. and to explore such other regulatory issues that stakeholders identify for rulemaking and/or a negotiated process.

Based on the assessment the FCRC concluded that the key interests affected by the new "registration" statutory language were willing to participate in a negotiation over rule language to implement the provisions. DACS agreed with the assessment results and concluded that a negotiated rulemaking procedure focusing on the 2001 provisions of Ch. 487.041 F.S. relating to establishing efficacy and performance standards for registering termiticides for use as a preventative treatment on new construction was a viable option and path to seeking resolution of the issues and the promulgation of a rule; and noticed the first negotiation session for May 29, 2002 in Orlando. (A full assessment report is available at: consensus.fsu.edu)

II. INTERESTS REPRESENTED

Following the assessment report recommendations relative to interests substantially affected by a new DACS rule on Registration, the department appointed negotiated rulemaking Committee members representing the interests of chemical companies, pest control operators, homebuilders, building officials, insurance industry, the agricultural extension service, and the agency. The members of the committee are:
Committee Members and Representation
- Frank Gasperini, Responsible Industry for a Sound Environment (RISE)
- Norm Smith, Certified Pest Control Operators
- DR Sapp, Florida Pest Management Association
- Bob Rosenberg, National Pest Management Association
- Jack Glenn, Florida Home Builders Association
- Roland Holt, Building Officials of Florida
- Michael C. Beckers, Wilson and Schmidt Insurance
- Phil Koehler, University of Florida
- Steve Dwinell, Department of Agriculture and Consumer Services

Chapter 120.54 (2)(d) F.S. Negotiated Rulemaking
1. ...The agency should consider, but is not limited to considering, whether a balanced committee of interested persons who will negotiate in good faith can be assembled...

III. COMMITTEE MEETING SCHEDULE AND LOCATIONS
- Organizational Meeting I May 29, 2002 Orlando
- Second Meeting II July 9, 2002 Gainesville
- Third Meeting III August 20, 2002 Orlando
- Fourth Meeting IV September 10, 2002 Orlando
- Fifth Meeting V October 2 – 3, 2002 Orlando
- Sixth Meeting VI November 12 - 13, 2002 Orlando

IV. FACILITATION TEAM

The negotiated rulemaking sessions were facilitated by a team of neutrals from the Florida Conflict Resolution Consortium, a university based consensus-building organization headquartered at Florida State University with regional offices around the State. The team consisting of Jeff Blair and Robert Jones was approved by unanimous consent of the Committee at the May 29, 2002 meeting.

V. WEBSITE COMMUNICATION

Members of the public as well as Committee members were able to access all relevant Committee documents before and after each of the six negotiation sessions at the FCRC’s website: consensus.fsu.edu

The website contains the assessment report, agenda packets and summary reports for each of the six negotiation sessions, as well as draft rule language documents as developed by the Committee.
VI. PROCEDURAL AGREEMENTS

At the first Committee meeting members reached consensus on the following key procedural agreements. (A full report is available at: consensus.fsu.edu)

A. Goal Of The Committee

The purpose of this negotiated rulemaking proceeding is to seek consensus among the members of the committee for establishing efficacy and performance standards for registering termiticides for use as a preventative treatment on new construction, provided that federal efficacy performance standards may be adopted by reference, as intended by recently enacted legislation, chapter 487-041, Laws of Florida.

B. Decision Making

Consensus. The DACS Negotiated Rulemaking Committee will seek consensus decisions on particular issues and their package of recommendations to be incorporated into language for proposed Rule 5E-2.0311. The Committee will operate by consensus with the assistance of a neutral facilitator. Committee substantive decisions will be made only with the concurrence of all members. Final rule language will require a full consensus—100% agreement—of the Committee. This consensus decision rule underscores the Committee’s view of the importance of seeking and developing agreements with the participation of all members and with which all can live with and support.

1. Levels of Consensus. The Committee’s consensus-building and decision-making process is a participatory one whereby on matters of substance, the members jointly strive for agreements which all of the members can accept, support or at least agree not to oppose. In a consensus outcome, the level of enthusiasm for the agreement may not be the same among all members on any issue, but on balance all should be able to live with the overall package. Levels of consensus on a committee outcome can include a mix of:

- Participants who strongly support the solution
- Participants who can “live with” the solution
- Some participants do not support the solution but agree not to veto it.

2. Dealing with Disagreements. Disagreements arising in the process should be respected; they can illuminate unrecognized problems and serve as a catalyst for improving the draft rule. In the event that a member feels compelled to block a proposal, that member agrees to articulate their objection(s) and offer alternatives for consideration. When someone objects or disagrees, the goal of the Committee, with the assistance of the facilitator, is to discover the unmet need that has produced the objection and to find a way to meet that need in a revised agreement, rather than suppress the objection.
3. **Consensus Building Techniques.** As part of the consensus building process, the facilitator(s) will suggest techniques such as straw polls and consensus ranking to enhance those proposals/options which currently enjoy the greatest level of support.

4. **Proceeding on a Conditional Basis.** The Committee may decide to agree to proceed with options/proposals on a conditional basis and consider amendments to the original proposal at subsequent Committee meetings.

5. **Meeting Guidelines.** The Committee will utilize their agreed upon meeting guidelines for conduct during meetings.

6. **Procedural Decisions.** The Committee will make procedural decisions only when a quorum is present. A quorum shall be constituted by 7 out of the 9 members being present.

7. **Final Draft.** All final rule language will require full consensus of the committee at its final meeting.

C. **Selected Procedural Agreements**

**Impasse.** Before a deadlock or impasse is declared by any member, that member agrees to work with the facilitator(s) who will seek ways to help the Committee to resolve the impasse.

**Caucus.** A caucus can be declared by any member at any time during the negotiations.

**Other Participants and Observes.** The member may be accompanied by such other individuals as the member believes is appropriate to represent his/her interest, but only the member will have the privilege of engaging from the floor in the negotiations and reaching agreements. Through the Facilitator, members may call upon a technical adviser at any time to elaborate on a relevant point. Any person attending and observing the Committee’s meetings may file written statements with the Committee or address the committee during scheduled comment periods, if time permits.

**Facilitator(s).** The negotiating committee’s sessions will be facilitated by a neutral third party who will work with all the members to ensure that the process runs smoothly. The facilitator(s) serve at the will of the Committee.

D. **Safeguards For The Parties**

**Good Faith.** All members of the committee must act in good faith in all aspects of these negotiations. Specific offers, positions, statement made during the negotiations may not be used by other parties for any other purpose or as the basis for future litigation. Personal attacks will not be tolerated.

**Procedural.** All final rule language decisions shall require full consensus of the Committee.
VII. PUBLIC PARTICIPATION  
All negotiation sessions were noticed in the Florida Administrative Weekly (FAW) and open to the public. At each meeting there were written comment forms provided as well as a public comment period. All written comments were included in the facilitator’s summary report for each of the six meetings. In addition, Committee members were allowed to identify members of the public to serve as their technical consultants, who could address the Committee at member’s requests.

VIII. SUMMARY OF NEGOTIATION SESSIONS  
A. Organizational Meeting (Meeting I) May 29, 2002; Orlando, Florida  
The first Committee meeting was limited to procedural agreements as well as defining and agreeing to the scope of issues for the negotiation sessions. (A full report is available at: consensus.fsu.edu)

B. Meeting II; July 9, 2002; Gainesville, Florida  
The Committee reached agreement on a strategy for coordinating the State and Federal rulemaking efforts; and, following a technical presentation and discussions, developed conceptual agreements for soil applied residual treatments.

C. Meeting III; August 20, 2002; Orlando, Florida  
The Committee reached agreement on draft rule language for soil applied residual treatments; and, following a technical presentation and discussions, developed conceptual agreements for stand-alone bait systems.

D. Meeting IV; September 10, 2002, Orlando, Florida  
Following discussions, consensus ranking, and refinements the Committee reached agreement on draft rule language for soil applied residual treatments and stand-alone bait systems.

E. Meeting V; October 2 - 3, 2002, Orlando, Florida  
Following discussions, consensus ranking, and refinements the Committee reached further agreements on draft rule language for soil applied residual treatments and stand-alone bait systems. In addition, following a technical presentation and discussions the Committee reached agreement on draft rule language for wood treatment.

F. Meeting VI; November 12 - 33, 2002, Orlando, Florida  
The Committee discussed, refined, solicited public comment, and voted unanimously, 9 – 0 in favor, on final rule language that DACS will use to proceed with the rule adoption process. In addition, the Committee discussed, refined, solicited public comment, and voted unanimously, 9 – 0 in favor, on final language for a Protocols Review Process that will be referenced in the rule. Finally, the Committee voted unanimously to dissolve as a negotiation committee operating under Florida Chapter 120.54 (2)(d).
IX. STRATEGY FOR COORDINATING THE STATE AND FEDERAL RULEMAKING PROCESS

It was agreed that during the course of negotiations the Committee would monitor the Federal rulemaking effort for developing efficacy and performance standards and to the greatest extent possible correlate the State effort with the Federal effort. The Committee reached consensus on the following strategy:

The Committee should establish close coordination and communication including reporting and sharing information with the federal and national initiative. The Committee will review and adopt any agreements reached at the federal level during their efforts. The Committee will seek a clear understanding of what EPA is doing and will clarify what Florida needs and what would be acceptable for inclusion in the State rule by DACS from EPA and the national initiative. Any standard adopted by EPA subsequent to the development of the proposed rule should be adopted by the Department provided the conditions of the statute are met by the EPA standards.

X. COMMITTEE CONSENSUS AGREEMENTS

A. Draft Rule Language

The Committee voted unanimously, 9 – 0 in support, on consensus proposed rule language for establishing efficacy and performance standards for registering termiticides for use as a preventative treatment on new construction. The draft text is included as Attachment 1.

B. Termiticide Efficacy Protocol Review Process

The Committee voted unanimously, 9 – 0 in support, on consensus proposed language for a termiticide efficacy protocol review process. The draft text is included as Attachment 2.
ATTACHMENT 1

FLORIDA DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES
Division of Agricultural Environmental Services

NEGOTIATED RULEMAKING COMMITTEE
Chapter 487.041 Registration

FINAL CONSENSUS RULE LANGUAGE
Unanimously Adopted by the Committee, November 13, 2002

PERFORMANCE STANDARDS AND ACCEPTABLE TEST CONDITIONS FOR
PREVENTIVE TERMITE TREATMENTS FOR NEW CONSTRUCTION

PURPOSE, EFFECT AND SUMMARY

The purpose and effect of this proposed rule is to adopt performance standards and
acceptable test conditions for pesticides with directions for use as preventative termite
treatments for new construction. The language of this rule was developed through a
negotiated rulemaking as provided for in Chapter 120.54(2)(d), F.S., noticed by the
Department in the April 26, 2002 issue of the Florida Administrative Weekly, Vol. 28,
No. 17. The negotiating committee represented pesticide registrants, pest control
operators, home builders, building officials, insurance industry, university extension
service, and the Department. The language proposed in this notice represents the
consensus of the negotiating committee. The committee also agreed that any
performance standard for these pesticides adopted by the United States Environmental
Protection Agency subsequent to the adoption of the rule should be adopted as allowed
under Chapter 487.041(4)(e), F.S., provided the conditions of the statute are met.

5-E-2.015 DEFINITIONS

Building structure and its contents - For the purpose of the rule the term structure and its
contents shall mean: the building, both structural and nonstructural components assembled as
a part of the construction.

Building test - is a test conducted on a building as defined in the Florida Building Code
(2001 edition) with an area not less than 350 square feet.

Field plot test is a test conducted at a research site other than a building and at which there are
no termite preventative treatments other than the product being tested.

Formulated Bait is a mixture of an active ingredient in the concentration proposed for
registration and a material that can be fed upon by subterranean termites.

Independent monitors - Cellulose available and palatable to the subterranean termite
population that does not contain a termicidal and is used to assess treatment effects on the
termite population.
Infestation – Is defined in Chapter 482.021 as “presence of living pests in, on, or under a structure, lawn, or ornamental”.

Inspection Ports are devices or building modifications that provide access to visual inspection of an area of a structure.

Randomly Selected means each item in a population has an equal chance of being chosen.

Re-infestation is an occurrence of an infestation in a building after a previous infestation has been eliminated.

Stand-Alone is a product or device containing active ingredient pesticide or pesticides used to control a termite infestation without the required use of another pesticide or procedure.

5E-2.0311 Performance Standards and Acceptable test conditions for Preventive Termite Treatments for New Construction.

(I) PERFORMANCE STANDARDS FOR PREVENTIVE TERMITE TREATMENTS FOR NEW CONSTRUCTION

The registrant of any pesticide product containing a label statement that includes directions for use as a preventive treatment for subterranean termites for new construction shall provide data to the Department demonstrating that the product meets the performance standard specified for the type of pesticide product listed below. For products registered prior to the effective date of the rule, the registrant shall have one year from the effective date of the rule to provide the data required to meet the performance standards or the period of time specified to meet the test conditions herein, whichever is greater. When data generation requires more than one (1) year, the registrant shall provide annual reports to the Department. In the event that a performance standard is not met during the test period, the provisions of 487.041 (4)(e) shall apply.

A. For soil applied residual treatments:

1. In field plot tests, subterranean termite damage to wood in the test must equal a rating of 9 or higher under the ASTM D1758–96 scale in at least 90% of test samples for a minimum of five years. For products registered before the effective date of this rule, the test must equal the USDA Forest Service scale rating of 1 or an ASTM scale rating of 9 or higher in at least 90% of test samples for a minimum of five years.

2. In field plot tests, if the data meet the conditions of (I)(A)(1) above, then the product tested shall be considered to meet the requirement that it protects the structure and its contents from subterranean termite damage.
B. For products formulated for use in stand-alone bait systems:

1. General. Formulated bait products submitted for registration after the effective date of this rule must be tested in field plot tests that meet the acceptable test condition requirements of (II)(B), and must meet the performance standards for field plot tests specified in (I)(B)(2), and for building tests specified in either (I)(B)(3) or (I)(B)(4). For products registered prior to the effective date of this rule, formulated bait products must be tested in building tests that meet the requirements of (II)(B) and must meet the performance standards in either (I)(B)(3) or (I)(B)(4) to be re-registered. The Department shall not grant permission in Florida for a building test until (I)(B)(2) is met.

2. Field plot tests. Field plot tests must reduce each baited termite population by a minimum of 50% or reduce wood consumption by a minimum of 50% in at least 75% of baited population colonies within 12 months of initiation of feeding on bait active ingredient; and the minimum required reduction must be maintained for at least 6 months.

3. Building Tests with Existing Infestation. Building tests with existing infestation of the building by subterranean termites must show:
   a. Independent monitors. At least a 90% reduction of termite activity in at least 90% of the test buildings where independent monitors are used as measured by independent monitoring of termite populations within 12 months after initiation of feeding on a formulated bait; and,
   
   b. Building Monitoring. The cessation of the live termite activity in at least 90% of the test buildings within twelve months after initiation of feeding on the formulated bait and:
      i. No re-infestation may occur within two years as verified by visual inspection, or
      
      ii. No re-infestation may occur within 12 months as verified by the use of a combination of research and visual inspection techniques to delineate the location of infestation such as bath trap inspection ports, moisture meters, acoustic detection, chemical detection, microwave technology, canine detection, fiber optics or infrared technology, or
      
      iii. For building tests conducted prior to the effective date of the rule, verification of no re-infestation within 12 months using a combination of the techniques set forth in 2 above is sufficient.

4. Building Tests with No Existing Infestation. Building tests where all buildings used in the test had no existing infestation but demonstrated termite activity within 10 feet from the structure, must show:
   a. Independent Monitors. At least a 90% reduction of termite activity in at least 90% of the test buildings as measured by independent monitoring of termite populations within 12 months after initiation of feeding on a formulated bait; and,
b. Building Monitoring.

i. No infestation can occur in a minimum of 90% of test buildings within three years of initiation of feeding on baiting system, or

ii. Within 12 months if a 100% reduction of termite activity in the independent monitors at a minimum of 90% of the test buildings within 12 months after initiation of feeding on a formulated bait as documented using termite population delineation techniques such as mark/recapture, DNA analysis or cuticular hydrocarbon analysis and, no infestation in at least 98% of the test buildings is verified using a combination of research and visual inspection techniques to delineate the location of infestation such as bath trap inspection ports, moisture meters, acoustic detection, chemical detection, microwave technology, canine detection, fiber optics or infrared technology for 12 months after the elimination of the population.

C. For pesticides applied to wood:

1. Field plot tests and building tests must be conducted.

2. In field plot tests, subterranean termite damage to both treated and untreated wood in the test must equal a rating of 9 or higher under the ASTM D1758–96 scale in at least 90% of test samples for a minimum of five years. For products registered before the effective date of this rule, the test must equal the USDA Forest Service scale rating of 1 or a ASTM scale rating of 9 or higher in at least 90% of test samples for a minimum of five years.

3. Building tests must show no infestation in a minimum of 90% of buildings in the test within five years of the treatment.

D. For systems that use combinations of pesticides or application techniques otherwise not covered by sections above

1. Systems registered after the date of the rule claiming to protect structures by affecting termite populations shall conduct field plot tests and building tests as specified in (II)(B) and shall meet the performance standard for baits in field plot tests (I)(B)(2) and building tests (I)(B)(3) or (I)(B)(4). Systems registered prior to the effective date of the rule shall conduct the building tests as specified in (II)(B) and shall meet the performance standards in (I)(B)(3) or (I)(B)(4).

2. Building tests must be conducted for all products other than those in section (I)(D)(1).

   a. Building tests must show no infestation in at least 90% of buildings in the test within five years of treatment
(II) ACCEPTABLE TEST CONDITIONS FOR PREVENTIVE TERMITE TREATMENTS FOR NEW CONSTRUCTION

Acceptable test conditions for the development of data showing that the product meets the performance standard shall be as specified for the type of pesticide listed below:

A. For soil applied residual treatments:

1. Field plot tests shall be conducted in conditions which approximate Florida conditions with respect to rainfall, temperature, soil types and termite species.

2. Field plot tests shall be conducted with at least ten replications of the treatment tested. If more replications have been used, the results of all the replications shall be reported.

3. Wood used in the tests shall not be treated to resist termite attack or shall not be wood resistant to termites as defined in the Florida Building Code (2001 Edition).

4. Field plot tests data shall be collected from tests:
   a. Accepted by the USEPA as in compliance with USEPA’s Product Performance Testing Guidelines for Soil Applied Liquid Termiticides (OPPTS 810.3600); or,
   b. Conducted by USDA/FS using their soil residual treatment testing protocol; or,
   c. Conducted in accordance with DACS approved protocols.

B. For Stand-Alone Bait Systems:

For products formulated for use in bait systems without other pesticides:

1. Field plot tests evaluate the effect of the bait active ingredient on the population of termites. The existence of foraging population and feeding activity must be demonstrated prior to the introduction of the bait active ingredient. Field plot tests must evaluate a minimum of three (3) separate baited termite colonies and one (1) un-baited termite colony. Effect on foraging activity can be quantified by measuring consumption of foraging monitors, estimation of population size by mark/recapture techniques, or numbers of termite attacks on monitors.

2. Field plot tests and building tests shall be conducted in conditions which approximate Florida conditions with respect to rainfall, temperature, soil types and termite species.

3. For building tests conducted after the effective date of the rule, 10% of buildings with known existing infestations of subterranean termites or 10% of buildings known not to have existing infestations of subterranean termites, or ten (10) sites of each type (whichever is greater) must use independent monitors deployed in the same manner as the bait to quantify termite activity. A minimum of twenty (20) building tests must be conducted. Termite activity can be measured as wood consumption in the independent monitors, numbers of termite attacks on independent monitors, a population estimate using mark/recapture techniques, DNA analysis, or cuticular hydrocarbon analysis.
4. For all building tests initiated after the effective date of the rule, tests shall be conducted on buildings which have not been treated with a soil applied residual treatment within 5 years of the initiation of tests.

5. For building tests conducted prior to the effective date of the rule:

a. **Building Tests with Existing Infestation.** For building tests with existing infestation, 20% of buildings in the data set provided to the Department must have records for a minimum of two years of monitoring termite activity after the initiation of termite feeding on the formulated bait; or monitoring using a combination of research and visual inspection techniques to delineate the location of infestation such as bath trap inspection ports, moisture meters, acoustic detection, chemical detection, microwave technology, canine detection, fiber optics or infrared technology, for a minimum of 12 months after the initiation of feeding on the formulated bait.

b. **Building Tests with No Existing Infestation.** For building tests with no existing infestation, 20% of buildings in the data set provided to the Department must have either:
   
i. Records for a minimum of three years of monitoring of termite activity after the initiation of termite feeding on formulated bait; or
   
ii. Records using termite population delineation techniques such as mark/recapture, DNA analysis or cuticular hydrocarbon analysis for a minimum of 12 months after initiation of feeding on a formulated bait and monitoring using a combination of research and visual inspection techniques to delineate the location of infestation such as bath trap inspection ports, moisture meters, acoustic detection, chemical detection, microwave technology, canine detection, fiber optics or infrared technology, for a minimum of 12 months after the initiation of feeding on the formulated bait.

6. For tests conducted after the effective date of the rule:

a. Building tests with existing infestations must be documented with collection of termites from the test site and preservation for identification.

b. Building test inspections must include a combination of visual and research inspection methods including bath trap inspection ports, moisture meters, acoustic detection, chemical detection, microwave technology, canine detection, fiber optics or infrared technology.

c. Data from field plot and building tests must be developed under Good Laboratory Practices Standards (40 CFR Part 160), a United States Environmental Protection Agency Quality Assurance Agreement, or using a DACS approved protocol.

7. Building tests must use the bait as formulated for registration and must follow directions for use on the registered label or the label proposed for registration.
C. **For pesticides applied to wood:**

1. Field plot tests and building tests shall have been conducted in conditions which approximate Florida conditions with respect to rainfall, temperature, soil types and termite species.

2. Field plot tests shall have been conducted with at least ten (10) replications of the treatment tested. If more replications have been used, the results of all the replications shall have been reported.

3. Field plot tests shall include at least one untreated control for each ten (10) replications.

4. Wood used in building and field plot tests that is treated shall be treated in accordance with the directions for use on the registered label or label proposed for registration.

5. Wood used in the tests shall be a species commonly used in wood frame construction in Florida.

6. For field plot tests, test units shall incorporate untreated wood placed on top of the treated wood to demonstrate that the treatment will protect untreated building components from attack by subterranean termites that require ground-soil contact.

7. For building tests conducted after the effective date of the rule, building test inspections must include bath trap inspection ports, moisture meters, acoustic detection, chemical detection, microwave technology, canine detection, fiber optics, or infrared technology.

8. Field plot tests or building test data shall be collected from tests:
   a. Accepted by the USEPA as in compliance with USEPA’s Product Performance Testing Guidelines (OPPTS 810.3600); or,
   b. Conducted in accordance with DACS approved protocols.

9. Building tests prior to the date of the rule, shall be on a minimum of twenty-five (25) buildings with wood framed exterior walls and treatment shall have been applied according to the label or proposed label directions for use with documented annual inspections.

10. Building tests after the date of the rule shall be on a minimum of twenty-five (25) buildings with wood framed exterior walls and a minimum of ten (10) of the buildings shall have demonstrated termite activity within ten (10) feet of the structure, and treatment shall be applied according to the label or proposed label directions for use.
D. For systems that use combinations of pesticides or application techniques otherwise not covered by sections above:

1. Systems registered after the date of the rule claiming to protect structures by affecting termite populations shall conduct field plot tests and building tests that meet the acceptable test conditions specified in (II)(B).

2. Systems registered prior to the effective date of the rule claiming to protect structures by affecting termite populations shall meet the acceptable test conditions specified in (II)(B).

3. All other systems shall meet the acceptable test conditions specified in (II)(C).

(III) DACS REVIEW OF DATA SUBMISSIONS

A. Publication of Results

1. The Department shall publish the results of its review of data submitted to comply with this rule within 90 days of receipt of a complete set of data developed under the acceptable test conditions established in (II). When the Department determines that the product tested does not meet the performance standard in (I), the data submitter will be allowed 90 days to provide supplemental data and data interpretations for the Department’s consideration. The Department shall review an earlier determination of failure to meet product performance standards based on this supplemental data only if additional data meets the conditions of (II), or shall review an earlier determination based on a data interpretation only if that interpretation demonstrates that the data developed under (II) meets the performance standards established in (I).

B. Data from field plot tests or building tests conducted prior to the effective date of the rule

Data from field plot tests or building tests conducted prior to the effective date of the rule shall be acceptable for review by the Department if any of the following conditions are met:

1. Data and results reported are from all field plots or buildings in a study conducted in accordance with acceptable test conditions; or,

2. Data and results reported are a subset of field plots or buildings with acceptable test conditions from the entire data set where all plots or buildings met acceptable test conditions, provided data were selected in a statistically random manner from the entire data set, represent a minimum of fifty (50) sites, and the method used for selection is reported and documented; or,

3. Data and results reported are from all field plots or buildings with acceptable test conditions, however the entire study included plots or buildings that do not meet acceptable test conditions; or,
4. Field plots or buildings reported were selected in a statistically random manner from the set of existing sites for which records that meet the acceptable test conditions requirements of (II) exist, and the results of fifty (50) sites are reported, and a description of the statistical method used is included in the data submission. Field plots or buildings reported that are a subset of field plots or buildings with acceptable test conditions from the entire data set where some plots or buildings do not meet acceptable test conditions, providing data were selected in a statistically random manner from the set of existing plots or buildings that meet acceptable conditions, represent a minimum of fifty (50) sites, and method used for selection is reported and documented.

C. Use of Termiticide efficacy protocol review process

Termiticide efficacy protocol review process for field and building tests shall be reviewed by the Department using the protocol review process adopted by DACS, dated ____________, document # __________, and hereby adopted by reference.

D. DACS Publication Following Grant of Registration

Upon granting of a registration, DACS will publish the following information:

1. A description of the testing used to evaluate the product’s efficacy, including test locations and who conducted the testing.
2. The results of the efficacy testing relative to the applicable performance standards.
3. Information about which test standards and methods were used to evaluate the registration.
4. Any potential limitations to evaluating product efficacy associated with using this test methods and data.
5. Any additional information that would assist the public in evaluating the product’s efficacy.
ATTACHMENT 2

PROTOCOLS REVIEW PROCESS—To be adopted by DACS and referenced in the rule in the following sections: (II)(A)(4)(C), (II)(B)(6)(c), (II)(C)(8)(b), and (III)(C).

DACS shall review proposed protocols for testing of pesticides proposed for registration as a preventive treatment for new construction for subterranean termites using the following standards:

1. Research and data collection for Field plot tests and building tests shall be directed by one of the following:
   a. Researchers who are employees of USDA/FS; or,
   b. Researchers who have a graduate degree in entomology or other biological sciences.

2. Research and data collection for field plot tests and building tests shall be conducted in accordance with the requirements of the rule 5E-2.0311.

3. Research and data collection for field plot tests and building tests shall be conducted using one of the following quality assurance measures:
   a. Good Laboratory Practice Standards (40 CFR Part 160); or,
   b. USEPA approved Quality Assurance Program; or,
   c. DACS approved quality assurance plan that contains the following elements:
      i. Raw data collected in a manner that allows archiving and independent review.
      ii. Name and affiliation of all raw data collectors and data compilers.
      iii. Signed statement from lead researcher that all data collected and reported is valid and accurate.

4. Field plot tests and building tests must be a scientifically valid test of the effect of the pesticide tested.