

**PROCEDURAL GUIDELINES AND STANDARDS FOR THE REVIEW OF  
STATE PESTICIDE REGISTRATIONS, EMERGENCY EXEMPTIONS  
AND EXPERIMENTAL USE PERMITS**

Currently Under Revision

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**SECTION I**  
**BASIC REGISTRATION REQUIREMENTS/INSTRUCTIONS**  
**FOR PESTICIDE PRODUCTS TO BE REGISTERED**  
**UNDER SECTION 487.041, FLORIDA STATUTES**

## **A. RENEWAL OF BRAND REGISTRATION:**

This category includes current product brand registrations to be renewed. A renewal notice listing currently registered product brands is forwarded by the Department to the applicant 60 days prior to the end of the calendar year (December 31). For the renewal request to be processed on time and registrations to be valid for the new calendar year, the following must be received no later than January 31, of each year:

1. The signed and dated renewal notice shall include updates of product brands discontinuance status. Product brands for which renewal is not requested should be struck through with a single line. Product brands beginning the discontinuance phase must be identified using D1 for the first year discontinuance and D2 for the second year discontinuance. New product brand registrations must be submitted separately on a new or amended brand registration form (DACS13342) in accordance with the procedure in subsection B.
2. One current final printed label (that which appears on the product brand containers) for each product brand if there are any text amendments that are not reflected on the label(s) currently on file with the Department. Copies of pertinent correspondence with the EPA demonstrating compliance with the notification or approval requirements in EPA PR Notice 88-6 should accompany amended final printed labels. Label text or registration amendments involving product transfers, registration number changes, changes in active ingredient type or concentration, and company name changes may not be amended using the product brand registration renewal process. These may only be amended through submission of a separate application for new or amended brand registration as outlined in subsection B. Product brands with these types of amendments should be deleted from the registration renewal notice by striking through with a single line, and submitted on an application for new or amended brand registration form (DACS13342).
3. An updated EPA stamped accepted label, material safety data sheet, and confidential statement of formulation if there are any amendments to these documents that are not part of the Department's current registration records for each product. Any comment, notification or amendment letters issued by EPA in connection with the agency's acceptance of the stamped accepted labels should be included.
4. A check or money order made payable to the Florida Department of Agriculture and Consumer Services to cover the required fee payment for each product brand. The Department's acceptance of a registration fee does not imply or constitute acceptance of the requested registration(s).
5. Definitions:
  - a. Product is defined as all brands, which are, registered under one EPA registration number.
  - b. Product brand is defined as the name or brand name designation, which distinguishes labels from one another.

## **B. NEW OR AMENDED BRAND REGISTRATIONS:**

This category includes product brands not registered with the Department at the time of application (not an existing product brand registration renewal). It also includes currently registered product brands where there is a product transfer, registration number change, change in active ingredient type or concentration, or company name change. Application requirements for this category are:

1. An application for new or amended brand registration (form DACS13342), completely filled out and submitted with the supporting documents listed in items 2-6.
2. One current final printed label (that which appears on the product containers) for each product brand to be registered.
3. One current EPA stamped accepted label for each product along with any comment letter issued by EPA in connection with its acceptance. One EPA stamped accepted label is permissible to support multiple product brands to be registered under one product registration number. For supplemental registrations, at least one EPA stamped accepted label for the basic registrant's product is required.
4. One current confidential statement of formulation (CSF) for each product. A single CSF is acceptable to support multiple product brands to be registered under one product registration number. A letter authorizing the use of the basic registrant's CSF is acceptable for subregistrations (the basic registrant's CSF must be submitted with this letter if it is not already on file with the Department).
5. One current material safety data sheet (MSDS) including a statement of emergency treatment for each product. A single MSDS is acceptable to support multiple product brands to be registered under one product registration number.
6. A check or money order made payable to the Florida Department of Agriculture and Consumer Services to cover the required fee payment for each product brand.
7. Applications for the registration of products with significant new uses or new active ingredients are subject to special registration and data submission requirements. A supplemental data package will be forwarded to the applicant upon receipt of the information in items 1-6 if these data are required. The processing and review time frames for these products will be dependent upon the type of data required and whether or not additional studies must be performed by the applicant.
8. Complete new product brand registrations not subject to the requirements covered in item 7 will be reviews and registers pesticide product brand(s) in the order that they are received. At the end of each calendar year, all existing pesticide product brands must be re-registered with the State in order to remain legal in trade channels.

Registrants are responsible for assuring that pesticide brands are not sold or distributed in the state prior to the receipt of a confirmation notice from the Department. This confirmation notice will be sent by email, fax and/or letter to the contact(s) listed on each renewal notice or application form.

**SECTION II**  
PROCEDURAL GUIDELINES AND OBJECTIVES  
FOR THE SELECTION, PROCESSING AND REVIEW OF ACTIONS  
TO ADDRESS POTENTIAL RISKS

This section sets forth the standards that will be used in determining which pesticide actions will be subject to the requirement for additional data submission so that reviews may be conducted to ascertain and address potential risks. The data to be required and reviewed will be dependent on the individual pesticide's toxicity and proposed use pattern. This "applicable data" selection process will be based on review of the proposed actions by the Scientific Evaluation Section, the Pesticide Registration Evaluation Committee (PREC), and the Pesticide Review Council (PRC).

#### **A. BACKGROUND:**

The Department of Agriculture and Consumer Services (DACS) is the designated State Lead Agency for pesticide regulation in Florida. In accordance with this designation and responsibilities assigned the Department under provisions of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Florida Pesticide Law (F.S. 487), DACS processes and accepts or rejects applications authorizing sale and distribution of pesticides in the state.

DACS annually registers about 12,000 pesticide brands, of which about 1,500 are new registrations. An even smaller portion of the new registrations are comprised of products that contain a new active ingredient or a new use pattern for an existing active ingredient. In addition to these, other DACS actions include the registration of products to meet special local needs, the exemption of pesticide products from registration to address pest emergencies, and the issuance of experimental use permits to conduct research. DACS is also responsible for coordination and interaction with the Pesticide Review Council, a statutorily created body, and affected state agencies.

#### **B. OBJECTIVES OF THE DATA SUMMARY REVIEW PROCESS:**

1. Because of limited resources and the need to avoid the duplication of EPA efforts, the general objectives of DACS will not include critical analysis of conclusions or decisions made by the EPA in connection with the acceptance of an existing action. However, clear defects, errors or omissions that are identified should be evaluated and rectified if the circumstances warrant.
2. Evaluate proposed actions to assure Florida needs and conditions are addressed: The primary focus of the data summary review process is to cooperatively conduct reviews and evaluations of proposed actions to determine if they may present unreasonable hazards to man or the environment (given Florida's unique hydrogeologic, soil, climatic, demographic, crop/site, ecological and other conditions), and also to insure that the proposed actions are consistent with both state and federal regulations.
3. Provide input regarding information necessary to properly evaluate a proposed action: It is the responsibility of DACS to determine what, if any, additional data and materials may be needed to properly evaluate a proposed action, and recommend the acquisition of this information if DACS does not already have it in its possession.
4. Develop recommendations on proposed actions based on results of evaluation: If DACS decides, based on input from review participants, that a proposed action poses negligible risks, it should recommend approval of the action. In the case of significant risks, DACS should evaluate viable solutions and alternatives that may be used to reduce them to an acceptable level. If risks can not be reduced to an acceptable level and/or violations of regulations exist that can not readily be corrected, then DACS shall reject the proposed action.

### **C. ACTIONS SUBJECT TO THE SUBMISSION OF DATA:**

Based on available resources, priorities, and input to the Department, certain registration and experimental permit actions will be subject to routine review to meet the objectives outlined in this Section. These are defined as follows:

1. New Active Ingredients (NAIs) - Are products containing AIs not fully registered with the Department by any registrant at the time of registration application.
2. Significant New Use Products (SNU) - Are active ingredient registrations for uses not previously registered with the Department by any registrant, or which have been previously cancelled or suspended by the Department or EPA, provided that:
  - a. The proposed use represents a significant expansion in the number of acres in the state that may be treated; or
  - b. The proposed use represents the addition of new sites or crops to the label that are dissimilar to those currently registered.

Examples of significant new uses include but are not limited to the following:

- a. New product or label change is for outdoor use when all previous registrations are for indoor use;
  - b. New product or label change is for aquatic use when all previous registrations are for terrestrial uses and vice versa;
  - c. New product or label change is for soil application, incorporation or injection when all previous registrations were foliar;
  - d. New product or label change is for use on a crop or site which will expand its use into an area of high ground or surface water vulnerability;
  - e. New product or label change has a formulation, or an application method or rate that may increase its potential for contamination of ground or surface water.
3. Section 24(c) Special Local Need (SLN) Registrations - Are state registrations for new uses to address Special Local Needs as authorized under Section 24(c) of FIFRA.
  4. Experimental Use Permits (EUPs) – Are permits granted by the state authorizing limited field trials for experimentation to generate data as authorized under Section 5 of FIFRA.
  5. Section 18 Crisis and Emergency Exemptions - Are exemptions from the requirement for federal registration which are issued by the EPA to address pest emergencies.
  6. Other Products or active ingredients selected under the special review program, will be included in the review process on a case-by-case basis when deemed appropriate. Data requirements associated with requests for exemptions under Section 18 of FIFRA are addressed in Section V of this document.

### **D. DATA TO BE REQUIRED:**

Set forth below are the conditions which establish which data are to be submitted in support registration applications meeting the criteria in subsection C.

1. NEW ACTIVE INGREDIENTS - Active ingredients to be registered for the first time in Florida for products applied to the following sites: soil, foliage, outside buildings, inside greenhouses, water or wetlands, a system in which waste containing the pesticide is discharged to water or soil. Toxicological data only will be requested for products exclusively used inside buildings (excluding greenhouses). Otherwise the following data will be required:
  - a. All products:
    - i. Acute mammalian toxicity (one copy of each form for each except where noted)
      - T-1 – acute oral LD<sub>50</sub>; acute dermal LD<sub>50</sub>; acute inhalation LD<sub>50</sub>
      - T-2 – primary eye irritation; primary dermal irritation
      - T-3 – (skin sensitization)
      - T-7 – (acute delayed neurotoxicity) Mutagenicity (no summary form – request summary of study as required per 40 CFR 158.135)
    - ii. Residue chemistry data (one copy of form)
      - CR-1 (check applicable items on form analytical standards; analytical methodologies for soil, water, vegetation, fish, crops, animal fat and tissues, etc.; summary of nomenclature; chemical and physical properties)
  - b. All “outdoor” uses (items under 1a plus the following):
    - i. Environmental fate (one copy of each form)
      - EF-1 (product chemistry and K.)
      - EF-2 (adsorption/desorption)
      - EF-3 (hydrolysis)
      - EF-4 (aqueous photodegradation: specify water as media) - (not required for greenhouse or domestic outdoor uses)
      - EF-5 (aerobic soil metabolism) - (not required for aquatic uses)
      - EF-6 (anaerobic soil metabolism) - (required for terrestrial food uses only)
      - EF-7 (aerobic aquatic metabolism) (required for aquatic uses only)
      - EF-8 (anaerobic aquatic metabolism) (required for aquatic and forestry uses only)
      - EF-9 (field dissipation) - (soil studies for terrestrial and domestic outdoor uses only; aquatic sediment studies for aquatic uses only; forestry studies for forestry uses only) - (no summary forms for aquatic and forestry studies -request summaries of studies as required per 40 CFR 158.130)
    - ii. Wildlife and aquatic toxicity (one copy of each form except where noted)
      - T-10 (avian oral LD.) - (not required for greenhouse uses)
      - T-11 (avian dietary LC50) - (not required for greenhouse uses)
      - T-12 (one copy of form for each study - LC50 for freshwater fish; invertebrates) (not required for greenhouse uses)
      - Bioaccumulation in fish/aquatic organisms (no summary form - request summary of study as required per 40 CFR 158.130 and 158.145) - (conditionally required for terrestrial, aquatic and forest uses; not required for greenhouse and domestic outdoor uses)
  - c. All food use products (items under I-A and I-B, plus the following):

- i. Chronic toxicity (one copy of each form except where noted)
      - T-8 (one copy of form for each study - 90-day feeding study for rodents; for nonrodents)
      - T-4 (one copy of form for each study - chronic feeding/oncogenicity for rat; for mouse)
      - T-5 (one copy of form for each study teratogenicity for two species)
      - T-6 (multi-generation reproduction)
      - General metabolism (no summary form request summary of study as required per 40 CFR 158.135)
- 2. SIGNIFICANT NEW USES - This includes active ingredients that have been previously registered where the requested registration includes a significant new use pattern for the product. If Significant New Use product is already included in the Special Review Program and is scheduled for review within the next year, then a data package will not be requested.
  - a. Aquatic uses when all previous uses terrestrial (all other data should be on file to cover terrestrial uses)
    - i. Environmental fate data for aquatic uses (one copy of each form)
      - EF-4 (aqueous photodegradation: specify water as media)
      - EF-7 (aerobic aquatic metabolism)
      - EF-8 (anaerobic aquatic metabolism)
      - Aquatic field dissipation (no summary form - request summary of study as required per 40 CFR 158.130)
  - b. Terrestrial, greenhouse, forestry or domestic outdoor use when no previous uses "outdoor"
    - i. Requirements same as NAI for that use
  - c. Food use when no previous uses for food
    - i. Requirements same as NAI for that use
  - d. Data requests for other SNU categories will depend on the nature of the use pattern and potential for use expansion
- 3. EXPERIMENTAL USE PERMITS - When the EUP request is for a new active ingredient, a standard EUP Data Summary form will be necessary plus an analytical standard and applicable analytical methodologies. EUP requests for products whose active ingredient is already registered will not need any additional support data; however, analytical methodologies may be necessary depending on the request. Refer to Section VI for additional information about applicable data submission/application support requirements.
- 4. SPECIAL LOCAL NEED REGISTRATIONS - Data will only be required to support a SLN registration when it is determined that the use is considered to be a SNU. If that is the case, data will be requested according to the rules under the SNU section. Otherwise, no additional support data will be necessary. Refer to Section IV for additional information about applicable data submission/application support requirements.
- 5. CRISIS AND EMERGENCY EXEMPTIONS - Refer to Section V for additional information about applicable data submission/petition support requirements.
- 6. PRODUCTS OF SPECIAL CONCERN - Active ingredients that may be of special concern for a period of time or for a particular reason. These active ingredients will be identified by the PREC and a list of these products supplied to the Registration Section of DACS. Data requests will be dependent on the nature of the registration request and the special concern.

## E. NEW ACTIVE INGREDIENT ASSESSMENT:

1. New Active Ingredients (NAIs), as defined in Section IIC 1, shall be supported by the applicable summary data listed in Section IIC 1. The Department will assess the toxicity and environmental behavior of the active ingredient (parent compound) and any degradation products of concern, primarily based on these summary data. In cases where there exists a range of values for selected parameters (partition coefficient, soil half-life, etc.), the Department will determine the appropriate values given the sites and conditions under which the product is to be used. NAIs for indoor use only are exempt from the above requirements.
2. Part of the Department's evaluation of the NAI will involve the calculation of a ranking index (RI) for the parent compound and significant metabolites. This ranking index is used as a broad, first step screening process to aid interested parties who may be unfamiliar with the FDACS registration process. The ranking index is an indicator of the compound's leaching potential and is calculated using values for the following chemodynamic parameters:
  - a. Vapor pressure (Pa at x degrees C)
  - b. Molecular weight of compound
  - c. Kelvin temperature (degrees C + 273)
  - d. Solubility (mg/l)
  - e. Henry's constant (Kh, dimensionless)
  - f. Partition coefficient ( $K_{OC}$ , m<sup>3</sup>/kg)
  - g. Degradation half-life in soils  $t_{1/2}$  in days)

Values for the above parameters will be entered into a computer program (FDACSNBAI.EXE) which will calculate the corresponding Kh and RI based on the formulas below:

$$Kh = 16.04 * (\text{Vapor pressure} * 0.0075) * \text{Molecular weight} / (\text{degrees Kelvin} * \text{Solubility})$$

$$RI = L((1 + (\text{BD} * \text{OC} * K_{OC}/\text{FC}) + (\text{AC} * Kh/\text{FC}) (\text{FC}/q)) * (0.693/t_{1/2}))$$

where soil profile characteristics can be modified to specific sites which include depth to groundwater (L), volumetric soil-water contents at field capacity (FC), soil bulk density (BD), soil organic carbon content (OC), air content (AC), and groundwater net recharge rate (q).

Updated computer programs and printouts of pesticides ranked by means of the RI are available. This RI is based on the Attenuation Factor index published by P.S.C. Rao, A.G. Hornsby, and R.E. Jessup: "Indices for Ranking the Potential for Pesticide Contamination of Groundwater", Soil and Crop Science of Florida Proceedings, Vol. 44, 1985. This RI was chosen from the many available for the close correlation with pesticides actually found in Florida ground water. While the relative rankings of pesticides with different soils remain mostly constant, for purposes listed in this assessment document, values published in the paper by Rao *et al.* for a "reference" Tavares soil, depth to ground water, and net recharge rate will be used.

3. If the ranking index is calculated to be 500 or greater, while using the "reference" Tavares soil at 10 meters to ground water and a 28 cm recharge rate, the Department may conclude its

assessment process and grant full registration of the NAI. If the ranking factor is less than 500, the Department will require the registrant to submit complete reports of the following studies before further evaluation of the NAI can proceed:

- a. Leaching and adsorption/desorption
- b. Hydrolysis
- c. Aerobic Soil Metabolism
- d. Anaerobic Soil Metabolism
- e. Field dissipation (soil)
- f. Any existing field or ground water monitoring studies

The reports should be the latest available, adequate to satisfy the needed information, and comply with the requirements specified in 40 CFR Part 158 and the EPA Study Reference Numbers listed in Section IID1. The above "500" value used as a cut-off point is based on an interagency consensus of a separation point of those pesticides whose index values cluster in a group likely to leach versus those pesticides whose index values cluster in a group not likely to leach.

4. Using the data listed in items 3 (v) and (vi), the Department will determine if the results from field or monitoring studies provide a definitive answer for the NAI's potential to leach to groundwater under Florida conditions. If so, one of the following registration decisions will be made:

- a. Register without restriction.
- b. Register with restrictions which may include but are not limited to:
  - i. Restrictions/ limitations on the total quantity of active ingredients that may be used.
  - ii. Establishment of buffer zones or setbacks to protect vulnerable sites (e.g., wells, sinkholes, depressions, etc.).
  - iii. Application method restrictions.
  - iv. Prescriptive use requirements, including, but not limited to, the required submission of use permit applications (with supporting data) and the evaluation of treatment site characteristics as a condition of permit approval.
- c. Deny registration
  - i. Should the data from existing field monitoring not be definitive and one of the above decisions cannot be made, then the Department will conduct 28-year minimum computer modeling using appropriate data listed in item 3. Gumbel (1958) and Carsel *et al.* (1984) have shown that twenty-five to thirty years are required to insure with 95% confidence that the data will be within one standard deviation from the mean. (Gumbel, E.J. 1958. Statistics of Extremes. New York, NY: Columbia University Press. Carsel *et al.* User's Manual for the Pesticide Root Zone Model (PRZM). EPA-600/3-84-109, December 1984.) Such modeling will simulate movement of the parent compound and metabolites of toxicological concern through and past the root zone. Several existing models are suitable for this purpose. They include:

- (1) GLEAMS, Ground Water Loading Effects of Agricultural Management Systems, (R. A. Leonard and W. G. Knisel, USDA-ARS, Tifton, Georgia);
- (2) LEACHMP (Wagenet and Hutson, Cornell University, Cornell, New York);
- (3) PRZM, Pesticide Root Zone Model, (Carsel, U.S.E.P.A., Athens, Georgia); and
- (4) CMLS, Chemical Movement in Layered Soils (Nofziger--University of Oklahoma, Hornsby--University of Florida).

ii. The use of more than one model in these simulations is advantageous for comparative purposes. The model simulations will be conducted using reasonable worst-case data to include:

- (1) Daily rainfall
- (2) Method of application
- (3) Application rates and timing
- (4) Solubility
- (5) Degradation half-life in soil
- (6) Partition coefficient ( $K_{OC}$ ,  $m^3/kg$ )
- (7) Rooting depth
- (8) Soil type and porosity
- (9) 1/3 bar water capacity
- (10) The curve number (as developed by USDA-SCS)

The number of simulations to be conducted will be dependent upon use patterns and site characteristics for the proposed registration, and will be chosen from among several "suites" representative of Florida hydrogeological/cropping settings.

5. DACS and DEP will use these "suites" and will agree to other appropriate model conditions similar to which the subject pesticide would be subjected to, based on the proposed registration. DACS and DEP will also agree on values or a range of values for the input pesticide parameters ( $K_{OC}$ ,  $t_{1/2}$ , etc.). Using the 28-year minimum output, a determination of the median values for total annual leaching loss of the subject pesticide will be made. If 0.1% of the application rate leaches below a specified depth in at least 10% of the years modeled, then a full toxicological assessment of the product may be requested. Using 28-year minimum data simulation sets and "suites" inputs, DACS, and DEP will compare these median values of the proposed (subject) pesticide with the median values for the total annual leaching loss of five reference pesticides known to leach or having the potential to leach to ground water under Florida use conditions. Currently the five will be: aldicarb, bromacil, diuron, metribuzin and simazine. The following rule will assign a relative leaching value to the subject pesticide (S),k relative to each of the reference pesticides (R):

$S < .1 R$	assign a value of 1
$.1 R \leq S < 10R$	assign a value of 2
$10 R \leq S$	assign a value of 3

For the subject pesticide, add the five relative leaching values and divide by five to obtain the average. The leaching category is assigned based on the following:

Low: < 1.5                      Med: 1.5 to < 2.5                      High: 2.5 or greater

In this manner each new subject pesticide is assigned either to a Low, Medium or High leaching potential category. This category is assigned to the subject pesticide in the decision matrix (Figure 1). The "rule" as stipulated above, in conjunction with toxicity categories, places the reference pesticides into the same registration decision categories as intended by prior interagency consensus. This same pesticide will also be assigned to a toxicological concern category by means of the criteria set forth in the following section.

6. Where data indicate a high probability of the parent compound or metabolite to move through and past the root zone under Florida-specific conditions, the Department, in coordination with the PREC, will conduct a full toxicological assessment using data provided by the registrant and from other sources available to the Department. From the assessment of all toxicology data available, the Department will classify the compound(s) suspected as having the potential to reach ground water into one of four categories of concern for chronic toxicity (High Chronic Toxicity Concern, Moderate Chronic Toxicity Concern, Low Chronic Toxicity Concern, and Minimal to No Chronic Toxicity Concern), as indicated below.

This classification applies only to the potential effects associated with chronic exposure. These categories are not absolutely defined; additional factors which may allow placement into a higher or lower category include data quality, completeness of data base, reference doses, dose response, etc. Acute toxicity will be a ranking factor only where there is a maximum concern for high concentrations of the product to reach ground water.

#### HIGH CHRONIC TOXICITY CONCERN

- a. Group A or B carcinogen<sup>1</sup>; or
- b. Group D carcinogenic<sup>1</sup> where no data exist (Carcinogen D1); or
- c. Group C carcinogen<sup>1</sup>, where the risk associated with the Health Advisory Level exceeds  $10^{-6}$  (Carcinogen C1) and reproductive toxicity is demonstrated in either sex in two or more species at doses not toxic to the parental generation (Reproductive 1); or
- d. Carcinogen C1 and teratogenicity is positive in two or more species at < maternally toxic levels (Teratogen 1); or
- e. Carcinogen C1 and mutagenicity is a potential human mutagen (Mutagen 1) as adapted from Tardiff and Roricks<sup>2</sup>; or
- f. Teratogen 1 and Mutagen 1; or
- g. Teratogen 1 and Reproductive 1; or
- h. Reproductive 1 and Mutagen 1.

#### MODERATE CHRONIC TOXICITY CONCERN

- a. Carcinogen C1 and reproductive toxicity is demonstrated in either sex in 1 specie at doses not toxic to the parental generation (Reproductive 2); or

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<sup>1</sup> As defined in "Guidelines for Carcinogen Risk Assessment", Federal Register, Vol. 51, #185, September 24, 1986, p 34000

<sup>2</sup> As defined in "Substance and Human Risk", ed. R.G. Tardiff and J.v. Rodicks, p352, Table 15-2: 1989

- b. Carcinogen C1 and mutagenicity is a possible animal (human) mutagen (Mutagen 2) as adapted from Tardiff and Roricks<sup>2</sup>; or
- c. Carcinogen C1 and teratogenicity is demonstrated in 1 specie at < maternally toxic dose (Teratogen 2); or
- d. Group C carcinogen<sup>1</sup> where the risk associated with the Health Advisory Level < 10<sup>-6</sup> (Carcinogen C2) and Reproductive 1; or
- e. Carcinogen C2 and Teratogen 1; or
- f. Carcinogen C2 and Mutagen 1; or
- g. Teratogen 1 and Reproductive 2; or
- h. Teratogen 1 and Mutagen 2; or
- i. Reproductive I and Mutagen 2; or
- j. Reproductive 1 and Teratogen 2; or
- k. Mutagen 1 and Reproductive 2; or
- l. Mutagen 1 and Teratogen 2; or
- m. Teratogen 2 and Reproductive 2; or
- n. Teratogen 2 and Mutagen 2; or
- o. Reproductive 2 and Mutagen 2; or
- p. Teratogen 1 OR Reproductive 1; or
- q. Carcinogen C2 OR Reproductive 2 OR Teratogen 2; or
- r. Group D carcinogen<sup>1</sup> where data are inconclusive (Carcinogen D2) and Mutagen 1.

#### LOW CHRONIC TOXICITY CONCERN

- a. Carcinogen C2; or
- b. Carcinogen D2; or
- c. Mutagen 1 OR Mutagen 2 OR the compound is shown to be a "genetically toxic agent", a "mutagenic agent" or an "animal cell somatic mutagen" as developed in Tardiff and Roricks<sup>2</sup> (Mutagen 3); or
- d. Reproductive Toxicity at doses toxic to the parental generation (Reproductive 3); or
- e. Teratogenic at maternally toxic doses (Teratogen 3); or
- f. Carcinogen C2 and Mutagen 2; or
- g. Carcinogen C2 and Mutagen 3; or
- h. Carcinogen C2 and Reproductive 3; or
- i. Carcinogen C2 and Teratogen 3; or
- j. Carcinogen D2 and Mutagen 2; or

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<sup>2</sup> As defined in "Substance and Human Risk", ed. R.G. Tardiff and J.v. Rodicks, p352, Table 15-2: 1989

<sup>1</sup> As defined in "Guidelines for Carcinogen Risk Assessment", Federal Register, Vol. 51, #185, September 24, 1986, p 34000.

- k. Carcinogen D2 and Mutagen 3; or
- l. Carcinogen D2 and Reproductive 3; or
- m. Carcinogen D2 and Teratogen 3; or
- n. Acute irreversible delayed neurotoxicity positive.

MINIMAL TO NO CHRONIC TOXICITY CONCERN

- a. Group E Carcinogen; or
  - b. No mutagenic response; or
  - c. No teratogenicity; or
  - d. No reproductive effects; or
  - e. Irreversible neurotoxicity negative.
7. Upon completion of the leaching potential and a toxicological concern assessment, the subject pesticide will be categorized in accordance with the decision matrix in figure 1.

The decision matrix result will be used as a guideline for a PREC recommendation based-on the following decision categories:

- a. Register with no further data generation - products containing parent compounds or metabolites in Figure 1 (A) will be eligible for full registration without further restriction or review in relation to ground water.
- b. Register but monitor use - products containing parent compounds or metabolites in Figure 1 (B1) will be eligible for conditional registration, provided the registrant agrees to monitor use of the Federal Register, product and submit monitoring data specified by the Department in accordance with established reporting requirements and time frames. Such monitoring data may include, but is not limited to:
  - i. Annual reporting of amount of material shipped into the state; and
  - ii. Identification of regions of use.Products containing parent compounds or metabolites in Figure 1 (B2) will be eligible for conditional registration, provided the registrant agrees to monitor use of the product and submit monitoring data specified by the Department in accordance with established reporting requirements and time frames. Such monitoring data may include, but is not limited to sampling of ground water in representative use areas using an accepted protocol.
- c. Register conditional on field study - products containing parent compound or metabolites in Figure 1 (C) will be eligible for conditional registration, provided the registrant agrees to subsequently complete a prospective field dissipation study in a representative use area using an accepted protocol.
- d. Register contingent on completion of field study - registrants with products containing parent compounds or metabolites in Figure 1 (D) must complete a prospective field dissipation study in a representative use area using an accepted protocol prior to further consideration of the registration.

8. Based on peer review of the newly-required monitoring studies, the Department may consider additional management options to reduce contamination risks to an acceptable level. These options include, but are not limited to those previously listed in item 4.
9. The Department's consideration of available management options will be dependent on reviews and conclusions involving the likelihood of the product or its metabolites to cause significant health or environmental risks, the potential for amount of use in Florida, the use of effective products stewardship programs by the registrant, and the likelihood that the proposed management option will mitigate risks to an acceptable level.

Figure 1  
 DECISION MATRIX  
 Toxicological Concern

Leaching Potential	None	Low	Moderate	High
Low	A	A	B-1	B-1
Moderate	A/B-1	B-2	C Pesticide X	C/D
High	B-1	B-2	C/D	D

**SECTION III**  
DATA ORGANIZATION AND REPORTING FORMS

In conducting its evaluation of the registration actions in Section II, the Department may require the submission of data to address potential risks or to determine the need for additional studies to evaluate pesticide behavior under Florida conditions. In doing this, the Department, where possible, will utilize data that have been generated by the registrant and submitted to the EPA in support of a federal pesticide product registration. Table I lists the data types (test names) that may be required by the EPA to support a federal registration. It also includes the EPA guideline reference number which identifies the location of the EPA guidelines that specify how the listed test data are to be generated and reported. The Department will select the applicable test data needed for its assessment of a pesticide registration from this table by the listed EPA guideline reference number. The test data will generally be requested in summary format using the forms listed in table II. The summary forms themselves follow table II.

TABLE I and II  
EPA TEST NAMES, REFERENCE NUMBERS

(These forms are currently being revised, please contact the Pesticide Registration Section 850-487-2130 for forms and reference information.)

**SECTION IV**  
REQUIREMENTS AND PROCEDURES FOR THE STATE REGISTRATION  
OF PRODUCTS TO MEET A SPECIAL LOCAL NEED

## **A. DEFINITIONS:**

1. "Special local need" means an existing or imminent pest problem within the State for which the Department of Agriculture and Consumer Services (hereafter referred to as "the Department"), based upon satisfactory supporting information, has determined that an appropriate federally registered pesticide product is not sufficiently available.
2. The term "new product" means a pesticide product which is not a federally registered product.
3. The term "24(c) supplemental label" means a supplemental label issued pursuant to section 24(c) of FIFRA, to an already existing federally registered pesticide product to allow for the addition of a crop or animal, site, pest, application technique or equipment, different application rate, or special label directions.
4. The term "third party registration" means a registration for a new use of a federally registered product by a person other than the federal registrant.

## **B. STATUTORY LIMITATIONS:**

In accordance with section 24(c) of FIFRA, the Department is authorized to register a new end use product for any use, or an additional use of a federally registered pesticide product, if the following conditions exist:

1. There is a special local need for the use within the State;
2. The use is covered by necessary tolerances, exemptions or other clearances under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 346 et. seq.), if the use is a food or feed use;
3. Registration for the same use has not previously been denied, disapproved, suspended or cancelled by the Department or EPA, or voluntarily cancelled by the registrant because of health or environmental concerns.

## **C. NEW PRODUCT REGISTRATIONS:**

A registration to meet special local need may be issued for the following types of new end-use products:

1. A product which is identical in composition to a federally registered product, but which has differences in packaging, or in the identity of the formulator.
2. A product which contains the same active and inert ingredients as a federally registered product, but in different percentages. (A new product may be registered only if each of the active ingredients in the new product is present because of the use of one or more federally registered products and if each of the inert ingredients in the new product is contained in a federally registered product.)

## **D. REGISTRATION PROCEDURES:**

Applications for special local need registration shall contain the information specified in this section. Unless specified otherwise, twelve (12) copies of each of the listed items shall be provided in an individualized package format. The items where twelve (12) copies are not required should be physically segregated from the packages. Application requirements are:

1. Name and address of the applicant and any other person whose name will appear on the labeling or in the directions for use.
2. The name of the pesticide product and, if the application is for an amendment to a federally registered product, the EPA registration number of that product. In addition, the application shall indicate if coloration, special packaging, or restricted use classification will be necessary for the product.
3. The proposed special local need labeling, including all claims made for the product as well as directions for its use to meet the special local need, consisting of:
  - a. For a new product, a copy of the complete proposed labeling; or
  - b. For an additional use of a federally registered product, a copy of proposed supplemental labeling.
4. The complete formula of the product, if the application is for a new product registration.
5. A justification narrative detailing how the proposed registration meets the criteria for a special local need registration. This should include:
  - a. A discussion of the nature, distribution, frequency and severity of the pest problem.
  - b. A listing of registered pest control products or other control mechanisms that have been considered.
  - c. A description and evaluation of data which demonstrates why the existing registered alternatives and other control mechanisms are unsuitable or inadequate.
6. An appropriately completed application form (EPA form 8570-25).
7. The efficacy data demonstrating effectiveness of the product when used according to label instructions; and comparative efficacy data when product performance is claimed to be superior to existing registered alternatives (further instructions for the generation of these data are included under Section L).
8. If the basis for meeting a special local need includes claims of greater safety when the product is used according to label instructions, comparative safety data demonstrating a significant margin of increased safety over the registered alternatives.
9. For food or feed uses, a statement of the maximum residue concentrations that are anticipated as a result of the proposed use(s). For aquatic uses, a statement of the maximum residue concentration immediately after application in and down gradient from the treatment site.
10. A narrative discussion and evaluation of any additional risks to man and the environment that may be posed through use of the product in accordance with the special local need registration. The evaluation should include a discussion about possible hazards from exposure to applicators, field workers, non-target plants and animals, and surface and ground water.
11. For new products, or additional uses of federally registered products which are not registered with the Department at the time of application to register as a special local need product:
  - a. One (1) application for new or amended brand registration (form DACS13342), completely filled out and submitted with the supporting documents listed in items 1 - 5;
  - b. Current final printed labels (that which appears on the product containers) for the basic federal registration upon which the special local need registration is based (this requirement does not apply to new end use products);

- c. One (1) current EPA stamped accepted label for the basic federal registration upon which the special local need registration is based (this requirement does not apply to new end use products). Included with this should be any comment letter -issued by EPA in connection with the acceptance of the basic federal registration;
- d. one (1) current confidential statement of formulation (CSF) for the basic federal registration upon which the special local need registration is based (this requirement does not apply to new end use products);
- e. One (1) Current material safety data sheets (MSDSs) including a statement of emergency treatment; and
- f. One (1) check or money order made payable to the Florida Department of Agriculture and Consumer Services in the amount of \$100 to cover the registration fee payment for the basic federal registration or new product registration.

**E. SPECIAL LOCAL NEED DETERMINATION:**

In reviewing any application for registration, the Department will determine whether there is a special local need for the registration. Situations which may be considered as not involving a special local need may include, but are not limited to, applications for registrations to control a pest problem

present on a nationwide basis, or for use of a pesticide product registered by other states on an interregional or nationwide basis. The Department will verify these facts through data review, knowledgeable experts, user groups, and other affected parties.

**F. UNREASONABLE ADVERSE EFFECTS DETERMINATION:**

Prior to issuing a registration in the following cases, the Department will determine that use of the product for which registration is sought will not cause unreasonable adverse effects on man or the environment when used in accordance with labeling directions or widespread and commonly recognized practices. Registrants will be required to submit the applicable data described in Section II in order to assess risks if the registration is considered to meet any of the following criteria:

- 1. For use of a product which has a composition not similar to any federally registered product.
- 2. For use of a product involving a use pattern not similar to any federally registered use of the same product or of a product with a similar composition.
- 3. For use of a product for which other uses of the same product, or of a product with a similar composition, have had registration denied, disapproved, suspended, or cancelled by the Department or the EPA.

**G. LABELING REQUIREMENTS:**

Prior to issuing any registration, the Department will review the proposed labeling submitted with the application to determine compliance with this section. Florida special local need registration labeling format requirements for supplemental directions for use and for new product registrations are as follows. Supplemental label format examples are provided in subsection N.

1. For a new product, the product must be accompanied from the time it enters the stream of commerce by labeling meeting all applicable criteria contained in 40 CFR Part 162.10. New product labeling must also contain:
  - a. A statement identifying the state where registration is to be valid.
  - b. The special local need registration number assigned by the state.
2. Except as provided in paragraph 3 of this subsection, as a condition' for a registration of an additional use of a federally registered product, the applicant must assure that at the time of sale to users, labeling from the federally registered product be accompanied by supplemental labeling which contains:
  - a. A statement identifying the state(s) where the registration is valid.
  - b. The heading "Directions for Use" followed by the directions for use that meet the special local need and provide the minimum information required under 40 CFR 162.10(i)(2). This includes the crop/site, target pest, dosage, minimum diluent rate, and other information necessary for effective use of the product.
  - c. The EPA Registration number of the registration being amended.
  - d. The statement "1124(c) Registrant" followed by the name and address of the registrant.
  - e. Where applicable, the statement "restricted-use pesticide" and any other language present on the basic federal label which limits sale, distribution, or use of the product to specific applicator classes or categories.
  - f. The special local need registration number assigned by the Department. It should be printed as: EPA SLNFLYY#### (SLN = Special Local Needs, FL = Florida, YY = year accepted for registration, #### = number in series for SLN accepted for registration; Example: SLNFL040001 = this is the first SLN accepted for registration in 2004).
  - g. The statements:
    - i. "It is a violation of State and Federal law to use this product in a manner inconsistent with its labeling. Persons using this product must comply with all applicable directions, restrictions, and precautions found on this labeling and that of the label of the federally registered product upon which this amendment is based."
    - ii. "For Distribution and Use Only Within Florida".
    - iii. "This labeling must be in the possession of the user at the time of pesticide application."
  - h. The trade name of the product.
    - i. A complete ingredient statement, as it is shown on the basic federally registered label that is being amended:
3. When a federally registered product is already in the stream of commerce at the time the Department issues a registration for an additional use of that product, the applicant must ensure that supplemental labeling for the additional use, meeting the criteria of paragraph 2 of this subsection, is made available to purchasers and users of the product within 45 days of the date on which the Department approves the final printed supplemental labeling.
4. Labels accepted for registration in Florida that are identical to those registered in other states may show the SLN registration numbers of each of those states registered on the label.

## **H. TOLERANCE CITATION:**

If the pesticide is for food or feed, the use must be covered by the necessary tolerance, exemptions or other clearances under the Federal Food, Drug and Cosmetic Act. The appropriate tolerance must be cited on the application form under item number 7. If some other clearance under the Federal Food, Drug, and Cosmetic Act is cited, a copy of the clearance must be provided within the application package.

## **I. APPLICATION REVIEW PROCEDURES.**

The Department will abide by the following procedures in reviewing the special local need applications for registration.

1. Verify the special local need justification.
2. Review application to assure that correct and complete data have been submitted.
3. Determine that use of the product for which registration is sought will not cause unreasonable adverse effects on man or the environment, when used in accordance with labeling directions or widespread and commonly recognized practices:
  - a. For use of a product which has a composition not similar to any federally registered product.
  - b. For use of a product involving a use pattern not similar to any federally registered use of the same product or of a product with a similar composition.
  - c. For use of a product for which other uses of the same product, or of a product with a similar composition, have had registration denied, disapproved, suspended, or cancelled by the Department or EPA.
4. Request and evaluate additional data that are needed to assess potential risks. Registrants may be required to submit the data described in Rule 5E-2.031, FAC, which are designated by the Department as appropriate.
5. Consult with EPA on applications which have had a use denied, cancelled or suspended.
6. Forward copies of the application to the Institute of Food and Agricultural Sciences (IFAS, the PREC, and any other appropriate data review agency. (Notify the applicant, in writing, of the date the application packet is sent to the reviewing agency.)
7. After return of packets from IFAS or other agency, conduct final review considering recommendations.
8. Forward required information to EPA after acceptance notification has been issued to the applicant.
9. Report all actions (acceptance or rejection) to the Pesticide Review Council and other interested parties.
10. Notify applicant of final action and requirements of subsection G, paragraphs 2 and 3.

#### **J. "ME-TOO" SLNs AND SLN TRANSFER REQUIREMENTS:**

1. "Me-Too" SLN Registrations consist of applications submitted by additional registrants in order to market the same product for an identical use pattern. "Me Too" application requirements include the following:
  - a. Valid Federal/State Registration for the active ingredient for the "me-too" registrant.
  - b. Letter from SLN registrant authorizing use of primary SLN registrant's data if there is any proprietary information on file in support of the basic SLN.
  - c. SLN application and proposed labeling.
2. SLN Transfer Requirements:
  - a. Proof of the transfer of ownership of the basic Section 3' registration to the transferee.
  - b. A valid state registration for the basic registration under the transferee's name.
  - c. Amended SLN labeling.
  - d. Letter from the current SLN registrant authorizing transfer of the SLN to the transferee.

#### **K. TIME FRAME FOR APPLICATION REVIEW:**

Application review times will vary with the data requirements and with the difficulty in verification of the facts supporting the applicant's justification of the special local need. Applications not completed within 90 days because of the lack of information will be denied and returned to applicant or destroyed if applicant does not want it returned.

#### **L. GUIDELINES FOR THE GENERATION AND SUBMISSION OF EFFICACY DATA:**

Prior to registration of any use of a special local need product, the Department will determine that the product warrants the claims made for it in the registration application. Such determinations shall be based on data that are furnished by the applicant in support of the special local need registration. The data shall accurately reflect performance of the formulated product when used according to label instructions. It should also include information demonstrating product performance under Florida or Florida-like conditions, including trials at sites representative of conditions in areas of the state in which the product will be used. Data in support of a special local need registration should be generated, prepared and submitted to the Department using the applicable provisions in this guideline. The Department will review the quality and content of available efficacy data to be used in support of individual applications to determine if it suitably demonstrates claimed levels of performance.

1. Test standards.
  - a. Personnel. All testing and evaluation should be done under the direction of personnel who have the education, training, and/or experience to perform the testing and evaluation in accordance with sound scientific experimental procedures.
  - b. Test substance. The test substance shall generally be the formulated product.
  - c. Dosage rates. Typically, the test substance should be tested at various rates which include the dosage rates associated with the proposed use. These rates should correspond to the current label rates for the test substance. If a change in the label rate is proposed, special attention should be paid to treatment rates on food crops in relation to (the established) tolerance or the proposed tolerance.

- d. Tank mixes. Product labeling which implies or recommends mixing products in the spray tank before application should have acceptable supporting data as described below.
    - i. Directions for tank mixing of products should be supported by performance data on each component (of the proposed mixture) tested separately as well as data on the mixture used at the dosage rate(s) specified for each pest indicated.
    - ii. The components of a pesticide tank mixture should be evaluated for physical and chemical compatibility.
  - e. Adjuvants. Products with labeling which recommends the addition of separately packaged adjuvants to the spray tank should be supported with data indicating their benefits (if claimed) and any detrimental effects (such as increased crop phytotoxicity) which may result from their addition to the pesticide.
2. Test design and statistical procedures.
- a. General test design. Sound statistical designs and procedures are necessary to assure that valid and appropriate statistical analyses of the data can be performed. Direct comparison of group means of treated sites and untreated control sites is usually sufficient for evaluating treatment effects.
  - b. Multiple site and pest target combinations. When more than one pest or site is involved in pesticide applications, separate tests are usually necessary to evaluate product performance against each kind of pest or each kind of plant under each set of variables or use conditions. If more than one method of application is to be employed (for example, air and ground sprays, drenches and injections, or impregnation and surface coating), experiments should be designed to obtain the required data for each method on or in the same experimental sites.
  - c. Replicates. Generally, the number of replicates necessary to demonstrate treatment differences will depend upon several factors, such as variability of test organisms and materials (crops, pests, application equipment, soil conditions), magnitude of treatment effects, and the desired statistical confidence level.
  - d. Sampling Procedures. Sampling procedures should assure that all of the characteristics of the test population to be measured are represented in the samples. The size and number of samples necessary for reliable estimates will vary mainly with the level and uniformity of the organism or the effect to be measured as well as the size and precision of available equipment.
  - e. Considerations for crop test design. In designing the test, all variables, both uncontrollable such as soil texture and microclimate) and controllable (such as irrigation, cultivation, pruning, fertilization, cultivar, and test product application) should be considered. Care should be taken to duplicate carefully all controllable variables (other than test product application) on all treated and untreated plots.
    - i. Plot sizes. Plots should be large enough to reflect actual use conditions and to allow representative application techniques, which may include commercial application equipment. Factors such as the crop grown, equipment used, expected incidence of the pest, need for residue samples, yield data, and quality studies should be considered in selecting the size of field plots. The plots should be located within a field so as to be representative of conditions throughout the field. Areas of fields such as borders and atypical wet or dry locations must generally be avoided, unless these are the optimum areas for pest damage.

- ii. Crops or sites treated. A representative number of the major cultivars of crops should be represented in the tests. Cultivars should be more extensively utilized as a test variable to demonstrate adverse responses in tests.
  - iii. Climatic factors. The testing schedule should be designed to permit evaluation of the effectiveness of pesticides applied under different environmental conditions such as low versus moderate and high precipitation, cool and cloudy versus normally hot and sunny conditions, and low versus high humidity and dew formation, as appropriate to the product use.
  - iv. Spray volume. The volume of spray is another important variable affecting the performance of pesticides because it directly relates to the distribution and coverage obtained on the target site.
  - v. Timing of applications. Test reports should specify the time at which treatment was begun, duration of exposure (if applicable), and intervals between succeeding applications. For example, data on crop treatments should include the following information (when applicable) in relation to timing of applications:
    - (1) Date(s) of treatment(s) and harvest.
    - (2) Treatment time in relation to number of days before or after planting, plant emergence, or harvest.
    - (3) The stage of growth of the crop when treatment was made.
    - (4) The stage of growth or expected appearance of the pest at treatment time.
    - (5) Duration of exposure to pesticide treatment.
    - (6) Treatment-to-observation interval(s).
3. Suggested performance standards. Performance standards will represent the levels of product performance that are exhibited by pesticides on specific site/pest combinations and considered acceptable for registration purposes. Suggested performance standards are usually expressed as percentages of pest control, or percentages of other intended responses, calculated from measurements made on treated plots compared with those made on untreated control plots. Reliance only on untreated control plots, however, is not always sufficient or appropriate. In such cases, a product should be tested against some other base, such as against another formulation or chemical of known efficacy. Efficacy data should be obtained under a full range of pest severity conditions, with particular emphasis on the maximum pest severity likely to be encountered by users.
- a. Adverse effects. To the extent possible, efficacy tests should be designed to evaluate possible adverse effects resulting from use of the pesticide. The following are examples of adverse effects which should be considered:
    - i. Phytotoxicity. A good test design providing for dosages higher than necessary for pest control on plants will allow an estimate of the adequacy of the margin of safety between effective pesticide levels and those which may injure the plants intended to be protected. Phytotoxicity is usually measured in terms of chlorosis, malformed plant parts, leaf burning, plant wilting, stunting (reduced height), reduced stand, and death. All injuries should be evaluated and reported. Accordingly, the lack of observable phytotoxic effects should also be reported.
    - ii. Effects on quality of commodities and inanimate objects. Test programs should be designed to evaluate adverse pesticide effects on treated commodities and

surfaces, such as discolored and weakened fabrics, deteriorated food quality, milk production, and unsightly residues on plant foliage.

- iii. Yields and other effects. Such determinations will aid in advanced planning in the test design. Pesticide treatments may decrease yield, reduce crop quality, or so alter the normal ripening or maturing process that economic problems arise in harvesting. Data should address the absence or the extent to which such effects occur.
  - iv. Effects on wildlife and aquatic organisms. Observations and evaluation of efficacy test results should include relevant information about possible adverse effects on wildlife and other organisms, as well as possible increases in harmful nontarget organisms as a result of the pesticide use and application. Treated dead and dying pest organisms as potential food for domestic or wild nontarget organisms should be considered also.
4. Test descriptions and data reporting. Systematic and complete descriptions of the tests employed and accurate reporting of data derived from laboratory tests and field tests to support label claims for performance of a product or mixture are essential for proper review and evaluation.
- a. Assembly of report. Considerations for assembling the reported efficacy data to expedite review of the detailed report include:
    - i. An index of the test reports arranged primarily according to the general types of performance data and secondarily by the site/pest combinations on the label. Additional subdivisions based on methods of application, soil textures, geographic areas, or other pertinent variables are encouraged wherever it is feasible and will facilitate an evaluation of the data. It is recommended that numbered tabs be used to identify the individual test reports.
    - ii. Tabular summaries of the data. The purpose of summary tables is to present a condensed and simplified overview of the scope of the test program and the level of product performance obtained. It is recommended that each horizontal line (or series of several lines) be equivalent to a test, and that columns reflect the major test variables being reported. These summaries should be organized primarily according to site/pest combinations and secondarily according to pertinent variables, such as methods of application, soil textures, or test locations
    - iii. Summarized conclusions related to label claims. Data analyses and evaluations should be included.
  - b. Details of report. All details of the tests should be reported giving particular emphasis to variables that relate to the label directions, I imitations, and precautions. Such details may include:
    - i. Personnel data. Names, positions, and addresses of persons who conducted and supervised the tests should be reported. Names of all persons who recorded or generated data for the tests should be made part of the record (not submitted but held as, records) along with the dates when the items of data were recorded.
    - ii. Test substance. Identification should be made of the test substance, including chemical name. Manufacturer and lot sample numbers of the test substance should be reported. Type of formulation and content [percent and, for liquids, pounds per gallon (kg/l)] of active ingredient should be reported. When a product is diluted before or during application, the report should specify the quantities and identification of each diluent.

- iii. Testing period. Report dates during which each test was conducted.
- iv. Method of application. The methods and types of pesticide placement, such as surface, sub-surface (as in soils), or incorporated, shall be reported. Descriptions of surface placements should indicate the method of application.
- (1) If the surface is to be sprayed, details on spray volume such as ultra low volume (ULV), low volume (LV): concentrate, or conventional full coverage spray, should be given in terms of volume per unit area.
  - (2) For sub-surface methods, descriptions should indicate whether done by furrow placement, side-dressing, injection, or burrow building. When describing injection methods, such information as spacing, number, and arrangement of chisels with respect to the row and depth of injection should be given.
  - (3) Descriptions of incorporated methods of application should indicate whether done by mixing, drenching, or impregnating.
  - (4) Information detailing the type of application, such as row (furrow placement, band, or side-dressing) or broadcast, bait boxes, swath placement, pressure-treated, or soaked, should accompany the test report data. Pesticides applied as row or band treatments should specify the bandwidth and the amount of material used per unit of linear row distance, and the amount of material per acre (or hectare) and the row spacing. When per acre (hectare) figures are included in test reports for row or band treatments, the report should specify whether these figures represent the "actual" amounts of pesticides applied or the "broadcast equivalent" rates.
- v. Equipment. The types of equipment used should be reported. This may include such items as mistblowers, cyclone seeders, hydraulic injectors or incorporators, aircraft systems (specify whether fixed wing or helicopter), etc. For pesticide application through irrigation systems, the information should include the types of systems used, such as sprinkler (stationary or mobile), furrow, drip, or flood; pesticide concentrations in water samples collected at various points throughout the system; and any spatial arrangement of crops (if applicable). When pesticides are to be mechanically incorporated into soil, information should be reported on the equipment used, speed and depth of operation, number of passes over the treated area, and intervals between repeated incorporations (if applicable).
- vi. Dosage rate. The dosage rate expressed as active ingredient and formulated product should be reported. Dosages should be reported in terms of amounts per unit of surface area, per unit volume of solvent or diluent, per unit volume or weight of commodity, per unit volume of space, per unit area and depth (acre-foot or hectare-meter), per linear distance of crop row, per animal, per unit weight of animals, and the length of time of spraying and the distance from the target surface (as for certain pressurized products).
- (1) Texture of soil and its organic matter content should be reported if applicable to the pesticide usage.
  - (2) Dimensions of test plots or sites and number of replicates should be reported.

- (3) Number and length of crop rows, row spacing, and plant spacing within rows, if applicable, should be reported.
  - vii. Climatic factors. Critical environmental conditions at application time, such as precipitation, temperature, sunlight, humidity, and wind velocity, should be reported. Abnormal climatic conditions may occur within a given area which cannot be considered in the test design but these may markedly affect results. Such conditions and effects observed should be reported in the discussion or conclusions.
  - viii. Pest populations and crop stage. Target pest population levels at the beginning of treatment, at periodic intervals after treatment, and at the end of the test period should be reported when applicable. The growth stages of the pests and host plants should be reported. Crop growth stage should be referenced to the number of days before or after planting, emergence, or specific development stage or to its height.
  - ix. Unusual events. Pertinent comments regarding effects test conditions on performance should be reported, particularly when they adversely affect the level of product performance or would invalidate the test data obtained.
  - x. Mode of pesticide entry, movement, and action. A description of the mode of action and movement of the pesticide (e.g., translocation, tenacity, redistribution through rain) should be submitted or referenced when known. For a pesticide used to control vertebrate animals, the report should note how the pesticide enters the pest organism, such as by body contact, inhalation, oral ingestion, or by any combination of these routes.
- c. Performance evaluation. A special section of the test report should be devoted to product performance evaluations. The following are examples of systems that may be used to evaluate the submitted data:
- i. Dose-response data for all site/pest combinations for which registration is proposed.
  - ii. Clearly defined statements of benefits, such as increased yields, unblemished fruits, reduction in nuisance pest levels, reduced disease incidence, fewer rat bites, to be derived from the pesticide use should be included. The applicant should indicate what he considers to be a commercially acceptable level of pest control.
  - iii. Report adverse effects such as phytotoxicity, spotting of paint, weakening of cloth or fibers, presence or odors of dead pest organisms, secondary poisoning, increase of nontarget species to intolerable levels, adverse impacts on fish and wildlife and similar adverse or undesirable results.
  - iv. Supporting statements. An applicant may submit written statements of opinion regarding the efficacy and limitations of a particular product, when expressed by individuals reasonably expert in observation and having experience with repeated use of such products. Evidence of the expert's experience should accompany such statements. Testimonials or letters of recommendations from individuals with less than the qualifications described in this paragraph are not acceptable as support for effectiveness claims.

**H. GUIDELINES FOR THE REVIEW OF SPECIAL LOCAL NEED REGISTRATIONS BY THE INSTITUTE OF FOOD AND AGRICULTURAL SCIENCES (IFAS):**

1. Overview of Review Process and Purpose of IFAS Review. Congress passed the amendment to FIFRA in 1972 giving states the authority to issue: "Special Local Needs" registrations for pesticide uses under Section 24, Paragraph C. The state lead agency, Florida Department of Agriculture and Consumer Services (FDACS), Division of Agricultural Environmental Services, is responsible for issuing 24(c) registrations to basic manufacturers, formulators, distributors, dealers, grower groups or individuals. IFAS review of 24(c) registration applications was requested by the state lead agency because considerable pesticide expertise exists within the research and extension functions of IFAS. Therefore, when a registration application is submitted to FDACS, the Pesticide Registration Section sends three copies to the Coordinator.
2. Responsibility of Pesticide Information Coordinator. The Pesticide Information Coordinator in IFAS, henceforth referred to as the Coordinator, is responsible for coordinating the IFAS review of each 24(c) registration application. The Coordinator will consult with appropriate departmental contact person(s) to select three (3) reviewers. After the review process has been completed, the Coordinator will return the completed reviews to FDACS with the IFAS recommendation.
3. Procedures for Selecting Reviewers. The expression above, "appropriate department", means that department in IFAS with the greatest expertise for a particular type of pesticide; however, departmental contact person(s) may select faculty from the department or from faculty located at Research and Education Centers depending upon the expertise and availability of personnel. Appropriate departments are as follows:

<b>TYPE OF PESTICIDE</b>	<b>APPROPRIATE DEPARTMENT</b>
Insecticides .....	Entomology Section of E/N Dept
Nematicides .....	Nematology Section of E/N Dept
Fungicides, bactericides and other chemicals used for plant disease control .....	Plant Pathology Dept.
Herbicides for: Agronomic crops .....	Agronomy Dept.
Fruit and nut crops .....	Fruit Crops Dept.
Ornamentals .....	Ornamental Horticulture Dept.
Vegetable crops .....	Vegetable Crops Dept.
Rodenticides, growth regulators*, etc .....	Coordinated by Coordinator

\*The Pesticide Information Coordinator will direct the registration application to the commodity department of the intended crop for which the growth regulator is to be applied.

- a. The Extension faculty member who has primary responsibility for pesticides in the appropriate department will serve as the "departmental contact" for 24(c) registration applications. The "departmental contact" will be assigned by common agreement within the department.
- b. The "departmental contact" in conjunction with the Coordinator will select three faculty reviewers who are best qualified to review a particular registration application. At least one reviewer for each registration shall be a faculty member with an extension assignment. Criteria for reviewer qualifications should include expertise on crop(s),

pest(s), or pesticide(s) involved in the registration application and overall expertise on pesticides.

- c. The Coordinator will submit 24(c) registration applications with supportive data to the contact person in the appropriate department. After the review is completed and the review forms (see item seven) signed, it will be the responsibility of the contact person to return the written reviews, registration applications, and supportive dossiers to the Coordinator.
4. Responsibility of Reviewers. The responsibility of each reviewer is to provide an individual review of the proposed label to determine if supporting data justifies label efficacy claims. Reviewers are encouraged to consider and assess all available data sources and possible situations that may affect the efficacy or safe use of the pesticide such phytotoxicity and pest resistance. Based on the data submitted and the practical experience of the reviewer, the reviewer may:
- a. recommend the acceptance of the proposed registration and add optional comments;
  - b. recommend and justify changes in the proposed label based on available research data, personal experience or discussions with knowledgeable persons. An IFAS reviewer can attach additional data to the petition with a reference on the review form. The reviewer may also contact the registrant for label clarification, if necessary;
  - c. request that relevant data be included with the proposed label;
  - d. request that the contact person or the Coordinator identify a better qualified reviewer;
  - e. reject the registration and state reasons for rejection.

(NOTE: IFAS reviewers will type or print clearly comments regarding their review.)

- f. FDACS assumes the responsibility for determining whether a "special local need" exists, whether the pesticide has an established residue tolerance, and whether the pesticide poses significant risks to man or the environment. The registrant has final responsibility for submitting appropriate data or adding pertinent data to clarify or support label claim(s).
5. IFAS Interpretation of Review. The review of a proposed 24(c) registration consists of opinions from three IFAS faculty reviewers. If the resulting vote is 3 in favor and none against the registration, the Coordinator will inform FDACS in writing that IFAS supports the registration. If the resulting vote is none in favor and 3 against registration, or two against and one in favor, the Coordinator will inform FDACS in writing that IFAS does not support the registration. If the resulting vote is 2 in favor and 1 against, the contact person will designate a fourth reviewer. If the fourth reviewer votes in favor of the registration, making the vote 3 in favor and 1 against, the Coordinator will inform FDACS in writing that IFAS supports the registration.
6. Suggested Data Requirements for Review. Reviewers are responsible to review the proposed label to determine if the supporting data justify the label claim(s). Data should be reviewed with the following points in mind:
- a. Data for each intended use site. Data should be included for all pests in each application situation. Data from crop groupings (e.g., citrus, cucurbits, etc.) can be used to support the registration. The reviewer may reject the consideration of such data if he/she determines that data pertaining to similar crops is inadequate or invalid.
  - b. Data demonstrating efficacy for all pest species listed on the proposed label. The reviewer is responsible to screen data to insure efficacy for all pest species listed on the proposed label.

- c. Florida or Florida-like environmental conditions. Experiments should be conducted under conditions similar to actual Florida use conditions specified on the label. Although it is preferable to have data from Florida, data may be accepted from other states.
- d. Data comparisons. Experimental design should have control or check plots, pre/post treatment counts of pests for a reasonable period following application, and a designated standard, when available, to demonstrate efficacy. Individual departments may require specific standards for certain crops or pest situations. Additional data requirements or standards can be added to these 24(c) review guidelines by submitting them in writing to the departmental contact and the Pesticide Information Coordinator.
- e. All materials must be applied with commercial application equipment duplicating label directions.
- f. Data from more than one trial at more than one location should be included. If appropriate with the proposed use, data involving more than one variety should also be included.
- g. Replication of subsampling. Some method of measuring or assessing variability must be included in the experimental design.
- h. Rates listed on the label. Reviewers should cross reference label rates with experimental data to insure the experiments were conducted at the proposed rate.
- i. Sampling procedure adequate. Reviewers should certify that the sampling procedure was adequate to support the experimental design. Phytotoxicity and safety. Where phytotoxicity may be possible such as the application of pesticides to plants, data on phytotoxicity should be included as supporting information. Pesticides applied to sites where damage to crops or animals may be likely, should have data demonstrating safety.

**SECTION V**  
REQUIREMENTS AND PROCEDURES FOR SPECIFIC AND CRISIS EXEMPTIONS  
UNDER SECTION 18 OF FIFRA

## **A. DEFINITIONS:**

1. "Emergency condition" means an urgent, non-routine situation that requires the use of a pesticide(s) and shall be deemed to exist when:
  - a. No effective pesticides registered for control of emergency; and
  - b. No economically or environmentally feasible alternative practices which provide adequate control are available; and
  - c. The situation:
    - i. Involves the introduction or dissemination of a pest new to or not theretofore known to be widely prevalent or distributed within or throughout the United States and its territories; or
    - ii. Will present significant risks to human health; or
    - iii. Will present significant risks to threatened or endangered species, beneficial organisms, or the environment; or
    - iv. Will cause significant economic loss due to:
      - (1) An outbreak or an expected outbreak of a pest; or
      - (2) A change in plant growth or development caused by unusual environmental conditions where such change can be rectified by the use of a pesticide(s).
2. "Significant economic loss" means that, under the emergency conditions: for a productive activity, the profitability would be substantially below the expected profitability for that activity; of activities, where profits cannot be calculated or, for other types the value of public or private fixed assets would be substantially below the expected value for assets. Only losses caused by the emergency conditions, specific to the impacted site, and specific to the geographic area affected by the emergency conditions are included. The contribution of obvious mismanagement to the loss will not be considered in determining loss. In evaluating the significance of an economic loss for productive activities, the EPA will consider whether the expected reduction in profitability exceeds what would be expected as a result of normal fluctuations over a number of years, and whether the loss would affect the long-term financial viability expected from the productive activity. In evaluating the significance of an economic loss for situations other than productive activities, the EPA will consider reasonable measures of expected loss.
3. "First food use" refers to the use of a pesticide on a food or in a manner which otherwise would be "expected to result in residues in a food, if no permanent tolerance, exemption from the requirement of a tolerance, or food additive regulation for residues of the pesticide on any food has been established for the pesticide under section 408 (d) or (e) or 409 of the Federal Food, Drug, and Cosmetic Act.
4. "New chemical" means an active ingredient not contained in any currently registered pesticide.

## **B. TYPES OF EXEMPTIONS:**

There are four types of emergency exemptions which may be authorized by the EPA: specific, quarantine, public health, and crisis exemptions.

5. Specific exemption. A specific exemption may be authorized in an emergency condition to avert:
  - a. A significant economic loss; or
  - b. A significant risk to:
    - i. Endangered species,
    - ii. Threatened species,
    - iii. Beneficial organisms, or
    - iv. The environment.
6. Crisis exemption. A crisis exemption may be utilized in an emergency condition when the time from discovery of the emergency to the time when the pesticide use is needed is insufficient to allow for the authorization of a specific, quarantine, or public health exemption.

### **C. GENERAL APPLICATION REQUIREMENTS:**

Applications for specific and crisis exemptions must be submitted in writing to the Commissioner of Agriculture. The Commissioner, through designated staff, will conduct an evaluation of the exemption application to determine that it is complete and meets all minimum criteria as contained in this section. Upon review and approval by the Commissioner, applications for specific exemptions will be forwarded to the EPA for approval. In cases where a crisis declaration is requested, the Commissioner will notify the EPA of his intent to declare a crisis and proceed accordingly. Applications must contain all applicable information specified in paragraphs 1 through 11 of this subsection.

1. Identity of contact persons.
  - a. Unless otherwise specified, the person who submits the application 'will be considered the contact person for all matters relating to administration of the emergency exemption.
  - b. Requests should identify by name and telephone one or more qualified experts who may be contacted in case any questions arise concerning the application.
2. Description of the pesticide. The application shall contain a description of the pesticide(s) proposed for use under the exemption.  
Such information shall include:
  - a. For a federally registered pesticide product:
    - i. The registration number and the name of the pesticide product if a specific product is requested; or the formulation(s) requested if a specific product is not desired; and
    - ii. A copy of any additional labeling proposed for the emergency exemption; or
  - b. For any other pesticide products:
    - i. A confidential statement of formula or reference to one already submitted to the EPA and the Department; and
    - ii. Complete labeling to be used in connection with the proposed exemption use.
3. Description of the proposed use. The application shall identify all of the following:
  - a. Sites to be treated, including their locations within the state;
  - b. The method of application;

- c. The rate of application in terms of active ingredient and product;
  - d. The total acreage or other appropriate unit proposed to be treated;
  - e. The total amount of pesticide proposed to be used in terms of both active ingredient and product; and
  - f. All applicable restrictions and requirements concerning the proposed use and the qualifications of applicators using the pesticide.
4. Alternative methods of control. The application shall contain:
    - a. A detailed explanation of why the pesticide(s) currently registered for the particular use proposed in the application is not available in adequate supplies and/or effective to the degree needed to control the emergency. If the applicant states that an available registered pesticide is ineffective for the given situation, the statement must be supported by field data which demonstrate ineffectiveness of registered pesticides, or, if such data are unavailable, statements by qualified agricultural experts, extension personnel, university personnel or other persons similarly qualified in the field of pest control; and
    - b. A detailed explanation of why alternative practices, if available, either would not provide adequate control or would not be economically or environmentally feasible.
  5. Effectiveness of proposed use. The application shall contain data, a discussion of field trials, or other evidence which provide the basis for the conclusion that the proposed pesticide treatment will be effective in dealing with the emergency.
  6. Discussion of residues for food uses. If the proposed use is expected to result in residues of the pesticide in or on food, the application shall list the food likely to contain such residues and shall contain an estimate of the maximum amount of the residue likely to result from the proposed use, together with the information on which such estimates are based.
  7. Discussion of risk information. The application shall address the potential risks to human health, endangered or threatened species, beneficial organisms, and the environment expected to result from the proposed use, together with references to data and other supporting information.
  8. Coordination with other affected state or federal agencies. If the proposed use of the pesticide is likely to be of concern to other federal or state agencies, the application shall indicate that such agencies have been contacted prior to submission of the application, and any comments received from such agencies shall be submitted to the Department and the EPA.
  9. Notification of registrant or basic manufacturer. The application shall contain a statement that t5e registrants of all pesticide products proposed for use or, if appropriate, the basic manufacturer have been notified that a request has been made to the EPA for use of the pesticide under a specific, quarantine, or public health exemption.
  10. Description of proposed enforcement program. Prior to approval, the applicant shall provide an explanation of the authority of the applicant or related state or federal agencies for ensuring that use of the pesticide under the proposed exemption would comply with any special requirements imposed by the EPA and a description of the program and procedures for assuring such compliance.
  11. Repeated uses. Applications for the use of a pesticide at a site for which the applicant has previously been exempted under section 18 shall contain an interim report summarizing the results of the specific exemption previously issued, if the application is submitted prior to the time the final report for the previous exemption is due. The interim report shall contain that information specified in subsection G to the extent available at the time the application is made.

#### **D. INFORMATION REQUIRED FOR A SPECIFIC EXEMPTION:**

An application for a specific exemption shall provide all of the following information, as appropriate, concerning the nature of the emergency:

1. The scientific and common name of the pest or pest complex;
2. A discussion of the events which brought about the emergency condition;
3. A discussion of the anticipated risks to endangered or threatened species, beneficial organisms, or the environment that would be remedied by the proposed use of the pesticide; and
4. A discussion of the anticipated significant economic loss, together with data with other information supporting the discussion, which addresses all of the following:
  - a. Historical net and gross revenues for the site;
  - b. The estimated net and gross revenues for the site without the use of the proposed pesticide;
  - c. The estimated net and gross revenues for the site with use of the proposed pesticide.

#### **E. DURATION OF SPECIFIC EXEMPTION:**

The EPA shall allow use of a pesticide under a specific exemption for as long a period as is reasonably expected to be necessary but in no case for longer than 1 year.

#### **F. NOTICE OF EPA DECISION:**

The EPA shall notify an applicant of its decision to approve or deny an application request for an emergency exemption in a timely manner.

#### **G. REPORTING AND RECORD KEEPING REQUIREMENTS FOR SPECIFIC EXEMPTIONS:**

1. Unexpected adverse effects information. Any unexpected adverse effects resulting from the use of a pesticide under a specific exemption must be immediately reported to the Department and the EPA.
2. Final reports. A report summarizing the results of a pesticide use under a specific exemption must be submitted to the Department and the EPA within 6 months from the expiration of the exemption unless otherwise specified by the Department or the EPA. The information in this report shall include all of the following:
  - a. Total acreage, amount of commodity or other unit treated and the total quantity of the pesticide used;
  - b. A discussion of the effectiveness of the pesticide in dealing with the emergency condition;
  - c. A description of any unexpected adverse effects which resulted from use of the pesticide under the exemption;
  - d. The results of any monitoring required and/or carried out under the exemption;
  - e. A discussion of any enforcement actions taken in connection with the exemption;

- f. Method(s) of disposition of a food crop, if required to be destroyed under an exemption; and
  - g. Any other information requested by the Department or the EPA.
3. Records. Records for all treatments involving the first food use of a pesticide will be maintained by the agency to which the emergency exemption was granted for a minimum of 2 years following the date of expiration of the exemption. On request by the Department or the EPA, these records shall be made available. Records will include all of the following:
- a. Locations where the pesticide was applied;
  - b. Dates of application (range); and
  - c. Total quantity of the pesticide used.

#### **H. AUTHORIZATION TO DECLARE A CRISIS EXEMPTION:**

The head of a federal or state agency (the Commissioner), the Governor of a state, or their official designee, may issue a crisis exemption in situations involving an unpredictable emergency situation when:

- 1. An emergency condition exists; and
- 2. The time element with respect to the application of the pesticide is critical, and there is not sufficient time either to request a specific exemption or if such a request has been submitted, for the EPA to complete review of the request.

#### **I. LIMITATIONS ON CRISIS EXEMPTIONS:**

The crisis provisions may not be utilized to authorize a pesticide use if any of the following has occurred:

- 1. The EPA has informed the head of the federal or state agency (the Commissioner), the Governor, or their official designee, not to issue such an exemption;
- 2. The pesticide use has been suspended under section 6(c) of FIFRA;
- 3. The pesticide use has been cancelled following a notice issued under section 6(b) of FIFRA;
- 4. The pesticide contains a new chemical; or
- 5. The application proposes the first food use of a pesticide.

#### **J. NOTICE TO THE EPA AND REGISTRANTS OR BASIC MANUFACTURERS:**

- 1. When feasible, the state or federal agency issuing the crisis exemption must notify the EPA at least 36 hours in advance of utilization of the crisis provisions. In no case shall notice be given to the EPA later than 24 hours after the decision to avail itself of a crisis exemption
- 2. The state or federal agency issuing the crisis exemption shall notify the registrant(s) or, if appropriate, the basic manufacturer(s) of the pesticide(s) being used under the crisis exemption at the same time notice is given to the EPA or as soon thereafter as possible.

3. Contents of notice. Information required to be provided in notices shall include all of the following:
  - a. The name of the active ingredients authorized for use, including, if available, the common name and the Chemical Abstracts Service (CAS) number;
  - b. The site on which the pesticide is to be used or is being used;
  - c. The use pattern;
  - d. The date on which the pesticide use is to begin or the date on which use of the pesticide began;
  - e. An estimate of the level of residues of the pesticide expected to result from the use under the crisis exemption; and
  - f. Any other pertinent information available at the time.

#### **K. DURATION OF CRISIS EXEMPTION:**

A crisis exemption may be authorized for:

1. Only as long as is necessary to control the pest or conditions causing the emergency; and
2. No longer than 15 days, unless an application requesting a specific exemption for this use has been submitted to the EPA.

#### **L. REPORTING AND RECORD KEEPING REQUIREMENTS FOR CRISIS EXEMPTIONS:**

1. Adverse effects information. Any adverse effects resulting from the use of a pesticide under a crisis exemption must be immediately reported to the Department and the EPA.
2. Final report.
  - a. A report summarizing the results of treatment under a crisis exemption will be required to be submitted to the Department and the EPA within 3 months following the last date of treatment. If a specific exemption has been approved while the crisis exemption is in effect, however, the crisis exemption report may be incorporated into the specific exemption final report required under subsection E and submitted at the time it is due.
  - b. Information to be included in the crisis exemption report must include the same information as required in subsection E and an explanation as to why there was a need to utilize the crisis provisions.
3. Records. Records will be maintained for a minimum of 2 years following the date of expiration of the exemption. On request by the Department or the EPA, these records shall be made available. Records will include all of the following:
  - a. Location where the pesticide was applied;
  - b. Dates of application (range); and
  - c. Total quantity of the pesticide used.

**SECTION VI**

PESTICIDE EXPERIMENTAL USE REGULATIONS AND PERMIT REQUIREMENTS

## **A. PERMITS:**

Experimental use permits may be issued to any person for shipment and use of limited amounts of a pesticide for the purpose of gathering data in support of registration under Section (3) or Section 24(c), Federal Insecticide Fungicide and Rodenticide Act, (FIFRA). A public or private agricultural research agency or educational institution may obtain a permit for experimental purposes within the state not directly-intended to result in the registration of a specific pesticide product. The Department may issue an experimental use permit to a person who already holds a valid federal experimental use permit, or may issue a Florida permit for purposes specified in 40 Code of Federal Regulations, Part 172, sub-part B, or Section 487.081(l)(c), Florida Statutes.

1. An experimental use permit may be granted for a pesticide not state or federally registered, or for a non-registered use of a registered pesticide.
2. Pesticide products used under a State Experimental Use Permit and not registered in the state for other uses shall not be sold or distributed other than through authorized participants and may only be used at an application site of an authorized cooperator in accordance with the terms and conditions of the experimental use permit.
3. Federal and state registered pesticide products approved under an experimental use permit for a previously non-registered use must be used in accordance with the terms and conditions of the permit, and may be sold in the state for use in accordance with state registered label. The permittee's distribution of the Experimental Use Permit label should ensure that experimental use of the product is confined to authorized participants and cooperators.
4. Permittees holding a valid Federal Experimental Use Permit must make application for and be granted a state experimental use permit or exemption from such permit before initiating any shipment or use of the pesticide in the state under the experimental program.

## **B. EXEMPTIONS:**

1. Permittees holding a valid Federal Experimental Use Permit which includes experimental use in Florida on a cumulative per year statewide total of ten (10) or less treated terrestrial acres, or one or less treated surface aquatic acre, may be exempted from state experimental use permit requirements provided they file with the Department a notice of intended experimental use that includes the following:
  - a. Confidential Statement of Formulation;
  - b. Material Safety Data Sheet including a statement of emergency treatment;
  - c. Proposed experimental label; and
  - d. Copy of EPA letter granting the federal permit.
2. Experimental use of pesticides in small plot replicated studies are exempt from permitting requirements described herein provided the following criteria are met:
  - a. The cumulative area treated per site, per crop, per experimental compound is less than 1 surface aquatic or terrestrial acre per year.
  - b. The Department shall be notified of experimental trials conducted on cumulative treated areas of equal to or greater than 1 acre but less than ten acres, per site, per crop, per experimental compound within 60 days of the initiation of such experimental trials. Such notification shall include:

- i. Name of experimental compound and EPA registration number if federally registered;
  - ii. Name and mailing address of the manufacturer of the experimental compound;
  - iii. Activity of the compound i.e. insecticide, herbicide, etc.;
  - iv. Amount of the experimental compound used;
  - v. Total area treated including the number of replicate applications;
  - vi. Location of the treated area; (vii) Crop treated; and
  - vii. Agency and contact person responsible for the experimental use.
- c. All food or feed derived from the experimental use will be destroyed or fed only to experimental animals for testing purposes.
  - d. Excess experimental compound will be used only in accordance with the federal and state registered label, if any, or, if not registered, returned to the manufacturer.

### **C. DEFINITIONS:**

Definitions of terms in this section are identical to those set forth by EPA in Title 40 CFR, Part 172.

### **D. DATA REQUIREMENTS:**

Applicants should follow Title 40 CFR 172.4 for submission of data summaries in support of Florida experimental use permits. Data requirements are designed to be flexible and will vary depending on the proposed use pattern and the sites to be treated. The Department may waive data required to support an experimental use permit if the data are determined to be inapplicable in assessing potential hazards to man and the environment due to use of the pesticide under the experimental use permit. The Department may request data in addition to that described in this section if such data are necessary to determine the potential hazard to man or the environment.

Each application for an experimental use permit shall include one (1) copy of:

Confidential Statement of Formulation (CSF) and Material Safety Data Sheet (MSDS) and twelve (12) copies of the following:

1. Name and address of the applicant;
2. Proposed experimental use permit label and federal label if registered;
3. Names and addresses of all participants and cooperators available at the time of application to whom the pesticide will be delivered for experimental use in Florida;
4. Temporary tolerances for the pesticide in food, feed, or potable water if established, or exemptions from tolerances, if the pesticide is to be used on food, feed or aquatic sites. If temporary tolerances \*have not been established or exemptions from tolerances not granted, permittees must certify that treated food or feed products will be destroyed or fed only to experimental animals;
5. Summary of data, as outlined on form EUP-1 in subsection J, or similar summary to include:

- a. Physical/chemical properties, including water solubility, partition coefficient ( $K_{OC}$ ,  $K_{OW}$ ), vapor pressure and specific gravity;
  - b. Toxicity, including toxicity to fish and wildlife where pertinent;
  - c. Environmental fate and residue analytical methodology (complete or rudimentary).
6. The purpose or objectives of the proposed experimental program to include:
- a. Type of data to be collected and purpose of such data collection;
  - b. Target pests;
  - c. Sites, method of application, application rates and total amount of pesticide to be applied;
  - d. Number of acres, or structural sites, or animals to be treated;
  - e. Period during which the tests will be conducted.
7. The intended method of storage or disposal of excess pesticide. In the case of a non-state-registered pesticide product used under an experimental use permit, a statement to the effect that the permittee will collect for storage or disposal, in accordance with Title 40 CFR, Part 172 subpart B, all excess pesticide from participants and cooperators at the termination of experimental use or expiration of the experimental use permit.

#### **E. REPORTING:**

Permittees must submit to the Department final reports describing data collected and progress made towards achieving objectives. All permittees must submit pesticide use information as part of this report, i.e., quantity of pesticide sold, quantity of pesticide applied, locations and dates of application, name of applicators, application rate, and names of cooperators, suspected or documented adverse human or environmental effects, and participants to whom the pesticide was shipped during the period. All permittees must notify the Department if experimental use is interrupted prior to the permit expiration date.

#### **F. PERMIT RENEWALS:**

Applications for renewal of experimental use permits must be accompanied with a copy of the above mentioned final report and will be reviewed on a case-by-case basis. The Department may require additional information from product performance tests or other data to review in determining if the renewal involving additional quantities of pesticide is warranted.

#### **G. RESTRICTIONS:**

The Department may specify permit restrictions or conditions for the Florida experimental use permit. The permit may be amended at any time by the Department to address data requirements or application restrictions or conditions.

#### **H. REVOCATION, SUSPENSION, CANCELLATION:**

An experimental use permit may be revoked, canceled or suspended if the Department determines that the permittee is in violation of terms of the permit.

#### **I. APPLICATION REVIEW PROCEDURES AND TIME FRAME**

1. Application packages will be reviewed by Department technical staff for completeness;
2. Additional information as required will be requested from the applicant;
3. Complete application packages will be reviewed and action to grant, amend or deny the permit taken within ninety (90) days;
4. Applications not completed within ninety (90) days because of lack of required information will be denied and returned to the applicant along with a written explanation of such denial;

#### **J. EUP DATA SUMMARY REPORTING FORM:**

Contact Pesticide Registration 850-487-2130 for form and additional information

**SECTION VII**

**PESTICIDE REGISTRATION EVALUATION (PREC) COMMITTEE OPERATING POLICIES**

## **A. PURPOSE:**

The purpose of the PREC is to review certain registration actions and make recommendations to the Department concerning the proposed pesticide registration. This is necessary to prevent the possible unreasonable risk and adverse impact on Florida's environment that could result from a proposed pesticide use, and to ensure compliance with all applicable pesticide laws and rules, including statutory requirements for interagency consultation and coordination.

## **B. BACKGROUND:**

The PREC was established by DACS in 1984 as a means to implement review responsibilities and obtain input from involved DACS staff and affected state agencies. It was also intended to implement cooperative language contained in Memoranda of Understanding (MOUs) with the Florida Department of Environmental Regulation (DEP), Florida Fish and Wildlife Conservation Commission (FFWCC), Florida Department of Health (DOH), and the Institute of Food and Agricultural Sciences (IFAS). The MOUs generally state that DACS will consult with these agencies on registration matters in order to assure that deliberations include their input.

## **C. OBJECTIVES AND ROLE OF THE PREC:**

NOTE: All packages for consideration by the Committee must be received by the 10th of each month. PREC meetings are scheduled for the 1st (first) Thursday of each month.

The PREC is a consensus determining body (not a decision making body) which uses the resources of its members during its deliberations. Because of limited resources and the need to avoid the duplication of EPA efforts, the general objectives of the PREC will not include a critical analysis of conclusions or decisions made by the EPA in connection with the acceptance of an existing action. However, clear defects, errors or omissions that are identified should be evaluated and rectified if the circumstances warrant. In connection with its operations, the general objectives of the PREC are as follows:

1. Evaluate proposed actions to assure Florida needs and conditions are addressed: The primary focus of the PREC is to conduct reviews and evaluations of proposed actions to determine if they may present unreasonable hazards to man or the environment (given Florida's unique hydrogeologic, soil, climatic, demographic, crop/site, ecological and other conditions), and also to insure that they (the proposed actions) are consistent with both state and federal regulations.
2. Provide input regarding information necessary to Properly evaluate a proposed action: It is the responsibility of the PREC to advise DACS about what, if any, additional data and materials may be needed to properly evaluate a proposed action, and recommend the acquisition of this information if DACS does not already have it in its possession.
3. Develop recommendations on proposed actions based on results of the PREC's evaluation: If the PREC decides that a proposed action poses negligible risks, it should recommend DACS1 acceptance of the action. In the case of significant risks, the PREC should recommend viable solutions and alternatives that may be used to reduce them to an acceptable level. If risks can not be reduced to an acceptable level and/or violations of regulations exist that can not readily be corrected, the PREC should recommend rejection of the proposed action.
4. Develop proposed registration evaluation mechanisms and improvements: As an advisory body, the PREC should evaluate existing registration procedures in order to determine if the process for

data collection, risk assessment and risk management is comprehensive, systematic and meets stated objectives. The PREC should make recommendations to the Department for any changes that are needed to address identified problems or make improvements.

#### **D. ACTIONS SUBJECT TO PREC INPUT:**

All special registrations and permits (SLNs and EUPs) will be reviewed by the PREC, with the exception of “me-too” SLNs and EUP renewals which are an exact continuance authorized by the EPA. All regular state pesticide registration requests will be screened by the appropriate registration coordinator to determine if the product contains a new active ingredient (NAI -an active ingredient which has not been previously and is not currently registered in the State of Florida), or if the use pattern constitutes a significant new use (SNU – a use pattern which has been determined to be significantly different than uses currently registered). Determination of an SNU will be based upon a standard set of criteria or triggers, and represent uses which could result in new sites being treated and/or an expansion of the amount of product being applied in the state possibly increasing the potential for contamination of ground or surface water or creating a situation of unacceptable risk to the environment. Use pattern changes that will be considered to be in this category are listed in Section II.

#### **E. PROCEDURES:**

The registration coordinator will review applications utilizing the criteria in Section II to determine if data are required to support the submission, and if so, what type of data to request. The coordinator will screen the data submissions to ensure that all required data have been submitted. Once the data submission has been determined to be complete, the coordinator will place the registration matter on the PREC agenda and distribute the data to the appropriate agency personnel for their review at least two weeks prior to the scheduled meeting. Environmental fate data will be distributed to DACS and DEP personnel and toxicity data will be distributed to DACS, FFWCC, and DOH personnel. Data can be routed to other personnel within each of these or any other agencies as soon as the initial reviewers have completed their review. Residue data and methodology will be sent to the Chemical Residue Lab.

#### **F. MEETINGS AND AGENDA:**

A proposed meeting schedule will be prepared annually and the PREC will meet the first Thursday of each month. A heavy work load or the absence of business may result in changes to this. At least two weeks days prior to each meeting, the proposed agenda and minutes from the previous meeting will be distributed to the PREC members and interested parties. Because of the volume of certain data and staff resource limitations, full document or data package distribution will be limited according to the designations contained in the PREC membership list. The agenda and supporting materials will be distributed prior to the scheduled meetings to provide time for the review of pertinent documents and the development of requests or recommendations for presentation at the meeting. With the exception of extenuating circumstances or cases where special arrangements have been made ahead of time, the PREC members Will be required to provide specific recommendations, requests or input, if any, pertaining to listed agenda items at the time of the regularly scheduled meeting. The agendas will generally be broken into three sections: action items, registration actions on pending items, and pending business. The items listed under action items will be those actions that PREC must be prepared to act on. Registration actions on pending items outlines the next step in the registration process as directed in the recommendations

from a previous PREC meeting. Items under pending business are those which are in temporary abeyance pending receipt of additional information.

#### **G. MINUTES:**

The minutes of each meeting will be distributed to the PREC members along with the proposed Agenda which precedes the next regularly scheduled meeting. Any input or proposed corrections to the minutes will be considered at the meeting following their distribution. Other interested parties, including the Pesticide Review Council (PRC), will receive copies of the agenda and minutes.

#### **H: DATA REQUESTS, RECOMMENDATIONS AND TIME FRAMES:**

Statutory deadlines and the changing nature of pest problems make it important that the processing and review of applications be handled as expeditiously as possible. Because of its responsibilities in this area, the Department tracks turn-around on actions and assures compliance with imposed deadlines. As previously stated, the PREC will be required to provide specific recommendations, requests or other input on proposed actions, for new business at the time of the first meeting. For old business, the time frames for the development of recommendations or input will be based on schedules established by the chairman. In order to expedite turn-around and establish consistency in the review process, standard data summary forms will be used to obtain data requested by the PREC. At the time of the initial review of a proposed action, the PREC may request portions or all of the data available in summary form. If data other than that contained in the standard forms is needed, the requestor will be required to provide a written request to the PREC chairman, specifying the additional data that is needed and the reason(s) for the request. The Department will review and track data requests forwarded to individual applicants or registrants to assure that the required responses are received. Time frames for the review of requested data and the development of written recommendations will be established by the chairman in order to assure compliance with established timeframes. Extensions may be requested to deal with additional problems or issues; however, in the absence of a deadline extension request, the PREC will proceed with the review and development of recommendations for final action for the matter(s) under consideration. Concerns about the applicability, quality, interpretation, or absence of data should be brought to the attention of the Chairman or designated DACS staff before the regularly scheduled meeting so that additional data or interpretations can be obtained before the meeting and made available in a timely manner.

#### **I: PROTECTION OF TRADE SECRETS AND OTHER INFORMATION:**

Section 10 (ten) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), protects confidential trade secrets and other information that may be submitted from unauthorized use or distribution. Proprietary information submitted by applicants to support proposed actions will be identified as such and distributed on an as needed basis to PREC members. PREC members will be responsible, under penalty of law, for adherence with the requirements of this action.