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PESTICIDE PRODUCT REGISTRATION PROCEDURES

IN NEW YORK STATE

I. INTRODUCTION AND GENERAL REGISTRATION REQUIREMENTS

The purpose of this booklet is to inform pesticide product registrants of their responsibilities in registering products in New York State and the procedures for applying for registration.

In addition to providing guidelines for submitting new registration applications, this chapter also outlines:

- Registration amendments;
- Renewal procedures;
- The Department's FIFRA 2(ee) policy;
- Procedures for obtaining a Commercial Permit - required **only** of registrants who sell **restricted use** pesticides directly into or within New York State (NYS).

The booklet is organized to first list the general requirements common to applicants of all types of registrations, and then, in separate sections, list additional requirements particular to different types of registrations.

References are made in this chapter to Environmental Conservation Law (ECL) Article 33 and Chapter 6 of the New York State Code of Rules and Regulations Part 326. These documents, which are available from the New York State Department of Environmental Conservation (NYSDEC), and which are also available from the Department=s website (www.dec.state.ny.us), should be used as companions to this book. References are also made to the Code of Federal Regulations Chapter 40 (40 CFR). The Code of Federal Regulations and other pesticide related information and guidance may be obtained from the United States Environmental Protection Agency=s Office of Pesticide Programs= website (www.epa.gov/pesticides).

The Environmental Conservation Law (ECL) '33-0701 requires every pesticide product which is used, distributed, sold or offered for sale in New York State to be registered with the NYSDEC. The registration period is two years. Pesticide products include:

A. Any pesticide product registered or required to be registered by the United States Environmental Protection Agency (EPA). Products requiring NYS registration include:

1. Products with basic EPA registrations;
2. Supplemental (distributor) registrations (each must be registered as a separate product); and
3. Additional brand names (each must be registered as a separate product). However, paint products that vary **only** in the color, or fertilizer products that vary **only** in the fertilizer analysis will be registered as one product, with labels for additional colors or fertilizer analysis added via notification.

Products **not** regulated as pesticides by the EPA are **not** regulated as pesticides by the NYSDEC. Products not requiring registration include:

1. Products specifically exempted in 40 CFR Sections 152.8, 152.10, 152.20, 152.25, 152.30;
2. Plant strains developed from EPA registered transgenic plant pesticide material.

B. Any Special Local Need registration, whether it is a new product or an additional use for an existing EPA registered product.

C. Experimental use products used pursuant to a Federal Experimental Use Permit (EUP), regardless of whether the product is sold or given free to cooperators. The Department does not require registration for other proposals for testing of experimental use products. However, notification requirements apply. See Section II (F).

D. Any amendment to a registration that involves a major change in labeling as defined in Section V (A) will be considered a **new** product; and an application for a new registration must be submitted.

E. Product registrations cannot be transferred. If there is a change in ownership of the product, a new application for registration must be submitted. A change in the company name of the registrant without a change in the ownership does not require a new registration, providing product names do not change. If there is no change of ownership, label changes may be made under amended registration procedures.

II. Registration Application Submission Requirements for New Products

There are general requirements that apply to **all** new pesticide registration applications. These are discussed in II (A) and (B) below. There are additional requirements for certain special registrations that are discussed in II (C) through II (F). All required forms and documents must be fully completed. Copies of pesticide product registration forms may be obtained from the Department=s website (www.dec.state.ny.us). All labels and labeling must be totally legible and must be complete, including correct EPA registration number, directions for use, precautionary statements and all pamphlets, booklets, technical bulletins and other materials referred to on the label.

A. General Information on Submitting All Applications

1. Separate application packages must be submitted for **each** of the following types of new registration:

   a. Registration of a product with a new active ingredient; see II (C);
   b. Registration of a new product which represents a "major change in labeling" for a previously registered active ingredient; see II (C);
   c. Amendment to an existing federal registration requiring a new registration application for New York State; i.e., major change in labeling, product name change, significant change in formulation, change in general/restricted use classification, change in EPA registration number, or change in ownership of the product; see V (A)
   d. Special Local Need (SLN) application;
   e. Experimental Use Permit (EUP) product application;

f. New registration of a product containing a currently registered active ingredient, for existing use patterns;
g. Renewals of registration.

2. Application packages must be clearly identified as to registration type (i.e., new active ingredient, major change in labeling, renewal or new Aroutine@ product).

3. All submitted documents must be legible and in intact physical condition.

4. Mail applications to:
   NYS Department of Environmental Conservation
   Division of Solid & Hazardous Materials
   Pesticide Product Registration Section
   625 Broadway
   Albany, N.Y. 12233-7257

5. Checks, made payable to the Commissioner, NYSDEC, for the required application fees must accompany each application. The fees are: $310 per product; or $300 per product, if a copy of the company's annual **federal** income tax return for the previous year is submitted, showing the company's gross annual sales for federal income tax purposes are $3,500,000 or less. The tax return must be signed and dated. **The fee is an application fee and is non-refundable.**

6. If a **complete** application (as described below) is not received, the entire package will be returned with a form identifying the missing information. If the missing information is not submitted within the time specified on the letter, the application will be denied.

B. Information Required For All New Product Applications

The following information and forms must be provided:

1. A completed "Pesticide Registration Application" [NYSDEC Form 44-19-9] listing the names and EPA registration numbers of each product proposed for registration. More than one product may be entered on one form. Instructions are on the reverse side of the form.

2. A completed "Product Data Sheet for Registration of a Pesticide" [NYSDEC Form 44-14-5]; one for each pesticide product to be registered. All required information can be obtained from the product label. Instructions are on the reverse side of the form.

3. One copy of the **most current** EPA approved labeling for each product to be registered. Approved labeling consists of a label stamped "ACCEPTED" by the EPA, plus any comment letter from the EPA, letter of amendment via "notification," or EPA policy notice. If label wording varies on different container sizes, e.g., disposal instructions, labels for different sizes must be submitted.

   If the label is a supplemental distributor label, the EPA stamped "ACCEPTED" label must be submitted for the basic registration upon which the distributor label is based. This label may be submitted by the distributor or the basic registrant. If the label has been requested from the basic manufacturer, a copy of the request must accompany the application.

4. Three copies of the final printed labeling for each product to be registered. Accurate facsimiles are acceptable where it is impractical to submit an actual label. If the label is larger than 8 1/2" x 14", the original and three copies of that label reduced to 8 1/2" x 14" or 8 1/2" x 11" are required. If the label is smaller than 8 1/2" x 11", the actual label and the label enlarged to 8 1/2" x 11" must be submitted.

5. A copy of the EPA "Confidential Statement of Formula" (CSF) on EPA Form 8570-4, or predecessor, for each product. Substitute forms are **not** acceptable. If you are not the basic registrant, this form may be submitted by the basic registrant directly. If the form has been requested from the basic manufacturer, a copy of the request must accompany the application. If the CSF is already on file with the NYSDEC for the subject product, a letter so stating may be substituted.

6. A check (payable to the Commissioner, NYSDEC) for the non-refundable application fee. The fees are: $310 per product; or $300 per product, if a copy of the company's annual **federal** income tax return for the previous year is submitted, showing the company's gross annual sales for federal income tax purposes are $3,500,000 or less. The tax return must be signed and dated.

   The fee is an application fee and is non-refundable.

C. Products Containing New Active Ingredients or Major Changes in Labeling

Products containing "New Active Ingredients" are those with an active ingredient not contained in any pesticide product currently registered with the NYSDEC.

Products constituting a "Major Change in Labeling" are those that represent either;

1. A change in the general use pattern involving a category or site previously not registered for the active ingredient. Refer to the "Code of Federal Regulations" 40 CFR Part 158.100. Examples include, but are not limited to, addition of terrestrial food or nonfood use, aquatic food and nonfood use, domestic outdoor use, indoor use, forestry use, or greenhouse food or nonfood use; or

2. A change that is likely to increase the exposure of any nontarget organism or that increases the potential for significant impact to humans, property, or the environment. Examples include, but are not limited to: addition of aerial application, addition of direct soil application, or addition of a major crop.

If a prospective registrant has any question whether a proposed application will constitute a new active or major change in labeling, they should contact the Department prior to the submission of the application.

The procedures for submitting applications for these products have been placed in Appendix 1 because they are lengthy and only a small percentage of registrants (approx. 1 percent) submit this type of application. If your application is for a product of this type, refer to Appendix 1.

The requirements in Appendix 1 are in addition to the general information required for registration in II (B) above.

D. Supplemental Distributor Products

Supplemental distributor products are products distributed under a name and address other than the EPA basic registrant. These products are also called supplemental registrations or distributor labels. **The EPA basic registrant is responsible for both the content of the distributor product and the content of the distributor label.** This is true even if the supplemental distributor formulates the product under a "contract packaging" agreement with the EPA basic registrant.

All distributor labels submitted must be identical to the most current basic EPA stamped "ACCEPTED" label (which includes any comment letter from the EPA, letter of amendment via "notification," or EPA policy notices) in all respects, except for differences authorized under federal regulations 40 CFR Part 152.132. If there are **any** differences, they must be specifically identified on the label or in writing when applying for registration.

Applicants proposing to distribute pesticide products under distributor labels must provide the following information, **in addition to the information required in II (B) above**:

1. A copy of the signed "Application for Supplemental Registration of Distributor" (EPA Form 8570-5 or predecessor) filed with the EPA by the basic registrant and signed by the EPA basic registrant and the distributor.

2. A certification statement **signed by the EPA basic registrant** stating that the final label as offered for sale is identical to the most current EPA stamped "ACCEPTED" label (which includes any comment letter from the EPA, letter of amendment via either "notification," or EPA policy notice) except for variations allowed in 40 CFR Part 152.132.

   The following type of certification statement is acceptable:

   "I hereby certify that I have reviewed the distributor label(s) included in this registration package and that the label(s) is(are) identical to the label(s) for the most current EPA accepted basic product registration in all respects, except for the differences authorized under federal regulations 40 CFR Part 152.132."

NOTE: According to 40 CFR Part 152.132(d); the label of the distributor product is to be the same as that of the registered product, except that:

- **$** The product name of the distributor product may be different (but may not be misleading);

- **$** The name and address of the distributor, with the appropriate qualifying statement, may appear instead of that of the federal registrant;

- **$** The registration number of the registered product must be followed by a dash, followed by the distributor's company number assigned by EPA;

- **$** The establishment number must be that of the final establishment at which the product was produced; and

- **$** Specific claims may be deleted, provided that no changes would be necessary in precautionary statements, use classification, or packaging of the product.

E. Registrations to Meet Special Local Needs: FIFRA Section 24(c) Registration

Special Local Need (SLN) registrations for product use(s) not on the federally registered label will be considered subject to the limitations specified in federal regulations 40 CFR 162.152.

1. Conditions for SLN's

    a. There is a demonstrated Special Local Need within the State;

    b. If a food use, is covered by the necessary tolerances or exemptions under the Federal Food, Drug & Cosmetic Act.

    c. Registration for the same use has not previously been denied, disapproved, suspended or cancelled by the EPA administrator or voluntarily cancelled by the registrant subsequent to issuance by the administrator of a notice of intent to cancel that registration.

    d. The registration is in accord with the purposes of FIFRA.

SLNs will be considered only if the applicant demonstrates that there is an existing or imminent pest problem in New York State that cannot be met by an existing federally registered product.

NOTE: Requests for multi-year SLNs must also be accompanied by evidence that the registrant is pursuing a modification or a change to the federal Section 3 registration.

2. Requirements

In addition to the requirements of II (B), the following is required:

a. **Four** copies of the proposed label or supplemental labeling. All labeling must comply with federal regulations pertaining to SLN registrations [40 CFR 162.153(e)].

b. **Three** completed copies of the EPA "Application for/Notification of State Registration of a Pesticide to Meet a Special Local Need" (EPA Form 8570-25).

c. **Three** sets of data supporting the proposed use. Data may vary depending on the nature of the proposed use. The following types of data are required as described:

- **$** Efficacy Data - Required with **all** applications.
- **$** Crop Residue Data - Required, if the use is a food/feed use and involves an additional crop; or, if there is a change in application to a food or feed crop that could result in increased crop residues.
- **$** Toxicology Data (Human Health Effects) - Required, if the use involves a change in use pattern or could result in increased exposure to humans.

- **$** Environmental Fate Data - Required, if the use involves a change in use pattern **or**, if there is an increase in dosage rate for an existing federally labeled use.

- **$** Ecological (Impact to Nontarget Organisms) - Required, if there is a change in use pattern to one involving outdoor use or if the use could result in increased exposure by nontarget organisms.

d. A detailed justification of the Special Local Need that must include:

- **$** A discussion of why existing federally registered products will not meet the need; and

- **$** Why the need should be considered "Local" (State or sub-State level) and not "National," warranting a Section 3 federal registration.

F. Experimental Use Products

It is the intention of the NYSDEC to obtain all information necessary to ensure the safe use of new pesticide products without inhibiting research in New York State.

1. **All** experimental products for which a Federal Experimental Use Permit (EUP) has been issued or is required must be registered in New York State, regardless of whether the product is sold or given free to cooperators.

   For registration of an Experimental Use product, the following information is required:

   a. All information required in II (B) Data Requirements.
   b. A copy of the Federal Experimental Use Permit (EUP), if applicable, including the experimental label.
   c. A copy of the proposed experimental program for New York State, including: i) amounts and acreage of use; ii) name, address, and phone number of person supervising program in New York State; and iii) list of cooperators. Cooperators are the individuals on whose property the application is to be made.
   d. Summaries of toxicology, environmental toxicology, and environmental-fate data for the active ingredient, if the active ingredient is not registered in New York State.

2. Experimental Use products not requiring a Federal EUP are **not** required to be registered. However, the following conditions apply:

   a. For experimental programs conducted on property owned or managed by registrants or recognized research institutions, **no** notification is required.

   b. For experimental programs conducted on property **other than** that owned or managed by registrants or recognized research institutions, the person proposing to conduct the program must notify the NYSDEC with the details of the proposed program as soon as they are available, but not less than 30 days in advance of the program. The notification must include essentially the same information as required in II (F) (1) above with the exception of item (b.) the Federal EUP. A final list of cooperators must be provided at least five business days prior to the date of the proposed application.

III. General Review Procedure

These procedures apply to all product registration types. More detailed procedures apply to applications for registration of products containing new active ingredients or major changes in labeling. See Appendix 1.

Within the time frames prescribed in ECL '33-0704, all applications will be initially screened for necessary information including; proper forms, application fees, labels, supporting documentation and Confidential Statements of Formula. An incomplete application will be returned to the applicant with a notice of deficiencies.

If applications for products, containing new active ingredients or major changes in labeling, are found in the completeness review to be missing the required data, the applicant will be notified. The application will be held until the date specified in the notice (approximately 45 days); after which the application will be denied, if required information is not submitted. The data package will either be returned to the applicant, at the applicant=s expense, or discarded, whichever is mutually agreeable.

Any application, if still incomplete, will be denied.

Products which are registered will be classified as either "restricted" or "general" use. The applicant must obtain a Commercial Permit, issued by the NYSDEC, in order to sell products classified as "Restricted Use" into or within New York State. Also, according to the Pesticide Reporting Law (PRL) (Chapter 279, Laws of 1996), Commercial Permittees (including Importers, Manufacturers and Compounders) must submit to the NYSDEC, Annual Reports for Sales of Restricted Use Pesticides. Consult Chapter VII of Pesticides Product Registration Procedures in New York State for further instructions.

Notification of Registration of Products will consist of:

11 A "Registration Certificate" which lists all products registered, designates restricted use classification where applicable, and gives the expiration date of the registrations; and

12 A copy of the label stamped "ACCEPTED" by the Department.

Applications for products that are not acceptable will be denied; and the reasons for denial will be specified in correspondence from the Department.

IV. Product Registration Renewals

A. General Requirements

Under New York State Law, a pesticide product must be registered in order to be sold, offered for sale, distributed, or used. **There is no provision to allow continued sale, distribution or use, if the New York State registration ceases to remain in effect.** If a New York State registration of a product lapses for any reason, any further sale, distribution, or use by anyone is illegal and would be subject to an enforcement action by the NYSDEC. It is the responsibility of the registrant to maintain the registration of a pesticide product which is in the channels of trade in New York State.

The NYSDEC sends pesticide product registration renewal notices for all currently registered pesticide products to the registrant, at the address on record, approximately three months prior to their expiration date. It is the responsibility of the registrant to renew the registration of their products prior to their expiration date regardless of non-receipt of the renewal notice.

The NYSDEC requests that applications be received **30 days prior** to the registration expiration date in order to ensure that applications are complete prior to the expiration of existing registrations. Under the New York State Administrative Procedures Act (SAPA), **if a complete renewal application is received prior to the registration expiration date,** the product will be considered registered until a registration decision is made and either a new certificate is issued, or renewal is denied.

If a product is being phased out and a new product with the same name will be marketed simultaneously, both products must be registered for as long as the products remain in the channels of trade. This includes the circumstance where a product has been transferred on the EPA level and two products have the same name with different EPA registration numbers.

1. **Discontinued products** that are no longer being manufactured and released for sale by the registrant must still be registered for as long as the product is expected to remain in the channels of trade. The "discontinued" status accommodates this situation. It is to be used **only** for products that are no longer being manufactured and shipped into New York State. Products may not be in the "discontinued" status for longer than one registration cycle (2 years) without specific approval by the Department. The application fee to register products as "discontinued" is the same as for other types of registrations.

The following documents must be submitted with a renewal, **if** they have not been previously sent to the NYSDEC:

a. One copy of the most current EPA approved labeling for each product to be renewed. Approved labeling consists of a label stamped AACCEPTED@ by the EPA, plus any EPA comment letter, letter of amendment via Anotification,@ or EPA policy notice. If label wording varies on different container sizes, e.g., disposal instructions, labels for different sizes must be submitted.

   If the label is a supplemental distributor label, the distributor should check with the basic registrant regarding any changes to the EPA approved labeling. The most current EPA stamped AACCEPTED@ label must be submitted for the basic registration upon which the distributor label is based. This label may be submitted by the distributor or the basic registrant. If the label has been requested from the basic manufacturer, a copy of the request must accompany the application.

b. A copy of the most current "Confidential Statement of Formula" (CSF), EPA Form Number 8570-4 or predecessor. If the most current CSF has already been submitted, a letter to that effect should accompany the application. For distributor labels, the CSF may be submitted directly by the basic registrant.

c. **Three** copies of the most current final printed container labeling for each product to be re-registered. Accurate facsimiles are acceptable where it is impractical to submit an actual label. If the label is larger than 8 1/2" x 14", the original and three copies of that label reduced to 8 1/2" x 14" or 8 1/2" x 11" are required. If the label is smaller than 8 1/2" x 11", the actual label and the label enlarged to 8 1/2" x 11" must be submitted.

d. A copy of the most current EPA Form Number 8570-5 "Notice of Supplemental Registration of Distributor," if the product is a distributor product label.

2. Special Local Need (SLN) registrations can be renewed only if it is determined that the Special Local Need continues to exist. Therefore, a statement of current justification and support data must also be submitted with the renewal application for all SLNs.

   NOTE: Requests for multi-year SLNs must be accompanied by evidence that the registrant is pursuing a modification or a change to the federal Section 3 registration.

3. Experimental products can only be renewed if the federal EUP is in effect at the time of renewal and the product/use has not subsequently been registered by the EPA. If an EUP has been extended by the EPA, documentation of that extension must be submitted.

B. Review Procedures

Renewal notices are sent out approximately 90 days prior to the expiration of product registrations, on the "Application for Renewal" form, for products **currently** registered.

The list of products on the application should be reviewed. Product registrations not being renewed should be deleted by drawing a line through the product name(s). Only products appearing on the renewal application require renewal. Products registered between the time the renewal form is sent and the application for renewal is processed, will be renewed automatically without additional fee.

Note: New registrations of any type may **not** be included in the renewal application.

It is the responsibility of the applicant to determine that the information submitted to NYSDEC on a renewal notice is correct and accurate. The Department will not refund the product application fee should the applicant withdraw a product after submitting for renewal.

If any products have been cancelled for **any** reason or suspended by the EPA, this must be noted by the product name on the application. Changes in product names and/or EPA registration number for any products may not be made on the application. These must be submitted as new products.

Sign and return the "Application for Renewal" along with the required information and any necessary registration forms. Enclose a check made payable to "Commissioner, NYSDEC" to cover the registration of all products. Application fees are non-refundable. The renewal application fees are: $310 per product; or $300 per product, if a copy of the company's annual federal income tax return for the previous year is submitted, showing the company's gross annual sales for federal income tax purposes are $3,500,000 or less. This means all sales, not just sales in New York State. If a company wishes to register products under two different registration ownerships and receive separate registration certificates, each must have a separate EPA company number.

V. Amended Labeling

NYSDEC must be notified **immediately** whenever there is any change in the formulation or labeling of any pesticide product registered with the Department.

A. Amendments to New York Registered Products That Require New Registration

The following types of amendments to products currently registered with the Department require a new application for registration:

1. A major change in use pattern;

2. Addition of a major crop in New York State that will significantly increase acreage;

3. Significant increase in application rate;

4. All changes in formulation **except**:

    a. changes in formulation allowed by notification to EPA, such as a change in the source of an active ingredient;
    b. minor changes in either active ingredient percentages, or inert ingredient percentages; modification of fertilizer percentages in pesticide-fertilizer mixtures;
    c. adjustments to percentages of ingredients resulting from changes in methods of analysis;

    Note: These exceptions to changes in formulation do **not** require new registration, **but** are subject to the requirements of either V (B) or V (C), Changes in Labeling.

5. Changes in classification between restricted and general use, except for products that fall under Part 326.2(g);

NOTE: This exception to change in classification between restricted and general use does not require new registration, but is subject to the requirements of either V (B) or V (C), Changes in Labeling.

6. Changes in product name. If both names are to be marketed concurrently, both must be registered;

7. Change in EPA registration number;

8. Change in product ownership. **Note:** Change in company name **without** a change in ownership does not require a new registration, but can be handled under V (B); and

9. Any change which increases the exposure and, thereby, the potential risk to nontarget organisms.

For **all** amendments to products registered with the Department that require new registration, the following information is required **in addition to the information required for registration in II (B) above:**

1. A statement identifying the product as involving one of the categories of change described above. This information may be provided on the application form (Form 44-19-9) accompanying the application;

2. **Three** copies of the final printed labeling or accurate, legible facsimile, **with all changes noted or highlighted on the label.** If the change involves an amendment to the EPA registration, the stamped EPA approved label must be filed;
3. All correspondence with the EPA relating to the change, i.e., letters for changes via "notification," EPA comment letters, EPA stamped AACCEPTED@ labels, EPA letters of Product Transfer, etc.

For amendments to products registered with the Department that represent a "major change in labeling," the information in II (C) is required, as well as the information in II (B).

As with any new registration, products bearing labels with any of the above changes may **not** be marketed until the new registration is issued. If registration is issued, a copy of the label will be stamped "ACCEPTED" by the Department and returned as soon as possible; but, in all instances, within the legislatively mandated time frame.

B. Registration Amendments Not Requiring New Registration, but Requiring Department Approval Prior to Sale

There is no fee associated with the submission or review of registration amendments, unless new registration is required.

Except as specified in V (C), all amendments to any pesticide product registered with NYSDEC, involving minor registration amendments, must be filed with and accepted by the Department as an amendment to the registration of the product **prior** to its distribution or use in New York State. Examples of this type of amendment include: Addition of a crop or site (not major); change in hazard statements.

The following information must be submitted with requests for approval:

1. Three copies of the final printed labeling or accurate, legible facsimile. All changes **must** be noted or highlighted on the label;

2. If the change involves an amendment to the EPA registration, the EPA stamped "ACCEPTED" amended label must also be filed;

3. If the amendment involves a change in the Federal Confidential Statement of Formula (CSF), the new CSF must be filed;

4. If the amended label is for a supplemental distributor product, the distributor label must be identical to the label for the basic registration in all respects, except that:

    a. The product name of the distributor product may be different;
    b. The name and address of the distributor, with the appropriate qualifying statement, may appear instead of that of the federal registrant;
    c. The registration number of the registered product must be followed by a dash, followed by the distributor's company number assigned by EPA;
    d. The establishment number must be that of the final establishment at which the product was produced; and
    e. Specific claims may be deleted, provided that no changes would be necessary in precautionary statements, use classification, or packaging of the product.

If approved, the Department will return a copy of the label stamped "ACCEPTED" as soon as is possible, but, in all instances, within the legislatively mandated time frame.

C. Minor Registration Amendments Requiring Notification, but Not Requiring Approval Prior to Sale or Distribution

1. Amendments to products registered with NYSDEC may be made by notification to the Department, providing:

    a. The modifications to the federal registration meet EPA criteria for notification under federal regulations and policies, (Consult 40 CFR Part 152.46 and PR Notice 98-10) e.g. Use of Symbols and Graphics;
    b. The modification does **not** involve the addition of an alternate or additional brand name.

2. The following procedure must be followed for amending a Department registration via notification;

    a. The registrant must submit the following documents:

        - A copy of the EPA Application for Registration Amendment, indicating that the change is being made via notification;

        - A copy of the transmittal letter to EPA, bearing the certification statement required by EPA that the change meets the criteria for change via notification;

        - Three copies of the final printed labeling or accurate, legible facsimile. All changes must be noted or highlighted on the label.

    b. If NYSDEC determines that prior approval is required, it will notify the registrant. If so notified, the registrant must wait for approval prior to sale or distribution in New York State.

    c. Distribution may begin on the 61st day after NYSDEC receives notice of change via notification, unless the registrant is notified by the Department that prior approval is required.

    d. The Department will return, as soon as is possible, but in all instances, within the legislatively mandated time frame, a copy of the label stamped "Accepted Via Notification - Label Not Reviewed."

D. Label Amendments Not Requiring Notification, and Not Requiring Approval Prior to Sale or Distribution

1. The following types of label amendments may be made **without any notification to NYSDEC** and, thus, do not require acceptance prior to the sale, distribution or use in New York State:

    a. Correction of typographical and printing errors in labeling unless, as a result of a label review by the Department, the registrant has been requested to correct an error and submit the corrected label;
    b. Changes in net contents, providing that no other label changes are necessary under federal or State requirements;
    c. Use of metric units in addition to standard U.S. units;
    d. Redesign of label format that does not modify approved label text and which is consistent with federal and State requirements;
    e. Revision, addition, or deletion of nonmandatory label elements, such as:
        - Inclusion of the DOT hazard diamond;

- $ Addition of State-required analysis of a fertilizer product;
- $ Inclusion of lot or batch codes;
- $ Date of manufacture or label approval; or

f. Change of establishment number.

VI. FIFRA 2(ee) Recommendations

Certain limited variations from the use directions specified on pesticide labels are authorized under FIFRA Section 2(ee). These "2(ee) recommendations" allow:

1. Use at any dosage, concentration or frequency less than specified on the labeling.

2. Use against any target pest not specified on the labeling.

3. Methods of application not prohibited on the labeling.

4. Mixtures with fertilizer, unless prohibited on the labeling.

Chapter 6 of the New York Code of Rule and Regulations (6NYCRR) Part 325.2(b) states APesticides are to be used only in accordance with label and labeling directions or as modified or expanded and approved by the department.@ Therefore, In New York State, all 2(ee) recommendations must be approved in writing by NYSDEC.

However, there are two exceptions. 2(ee) recommendations, approved in writing by the NYSDEC, are **not required** for the following:

13 Use of a New York State registered agricultural pesticide at a dosage, concentration or frequency less than specified on the labeling, unless specifically prohibited on the labeling (see ECL Section 33-0725).

14 Mixtures with fertilizer, unless prohibited on the labeling.

There is no fee required for a request for a 2(ee) recommendation.

Requirements:

1. Anyone receiving approval of a 2(ee) recommendation is responsible for distributing the recommendation to **all users of the product pursuant to the approved recommendation.**

2. Any user must have the 2(ee) recommendation in their possession at the time of application, e.g. "Cornell Recommends."

Information required for submission of 2(ee) requests:

1. Requests for approval of 2(ee) recommendations must be made in writing by Federal or State institutions or agencies authorized by law to conduct research in the field of pesticides. Certified crop advisors, manufacturers (registrants), organizations representing individual users, or individual users may **not** request approval of 2(ee) recommendations;

2. Requests must be accompanied by data demonstrating that the use will be effective.

VII. Commercial Permits

A. General Information

ECL Section 33-0901(1) states that "A commercial permit is required for the distribution, sale, offer for sale, purchase for the purpose of resale or possession for the purpose of resale of a **restricted use pesticide**."

A Commercial Permit is required **only** of registrants who sell Federal or New York State **restricted use** pesticides directly into or within New York State. No permit is required if **only** general use pesticides are sold.

A commercial permit is required for the sale of restricted-use pesticides to distributors for resale as well as sale to the end user. Commercial permits are issued for a two-year period.

Restricted use pesticides are those either:

1. Classified as restricted use by the Federal EPA;

15 Classified as restricted use by NYSDEC in accordance with 6 NYCRR Part 326.23(e);

3. Listed by active ingredient in 6 NYCRR Part 326.2(a) or (b);

4. Professional/commercial use products as defined in 6 NYCRR Part 326.2(g); or

5. Aquatic use products as defined in 6 NYCRR Part 326.2(h).

A separate permit is required for **each** location in the State where restricted use pesticides are distributed, sold or offered for sale. Out-of-State dealers with no sales or distribution locations in New York State need only one Commercial Permit.

Storage facilities, from which there is no transfer of product to customer, sale or offer for sale, do not require a commercial permit.

The ECL Section 33.0905(1) also states "any person who engages in ... the sale of restricted use pesticides shall be certified by the Commissioner...." Each location requiring a Commercial Permit must employ at least one applicator who is certified in New York State. Certification may be in any commercial or private category. Technician certification is **not** acceptable. Commercial Permit holders located out of State must have at least one employee who is certified in New York State, for example, a technical or sales representative.

Also, according to the Pesticide Reporting Law (PRL) (Chapter 279, Laws of 1996), Commercial Permittees (including Importers, Manufacturers and Compounders) must submit, to the Department, Annual Reports for Sales of Restricted Use Pesticides. Any questions regarding the Pesticide Reporting Law and/or specific reporting requirements, should be directed to the Pesticide Reporting Section at (518) 402-8765.

B. Application Requirements

The following information/forms must be provided:

1. A separate, completed and signed "Commercial Permit Application" for each location. This application is available from the NYSDEC website (www.dec.state.ny.us).

    a. If the business is a corporation, the application must be signed by an officer of the corporation, indicating his/her title;

    b. If the business is a partnership, the application must be signed by a partner;

    c. If the applicant is an individual, the application must be signed by that individual.

2. The name and address of every location in New York State where restricted use pesticides are stored, but not offered for sale, sold or transferred directly to customers.

3. The certified applicator's name and I.D. number (e.g., C1-234567 or P1-234567).

4. A check for the required fee ($300 per commercial permit), made payable to the Commissioner, NYSDEC.

5. Mail to: New York State Department of Environmental Conservation
   Bureau of Pesticides Management
   Pesticide Certification Section
   625 Broadway
   Albany, New York 12233-7254

6. Any questions relating to obtaining a Commercial Permit should be directed to the above address, or to the following phone number: (518) 402-8748.

REFERENCE MATERIALS

The New York State Registration Review Process

The New York State Pesticide Product Registration Section reviews all applications and labeling for pesticide products prior to granting registration in New York State. Applications for registration are reviewed for completeness and for content. Applications must contain all required forms and documentation. This includes a copy of the most current United States Environmental Protection Agency (EPA) accepted labeling (which consists of the most current EPA stamped AACCEPTED@ labeling and all applicable notifications submitted to the EPA via EPA Form 8570-1), copies of final product (container) labeling, and, if applicable, supporting documentation for a supplementally distributed product.

As labels are updated with the EPA, the corresponding final product labeling is to be updated. Revised and/or updated labels are to be submitted to the Department for review and approval before products bearing the new labeling can be distributed in New York State.

Pesticide Product Registration Section staff does a side-by-side comparison of the final product labeling and the most current EPA accepted labeling. Staff also takes a comprehensive look at the appearance of the final product labeling. This includes, but is not limited to, the overall presentation and intent of the labeling, formatting of the labeling, legibility, graphics, labeling color, marketing statements, and product names.

Title 40 of the Code of Federal Regulations (40 CFR) Section 156.10 is entitled ALabeling Requirements.@ Pesticide Product Registration Section staff utilizes this guidance extensively during our review of final product labeling.

The basic pesticide product registrant bears the ultimate responsibility of ensuring that pesticide products which are supplementally distributed bear labeling which is in compliance with labeling currently approved by the EPA. **The EPA does not review final product labeling for supplementally distributed products**. However, **New York State does**.

New York State will not register labels inconsistent with the most current EPA stamped AACCEPTED@ labeling or variations allowed by 40 CFR Sections 152.130 and 152.132.

The majority of problems which are identified during the New York State review process are discrepancies between the final product labeling and the currently approved EPA labeling. Statements are added to the labeling which do not appear on the most current EPA stamped AACCEPTED@ labeling or do not have a notification submitted to the EPA to support the addition. Also, statements are deleted from the final product labeling without supporting documentation. Statements are frequently added and/or rearranged on the labeling for marketing purposes without the correct supporting documentation.

The EPA has also compiled a ALabel Review Manual@ which the EPA label reviewers and product managers utilize during their label review process.

The Pesticide Product Registration Section urges pesticide product registrant to familiarize themselves with the above-mentioned sections of 40 CFR and the EPA Label Review Manual. These are the same guidelines that section staff refer to during our label

review process. Links to 40 CFR and the Label Review Manual can be found on the EPA Office of Pesticide Programs: (OPP) website (www.epa.gov/pesticides).

Documentation Required for Registration of Products

DOCUMENTS REQUIRED	REGISTRATION TYPE				
	New Basic Registration	New Distributor Registration	Renew Previously Registered Products	Major Change in Labeling*	New Active Ingredient*
Application Form (NYSDEC Form 44-19-9)	**X**	**X**	application form (yellow NYSDEC Form 44-19-10)	**X**	**X**
Product Data Sheet (NYSDEC Form 44-14-5)	**X**	**X**		**X**	**X**
One copy of most current EPA stamped accepted label and relevant notifications.	**X**	**X**	only to update previously submitted labeling	**X**	**X**
THREE copies of final printed labeling	**X**	**X**	only to update previously submitted labeling	**X**	**X**
Confidential Statement of Formula (CSF) (EPA Form 8570-4)	**X**	**X**	only if revised	**X**	**X**
Non-refundable application fee	**X**	**X**	**X**	**X**	**X**
Notice of Supplemental Registration of Distributor (SRD) (EPA Form 8570-5)		**X**			
Distributor Certification Statement signed by the basic registrant		**X**	submitted with updated labeling		
Reference Pages	see page 5	see page 7	see page 10	see page 6	see page 6

* Applications which contain New Active Ingredients or represent Major Changes in Labeling also require the submission of four copies of an extensive data package. Please refer to the New Active Ingredients and Major Changes in Labeling sections for the complete directions for the submission of these types of applications.

Supporting Documentation Required for Submission of Revised Labels

DOCUMENTS TO BE SUBMITTED	REVISION TYPE		
	Revised Label Via EPA Amendment	Revised Label Via EPA Notification	Revised Confidential Statement of Formula
Transmittal letter from applicant to EPA or NYSDEC which identifies the proposed revision(s)	**X**	**X**	**X**
EPA Form 8570-1 Application for Pesticide AAmendment@	**X**		
EPA approval letter and stamped AAccepted@ label	**X**		
THREE copies of final product labeling. Proposed revisions **must** be highlighted, underlined, or otherwise denoted on one copy of the labeling	**X**	**X**	
EPA Form 8570-1 Application for Pesticide AOther@ including attachments (labeling)		**X**	
Self-Certification statement from applicant to EPA which states that the changes meet the criteria for change via notification		**X**	

One copy of EPA approved revised Confidential Statement of Formula (CSF) EPA Form 8570-4			**X**

Definitions:

2(ee) - Recommendation for use of a product in a manner inconsistent with its approved EPA labeling. 2(ee) refers to that section of FIFRA. In New York State, 2(ee) recommendations must be made in writing by Federal or State institutions or agencies authorized by law to conduct research in the field of pesticides. All 2(ee) recommendations, except for use of a New York State registered agricultural pesticide at a dosage, concentration or frequency less than specified on the labeling (unless prohibited on the labeling) [see ECL '33-0725], and mixtures with fertilizer (unless prohibited on the labeling), must be approved in writing by the NYSDEC.

Additional Brand Names - Product names that are secondary to the originally registered product name. Submitted to the EPA by Notification (via EPA Form 8570-1). In NYS, these are considered separate pesticide products which require separate registration.

Amended label - Also referred to as a revised label. A final product labeling for a pesticide product currently registered with the Department which has undergone a revision.

Application Rate - The amount of product applied to a particular site at a given time.

Application Fee - The required payment to submit a product for review for possible registration [see ECL '33-0705]. It is not a registration fee and therefore is not refundable.

Basic Registrant - Also known as the Manufacturer, this is the company that registers and maintains the registration of a pesticide product with the EPA.

Basic Registration - The product that is registered directly with the EPA, bearing the corresponding name of record on file with the EPA. Any changes to labeling must be filed with the EPA in conjunction with this registration.

Certificate of Registration - The document (NYSDEC Form 44-06-2 (25a)) providing the most current registration information for one registrant. It includes product names, numbers, registration status, restricted use classifications, expiration date and date of issuance.

Change in company name - If the name of a company has been changed, but there have been no other changes (e.g. the company still has the same owner(s) and same EPA company number), then a copy of the EPA letter acknowledging the change in company name must be submitted to the Department. Three copies of a revised final product label for each product registered in NYS must be submitted to the Department for review and approval.

Change in company ownership - If a change in ownership of the company occurs (e.g. the company name and/or EPA company number have been sold to a new owner), then a copy of the EPA letter acknowledging the change in company ownership must be submitted to the Department. Since the registration of a product cannot be transferred in NYS, the new owner must register all the products as new registrations if they wish to continue selling

these products in NYS. A complete new application, including final product labels listing the new company name and address, as well as the application fee, must be submitted for each product. The products registered by the previous owner should be registered as "discontinued" at the next renewal cycle to cover any product remaining in the channels of trade.

Change in product ownership - If a change in ownership of a company's products occurs (e.g. some or all of a company's products been sold to a new owner), then a copy of the EPA letter acknowledging the transfer of the products in question must be submitted to the Department. Since the registration of a product cannot be transferred in NYS, the new owner must register all the products as new routine registrations if they wish to continue selling these products in NYS. A complete new routine application, including final product labels listing the new company name and address, as well as the application fee, must be submitted for each product. The products registered by the previous owner should be registered as "discontinued" at the next renewal cycle to cover any product remaining in the channels of trade.

Commercial Permit - A commercial permit is required for companies selling restricted use products in NYS. This includes companies located in states other than NY. A commercial permit means the permit issued by the Commissioner, pursuant to the ECL, section 33-0901, for the distribution, sale, offer for sale, purchase for the purpose of resale, or possession for the purpose of resale, of a restricted use pesticide product.

Confidential Statement of Formula - Also known as a CSF, is an EPA form (EPA Form 8570-4) that the basic registrant must fill out and submit to the EPA when first registering a pesticide product (or upon change in formulation). The CSF lists the complete chemical composition of the pesticide product (actives and other). Each unique EPA registration number (e.g. 12345-678) may have one or more CSFs (basic formulation and alternate formulations). A copy of this form must accompany each registration application submitted to NYS. For supplemental distributor products, the basic registrant may submit this form directly to the Department upon the request of the sub-registrant.

Discontinued products - Discontinued status covers those products that are no longer being manufactured and released for sale by the pesticide product registrant. Products are registered in the "discontinued" status for one two-year registration cycle in order to allow for the sale of product remaining in the channels of trade in NYS. This status is to be used only for products no longer being manufactured and released for sale and use in NYS. Products may not be registered for more than one two-year registration cycle unless the registrant certifies that the products are no longer being shipped into NYS. The application fee to register products as "discontinued" is the same as for other types of registrations.

Distributor Certification Statement - After reviewing the distributor's final product labels, the basic registrant must sign a certification statement which states: "I hereby certify that I have reviewed the distributor label(s) included in this registration package and that the label(s) is(are) identical to the label(s) for the most current EPA accepted basic product registration in all respects, except for the differences authorized under federal regulations 40

CFR 152.132." Applications for registration of distributor products without this certification statement will not be accepted, nor will certification statements signed by the supplemental distributor.

Distributor registration - The basic pesticide product registrant may distribute or sell his EPA registered product under another person's name and address in addition to his own. Such distribution and sale is termed "supplemental distribution" and the product is referred to as a "distributor product." The supplemental distributor is considered an agent of the basic registrant and both the basic registrant and the supplemental distributor may be held for violations pertaining to the distributor product. The EPA permits supplemental distribution upon the proper notification. The EPA does not require the submission of distributor product labels and does not review nor register distributor product labels. However, the Department requires the registration of all products. Therefore, the submission of complete applications for registration of distributor products is required, and the labeling of distributor products is carefully reviewed for compliance prior to registration in New York State.

EPA Registration Number - (EPA Reg. No.) - The EPA assigns a unique number to basic pesticide products as they are registered. This unique number is referred to as the registration number and is assigned by the following process:

- The first group of numbers is the EPA company number of the basic registrant (the company which holds and maintains the federal registration), followed by a hyphen.

- The second group of numbers is the product number. The product number is the number assigned to an individual product of a specific basic registrant. For example: a company, which EPA assigned the company number "xxxxx," registers a new product with the EPA. The EPA assigns that particular product, a product number of "y." That product's EPA Reg. No. is "xxxxx-y."

- If a product is supplementally distributed, a hyphen and a third group of numbers is added to the EPA Reg. No. of the basic product. This third group of numbers indicates the EPA assigned number of the company which the basic registrant has agreed to be a supplemental distributor of their basic product.

Example: EPA Reg. No. aaa-bb-ccccc

This example shows that the company number of the basic registrant is "aaa," the product number is "bb" and this product is supplementally distributed by company number "ccccc."

EPA stamped "ACCEPTED" label - the label which has been reviewed and formally accepted by the EPA. The label is literally stamped "ACCEPTED" and indicates the acceptance date and EPA Reg. No. of the product.

EUP - Experimental Use Permit - allows manufacturers to field-test pesticides under development. Manufacturers of conventional pesticides are required to obtain experimental

use permits before testing new pesticides or new uses of pesticides. An Experimental Use Permit is required if conducted, on a national level, on ten acres or more of land or one acre or more of water. Biopesticides also require an EUP when used in experimental settings.

Final product label - the written, printed, or graphic matter on, or attached to, a pesticide product or any of its containers or wrappers. Labeling includes all labels and all other written, printed, or graphic matter which accompanies the pesticide product at any time, or to which reference is made on the label or in literature accompanying the pesticide product. (FIFRA Sec.2 (p)).

Formulation - pesticide active ingredients are usually mixed with other ingredients (carriers, diluents, solvents, wetting agents, emulsifiers, etc.) before they are packaged for sale. The prepared, or formulated, mixture is referred to as the formulation. Common formulations include granular, liquid, dust, emulsifiable concentrate, pressurized spray, wettable or soluble powder, fumigant, tablet, and lotion.

General use pesticide - a pesticide product which does not meet the state criteria for a restricted pesticide product, as established under authority of Article 33-0303 of the Environmental Conservation Law.

Initial registration - the registration of a pesticide product, by a particular registrant, with a specific name and corresponding EPA Registration Number in New York State.

Label amendment - is a revised label with an EPA Stamped "Accepted" label via amendment.

Major change in labeling - shall mean any new label or labeling or any amended label or labeling for a pesticide product which contains an active ingredient previously registered in New York State and which (see Part326.1(n)):

(1) results in a major change in the use pattern for the active ingredient;
(2) changes the classification of the active ingredient or the product to general use or restricted use;
(3) increases the application rate;
(4) changes the percent concentration of an active ingredient other than an increase due to changes in methods of analysis;
(5) adds a previously-registered active ingredient or deletes any active ingredient;
(6) any other change which significantly increases the potential exposure of any non-target organism or which increases the potential for a significant impact to humans, property or the environment.

Major change in use pattern - means a change in the general use pattern involving a category or site previously not registered for the active ingredient in New York State. Examples of major changes in use pattern include but are not limited to addition of: terrestrial food or non-food use, aquatic food or non-food use, domestic outdoor use, indoor use, forestry use, or greenhouse food or non-food use. (Part 326.1 (o)).

"Most current" EPA label - The most recent label bearing the EPA "accepted" stamp and all changes made to that label including (Part 326.1 (j)):
(1) Changes required by EPA in the comment letter accompanying the EPA approved label; and
(2) changes made via notification to EPA

MSDS - Material Safety Data Sheet. An MSDS is a summary of a variety of fundamental information related to the chemical that will allow the user to recognize and prepare for potential hazards associated with the chemical and prepare for and react to emergency situations.

New Active Ingredient - Any active ingredient which is not in any pesticide product currently registered in New York State. (see Part 326.1(q))

New registration - Any pesticide product which is currently not registered in New York State. New York State considers products with different EPA registration numbers, different product names and/or different formulations to be separate products which would require separate registration.

Notification to the EPA - 40 CFR Section 152.46(a) allows certain registration amendments to be accomplished by notifying the EPA of those changes before the product is distributed or sold. Notifications are sent to the EPA on EPA Form 8570-1. EPA Pesticide Registration (PR) Notice 98-10 lists all registration changes which can be made via notification, non-notification and amendment. Notifications made via EPA Form 8570-1 are considered part of the most current EPA approved labeling.

Pesticide Registration Application - the New York State Department of Environmental Conservation (NYSDEC) form [NYSDEC Form 44-19-9] which is required to be submitted in support of registration for all new pesticide products. The application form contains the type of registration, information regarding the company applying for registration (EPA company number, company name, mailing address, name, title and signature of person acting as the registration official, and telephone number), and the list of names and EPA registration numbers of each product proposed for registration.

Product name change - If a pesticide product has a different name and corresponding EPA registration number than any other pesticide product which is currently registered in New York State, it is considered a new pesticide product. Therefore, a pesticide product which has undergone a name change would be treated as a new pesticide product. If pesticide products bearing the previous name and the new name will be in the channels of trade at the same time, both products are required to be registered.

Registration renewal - Environmental Conservation Law (ECL) '33-0701 requires registration of every pesticide product which is used, distributed, sold or offered for sale in New York State (NYS). The registration period is two years. Approximately 90 days prior to the expiration date, an "Application for Renewal of Pesticide Registration" is sent to the registrant of record. This application lists products currently registered in NYS.

Restricted use - Classification assigned to certain pesticide products based on EPA classification as a "Restricted Use Pesticide" or pursuant to New York State regulations 6 NYCRR Part 326.2(a)(b)(g)(h) and 6 NYCRR Part 326.23(e). Designated by "YES" in the "Restriction" column on the "Certificate of Pesticide Registration." A commercial permit is required for the distribution, sale, offer for sale, purchase for the purpose of re-sale or possession for the purpose of re-sale of a restricted use pesticide.

Revised label - Also referred to as an amended label. A final product labeling for a pesticide product currently registered with the Department which has undergone a revision.
SAPA - State Administrative Procedures Act. Under the New York State Administrative Procedures Act (SAPA), if a complete renewal application is received prior to the registration expiration date, the product will be considered registered until a registration decision is made and either a new certificate is issued, or renewal is denied. See New York State Consolidated Laws, Article 4, Section 401 of SAPA pertaining to Licenses.

Section 18 - Refers to Section 18 of FIFRA which authorizes EPA to allow States to use a pesticide for an unregistered use for a limited time if EPA determines that emergency conditions exist.

SLN (24(c)) - Refers to Section 24(c) of FIFRA whereby States may register an additional use of a federally registered pesticide product, or a new end use product to meet special local needs. Also known as a "Special Local Need" (SLN) registration.

SRD - "Notice of Supplemental Distribution of a Registered Pesticide Product" (EPA Form 8570-5). This application form must be signed by both the registrant and the distributor, and must include the names and addresses of both parties, the distributor's company number, the additional brand name to be used, and the registration number of the registered product.

Product Data Sheet - Refers to New York State Form 44-14-5. This form summarizes all of the information about the pesticide product which is entered into the New York State Pesticide Products Database.

Supplemental Distributor Registration - Pesticide products that are distributed by a company other than the basic registrant of that product, require separate registration of the pesticide product under the name of the distributor/supplemental registrant.

Supplemental Label - A label which contains a subset of additional use directions and refers the user to the federal label for all applicable directions, restrictions, and precautions. Supplemental labeling is usually only used until the new use can be integrated into the final printed product labeling.

Suspended Products - Pesticide Products that are no longer registered for use, distribution, or sale in New York State. Products may be suspended by the registrant or by the Department in the event that the registrant does not comply with federal or State requirements. To avoid enforcement actions, companies should not suspend pesticide

products until they are certain that existing stocks have cleared the channels of trade in New York State.

Use Pattern - Use patterns are identified on product labeling as applications of the active ingredient against targeted pests. An example of a use pattern would be the use of an herbicide to control broadleaf weeds.

APPENDIX 1

PROCEDURES FOR REGISTERING

NEW ACTIVE INGREDIENTS

OR

MAJOR CHANGES IN LABELING

APPENDIX 1

New York State
Pesticide Product Registration Procedures
Guidance for Submission of Data

The purpose of this document is to provide guidance to applicants for submission of data to support an application for registration of a "new active ingredient" or a "major change in labeling." These procedures are used by the NYSDEC to determine the completeness of an application. These requirements enable NYSDEC to:

1) streamline the process of gathering and maintaining needed documents from applicants; and

2) establish consistent guidelines for data submission for all applicants.

Most of the data requirements are based on procedures established by the United States Environmental Protection Agency (EPA) in Chapter 40 of the Code of Federal Regulations (40 CFR) and outlined in Article 33 of the Environmental Conservation Law.

Applicability

This guidance applies to all data submitted to the NYSDEC=s Pesticide Product Registration Section to satisfy requirements for registration of pesticide products that contain a new active ingredient or represent a major change in labeling. This section does not apply to registration of experimental use products under federal or state EUPs.

Each application for registration will be screened within seven days of receipt to determine if it meets the requirements set forth in this document. If the data package meets the guidelines, the application will be reviewed for completeness. The Department has 60 days from receipt of the application to determine whether the data package is complete.

Data packages that do not conform to these requirements will be returned to the registrant for revision. Return shipping costs will be paid by the registrant. The registrant has the option to retrieve the package within 21 calendar days of being notified by this Department. If the nonconforming package is not retrieved within 21 calendar days, the package may be discarded by the Department.

Content of Application

The data requirements specified below have been deemed sufficient to permit DEC to perform a proper assessment of a pesticide product in most cases. However, if the information required under these sections is not sufficient to evaluate the potential impact of the product on health or the environment, additional data may be required.

Note: **Complete studies are not required with the initial application. However, the Department may request complete studies at any time during the review process, when they are deemed necessary to make a registration decision.**

A. Products Containing New Active Ingredients

Each application for a product containing a new active ingredient must include, in the format specified by the Department, **four** copies of the following information:

1. All General Registration requirements identified in Section II.B. of the "Pesticide Product Registration Procedures";

2. EPA "Notice of Pesticide Registration" (EPA Form 8570-6);

3. Material Safety Data Sheet (MSDS) for each product;

4. Comprehensive Table of Contents/Index of Available Studies in tabular form specified in the format Section; and

5. All EPA registration review documents, including, but not limited to, EPA Data Evaluation Record (DER) reports for individual studies, EPA Branch reviews, reviews/evaluations prepared for or by the EPA panels convened to review a pesticide (e.g., Toxicology Branch Peer Review Committee, Science Advisory Panel, etc.);

6. All correspondence between the EPA and the registrant regarding registration or data submitted in support of registration;

7. Summaries or abstracts of individual studies submitted to EPA to support registration of the new active ingredient;

8. Validated analytical methodologies (only TWO copies needed) for measuring active ingredients and major degradates in the following media:

   a) soil and water for outdoor uses;
   b) air and surfaces for indoor uses;
   c) any other media, if specifically requested.

   Analytical methodologies must be submitted in a separate bound volume.

9. Any information regarding adverse effects submitted to EPA as FIFRA 6(a)(2) data;

10. The following information **may** be requested during the technical review:

A. Summaries of any newly developed toxicity, exposure, environmental fate data, or any additional data required by EPA since the initial federal registration;

B. An overview of the potential for the pesticide product to contaminate groundwater from normal labeled use in New York State conditions;

C. Efficacy data sufficient to support the label claims; and

D. Data on indoor air impacts and indoor surface residues of active ingredients and carriers for products that involve the application of large amounts of pesticides to occupied buildings (e.g., termiticides and crack and crevice control products).

B. Products Representing Major Changes in Labeling

Each application that represents a major change in labeling must include, in the format specified by the Department, **four** copies of the following requirements:

1. All General Registration requirements identified in Section II.B. of the "Pesticide Product Registration Procedures ";

2. EPA Notice of Registration of Supplemental Labeling or Amended labeling;

3. Material Safety Data Sheet (MSDS) for each product;

4. Comprehensive Table of Contents/Index of available studies, in tabular form specified in the format section; and

5. All EPA registration review documents related to the new use pattern, including, but not limited to, EPA Data Evaluation Record (DER) reports for individual studies, EPA Branch reviews, reviews/evaluations prepared for or by the EPA panels convened to review the new use pattern of the pesticide; i.e., Toxicology Branch Peer Review Committee, Science Advisory Panel, etc.;

6. All correspondence between the EPA and the registrant regarding registration of the new use pattern;

7. Summaries or abstracts of individual studies submitted to EPA to support registration of the new use pattern;

8. Additional product chemistry, toxicology, exposure and environmental fate data for the chemical, **if requested**.

Format of Data Submission

This section establishes the format in which data and information to support the registration of a "new active ingredient" or a "major change in labeling" must be submitted. **All required data for review to support the registration of a new active ingredient or a major change in labeling must be submitted at the same time.**

Each submitted binder may contain more than one review document or summary. However, each separate document in a binder must be partitioned by tabbed markers.

Four **identical** copies of the information identified in the "Content of Application" section must be submitted. Each **identical** copy must be separately bound to facilitate distribution to review groups.

Submitting Review Documents/Correspondence

Copies of the EPA registration review documents and all correspondence between the EPA and the registrant must be submitted as follows:

EPA registration review documents and correspondence must be organized by discipline reflecting the order in which EPA Guideline Reference requirements appear in 40 CFR 158. All review documents must be submitted collectively. Each **identical** copy must be separately bound.

Each binder which contains review documents and/or correspondence must be clearly marked (e.g., "Review Documents/correspondence") on the binder cover. The contents of each binder must be demarcated with tabs.

Each review document shall be identified in the binder using a tab containing a sequential ordering system [e.g.. Data Evaluation Record (DER) A, DER B, DER C, or Correspondence Date (CD) 01/02/94, etc.], or by a similar labeling system. The identification used on the tab must be entered in the Table of Contents cross-referenced to the applicable Guideline Reference Number.

Submitting the Study Summaries

Copies of the study summaries (or abstracts) must be submitted as follows:

Study summaries should be organized by discipline, reflecting the order in which EPA Guideline Reference requirements appear in 40 CFR 158. All review documents must be submitted collectively. Each **identical** copy must be separately bound.

Each binder which contains study summaries must be clearly marked (e.g., "Study Summaries") on the binder cover. The contents of the binder must be demarcated with tabs.

Each study summary shall be identified in the binder using a tab containing the EPA Guideline number(s) and MRID number(s) of the study(ies) to which the review/correspondence refers.

Submitting the Table of Contents/Index of Studies

The Table of Contents shall arrange the information and documents into an organized format. **Each** submitted document must be cited in a tabulated index for easy reference. The following tips should assist in the organization of the Table of Contents:

Refer to 40 CFR subparts C and D (**''** 158.150 through 158.740) for the list of the specific kind of data/studies required by the EPA to organize the Table of Contents.

List **each** test by guideline number, although the group of tests that must be performed depends on the proposed use of the pesticide. Tests which were not required by EPA for registration of a product should be identified with a statement such as "NOT REQUIRED FOR FEDERAL REGISTRATION."

The following is a sample of an acceptable format for the Table of Contents:

158.150 PRODUCT CHEMISTRY DATA

1. PRODUCT IDENTITY AND COMPOSITION

GUIDELINE REF#	STUDY TITLE	MRID NO.	EPA STATUS	REVIEW DOCUMENT	CORRESPONDENCE
61-1			Acceptable	DER A	CD 4/95

The following information is cited in the above Table of Contents:

1. Guideline Reference - Number — EPA Guideline Reference Number from 40 CFR 158
2. Study Title - registrant study title as submitted to EPA (actual studies not required with the initial data submission, but may be requested at a later date)
3. MRID Number - Number assigned by EPA to each study submitted to EPA
4. EPA Status - identifies the status/comments regarding the cited study as determined by the EPA (e.g., core minimum, unacceptable, acceptable to establish NOEL)
5. Review Documents - references **all** applicable review documents submitted to the Department (as indicated by tab)
6. Correspondence - references **all** applicable correspondence submitted to the Department (as indicated by tab)

The table which appears in Appendix 2 was developed for the data requirements of a conventional chemical pesticide. Registrants may use this sample table as a guide in preparing the Table of Contents or may develop a similar one.

The exact group of tests may vary somewhat for biopesticides, microbial and biochemical pesticides. Applicants must evaluate the data requirements from 40 CFR subparts C and D (**''** 158.150 through 158.740) to determine the requirements for a particular product.

Notes about Other Application Types

A. Applications for registration of new products containing two new active ingredients must include the data requirements for both active ingredients.

B. Applications for registration of new products where the new product is formulated from a new active and an active ingredient already registered must include the following:

1) For the new active ingredient: the complete list of data requirements as outlined in Section II (C); and

2) For the active ingredient already registered, the following data are not required for the initial submission, but may be requested during the technical review of the product:

Review documents and studies for whole product chemistry, toxicology, environmental fate, ecological effects, efficacy, and residues in food and feed, as applicable.

Each applicant is responsible for submitting all appropriate data. The applicant may: 1) submit the information, 2) get someone else (in most cases the basic manufacturer) to submit the information, or 3) reference information submitted by someone else to support their registration. In each case, written documentation must be provided to this Department by the applicant as well as the data supplier.

Appendix 2

Format for Product Registration Submission/Table of Contents

APPENDIX 2

Pesticide Product Data Submission
Table of Contents

GUIDELINE REF. #	DATA DESCRIPTION	STUDY TITLE	MRID #	EPA STATUS	REVIEW DOCUMENT #	CORRES.#
158.150	PRODUCT CHEMISTRY DATA					
A.	Product Identity & Composition					
61-1	Product identity & disclosure of ingredients					
61-2(a)	Description of beginning materials & manufact. process					
61-2(b)	Discussion of formation of impurities					
B.	Analysis and Certification of Product Ingredients					
62-1	Preliminary analysis					
62-2	Certification of limits					
62-3	Analytical methods to verify certified limit					
C.	Physical and Chemical Characteristics					
63-2	Color					
63-3	Physical state					
63-4	Odor					
63-5	Melting Point					
63-6	Boiling Point					
63-7	Density, bulk density, or specific gravity					
63-8	Solubility					
63-9	Vapor pressure					
63-10	Dissociation constant					
63-11	Octanol/water partition coefficient					
63-12	pH					
63-13	Stability					
63-14	Oxidizing or reducing action					
63-15	Flammability					
63-16	Explodability					
63-17	Storage stability					
63-18	Viscosity					
63-19	Miscibility					

GUIDELINE REF. #	DATA DESCRIPTION	STUDY TITLE	MRID #	EPA STATUS	REVIEW DOCUMENT #	CORRES.#
63-20	Corrosion characteristics					
63-21	Dielectric breakdown voltage					
158.240	RESIDUE CHEMISTRY					
171-2	Chemical identity					
171-3	Directions for use					
171-4	Part A: Nature of the residue					
	1. Plants					
	2. Livestock					
171-4	Part B: Residue analytical method					
	Part C: Magnitude of residue					
	1. Crop field trials					
	2. Processed food/feed					
	3. Meat/Milk/Poultry/Eggs					
	4. Potable water					
	5. Fish					
	6. Irrigated crops					
	7. Food handling					
171-5	Reduction of residue					
171-6	Proposed tolerance					
171-7	Reasonable grounds in support of the petition					
171-13	Submittal of analytical reference standards					
158.290	ENVIRONMENTAL FATE					
A.	Degradation Studies - Lab					
161-1	Hydrolysis					
161-2	Photodegradation in water					
161-3	Photodegradation in soil					
161-4	Photodegradation in air					
B.	Metabolism Studies - Lab					
162-1	Aerobic soil metabolism					
162-2	Anaerobic soil metabolism					
162-3	Anaerobic aquatic metabolism					
162-4	Aerobic aquatic metabolism					
163-1	Leaching and adsorption/desorption					
163-2	Volatility - lab					
163-3	Volatility - field					

GUIDELINE REF. #	DATA DESCRIPTION	STUDY TITLE	MRID #	EPA STATUS	REVIEW DOCUMENT #	CORRES.#
C.	Dissipation Studies - Field					
164-1	Soil					
164-2	Aquatic (sediment)					
164-3	Forestry					
164-4	Combination in tanks and mixes					
164-5	Soil - long term					
D.	Accumulation Studies					
165-1	Confined rotation crops					
165-2	Field rotation crops					
165-3	Irrigated crops					
165-4	Accumulation studies in fish					
165-5	Accumulation studies in aquatic non-target organisms					
158.340	TOXICOLOGY					
	Acute Testing					
A.	Acute oral toxicity - rat					
81-1	Acute dermal toxicity					
81-2	Acute inhalation toxicity - rat					
81-3	Primary eye irritation - rabbit					
81-4	Primary dermal irritation					
81-5	Dermal sensitization					
81-6	Acute delayed neurotoxicity - hen					
81-7						
	Subchronic Testing					
B.	90-day feeding studies - rodent and					
82-1	nonrodent					
	21-day dermal					
82-2	90-day dermal					
82-3	90-day inhalation - rat					
82-4	90-day neurotoxicity					
82-5						
	Chronic Testing					
C.	Chronic feeding - 2 supp. rodent and					
83-1	nonrodent					
	Oncogenicity study - 2 spp. rat and					
83-2	mouse preferred					
	Teratogenicity - 2 species					
83-3	Reproduction, 2-generation					
83-4						
	Mutagenicity Testing					

GUIDELINE REF. #	DATA DESCRIPTION	STUDY TITLE	MRID #	EPA STATUS	REVIEW DOCUMENT #	CORRES.#
D.	Gene mutation					
84-2	Structural chromosomal aberration					
84-3	Other genotoxic effects					
84-4						
	Special Testing					
E.	General metabolism					
85-1	Dermal penetration					
85-2	Domestic animal safety					
86-1						
	SPRAY DRIFT					
185.440						
	Droplet size spectrum					
201-1	Drift field evaluation					
202-1						
	WILDLIFE AND AQUATIC ORGANISMS					
158.490						
	Avian and Mammalian Testing					
A.	Avian oral LD50 (mallard or bobwhite)					
71-1	Avian dietary LC50 (mallard & bobwhite)					
71-2	Wild mammal toxicity					
71-3	Avian reproduction (mallard & bobwhite)					
71-4	Simulated and actual field testing-					
71-5	mammals & birds					
B.	Aquatic Organism Testing					
72-1	Freshwater fish LC 50 (rainbow and bluegill)					
72-2	Acute LC50 freshwater invertebrates (daphnia)					
72-3	Acute LC50 estuarine & marine organisms					
72-4	Fish early life stage and aquatic invertebrate life-cycle					
72-5	Fish-life-cycle					
72-6	Aquatic organism and accumulation					
72-7	Simulated or actual field testing - aquatic organisms					
158.540	PLANT PROTECTION					
121-1	Target area phototoxicity					
	Nontarget area phototoxicity - Tier 1					
122-1	Seed germination/seedling emergence					
	Vegetative vigor					
122-2	Aquatic plant growth					

GUIDELINE REF. #	DATA DESCRIPTION	STUDY TITLE	MRID #	EPA STATUS	REVIEW DOCUMENT #	CORRES.#
	Nontarget area phytotoxicity - Tier 2					
123-1	Seed germination/seedling emergence					
	Vegetative vigor					
123-2	Aquatic plant growth					
	Nontarget area phytotoxicity - Tier 3					
124-1	Terrestrial field					
124-2	Aquatic field					
158.590	NONTARGET INSECT					
A.	Nontarget Insect Testing - Pollinators					
141-1	Honey bee acute contact LD50					
141-2	Honey bee - toxicity of residues on foliage					
141-4	Honey bee subacute feeding study					
141-5	Field testing for pollinators					
B.	Nontarget Insect Testing - Aquatic Insects					
	Acute toxicity to aquatic insects					
142-1	Aquatic insect life-cycle study					
142-2	Simulated or actual field testing for					
142-3	aquatic insects					
	Nontarget insect testing - predators					
143-1-143-3	and parasites					