REGISTRANT'S RESPONSIBILITIES

AFTER EPA REGISTRATION

This paper describes:

- ***action required before a product may be marketed;***
- ***action required to maintain a product registration;***
- ***action required before making changes to a product formula or label.***

Please contact Delta staff at (301) 680-7971 with any questions or comments.

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Action Required Before a Product May Be Marketed

Labeling

EPA's letter accompanying the stamped label describes conditions of registration. If EPA's stamped label requires specific wording changes as a condition of registration, the staff at Delta will consult with you, then incorporate the changes into the master label, and send the revised label to you for use in developing your marketplace label .

Marketplace Label

Once wording on a label has been approved by EPA, it must be followed exactly. In addition, the order of sections often is important. However, the EPA approved label is considered a "master label" and sometimes complete sections of claims and Directions for Use may be deleted; contact Delta staff for more details.

We strongly recommend that your printer send us the proof for review before printing. EPA has specific regulations governing placement and size of the signal word, Keep Out of Reach of Children, Storage and Disposal, ingredient statement, and other elements of the label. If we review the label proof, we can advise you of any changes needed ***before*** labels are printed. As discussed below, States will be reviewing the marketplace label. The time for obtaining initial State registration is reduced if all documentation presented meets regulatory requirements. Please note: According to EPA requirements, **label text on the final printed label may not be smaller than 6 point type at any time**.

Multiple EPA Producing Establishments

If your product is produced at multiple EPA producing establishments, please discuss with Delta staff to ensure that the label addresses this as required.

Batch Codes

In accordance with EPA's container rules, batch codes must be listed on marketplace labeling or product containers. Please discuss this with Delta staff to ensure you meet all requirements.

Websites

An important issue for marketplace labeling is EPA's stance on website addresses on labeling. If a marketplace label includes a website address, EPA considers the website part of labeling. This means that EPA can review the website to determine whether any "false or misleading" claims are used. EPA discourages use of website addresses on labeling, but if they are included, the registrant needs to be certain that the website is consistent with the labeling, especially any label claims.

Please talk with Delta staff if you have any questions.

State Registration

Products must be registered in the States in which the product is sold, marketed, advertised, transported through or distributed. Each State has its own regulations, application process, fee structure and supporting documentation requirements. Most States register products within a few weeks of submission of the paperwork. However, there are a few States which require more extensive review.

California

The most complete review is conducted by California, which reviews registrations in a manner similar to EPA. For some products, California's review is more rigorous than EPA's. A complete registration package with all studies and product information must be submitted to California for registration. California often requires efficacy studies in situations in which EPA does not. CA also has more stringent rules governing volatile organic compounds in consumer products than other States and "right to know" rules regarding certain ingredients. For relatively simple products in which data in CA files are being cited, California registration takes approximately 3 - 4 months. For products which require data submission, CA registration will take much longer as all data must be reviewed by CA staff.

Other States

Other States require a substantive review on a case-by-case basis, especially when a particular type of product or active ingredient has not been previously registered in the State. Graphics and websites are also closely reviewed. These States include Colorado, Florida, New York, North Carolina, South Dakota and Texas. The average time for obtaining registration in New York and Texas is between 2 and 3 months as long as the application and documents submitted are complete and accurate.

Additional Brand Names

There are additional rules regarding alternate brand names (including scents). Please contact Delta staff for further information regarding State registrations.

Marketing/Advertising

EPA and numerous States review Internet advertising and marketing literature, including websites. Usually non-compliant advertising comes to EPA's attention through a registrant's competitors. Advertisements must be consistent with a product's labeling and must not be "false or misleading," which EPA interprets conservatively in its favor. In addition, there are certain claims that may not be made and wording that may not be used. Of particular concern to EPA are safety and environmental claims, whether explicit or implied (e.g., "all natural" and "non-toxic" are two phrases that have caused particular concern). Phrases implying heightened efficacy also have come into special scrutiny from EPA in recent years. Please contact Delta staff if you have questions.

Supplemental Distributors (Subregistrants)

Supplemental Distributors Requirements

Once a product is registered with the US EPA, other companies may distribute the product under a supplemental distributor registration. This entails filling out a simple form signed by both the registrant and distributor. Delta staff can provide a copy of the form and information to be included. The distributor must have an EPA company number before completing the form; Delta can handle this for your company or your company's distributor.

Note that EPA's Supplemental Distributor form requires that the registrant (<u>not</u> the supplemental distributor) package and label the product. Sometimes a contract manufacturing agreement can be executed allowing the distributor to package and label the product; contact Delta staff for details.

State Registration Required

Once the form is submitted to EPA, the supplemental distributor must register the product in the States in which it wishes to sell, market, transport through or distribute before releasing the product into the marketplace. There is no further action on the Federal level.

Supplemental Distributor Labels

A Supplemental Distributor may make the following changes to the registrant's approved label: Product name; name and address of the distributor (instead of the registrant); deletion of certain label claims; use of a subset of directions. EPA holds the basic registrant responsible for its distributors' labels. Delta can advise you on what is permissible.

The complete EPA registration number for a supplemental distributor must be included on the supplemental distributor's label. The EPA company and product numbers will be consistent with the signed supplemental distributor form with the distributor's EPA company number after the second dash (e.g., 00000-00-00000).

The EPA establishment number on the product label must be that of the actual production facility. In many cases the actual EPA establishment number will not be the same as the basic registrant's or supplemental distributor's EPA company number.

Maintaining a Product Registration

State Registration Renewal

After initial registration, each State requires that the registration be renewed. Most States renew registrations on an annual basis with renewal fees due by December 31 of each year. Some States renew annually at other times of the year, and a few States renew registrations mid-year or on a multiple year basis.

State Assessments and Mill Tax

Some States also impose special taxes based on gross sales of product in the State. If the product is registered in California, on a quarterly basis you will be required to report and pay CA mill tax based on sales. Delta will provide informational materials upon request.

EPA Maintenance Fees

On January 15 of every year, EPA pesticide registration maintenance fees are due. Delta contacts all current clients regarding fees and payment. Non-payment of fees results in cancellation of a product registration. Fee varies from year to year.

EPA Pesticide Producing Establishments

On March 1 of every year, all pesticide producing establishments are required to report their production quantities to EPA. This applies to repackagers as well as manufacturers. The report must be filed even if the facility has had no production that year. Delta alerts all current clients that the forms are due and assists clients as requested. If a facility produces both pesticide and non-pesticide products, only the pesticide production must be reported. A record keeping system should be set up to easily retrieve this information annually. There are special instructions for foreign establishments. Once the forms have been filed, EPA requires that a copy of the forms be kept on-site at the pesticide-producing establishment for two years. Failure to report or to report by the March 1 deadline results in monetary EPA enforcement action. **It is important to file the report on time.**

Record Keeping

In accordance with EPA regulations, all of the following records must be retained for two years:

- Registrants are required to keep records showing the product name, EPA registration number, batch identification (lot numbers or the like), and quantity of each batch.

- If other products are used as the active ingredient, then the registrant must keep records showing the name of the product or active ingredient, the name/address of the shipper, name of the delivering carrier, date received, and quantities received. Shipping and receiving documents may serve as the record as long as they include the information required.

- Registrants are required to keep records showing the name/registration number of the product being shipped, name/address of the consignee, name/address of the establishment from which the product is being shipped, name of originating carrier, date shipped, and quantities shipped. Such records are required even when a shipment is between plants owned or controlled by the same person. Shipping and receiving documents may serve as the record as long as they include the information required.

- Sometimes the same product has both pesticidal and non-pesticidal uses and is labeled separately for those uses. Delta recommends that clients clearly record on the invoices and shipping records whether the sales/shipment is the registered pesticide or a non-pesticide. (Putting the registration number or “non-pesticide” as appropriate on the invoice and shipping records is one way of accomplishing this.) Such action will assist record keeping and can reduce California mill tax and other State assessments.

Adverse Effects Reporting

Under FIFRA Section 6(a)(2), registrants are required to report all adverse information that comes to their attention (including to their agents, supplemental distributors, and/or any employees) regarding their registered pesticide. Reporting requirements include:

- submitting all studies showing adverse effects (for public health uses, this includes efficacy studies showing a product does not work as labeled);

- reports from people about incidents involving humans, domestic animals, wildlife (non-target organisms), ground water, surface water, and in some instances damage to property that would have adversely affected a human if one had been present (for example a pesticide exploding); and

- even expert opinions expressing concern about an adverse effect.

Registrants are not required to conduct followup on incidents or studies etc., but if they do followup or conduct a risk assessment or conduct a study (even if non-GLP), and any of these show an adverse effect, then the registrants must report results to EPA. Companies need to show "due diligence" in setting up procedures to ensure proper reporting.

Delta has prepared a detailed packet of information discussing this requirement. Please call Delta staff if you do not have a copy or if you have questions.

Imports and Notice of Arrivals

All imports of EPA registered products are required to be cleared by the relevant EPA Regional Office prior to arriving at the US border and being cleared for entry into the United States. EPA's "Notice of Arrival" form must be filed with the relevant Regional Office and approved in advance of customs processing. EPA Regional Offices scrutinize marketplace labeling against stamped labels and flag any discrepancies. Likewise, the Agency has focused on manufacturing sites listed on approved Confidential Statements of Formula to be certain they match establishments listed on the market label and these sites are registered and up-to-date on establishment reporting. If your EPA registered product, or your supplemental distributors' products are being imported, Delta should discuss possible issues and concerns with you.

Inspections

Various inspections take place for registered products. Most commonly, States under contract to EPA pull products from the shelves of retail stores and review the labeling to ensure it is consistent with labeling registered in the State. States also pull products for testing to ensure the percentage of active ingredient is the same as claimed on the label. States may ask to inspect records to ensure that "mill taxes" or other special taxes have been paid properly. Sometimes EPA or State officials under contract to EPA will inspect a manufacturing plant to review records, labeling, or production methods. If you are notified that States or EPA will be inspecting your company's facilities, you should call Delta immediately.

Registration Review

EPA is required by law to review active ingredient registrations every 15 years. At first, just the registrants for the technical grade active ingredient are required to submit data and information to EPA. Delta assists clients with preparation of this information, meetings with EPA and other similar work to support registrant's response to EPA registration review notices and requirements. When EPA makes the formal determination that an active ingredient is cleared to continue registration, EPA issues a data call-in for all registered products with the specific active ingredient. This requires a registrant to submit labeling, all current CSFs, and possibly other data and information specified by EPA. If this occurs, Delta staff can assist you in responding to the data call-in.

Action Required Before Making Product Changes

Changes to EPA Approved Labels

EPA has specific requirements regarding changes that may be made to EPA approved labeling; almost all changes require EPA amendment or notification. Any pamphlets, booklets, bag tags or other informational materials accompanying the product at the point of sale or referred to on the product label are considered part of the label and subject to EPA approval. **Please consult Delta staff before making any label changes. We will advise you of the likelihood of EPA approval and what data, if any, may be required to support the proposed change.**

Changes to EPA Confidential Statement of Formula (CSF)

A registrant may not make any changes to a product formula without EPA approval. This includes changes to suppliers of ingredients, addition of fragrances or dyes, or any other changes regardless of how minor. In addition, after notification to EPA or EPA approval of amendment, States must be notified of the changes. California often will require special review for some types of changes. **Please consult Delta staff on all formula changes being considered.**

State Amendments and Notifications

It is important to keep State registration files up-to-date. **Any time a registrant amends or makes any changes to a label or formula for a registered product, the States in which the product is registered must be notified and the revised labeling must be provided to them**. Changes must comply with the most recent EPA approval. States are largely responsible for enforcement of Federal and State pesticide laws. Labeling in the marketplace must match the label on file in the States. If they are not the same, an inspector may file an enforcement action against your company. **Please keep in mind that any change in company name, product name, or ingredient, will require an amendment (or notification) to EPA and <u>new</u> registration in the States.** Changes must be approved by States prior to releasing for sale. Please call Delta staff for cost implications prior to making changes.

Again, California rules and procedures for label and formula changes are different than for other States. Some changes can be made by notification to CA and others will require an amendment, sometimes with data and a small review fee.

Company Name and Address Changes

EPA

A registrant is required to inform EPA of any changes in the company name or address in EPA records. Registrants must wait for EPA approval of the name/address change before using the new name or address.

States

States also must be informed of name and address changes, once EPA has approved the change. The new company name/address typically will appear on the marketplace label. **Please be aware that in most cases company name changes will require new State registrations which will result in significant cost implications.** Contact Delta staff for more information.

Transfers/Ownership Changes

EPA must approve all transfers of registrations from one company to another. If you sell your company or the product registration, the EPA registration (and associated data rights) must be formally transferred to the new owner. The transfer requires EPA approval and Delta can prepare the necessary paperwork to accomplish the transfer in a timely fashion. If the transfer results in a change to the company name and/or EPA registration number, the company name information discussed above will apply. Please consult Delta with questions on appropriate procedures.

Non EPA Registered Products

Although the following does not pertain directly to a registrant's responsibilities after EPA registration, Delta finds that some registrants have questions about the following:

25(b)

25(b) refers to the section of the pesticide law (FIFRA), that allows products to be marketed without EPA registration. EPA considers these products to be minimal risk. The 25(b) products are limited to products that contain ingredients which appear on EPA's active and inert minimal risk table. There also are limitations with regard to label claims and other language that appear on the label. Although not registered by EPA, many States require 25(b) labels to be registered and some have their own additional rules regarding label language and data (including efficacy) that must be submitted. Please contact Delta if you have products that may be defined as 25(b).

Devices

In some instances, EPA regulates devices. Although EPA does not require registration, if the device claims to repel or destroy a pest or is packaged with a product registered with EPA, the device must meet certain label requirements to ensure the product is not misbranded. These units must be produced at an EPA approved establishment and the establishment number must be shown on the label. A number of States will require the device to be registered. Please contact Delta if you have products that may be defined as devices.

Adjuvants

Some States require registration of products that aid pesticidal products. CA has the most complete and stringent rules on this, but a few other States also require registration. Please contact Delta if you have products that may be defined as adjuvants.

Important Dates

January 15	• EPA Maintenance Fee Filing Due at EPA
January 31	• 4th Qtr California Mill Tax Due (for previous year) at California
March 1	• EPA Establishment Reports Due at EPA • Iowa Sales Report Due • Minnesota Sales Report Due
April 30	• 1st Qtr California Mill Tax Due at California • Renewal Fees Due to Delta for Mid-year State Renewals
June 30	• Mid-year State Renewal Forms Due
July 31	• 2nd Qtr California Mill Tax Due at California • Michigan Sales Report Due (if applicable)
October 31	• 3rd Qtr California Mill Tax Due at California • Wisconsin Sales Report Due
November 1	• Renewal Fees Due to Delta for End-Of-Year State Renewals
December 31	• End-Of-Year State Renewals Due

Conclusion

The above information does not cover all instances with regard to EPA or States registration but is intended as a guide. For detailed information on any of the subjects above, please contact Delta staff. Our goal is to assist you in complying with EPA regulations.

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