Frequently Asked Questions: Pesticide Product Registrations

To help assist Industry with Pesticide Product Registrations and Renewals, OISC has created this FAQ document. We have provided some examples to help answer questions. Please note, the listing of examples is not all encompassing. This document will be updated accordingly.

CONTENTS

All Pr	oc	lucts	3
A.		When a Product Requires Multiple Registrations	3
:	1.	OISC Registered my product but added additional information to the product name. Why?	3
:	2.	My company branding has changed. What does that mean for my currently registered products?	3
	3. sp	My product comes with different application devices (i.e.: manual pump sprayer, battery powered rayer), do these require different registrations?	3
	4.	My product comes with different use directions, do these require different registrations?	3
!	5.	My company just changed their name. Does this require new registration of our products?	4
	6. wc	My product is sold in different scents (individually) and a combination of the scents (together). What ould OISC require for registration?	4
	7.	My product is sold and marketed in different colors. Does each color require registration?	4
В.		Registration Certificates	4
:	1.	How can I find if certain products are registered in Indiana?	5
C.		Multiple Contacts within an Organization	5
	1. da	I have different team members within my State Registration Team, can we each be listed in the tabase for our company?	5
	2. be	I use a submitting company for my renewals but would like to receive notifications when a product have registered. Can OISC send this information directly to me?	
D.		Labeling and Labels	5
:	1.	How long does it take to receive my registration in Indiana?	5
:	2.	What if OISC requires label revisions to my pending application?	5
;	3.	What does Indiana review with the application?	6
	4.	Can I include "EPA Registered" statements on websites/marketing?	6
Section	on	3 Products	6
A.		Indiana's Use of PPLS	6
;	1.	What if my ABN or Supplemental Distributor Product is not listed on PPLS YET?	6
В.		Common Sec. 3 Labeling Questions	6
:	1.	I am a Supplemental Distributor; can I add additional information to my label?	6
	2.	What is required to be under the header "Directions for Use"?	6

Office of Indiana State Chemist

Pesticide Product Registration Team

Pesticide Product Registration Team	
5. My Product is packaged in a kit or co-pack. What are the requirements for this label?	7
6. My product includes comparative claims approved by EPA on the master label. Why is OISC requirevisions?	_
25(b) Minimum Risk Pesticide Products	7
1. My company utilized a PO Box. Can this be listed as our contact information?	8
2. Can I claim that my product is free of certain chemicals?	8
Pesticide Devices	8
A. What does not require registration in the state of Indiana?	8
B. What does require registration in the state of Indiana?	8
C. Device Labeling	8
1. What is required on my device label?	9
2. The company and address of where the device is produced is on the device. Does my company's information need to be as well?	
3. Can I say that my device is safe because it doesn't utilize any conventional pesticides?	9
State Specific Registrations	10
Annual Renewals	10
Resources	10
EPA Resources	10
AAPCO Resources	10
OISC Resources	10
Other Resources	10

ALL PRODUCTS

A. WHEN A PRODUCT REQUIRES MULTIPLE REGISTRATIONS

According to IC 15-16-4-56: "For more than one (1) pesticide product to be considered the same pesticide product, each pesticide product must exhibit the same: (1) product name; (2) registrant name; (3) United States Environmental Protection Agency registration number; (4) labeling, claims, and branding; and (5) ingredient statement."

Please see the "Indiana Pesticide Product Registration Requirements, Products that are Considered Different" document for additional information.

1. OISC REGISTERED MY PRODUCT BUT ADDED ADDITIONAL INFORMATION TO THE PRODUCT NAME. WHY?

In order to track the different branding and labeling for a product, OISC may add additional information to the product listing. OISC may add specific branding information, product type information (i.e.: insecticide, ready-to-use)

2. MY COMPANY BRANDING HAS CHANGED. WHAT DOES THAT MEAN FOR MY CURRENTLY REGISTERED PRODUCTS?

If your product branding has changed, this may require a new registration in the state of Indiana. This requires a new registration even if the product name listed with EPA does not include this branding. Some examples include:

- a. (if your product was previously labeled to include "Bob's Pest Products" but is changing to "BPP".
- b. (Your logo has changed from "Bob's Pest Products" to "Bob's Professional Pest Products"
- c. Your branding has changed from "Bob's Pest Products" to "Simple Products"

If the graphic associated with your branding has changed, but the language has not, this may not require new registration.

3. MY PRODUCT COMES WITH DIFFERENT APPLICATION DEVICES (I.E.: MANUAL PUMP SPRAYER, BATTERY POWERED SPRAYER), DO THESE REQUIRE DIFFERENT REGISTRATIONS?

Yes. If the application equipment provided with the product differs between different label types, this would require multiple registrations.

4. MY PRODUCT COMES WITH DIFFERENT USE DIRECTIONS, DO THESE REQUIRE DIFFERENT REGISTRATIONS?

Yes. If the product has different use directions provided with different marketplace labels, this will require multiple registrations. Some examples of what would require different registrations include:

- a. One label was a concentrate that directs the user to connect to a hose and another label was a concentrate that directs the consumer to mix in a watering can.
- b. A product packaged specifically to refill another container would also require registration.
- c. One label is identified for homeowner use, the other for professional use

If the difference is only the Storage and Disposal, this does not require multiple registrations, but all versions should be provided to the state.

5. MY COMPANY JUST CHANGED THEIR NAME. DOES THIS REQUIRE NEW REGISTRATION OF OUR PRODUCTS?

Yes, any change in the company name requires new registration. Some examples include:

- a. Change from LLC to INC
- b. Inclusion of a DBA
- c. Change from one company to another

6. MY PRODUCT IS SOLD IN DIFFERENT SCENTS (INDIVIDUALLY) AND A COMBINATION OF THE SCENTS (TOGETHER). WHAT WOULD OISC REQUIRE FOR REGISTRATION?

OISC would require each scent to be registered individually and the combination of scents to be registered as a co-pack. If one scent is sold individually and in a three pack (with the same DFU), these would not require different registrations.

Additional examples of co-packs that requires registration is when a pesticide product is packaged with non-pesticide products, or two different products are packaged together.

7. MY PRODUCT IS SOLD AND MARKETED IN DIFFERENT COLORS. DOES EACH COLOR REQUIRE REGISTRATION?

Yes, if your product is sold and marketed in different colors it would require registration in Indiana. If your product is sold in different colors but is not marketed for the different colors, these would not require different registrations.

An example of marketing different colors would include - A device that is sold in white and black. The container labeling for the device specifies the color and/or the supplemental marketing (i.e.: online websites) allow for the consumer to purchase a specific color.

An example of not marketing different colors would be when a color selection would vary. An example of online marketing language for a product that would not require different colors to be registered would say something like "colors vary" or "different colors provided by random selection". In a retail setting, this would happen where the labeling does not clearly identify the different colors.

An instance where different colors would not require registration is if the products are custom made. If this is specific to your products, we recommend that you request confirmation on what requires registration.

B. REGISTRATION CERTIFICATES

OISC does not mail pesticide product registration certificates. However, the applicant will receive an automated e-mail from our database when the product has been registered or renewed. After registration, the product can be legally sold, distributed, or used within the state of Indiana.

1. HOW CAN I FIND IF CERTAIN PRODUCTS ARE REGISTERED IN INDIANA?

Registered products can be searched through either:

- http://npirspublic.ceris.purdue.edu/state/state menu.aspx?state=IN
- https://www.inplants.oisc.purdue.edu/USAPlantsIN/ProductRegFSA/BrandSearch.aspx

C. MULTIPLE CONTACTS WITHIN AN ORGANIZATION

1. I HAVE DIFFERENT TEAM MEMBERS WITHIN MY STATE REGISTRATION TEAM, CAN WE EACH BE LISTED IN THE DATABASE FOR OUR COMPANY?

OISC can only list one contact for each account. We recommend utilizing a shared team email (like statereg@company.com) if you have multiple people connected to an account.

2. I USE A SUBMITTING COMPANY FOR MY RENEWALS BUT WOULD LIKE TO RECEIVE NOTIFICATIONS WHEN A PRODUCT HAS BEEN REGISTERED. CAN OISC SEND THIS INFORMATION DIRECTLY TO ME?

OISC can only utilize one email/contact per account. If you would like the automated emails and renewal information to go directly to the registrant (and not the submitter), the submitter information should not be included on the application. It is also recommended that a cover letter is included identifying the correct path of contact.

D. LABELING AND LABELS

1. HOW LONG DOES IT TAKE TO RECEIVE MY REGISTRATION IN INDIANA?

Prior to COVID, a Section 3 registration would take 3-6 months, a device or 25(b) would take 9-12 months. A product must be registered with the state before any manufacturing, distribution, use, or sale happens within the state.

The "COVID Product Registration Policy" was first provided in 2021. This policy has recently been updated and will expire July 1, 2022.

2. WHAT IF OISC REQUIRES LABEL REVISIONS TO MY PENDING APPLICATION?

If labeling revisions are identified during the review process, the registrant is expected to make the changes and submit revisions by a provided deadline.

If revisions are not provided, the application will be denied.

We recommend that registrants plan accordingly with enough time to obtain state registration prior to printing labels. If labels are printed already, the registrant will be responsible for making sure only the corrected labels are sold/distributed into Indiana.

3. WHAT DOES INDIANA REVIEW WITH THE APPLICATION?

OISC reviews all required documents during the review process. OISC may also review product claims available through additional labeling (ie. online marketing, sale sites, etc.).

4. CAN I INCLUDE "EPA REGISTERED" STATEMENTS ON WEBSITES/MARKETING?

As defined in FIFRA Section 2(q)(1)(A) a pesticide is misbranded if its labeling (including websites or advertisements) bears any statement, design or graphic representation which is false or misleading.

EPA's regulation, at 40 CFR 156.10(a)(5) provides examples of statements that are considered to be misbranded, such as:

- Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by an agency of the Federal Government.

Inclusion of the EPA symbol, inclusion of federal registration, may be considered misbranded.

SECTION 3 PRODUCTS

A. (INDIANA'S USE OF PPLS)

Products must be found in <u>EPA's Pesticide Product and Label System (PPLS)</u> prior to being registered with the state of Indiana. This means that an ABN must be listed and a Supplemental Distributor Product (by searching for the full EPA Reg. No.) must be available.

1. WHAT IF MY ABN OR SUPPLEMENTAL DISTRIBUTOR PRODUCT IS NOT LISTED ON PPLS YET?

For an ABN, proof of submission to EPA is required. For a Supplemental Distributor Product, an 8570-5 form, that is stamped by EPA is required. Proof should be submitted with the label via email to pestproducts@groups.purdue.edu or uploaded into ALSTAR if it is not readily available on EPA's PPLS site.

B. COMMON SEC. 3 LABELING QUESTIONS

When reviewing Section 3 labels, OISC utilizes EPA guidance documents and websites, as well as applicable rules and regulations (federal and state).

I AM A SUPPLEMENTAL DISTRIBUTOR; CAN I ADD ADDITIONAL INFORMATION TO MY LABEL?

40 CFR 152.132 outlines the specifics about what a supplemental distributor can and cannot do.

For example, the 40 CFR does not allow the supplemental distributor to add graphics that are not on the master label. If you have images (such as scents, pests, use locations, etc.) these must first be identified on the master label.

2. WHAT IS REQUIRED TO BE UNDER THE HEADER "DIRECTIONS FOR USE"?

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Pesticide Product Registration Team

Directions for Use (DFU) requirements are included in 40 CFR 1560.10(i). This provides detailed information about the placement of the DFU on the label and what is required under the DFU header (156.10.i.2).

If your label does not include the elements of the DFU under the appropriate header, revisions will be required.

5. MY PRODUCT IS PACKAGED IN A KIT OR CO-PACK. WHAT ARE THE REQUIREMENTS FOR THIS LABEL?

When submitting a kit or co-pack to OISC, all elements of the labeling must be included in one PDF. This includes outer packaging and any packaging that is on individual containers.

A supplemental distributor product can be a kit or co-pack only if the specific details for the package are identified on the basic's master label as submitted to EPA and available on EPA's PPLS site.

6. MY PRODUCT INCLUDES COMPARATIVE CLAIMS APPROVED BY EPA ON THE MASTER LABEL WHY IS OISC REQUESTING REVISIONS?

Per the EPA Label Review Manual, "The claim should not be presented in an overly large font, such that the claim is set in a font type no larger than that of the Signal Word on the label. Furthermore, the claim should not be presented with heavily bolded or highlighted type or use coloring to cause the claim to excessively stand out over the rest of the labeling text. The format of the claim should not be in such a way that is causes greater attention than other required precautionary labeling on the label." (LRM Chapter 12.4.V.B)

Per EPA's Labeling Q&A Site, LC21-1208; 10/14/21, "claims such as "free of [active ingredient]" or "contains no [active ingredient]" may constitute misbranding and may need to be removed. EPA is concerned that users might understand these types of statements to be safety claims. This could give users the impression that products without a certain active ingredient are safe or safer than products with the active ingredient, which may be false or misleading. Safety claims are considered false or misleading statements that constitute misbranding under 40 CFR 156.10(a)(5)(ix) and (x). Misleading comparative claims about the safety of the product versus other products also constitute misbranding under 40 CFR 156.10(a)(5)(iv) and (vii). These claims are therefore disallowable under FIFRA sections 2(q)(1)(A) and 12(a)(1)(E).

Consumers can readily determine if a pesticide product contains an active ingredient (e.g., DEET) by reviewing the active ingredients listed on the front panel of the label in accordance with 40 CFR 156.10(g). Because all active ingredients must be listed, the absence of an active ingredient in the ingredient statement would indicate it is not in the product."

25(B) MINIMUM RISK PESTICIDE PRODUCTS

OISC references all <u>AAPCO</u> guidance documents for 25(b) minimum risk products when reviewing and registering 25(b) products. We strongly recommend that you review and comply with all AAPCO 25(b) guidance prior to submitting an application.

Products must comply with EPA's Minimum Risk Conditions and EPA's Final Rule

- 1. MY COMPANY UTILIZED A PO BOX. CAN THIS BE LISTED AS OUR CONTACT INFORMATION?
 - According to 40 CFR 152.25(f)(3)(iii), the registrant is required to include the name of company and contact information that includes street address, ZIP code and telephone number.
- 2. CAN I CLAIM THAT MY PRODUCT IS FREE OF CERTAIN CHEMICALS?

No. For further information, please review the "25(b) Claims about the Absence of an Ingredient" document on the AAPCO website. OISC also includes information about the absence of ingredient claims within the Audit Letter Update, as provided on the OISC Pesticide Products website. EPA confirmed that the Questions and Answer LC21-1208; 10/14/21 aligns with 25(b) products as well.

PESTICIDE DEVICES

Any device that makes pesticidal claims requires registration as a device in the state of Indiana. Pesticidal Devices are registered based on Labeling and Marketing. OISC can help determine which devices and device components require registration prior to the submission of the applications.

A. WHAT DOES NOT REQUIRE REGISTRATION IN THE STATE OF INDIANA?

OISC does not register simple mechanical devices, such as: barriers, traps, or adhesives, or other simple contrivances. As examples, the following are exempt from registration

- Snap traps for mice
- Glue traps for insects
- Fabric barriers for weeds

A pheromone trap is exempt from registration when the purpose of the trap is for monitoring the number of pests in an area.

B. WHAT DOES REQUIRE REGISTRATION IN THE STATE OF INDIANA?

The above-mentioned products (Devices.A) are not exempt from registration in Indiana when they include a substance (pheromone or food bait). A pheromone trap sold with the purpose of mitigating/removing the pest requires registration in Indiana.

OISC requires the registration of any device that makes a pesticidal claim (outside of those identified above). If your device includes replacement filters or light bulbs that impact the efficacy of the product (ie: HEPA filters, UVC light bulbs), these require their own registration as well.

C. DEVICE LABELING

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When submitting device labeling to OISC, it should be submitted as a single text- searchable PDF. Elements to include would be 1) outer packaging, 2) user manuals (including: directions for use, precautionary statements, instructions), 3) any images that appear on the device itself (EPA Est. Number, warning stickers, etc)

1. WHAT IS REQUIRED ON MY DEVICE LABEL?

40 CFR 156 is titled "Labeling Requirements for Pesticides and Devices". OISC follows the 40 CFR in review of device labeling.

Devices are subject to the labeling requirements of FIFRA section 2(q)(1) and 40 CFR Part 156.

Under FIFRA section 2(q)(1) a device is considered to be misbranded and subject to enforcement action if:

- the labeling bears any statements, designs, or graphic representations that are false or misleading (see 40 CFR 156.10(a)(5));
- its packaging or wrapping does not conform to standards established pursuant to FIFRA section 25(c)(3) (as of 2010, such standards have yet to be established for devices);
- it is an imitation of, or is offered for sale under the name of another device;
- the label fails to bear the establishment number of the establishment where it was produced;
- any required information is not prominently displayed on the label;
- it lacks adequate directions for use; or
- it lacks an adequate warning or caution statement.

False or misleading elements identified in 40 CFR 156.10(a)(5) apply to pesticide devices.

Required information that must be prominently displayed on the label can be located in 40 CFR 156, as applicable to devices.

According to Indiana Law, the EPA Establishment Number must be on the device itself. The EPA Establishment Number must also be visible at the time of purchase (ie: on the outer box if it is not visible through the container).

2. THE COMPANY AND ADDRESS OF WHERE THE DEVICE IS PRODUCED IS ON THE DEVICE. DOES MY COMPANY'S INFORMATION NEED TO BE AS WELL?

According to 156.10.a.1.ii, the name and address <u>for whom</u> the product is produced is required to be on the labeling. The "for whom" is the registrant company information entered into our database.

At a minimum, the "for whom" (company name, address) must be on the outer packaging and any users' manuals.

If the label includes the name and address of the producer (EPA Establishment) and this is different from the registrant, the registrant's name should be qualified with appropriate wording such as "distributed by" or "sold by". These should be in the same section of the label (ie: If the name of the producer is on the device itself, the registrant contact information must also be located here).

3. CAN I SAY THAT MY DEVICE IS SAFE BECAUSE IT DOESN'T UTILIZE ANY CONVENTIONAL PESTICIDES?

A pesticide or a device cannot make any safety claims, including statements such as safe, harmless, or nontoxic – with or without the qualifying phrase "when used as directed" (156.10.a.5.ix).

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STATE SPECIFIC REGISTRATIONS

Coming soon – details related to 24(c), Section 18, EUPs and 2(ee)s.

ANNUAL RENEWALS

Coming Soon!

RESOURCES

EPA RESOURCES

- 1. Label Review Manual: https://www.epa.gov/pesticide-registration/label-review-manual
- 2. Pesticide Labeling Q&A: https://www.epa.gov/pesticide-labels/pesticide-labeling-questions-answers
- 3. Labeling Requirements: https://www.epa.gov/pesticide-registration/labeling-requirements
- 4. 40 CFR: https://www.epa.gov/laws-regulations/regulations
- 5. Pesticide Registration Notices: https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year
- 6. Pet Product Mitigation: https://www.epa.gov/pets/epa-evaluation-pet-spot-products-analysis-and-plans-reducing-harmful-effects
- 7. Pesticide Devices: https://www.epa.gov/pesticides/pesticide-devices-guide-consumers
- 8. Pesticide Registration Manual: https://19january2017snapshot.epa.gov/pesticide-registration/pesticide-registration/pesticide-registration/pesticide-registration-manual.html
- 9. Minimum Risk Pesticides: https://www.epa.gov/minimum-risk-pesticides

AAPCO RESOURCES

1. 25(b) Workgroup: https://aapco.org/2015/07/02/fifra-25b-workgroup/

OISC RESOURCES

- 1. OISC Pesticide Products Website: <a href="https://oisc.purdue.edu/pesticide/pestici
- OISC Product Search: https://www.inplants.oisc.purdue.edu/USAPlantsIN/ProductRegFSA/BrandSearch.aspx

OTHER RESOURCES

1. NPIRS Public Search: http://npirspublic.ceris.purdue.edu/state/state menu.aspx?state=IN