



## *State FIFRA Issues Research Evaluation Group*

### **Pesticide Operations and Management Working Committee**

## **SFIREG Multiple Products Packaged Together Registration Review Guidance**

August 8, 2022

### **SUMMARY**

There is a federal registration/labeling compliance issue in the marketplace. With the challenges and complexities in determining which multiple products packaged together (\*MPPT) require separate federal registration and/or United States Environmental Protection Agency (EPA) label review, the State FIFRA Issues Research and Evaluation Group (SFIREG) working committee, Pesticide Operations and Management (POM), has developed this guidance as a reference document for State Lead Agencies (SLAs) and industry. This guidance brings together all currently available resources and answers to frequently asked questions (FAQs) about MPPT that include one or more FIFRA Section 3-regulated pesticide products.

This guidance is intended for SLAs responsible for administering and enforcing pesticide laws and regulations. The goal of this document is to provide guidance on labeling consistency for industry and label reviews for SLAs. This guidance is based on Title 40 Code of Federal Regulations (CFR) and existing documented EPA guidance.

Approaches regarding the labeling for MPPT are dependent on the specific issues of each case. Registrants should contact the appropriate EPA division for additional information before submitting registrations or amendments that feature MPPT or before deciding whether such packaging requires federal registration.<sup>1</sup>

\*For the purpose of this document, the term “MPPT” will include all versions of kits, co-packs and multipacks that contain at least one federally registered pesticide product. MPPT can contain one or more FIFRA-regulated products or in some cases, FIFRA-regulated products along with one or more non-FIFRA products. MPPT is a new term for SLAs and Industry; however, it is used as a header in the EPA Pesticide Labeling Questions & Answers (Q&A) website.

According to EPA, a new registration is required when there is a change in the directions for use or there is a new overarching product/brand name for the MPPT, or the MPPT, such that the MPPT is a new pesticide product (defined in 40 CFR 152.3 as “a pesticide in the particular form (including composition, packaging, and labeling) in which the pesticide is, or is intended to be, distributed or sold. The term includes any physical apparatus used to deliver or apply the pesticide if distributed or sold with the pesticide.”). An amended registration may be required if alternate brand names (ABNs) are

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<sup>1</sup> US EPA Label Review Manual 18.IV.A, page 18-3



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being added to individual MPPT components to indicate they are part of the MPPT (see additional information below).

#### **BACKGROUND**

There has been a proliferation of MPPT in the marketplace. These could include:

- Multiple containers of the same pesticide product
- Different pesticide products
- Pesticide products(s) plus non-pesticide products(s) (i.e., non-FIFRA product(s))

Examples of terms used by industry to refer to MPPTs: kit, pak/pack, multipack, co-pack, value pack, twin pack, combo/combo combination pack, pallet, pallet pak/pack, cube, cube pack, season pak/pack.

Examples of MPPTs seen in the marketplace include:

- Disinfectants/sanitizers (e.g., first aid kits, pool/spa kits, home cleaning kits, home brewing kits, disinfectant wipe multipacks)
- Fungicides/insecticides, Herbicides/algaecides, including conventional pesticides and biopesticides (e.g., Fungicide, herbicide and Insecticide packaged together for use on turfgrass, Herbicides packaged together for treatments in crops and non-crop areas, Fungicide and Insecticide packaged together for organic gardening)
- Repellents, including skin-applied (e.g., pet care topicals multipack, outdoor repellent kits)

Some MPPTs are simply multiple containers of the same pesticide products or different pesticide products packaged together, without the addition of a new overarching product/brand name and with each pesticide label completely visible from the outside of the package.

- According to existing EPA guidance, such an MPPT would not require its own registration (and its own label review) with EPA. However, the individual products contained in the MPPT are still subject to EPA's registration and label review requirements.
  - Individual states may require such an MPPT to be registered as its own product/brand. It is recommended to connect with the SLA responsible for administering and enforcing pesticide laws and regulations in each state to clearly identify if your MPPT requires registration. [AAPCO State Lead Agencies - Points of Contact](#)
- The package may include a "boot" with partial label information, but the full pesticide label is also visible.



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Other MPPTs are sold/marketed under an overarching product/brand name that is different from the name of each pesticide product inside and/or each pesticide label is not completely visible from the outside of the package.

- Based on existing EPA guidance, these products require separate EPA registration and/or label review by EPA.
- Based on preliminary product reviews by SLAs, there are MPPTs currently in the channels of trade that may require separate registration and/or label review with EPA.
- Examples of potentially problematic MPPTs seen in the marketplace:
  - The MPPT has a name that is different from the name(s) of the pesticide(s) inside, and the MPPT does not have its own unique EPA Registration Number. This has been primarily observed with kits.
  - The outer packaging labeling of the MPPT deviates from the content of the EPA-accepted labels on the pesticide containers inside the MPPT (e.g., additions, omissions, formatting changes).
  - The pesticide label(s) are not visible, or not completely visible, from the outside of the MPPT package.
  - The MPPT is marketed by a supplemental distributor, potentially without the oversight of the basic registrant. This has been primarily observed with kits.
  - A third-party seller (any business other than a registrant or supplemental distributor) has packaged and marketed their own MPPT, presumably without the oversight of the basic registrant/supplemental distributor. This has been primarily observed with kits.
    - Examples:
      - i. A home brewing store selling home brewing cleaning kits that include a sanitizer
      - ii. A pond supply store selling various combinations of herbicides/algaecides packaged with adjuvants.
  - The MPPT includes an unregistered pesticide that is not exempt from federal registration.
  - An MPPT that requires a separate state and/or EPA registration is opened by a retailer who then sells the products inside the MPPT separately from one another.

Lack of EPA registration results in administrative challenges for SLAs and possible misbranding issues.



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#### **TYPES OF MPPTS SEEN IN THE MARKETPLACE:**

Approaches regarding the labeling for MPPT are dependent on the specific issues of each case. Here are some types of MPPTs seen in the marketplace. EPA does not reference “kits”, nor do they differentiate between co-packs and multipacks in the US EPA Label Review Manual. Kits are referenced on the US EPA Pesticide labeling Q&A website.

#### **1. Kits**

A kit includes multiple products and can contain one or more FIFRA-regulated products, along with one or more non-FIFRA products. Each product in the kit is separately packaged and labeled – just as it would be if sold separately. The kit consists of an outer container, such as cardboard box, which houses the separately-packaged FIFRA and non-FIFRA products placed inside the outer container.<sup>2</sup>

If the approved label(s) is visible through the outer packaging (e.g. visible through shrink-wrap), or if the outer packaging is an exact replica of the approved label(s)\*, EPA does not need to review the kit label.<sup>3</sup>

\*A booklet or other “pull-off” type labeling may be used if EPA has approved it for each individual FIFRA-regulated product when it is not feasible to fit the entire label text directly on the product outermost container.

The contents of a kit are usually not mixed together, they are packaged together for convenience. For example, a pool kit could include an algaecide, sanitizer, chlorine test kit, pH test strips, measuring cup and water sampling bottle. Other examples of kits are:

- Roach control kit that includes a roach killing gel and roach killing bait
- Bathroom cleaning/disinfectant kit that includes a toilet bowl cleaner, toilet bowl brush and disinfectant spray

#### **2. Co-packs**

A co-pack is a combination of two or more pesticide products when the products are 1) packaged in separate containers but sold together as a single unit OR 2) are packaged in one container that keeps the chemicals separate until the consumer purchases the product and mixes the different pesticides together. Co-packs may direct the user to mix the two products together before application. Co-packs may also contain non-FIFRA

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<sup>2</sup> US EPA Pesticide labeling Q&A website, LCO7-106;10/29/07

<sup>3</sup> US EPA Pesticide labeling Q&A website, LCO7-106;10/29/07



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products and have instructions directing users to mix them with the pesticide products in the Directions for Use.

The pesticide products included in the co-pack may have different EPA Registration Numbers. However, if the design of the co-pack container (e.g., divided container with two pesticides with just one spout) combines both pesticides when poured, then the co-pack would have its own Registration Number, as new product specific data would be required to register this product.

Each container must bear, or be accompanied by, full labeling, and the full labels of both containers must be visible. If the outermost packaging obscures any part of the labeling of the pesticides, the full labels\* must be duplicated and securely attached to the outermost container. (40 CFR 156.10(a)(4)(i))<sup>4</sup>

\*A booklet or other “pull-off” type labeling may be used if EPA has approved it for each individual FIFRA-regulated product when it is not feasible to fit the entire label text directly on the product outermost container.

An example of a non-FIFRA product in a co-pack would be an adjuvant, which is to be mixed with the pesticide before application. This may be sold with the co-pack only if the adjuvant is referred to in the Directions for Use on the pesticide product label. If the adjuvant is not referred to in the Directions for Use the co-pack would require amended registration by EPA.

### **3. Multipacks**

A multipack is when two or more pesticide products with the **same** EPA Registration Number are packaged together. This type is not referring to items packaged together for shipping purposes only.

Multipacks contain:

- a. Product components that are different (e.g., different scents or different names, but the same EPA Registration Number, etc.) **OR**
- b. Product components that are identical (i.e., same scent, same name, same EPA Registration Number, etc.)

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<sup>4</sup> US EPA Label Review Manual 18.IV.A, page 18-3



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These products are typically packaged together through shrink-wrapping or in a box and the entire container for the pesticides are visible to the consumer at the point of purchase.

Each container must bear, or be accompanied by, full labeling, and the full labels of both containers must be visible. If the outermost packaging obscures any part of the labeling of the pesticides, the full labels\* must be duplicated and securely attached to the outermost container. (40 CFR 156.10(a)(4)(i))<sup>5</sup>

\*A booklet or other “pull-off” type labeling may be used if EPA has approved it for each individual FIFRA-regulated product when it is not feasible to fit the entire label text directly on the product outermost container.

The labels of the products within the multipack may have differences that are allowed by the EPA-accepted label. For example, the multipack may contain two disinfectants with the same product/brand name and EPA registration number, but different fragrances/scents. Alternatively, the labels of the products within the multipack may be completely identical or may be identical except for net contents (e.g., different sizes of the same container sold together).

It is important to differentiate whether the multipack contains different components or identical components. Individual States may require multipacks that contain different components to be registered as its own product/brand. It is recommended to connect with the SLA responsible for administering and enforcing pesticide laws and regulations in each state to clearly identify if your multipack requires registration. [AAPCO State Lead Agencies - Points of Contact](#)

#### **THINGS FOR SLAS TO LOOK AT DURING INSPECTIONS OR LABEL REVIEWS:**

- If the full pesticide label (on the immediate container) cannot be seen through the outer package, the full pesticide label must be duplicated on the outermost container (box, wrapping, etc.) for the MPPT. Also see FAQ #1.
- When the pesticide product is sold with a non-pesticide which is to be added to the pesticide during mixing, such as an adjuvant, the two products can be sold together as a single unit only if the adjuvant is referred to in the Directions for Use on the Label.<sup>6</sup> If the adjuvant is to be added to the pesticide during mixing but is not referred to in the Directions for Use for the pesticide, the MPPT would require an amended registration by EPA.

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<sup>5</sup> US EPA Label Review Manual 18.IV.A, page 18-3

<sup>6</sup> US EPA Label Review Manual 18.IV.A, page 18-2



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- The outermost container packaging claims must be on the EPA-accepted label for each product contained in the MPPT. For example:
  - Pricing and packaging statements (e.g., “2 for 1”, “Value Pack”, “150 More Wipes”, BOGO)
  - Non-efficacy related marketing (non-pesticidal) claims (e.g., “Clean more with 24 extra wipes”)
- For a distributor product to be placed in the MPPT it must be identical to the basic registrant’s MPPT packaging and EPA-accepted labeling. See more about distributor products below.

#### **DISTRIBUTOR PRODUCTS:**

According to 40 CFR 152.132(d), the label of the **distributor product must be the same** as that of the basic 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 may appear instead of that of the registrant;
- The registration number of the registered product must be followed by a dash, followed by the distributor's company number (obtainable from the Agency upon request);
- 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 other changes are necessary.

This applies to the MPPT as well, 40 CFR 152.132(b) states “the distributor product is produced, packaged and labeled in a registered establishment operated by the same producer (or under contract in accordance with § 152.30) who produces, packages, and labels the registered product.”. The distributor product cannot create an MPPT, add/remove components, modify labels or make additional claims that do not appear on the basic registered product(s) EPA-accepted label(s).

#### **FREQUENTLY ASKED QUESTIONS:**

##### **1. What should be on the outer package of a Kit?**

In general, the full label of each product contained in a kit must be consistent with the labeling requirements at 40 CFR 156.10. For example, the full label of each product contained in the kit must be visible on the outermost container. However, upon review, EPA may allow, if appropriate, a subset of the approved label to appear on the outer container. In all cases, the following items are required to be fully visible either through the outer packaging or on the outer container:



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- Product Name.
- Registration Number.
- Ingredient Statement.
- Signal Word.
- Keep out of reach of children statement.
- Precautionary Statements.
- The full directions for use or a referral statement to read the labels on the containers in the box for full directions for use, including mixing or sequential use of the products.
- Name and address of producer or registrant.
- Net weight.
- If highly toxic, skull and crossbones, “poison,” and a statement of practical treatment in case of poisoning.
- Use classification (e.g., Restricted use).
- Establishment Registration.<sup>7</sup>

#### **2. When does EPA require the review of an MPPT?**

A new or amended registration is required by EPA when there is a change in the directions for use or there is a new overarching product/brand name given for the MPPT.

If the kit is sold under a separate name from its previously registered contents, the kit must be registered as a separate product and the label must be reviewed. 40 CFR 152.3 defines “pesticide product” as “a pesticide in the particular form (including composition, packaging, and labeling) in which the pesticide is, or is intended to be, distributed or sold.” 40 CFR 156.10(b)(2)(ii) prohibits names on a label that have not been approved by EPA. Therefore, if the kit is considered anything more than the combination of separately named products (e.g., when a kit is marketed with its own distinct name), the kit must be registered.<sup>8\*</sup>

EPA must review the labeling through the registration (in the case of a new product) or registration amendment process if:

- the kit is being sold as a unique product requiring separate registration, or
- the individual product labels are not visible from the outer container, or

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<sup>7</sup> US EPA Pesticide Labeling Q&A Website, LC07-0106; 10/29/07

<sup>8</sup> US EPA Pesticide Labeling Q&A Website, LC07-0106; 10/29/07



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- the previously approved labels are not used on the outer container in their entirety without modification.<sup>9\*</sup>

\*These references refer to “kits”, however this applies to all types of MPPTs.

The regulation at 40 CFR 152.3 states that the “pesticide product” includes the package intended to be distributed or sold. EPA has jurisdiction over the packaging and labeling of any “non-pesticide” which is part of the package. This means that EPA reviews and accepts or disapproves of the non-pesticide that is packaged with the pesticide.<sup>10</sup>

#### **3. If a pesticide product is included within a kit, what is required on the immediate pesticide container within the Kit?**

The pesticide product in the kit is required to be separately packaged and labeled – just as it would be if sold separately; therefore, the full pesticide product label must be on the immediate pesticide container within the Kit.

#### **4. If the basic registrant’s EPA-accepted label only identifies MPPT combinations of A, X and Y, can the supplemental distributor product have an MPPT that contains X, Y and Z?**

NO, If the stamped EPA-accepted label for the basic product includes MPPT language, then the supplemental distributor of that basic product can also have it, provided it mirrors the EPA-accepted label for the basic product. A supplemental distributor cannot make their own MPPT containing the distributor product if it is not allowed by the basic EPA-accepted label. See also 40 CFR 152.132 and the earlier section on distributor products.

#### **5. Does my MPPT require state registration if the pesticides contained within the MPPT are already registered in that state?**

States have different laws regarding which products require registration. It is recommended to connect with the SLA responsible for administering and enforcing pesticide laws and regulations in each state to clearly identify if your MPPT requires registration. [AAPCO State Lead Agencies - Points of Contact](#)

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<sup>9</sup> US EPA Pesticide Labeling Q&A Website, LC07-0106; 10/29/07

<sup>10</sup> US EPA Label Review Manual 18.IV.A, page 18-2



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**6. EPA has accepted the ABN or received an 8570-5 form for a distributor product name that includes the word “kit”. Do SLAs need to review the kit’s label?**

YES, If the kit contents are not included in the EPA-accepted label, SLAs can confirm with the Product Manager at EPA for the basic product that the required review of kit contents has been satisfied.

**7. I want to sell an MPPT that includes a pesticide and market it for my small business. The MPPT would include non-FIFRA products and a pesticide. Can I do this if I am not the basic registrant?**

YES, this would be considered supplemental distributor of a registered pesticide. In order to sell such an MPPT, you would need to comply with 40 CFR 152.132, including the following:

- i. Agreement with the basic registrant
- ii. EPA Establishment Number
- iii. Language approving the use of a MPPT on the basic registrant’s EPA accepted label

You would need to submit EPA Form 8570-5, signed by you and the basic registrant, to EPA. This form is available at <https://www.epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms>

Individual states may also require that this MPPT be registered as its own product. It is recommended to connect with the SLA responsible for administering and enforcing pesticide laws and regulations in each state to clearly identify if your MPPT requires registration. [AAPCO State Lead Agencies - Points of Contact](#)

**8. If all I am doing is shrink-wrapping a pesticide into a MPPT, does that need to be completed in an EPA establishment?**

YES, because shrink-wrapping is still considered pesticide production.

**9. If I am supplemental distributor, can I shrink-wrap products together without an agreement?**

NO, see 40 CFR 152.132 and the section above on distributor products.

**10. If my MPPT is shrink-wrapped and I add a sticker on the outside of the shrink-wrap (like “value pack”), does this constitute labeling? Must this be done in an EPA-Registered Establishment?**

YES, affixing a sticker (other than a bar code sticker, see below) to a container is considered labeling and therefore production as defined in 40 CFR 167.3. 40 CFR



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167.20(a)(1) requires any establishment where production occurs to be registered.

Affixing a sticker must take place in a registered establishment.<sup>11</sup>

The exception is bar code stickers: Provided the bar code sticker is not being added to the label to meet a labeling requirement and the bar code does not cover or obscure any required label element, EPA does not consider the placement of the bar code sticker on cartons and containers to be production that must occur in a registered establishment.<sup>12</sup>

#### **CURRENT RESOURCES FOR MPPT:**

**EPA Pesticide Labeling Q&A Website:** <https://www.epa.gov/pesticide-labels/pesticide-labeling-questions-answers>

#### **EPA Label Review Manual (LRM)**

- Chapter 18, IV Multi-packs / co-packs [US EPA - Label Review Manual - Chapter 18: Unique Product Labeling](#)
- *Submit errors or suggestions for the LRM on the [Pesticide Labeling Questions and Answers](#) page, which is a component of the [Pesticide Labeling Consistency](#) Web page.*

#### **OTHER RESOURCES NOT INCLUDED FOR REFERENCE IN THIS GUIDANCE:**

##### **PESTICIDE DEVICES:**

##### **For questions about devices visit:**

- [Pesticide Registration Manual: Chapter 13 - Devices | US EPA](#) or
- email [OPPDeviceDeterminations@epa.gov](mailto:OPPDeviceDeterminations@epa.gov)

##### **FIFRA SECTION 25(b) MINIMUM RISK PESTICIDES:**

##### **For questions about 25(b) pesticide products visit:**

- [FIFRA 25\(b\) Workgroup – Association of American Pesticide Control Officials \(aapco.org\)](#)
- [Minimum Risk Pesticides Exempted from FIFRA Registration | US EPA](#)

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<sup>11</sup> US EPA Pesticide Labeling Q&A Website, LC09-0303; 12/10/09

<sup>12</sup> US EPA Pesticide Labeling Q&A Website, LC12-0567; 10/23/12