

100% Repacks: Guidance on Alternate Formulations and Allowable Uses

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This guidance is intended to clarify Office of Pesticide Programs (OPP) policies regarding alternate formulations and labeling for 100% repack products. Consistency in applying this guidance across product teams, branches and divisions is important to ensure program integrity and a level playing field for the registrant community.

This guidance only pertains to 100% repack products. A 100% repack product is a pesticide product that is manufactured by simply repackaging another EPA-registered product, with no changes to its composition. A 100% repack product may be either a manufacturing use or an end use product.

The guidance is divided into two parts, addressing (I) new (proposed) 100% repack products; and (II) revisions to the basic formulation or addition of one or more alternate formulations for an existing 100% repack product.

I. New (Proposed) 100% Repack Products:

If the new 100% repack product has a basic formulation only and no alternate formulations/sources:

- All labeling required by FIFRA must be the same on the new product as it is on the product being repackaged. This includes the following:
 - ✓ Ingredient Statement
 - ✓ Hazard and Precautionary Statements (including Signal Word, First Aid, Hazards to Humans and Domestic Animals, Environmental Hazards, Physical and Chemical Hazards, and WPS requirements, if applicable).
 - ✓ Directions for Use, including the Storage and Disposal Statements, **except as described below.**

Note: Company-specific information, such as emergency contact information, company name and address, etc., may be different on the new product label.

- The Directions for Use on the new 100% repack product may include all of the use sites approved on the label of the product being repackaged or a subset of these sites. The new product may not include any use sites on its label that are not approved on the label of the product being repackaged. The new product may not include use sites that are merely similar to use sites on the label of the product being repackaged. For example, if the product being repackaged includes directions for use on commercial apple orchards, it would not be acceptable for the new product to include directions for use on apple trees in residential areas. The sites must be the same.

- Minor wording changes are permitted in the new product's Directions for Use section, provided wording changes do not alter the meaning of language approved for the product being repackaged.
- As part of the application for registration, the registrant must submit a formulator's exemption form (EPA Form 8570-27) citing the repackaged product.

If the new product has a basic formulation and one or more alternate formulations:

- The FIFRA-required label language (See the first bullet above in section I) must be the same across all products being repackaged (basic and alternate formulations), and the new product must have the same language as on these products, except as described below for the Directions for Use. Note: Company-specific information, such as emergency contact information, company name and address, etc., may vary among the products.
- The nominal concentration of the active ingredient(s) must be identical for the basic and alternate formulation source products. An alternate source is not acceptable if the nominal concentration of the active ingredient(s) differs from that of the basic source product, even if the nominal concentration falls within the certified limits of the active ingredient for the basic source.
- The new product's label may include **only** those use sites approved on the labels of **all** products being repackaged. The example below shows a hypothetical situation for a new 100% repack product with a basic formulation and two alternate formulations:

Uses on the Basic formulation product: tomatoes, eggplant, peppers, squash, cucumbers, lettuce, and celery.

Uses on Alternate formulation (A) product: tomatoes, eggplant, peppers, squash, and cucumbers.

Uses on Alternate formulation (B) product: tomatoes, eggplant, peppers, lettuce, and celery.

In this example, the only use sites that may appear on the 100% repack product are tomatoes, eggplant, and peppers (or a subset of these), since they are the only sites common to all three products being repackaged.

- Minor wording changes are permitted in the new product's Directions for Use, provided wording changes do not alter the meaning of language approved for the product being repackaged.
- If the directions for use on a site differ among the products being repackaged in terms of application rate, no of applications, PHI, etc., the repack product's label must include the

most conservative directions (lowest application rate, fewest number of applications, shortest PHI, etc.).

- As part of the application for registration, the registrant must submit a formulator's exemption form (EPA Form 8570-27) citing each basic and/or alternate formulation source product. Source products may be listed on the same or separate forms.

II. Existing 100% Repack Products - Amendments to Revise the Basic Formulation or Add One or More Alternate Formulations:

A registrant may revise a 100% repack product's basic formulation to specify a different source product. Registrants may also add alternate formulations for 100% repack products. Such changes are subject to the following conditions and limitations.

- The new basic or alternate formulation source product must have the same nominal concentration as the existing source product(s).
- The new basic or alternate source product's label must include all of the uses on the 100% repack product's current label. If the new source product's label has fewer uses, it is not acceptable as a source product for the 100% repack product, as explained below.

New source products with fewer uses are not acceptable, since uses would have to be deleted from the existing product's label before the new source could be approved. FIFRA sec. 6(f) requires EPA to publish a notice of receipt of a request to delete uses and allow a comment period before acting on the use deletion request, a process that often takes 9 months or more to complete. The use deletions must be completed before new basic or alternate sources with fewer uses on their labels can be approved for 100% repack products.

- The new basic or alternate source product's label must have the same FIFRA-required language as the 100% repack product's label (see the first bullet under sec. I, above).

Note: The reviewer need only compare the label of the proposed (new) source product with the 100% repack product's label in determining whether it is acceptable. It is not necessary to re-review the labels of all other source products in determining if the new source product label is acceptable.

- As part of the application to amend the registration, the registrant must submit a formulator's exemption form (EPA Form 8570-27) citing each new basic and/or alternate formulation source product. Source products may be listed on the same or separate forms.
- If a registrant proposes to amend the registration of a 100% repack to allow the company to manufacture the product instead of (or in addition to) repackaging an EPA-registered product, the product would no longer qualify as a 100% repack, and the guidance presented here would no longer apply.