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This Entire Policy Is New

February 25, 2022

Indiana Pesticide Product 25(b) – Minimum Risk Update

Attn: Companies with 25(b) Products

Indiana Backlog of Pending 25(b) Applications

For registrants with currently registered 25(b) products, OISC will register those 25(b) products with applications in our present queue. A full review of the products registered in this timeframe will be completed with the 25(b) Audit of the previously registered products.

Upon initiation of the registration of the pending applications, OISC will send an email to registrants requesting an updated 25(b) Audit Excel document listing the products that were not included in the initial Audit submission. Moving products through the registration process reduces the continued delay in products entering the market in Indiana. We appreciate your assistance as we work through the pending applications.

This information has been communicated on the updated Pesticide Product Registration Response to COVID Influences (dated February 25, 2022) as well.

Absence of an Ingredient Claims

EPA recently updated their Labeling Q&A website (<https://www.epa.gov/pesticide-labels/pesticide-labeling-questions-answers>) to include the following:

Can a manufacturer advertise that their product does not contain a certain active ingredient (e.g., “DEET free”)? 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.

EPA confirmed that this assessment also applies to 25(b) products. During the Audit review, comparative claims will be identified and require revisions. Products that include a claim like “DEET Free” in the product name, will require a new registration with the revised label because a product name change in Indiana is considered a different product. OISC recommends that registrants start the process of removing claims from labels and labeling (including marketing, websites, promotional documents, etc.).

New Product Applications received in 2022 will not be registered with claims related to the absence of an ingredient. Registrants will receive 30 days to revise their labels accordingly.

Update 25(b) Audit

Unfortunately, this is no longer as collaborative as originally planned. As identified previously, the Audit is to ensure that all registered 25(b) products are held to the same standards.

Wisconsin has already started reviews and is in the process of contacting companies based on their findings, specific to the review process that they have within their state. Please contact Wisconsin (DATCPPesticideRegistration@wisconsin.gov) if you have any questions directed to their Audit.

Indiana will start review of Audit packets in Summer of 2022. We aim to have the reviews completed by Summer of 2023.

Audit Timeline for Indiana:

- Submission of Required Audit Documents by December 31, 2020.
- Review Process
 - 2021-23: SLAs will conduct Audit and prepare documents
 - 2021: Audit packets have been reviewed for completion; companies have been notified about incomplete packages.
 - 2022-23: Review of packets, prepare review documents
 - Fall 2023: Registrants will receive the Audit documents containing information on what information or changes registrants will be required to make for each product.
- Registrant Revisions and Updates
 - Registrants will be given the opportunity to make the required revisions, submit new registration applications or cancel their product's registration.
 - 2025 Renewals: All registered products must meet the standards and guidelines, or they will not be renewed. Extensions may be provided for companies that are required to provide additional/revised efficacy.

Please direct all questions to pestproducts@groups.purdue.edu.

Thank you,

Sarah K Caffery
Pesticide Product Program Manager