

September 24, 2020 - Updated October 22, 2020

Attn: Companies with Registered 25(b) Products

2021 Multi-State 25(b) Audit

The Office of the Indiana State Chemist (OISC) included a notification with the 2020 renewal packet of the upcoming audit of all 25(b) registered products. This Audit project has been taken on by multiple State Lead Agencies (SLA) and the process is outlined below. The Audit is to ensure that all registered 25(b) products are held to the same standards. The SLA team has reached out to industry during the planning process; frequently asked questions are included at the bottom of this document.

The Audit will be conducted by the following states: Arizona, Indiana, Maine, Mississippi, South Dakota, Washington DC, and Wisconsin.

Audit Timeline

- Communications:
 - OISC 2020 Renewals: Companies were informed of the 2021 25(b) Audit
 - March 2020: OISC sent an email to all companies and submitting companies with registered 25(b) products about the Audit
 - Summer 2020: SLA Audit Team communicated plans with the AAPCO 25(b) Industry group, HCPA, American Chemistry Council, and EPA.
 - September 2020: 25(b) Registrants are informed of the process and given information on how to submit their Audit packets.
- Submission of Required Audit Documents:
 - Audit packets must be received by the SLA team by December 31, 2020.
- Review Process
 - 2021-22: SLAs will conduct Audit and prepare documents
 - Fall 2022: 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
 - 2023-24: Registrants will be given the opportunity to make the required revisions or cancel their product's registration.
 - 2025 Renewals: All registered products must meet the standards and guidelines, or they will not be renewed.

Audit Packet – Registrant Submission

- Registrants will submit their full packet to all SLAs involved in the Audit. The packet must be submitted on CD, thumb drive or through email.
- Please note:
 - **Maine, South Dakota and Wisconsin require documents to be sent via email.**
- The packet must include
 - Excel Document: Can be found here: <https://aapco.org/2015/07/02/fifra-25b-workgroup/>

- Directions for the Excel document are included as the first tab within the document.
- There must be an individual folder (within the CD/thumb drive/email) for each product. This folder must include all the required documents for the product's registration. Required documents include:
 - Current marketplace label
 - Labels must be text-searchable PDFs
 - Statement of Formula
 - Must be submitted on this form: <https://aapco.org/2015/07/02/fifra-25b-workgroup/>
 - Tips:
 - Make sure to properly identify the function of each ingredient and use the correct CAS numbers.
 - The function "active" or "inert" does not qualify
 - Efficacy Data
 - Tip:
 - If the efficacy includes multiple formulations, clearly identify which formulation corresponds with the product in audit
 - SDS
 - Any additional human health toxicity data or hypoallergenic testing that is available

Audit Results

The audit results will vary depending on the state. Any of the following may be the result of the audit:

- Product requires no revisions
- Product requires revisions to formula, labeling, and/or additional efficacy.

If a state requires revisions to the formula, labeling or additional efficacy, the process may look like this:

- Product requires formulation revisions
 - Depending on the State, this may require discontinuance of the old formulation and a new registration
- Product requires new data
 - Conditional Registration 2 years
 - Product will be cancelled after two years (end of 2024) if the new data cannot be provided
- Product requires labeling revisions
 - Must provide updates by October 1, 2024 or products will be cancelled.
 - Products may be placed under conditional registration until revisions are received
- If the registrant decides not to revise/supply new data
 - Product will be placed in discontinuance
 - Final year of discontinuance would be 2024*

***Note – previous letter stated 2025. This was a mistype and inconsistent with the earlier point "Product requires new data"**

Registrants may be required to identify how they will move forward with the products before the 2023 renewal will be processed

Upon completion of the Audit, SLAs will identify what their state requires.

SLA Contact Information

SLA	Contact Person	Email
Arizona:	Licensing 602-542-3578	licensing@azda.gov
Indiana:	Sarah Caffery or L.E. Bradford	pestproducts@purdue.edu
Maine:	Mary Tomlinson	mary.e.tomlinson@maine.gov
Mississippi:	Denise Clanton	denisec@mdac.ms.gov
South Dakota:	Kristia Thomas or Katie Nold	Kristia.Thomas@state.sd.us Katie.Nold@state.sd.us
Washington DC:	Howard Brown or Manish Poudel	howard.brown@dc.gov or manish.poudel@dc.gov
Wisconsin:	Monica Sipes	DATCPPesticideRegistration@Wisconsin.gov

Frequently Asked Questions

If you have questions about how to submit the data to a specific state, please contact them directly. It is recommended that if you are sending an email, **enter in subject line “Company-25(b) audit documents”**

Q: Will all products be included, or only those first registered in one or more of the participating states before a certain date?

A: Audit will include all currently registered 25(b) products. If your product is registered in only one of the participating states, it must be provided to all states.

Q: Given that every product may not be registered in each of the participating states, will states potentially be evaluating products not registered in their state? Will the findings of one state be binding upon the product in the other 8-12 states? Is that legal according to each state’s laws?

A: There is a potential that SLAs will be evaluating products not registered in their state. The Audits will identify where the deficiencies are in the product’s registration package. Each SLA

will determine the final actions taken in their state. Please see the different possible outcomes as outlined under the Audit Results section above. There will be extensive interaction between states to help ensure uniformity so labels will be acceptable in all states.

Q: What if the Audit determines that I need to change my formulation?

A: The final process of the Audit differs among the SLAs. In some States, if applicable through their law, a formulation changes may be considered a label revision and can remain under the current registration. In other States, a change in formulation requires a new registration. For the states that require new registration, the current formulation/product will be placed under a two-year discontinuance.

Here is an example of the Indiana rules that identifies that a change in the formulation would be considered a different product; therefore, a new registration is required.

IC 15-16-4-56 Pesticide products that are considered to be the same

Sec. 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, if applicable; (4) labeling, claims, and branding; and **(5) ingredient statement.**

SLAs will identify how the Audit impacts their specific state registrations.

Q: Why do I need to send all my information to all SLAs involved in the Audit?

A: The SLAs are collaborating on the Audit review for each product. By sending all documents to all SLAs, you are ensuring that the appropriate documents get to the appropriate reviewer. Also, if an SLA is running behind on their review, a different SLA can assist without waiting for data to be sent to their state. In order to promote consistency across the reviews and have open conversations about the products, SLAs will have all the documents in question and will not share the confidential information.

The excel document identifies the registration/state ID for each state. This confirms that the SLAs are reviewing the same product and it is correctly identified in each SLA's internal database. This document also ensures that all SLAs receive the same data and agree on the type of product because it is provided by the registrant.

If you are comfortable with SLAs sharing your full Audit Packet, you can submit it to just Indiana and OISC will forward it to the other SLAs. This must be specifically noted with the submission.

Q: If my product is registered in one state but pending in another, will this Audit delay the outcome of the initial registration?

A: Registration review processes are unique to each state. If an application is still pending in one of the Audit states, it will remain in the queue and be processed according to the SLA's current review process. If the Audit review has already taken place for this product, it may assist in the initial registration of the product.

Q: Are Discontinued products included in the Audit?

A: If the product is discontinued in all states involved in the Audit, the registrant does not need to send an Audit packet for this product.

Q: How can we request an extension?

A: Registrants can request an extension on providing Audit packets to the states. Send an email to Indiana – pestproducts@purdue.edu

Q: Why am I sending CDs or thumb drives to all SLAs – why not utilize a portal or online system for this so that I only need to create one submission?

A: CDs/thumb drives are being offered because some registrants do not share their own confidential information through email or other online portals.

Q: What if we have different labels for the SLAs involved in the audit?

A: If a registrant has different labels that are distributed into different states, provide all labels that are in distribution and identify (the files) accordingly to which States the products are registered in.

Q: How will SLAs ensure consistency across the reviews and hold all products to the same standard?

A: The Audit is a collaborative effort. Multiple SLAs will review the Audit before it is finalized. The SLA Audit Team will also communicate concerns to ensure consistency across product type. There will be much interaction between states to help ensure uniformity so labels will be acceptable in all states.

Q: When will I receive my Audit review?

A: All registrants will receive the Audit review at the same time, the goal is to provide this information in the fall of 2022. (See Audit Results above)

Q: If new efficacy is required, could multiple companies go in on the same efficacy study?

A: Registrants can go in on the same efficacy report. The requirement is that the efficacy is done with the final product's formulation; therefore, representing the same formulation for actives and inerts as the final product.

Q: It is unclear how an audit completed by one state will impact the registration of that product in other States and whether the audit outcomes can be acted upon. While this appears to be a voluntary cooperative action by the states, there are concerns that this may be a restriction upon interstate commerce.

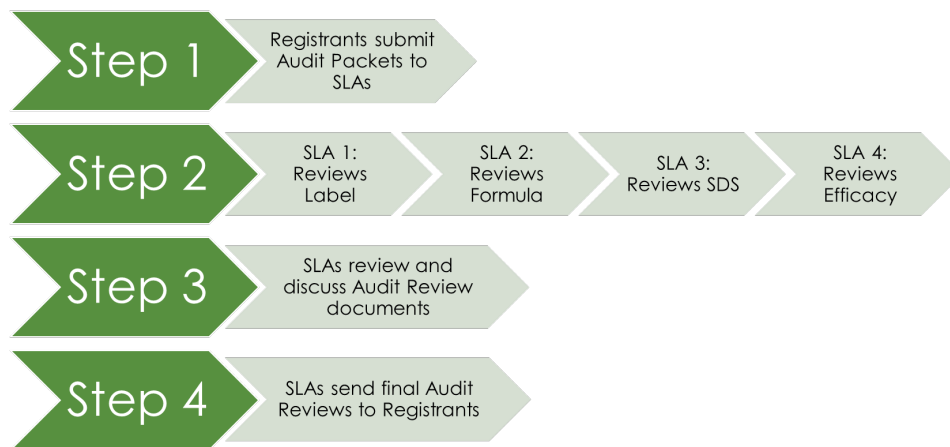
A: SLAs are participating to ensure the products meet the 25(b) requirements of the EPA to be exempt from federal registration and the guidelines identified by the AAPCO 25(b) workgroup that helps clarify the exemption. Some states have more requirements than others and that is why the outcome of the Audit varies by the specific state. There will be much interaction between states to help ensure uniformity so labels will be acceptable in all states.

Q: Will the States allow bridging of data?

A: As identified in the question about multiple companies sharing one efficacy report – the efficacy must be done on the final formulation. If the bridging is between products that share the same formulation, that would be acceptable. Changes in the formulation would require new efficacy. There are additional points about bridging data on the 25(b) Efficacy Guidance Q&A document (available on the AAPCO website).

Q: Previous conversations identified that the review would be done in clusters (by specific types, etc...), is this still the path that the SLAs are going to use for the audit? Will registrants know when their product is up for review?

A: The reviews are being completed collaboratively. The SLA Audit Team will be assigned products to review, upon completion of that product type, they will move to the next group. Registrants will not be notified when their review is taking place. All registrants will receive their review at the same time.



Q: How will this audit address those products on the market in any of the states that are not currently registered?

A: The goal of this Audit is to level the playing field for registered products. This project does not address unregistered products in the market. The Audit falls in-line with the goals identified within the 25(b) workgroup’s mission:

The workgroup’s mission is to facilitate the collaboration of states and industry in order to share information, provide guidance, foster label consistency, and reduce the duplication of efforts in the review and registration of Minimum Risk Pesticide products.

SLAs and Industry share concerns about unregistered 25(b) products in the market. Unregistered 25(b) products should be identified and shared with the enforcement departments of EPA and SLAs.

Example from Indiana:

Tips on non-compliant 25(b) or any unregistered pesticide product can be submitted through: <https://www.oisc.purdue.edu/pesticide/index.html> - 7th point option “Filing a Pesticide or Fertilizer/Manure Complaint”

Q: Will the SLA reviewing an audit package contact the company directly, or can we expect all communication to come to us through OISC? If all communication will be handled by OISC, will registrants be told which SLA was responsible for reviewing their audit package?

A: The Audit review will include a collaboration among the SLAs. While each state may vary in the outcome, the revisions documented and/or additional efficacy will be the same for all. Currently, the idea is to provide one review document with the final review. How this is provided is still to be determined.

Q: Industry groups had requested that at the conclusion of the audit, a trend analysis of the overall findings would be provided to the registrant community to ensure full transparency of findings and how those findings might be used to identify next steps. Are the SLAs still planning for this?

A: This was submitted as a recommendation. It has not been finalized/confirmed how data connected to this audit will be shared with a broader audience outside of the individual registrant.

Q: There is a pending ANPRM through EPA about 25(b) Minimum Risk products. How would this ANPRM affect the efforts connected to this Audit?

A: Without knowing what EPA's intention is with the ANPRM, SLAs cannot provide a specific account as to how the ANPRM might impact the Audit process.

**As of 10/6/20, the ANPRM has not been open for comments. The original date for the ANPRM was March 2020.

Q: Specific to the possible audit outcomes listed in the letter to registrants dated September 24, 2020, will registrants requiring either formulation revisions (and possibly new registration), new data or labeling revisions all receive a 2 year conditional registration while working to address the requested changes? And, if new registration is required to address formulation revisions, will discontinuance (if required by state law) begin only following the 2-year conditional registration period?

A: Products that require revisions will all receive a 2-year conditional registration. The 2-year conditional registration would constitute the discontinuance period for these products.

This document will be updated with additional questions as they are presented.