Documents provided:

1. 25(b) Audit Review Information Sheet, including the FAQ and reference sections.
2. General Audit Checklist: this sheet shows all the elements that were considered during the audit process.
3. Audit Review Results: One document per product that was reviewed. This document highlights the revisions or additional documents required to renew this product and maintain registration in the state of Indiana.

   This document may also highlight recommended revisions the OISC has identified. Recommended revisions provide the end user with additional information to either enhance the reader clarity on the label or provide additional safety measures. Although registrants are not required to make the recommended revisions, they are highly recommended to ensure the safe use of the product.

Next steps:

Review the review documents. If you have any questions, you may contact Victoria Matsumura directly at fickle@purdue.edu. Submit the required items by the deadlines provided below.

To streamline the submission process:

1. Submit all required revised documents with highlighted revisions within one email to fickle@purdue.edu. Do not submit items one at a time. Incomplete revision packages will be returned. Different products can be in different emails, but all documents for a single product must be in a single email. If attachments exceed the maximum file size that can be attached in a single email: you may consider zipping the files, using a drop box, or submitting files via thumb drive or CD.
2. Provide all required items as separate text-searchable pdfs.
3. Use the subject line: “25(b) AUDIT REVISIONS SUBMITTED [COMPANY NAME]”
4. In the body of the email, include which products and documents are included in that email.

Once the revisions have been reviewed, OISC will request a non-highlighted label or identify if any elements from the audit are still missing or not addressed.

Deadlines

If revisions are required or recommended – intent to make these revisions must be submitted to OISC by September 1, 2024. All revisions must be submitted by September 1, 2025. If we do not receive a response with your intent by September 1, 2024, it will be assumed that you do not intend to revise the required documents.

If you do not intend to make the required revisions, the product will go in discontinuance in 2025, and will not be renewed for 2026. Non-revised products cannot be distributed into the state after 12/31/2025. These products will only be given one year of discontinuance.

FORMULATION REVISIONS: If you intend to provide efficacy that proves your ingredient has the function identified on the CSF and is compliant with federal regulations (i.e. an inert does not have pesticidal properties), this intent must be provided by September 1, 2024. If the product requires reformulation, it will not be renewed for 2026. Products in this category will be placed into discontinued status for the 2025 renewal. Reformulated products will require a new registration in the state of Indiana. See item 5 below for more information on formulation revisions.

Types of Revisions & What to do if Revisions Are Required

1. *Website revisions*

   The website review will detail what changes need to be made to the website to remove false or misleading claims, or other claims that are prohibited by FIFRA or the Indiana Code. Website reviews may include the registrant's site OR other eCommerce sites. Revisions may include claims for pests for which no data was provided, reapplication times that are not supported by the data, unqualified safety claims, or other false or misleading claims.
   What to do: Revise accordingly and submit documentation of the revisions. Including website links.

   It is the registrant's responsibility to ensure that all websites are free of any false or misleading claims. Websites include those managed directly by the registrant, social media, and additional eCommerce sites.

2. *Label revisions*

   Label revisions are required for any number of reasons. Sometimes revisions on the label may require that other documents also be revised to ensure

consistency throughout all documents. Revisions may be required to match efficacy, ensure safety, to provide clarity to the user, and other reasons as identified in the product's review.
What to do: Revise accordingly and resubmit.

3. *SDS revisions*

   SDS revisions are generally only required if the SDS lists ingredients not included in the statement of formula and/or ingredient statement. AAPCO and OISC highly recommend that all active ingredients on the label should be listed on the SDS. Occasionally, there may be additional information from the SDS that OISC may require or recommend be added to the label. Many of the revisions are connected to the health & safety of the users and/or environment.
   What to do: Revise accordingly and resubmit.

4. *CSF revisions*

   Revisions to the CSF are generally required if the CSF does not match the ingredient statement on the label, the CAS numbers are incorrect, information is missing, or if the function of ingredients is not appropriately identified.
   What to do: Revise accordingly and resubmit.

5. *Formulation* revisions:

   A formulation revision is not a CSF revision (as identified above). Formulation revisions are required when an ingredient is identified as noncompliant with the federal regulations and therefore the product, as formulated, does not qualify as a 25(b)-exempt pesticide. This may be because the ingredient does not have active properties in the formulation and is not an acceptable inert, or because an inert ingredient is suspected to have active properties in the formulation but is not an acceptable active.

   What to do:

   A. If active or inert ingredients were found to not be EPA compliant.
      The product cannot be renewed. A new registration with a new formulation that meets the EPA criteria must be submitted with a new submission packet (including new efficacy data).
   B. If the formulation was found to have either

a. Listed active ingredients not having active functions *and* those ingredients (such as SLS) are not permitted inert ingredients.
    i. Evidence must be shown that the ingredient in question is acting as an active ingredient. You can do this through submission of additional efficacy. OISC may also consider the submission of research you can provide on the ingredients role as an active ingredient.
        i. Inert Ingredients that, based on the AAPCO guidelines, are suspected to function as active ingredients *and* those ingredients are not permitted as active ingredients/ You will be required to submit proof that those inert ingredients are not functioning as active ingredients. You can do this through submission of additional efficacy data with those inert ingredients removed, or data showing the concentration of that inert is not acting as an active ingredient on its own OISC will also consider research you can provide on the ingredients role as an inert (e.g. its function as a catalyst, a pH modifier, a sticker, etc.)

If you are unable to provide this evidence, the product cannot be renewed. A new registration with a new formulation that meets the EPA criteria and AAPCO guidance must be submitted with a new submission packet (including new efficacy data with the revised formula).

6. *Efficacy revisions*

Efficacy revisions are based on the AAPCO standards.

A. If no efficacy data was submitted, efficacy data that meets the AAPCO standards must be submitted.
B. If efficacy data was submitted but it did not meet AAPCO standards, new efficacy data that meets the standards must be submitted.
C. If efficacy data was submitted and it met the standards for some pests, but not all pests, then new data can be submitted for those pests OR you may simply revise the label (and other marketing material) to remove those claims. If you have bridging documents to justify why the submitted data applies to the pest on the label, this may be considered.

Collaboration Opportunities

OISC encourages you to request a meeting for collaboration and to ask any questions you may have as early in the process as possible. We will be available throughout the revision process to help assure you have all the information you need in order to meet deadlines with appropriate revisions.

FAQ:

Q1: Why did Indiana audit all these 25(b) products? Weren't all my documents already reviewed?

A: When most of the currently registered 25(b) products were submitted for registration, there were no guidelines set forth to assure consistency throughout the products. After the AAPCO guidelines were implemented, there was concern that newly registered products were being held to a higher standard than older products. Additionally, during the Covid registration period, when there was a long backlog of pesticide products, new 25(b) products were registered without efficacy review under the condition they would be subject to the audit. This extensive audit process is to ensure that all pesticide products are being held to the same standard.

Q2: How long do I have to submit the required documents?

A: You must state your intent to provide these revisions by September 1, 2024. All final revisions are due September 1, 2025.

Q3: Do all registrants have the same time frame?

A: Yes, all registrants who submitted documents for the audit are receiving their reviews at the same time with the same deadlines.

Q4: How can I submit my revised documents?

A: Submit your revised documents as .PDF attachments to an email. Follow the submission directions provided in the informational document. OISC does not accept paper documents. If you are unable to email a .PDF, a thumb drive or CD with the .PDF files may be mailed to our office.

Q5: Were all 25(b) products audited?

A: All products that we registered in 2022 or prior were subject to the audit. If registrants opted out of the audit or did not send the required items for the audit, those products will not be able to be renewed for 2024.

Q6: I had previously registered products but missed the audit. Can I still be included in the audit?

A: No. OISC provided reminder emails to all registrants with 25(b) products, that we did not have audit material for in 2022, 2023 and again at the beginning of 2024. If you fail to provide the required documents by the final date (1/25/24), your product will be required to submit a full new application package with the $170 application payment.

Q7: Were there any 25(b) products that were not included in the audit?

A: If a product was listed in discontinued (D1 or D2) status, the product did not go through the audit. OISC has tracked the registration status of the 25(b) products throughout the audit period. Products will not be permitted to remain in Discontinued status for more than the recommended two years. NOTE: OISC cannot track the changes until after renewals for the following year are processed. If a product is marked to remain in D2 status for an additional year (i.e. 2024 and 2025), it will be cancelled in our database for the 2nd D2 year, and an email will be sent to the registrant. The $170 submitted with the product during the renewal process is non-refundable.

Q8: We had a product that was in discontinued status, but our company wants to move it back to active. Can we change the status and be part of the audit?

A: A product that moves from discontinued status back to active status will require full review, as it did not go through the audit. Per Q7, OISC will only be able to identify these status changes after the renewals for the following year are processed. When a change in status has been confirmed, OISC will require all registration materials (label, SDS, statement of formula and efficacy) to be provided within a week of notice. OISC will then provide a review and inform the registrant of any required revisions. There will be quick deadlines for any revisions. We recommend that registrants ensure that all documents meet the standards prior to submission.

Q9: Why does Indiana require the storage and disposal statement, including the disposal of excess pesticide product to be on the 25(b) label when this is not in the AAPCO guidelines?

A: Indiana Code 15-16-4-25 provides: "Misbranded" . . . As used in this chapter, "misbranded" refers to any of the following . . . (2) Any pesticide product if any of the following apply: (C) The labeling accompanying it does not contain instructions for use that are necessary and, if complied with, adequate for the protection of the

public. (D) The label does not contain a warning or caution statement that may be necessary and, if complied with, adequate to prevent injury to humans and other vertebrate animals."

To prevent the product being misbranded, OISC required that the storage and disposal statement be complete with directions for the disposal of excess product.

Q10: What are required revisions vs. recommended revisions?

A: Required revisions are required to maintain registration within the state. Recommended revisions are ***not*** *required but* ***are highly recommended.*** *They also serve as a guideline for future registrations to streamline the review process.*

Q11: Once all my submissions are approved, how long do I have to get my revised labels into the marketplace?

A: Revised labels should be used at the next printing. All the old labels should be out of the channels of trade within 2 years.

Q12: ***What if I have other questions?***

A: All questions regarding the 25(b) audit or product specific questions can be submitted to Victoria Matsumura at fickle@purdue.edu.

Q13: What if I disagree with the results of the audit?

A: Submit any disagreements (with reasoning and applicable documentation) as soon as possible. All items must be settled prior to the deadlines outlined above. This will allow for the registrant to submit a full revision package based on an updated review.

Q14: ***I have my label revisions finished but have not received the new efficacy data yet. Can I send the label revisions to OISC now?***

A: No, do not send a partial revision to OISC. Ensure that all revisions are completed and sent to OISC together (in the same email). Incomplete revision packages will be returned to the registrant.

Q15: ***My audit includes revision needs for multiple products. Can I send all product revisions in one email?***

A: Yes, you can send revisions for multiple products in one email. Ensure that the body of the email clearly identifies what products are included in the email and the changes made to each product. Remember to send the highlighted versions for

each document as a text-searchable PDF. Additions to the document should be highlighted in yellow and deletions should use a ~~strike through markup.~~

Q16: What if I need an extension?

A: Extensions will be provided given an adequate explanation is provided with the extension request. I.E. Efficacy data is being finalized but won't be completed by the testing location for two more weeks. It is recommended to request extensions as soon as you are aware of any delays, especially as it pertains to efficacy data. ***Include in your extension request:*** *1) how long of an extension you are requesting, 2) the reason for the extension, and 3) any other information that may be pertinent to the extension request. Once an extension is accepted, you may be required to provide updates to OISC.*

Q17: What happens after we submit our revisions to OISC?

A: OISC will review the revisions package and confirm that all required elements are addressed. If the revisions are acceptable, OISC will request a non-highlighted final version of the label (if applicable). If there are missing elements, the package will be returned. If all audit revisions are not completed, the package will be returned.

Q18: What is discontinuance, can I still sell the product?

Q19: My review says "remove DEET-FREE claims" but EPA's new guidance allows DEET-FREE claims under conditions. What am I supposed to do?

A: Please refer to the EPA guidance on absence of ingredient claims. When these claims are implied safety claims, they are still considered false or misleading. You will need to submit justification as to why these claims should be able to be included and why they are not implied safety claims.

Q20: Will OSIC meet or collaborate to help go through the required and recommended items?

A: OISC encourages you to collaborate with our staff to ensure guidelines are met prior to deadlines. Contact Victoria Matsumura at fickle@purdue.edyu to schedule a meeting for collaboration.

References:

Indiana Code: https://oisc.purdue.edu/pesticide/pdf/15-16-4.pdf
40 CFR 152.25: https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-152/subpart-B/section-152.25

Minimum Risk Information: https://www.epa.gov/minimum-risk-pesticides
AAPCO 25(b) Workgroup Guidelines: https://aapco.org/2015/07/02/fifra-25b-workgroup/
https://www.epa.gov/system/files/documents/2024-02/absence-of-an-ingredient-claims-guidance_02-2024_0.pdf