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Avoiding EPA Registration Delays

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Practical Submission Tips for CPDA Members

CPDA developed this member resource following consultation with EPA, review of recent Agency presentations, and publicly available EPA registration guidance. The goal is to help companies prepare clearer, more complete submissions that are easier for EPA reviewers to process.

While every submission is different, many avoidable delays come from common issues: incomplete forms, unclear cover letters, inconsistent labels and Confidential Statements of Formula, missing explanations, or late changes during review. Addressing these issues before submission can help reduce unnecessary questions, limit additional review cycles, and support a more efficient registration process.

This checklist is intended as a practical best-practices tool for CPDA members. It should be used alongside applicable EPA guidance, product-specific regulatory requirements, and company-specific regulatory judgment.

EPA Registration Submission Checklist

1. Start with a Clear Cover Letter

A strong cover letter helps EPA understand what is being submitted, why it is being submitted, and how the pieces of the package fit together. Before submitting, make sure the cover letter clearly identifies:

- The purpose of the action.
- Whether the action is a PRIA or non-PRIA submission, as applicable.
- The specific label, CSF, formulation, or administrative changes being requested.
- The data submitted or cited in support of the action, if applicable.
- Any related or linked submissions.
- Any related products or substantially similar products being cited.
- The best company contact for EPA questions.
- A backup contact, when appropriate.

For amendments, the cover letter should also explain the reason for the change. Examples may include:

- A substantially similar ("me-too") new use from a recently approved label.

- Updating directions for use based on user feedback.
- Clarifying existing directions for use.
- Responding to prior EPA comments.
- Updating a CSF or replacing a previously accepted CSF.
- Making changes tied to a registration review decision, science review, or other Agency action.

Best practice: Do not make EPA guess what changed or why. Put the explanation up front.

2. Make Cited Labels Easy to Follow

When citing a previously registered product, try to cite uses from a single registered product whenever possible. This can make the review cleaner and reduce the chance of confusion.

If multiple products or labels are being cited, be explicit in the cover letter. EPA reviewers should be able to quickly understand which cited label supports which part of the proposed label.

Consider including a table or crosswalk that clearly shows:

- The proposed label language.
- The cited EPA-accepted label language.
- The source product and EPA registration number.
- The specific use, rate, claim, restriction, or direction being relied upon.
- Any differences between the cited label and the proposed label.

When choosing among multiple accepted labels, always use the most recent stamped approved label, since older labels may not reflect more recent Agency changes or registration review updates.

Best practice: If adding directions for use or deleting restrictions, explain where the change came from. For example, identify whether it came from a cited label, registration review decision, science review, prior EPA correspondence, or another Agency action.

3. Complete All Forms Carefully

Incomplete or inconsistent forms can create avoidable delays. Before submitting, confirm that:

- All required forms are included.
- EPA Form 8570-1 ("Application for Pesticide Registration/Amendment") is fully completed.
- Section III of Form 8570-1 is complete, including container size information when applicable.

- The submission type and requested action are clear.
- All relevant data matrix guidelines are addressed.
- Data citation (EPA Form 8570-32) and data matrix (EPA Form 8570-35) forms are included when needed.
- The forms, cover letter, label, CSF, and supporting materials are consistent with each other.
- Ensure that all forms have required signatures.

Best practice: Review the full package as one regulatory story. If the form says one thing and the cover letter, CSF, or label says another, EPA may need to stop and ask questions.

4. Double Check the Confidential Statement of Formula (EPA Form 8570-4)

CSF issues are a common source of avoidable review questions. Build in a careful internal review before submission. Before submitting a CSF, confirm that:

- All required boxes are completed.
- Certified limits are calculated correctly (column 14).
- The formulation components add up to 100 percent (Column 13).
- The CSF matches the proposed label and other submission materials.
- Current and previously accepted CSFs are identified when relevant.
- The last accepted CSF or CSF approval letter is included when helpful.
- The cover letter explains what is changing from the previously accepted CSF.
- Any replacement, superseded, or consolidated CSFs are clearly identified.

EPA has issued updated guidance on CSF attachments for certain end-use products and manufacturing use products formulated with EPA-registered sources of active ingredient. When appropriate, companies should consider whether that CSF attachment format may reduce the number of CSFs needed for a product. Companies should consult the EPA guidance directly to confirm whether the approach applies to a specific submission.

Best practice: Do the math before EPA has to. Confirm every box, every certified limit, and the 100 percent total.

5. Clearly Mark Proposed Label and CSF Changes

EPA reviewers need to quickly see what changed. When submitting revised labels or CSFs:

- Include proposed CSFs when appropriate.
- Highlight changes clearly.
- Include clean and marked-up versions of the revised CSF when useful.
- Make sure the highlighted changes match the explanations in the cover letter.

- Address prior comments received from the Agency on similar labels.
- Explain whether the change is new, responsive to EPA comments, or based on a cited source.

Best practice: Do not assume EPA will recognize why a change matters. Identify the change and explain the basis for it.

6. Reduce Label Comment Cycles

Additional label comment cycles can slow the review process. Companies can help reduce the number of cycles by submitting labels that are complete, current, and easy to review. Before submitting a label, confirm that:

- The label reflects applicable EPA decisions or prior Agency direction.
- Use sites and application rates are clear.
- Directions for use are clear.
- Claims are organized and supported.
- Prior EPA comments on similar labels have been considered.
- The cover letter explains the basis for proposed additions, deletions, and changes.

Best practice: Use EPA's Label Review Manual and applicable registration guidance before submission. A label that is clearer and better supported is easier to review.

7. Avoid Mid-Cycle Label Changes When Possible

While delays in the review of a registration action can collide with the need for further label updates, making additional label changes in the middle of an active review can create new questions and additional review cycles. To help keep the review moving:

- Avoid adding new label changes mid-cycle unless necessary.
- If additional changes are needed, proactively discuss them with the EPA reviewer.
- If the new change is based on EPA comments on a similar label, explain that clearly.
- When EPA sends labeling comments, revise the label as soon as possible.
- At minimum, acknowledge EPA's email promptly and provide a realistic response timeframe.

Best practice: Communicate early. A quick acknowledgment and clear timeline can help avoid unnecessary confusion.

8. Keep Linked Submissions Organized

When multiple submissions are related, EPA needs to understand how they connect. For linked submissions:

- Provide individual cover letters for each action.

- Mention all other related submissions in each cover letter.
- Identify the linked product registration numbers, action numbers, or related applications when available.
- Explain how the actions relate to one another.
- Do not assume the reviewer will know the connection between separate packages.

Best practice: Treat each submission as a stand-alone package while clearly explaining how it fits with related actions.

9. Quick Pre-Submission Review

Before submitting the package to EPA, ask yourself these questions. Review by a colleague can find problems you may be overlooking.

- Is the purpose of the action clear?
- Is the type of submission clearly identified?
- Does the cover letter explain what has changed and why?
- Are all related registration submissions and products identified?
- Are cited labels clearly identified and crosswalked where needed?
- Are all forms complete, including Form 8570-1?
- Are all relevant data matrix guidelines addressed?
- Are CSF calculations correct, and do components add up to 100 percent?
- Are current and previously accepted CSFs identified when relevant?
- Are label and CSF changes clearly marked?
- Have prior EPA comments on similar labels been addressed?
- Are company contact details current and accurate?
- Is there a backup contact listed when appropriate?
- If EPA has questions, will the reviewer know who to contact and what the company is requesting?

10. Helpful EPA Links

Cover Letter Suggestions for Notifications and Fast Track Amendments

Common reasons a notification may be rejected (updated 10/2/24)

Common deficiencies associated with product chemistry and acute toxicity submissions (10/2/24)

Pesticide Registration Manual

The Pesticide Registration Manual is a resource for companies and individuals who want to have their pesticide products registered for sale in the United States. The manual describes the EPA's review and decision-making process for registering a pesticide product and its use. Detailed information for pesticide registrants (the company or individual applying to register a pesticide) concerning their responsibilities before, during and after the review process is also included in the manual.

EPA has emphasized that clearer, more complete submissions can support a more efficient review process. Registrants can help by submitting packages that are complete, well-organized, and easy for reviewers to follow.

CPDA will continue working with EPA and industry partners to support a more efficient, transparent, and predictable regulatory process for pesticide products and related technologies.