EPA AND USDA · TRAINING GUIDE

# Pesticide Registration Package

Plan an EPA pesticide registration under FIFRA section 3: the 40 CFR 158 data matrix with every requirement met, cited data supported by an offer to pay, the forms for the application type and the PRIA decision date.

| WRITES | PRODUCT TYPE | GUIDANCE IT FOLLOWS | TIME TO LEARN |
|---|---|---|---|
| `FIFRA 3`<br>`40 CFR 158` | EPA and USDA | FIFRA section 3 (7 U.S.C. 136a); 40 CFR 152 (registration procedures, data citation 152.80–152.99); 40 CFR 158 (data requirements); 40 CFR 160 (GLP); 40 CFR 156 (labeling); 40 CFR 180 (tolerances); PRIA 5 (FIFRA section 33); PR Notice 86-5; PR Notice 98-5 (data matrix) | About 20 minutes with the example |

Open the tool at https://app.cmcfy.com/app/pesticide-registration.html. This guide is also online at https://cmcfy.com/guides/pesticide-registration.html

## 1. What this module does

You give the product, the application type, the use pattern and the PRIA category, then list each 40 CFR 158 data requirement with its status, MRID and data owner.

The tool flags required studies that are missing, waivers without a rationale, other companies' data cited without an offer to pay, submitted studies without a GLP statement, forms that are not ready and a missing tolerance for food use, and dates the PRIA decision.

### What you get

- A Word or PDF file: cover letter, data matrix and forms list.

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## 2. Before you start

Have these ready. You can still start with the example data and replace it piece by piece.

- The 40 CFR 158 data requirements for the product type and use pattern.
- MRIDs of submitted and cited studies.
- Data compensation agreements or offers to pay.
- The PRIA category and its decision review time.

> **Your data stays on your computer.** The bar under the title counts every network request the page makes; it stays at 0 because your data never leaves your computer. `Download offline copy` saves a single file that opens from your own computer with all network access blocked, for air-gapped PCs.

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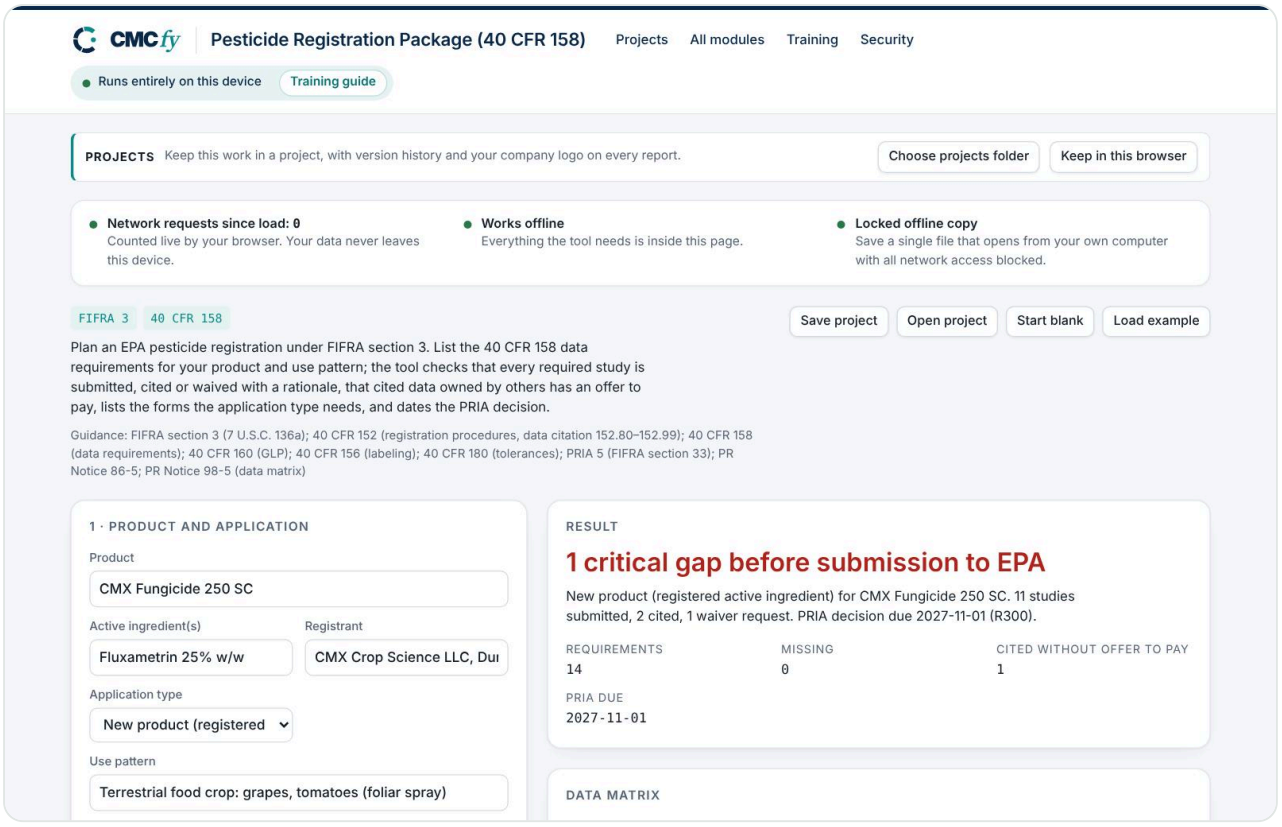
## 3. Step by step with the example

Open the tool at app.cmcfy.com/app/pesticide-registration.html. The example is loaded when the page opens, so every panel already has realistic data. Follow the steps to see how it works, then replace the example with your own data.

### 1 Describe the application

Choose the application type, give the use pattern and tick food use. Enter the PRIA category and its decision review time.




## 2 Fill in the data matrix

One row per data requirement. Status is submitted, cited, waiver requested, not required or missing. For cited data owned by another company, say whether you offered to pay.

## 3 Read the result

The headline gives the outcome, for example "1 critical gap before submission to EPA".

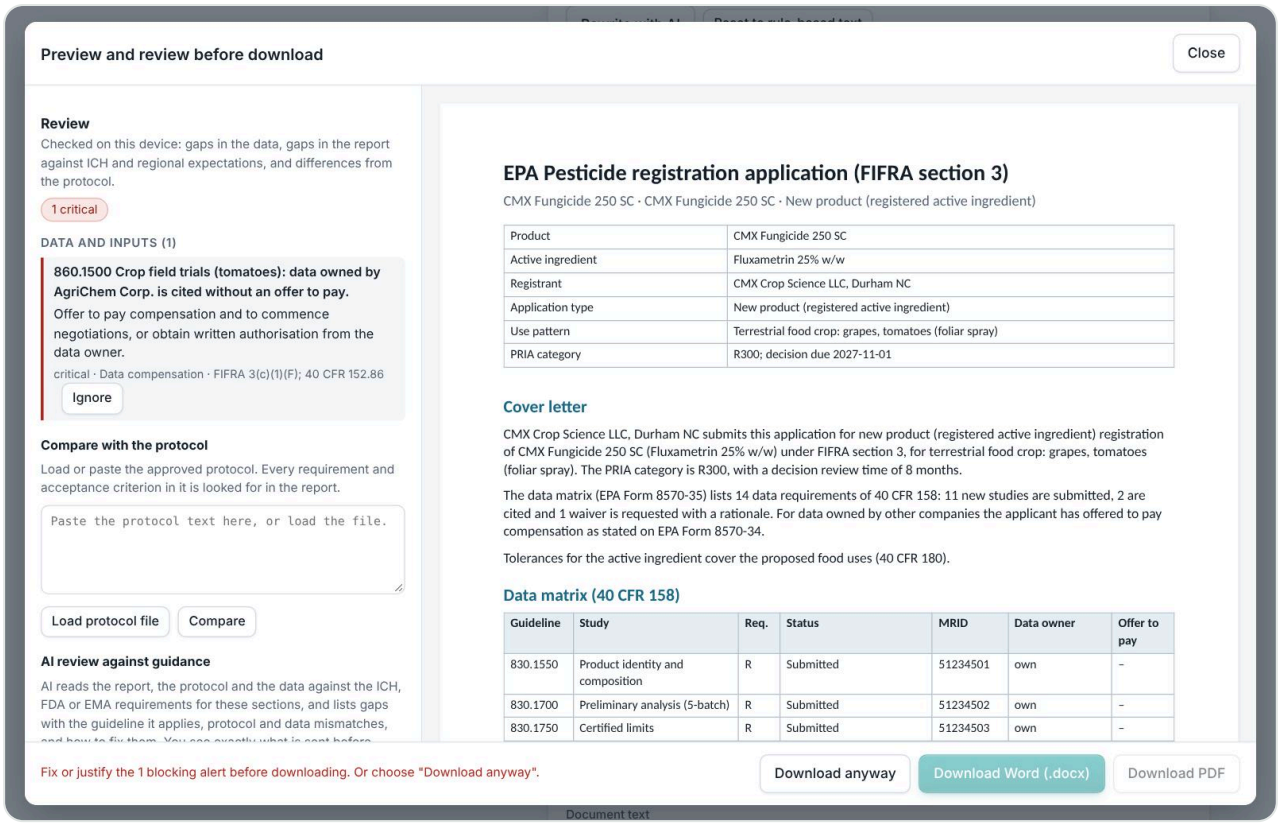
DATA MATRIX

| GUIDELINE | STUDY | REQ. | STATUS | MRID | OWNER | GLP |
|---|---|---|---|---|---|---|
| 830.1550 | Product identity and composition | R | Submitted | 51234501 | own | Yes |
| 830.1700 | Preliminary analysis (5-batch) | R | Submitted | 51234502 | own | Yes |
| 830.1750 | Certified limits | R | Submitted | 51234503 | own | Yes |
| 830.6302 | Colour | R | Submitted | 51234504 | own | Yes |
| 830.6317 | Storage stability | R | Submitted | 51234505 | own | Yes |
| 830.6320 | Corrosion characteristics | R | Submitted | 51234505 | own | Yes |
| 870.1100 | Acute oral toxicity | R | Submitted | 51234506 | own | Yes |
| 870.1200 | Acute dermal toxicity | R | Submitted | 51234507 | own | Yes |
| 870.1300 | Acute inhalation toxicity | R | Waiver requested | – | own | – |
| 870.2400 | Primary eye irritation | R | Submitted | 51234508 | own | Yes |
| 870.2500 | Primary dermal irritation | R | Submitted | 51234509 | own | Yes |
| 870.2600 | Dermal sensitisation | R | Submitted | 51234510 | own | Yes |
| 860.1500 | Crop field trials (grapes) | R | Cited | 49871203 | AgriChem Corp. | – |
| 860.1500 | Crop field trials (tomatoes) | R | Cited | 49871204 | AgriChem Corp. | – |

The data matrix and the forms.

## 4 Resolve alerts and download

Missing required studies, cited data without an offer to pay, a missing EPA Form 8570-1 and a missing tolerance for food use are critical. Then preview and download.




# 4. Field reference

Every input in the tool, panel by panel. Tables accept rows pasted straight from Excel, comma-separated text, or a loaded file; check the columns after loading a file. Fields marked “when it applies” appear only for the choices that need them.

## 1 · Product and application

| FIELD | WHAT TO ENTER |
|---|---|
| Product | Type it in. |
| Active ingredient(s) | Type it in. |
| Registrant | Type it in. |
| Application type | Choose one: New active ingredient; New product (registered active ingredient); Identical or substantially similar (me-too); Amendment. |
| Use pattern | Type it in. |
| Food or feed use | Tick the box if it applies. |

| FIELD | WHAT TO ENTER |
|---|---|
| Tolerances established, or petition included | Tick the box if it applies. |
| Formula changes (amendment) when it applies | Tick the box if it applies. |
| Uses the formulator's exemption (registered source of active ingredient) when it applies | Tick the box if it applies. |
| PRIA category | Type it in. |
| Decision review time (months) | Type a number. |
| Planned receipt date at EPA | Type it in. |
| Forms and items ready | List the forms by number, for example 8570-1, 8570-4. Type or paste text. |

### 2 · Data matrix

One row per 40 CFR 158 data requirement for this product and use pattern.

| FIELD | WHAT TO ENTER |
|---|---|
| Data requirements | MRIDs are 8 digits. EPA assigns them to new studies at receipt. A table. Columns: OCSPP guideline \| Study \| Requirement (R/CR) \| Status \| MRID \| Data owner \| Offer to pay (yes/no) \| GLP (yes/no) \| Waiver rationale. Paste rows from Excel, type comma-separated rows, or press `Load file` (Excel, CSV, Word, PDF or a scan). |

## 5. Checks and alerts

Calculations and pass/fail outcomes always come from fixed rules, never from AI. The tool checks:

- Each 40 CFR 158 requirement met, cited or waived with a rationale.
- Offer to pay for data owned by others.
- GLP statements, forms and tolerances.

### How to resolve alerts

- **Critical** alerts block the download and must be fixed in the data. A failing result can instead be linked to an investigation: type the investigation reference and outcome and press `Record`.
- **Major** alerts block the download until you fix them or type a justification and press `Accept justification`.
- **Minor** alerts do not block anything. They are listed in the documents so the reviewer sees them.
- Some alerts have an `Apply fix` button that makes the change for you. `Reopen` undoes a justification.

### Narratives

This module writes: Cover letter. Each narrative is written by fixed rules from your data. You can edit it in the box. `Rewrite with AI` (where your plan includes AI) rewrites it in regulatory style; every number in the text is checked against your data, and a number that does not match is flagged under the box and blocks the download until you correct it. `Reset to rule-based text` brings back the original.

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## 6. Preview, gap review and download

1. Press `Preview` next to a section, or `Preview and download all`. The document opens in a preview window, exactly as the Word file will read.
2. The left side lists the review, run on your device: **gaps in the data** (missing values, open alerts), **gaps in the report** (missing content the guidance expects, placeholders such as [site] or TBD left in the text) and, if you load the approved protocol under `Compare with the protocol`, **differences from the protocol** (requirements, criteria, batches or time points it plans that the report does not show).
3. Click a finding to jump to the place in the preview. Fix it in the tool, then preview again.
4. Optional `AI review`: a second read for contradictions, claims without data and vague wording. The report text is sent to Claude only when you press it, and only where your plan includes AI. Check every AI finding; AI can be wrong.
5. Press `Download Word (.docx)` or `Download PDF`. With several documents open, `All as Word (.zip)` and `All as PDF (.zip)` download the set. The download buttons stay disabled while a blocking alert is open; the preview still works.

### Documents this module produces

| SECTION | DOCUMENT |
|---|---|
| EPA | Pesticide registration application (FIFRA section 3) |

Use `Save project` to keep your work as a file on your computer, and `Open project` to continue later. `Start blank` clears every field; `Load example` brings the example back. Nothing is stored on CMCfy servers.

## 7. US and EU submissions

US only: EPA Office of Pesticide Programs under FIFRA and FFDCA 408.

## 8. Working with other modules

- Report the acute studies in the Pesticide Acute Toxicity Report module.

## 9. Common pitfalls

- Citing another company's data without an offer to pay.
- Requesting a waiver with no scientific rationale.

## 10. Practice exercises

Each exercise starts from the example (press `Load example` to reset). We run these on every update of this guide, so the result you see should match.

1. **Offer to pay for the tomato field trials**

   Change the offer to pay for MRID 49871204 to yes.

   EXPECTED RESULT

   No critical gap remains.

Guide updated 28 October 2026 for the current version of the tool. CMCfy drafts are for review by a qualified person before use in a submission.