

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

FIFRA 3

40 CFR 158

PRODUCT TYPE

EPA and USDA

GUIDANCE IT FOLLOWS

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)

TIME TO LEARN

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.

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.

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.

CMCfy Pesticide Registration Package (40 CFR 158) Projects All modules Training Security

Runs entirely on this device Training guide

PROJECTS Keep this work in a project, with version history and your company logo on every report. Choose projects folder Keep in this browser

- Network requests since load: 0**
Counted live by your browser. Your data never leaves this device.
- Works offline**
Everything the tool needs is inside this page.
- Locked offline copy**
Save a single file that opens from your own computer with all network access blocked.

FIFRA 3 40 CFR 158 Save project Open project Start blank Load example

Plan an EPA pesticide registration under FIFRA section 3. List the 40 CFR 158 data requirements for your product and use pattern; the tool checks that every required study is submitted, cited or waived with a rationale, that cited data owned by others has an offer to pay, lists the forms the application type needs, and dates the PRIA decision.

Guidance: 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)

1 · PRODUCT AND APPLICATION

Product
CMX Fungicide 250 SC

Active ingredient(s) Registrant
Fluxametrin 25% w/w CMX Crop Science LLC, Dui

Application type
New product (registered)

Use pattern
Terrestrial food crop: grapes, tomatoes (foliar spray)

RESULT

1 critical gap before submission to EPA

New product (registered active ingredient) for CMX Fungicide 250 SC. 11 studies submitted, 2 cited, 1 waiver request. PRIA decision due 2027-11-01 (R300).

REQUIREMENTS	MISSING	CITED WITHOUT OFFER TO PAY
14	0	1

PRIA DUE
2027-11-01

DATA MATRIX

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.

Preview and review before download

Close

Review

Checked on this device: gaps in the data, gaps in the report against ICH and regional expectations, and differences from the protocol.

1 critical

DATA AND INPUTS (1)

860.1500 Crop field trials (tomatoes): data owned by AgriChem Corp. is cited without an offer to pay.
Offer to pay compensation and to commence negotiations, or obtain written authorisation from the data owner.

critical · Data compensation · FIFRA 3(c)(1)(F); 40 CFR 152.86

Ignore

Compare with the protocol

Load or paste the approved protocol. Every requirement and acceptance criterion in it is looked for in the report.

Paste the protocol text here, or load the file.

Load protocol file Compare

AI review against guidance

AI reads the report, the protocol and the data against the ICH, FDA or EMA requirements for these sections, and lists gaps with the guideline it applies, protocol and data mismatches, and how to fix them. You see exactly what is sent before.

EPA Pesticide registration application (FIFRA section 3)

CMX Fungicide 250 SC · CMX Fungicide 250 SC · New product (registered active ingredient)

Product	CMX Fungicide 250 SC
Active ingredient	Fluxametrin 25% w/w
Registrant	CMX Crop Science LLC, Durham NC
Application type	New product (registered active ingredient)
Use pattern	Terrestrial food crop: grapes, tomatoes (foliar spray)
PRIA category	R300; decision due 2027-11-01

Cover letter

CMX Crop Science LLC, Durham NC submits this application for new product (registered active ingredient) registration of CMX Fungicide 250 SC (Fluxametrin 25% w/w) under FIFRA section 3, for terrestrial food crop: grapes, tomatoes (foliar spray). The PRIA category is R300, with a decision review time of 8 months.

The data matrix (EPA Form 8570-35) lists 14 data requirements of 40 CFR 158: 11 new studies are submitted, 2 are cited and 1 waiver is requested with a rationale. For data owned by other companies the applicant has offered to pay compensation as stated on EPA Form 8570-34.

Tolerances for the active ingredient cover the proposed food uses (40 CFR 180).

Data matrix (40 CFR 158)

Guideline	Study	Req.	Status	MRID	Data owner	Offer to pay
830.1550	Product identity and composition	R	Submitted	51234501	own	-
830.1700	Preliminary analysis (5-batch)	R	Submitted	51234502	own	-
830.1750	Certified limits	R	Submitted	51234503	own	-

Fix or justify the 1 blocking alert before downloading. Or choose "Download anyway".

Download anyway Download Word (.docx) Download PDF

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.

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.
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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.