Antimicrobials Division:
Best Practices

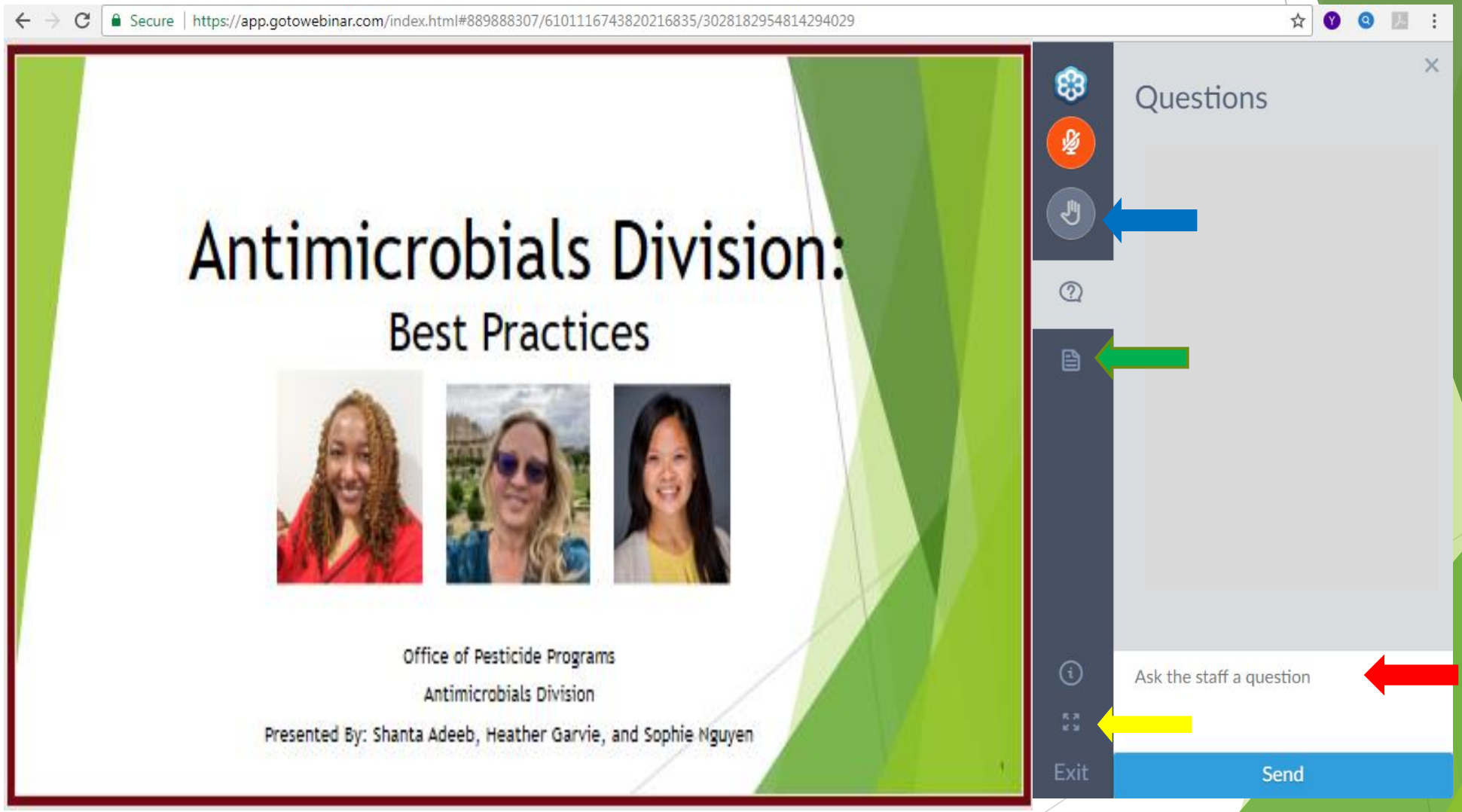


Office of Pesticide Programs

Antimicrobials Division

Presented By: Shanta Adeeb, Heather Garvie, and Sophie Nguyen

Tips for Participants



Agenda

ANTIMICROBIALS DIVISION ORGANIZATIONAL CHART

IMMEDIATE OFFICE (IO)

Anita Pease, Director
Kristen Willis, Deputy Director
Elizabeth Donovan, Acting Associate Director
Aline Heffernan, Senior Regulatory Advisor
Vacant, Regulatory Advisor

REGULATORY MANAGEMENT BRANCH I (RMB1)

Margaret Hathaway, Supervisor
Jake McFarley, Sr Reg. Advisor

Luisa Samalot, PM 31
Casscius Colbert
Carlos Corona
Karen Leavy-Munk
Emilia Oiguenblik/SEE
+1 Vacancy

Demson Fuller, PM 32
Jack Hall
Michael Varco
+2 Vacancy

REGULATORY MANAGEMENT BRANCH II (RMB2)

Jacqueline Hardy, Supervisor
Heather Garvie, Sr Reg. Advisor

Steve Snyderman, PM 33
Linda Amar
Aidan Fife
Zebora Johnson
Srini Gowda/SEE
+1 Vacancy

Marcel Howard, PM 34
Stacey Grigsby
Terria Northern
Lorena Rivas
+1 Vacancy

REEVALUATION BRANCH (RB)

Eric Miederhoff, Supervisor
Jose Gayoso, Sr Reg. Advisor

Kimberly Wilson, Senior EPS
Kendall Ziner, Acting TL 37

Jessica Bailey
Peter Bergquist
Erin Dandridge
Areej Jangahir
Stephen Savage
Megan Snyderman
+5 Vacancies

REGULATORY MANAGEMENT AND SCIENCE BRANCH (RMSB)

Erik Kraft, Supervisor
Shanta Adeeb, Sr Reg. Science Advisor

Vacant -TL (PC)
Jenny Tao, (AT) Senior Scientist
Ian Blackwell
Emily Li
Lindsay O'Dell
Wallace Powell
Joseph Williams
Nicole Person

Narayanan Parthasarathy/SEE
Aurash Shahripour/SEE
Lynette T. Umez-Eronini/SEE
Boris Yurchak/SEE
Mohammad Alavi /SEE
Cheryl Hooper/SEE

EFFICACY BRANCH (EB)

Thao (Tina) Pham, Supervisor
Vacant, TL
Son (Sophie) Nguyen, TL
***Tajah Blackburn,* PHS Sr Scientist**

Samantha Collins
Cesar Cordero
Nicole Karikari
Tracy Keigwin
Ibrahim Laniyan
Tahirah Morris
Atinuke (Tinu) Onyonyor
Marc Rindal
Caleb Ruiz-Jimenez
James Tauber
+1 Vacancy

RISK ASSESSMENT BRANCH I (RAB1)

Melissa Panger, Supervisor
Timothy Dole, Sr Scientist
***Jeanette Martinez*, Sr Scientist**
Andrew Byro, *RAPL*

Blossom Catacutan
Christina Ogunsuyi
Emily Saunders
Jacqueline Meadows
Shawn Garred
+4 Vacancies

RISK ASSESSMENT BRANCH II (RAB2)

Vacant, Supervisor
***Colleen Rossmeisl,* Sr Science Advisor**
Chuck Peck, Sr Scientist
Judy Facey, PHS RAPL

Jim Breithaupt
Deborah Burgin
Sophia Hu
Alex Kliminsky
Danielle McShan
Ana Terman
Dana Sackett
+3 Vacancies

What to do Before Submitting an Application to the Agency

- The site How to Register a Pesticide has a lot of agency guidance.
- Understand PRIA vs Non-coded PRIA action types:
  - PRIA 5 Codes and descriptions
  - Non- coded PRIA CSFs or non-coded PRIA Label Amendments
  - Non-coded PRIA Notifications
- Companies who have not previously registered pesticide products with the Agency may find it helpful to obtain the services of a regulatory consultant.
- If you have questions about what is required for a submission, don't hesitate to contract the Product Manager responsible for managing the active ingredient(s) in the product.

Non-Coded PRIA Notifications

- To prevent your non-coded PRIA Notification from being found unacceptable and help facilitate a more expedited review, please make sure your Notification application includes the following:
  - The Certification Statement in PRN 98-10.
    - This is required for ALL notifications including Confidential Statement of Formula (CSF) notifications, label notifications and additions of alternate brand names.
    - The easiest place to include it is on the application form 8570-1 or in a cover letter rather than a separate document. The certification statement reads:
    - "This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."
  - A label with all the changes highlighted as applicable.
  - A cover letter that explains the changes and where they are located on the CSF or label. While a cover letter is optional, it is recommended as there is limited space on the application form 8570-1.
  - While not required, please provide a list of the currently approved CSFs and their respective dates. If not provided, the reviewer may reach out to confirm the current CSFs on file.

Non-Coded PRIA Amendments

Non-coded PRIA Label Amendments

- Please submit a highlighted/annotated label for ease of review.
- On the application form 8570-1, clearly indicate what is changing. A cover letter is also helpful but not required.
- Be prepared for a complete label review.

Non-coded PRIA CSF Amendments

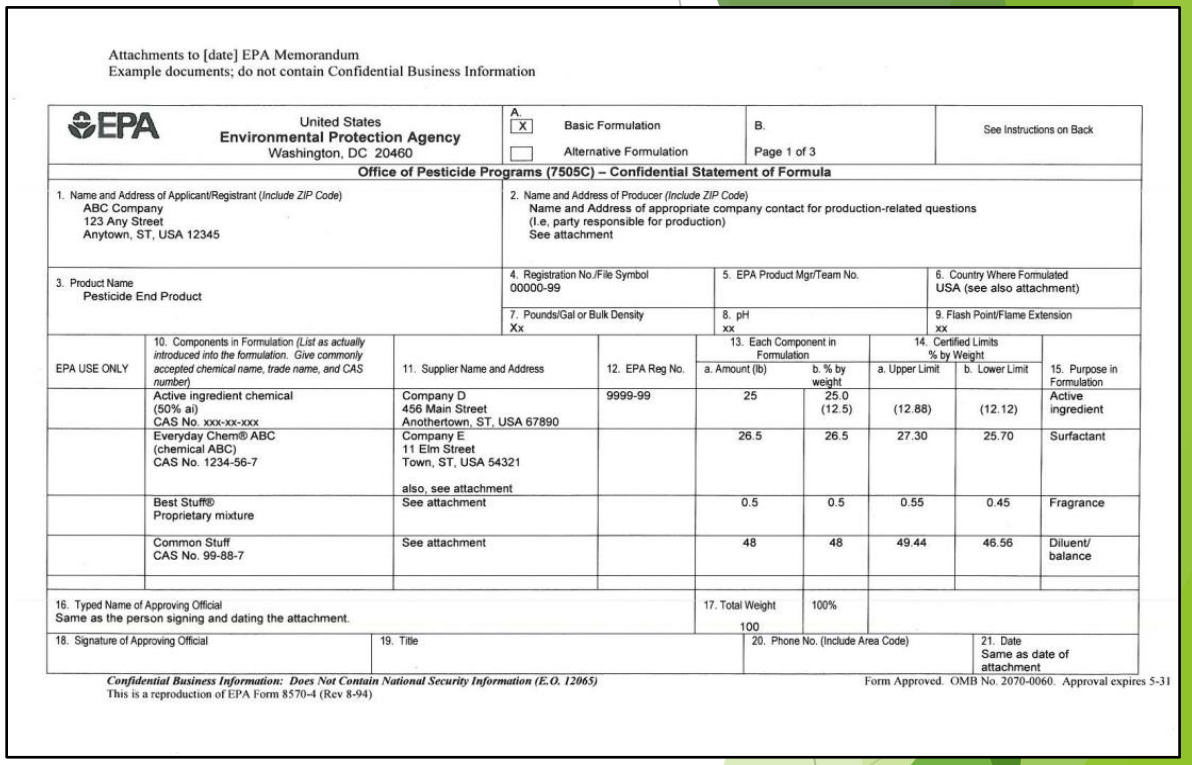
- Please include the previous EPA acceptance letter listing the approved CSFs; or submit a list of the current CSFs on file with their respective dates. While this is not required, it is helpful information for the reviewers.
- In the cover letter, clearly indicate what is changing if there is not enough space on the 8570-1 application form.
- Be prepared for a complete review of new or revised CSFs.

What to do Before Submitting an Application
PRIA Data Preparation

- All guidelines must be addressed for products regardless if it is a Technical Grade Active Ingredient, a Manufacture Use, or an End Use Product.
- If a registrant believes a guideline does not apply to their product, they must submit a wavier request, with justification stating why the guideline is not applicable.
- Human Health and Ecological Risk Requirements can be found in the
- 40 CFR Part 158 Subpart W.
- Efficacy data requirements can be found in the 40 CFR § 158.2220.
- Product Chemistry data can be found in the 40 CFR § 158.2210:
  - Group A
  - Group B
- Acute Toxicity data aka the “six pack can be found in the
- 40 CFR § 158.2230.
- Ensure the title of the study/waiver adequately addresses what is in the study.
  - An example of an inappropriate study name: Fish study
  - An example of an appropriate study name: Guideline No. 850.1075; Acute freshwater fish toxicity study.

Preparation of the Confidential Statement of Formula (CSF)

- The 8750-4 form and the Confidential Appendix communicate the details of the pesticide formula to the Agency.
- All the data for a product is based on the Basic CSF formula; therefore, it is important that the Basic CSF and any Alternate CSF are formatted in a manner that is easy for the Agency to quickly review.
- Inerts not previously approved for pesticide use should be submitted to the Chemistry, Inerts and Toxicology Assessment Branch (CITAB), located in the Registration Division for approval by the Agency.
- Standard Certified Limits are determined for each ingredient based the percentage used in a products the formula. This is described in the 40 CFR §158.350.
- Additionally, many AD products have characteristics by which a registrant may want to propose non-standard certified limits.



Attachments to [date] EPA Memorandum
Example documents; do not contain Confidential Business Information

EPA — United States Environmental Protection Agency, Washington, DC 20460

A. [X] Basic Formulation [ ] Alternative Formulation — B. Page 1 of 3 — See Instructions on Back

Office of Pesticide Programs (7505C) – Confidential Statement of Formula

1. Name and Address of Applicant/Registrant (*Include ZIP Code*)
ABC Company
123 Any Street
Anytown, ST, USA 12345

2. Name and Address of Producer (*Include ZIP Code*)
Name and Address of appropriate company contact for production-related questions (I.e, party responsible for production)
See attachment

3. Product Name
Pesticide End Product

4. Registration No./File Symbol
00000-99

5. EPA Product Mgr/Team No.

6. Country Where Formulated
USA (see also attachment)

7. Pounds/Gal or Bulk Density
Xx

8. pH
xx

9. Flash Point/Flame Extension
xx

EPA USE ONLY	10. Components in Formulation (*List as actually introduced into the formulation. Give commonly accepted chemical name, trade name, and CAS number*)	11. Supplier Name and Address	12. EPA Reg No.	13. Each Component in Formulation a. Amount (lb)	13. b. % by weight	14. Certified Limits % by Weight a. Upper Limit	14. b. Lower Limit	15. Purpose in Formulation
	Active ingredient chemical (50% ai) CAS No. xxx-xx-xxx	Company D 456 Main Street Anothertown, ST, USA 67890	9999-99	25	25.0 (12.5)	(12.88)	(12.12)	Active ingredient
	Everyday Chem® ABC (chemical ABC) CAS No. 1234-56-7	Company E 11 Elm Street Town, ST, USA 54321 also, see attachment		26.5	26.5	27.30	25.70	Surfactant
	Best Stuff® Proprietary mixture	See attachment		0.5	0.5	0.55	0.45	Fragrance
	Common Stuff CAS No. 99-88-7	See attachment		48	48	49.44	46.56	Diluent/ balance

16. Typed Name of Approving Official
Same as the person signing and dating the attachment.

17. Total Weight 100 — 100%

18. Signature of Approving Official — 19. Title — 20. Phone No. (Include Area Code) — 21. Date Same as date of attachment

Confidential Business Information: Does Not Contain National Security Information (E.O. 12065)
This is a reproduction of EPA Form 8570-4 (Rev 8-94)
Form Approved. OMB No. 2070-0060. Approval expires 5-31

Standard Certified Limits

If the nominal concentration (N) for the ingredient and percentage by weight for the ingredient is:	The certified limits for that ingredient will be as follows:	
	Upper Limit	Lower Limit
N ≤1.0%	N + 10%N	N - 10%N
1.0% ≤N ≤20.0%	N + 5%N	N - 5%N
20.0% ≤N ≤100.0%	N + 3%N	N - 3%N

Preparation of the CSF Continued

- There are various websites and guidance documents that can help registrants prepare their CSFs.
- CSF Appendix Memos:
  - Technical Grade Active Ingredient Memo (2012)
  - End Use Products and Manufacturing Use Product Memo (2012)
- Inert Finder
- Commodity Inerts

Commodity Inert Examples

Ethanol

Show 25 entries Search: ethanol

Commodity Inert Ingredient Name	CAS Reg. No.
2-(2-Methoxyethoxy)ethanol	111-77-3
2-Butoxyethanol	111-76-2
Diethanolamine	111-42-2
Ethanol, 2-(hexyloxy)-	112-25-4
Ethanol, SDA 40-B	64-17-5
Ethanolamine	141-43-5
Triethanolamine	102-71-6

EDTA

Show 25 entries Search: edta

Commodity Inert Ingredient Name	CAS Reg. No.
Ethylenediameinetetraacetic acid (EDTA), sodium iron (III) salt	15708-41-5
Ethylenediaminetetraacetic acid (EDTA)	60-00-4
Ethylenediaminetetraacetic acid (EDTA) tetrasodium salt	64-02-8
Ethylenediaminetetraacetic acid (EDTA), calcium disodium salt	62-33-9
Ethylenediaminetetraacetic acid (EDTA), disodium manganese (II) salt	15375-84-5
Ethylenediaminetetraacetic acid (EDTA), disodium salt, dihydrate	6381-92-6

Fragrance Guidance

- The Fragrance Notification Pilot can only be used for CSFs with fragrances that have a concentration of 1% or less of the total pesticide formula.
- Fragrances on CSFs greater than 1% do not qualify for the Fragrances Notification Pilot Program.
- Requests for inclusion of individual fragrance ingredients that are not currently approved by the Agency must be submitted directly to CITAB in the Registration Division.
- It is the registrant's responsibility to work with fragrance manufactures and verify all fragrances on currently approved CSFs have been submitted to the Agency.
- To allow registrants adequate time to get all the fragrances into the system, registrants will be given until ***December 31, 2024,*** to submit fragrance information to CITAB if they haven't already done so on previously approved CSF actions.
- Starting ***January 1, 2025,*** for companies that want to use the Fragrance Notification Pilot Guidance to apply to their new CSF submissions, these actions must be submitted with the appropriate self-certification statements as shown on the next slide.

Fragrance Certifications

Version I: For use when the fragrance supplier knows the fragrance identities and the registrant does not

(Basic Product Name)
EPA Reg. No.

Statement of Fragrance Supplier

On behalf of [name of fragrance supplier], I certify that all of the ingredients found in fragrance formula _____to be used in EPA Reg. No._____ are listed in the Fragrance Ingredient List (FIL) at http://www.epa.gov/opprd001/inerts/fmaingredient.pdf and meet the other requirements of the Pilot Fragrance Notification Program. I understand that it is a violation of 18 U.S.C. §1001 to willfully make any false statement in this letter. I agree

1) to maintain records documenting the identities of the fragrances in this formula for a period of 5 years after I cease selling this formula to [name of registrant] and to provide this documentation to the U.S. Environmental Protection Agency (EPA) upon request,
2) to notify EPA and [name of registrant] if fragrance formula changes in a manner that makes the formula ineligible for the Pilot Fragrance Notification Program and
3) to certify that the composition of new fragrances will be submitted to the Agency.

I understand that the registrant will contact the fragrance suppliers to ensure that the submissions are made to the Agency.

_____ _____

Signature, Fragrance Supplier
(Name, Fragrance Supplier, Address, Phone)

Date

Statement of Registrant

As the registrant of EPA Reg. No._____, I am aware that it is my responsibility to ensure that

1) this product meets the terms of the OPP Pilot Fragrance Notification Program and
2) EPA has access to complete and accurate formulation information for the pesticide.

I acknowledge that if this product does not meet the terms of the OPP Pilot Fragrance Notification Program, including the requirement that all fragrance ingredients are on the FIL, then the sale or distribution of this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under Sections 12 and 14 of FIFRA.

_____ _____

Signature, Registrant Company
(Registrant Name)
(Registrant
Address)
(Registrant city, state, zip code)

Date

Version II: for use when the registrant knows the fragrance identities

(Basic Product Name)
EPA Reg. No.

On behalf of [name of registrant], I certify that all of the fragrances in EPA Reg. No._____(or the new registration application) are listed in the Fragrance Ingredient List (FIL) at http://www.epa.gov/opprd001/inerts/fmaingredient.pdf and meet the other requirements of the OPP Pilot Fragrance Notification Program. I understand that it is a violation of 18 U.S.C. §1001 to willfully make any false statement in this certification. I further understand that if this product is not consistent with the terms of the OPP Pilot Fragrance Notification Program, 40 CFR 152.46, including the requirement that all fragrance ingredients are on the FIL, then the sale or distribution of this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under Sections 12 and 14 of FIFRA.

_____ _____

Signature, Registrant Company
(Registrant Name)
(Registrant
Address)
(Registrant city, state, zip code)

Date

Wipes and Towelettes Guidance for Acute Toxicity

- The acute toxicity six-pack testing requirements are defined in EPA's data requirement regulations (40 CFR part 158) and are further described in the Environmental Protection Agency Series 870 guidelines.
- The liquid applied to the towelette portion during manufacturing is defined as the "bulk liquid" formulation that is used to wet or impregnate the towelette.
- The Agency is recommending that the bulk liquid of wipe and towelette products be used to conduct the acute six-pack studies.
- Registrants may also cite or bridge to a substantially similar EPA registered product, or choose to submit a waiver request or weight-of-evidence rationale to address the acute toxicity for these products.

Data Preparation - Efficacy

- Test lots should be formulated at the lower certified limit (LCL) of each active ingredient in the formulation for base claims.
  - Nominal vs. LCL
  - The 810.2000 guideline provides an overview of claims for which data should be submitted at LCL vs nominal.
- A Certificates of Analysis (CoA) should be provided for each test lot, including:
  - The active ingredient(s),
  - Concentration of each active ingredient in each batch used in testing (analysis results),
  - The identity/name of the test substance (which should match the product's name),
  - Testing laboratory,
  - Manufacturing date,
  - Analysis date (which should reflect a date before efficacy testing), and
  - Laboratory signature.

Data Preparation – Efficacy Cont'd

- If dilutions are required for the product, include the following in both the Directions for Use and in test reports:
  - The dilution schemes,
  - The final use concentrations, and
  - The parts per million (ppm) conversion (if applicable).
- For product families that are diluted to the same end use-dilution, make sure the testing is done on the appropriate product/dilution. Make sure to include:
  - A detailed cover letter
  - Any differences between the formulations
  - Testing data on the appropriate formulation

EPA Registration Number	AI concentration at LCL (from CSF)	Label Dilution (and theoretical PPM at LCL)	AI concentration from CoA	Tested Dilution (and PPM)

Data Compensation

- All products must meet data requirements for registration. Each data requirement can be satisfied in one of four ways:
  1. A waiver
  2. A new study
  3. Citation of an existing study
  4. Citation of public literature (with MRID)
- When citing an existing study, you may be responsible for data compensation. Data compensation falls into two categories:
  1. Cite all – where all the data holders, who are eligible for data compensation, are sent an offer to pay.
  2. Selective Citation – where specific data holders are sent an offer to pay, or the study is not subject to compensation.
  - Data compensation rights apply to all data submitted to EPA to support or maintain a pesticide registration, including a tolerance or tolerance exemption, and extend for the 15-year period following submission of the data.

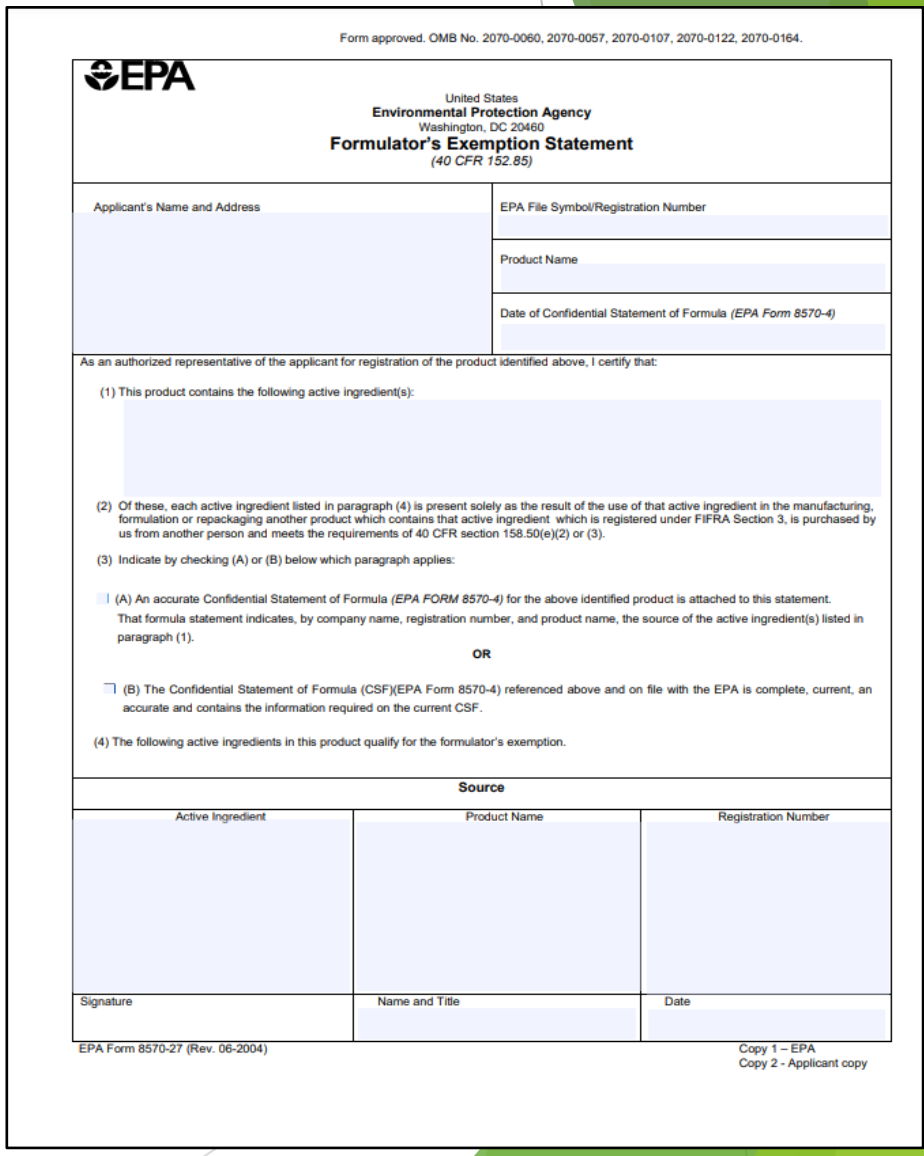
  Relevant links:
  - Link to the Pesticide Data Submitters List: https://www.epa.gov/pesticide-registration/pesticide-data-submitters-list-pdsl
  - Link to The Certification with Respect to Citation of Data form: https://www.epa.gov/sites/default/files/2013-08/documents/8570-34.pdf
  - Link to the data matrix form: https://www.epa.gov/sites/default/files/2013-08/documents/8570-35.pdf

Using a Formulators Exemption Statement (FES)

- A product's generic data requirements may be covered by the FES form (8570-22) if the source of active ingredient is registered by another company and has the same uses as the proposed product.
- An FES cannot be used when the registrant is using their own source of active ingredient.
- The proposed product may have a subset of the uses approved on the source of active ingredient product, but not more.
  - Link to FES form: https://www.epa.gov/sites/default/files/2013-08/documents/8570-27.pdf
- The crucial condition for applying an FES is that the applicant must purchase the registered product to formulate its proposed product. If that is the case, the data supporting the purchased product can be used to support the new product.

Formulators Exemption Cont'd

- If there are additional proposed uses on the end use product that go beyond the uses approved on the purchased active ingredient source product, the end use registrant would need to provide the data associated with those additional uses since those uses would not be covered under FES. In other words, the generic data requirements must be addressed in a different way if the FES form can't be used.
  - This includes citing data or requesting a waiver with rationale. The Agency encourages registrants to submit waiver rationales under PRIA prior to submission of the package to ensure the rationales are acceptable.



Form approved. OMB No. 2070-0060, 2070-0057, 2070-0107, 2070-0122, 2070-0164.

EPA

United States
Environmental Protection Agency
Washington, DC 20460

Formulator's Exemption Statement
(40 CFR 152.85)

Applicant's Name and Address	EPA File Symbol/Registration Number
	Product Name
	Date of Confidential Statement of Formula *(EPA Form 8570-4)*

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☐ (A) An accurate Confidential Statement of Formula *(EPA FORM 8570-4)* for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source

Active Ingredient	Product Name	Registration Number

Signature	Name and Title	Date

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 – EPA
Copy 2 - Applicant copy

Data Compensation for 100% Repack Products

- An identical Repack Registration is a complete (100%) repackaging of an already-registered product, where an identical label is used for the product other than name, address, name of the product, and registration number.
  - All data requirements are covered by the FES.
  - The uses listed on the repack product (the product that is repacking another product) must be the same or be a subset of the uses approved on the product being repacked.
  - Please do not submit a "repack" of another product that is pending registration. Packages must be complete with the submission.

Example

A company wants to register a new end use product. The proposed end use product will be a "repack" of another end use product belonging to another company.

The uses listed on the registered product that is being repacked are: "*Industrial Water Systems, Oil Drilling Muds, Workover and Completion fluids, and Coatings and Pigments for Paper and Paint.*"

The uses listed on the **repacked** product are: "*Coatings and Pigments for Paper and Paint.*"

The repacked product may list **fewer use sites** than that of the product they are repacking, but not more. In most circumstances, it would not be acceptable to list a use site such as *cooling towers*, as this use site is not on the product that the company is repacking from and the FES is being used for data compensation. If the repacked product wanted to add *cooling towers* or any other use site NOT on the product that is being repacked, the company would have to address all of the generic data associated with that additional use site.

Data Compensation for Unregistered Sources of Active Ingredients

- Companies can address generic data when using an unregistered source of active ingredient by using a:
  - Cite-All Data Matrix for generic data. A data matrix that states “Cite-All” must list all companies that have submitted data (from the Pesticide Data Submitters List). Additionally, a Certification with Respect of Citation of Data Form is required.

    or
  - Selective Data Matrix for generic data. A selective data matrix may be used to address all data requirements per the 40 CFR 158 Part W.

Document Check

- Forms that may be required for a PRIA action include:
  - Data Matrices
  - Certification with Respect to Citation of Data
  - Confidential Statement of Formula (CSF)
  - Formulator's Exemption Statement form
  - Label
  - 8570-1 form
  - Cover Letters (recommended, not required)
- Studies should be formatted according to PRN 2011-3.
- If the submission is a "me-too", the registrant should specify the substantially similar product and include a discussion of the substantially similar product on the application form (or cover letter).
- Do not submit documents and information **not** associated with the submission
- Packages must be complete upon submission. For example, do not submit an application to register a new end use product that is using a source of active or MUP that is not registered or pending registration (with the exception of "primary/secondary" submissions for same company).

Cover Letters

The more relevant information provided the better. The cover letter should provide all information about the action including:

- The proposed PRIA code.
- The purpose of the action.
- Data cited/submitted to support the registration.
  - Chemical characterization data (non-guideline) should be clearly explained in the cover letter (when provided) as it will go to the efficacy team rather than the chemistry team.
- Me-too reference product(s) if applicable.
- For currently registered products being amended:
  - Note if application rates have changed or are different than other registered products (this may trigger a risk assessment).
  - Note if use patterns have changed or are different than other registered products (this may trigger a risk assessment as well).
- Best email address to contact the company with any questions regarding the submission.
- Enumerated changes to the label and/or CSF.
- Updates to any data compensation.
- If a product is referenced for similarity or if the product is related to another product in some way, please note this as well.

Example of a Low-Quality Cover Letter

Dear PM 33,

We are submitting this action to add various organisms to the label. Please contact Joe Smith with any questions.

Thank you,

Joe Smith

Example of a High-Quality Cover Letter

Dear PM 33,

We are submitting 4 efficacy studies to support SARS-CoV-2 (MRID 123458901), Norovirus (MRID 123458902), Hepatitis A (MRID 123458903) and Avian Influenza (MRID 123458904) claims.

The organisms have been added to the table on page 6 of the label and new marketing claims on page 7-9 have been added. In addition, the address for the company has been updated on the label and the storage and disposal has been updated to include reusable containers. The directions for use have not been updated as the contact time for the new organisms is the same as the existing directions for use.

This product has 4 open non-coded PRIA actions, and the changes requested by the four actions (submitted 3/2019, 4/2020, 10/2020 and 8/2021) have been incorporated in the label. Once this PRIA is complete these four actions can be withdrawn. The changes are on pages 3, 7, 9, and 12 respectively.

There have been no changes to our data compensation.

Please reach me at joe.smith@abchemicals.org.

Joe Smith

"Me –Too" Products

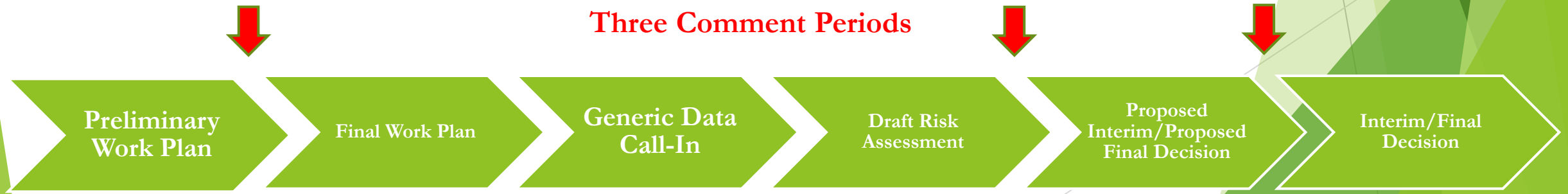
- “Me-Too” products (A530, A531 and A532) must cite a currently registered, substantially similar product.
- If currently approved use sites (and/or rates) are being added to a registered product, please ensure there is a cited product with the same use sites and application rates noted in Box 6 on the 8570-1 application form. It is also helpful to note this information in the cover letter.
  - If use sites or application rates are being cited from multiple labels, please provide as much detail as possible in the cover letter.
- If you would like regulatory certainty that the products are similar prior to formal submission, please submit under PRIA code M010. M010 is for Product Chemistry and Acute Toxicology similarity only.

During the Submission Process

- All documents submitted to the Agency should be submitted through CDX at the time of submission. This includes new studies or waivers that are submitted after the initial PRIA submission. All studies, waivers, or open literature citations need a MRID number.
- Here is a website where you can find more information about the electronic submission process: https://www.epa.gov/pesticide-registration/electronic-submissions-pesticide-applications.
- For further help with electronic submissions through CDX, we recommend the contacts on this website: https://www.epa.gov/pesticide-registration/electronic-submission-contact-information.
- Only complete studies (generic and product specific) should be submitted.
  - Do not submit data study summaries. They cannot be used for risk assessment and will slow down the process when the Agency identifies them during the review and then has to reach out for the full studies.
- If new information is requested by the Agency, please submit via CDX with a cover letter that clearly states it is a resubmission (unless instructed otherwise by the regulatory team).

Registration Review

- Utilize Registration Review Comment Periods
- Preliminary Work Plan (PWP)
  - Submit comments on the Agency's planned risk assessment and data needs
- Draft Risk Assessment (DRA)
  - Submit comments on science or risk assessment issues; New data
  - This webpage includes the type of benefits information most helpful to EPA: https://www.epa.gov/pesticide-reevaluation/
  - Submit Benefits information: https://www.epa.gov/pesticide-reevaluation/how-submit-benefits-information-antimicrobial-pesticides
- Proposed Interim/Proposed Final Decision (PID/PFD)
  - Submit comments on the Agency's proposed interim/final risk mitigation measures



Registration Review Cont'd

- Data Submissions
  - Respond to Data Call-Ins (DCIs) on time
- Label Submissions with Risk Mitigation Amendments
  - Send clean and red-line versions
  - Use "Registration" links to send the package as a non-coded PRIA amendment
    - Address the cover letter/application form to the AD Reevaluation Branch and note that the submission is for Registration Review
  - DO NOT use the "Reevaluation" links in CDX for Registration Review label amendments
    - The Reevaluation Branch is now using Salesforce for workload management, and the "Reevaluation" side of the portal does not currently link to Salesforce

Registration Review Cont'd

- Registration Review Schedule
  - https://www.epa.gov/pesticide-reevaluation/upcoming-registration-review-actions
  - Updated quarterly
- Registration Review Deadline
  - For pesticides that were registered prior to 2007, and for which registration review was not completed by Oct. 1, 2022, the current deadline to complete registration review is Oct. 1, 2026.

A Quality Label Submission

- Before submitting an application for registration of a new product, new use, or new rate, please make sure the label conforms with any applicable reregistration or registration review decisions, including the Reregistration Eligibility Decision (RED), or the latest Registration Review Interim or Final Decision. Please check out the Label Review Manual and the Pesticide Registration Manual prior to submitting an application.

- Labels must clearly identify the use sites, application rates, and whether the proposed product is a manufacturing use product (MUP) or end use product (EP). Labels should also indicate the physical state of the product (i.e. liquid, gas, solid powder, solid pellet, etc.)
  - MUPs do not have application rates

A Quality Label Submission Cont'd

- Please separate and identify public health claims from non-public health claims to help simplify the label review.
- The label should be submitted in a pdf readable format
  - The harder the label is to read, the longer it takes the Agency to review the document.
  - The label should have (preferably) black text and a standard font size.
    - By regulation, the minimum acceptable font size is 6pt for required label text on the final printed label (FPL)/market label.
  - The label should be readable for "Text to Speak" so that it is accessible to people with disabilities.

Common Label Issues

1. Products with the signal word “Danger” should have a note to reviewer on the master label regarding First Aid language placement.

   - **“Note to Reviewer**: In accordance with 40 CFR 156.68(d), all First Aid statements, as prescribed, will appear on the front panel of the product label.”
   - If a variance has been accepted by the Agency, a note to reviewer is also recommended describing the acceptance of a variance and where the First Aid is located.

2. Unclear labeling directions – i.e. A claim should read “the surface must remain visibly wet for X minutes…” **not** “the surface should remain thoroughly wet…”.

3. Inconsistent use of qualifiers. Qualifiers are not always used consistently throughout the label. Making sure they are consistent will help us with our reviews. Examples of qualifier issues include:

   - Some but not all virus claims are qualified to the list of organisms.
   - The same qualifier leads to two different descriptions

Common Efficacy Label Concerns

Efficacy claims must be supported by data.

- The use directions on the label must be specific and supported by organism specific efficacy data.
- Application instructions (e.g., liquid and spray), dilution, if applicable, surface type (i.e., visibly clean hard, nonporous surfaces), contact time (i.e., treated surfaces should remain visibly wet for 5 minutes) must all be clearly present in the use directions and reflect the submitted data.
- Testing as a towelette does not support liquid application.
  - For wipe products bridging from liquid products, more data are needed to support bridging of claims from liquid products. See 810.2200, section (K), for additional guidance.
- Label marketing claims cannot be misleading or imply enhanced efficacy. Consult Chapter 12 of the Label Review Manual for general guidance and examples.

Bracketed Claims

- Bracketed claims are difficult to review properly. Please use them as sparingly as possible.
  - It is useful when words can be made plural or abbreviated
    - Min[utes]
    - C. Diff
- Avoid brackets in the Directions for Use
- The example below and similar iterations should be avoided:
  - “[This product][product name][kills][fights][eliminates 99.9%][disinfects][bacteria][viruses*][pathogens][on hard, non-porous surfaces][in your house][in your kitchen][in your bathroom]”
- Examples of words that should not be bracketed on a label as they may lead to too many false and misleading claims:
  - Visible soil/visibly wet
  - Hard Non-Porous Surface
  - Eliminates 99.9%
  - Household
  - Common(ly)

Examples of Common Misleading Claims

Common False and Misleading Claims	Common Changes to Claims that make them Acceptable
Prevents Cross Contamination	• Reduces cross contamination between treated non-porous surfaces
Kills COVID-19	• Kills SARS-CoV-2 the cause of COVID 19 on hard, non-porous surfaces • Kills the COVID 19 virus* on hard, non-porous surfaces; *SARS-CoV-2
Kills viruses	• Kills viruses*; *Human Coronavirus 229E, Rhinovirus type 37
Prevents Infection	• Kills bacteria
Eliminates Germs	• Eliminates 99.9% of germs
Hospital Strength	• Hospital disinfectant
Makes surfaces hygienic	• Kills germs on surfaces
Prevents Hospital Acquired Infections	• For use in Hospitals
[kills][bacteria][*][hard][non-porous]surfaces[on]…	• The overuse of brackets is confusing. Please revise to make it easy to read: Kills bacteria on hard non-porous surfaces
Kills bacteria that could cause skin infections	• Kills *Staph aureus* on hard non-porous surfaces

Examples of Common Misleading Claims - Continued

Common False and Misleading Claims	Common Changes to Claims that make them Acceptable
Kills household bacteria	• Kills bacteria on hard nonporous surfaces in residential settings • Kills *household bacteria, *leads to list of relevant tested bacteria
Claims for air treatment^ – if no data is on file	• Limit claims to non-pesticidal claims (e.g., deodorizing)
Disinfects surfaces while deodorizing the air	• Disinfects hard non-porous surfaces • Deodorizes the air
Removes Allergens	• Removes Allergens* (*non-living organisms like pet dander and pollen)
Clinical	• For use in Hospitals
Safe for bathrooms	• Safe for sealed tiles
Remove gross filth from surface	• Remove visible soil from surfaces
Sanitary	• For use in Hospitals

^For non-public health claims, the agency has the ability to request efficacy data on a case-by-case basis.

Links

- 40 CFR 158W (Generic data requirements)
- Acute Toxicity (870 Guidelines)
- Benefits
- Commodity Inerts
- Contact List
- Efficacy (product performance) (810 Guidelines)
- EPA's Antimicrobial Website
- End Use Products and Manufacturing Use Product Memo (2012)
- How to Register a Pesticide – A Guide for Applicants New to the Process
- Inert Ingredients Overview and Guidance
- Label Review Manual (includes chapter 12 Labeling Claims)
- Pesticide Registration Manual
  - Pesticide Registration Manual Chapter 10 Data Compensation
  - Pesticide Registration Manual: Blank Forms
  - Cover Letter Suggestions for Notifications and Fast Track Amendments
- Pesticide Registration Improvement Extension Act (PRIA)
- Pesticide Submitters List
- PRIA Fees
- Product Chemistry (830 Guidelines)
- Standard study format PRN 2011-3
- Submitting an electronic application
- Technical Grade Active Ingredient Memo (2012)

Definitions

- **100% Repack Products** - Identical Repack Registrations – A complete (100%) repackaging of an identical, already-registered product, where an identical label is used for the product other than name, address, name of product, and registration number.
- **Confidential Statement of Formula (CSF)** - lists all the components and their percent by weight in a product.
- **"Fast Track" Amendments** - labeling changes or basic or alternate product formulation changes that do not require supporting data. Fast track amendments are also not subject to PRIA fees.
- **Notification** – 40 CFR § 152.46 "EPA may determine that certain minor modifications to registration having no potential to cause unreasonable adverse effects to the environment may be accomplished by notification to the Agency.."
- **Pesticide -** A "pesticide" is any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest; or intended for use as a plant regulator, defoliant or desiccant.
- **PRIA** - Pesticide Registration Improvement Extension Act.

Contact Information

- General Pesticide Questions:
  - pesticidequestions@epa.gov
- Efficacy Questions:
  - AD_Efficacy@epa.gov
- Device Questions:
  - opp_fifra_jurisdictional_issues@epa.gov
- AD Contacts:
  - https://www.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobials-division