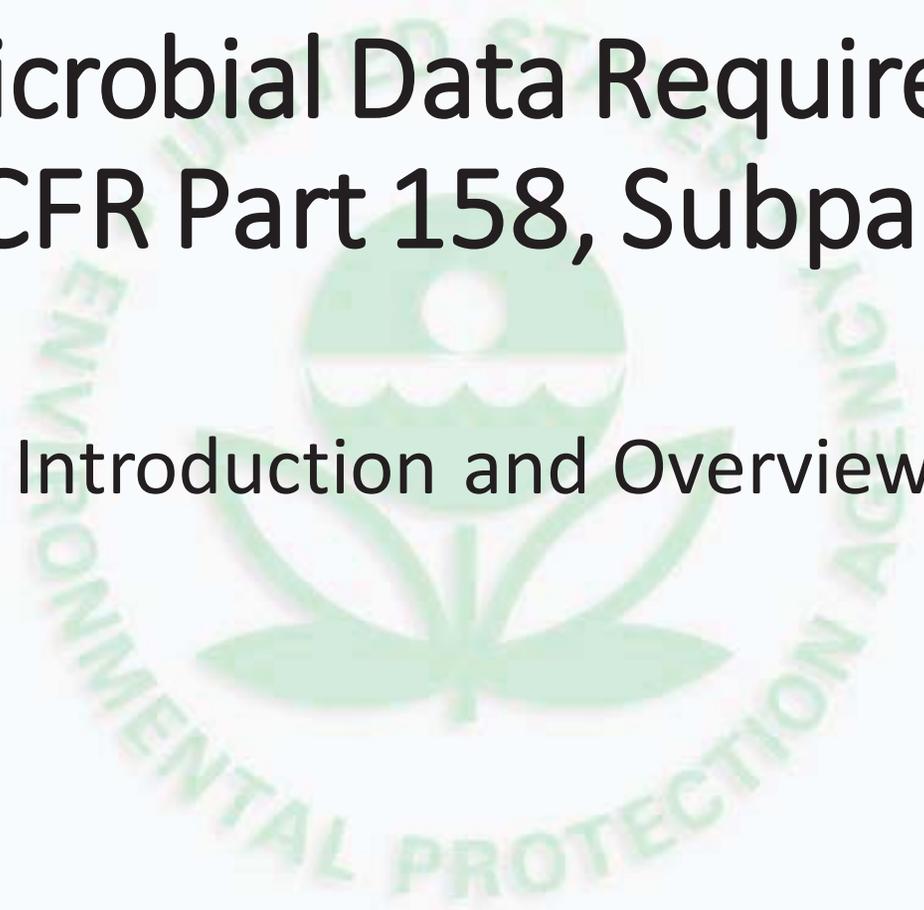


Antimicrobial Data Requirements 40 CFR Part 158, Subpart W

Introduction and Overview





Purpose & Agenda

Purpose: Provide an introduction to the EPA training series on 40 CFR Part 158W Data Requirements for Antimicrobial Pesticides final rule

Agenda:

- Background
- scientific disciplines in 158W
- sessions included in this training series
- 12 major use patterns
- 158W implementation
- Eco
- Human Health



Statutory and Regulatory Background

Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)

- Requires registration of a pesticide product with EPA
- Registration is a license
- Product must meet EPA standards

Federal Food Drug and Cosmetic Act (FFDCA)

- Allows EPA to set limits on the nature and level of pesticide residues on food



Data Requirements for Pesticides

- EPA assesses a wide variety of potential human health and environmental effects associated with use of pesticide products.
- Registrants must generate data to address concerns pertaining to the identity, composition, potential adverse effects, and environmental fate of each pesticide.
- The data allow EPA to evaluate whether a pesticide has the potential to cause harmful effects on certain non-target organisms and endangered species that include:
 - humans
 - wildlife
 - plants
 - surface water or ground water





40 CFR Part 158

- Subpart A: General Provisions 158.000
- Subpart B: How to Use Data Tables 158.100
- Subpart C: Experimental Use Permits 158.200
- Subpart D: Product Chemistry 158.300
- Subpart E: Product Performance 158.400
- Subpart F: Toxicology 158.500
- Subpart G: Ecological Effects
 - 158.630 Terrestrial and Aquatic Nontarget Organisms
 - 158.660 Nontarget Plant Protection
- Subpart H: Reserved 158.700
- Subpart I: Reserved 158.800
- Subpart J: Reserved 158.900
- Subpart K: Human Exposure
 - 158.1000 Applicator Exposure
 - 158.1050 Post-Application Exposure
- Subpart L: Spray Drift 158.1100
- Subpart M: Reserved 158.1200
- Subpart N: Environmental Fate 158.1300
- Subpart O: Residue Chemistry 158.1400
- Subpart P: Reserved 158.1500
- Subpart Q: Reserved 158.1600
- Subpart R: Reserved 158.1700
- Subpart S: Reserved 158.1800
- Subpart T: Reserved 158.1900
- Subpart U: Biochemical Pesticides 158.2000
- Subpart V: Microbial Pesticides 158.2100
- **Subpart W: Antimicrobial Pesticides 158.2200**
- Subpart X: Reserved 158.2300
- Subpart Y: Reserved 158.2400
- Subpart Z: Reserved 158.2500



Flexibility with Implementation of Part 158

- Additional data can be required beyond 158
- Alternative approaches can be accepted, and
- 158 data requirements can be waived



Reminder That Other Part 158 Sections Address Antimicrobial Data Requirements

- Requirements for additional data (§ 158.75)
- Minor use data policies (§ 158.60)
- Experimental use permit (EUP) data requirements (Subpart C)
 - Covers the field crop, horticultural crop, and turf use patterns, but requirements for the 12 general antimicrobial use patterns sites are on a case-by-case basis
 - Example of recent antimicrobial EUP: Ballast water





Eleven New Data Requirements

1. Photodegradation in soil
2. Soil residue dissipation
3. Activated sludge respiration inhibition (ASRI) test
4. Ready biodegradability study
5. Porous pot study
6. Simulation test – aerobic sewage treatment: activated sludge units
7. Simulation tests to assess the biodegradability of chemicals in discharged wastewater
8. Activated sludge sorption isotherm study
9. Developmental neurotoxicity
10. Immunotoxicity
11. Nature of the residue on surfaces.



Scientific Disciplines in 158W

Toxicology Data Requirements, **§158.2230**

Nontarget Animal Data Requirements, **§158.2240**

Nontarget Plant Protection Data Requirements, **§158.2250**

Applicator Exposure Data Requirements, **§158.2260**

Post-application Exposure Data Requirements, **§158.2270**

Environmental Fate Data Requirements, **§158.2280**

- All but Toxicity and Fate in Wastewater Systems
- Toxicity and Fate in Wastewater Systems

Residue Chemistry Data Requirements, **§158.2290**



Sequence of 158W Training Series

158W Overview

Presentations by Discipline

- Environmental Fate
- Ecological Toxicology
- Human Health Toxicology
- Occupational & Residential Exposure
- Residues Chemistry

Presentations by Use Pattern

- Down-the-Drain Assessments
- Cooling Towers
- Textiles/Plastics/Paints
- Wood Preservatives
- Antifoulant Paint
- Sanitizers/Disinfectants
- Future Use Pattern Presentations TBD



12 Major Use Patterns

1. Agricultural Premises & Equipment
2. Food Handling/Storage Establishments, Premises and Equipment
3. Commercial, Institutional and Industrial Premises and Equipment
4. Residential and Public Access Premises
5. Medical Premises and Equipment
6. Human Drinking Water Systems
7. Materials Preservatives
8. Industrial Processes and Water Systems
9. Antifouling Coatings and Ballast Water Treatments
10. Wood Preservatives
11. Swimming Pools and Spas
12. Aquatic Areas

12 Major Use Patterns





158W Implementation

- 158W Proposed Rule was published **October 2008**
- On **May 8, 2013** the EPA published a final rule amending 40 CFR part 158
- The rule was effective on **July 8, 2013**





158W Implementation

Current Registrations

- Each active ingredient will be reevaluated under the Registration Review program
- Evaluate whether new data are needed in the context of, but not limited to, the requirements in 158W





Overview of Antimicrobial Pesticides
Data Requirements –
Environmental Fate and Ecological
Effects



Outline of Fate and Effects Part 158 W Data Requirements Overview



- Data Requirement Sections
- Data Requirement Section Structure
- Data Requirement Table Structure
- Data requirements for an antimicrobial applied to a field crop, horticultural crop or turf.

Data Requirement Sections



- In Subpart 158 W the environmental fate and ecological effects data requirements are located in three sections
- § 158.2240 Nontarget organism (animals*)
 - *Technical change (future) – replace term organism with animals
- § 158.2250 Nontarget plant protection
- § 158.2280 Environmental fate

Data Requirement Section Structure



- “General” Subsection
- “Key” Subsection
 - Spells out the acronyms used in the data requirement table and test notes.
 - Definitions are under Subpart B of Part 158 (this is referenced in the “General” Subsection).
- Data Requirement Table
- Data Requirement Table Test Notes

§ 158.2240 Nontarget organisms.

(a) *General.* Subpart B of this part and §158.2201 describe how to use the table in paragraph (c) of this section to determine the terrestrial and aquatic nontarget organisms data requirements for a particular antimicrobial pesticide product. Notes that apply to an individual test, including specific conditions, qualifications, or exceptions are listed in paragraph (d) of this section.

(1) Terrestrial and aquatic nontarget organism data are required to support the registration of most end-use and manufacturing-use antimicrobial products.

(2) Data are generally not required to support end-use products of a gas, highly volatile liquid, or a highly corrosive product.

(b) *Key.* MP = Manufacturing use product; EP = End-use product; R = Required; CR = Conditionally required; NR = Not required; TGAI = Technical grade of the active ingredient; TEP = Typical end-use product; PAIRA = Pure active ingredient radiolabeled; a.i. = active ingredient.

Data Requirement Table Structure



Guideline Number Column: These are not data requirements.

Data Requirement Column

Use Pattern Columns

TABLE—NONTARGET PLANT PROTECTION DATA REQUIREMENTS

Guideline No.	Data requirement	Use pattern					Test substance		Test note No.
		Industrial processes and water systems	Antifoulant coatings and paints	Wood preservatives	Aquatic areas	All other use patterns category	MP	EP	
850.4225	Seedling emergence, Tier II—dose response.	CR	CR	CR	CR	CR	TEP	TEP	1, 2
850.4250	Vegetative vigor, Tier II—dose response.	CR	NR	CR	CR	CR	TEP	TEP	1, 3
850.4400	Aquatic plant growth (aquatic vascular plant) Tier II—dose response.	R	R	R	R	CR	TGAI, TEP ...	TGAI, TEP ...	4, 10
850.5400	Aquatic plant growth (algal) Tier II (dose response).	R	R	R	R	R	TGAI, TEP ...	TGAI, TEP ...	4, 5, 6
850.4300	Terrestrial field	CR	CR	CR	CR	CR	TEP	TEP	7, 8, 9
850.4450	Aquatic field	CR	CR	CR	CR	CR	TEP	TEP	7, 8, 9

Data Requirement Table Structure: Use Patterns



TABLE—NONTARGET PLANT PROTECTION DATA REQUIREMENTS

Use pattern				
Industrial processes and water systems	Antifoulant coatings and paints	Wood preservatives	Aquatic areas	All other use patterns category

- The environmental fate and effect tables in Part 158 W contain data requirements for 12 of the general antimicrobial use patterns divided into 5 categories
 - Industrial Processes and Water Systems
 - Antifoulant Coatings and Paints
 - Wood Preservatives
 - Aquatic Areas
 - All Other* Use Pattern Categories
- *Data requirements for an antimicrobial applied to a field crop, horticultural crop or turf can be found in the 158 subpart b tables

Data Requirement Table Structure: Use Patterns (continued)



TABLE—NONTARGET PLANT PROTECTION DATA REQUIREMENTS

Use pattern				
Industrial processes and water systems	Antifoulant coatings and paints	Wood preservatives	Aquatic areas	All other use patterns category

- “General” paragraph

- References other sections to visit which contain a list of the antimicrobial general use patterns contained within the tables (§ 158.2201)

- Defines which use patterns are under the “All Other Use Patterns” column in the data requirement tables

(5) For the purpose of determining data requirements, the all other use patterns category includes the following use patterns:

- (i) Agricultural premises and equipment.
- (ii) Food-handling/storage establish-

- References other sections to visit which contain a list of use patterns for applications to a field crop, horticultural crop or turf (Subpart B)

(4) If an antimicrobial may be applied to a field crop, horticultural crop, or turf, then the data requirements in § 158.630 apply.

Data Requirement Table Structure



Guideline Number Column: These are not data requirements.

Data Requirement Column

Use Pattern Columns

Test Substance by Product Type

TABLE—NONTARGET PLANT PROTECTION DATA REQUIREMENTS

Guideline No.	Data requirement	Use pattern					Test substance		Test note No.
		Industrial processes and water systems	Antifoulant coatings and paints	Wood preservatives	Aquatic areas	All other use patterns category	MP	EP	
850.4225	Seedling emergence, Tier II—dose response.	CR	CR	CR	CR	CR	TEP	TEP	1, 2
850.4250	Vegetative vigor, Tier II—dose response.	CR	NR	CR	CR	CR	TEP	TEP	1, 3
850.4400	Aquatic plant growth (aquatic vascular plant) Tier II—dose response.	R	R	R	R	CR	TGAI, TEP ...	TGAI, TEP ...	4, 10
850.5400	Aquatic plant growth (algal) Tier II (dose response).	R	R	R	R	R	TGAI, TEP ...	TGAI, TEP ...	4, 5, 6
850.4300	Terrestrial field	CR	CR	CR	CR	CR	TEP	TEP	7, 8, 9
850.4450	Aquatic field	CR	CR	CR	CR	CR	TEP	TEP	7, 8, 9

Data Requirement Table Structure: Test Substance by Product Type



Product Type	Test substance	
	MP	EP
.....	TEP	TEP

- Product Type Being Supported
 - MP: Manufacturing-use Product
 - EP: End-use Product .
- Test Substances in Table
 - TGAI: technical grade active ingredient
 - TEP: typical end use product
 - PAIRA: pure active ingredient radiolabeled
 - Degradate (limited occurrence in tables)
 - Treated wood (limited occurrence in tables)
- General Paragraph
 - Provides criteria for when data on transformation/degradation products or leachate residues of the parent compound are required in addition to or rather than test substance in the data requirement table (§ 158.2240(a)(3); § 158.2250(b); § 158.2280(a)(2)).

Data Requirement Table Structure



Guideline Number Column: These are not data requirements.

Data Requirement Column

Use Pattern Columns

Test Substance by Product Type

Test Note Number

TABLE—NONTARGET PLANT PROTECTION DATA REQUIREMENTS

Guideline No.	Data requirement	Use pattern					Test substance		Test note No.
		Industrial processes and water systems	Antifoulant coatings and paints	Wood preservatives	Aquatic areas	All other use patterns category	MP	EP	
850.4225	Seedling emergence, Tier II—dose response.	CR	CR	CR	CR	CR	TEP	TEP	1, 2
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850.5400	Aquatic plant growth (algal) Tier II (dose response).	R	R	R	R	R	TGAI, TEP ...	TGAI, TEP ...	4, 5, 6
850.4300	Terrestrial field	CR	CR	CR	CR	CR	TEP	TEP	7, 8, 9
850.4450	Aquatic field	CR	CR	CR	CR	CR	TEP	TEP	7, 8, 9

Data Requirement Table Structure: Test Note Numbers



- The test note numbers in the table correspond to paragraph numbers in the test note portion of the data requirement section.
 - General paragraph designates where the test notes corresponding to the test note number in the data requirement table are found.
- Test note numbers designate specific conditions, qualifications, or exceptions to an individual R or CR data requirement

- Examples:

- Designate number of species for which data are required → 2. Data are required on one freshwater aquatic invertebrate species.
- Designate type of test species for which data are required (e.g., warm water fish species; one mollusk species). → 1. Data on only one plant species (rice, *Oryza sativa*) are required.
- Provide criteria which would result in the data not being required. → 13. Not required when:
 - i. The octanol/water partition coefficients of the pesticide and its major
- Provide criteria which would result in the data being required. → 17. Data are required if the half-life of the pesticide in the sediment is equal to or less than 10 days in either

Antimicrobial Data Requirements 40 CFR Part 158, Subpart W



OPP Training
Overview of Human Health



Objectives of Human Health (HH) Overview

- Provide people with a general sense of what's available in 158W to help them understand the scope of the rule and some interpretation of the data requirements
- Identify the human health sections in 158W
- Provide an overview of the human health sections to pique your interest in subsequent training modules



What can you find in 158W?

- You may want to know what data requirements must be fulfilled for a specific use (e.g., wood treatment). The data tables in 158W will guide you through that process
- 158W will provide a better understanding of the data required in the Reregistration Eligibility Decision (RED) documents and Registration Review plans resulting in data call-ins (DCIs)



What can you find in 158W? (continued)

- Data requirement tables in a centralized location are a useful tool to determine the scope of each disciplines data requirements.
- Test Notes are a useful tool when explaining the circumstances when data are required versus when they can be waived.



What can you find in 158W? (continued)

- Alternative testing is the antimicrobial program's present & future. Some alternatives are discussed.
- Response-to-Comments section provide answers to many stakeholder questions and concerns. Much thought went into EPA's responses. Good reference source.
- Bottom Line: The more you understand the data requirement's sections the better!



Basic Structure of Data Requirements in Part 158W

- Retains most of the existing “original” pesticide data requirements from Part 158, while tailoring to be specific to antimicrobials
- Studies are tiered and categorized as required (R), conditionally required (CR), or not required (NR)
- Clarifying test notes provide conditions for certain requirements
- Data tables organized by scientific discipline



Key Elements of Data Requirements

Conditionally Required (CR) versus Required (R)

- CR *"...means a study is less likely to be required...up to 50 % of the time"*
- R *"...could be viewed as representing the submission of a study 50 to 100 % of the time"*

Triggers

- Exposure & toxicity data are required only if the toxicity criteria and potential for exposure are met

Test Notes! Read them

Alternative testing 21st C (not just check-box approach)



What Sections of 158W are Human Health (HH)?

Toxicology (§ 158.2230)

- Tox study requirements are delineated between food and non food uses
- Tier 1 & II Tox studies are based on exposure duration

Applicator (§ 158.2260)

- Includes studies to measure dermal and inhalation exposure and requires information to better understand how the pesticide is used
- Criteria for testing (chemical needs to be toxic and there needs to be the potential for exposure)



What Sections of 158W are HH? (Continued)

Post-application (§ 158.2270)

- Includes studies to measure dermal, inhalation, and incidental oral exposures and requires information to better understand how the pesticide is used and how people may be exposed based on labeled use.
- Criteria for testing (chemical needs to be toxic and there needs to be the potential for exposure)

Residue Chemistry (§ 158.2290)

- Defines the uses that require residue chemistry data
- Supporting information, food contact surfaces, higher tiers



Did We Fulfill the 3rd Objective of this Overview?

- What was that again?

“Provide an overview of HH sections to pique your interest in subsequent training modules”

- Understanding 158W will give you more knowledge not only to do your job but also to understand the Antimicrobials Division’s Mission:

“Protect human health and the environment by using the best science and regulatory efficiencies in the registration and reevaluation of chemicals used as pesticides against microbiological pests.”



Thank You!