

OVERVIEW OF 158W TRAINING SERIES FOR ANTIMICROBIAL DATA REQUIREMENTS

Slide	Narration
1	Hello and welcome to the training on 40 CFR part 158W. This presentation is an overview in a series of trainings on Antimicrobial data requirements.
2	<p>The purpose of this video is to provide an introduction to the EPA training series on 40 CFR part 158W data requirements for antimicrobial pesticides final rule.</p> <p>The agenda for this presentation includes discussion of the following topics: background; scientific disciplines that are in 158W; sessions to be included in this training series; major antimicrobial use patterns; 158W implementation; an overview of environmental fate and ecological data requirements; and an overview of human health data requirements.</p>
3	<p>The two major laws that cover the way EPA regulates pesticides are the Federal Insecticide Fungicide and Rodenticide Act, or FIFRA, and the Federal Food Drug and Cosmetic Act, or FFDCA.</p> <p>EPA grants a registration or license that permits a pesticide’s distribution, sale, and use only after the company meets the scientific and regulatory requirements.</p> <p>This includes data requirements that apply to companies that register pesticides under FIFRA or seek a tolerance or tolerance exemption for a pesticide under FFDCA.</p> <p>FIFRA provides the EPA with authority to establish or modify data needs and timing for individual pesticide registration actions.</p>
4	<p>In evaluating pesticides under our registration or re-evaluation programs, we assess a wide variety of potential human health and environmental effects associated with use of the pesticide products.</p> <p>Registrants are required to provide scientific data necessary to address concerns pertaining to the identity, composition, potential adverse effects, and environmental fate of each pesticide.</p> <p>The data will allow EPA to evaluate whether a pesticide has the potential to cause harmful effects on certain non-target organisms including humans, wildlife, and plants. It also allows for the assessment of endangered plants and wildlife and the consideration of the potential for pesticide residues in surface or ground water.</p>
5	Most of the Data requirements for pesticides are found in the Code of Federal Regulations at 40 CFR Part 158.

	<p>These regulations provide EPA with discretion to make registration decisions on the basis of what the Agency determines to be the most relevant and important data for that particular action.</p> <p>The data required under Part 158 provide the scientific basis for characterizing the potential risks associated with pesticide exposure.</p> <p>This training series will focus on the new 158 subpart W which contains the data requirements specifically applicable to antimicrobial pesticides.</p>
6	<p>A key point to remember is that considerable regulatory discretion is afforded to the Agency by 40 CFR 158W.</p> <p>For example, additional data requirements beyond those enumerated in 158W may sometimes be required, alternative approaches may sometimes be accepted, and 158W data requirements may sometimes be waived.</p>
7	<p>It is important to remember that there are data requirements that apply to all pesticides including antimicrobials.</p> <p>These include requirements for additional data in 158.75. This section indicates that if the data requirements are not sufficient to evaluate the product, additional data requirements will be imposed. Minor use data policies in 158.60 describe modifications of the data requirements for a minor use product registration.</p> <p>Experimental use permit, or EUP, data requirements are covered in Subpart C. AD does not receive many EUPs. These are evaluated on a case-by-case basis. One example of an antimicrobial EUP is ballast water application.</p>
8	<p>Though most of the data requirements in 158W are not new, there are eleven new data requirements for antimicrobial uses. They include photodegradation in soil, soil residue dissipation, activated sludge respiration inhibition or ASRI test, ready biodegradability study, porous pot study, simulation test which includes aerobic sewage treatment: activated sludge units, simulation tests to assess the biodegradability of chemicals in discharged wastewater, activated sludge sorption isotherm study, developmental neurotoxicity, immunotoxicity, and nature of the residue on surfaces.</p>
9	<p>This slide lists the 7 scientific disciplines by which data requirements are organized in 158W. These include toxicology, nontarget animals, nontarget plants, applicator exposure, post-application exposure, environmental fate, and residue chemistry. Data requirements for these scientific disciplines will be discussed in more detail later in this presentation.</p>
10	<p>This slide provides an overview of presentations included in this 158W training series. The first module, “presentations by discipline” mirrors the data requirement tables in</p>

	<p>the rule. Those presentations include environmental fate, ecological toxicology, human health toxicology, occupational and residential exposure and residue chemistry. The second module, “presentations by use pattern” covers potential data requirements for common antimicrobial use patterns. These include down-the-drain assessment, cooling towers, textiles plastics and paints, wood preservatives, antifoulant paint, sanitizers and disinfectants.</p> <p>Future use patterns will be included as needed and as new antimicrobial uses arise.</p>
11	<p>These are the 12 major use patterns for antimicrobial pesticide products that are identified in 158W. Within most of these 12 patterns there are additional categories for direct food uses, indirect food uses, and non-food uses which you will hear more about during later presentations. A use site index has also been developed that cross references a further sublevel of uses or use sites in each of the 12 patterns listed here. That use site index is posted in the docket and can be updated based on stakeholder comments and as new antimicrobial uses arise.</p>
12	<p>These pictures will illustrate some of the major use patterns.</p> <ul style="list-style-type: none"> • First is agricultural premises & equipment. This is a photograph of dairy farm milk handling facilities and equipment. • Second is food handling or storage establishments; pictured here is an egg-handling facility. • Third is commercial, institutional and industrial premises and equipment; this includes a photograph of an HVAC unit. • Fourth is residential and public access premises; this includes a photograph of a household food handling area. • Fifth is medical premises and equipment; this includes a photograph of a hospital operating room. • Sixth is human drinking water systems; this includes a photograph of a public water system. • Seventh is materials preservatives; this includes a photograph of in-can paints. • Eighth is industrial processes and water systems this includes a photograph of gas and oil drilling. • Ninth is antifoulant coatings and ballast water treatments, for example antifoulant paint being applied to a boat bottom. • Tenth is the wood preservatives treatment pattern; this includes a photograph of the pressure treatment of wood. • Eleventh is swimming pools and spas and this includes a photograph of a swimming pool. • Twelfth is aquatic areas. The photograph of an ornamental pond provides an example of the aquatic areas major use pattern.
13	<p>The proposed rule was published in October 2008. On May 8, 2013, the EPA published a final rule amending 40 CFR part 158. This final rule contains the data requirements specifically applicable to antimicrobial pesticides. The rule became effective on July 8, 2013.</p>

14	With the implementation of 158W, active ingredients that are already registered will be reevaluated under EPA’s registration review program to determine if data based on 158W will be required and included in a data call in or if any other data would be necessary.
15	The next part of this presentation is the overview of the environmental fate and ecological effects data requirements under 40 CFR part 158, subpart W. The objectives will be to provide a general understanding of where and how these data requirements apply. Later sessions will provide greater detail on specific data requirements for given use patterns.
16	This overview focuses on four major topics. The first topic is identification of the data requirement sections that pertain to environmental fate and ecological effects. The second topic is an overview of how these data requirement sections are structured or organized for a user to be able to determine what data requirements apply. The third topic is an overview of the data requirement table structure or organization. The fourth and last topic is a discussion of data requirements for an antimicrobial product applied to a field crop, horticultural crop or turf.
17	Which sections of 158W contain the environmental fate and ecological effects data requirements for antimicrobials? These data requirements are located in three sections. Section 158.2240 contains the data requirements for non-target animals. Section 158.2250 contains the data requirements for non-target plant protection. Section 158.2280 contains the environmental fate data requirements.
18	<p>What is the organizational structure of these data requirement sections? The data requirement sections just introduced are typically divided into four major subsections. The first is a general subsection, seen here as indicated with a red arrow, from the 158.2240 non-target animals data requirements section. It provides the user with general information about the data requirements, how to use the tables, additional information that can result in modification of the data requirements, additional instructions, and information as to where to find definitions.</p> <p>The second main subsection is the key subsection; an example seen here is indicated with a purple arrow. The key subsection spells out the abbreviations and acronyms used in the data requirements table and test notes for the given data requirements section. For instance, in the example provided, the abbreviation MP means manufacturing use product; EP means end- use product; R means required; CR means conditionally required; NR means not required and so on. The third main subsection is the data requirement table and the fourth is the data requirements table test notes. In the next few slides we will discuss the structure and general content of each of these in a little more detail.</p>

<p>19</p>	<p>Data requirements tables provide a list of the typical data that the agency has learned through experience is required to answer questions about the safety of a pesticide product before the agency can register it. To understand what specific data are required to support an antimicrobial product registration requires an understanding of the structure or organization of these data requirement tables. There are a few fundamental principles regarding how these tables are organized and how to identify a data requirement. First, the environmental fate and ecological effects data requirements tables are all structured the same way. If you understand how to use any one of these tables you'll understand how to use the other two tables as well. This slide displays a portion of the non-target plant protection data requirements table. Except for the table header rows, each row of a table represents a specific data requirement. The type of data requirement is designated in the data requirement column, located in the second column from the left of the table. The red arrow points to this column.</p> <p>The first column of the table contains the OCSPP test guideline number that corresponds to the data requirement. The brown arrow points to this column. The 835 series includes the environmental fate guideline and the 850 series includes the ecological effects guidelines. The OCSPP test guidelines are documents that specify methods that the EPA recommends be used to generate data that are submitted to the agency to support the registration of a chemical under FIFRA and the Toxic Substances Control Act. Studies conducted according to these test guidelines may be used to satisfy FIFRA data requirements. An OCSPP test guideline itself is not the data requirement. The test guidelines only provide descriptions of the test endpoints and standards by which the information submitted to fulfill a data requirement is evaluated for acceptability. This allows for test results conducted for other government organizations for example, PMRA, OECD, ASTM or for scientific publication, that provide essentially the same measurement endpoints and test standards as are needed to fulfill a data requirement.</p> <p>The next component of the data requirement table is the use pattern columns. As indicated by the green bracket, there are five use pattern groups or categories designated in these tables. These columns designate for the uses whether or not the listed data requirements in that row are required to support a given use pattern. Each use pattern has one of three designations: R for required; CR for conditionally required; or NR for not required to support registration.</p>
<p>20</p>	<p>All of the 12 major use patterns that were introduced in the introduction to this presentation are encompassed by five categories. Four of the categories directly correspond to four of the 12 major use patterns: industrial processes and water systems; antifoulant coatings and paints; wood preservatives; and aquatic areas. The remaining eight major use patterns fall under the "All other use patterns" category. There is one antimicrobial use pattern that is not covered in the 40 CFR part 158 subpart W tables and that is for an antimicrobial applied to a field crop, horticultural crop or turf. These data requirements are found in 40 CFR part 158 subpart B.</p>

21	<p>Returning briefly to the general paragraph which, in each data requirement section, describes what use patterns the data requirements table addresses, there are three types of information provided on use patterns in a general subsection.</p> <p>First, the general paragraph references other sections to visit that contain a list of the antimicrobial general use patterns covered in the subpart W tables. In this case it is 158.2201.</p> <p>Second, it includes a definition of which use patterns are covered under the “all other use patterns category” in the data requirement table. An example here is designated by the red arrow showing the beginning of the definition.</p> <p>Third, it provides instructions on where to find the data requirements for those antimicrobial use patterns not covered in the Part W tables. An example from the non-target animal data requirement is indicated by a brown arrow. In this example it states, “If any antimicrobial may be applied to a field crop, horticultural crop, or turf, then the data requirements in 158.630 apply. “</p>
22	<p>Continuing on with the data requirement table structure, the next major component of the table are the columns containing test substance by product type. The bracket in blue shows the location of these columns in the table.</p>
23	<p>The two types of product registration these tables support include a MP or manufacturing-use product and an EP or end-use product. If the product registration being supported is for a MP then the data from the tests using the designated test substance in the MP column are required. Alternatively, if the product registration being supported is for an EP then the data from the tests using the designated test substance in the EP column are required. Four types of test substances are usually found in these columns: the TGAI or the technical grade active ingredient; the TEP or typical end-use product; the PAIRA or pure active ingredient radiolabeled degradate; and treated wood. The example is included here of this criteria from 158.2240 paragraph a3, the Non-target Animal data requirement section. Included in the slide is the location of these criteria in the other two data sections, 158.2250 paragraph b, Non-target plants, and 158. 2280 paragraph a2 for environmental fate.</p>
24	<p>The last component of the data requirement table structure is the test notes number column, which is indicated here with a dark red arrow. The test notes are key in understanding specific conditions about data requirements. The test notes column is the right-most column in the data requirements table. The last part of this session discusses the relevance of test notes to interpreting data requirements.</p>
25	<p>The test note numbers in the table correspond to paragraph numbers in the test note subsection of the data requirements sections.</p> <p>Test note numbers delineate specific conditions, qualifications, or exceptions to an individual data requirement designated as required or conditionally required. This slide presents four examples of test notes, including test notes that designate the</p>

	<p>number of species for which data are required; the type of species for which data are required; criteria under which data would not be required; and criteria under which data would be required.</p> <p>The text next to the red arrow is from a test note that designates the number of species for what data are required. This text states that data are required on one freshwater aquatic invertebrate species. There can also be test notes that designate that two or more species are required.</p> <p>The text to the right of the brown arrow is from a test note that designates the type of species for which data are required. This text states that data on only one plant species (<i>Oryza sativa</i>) are required.</p> <p>The text to the right of the green arrow is from a test note that designates a criterion under which data would not be required. This text states, “not required when the octanol/water partition coefficient of the pesticide and its major degradates is less than 1000”.</p> <p>The text to the right of the orange arrow is from a test note that designates a criterion under which data would be required. This text states that data are required if the half-life of pesticide in the sediment is equal to or less than 10 days in either the aerobic soil or aerobic aquatic metabolism studies.</p>
26	This third and last section of the overview for Antimicrobial data requirements is an overview on human health aspects of Part 158 subpart W.
27	There are 3 objectives of the human health overview. The first objective is to provide a general sense of what’s available in 158W; to help users understand the scope of the rule and some interpretation of the data requirements. In addition to the data tables within the rule, it is also important to read through the public comment section to get an idea of what EPA is trying to accomplish and communicate to the stakeholders. The second objective is to identify the human health sections in 158W. The third objective is to pique interest in subsequent training modules on human health such as those on human toxicology and on occupational and residential exposure.
28	What can you find in 158W? If you are interested in identifying a specific use pattern and what data would be required for that use pattern, 158W will guide you through the tables. Also, 158W will provide a better understanding of the data required by the EPA Registration Eligibility Decision (REDs) and in data call ins. 158W will tell you when and why the data are required as well as when these data can be waived.
29	What else can you find in 158W? All of the data tables are centrally located which is useful when you want to determine the scope of the various data required for each discipline. The test notes provide information to explain the circumstances under which data are required versus when data can be waived.

30	<p>There is also a discussion in the preamble of 158W, about alternative testing methods such as Quantitative Structure Activity Relationships (QSAR) and the threshold of toxicological concern. There is also a response-to- comments section which presents some key stakeholder questions and concerns along with EPAs responses.</p> <p>The bottom line is the more you understand the data requirements, the better.</p>
31	<p>The basic structure of data requirements in 158W retains most of the existing “original” pesticide data requirements from part 158 while tailoring these to be specific to antimicrobials. Studies are tiered and categorized as either required, conditionally required, or not required. Clarifying test notes provide exceptions and describe conditions for when data are or are not required. Finally, the data requirements tables are organized by scientific discipline.</p>
32	<p>There are a few key elements regarding data requirements in 158W which are important to highlight. One is what is meant by conditionally required vs required data. Initially, the rule of thumb for determining whether a data requirement would be required or conditionally required was that CR “...means a study is less likely to be required...up to 50 % of the time” whereas R could mean a study would be likely to be required 50 to 100 % of the time. So a study designated by R does not necessarily mean it will be required, but it is generally required more than half of the time. The triggers for human health include exposure and toxicity. These data are required only if there is a potential for exposure and toxicity criteria are met. For example, if there is no potential for hazard for a selected chemical even though there might be exposure, no exposure data would be required.</p> <p>It is important to carefully read through the test notes.</p>
33	<p>So, which sections of 158W concern human health?</p> <p>The first is toxicology: Toxicology data requirements are designated as either food or nonfood uses. The toxicology studies were categorized as either tier 1 or tier 2, depending on if it’s a food use, and duration of exposure. An example of a long duration chronic exposure scenario would be a materials preservative in a metal working fluid where people are exposed on a daily basis. In this case the EPA would want more toxicity data.</p> <p>The next section is the applicator section. The applicators are those who mix load and apply the formulated product or products that have been preserved with an antimicrobial. This includes studies in the applicator section for studies to measure dermal and inhalation exposure and requires information to understand when developing the risk assessments how the pesticide is used and how people are being exposed. This section also provides criteria testing which basically says that the chemical has to have a hazard end point and has to have potential for exposure before the data needs to be required.</p>

34	<p>The next section that is human health related is the post- application section, these are people who are being exposed after the pesticide is applied and the EPA requires measurement of 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.</p> <p>Similarly if there is no hazard end point then there is no need to measure exposure. Finally the last section is residue chemistry. Residue chemistry tables define the uses that require residue chemistry data including supporting information, food contact surfaces, and also the need for higher tier testing</p>
35	<p>Was the third objective of this overview fulfilled? Did we pique your interest into reviewing the subsequent training modules? As this is only an overview there are more details to learn within 158W.</p> <p>Understanding 158W will give you more knowledge not only to do your job but also will give stakeholders a chance to understand what the Antimicrobials Division is trying to accomplish-namely to “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.”</p>
36	<p>This concludes the overview of Antimicrobial data requirements.</p>