	Narration – Introduction to Down-the-Drain Assessment
1	Welcome to the Antimicrobials Division Part 158, subpart W training session on Introduction to Down-the-Drain Assessment. Down-the-drain assessments are a relatively new and important piece of the 158W rule. The purpose of this training video is to provide an introduction to down-the-drain assessments including considerations for risk management.
2	The main topics for this training include background information, a discussion of key elements of down-the-drain assessment, results and their interpretation, and risk management considerations.
3	In this overview of down-the-drain assessment, the focus will be on the what, when, why and how of down-the-drain assessment. Some questions that will be addressed include: What is a down-the-drain assessment? When are the down-the-drain assessments conducted? Why are the down-the-drain assessments conducted? How are the down-the-drain assessments conducted? What information does a down-the-drain assessment provide?
4	Prior to the implementation of 158W, OPP designated many antimicrobial use sites as either “indoor uses” or “outdoor uses”. OPP assumed that, unlike “outdoor uses”, “indoor uses” of antimicrobials would not lead to releases of antimicrobials to environmental media. Consequently, OPP assumed that many environmental concerns for antimicrobial pesticides with “indoor uses” of products that went down-the-drain to a Wastewater Treatment Plant, or WWTP, would be mitigated through removal by processes that occur during wastewater treatment. Upon soliciting feedback from the public, however, EPA received comments that led the Agency to re-evaluate the assumption that “indoor uses” do not lead to releases of antimicrobials to environmental media. Following the implementation of 158W, OPP acknowledged that antimicrobials released down-the-drain are not necessarily removed during wastewater treatment and could have the potential to subsequently be released to surface water downstream of WWTPs. OPP no longer continues to designate antimicrobial use sites as either “indoor uses” or “outdoor uses” and has disbanded the idea that “indoor uses” of products containing antimicrobials do not lead to releases to environmental media. It is important to note that a down-the-drain assessment is applicable only for antimicrobials that are released to WWTPs and are persistent enough to have potential to subsequently enter surface water. Antimicrobials, however, can enter surface water through other exposure pathways without undergoing wastewater treatment. For example, antimicrobials can be released to storm drains and travel to surface water. In addition, antimicrobials can reach surface water by way of run-off from structures built with or painted with materials treated with products containing antimicrobials. Furthermore, some antimicrobials can be applied directly to surface water. Estimating

	Narration – Introduction to Down-the-Drain Assessment
	potential exposures to antimicrobials that can reach surface water through these other exposure pathways without going to a WWTP would be outside the scope of a down-the-drain assessment.
5	The large majority of wastewater treatment plants in the United States employ biological treatment; activated sludge treatment is the most common method of biological treatment. This slide provides a general schematic of a WWTP that employs activated sludge treatment. Wastewater treatment involves several steps, such as filtering, settling of solids, biological treatment, and anaerobic digestion, to name a few. In an activated sludge wastewater treatment plant, biological treatment is accomplished by activated sludge microorganisms.
6	Activated sludge consists of a mixed community of microorganisms consisting of approximately 95 percent bacteria and 5 percent higher organisms, such as protozoa, rotifers, and higher forms of invertebrates. The activated sludge process is a biological wastewater treatment process which speeds up waste decomposition by depleting and/or clumping organic matter and contaminants. Wastewater is transported to an activated sludge basin which is aerated and agitated. The activated sludge is allowed to settle out by sedimentation and may be wasted and then disposed or reused and returned to the activated sludge basin. Although many chemical substances can adversely affect these microorganisms, antimicrobial pesticides can be of particular concern since these chemicals are designed to kill microorganisms. When products containing antimicrobials are rinsed down a drain which leads to a WWTP, activated sludge microorganisms can potentially be wiped out or inhibited leading to ineffective treatment of incoming wastewater and subsequent release of antimicrobials, increased amounts of organic matter, and release of other chemical substances to surface water downstream of the WWTP. Release of these undesirable substances can degrade surface water quality and potentially lead to adverse effects to aquatic organisms and humans.
7	What is a down-the-drain assessment? A down-the-drain assessment considers the potential for the antimicrobial pesticide to pass through WWTP effluent to surface water where aquatic organisms and humans may be exposed. The potential for an antimicrobial to end up in WWTP effluent is driven in part by the potential adverse effects of the antimicrobial on microorganisms in the biological treatment process of a WWTP. This can be of particular concern for chemical substances such as antimicrobials that are designed to kill or slow the growth of microorganisms.

	Narration – Introduction to Down-the-Drain Assessment
8	Although there are new data requirements for assessing potential exposures and risks to antimicrobials released down-the-drain, these data requirements are not intended to increase economic burden; they are intended to provide more realistic, less conservative estimates of exposure than could be obtained using default assumptions. Only data for the particular chemical properties and use patterns that are needed to assess risk are required. Potential adverse effects of the antimicrobial to WWTP microorganisms are considered in determining WWTP data requirements. One mission of OPP is to assess potential adverse impacts from antimicrobial pesticides that are being released to the environment and to manage potential risks of these antimicrobial pesticides without bias.
9	This part of the presentation focuses on key elements of a down-the-drain assessment. This slide lists the 12 major use patterns for antimicrobial pesticides. OPP has developed an Antimicrobial Use Site Index, or USI, designed to provide guidance on determining the scope of risk assessments and data requirements for specific use sites within these 12 major antimicrobial use patterns. OPP has determined that there may be the potential for down-the-drain releases for all use patterns with the exception of aquatic areas.
10	A down-the-drain assessment may be appropriate when any antimicrobial is used in a manner in which it can be discharged to WWTPs, is persistent enough to enter WWTPs, and is persistent enough to subsequently be discharged to surface water downstream of these WWTPs. The following examples describe circumstances when these criteria would **not** be met. If a chemical is incorporated into an end-use product that would not be expected to come into contact with water and be released to a WWTP, then no down-the-drain assessment would be needed. For example, an antimicrobial used as a materials preservative in a mattress would not be expected to be released down-the-drain since the mattress would not be expected to be washed or rinsed. In addition, if a chemical is used in an end-use product that would be released down-the-drain, but degrades or dissociates either before it reaches a WWTP or during transport within a WWTP and the degradation or dissociation products have negligible toxicity to aquatic organisms, then no down-the-drain assessment would be needed. For some use patterns, OPP consults the Organization for Economic Cooperation and Development Emissions Scenario Documents, or OECD ESDs, for additional guidance on the types of scenarios which are likely to involve releases to WWTPs.
11	If after consulting the USI one determines that a product containing an antimicrobial has the potential to be discharged to a WWTP, how does one determine whether the antimicrobial is persistent enough that a down-the-drain assessment is needed?

	Narration – Introduction to Down-the-Drain Assessment
	There are new data requirements in the Final Rule for Part 158 subpart W, also referred to as "Data Requirements for Antimicrobial Pesticides", that can be used to determine environmental fate, transport, and effects of antimicrobials during wastewater treatment. Of the 11 new data requirements in 158W, six of these support down-the-drain assessments. These new data requirements, which are discussed more fully in the slides that follow, include WWTP tests for microbial respiration inhibition, listed as number 3 on this slide; sludge sorption, listed as number 8 on this slide; and biodegradation, listed as numbers 4 through 7 on this slide. Although there are four WWTP biodegradation tests listed within the 11 new data requirements, results for only one are needed for a down-the-drain assessment. The selection of an appropriate WWTP biodegradation test will be discussed later in this presentation.
12	There are three types of WWTP studies: a toxicity study, a sorption study, and a biodegradation study. Results of an Activated Sludge Respiration Inhibition, or ASRI, study are used to determine toxicity of a chemical substance to activated sludge microorganisms. If toxicity is high enough, this can lead to respiration inhibition of activated sludge microorganisms. Respiration inhibition impacts the ability of these microorganisms to remove organic matter and effectively treat wastewater. Sometimes toxicity can lead to an upset of the activated sludge basin. Results of the ASRI test are expressed as an IC_{50} value, sometimes also referred to as an EC_{50}. An IC_{50} value is a measure of the concentration of a chemical substance that inhibits 50 percent of the test microorganisms. The results of an ASRI test are also used to determine which type of WWTP biodegradation test would be required, a ready biodegradability test or a biodegradation simulation test. If a chemical substance is too toxic to microorganisms, the performance of the ready biodegradability test can be compromised and a biodegradation simulation test would be required. The protocol for the ready biodegradability test states that chemical substances with EC_{50} values of 20 mg/L or less are likely to pose serious problems for this test. Under such circumstances, a WWTP biodegradation simulation test, which performs adequately with chemical substances that are highly toxic to WWTP microorganisms, would be required. These tests include (1) Simulation test – aerobic sewage treatment: activated sludge units; (2) Simulation tests to assess the biodegradability of chemicals in discharged wastewater; and (3) Porous Pot Study. The results of an Activated Sludge Sorption Isotherm, or ASSI, test are used to determine the extent to which a chemical binds or is sorbed to sludge biomass where it may be removed during wastewater treatment along with other solids by clarification compared to the extent to which a chemical remains dissolved in the aqueous phase where it is subject to removal by biodegradation, chemical interactions, and/or volatilization. OCSPP guideline numbers and test notes for these WWTP tests can be found in the Environmental Fate Data Requirements Table located in Section 158.2280 of Part 158W. Test notes provide information to help determine specific conditions and exceptions to a requirement to perform WWTP and other fate and transport tests. For example, an ASSI test is required if the log Kow of the antimicrobial is 3.0 or higher, but not required if the

	Narration – Introduction to Down-the-Drain Assessment
	log Kow is less than 3.0. It is important to read these test notes to understand the conditions and exceptions for requiring WWTP tests for antimicrobials. Environmental fate test results for tests other than WWTP tests, such as aerobic aquatic metabolism, may also inform a down-the-drain assessment. Consult the Environmental Fate and Transport training video for Part 158W to obtain more information on environmental fate testing for antimicrobials released down-the-drain.
13	The flow chart on this slide presents the decision tree that describes the WWTP testing scheme for antimicrobials. The key at the upper left hand corner of this slide identifies the meaning of acronyms used in this decision tree. The abbreviation ASRI stands for Activated Sludge Respiration Inhibition study. ASSI stands for Activated Sludge Sorption Isotherm study. BAS stands for Biodegradation in Activated Sludge, which is one of the three biodegradation simulation tests. Note that the Porous Pot study found in this decision tree is also a biodegradation simulation study. Ready Bio stands for ready biodegradability study. EC_{50} is the concentration of a chemical substance that exhibits an inhibitory or toxic effect on half of the microorganisms in a test population, in this case activated sludge microorganisms. The lower the EC_{50} value, the higher the toxicity. The first step for the decision tree is to perform an ASRI study. If the result of the ASRI test is an EC_{50} value less than or equal to 20 mg/L, a biodegradation simulation test is required. In addition, an ASSI test would be required unless the antimicrobial meets any criteria in the test notes that would exempt this test. If the result of the ASRI test is EC_{50} greater than 20 mg/L, one can perform either a ready biodegradability test or a biodegradation simulation test; if a ready biodegradability test is performed and the chemical fails the ready biodegradability test, a biodegradation simulation test will be required. In addition, an ASSI test would be required unless the antimicrobial meets any criteria in the test notes that would exempt this test. An example of a criterion that would exempt an antimicrobial from an ASSI test would be that the chemical has a log Kow less than 3.0 The results of these WWTP tests would be used to determine percent removal of a chemical during wastewater treatment through sorption and biodegradation in the activated sludge basin.
14	Key input parameters needed to perform a down-the-drain assessment include: • Removal during wastewater treatment; • Concentrations of concern, or COCs, for aquatic organisms; and • Environmental loading The results of a down-the-drain assessment are usually based on a probabilistic approach. The probabilistic approach estimates the number of days per year of release to the aquatic environment that a concentration of concern, or COC, for aquatic organisms is exceeded downstream of multiple WWTPs to which an antimicrobial is discharged. For flowing freshwater bodies, the ratio of the distribution of stream flows to WWTP flows is used to predict exposure potential.

	Narration – Introduction to Down-the-Drain Assessment
	Note that an alternative to a probabilistic approach is a deterministic approach that provides a point estimate based on single values for stream flow and plant flow at a specific location. This alternative approach is useful for providing an upper-bound estimate of the concentration of a chemical substance discharged from a wastewater treatment plant at a specific location rather than estimating results based on multiple locations. A variation of this alternative approach is estimating an end-of-pipe concentration for a WWTP discharge to a non-flowing water body such as a lake, bay, tidally-influenced water body, or ocean. The next few slides discuss the key input parameters of a down-the-drain assessment in more detail.
15	Some of the key mechanisms by which chemical substances can be removed during wastewater treatment include: (1) biodegradation by WWTP microorganisms; (2) sorption to activated sludge biomass and removal along with other solids by clarification; (3) volatilization/stripping; and (4) hydrolysis. Biodegradation and sorption are key inputs for performing a down-the-drain assessment and can be estimated based on results from guideline studies. Volatilization and stripping may be important for some chemical substances and can be estimated using models, such as the Sewage Treatment Plant, or STP model, included in EPA's Estimation Program Interface or EPI-Suite. Hydrolysis is another key mechanism for degradation of chemical substances and is often estimated based on results from guideline studies.
16	Concentrations of concern, or COCs, for aquatic organisms are another set of key input parameters required to perform a down-the-drain assessment. Concentrations of concern are used in probabilistic assessment approaches and are derived from safety factors applied to measurement or toxicity endpoints for aquatic organisms. Measurement or toxicity endpoints, such as the LC_{50}, the concentration that is lethal to 50 percent of test organisms, and NOAEC, or No Observed Adverse Effects Concentration, are developed from ecological toxicity tests on aquatic organisms that represent key taxonomic groups including fish, such as rainbow trout; invertebrates, such as water fleas; sediment-dwelling or benthic organisms; algae; and aquatic vascular plants. The LC_{50} is an acute effects level and the NOAEC is a chronic effects level. Levels of Concern, or LOCs, are safety factors applied to toxicity endpoints to indicate whether or not there may be a presumption of risk. Presumptions of risk include: a presumption of acute risk to non-listed species; a presumption of acute risk to listed or endangered species; or a presumption of chronic risk to non-listed and listed or endangered species. An LOC of 0.5 is applied to an acute toxicity endpoint to determine the presumption of acute risk to non-listed aquatic species. The corresponding COCs used to determine whether or not there may be a presumption of acute risk to non-listed aquatic species would be half of the LC_{50} value. An LOC of 0.1 is applied to an acute toxicity endpoint to determine the presumption of acute risk to listed aquatic species, such as threatened or endangered aquatic species. The

	Narration – Introduction to Down-the-Drain Assessment
	corresponding COCs used to determine whether or not there may be a presumption of acute risk to listed or endangered species would be one-tenth of the LC_{50} value. An LOC of 1.0 is applied to a chronic toxicity endpoint, such as the NOAEC, to determine the presumption of chronic risk to both non-listed and listed aquatic species. The corresponding COC used to determine whether or not there may be a presumption of chronic risk to non-listed and listed aquatic species would be the NOAEC value. Risk quotients consist of estimated environmental concentrations, or EECs divided by toxicity endpoints, such as the LC_{50} or NOAEC. Risk quotients are used in deterministic approaches based on point estimates. In probabilistic assessments, the estimate of the number of days per year that the estimated surface water concentrations downstream of wastewater treatment plants exceed COCs for aquatic organisms serves as a basis for predicting the magnitude of exposure of aquatic organisms to a chemical substance being assessed. There are several uncertainties that should be considered for any ecological risk assessment. For one, the value for a given taxonomic group that is used in the assessment is that for the most sensitive species tested. There is no way, however, to determine how the sensitivity of the tested species compares to other species that have not been tested. Also, laboratory animals are different from wild species since the laboratory setting is a controlled environment in terms of water chemistry and temperature. Predator/prey stress and effects in the ambient environment could be different. For these reasons, safety factors, or LOCs are applied to determine presumption of acute and chronic risks to aquatic organisms.
17	Environmental loading is also a key input parameter required to perform a down-the-drain assessment. Information on maximum annual production volume is a key input parameter for down-the-drain releases to domestic WWTPs. Domestic WWTPs, also referred to as municipal WWTPs, receive wastewater from residential, commercial, and institutional establishments. To model the contribution of an antimicrobial from domestic WWTPs that are distributed throughout the United States, the down-the-drain model uses the maximum annual production volume of the antimicrobial to estimate a daily per capita release of the chemical substance to domestic WWTPs. Information on application rates from antimicrobial product labels is used, along with some other information about specific industrial use, to estimate environmental releases for industrial facilities expressed in kilograms per site per day. Examples of some industrial facilities that use antimicrobials include once-through and recirculating cooling water systems and pulp and paper mills. The label also provides information on application rates for different methods of product application, such as slug or intermittent and continuous applications. Different methods may be relevant depending on whether the treatment is an initial one-time treatment requiring a relatively high dose or a maintenance treatment generally applied more frequently or continuously at a lower dose.

	Narration – Introduction to Down-the-Drain Assessment
	It is helpful to obtain maximum annual production volume information from the applicant who is requesting EPA to register or reregister a product containing the antimicrobial as an active ingredient. There are data bases, such as the Section 7 Tracking System, that may include this type of information. Yet another source is the Kline Market Research report. It is particularly helpful to have annual production volume information based on the end-use or end-uses being registered rather than for all possible end uses in which the antimicrobial is an ingredient. Focusing more on the amount expected to be used for the use sites being considered for a regulatory decision will provide a less conservative estimate of exposure.
18	In summary, key inputs for down-the-drain modeling include: COCs derived from safety factors applied to results of ecotoxicity tests for aquatic animals and plants, such as an EC_{50} or No Observed Adverse Effects Concentration, also referred to as a NOAEC; estimated environmental loadings to wastewater treatment facilities expressed in kg/year for domestic wastewater treatment plants and kg/site/day for industrial wastewater treatment facilities; and percent removal during wastewater treatment by way of biodegradation and/or sorption, or other fate and transport processes.
19	The model AD uses to estimate potential exposures from down-the-drain releases was developed by OPPT as a screening tool. Screening tools are designed to use readily available data in models that require relatively few input values to quickly provide conservative results. Conservative results reflect estimated concentrations of chemicals and estimated exposures to humans and ecological organisms that are likely to be at the high-end of or higher than concentrations that might be expected in a real-world setting.
20	The modeling tool we use for down-the-drain assessment is the Exposure and Fate Assessment Screening Tool, or E-FAST. E-FAST has four modules that provide screening-level estimates of exposure. These modules include: General Population and Ecological Exposure from Industrial Releases, also referred to as the Industrial Releases module; Down-the-Drain; Consumer Exposure; and Probabilistic Dilution Model, or PDM. AD uses the Industrial Releases module and the Down-the-Drain module to assess potential exposures to humans and aquatic organisms downstream of wastewater treatment plants. Although E-FAST has a stand-alone PDM module, both the Industrial Releases module and the Down-the-Drain module have a PDM option. The PDM option was briefly described in Slide 14 of this presentation. AD generally uses the PDM option to estimate magnitude of exposure and risk to aquatic organisms downstream of wastewater treatment plants. The Industrial Releases and Down-the-Drain modules also have the capability of estimating exposures from releases of chemicals to landfills and air, but AD's analyses are usually limited to considering releases to surface water since surface water is the environmental medium affected by down-the-drain releases to WWTPs. These modules can also provide estimates of potential exposure to humans from ingestion of drinking water and fish.

	Narration – Introduction to Down-the-Drain Assessment
21	The key element that dictates which of the two modules of E-FAST to use to assess exposure to aquatic organisms downstream of WWTPs is the type of wastewater treatment plant to which an antimicrobial is discharged. The Down-the-Drain module is appropriate for screening-level assessments of exposures to antimicrobials that are discharged to domestic WWTPs. The General Population and Ecological Exposure from Industrial Releases module is appropriate for screening-level assessments of exposures to antimicrobials that are discharged to industrial WWTPs.
22	The pictorials on this slide provide simple illustrations of a domestic wastewater source and an industrial wastewater source. The pictorial on the left is a kitchen sink that might be found at a residential, commercial, or institutional dwelling whose wastewater is discharged to a domestic wastewater treatment plant. The pictorial on the right depicts effluent from a discharge pipe from a pulp and paper mill following industrial wastewater treatment.
23	The Down-the-Drain module is used to estimate exposures of humans and aquatic organisms to chemical substances that are used in products that enter domestic wastewater treatment plants from residential, commercial, and institutional sources. Products released down-the-drain from residential, commercial, and institutional sources can include laundry detergents, toilet bowl cleaners, bathroom sink and tile cleaners, sanitizer and disinfectant products that are rinsed or dumped down-the-drain following application and/or use. Specialty products may also be rinsed down-the-drain at institutional establishments, such as hospitals, and at commercial establishments, such as car washes, auto repair facilities, laundromats, and dry cleaners.
24	For a down-the-drain assessment, the amount of the antimicrobial pesticide released to WWTPs for the product being evaluated, also referred to as the annual loading, is used, along with the population served, to estimate the daily per capita household wastewater release in grams per person per day. If no information is available on the amount of antimicrobial that is used in products that are released down-the-drain, then the maximum annual production volume of the antimicrobial is used as input to the Down-the-Drain module to provide a conservative, upper-bound estimate. If no potential concern is triggered, then no further refinement is needed. If production volume data are not available, hypothetical production volume values can be used along with COCs for aquatic organisms and estimates of removal during wastewater treatment to determine the amount of antimicrobial released down-the-drain that would be expected to trigger a potential concern for exposure and risk to aquatic organisms. If the data on removal during wastewater treatment are not available, such as data on WWTP biodegradation and/or sorption, no removal during wastewater treatment can be assumed to obtain a conservative estimate of potential exposure.
25	The Industrial Releases model is appropriate for assessing potential exposure to antimicrobials used in industrial facilities that have their own WWTPs associated with

	Narration – Introduction to Down-the-Drain Assessment
	the industrial facility. Notable examples of industrial facilities include cooling water towers or systems, pulp and paper mills, and facilities that use metal working fluids.
26	Many of the input parameters for the Industrial Releases module are the same as those for the Down-the-Drain module. A key difference, however, is the input parameter used for the annual loading of the antimicrobial pesticide to WWTPs. Whereas the Down-the-Drain module internally calculates a per capita loading in grams per person per day based on the annual loading of the antimicrobial, the Industrial Releases module requires a loading of kg/site/day at a standard industrial facility, which is based on application rate information from the product label and other information that is specific to the type and size of industrial facility being evaluated. Although the environmental loading information for the Down-the-Drain module is different from that for the Industrial Releases module, the outputs are the same. Both modules provide estimates of the number of days per year of exceedance of concentrations of concern for aquatic organisms.
27	Both the Down-the-Drain and the Industrial Releases modules of E-FAST can estimate concentrations in flowing water bodies, such as rivers and streams, and numbers of days of exceedance of concentrations of concern for aquatic organisms. E-FAST, however, cannot be used to perform a probabilistic assessment of potential exposures of humans and aquatic organisms to chemical substances released to non-flowing water bodies, such as lakes, streams, bays, estuaries, or oceans downstream of municipal and industrial WWTPs. A screening-level evaluation can be performed, however, by estimating the concentration of an antimicrobial in a WWTP discharge pipe prior to being released to a non-flowing water body. This concentration of an antimicrobial in the WWTP discharge pipe is referred to as an "end-of-pipe" concentration. The "end-of-pipe" concentration is an estimate of the concentration of antimicrobial pesticide released prior to dilution by the receiving water body.
28	For releases of antimicrobials from both municipal and industrial WWTPs, potential exposures to both humans and to ecological organisms located downstream of these types of WWTPs can be estimated. For ecological assessments, the Down-the-Drain and Industrial Releases modules require COCs developed from ecotoxicity endpoints for aquatic organisms, such as LC_{50} and NOAEC values, and use these COC values along with the ratio of the distributions of stream flows to WWTP flows to estimate potential risks to aquatic organisms, expressed as the number of days per year of exceedance of COCs.
29	For human health assessments, both the Down-the-Drain and Industrial Releases modules use the ratio of the distributions of stream flows to WWTP flows to estimate concentrations of antimicrobials in surface water downstream of WWTPs. These surface water concentrations form the basis of upper bound estimates of potential exposures of humans to chemical substances from ingestion of drinking water and fish. Concentrations in surface water based on harmonic mean flows, which are the inverse mean of reciprocal daily arithmetic mean flow values, are used to evaluate potential chronic risks to humans. Concentrations in surface water based on 30Q5 stream flow

	Narration – Introduction to Down-the-Drain Assessment
	values, which are the lowest 30 consecutive-day average stream flow values that occur over a 5-year period, are used to estimate potential acute risks to humans.
30	This is an example of a table of ecological risk results which are expressed as the predicted number of consecutive days that discharge to surface water would result in exceedance of concentrations of concern for species selected to represent categories of aquatic taxa, such as freshwater fish, freshwater invertebrates, and aquatic plants. The Down-the-Drain and Industrial Releases modules of E-FAST have options to run a "high-end" scenario and an "average case" scenario. The high-end scenario is based on results from the upper 10th percentile of estimated surface water concentrations where the WWTP flow contributes considerable volume relative to stream flow. The average case scenario results are based on the 50th percentile or median estimated surface water concentrations where the WWTP and plant flows are more typical. The results are presented as the number of consecutive days per year that discharge to surface water would result in exceedance of concentrations of concern for organisms selected to represent key categories of aquatic organisms. Generally, OCSPP considers 20 or more consecutive days per year of exceedance of COCs a potential concern for chronic toxicity endpoints and 1 day or more per year of exceedance of COCs as a potential concern for acute toxicity endpoints.
31	For human health assessments, results of estimated surface water concentrations from the Down-the-Drain and Industrial Releases modules of E-FAST can be used as a screen to determine whether further refinement to the drinking water portion of a dietary assessment would be needed. The surface water concentrations used for the screen would be based on conservative assumptions, such as no removal of chemical during wastewater treatment, surface water concentrations immediately downstream of the WWTP discharge point, no biodegradation or sorption of the chemical substance in surface water from the point of discharge from the WWTP to the point of intake at the drinking water utility. If estimates of exposure to humans from ingestion of drinking water based on this screen indicate no potential for concern, then no further refinement would be needed. The results of estimated surface water concentrations from the Down-the-Drain and Industrial Releases modules of E-FAST and the bioconcentration factor, or BCF, in fish can also be used as a screen to estimate potential exposure of humans to chemical substances from ingestion of fish located downstream of WWTPs. The human health dietary assessment may consider this potential exposure pathway If there is evidence that an antimicrobial would be expected to bioconcentrate in fish.
32	The goal of risk management is to balance the risks and the benefits. To achieve this goal, questions that follow are considered: What are the potential risks? What are the risks from the alternative uses? What are the benefits from the use of the product being evaluated?

	Narration – Introduction to Down-the-Drain Assessment
	Risk management is more of an art than a science. Risk managers try to balance risks and benefits by understanding and managing the risks.
33	When reviewing and interpreting results from Down-the-Drain assessments to develop risk management options, there are a number of key points to consider. First, since Down-the-Drain assessments are relatively new to the Antimicrobials Division, or AD, and the regulated community, these assessments may require more explanation than some other types of assessments. Also, since a Down-the-Drain assessment is a screening assessment, it is conservative by design. In the absence of data, it is necessary to use default inputs. For example, while there may be some qualitative evidence to indicate that an antimicrobial might be expected to biodegrade rapidly, without a study that provides results to support this evidence, biodegradation potential cannot be quantified and considered in the assessment. Finally, there are no "bright lines" for risk management. The main purpose of many antimicrobial pesticides is to kill microorganisms, as well as some types of algae. Other antimicrobials are biocides designed to kill organisms, such as zebra mussels, so they may also be expected to adversely affect aquatic invertebrates. With these considerations in mind, if the results of the risk assessment indicate that the chronic COC for aquatic invertebrates is exceeded 20 consecutive days a year or more, risk managers need to ascertain whether there are factors that can mitigate potential concerns.
34	In conclusion, when evaluating results from down-the-drain assessments, here are some further questions to consider regarding managing risks: What uncertainties influence the results of the risk assessment? Would additional and/or better data help reduce uncertainties? Would filling data gaps that contribute to uncertainties be likely to lead to less conservative results? Are there measures that can be implemented to limit or mitigate potential risks? Can language on the label be revised to lower potential exposures by limiting application rates, application frequencies, or use sites? How do the potential risks from use of this product compare to risks from using other products that contain alternative chemicals?
35	This concludes the presentation on "Introduction to Down-the-Drain Assessment". If you need further information or have questions on down-the-drain assessment, please contact the Antimicrobials Division Ombudsman at OPP_AD_Ombudsman@epa.gov. Thanks for your interest.