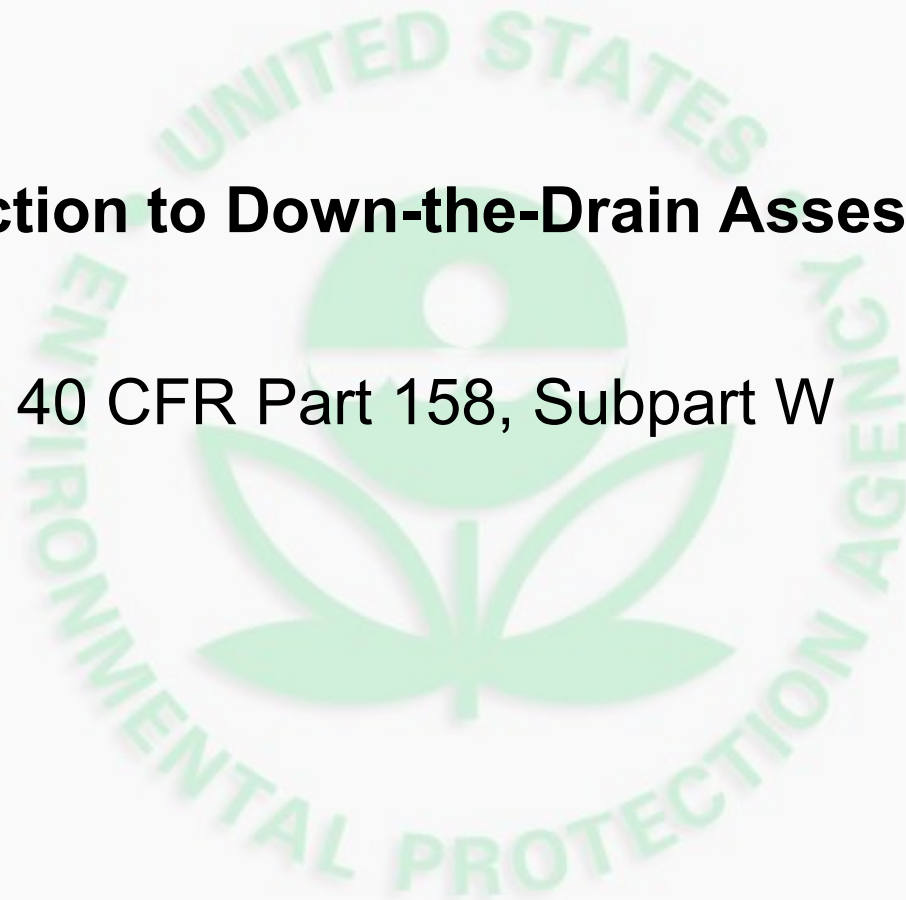


# **Introduction to Down-the-Drain Assessment**

40 CFR Part 158, Subpart W





# Agenda

- Background
- The Elements of the Assessment
  - What use patterns
  - Required Data
  - Assessment tools
- Results and Interpretation
- Risk Management Considerations



# Background

- Purpose: Provide a broad overview of Down-the-Drain (DtD) assessments including the what, when, why and how of DtD assessment.
- Questions to answer:
  - What is a Down-the-Drain assessment?
  - When do we conduct them?
  - Why do we do it?
  - How are the assessments conducted?
  - What does it all mean?



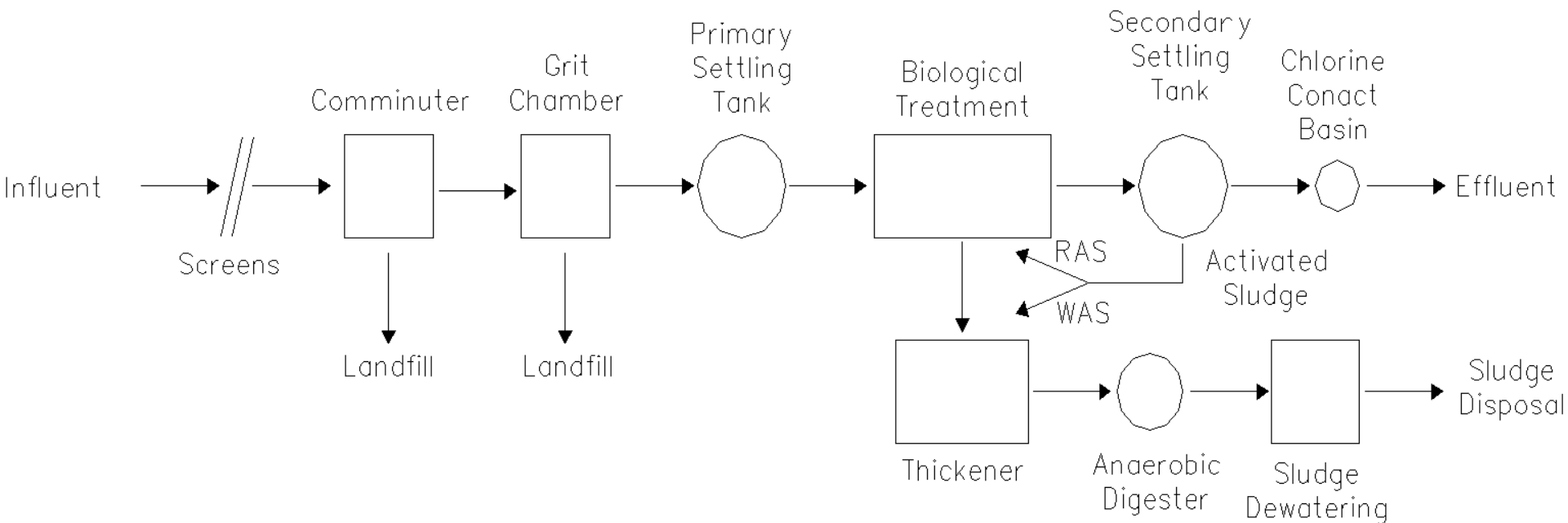
# Background

Before 158W was proposed and finalized:

- OPP assumed that most antimicrobial compounds particularly the “indoor uses” went down the drain to a Wastewater Treatment Plant (WWTP), and that WWTP processes would mitigate environmental concerns.
- Following the implementation of 158W, OPP acknowledged that antimicrobials released down-the-drain are not necessarily removed during wastewater treatment and have the potential to enter surface water.



# Wastewater Treatment Plant Schematic





# Background

- WWTPs have microorganisms (activated sludge) which function to break down organic matter and contaminants in wastewater.
- When antimicrobials are rinsed down a drain which leads to a WWTP, they can harm these microorganisms resulting in ineffective water treatment of the antimicrobial product, organic matter, and other contaminants.



## Background

### 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 adverse effects of the antimicrobial to WWTP microorganisms.



# What is a Down-the-Drain Assessment?







## Elements of the Assessment

# 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



## Elements of the Assessment

? Down-the-Drain Assessment is Appropriate when any antimicrobial:

- Is used in a manner in which it can be discharged to a WWTP **and**
- Is persistent enough to enter WWTPs and be discharged to surface water downstream of these wastewater treatment plants



# Eleven “New” Data Requirements

1. Photodegradation in soil
2. Soil residue dissipation
- 3. Modified 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 (ASSI) study**
9. Developmental neurotoxicity
10. Immunotoxicity
11. Nature of the residue on surfaces.



## Elements of the Assessment

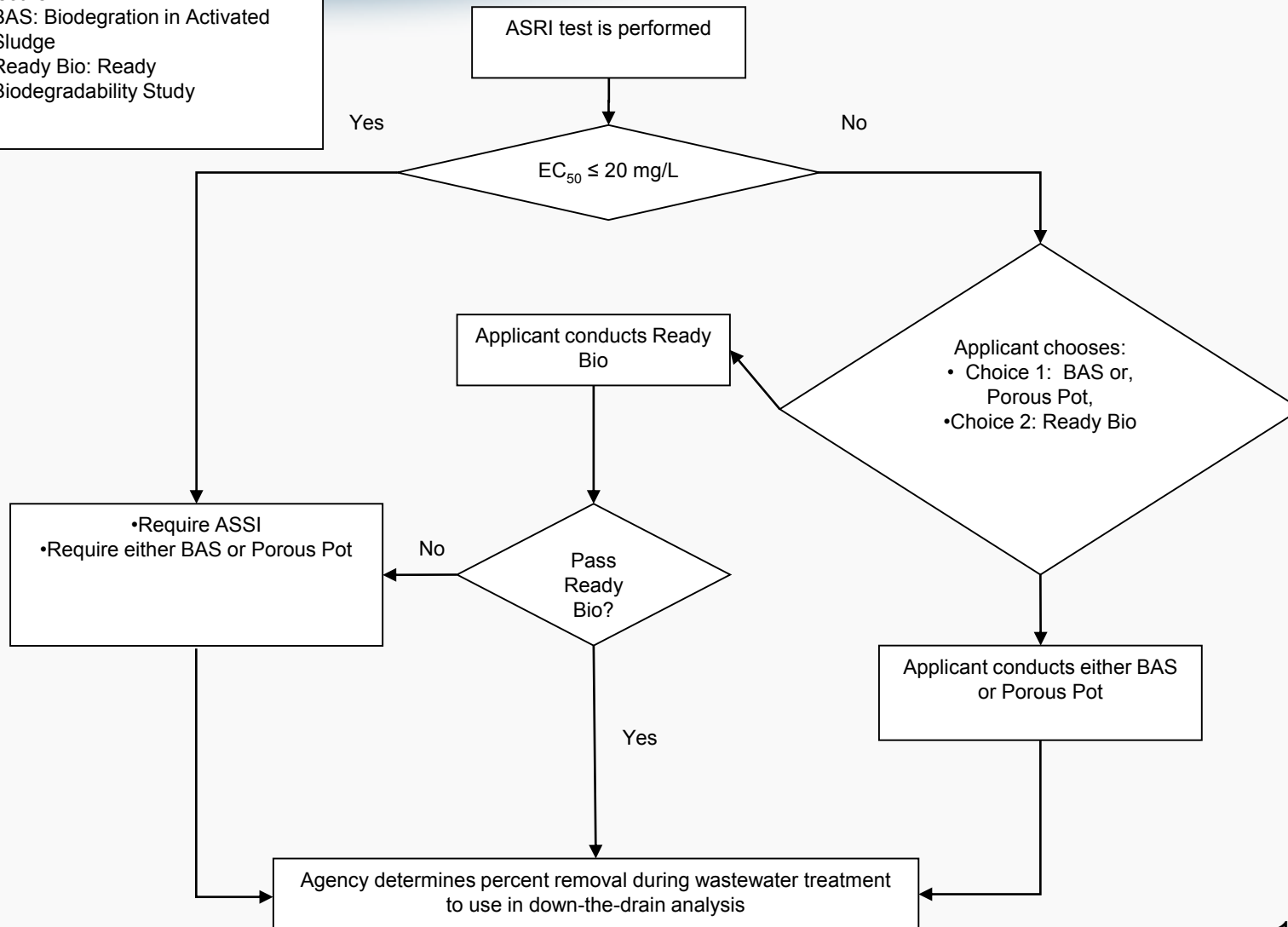
# New Data Requirements

- Three types of WWTP studies:
  - Activated Sludge Respiration Inhibition test determines toxicity of antimicrobials to microorganisms in the activated sludge basin; also determines type of WWTP biodegradation test required.
  - WWTP biodegradability tests determine biodegradability during wastewater treatment. Can choose one of 4 tests depending on toxicity to microorganisms.
  - Activated Sludge Sorption Isotherm test results are used to determine the extent to which a chemical binds or sorbs to sludge biomass and is removed with other solids during 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.



**Key:**

ASRI: Activated Sludge  
Respiration Inhibition Study  
ASSI: Activated Sludge Sorption  
Isotherm  
BAS: Biodegradation in Activated  
Sludge  
Ready Bio: Ready  
Biodegradability Study





# Elements of Assessment

- DtD Assessment Inputs:
  - Removal during wastewater treatment
  - Concentrations of Concern (COCs) for aquatic organisms
  - Environmental loading
- Probabilistic Approach based on distributions of values
  - DtD assessment is 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 for aquatic organisms is exceeded.
  - For flowing freshwater bodies, ratio of distribution of stream flows to WWTP flows is used to predict exposure potential.
- Deterministic Approach based on single values for a specific location



## Elements of the Assessment

### Key Mechanisms of Removal of Antimicrobials During Wastewater Treatment

- Biodegradation by WWTP microorganisms
- Sorption to activated sludge biomass with subsequent removal by clarification
- Volatilization/stripping
- Hydrolysis



## Elements of the Assessment

# Key Inputs - COCs

- COCs for aquatic organisms are used in probabilistic assessment approaches and are derived from safety factors applied to measurement or toxicity endpoints for aquatic organisms.
- Based on results of toxicity tests on fish, invertebrates (waterfleas), sediment dwelling (benthic) organisms, aquatic vascular plants, and algae. Test results = Toxicity endpoints such as LC50 and NOACC.
- LOCs or Levels of Concern are safety factors applied to toxicity endpoints to indicate whether or not there may be a presumption of risk, such as
  - presumption of acute risk to non-listed species
  - presumption of acute risk to listed (endangered or threatened) species
  - presumption of chronic risk to non-listed and listed species





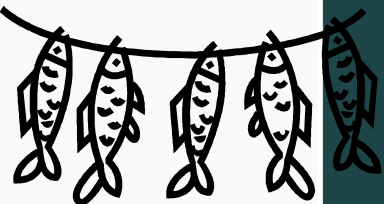
# Elements of the Assessment

## Key Inputs - Environmental Loading

- Domestic or Municipal WWTPs: Production volume (kilograms per year)
- Industrial WWTPs: Product application rate and industry data (kg/site/day)

### Ecotox Data:

- COCs for aquatic organisms



### From Risk Manager:

- Loading
- Maximum annual production volume
- Application rate



## KEY INPUTS

### Down-the-Drain Data (new in 158W):

- Biodegradation
- Sorption to sludge



### Fate/PChem Data:

- Log Kow
- Hydrolysis rate





## Assessment Tools

- **OPPT Screening-Level Tools**: use readily available data and models that require relatively few input values and are designed to quickly provide conservative results.
- With screening-level tools predicted concentrations of chemicals and predicted exposures are likely to be higher than those in the real-world.





# Assessment Tools: E-FAST

## Exposure and Fate Assessment Screening Tool (E-FAST)

- E-FAST consists of four modules that provide screening estimates of exposure:
  - General Population and Ecological Exposure from Industrial Releases, also referred to as Industrial Releases Module
  - Down-the-Drain
  - Consumer Exposure
  - Probabilistic Dilution Model
- Although E-FAST has a stand-alone PDM module, both the “Industrial Releases” and Down-the-Drain modules have a PDM option.
- AD generally runs “Industrial Releases” and “Down-the-Drain” modules using the PDM option.



# Down-the-Drain Assessment

AD presently uses two modules that are included in the Exposure and Fate Assessment Screening Tool (E-FAST) system:

- 1) **Down-the-Drain:** appropriate for screening-level assessments of exposures to antimicrobials that are discharged to domestic WWTPs.
- 2) **General Population and Ecological Exposure from Industrial Releases:** appropriate for screening-level assessments of exposures to antimicrobials that are discharged to industrial WWTPs.



Down-the-Drain



General Population and Ecological Exposure from Industrial Releases





# Down-the-Drain Module

- Appropriate for estimating potential exposure of humans and aquatic organisms to chemical substances that are used in products that enter domestic/municipal WWTPs from residential, commercial, and institutional antimicrobials used in households, medical premises, swimming pools, etc.
- These products can include laundry detergents; toilet bowl cleaners; bathroom sink, tub, and tile cleaners; and sanitizers and disinfectant products that are rinsed or dumped down-the-drain following application and/or use.





## Down-the-Drain Module -- Municipal WWTP

of an antimicrobial pesticide determined?

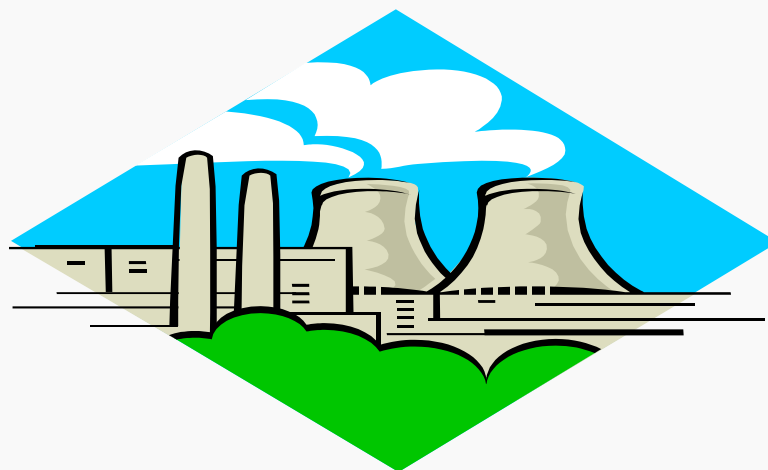
- The annual loading is derived from the maximum annual production volume of antimicrobial adjusted to consider the amount expected to go down the drain from use of the product being evaluated.
- For a conservative upper bound estimate, the entire maximum annual production volume of an antimicrobial is assumed to enter a WWTP. If no potential concern is triggered, no further refinement is needed.
- If production volume data are not available, hypothetical production volumes can be evaluated using COCs to determine amounts that trigger potential concerns.





## Industrial Releases Module- Industrial WWTPs

- Appropriate for antimicrobials used in large industrial facilities such as cooling water systems/towers, power plants, pulp and paper mills, and facilities that use metal working fluids.





## Industrial Releases Module

- Same inputs as for DtD module except that the application rate from product label and some industry-specific information are used to develop the loading to industrial WWTPs, which is expressed in kg/site/day.
- Different module in E-FAST, but no difference in assessment outputs.





# Results

## Down-the-Drain Assessment



### What do the results indicate?

**Ecological** -- Potential risks to aquatic organisms downstream of WWTPs expressed as number of days of exceedance of concentrations of concern (COCs) for aquatic organisms.

**Human** - Potential exposures of humans to chemical substances from ingestion of drinking water and fish located downstream of WWTPs



## Human Health Assessments: Surface Water Concentrations (SWCs)

- For human health assessments, both 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 SWCs form the basis of upper bound estimates of potential exposures of humans to chemical substances from ingestion of drinking water and fish.
- Harmonic mean stream flows are inverse mean of reciprocal daily arithmetic mean flow values: used to evaluate potential chronic risks
- 30Q5 stream flows are lowest 30 consecutive-day average stream flow values that occur over a 5-year period: used to evaluate potential acute risks



# Example -- Ecological Results

Average Case Scenario Estimates of Number of Days per Year of Exceedance of COCs for Aquatic Organisms Downstream of Moderate-Size Cooling Water Systems – Assumes No Removal During Wastewater Treatment

Environmental Release (kg/site/day)	Product Label Concentration (ppm)	Acute Fish	Chronic Fish	Acute Invert	Chronic Invert	Aquatic Plants
		<b># of Days per Year of Exceedance of COCs out of 360 Days of Release</b>				
1.7	24.4	11	22	34	50	44
0.41	5.9	4	9	15	24	21
0.13	1.95	1	4	7	12	10
0.03	0.5	0	1	2	4	3



# Human Risk Assessment Results

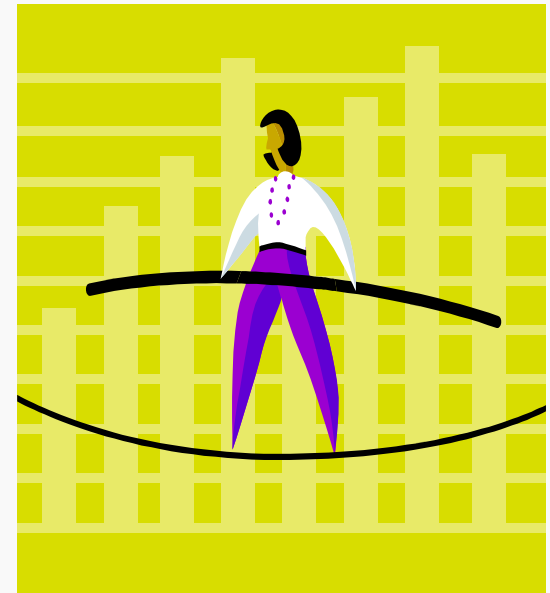
- Conservative concentrations in surface water can be used as a screen for drinking water portion of a dietary assessment.
- Conservative concentrations in surface water and bioconcentration factor (BCF) in fish can be used as a screen to evaluate potential of humans to be exposed to chemical substances from ingestion of fish located downstream of WWTPs.



# Risk Management

## Balance risks and Benefits

- What are the risks?
- What are the risks from the alternatives?
- What are the benefits from the use of this product?







# Considerations for Down-the-Drain Assessments



- The assessments are relatively new to AD and to the regulated community.
- These are screening assessments. Often we have to resort to default inputs.
- There are no “bright lines” for risk management.



# Risk Management Questions

- What uncertainties drive the assessment?
- Would better data help?
- Can you determine if the uncertainties make the assessment seem more or less conservative?
- Are there ways to limit or mitigate the risks?
- Can label language be revised to lower exposures by limiting application rate or use sites?
- How do the risks from use of this product compare to the risks from using products with alternative chemicals?



## For Further Information

- Need further information or have questions on Down-the-Drain assessment?
  - Please contact the Antimicrobials Division  
Ombudsman: [OPP\\_AD\\_Ombudsman@epa.gov](mailto:OPP_AD_Ombudsman@epa.gov)