Slide	Narration – Cooling Water Systems
1	Today we are going to talk about antimicrobials used in cooling water systems. This is part of our antimicrobial division training. Today's presenters will be Pat Jennings, Donna Randall, and Donald Wilbur.
2	This slide gives you an overview of our presentation today. In this presentation a number of topics will be covered including: function of cooling water systems, types of cooling systems which are basically recirculating and once-through, biofouling potential in once-through versus recirculating cooling water systems, basic approaches for modeling ecological exposures, ecological exposure modeling methodology for cooling water systems, evaluating potential effects to aquatic organisms, evaluating potential dietary exposure and effects to humans from ingestion of drinking water and fish.
3	We are now going to talk a little bit about water system function and types. The function of a cooling system is to remove heat from processes or equipment. Heat removed from one cooling medium is transferred to another medium or process fluid, usually water. Heated water can be handled in one of two ways. The water can be discharged at the increased temperature into a receiving body. That is once-through cooling system. Or it can be cooled and reused which is a recirculating cooling system.
4	This is a simplified diagram of the two general types of cooling water systems. The once though cooling water system is seen at the top of the slide and the recirculating cooling water system is seen at the bottom. You'll see that each system has a condenser. You'll also notice that make-up water is added to the recirculating cooling water system Condenser – In systems involving heat transfer, a condenser is a device or unit used to condense a substance from its gaseous to its liquid state, typically by cooling it; in this case, steam is condensed to water. In recirculating systems make-up water is added to offset water released via evaporation, leakage, and blowdown. Make-up water serves to keep the flow rate constant.
5	This slide goes over some general information about cooling water systems. There are basically two categories of cooling water systems. Electric generating facilities which is the majority and industrial non-utilities. The primary purpose of an electric generating facility is the generation and sale of electricity. Industrial non-utilities own generating capacity, but their primary purpose is not the generation and sale of electricity. These are electric generators that are co-located with other manufacturing activities such as chemical manufacturing or pulp and paper mills. In the US 90% of electricity comes from thermo-electric power plants such as coal, nuclear, natural gas and oil. The remaining 10% is produced by hydroelectric and other renewable energy facilities. Of thermoelectric generators in the US, 43% use once-through cooling and 56% use recirculating. According to USEPA types and numbers of electric generating facilities in the US in 2002 include: hydroelectric power, fossil fuel electric power, nuclear electric power, and other electric power. As of 2002, fossil fuel facilities comprised 58% of all electric generating facilities, hydroelectric comprised 19%, other electric power comprised 19%, and nuclear electric power comprised 4%.

6	This slide provides general information about once though cooling water systems. Steam electric facilities using once-through cooling water systems use large amounts of water. EPA calculated a discharge rate of 230 million gallons per day per cooling water system. Based on industry survey data, the average flow rate was approximately 305 million gallons per day per cooling water system. Very few new power plants use once-through cooling because of the disruptions such systems cause to local ecosystems from the significant water withdrawals involved and because of increased difficulty in siting power plants near available water sources
7	This slide presents general information about recirculating cooling water systems. Steam electric facilities using recirculating cooling water systems use smaller amounts of water than facilities using a once-through system. Based on industry survey data, the average blowdown flow rate was 0.94 million gallons per day. EPA calculated a flow rate of 6.04 Million gallons per day. These facilities require only about 5% of the water that once though circulating systems require. Discharge less than 1% of the flow typical of once-through systems is characteristic of recirculating cooling water systems.
8	This slide talks a little more about recirculating cooling water systems. Recirculating systems can be open or closed. In an open recirculating system cooling is achieved through evaporation which results in a loss of pure water from the system and a concentration of the remaining dissolved solids. Water must be removed, or blown down, to control concentration of dissolved solids and fresh water must be added to replenish the system. In a closed recirculating system water losses are usually small; little, if any, evaporation occurs. Water circulates in a closed cycle and is subjected to alternate cooling and heating without air contact. There is less susceptibility to biological fouling from slime and algae deposits than with open systems. Open recirculating systems provide the most common form of industrial cooling. AD's scenario for recirculating cooling systems is based on an open system.
9	We are going to talk a little bit about biofouling in this slide. Microbiological fouling in cooling systems is the result of abundant growth of algae, fungi, and bacteria on surfaces. Microbial growth on wetted surfaces can lead to formation of biofilms which can cause fouling and can adversely affect equipment performance, promote metal corrosion, and accelerate wood deterioration. Recirculating cooling water systems, whether open or closed, may support microbial growth, but fouling problems usually develop more quickly and are more extensive in open recirculating systems. Microbial growth is more rapid since microbes are scrubbed from the air and concentrate nutrients present in makeup water through evaporation. Once-through cooling water systems, since once-though systems contain relatively low levels of nutrients essential for microbial growth, growth is relatively slow.
10	Typically the majority of power generating facilities with once though and open cooing water recirculating systems are going to be located next to aquatic environments large enough to supply their daily water operational requirements such as small or large rivers, lakes, bays, and the ocean. This means that there are a wide variety of aquatic ecosystems that are potentially exposed to antimicrobials used in cooling water and/ or to their degredation and transformation products. The four examples I have provided on this slide include the Three Mile Island Nuclear Power Plant on the Susquehanna River; the Donald C.

	Cook Nuclear Power Plant on Lake Michigan; a coal-fired power plant on the Potomac River; and the Morro Bay gas-fired power plant on the coast of California. There are exceptions such as the Palos Verdes Nuclear Power Plant located in the desert outside Phoenix, AZ which uses about 130 to 150 million gallons per day of reclaimed municipal wastewater that is discharged into evaporation ponds after use. There are also facilities that use or supplement their daily operational water requirement with groundwater.
11	In addition to the variety of aquatic organisms that are potentially exposed to antimicrobials used in cooling water systems and/ or their transformation products, there's also the potential for terrestrial animals to be exposed. If an antimicrobial or one of its major degradates or transformation products is bioaccumulative food chain transfer may result in upper trophic level terrestrial wildlife being exposed. As represented in this side this essentially means birds and mammals may be exposed from ingesting fish, mollusks like clams and mussels, shrimp, crayfish, and other aquatic invertebrates that have been exposed to and accumulated the antimicrobial and/ or its transformation products. Humans too have the potential to be exposed in the same manor which I have included an example of on this slide with the fishermen fishing next to a power plant.
12	The ecological and fate assessment team developed ecological conceptual exposure model diagrams for the cooling water use pattern to summarize how nontarget organisms or receptors as they are called in the diagram may potentially be exposed to antimicrobials used in cooling water systems and the resulting changes to specific attributes of these nontarget organisms that are of concern. The ecological effects data requirements, which I'll be discussing later are geared to provide measurement endpoints used to either directly or indirectly evaluate the attribute changes in the diagram. The exposure modeling Pat is about to discuss provides estimated exposure concentrations reflecting the exposure pathways of concern outlined in the diagram for both freshwater and estuarine/marine nontarget organisms. You will also note on the diagram that the team included an inhalation exposure pathway for nontarget wildlife. For the most part, this pathway is not typically addressed via calculation of exposure and risk quotients. It is put there in case of a highly volatile and toxic compound where this would potentially be a pathway that should be addressed more quantitatively.
13	Exposure modeling estimates concentrations of an antimicrobial in the dissolved phase of the water column. For flowing freshwater bodies such as rivers and streams the ratio of the distribution of stream flows to cooling water system discharge flows are used to predict exposure. AD generally uses the General Population and Ecological Exposure from Industrial Releases Module of Exposure and Fate Assessment Screening Tool (E-FAST) with the probabilistic option. 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
14	AD uses a different approach for estimating exposure and risk to freshwater organisms in the sediment. To assess exposure in sediments AD uses a risk quotient approach or RQ approach. In the RQ approach, RQ is equal to the estimate of the concentration of antimicrobial in sediment divided by ecotoxicity endpoint value that is LC_{50} or the NOAEC established for freshwater benthic organisms. If the RQ>1, the level of concern for risk to freshwater benthic organisms is exceeded indicating potential concern. Sediment

	concentrations are determined by multiplying average leaching adsorption/desorption values by concentrations of antimicrobial in surface water predicted by E-FAST.
15	For estimating estuarine marine organisms in the water column these are some of the considerations. To assess exposure of estuarine marine organisms exposed to antimicrobials primarily via the water column AD uses a risk quotient approach. Results from E-FAST are not used. Since estuarine marine water bodies have no stream flows, it is inappropriate to use concentrations based on E-FAST results. E-FAST estimates ratios of distributions of stream flows to plant flows; estuarine marine water bodies are tidally-influenced and have no stream flows. A screening level estimate based on concentrations of antimicrobial at the point of discharge of cooling water prior to entry into the water body is used which is also referred to as an end-of-pipe concentration. RQs are estimated by dividing end-of-pipe concentrations by toxicity endpoints for estuarine marine organisms exposed via the water column. AD then determines dilution factors that would be needed to minimize potential risks.
16	For benthic dwelling estuarine marine organisms some key parts of the methodology are as follows. A risk quotient method is used. An upper bound estimate of exposure based on a residual concentration of antimicrobial at the discharge point (end-of-pipe concentration) is used to derive concentrations of antimicrobial in sediments. Worst case sediment concentrations are determined by multiplying average leaching adsorption/desorption values by end-of-pipe concentrations of antimicrobial. The risk quotient for estuarine benthic organisms is determined by comparing the worst case sediment exposure estimate to the available toxicity data for the most sensitive estuarine/marine organism.
17	Now I'm going to talk a little bit about the exposure modeling methodology for recirculating cooling water systems. Exposure to aquatic organisms is assumed to result predominantly from release of blowdown water. Key input parameters required to estimate recirculating cooling system exposures include: environmental release of antimicrobial to surface water expressed in kg/site/day, concentrations of concern for aquatic organisms usually in ug/L, standard Industrial Classification code to represent the ratio of stream flows to plant flows for cooling water system facilities usually this is SIC 4911 which represents Steam Electric Power Plants, percent removal of antimicrobial during wastewater treatment, annual number of days of release to surface water in days per year, and then selection of high-end or average case scenario.
18	The approach used to estimate potential exposures of freshwater organisms in the water column to antimicrobials released to surface water from recirculating cooling system blowdown water can be described in four steps. Step 1: estimate environmental release to surface water from recirculating cooling system blowdown water. Step 2: determine percent removal of antimicrobial during wastewater treatment. Step 3: derive concentrations of concern for aquatic organisms from LC_{50} and NOAEC values. And step 4: estimate aquatic exposures from releases of recirculating cooling system blowdown water to surface water using the general population exposures from industrial releases module of E-FAST.

19	In this slide I am going to elaborate a little bit on step 1 which is determining the release to surface water by way of blowdown. The daily release estimate in kg/site/day antimicrobial is based on a generic scenario developed by OPPT/CEB, that's our sister office here in OCSPP. The estimate is derived from information on concentration of antimicrobial in recirculating cooling water system and recirculation rate of cooling water. Concentration in cooling water is based on information from the product label. Information from the product label can include both initial treatment and maintenance applications. Recirculation rates of cooling water assumed are 2000 gallons per minute for a moderate size cooling system and 100,000 gallons per minute for a large size system. Blowdown is assumed to be about 0.6% of water used.
20	In this slide we are going to elaborate on step number 2 that that is estimating the waste water treatment plant percent removal. Key wastewater treatment plant fate tests include: biodegradability in WWT and sorption to activated sludge. These tests were discussed in the presentation on environmental fate and transport. An estimation program such as the STP module of EPI-WEB that is the sewage treatment plant module of EPI-WEB can be used to determine percent removal during wastewater treatment, but will tend to underestimate biodegradation potential. To determine percent removal of antimicrobial during wastewater treatment, information from wastewater treatment plant fate tests is usually preferred to estimation methods. Data from Office of Water treatability study can be used for metals for example, Copper and Silver.
21	This slide elaborates a bit on step number 3 where we estimate COCs or concentrations of concern. EPA's modeling results are expressed as number of days per year of exceedance of COCs for aquatic organisms. The Agency uses the most sensitive ecotoxicology endpoints for surrogate species to assess risk to each aquatic receptor group for example, freshwater fish, freshwater invertebrates, aquatic plants. COCs for acute effects were determined by dividing LC_{50} values from acute toxicity tests on aquatic vertebrates and invertebrates by a factor of 2. COCs for chronic effects for non-listed species were based on No Observed Adverse Effects Concentration values from tests on aquatic vertebrates and invertebrates. COCs for listed endangered and threatened aquatic organisms were determined by dividing LC_{50} values from acute toxicity tests on aquatic vertebrates and invertebrates by a factor of 20. Acute COCs for aquatic vascular plants and algae are based on EC_{50} values; COCs for endangered algae and aquatic vascular plants are based on NOAEC values.
22	And finally step number 4. We are elaborating here on the step needed to estimate ecological exposure. So using results from Steps 1 through 3 as inputs, the General Population and Ecological Exposure from Industrial Releases module of E-FAST is used to estimate the number of days of exceedance of COCs for aquatic organisms. The model provides estimates for both high-end and average case exposure scenarios. The high-end scenario is based on the 10^{th} percentile of the ratio of the 7Q10 that is lowest 7 consecutive-day stream flow over a 10-year period stream flows to plant flows. The average case scenario is based on the 50^{th} percentile of the ratio of the 7Q10 stream flows to the plant flows. The SIC code selected is used to provide data on the ratio of stream flows to plant flows as mentioned earlier this is usually SIC 4911 which is Steam Electric Power Plants. SIC stands for Standard Industrial Classification Code. Estimates are not generated for a specific power plant. They are generated for every steam electric power plant in the database.

23	Now we are going to talk a little bit about modeling for once though cooling water systems. Basically the same four steps that are used to model exposures for recirculating cooling water systems are used for once-through cooling water systems. The concept used to estimate kg/site/day antimicrobial released to surface water in Step 1 for once-through cooling water systems is similar to that for recirculating cooling water systems. One key difference: for a recirculating system, release of antimicrobial to surface water is limited to blowdown water; for a once-through system, release of active ingredient to surface water is based on the total throughput. The resulting eco exposure estimate in STEP 4 reflects the exposure based on total throughput
24	The ecological effects data required to support a manufacturing use-product or an end-use product for cooling water systems is one of the more comprehensive. By comprehensive I mean if you look at the animal and plant Part 158 Subpart W nontarget animal and plant effect data requirement tables if the active ingredient is persistent, then most of the data listed are required. If you think about why this is the case, it is because cooling water use represents a use pattern with the potential for both continuous loading of an active ingredient and/or its transformation or degradation products to the aquatic environment as compared to some other use patterns, and the potential for a wide variety of aquatic habitats and aquatic and terrestrial organisms to be exposed. For the once-through cooling system use pattern the ecological effects data being asked under Part 158 Subpart W does not differ greatly from what has historically been required. There are four new data requirements. The first new data requirement is an activated sludge respiration inhibition (or ASRI) test to provide effects data on the critical micro-organisms needed for wastewater treatment facilities to operate correctly. The second and third new data requirements are freshwater and estuarine/marine benthic invertebrate testing where sediment is included in test vessels and dosed with the active ingredient to address exposure and effects to organisms exposed via the sediment exposure pathway. The fourth new requirement does not change the number of plant tests required, but it does change the type of plant testing required to Tier II which are multiple dose tests resulting in a definitive NOAEC and IC_{50} versus allowing use of a Tier I single dose limit test. The reason for the change is that many active ingredients, especially those used in cooling water are used to control plant pests such as algae making them known phytoxicants and are expected to be phytoxic to nontarget plants once released into terrestrial or aquatic environments. Requiring Tier II testing for known phytotoxicants is consistent with conventional phytotoxicant pesticides such as herbicides which also start out at Tier II. For recirculating cooling water systems the data requirements are now the same as the once-through. This is a big change because historically it was considered an “indoor” use pattern with little or no exposure and therefore it historically had more limited data requirements as compared to the once-through cooling water use pattern. The change is in recognition that while the daily discharge rate for a recirculating system may be lower than that required to obtain the same cooling via a once-through system it does not mean there is no loading and no exposure. Therefore the data are still needed to assess the risk, and the models that Pat discussed earlier will account for the differences in loading to surface water between once-through and recirculating facilities.

25	There are essentially 6 types of organisms for which data are required. They include birds, wastewater treatment plant organisms, plants, aquatic invertebrates, benthic invertebrates, and fish.
26	As I present the ecological effects data requirements for each of the 6 organism groups I'm going to give it using an example active ingredient. This slide provides the assumptions about the example active ingredient's physical/chemical properties and a key to understanding the example tables that I'm going to review. The example is based on the data requirements in the non-target animal and plant protection tables found under the "Industrial Processes and Water Systems" use pattern where the cooling water system use pattern belongs. The active ingredient is going to be assumed to be persistent or stable. It's going to be assumed to be bioaccumulative, that is it has a Kow greater than or equal to 1,000 and it is expected to partition to sediment as indicated by having a Kow greater than or equal to 1,000. In the tables an R indicates the data are required and a CR indicates the data is conditionally required. A data requirement highlighted in yellow means that the data is required either because it has an R designation or because the data criteria were met for data designated as CR. A data requirement not highlighted means either additional information is needed such as toxicity data or results from lower tier data requirements, or information regarding components of the formulation or exposure are needed to inform the conditional requirements. It can also mean that no data is required.
27	For the cooling water system use the data requirements for birds include: two acute oral toxicity tests with the technical grade active ingredient, one with a water fowl and one with an upland game bird species. If either of these acute oral values are less than or equal to 100 mg of the active ingredient per liter, than one avian dietary test using the technical grade active ingredient with the more sensitive of the two species is required. An avian reproduction study is also required for this case, because the active ingredient is persistent and bioaccumulative and the exposure pattern would result in continuous loading and therefore potential for chronic dietary exposure. An activated sludge respiration inhibition or ASRI study is required with the technical grade active ingredient to address hazards to wastewater treatment micro-organisms.
28	For cooling water systems the data requirements for non-target plants include: a study with one aquatic vascular plant species, a duckweed, and four algal species (a green algae, a freshwater diatom, a saltwater diatom, and a cyanobacteria) using the technical grade active ingredient. Because the active ingredient in this example is persistent a vegetative vigor study using rice with the technical grade active ingredient is also required. If the duckweed or any of the four algal tests will result in a risk quotient greater than one (which is essentially the same as saying if the expected environmental concentration is greater than any of these tests NOAEC or IC_{50} values from this test), then a seedling emergence test with rice using the technical grade active ingredient is also required. The use of the technical grade active ingredient here for both the vegetative vigor and seedling emergence test is a technical change from the typical end-use product currently listed in the Part 158W non-target plant data requirement tables.

	Additional testing of the four algal species and duckweed using the end-use product is required where an ingredient in the formulation enhances the toxicity of the active ingredient. Terrestrial and aquatic field testing is a higher tier test and is used to support registration of end-use products. Both of these are conditionally required on a case-by-case basis and would be specifically designed to reduce uncertainties such as refining exposure and the type and magnitude of effects to the nontarget community, and to refine the risks to the non-target plant community. Field studies provide more realistic information on a pesticide's impacts than laboratory studies which focus only on one species at a time because field studies consider impacts to the plant communities. Under field conditions exposure and degree of effects can proceed differently from how they occurred under laboratory conditions. Study objectives, design, and protocols must be approved by the Agency prior to the initiation of such studies.
29	For cooling water systems the data requirements for non-target water column invertebrates include: one freshwater acute invertebrate test with the technical active ingredient, and if the label does not prohibit discharge of cooling water or cooling water effluent to estuarine/marine environments, two acute estuarine/marine invertebrate species one a penaeid shrimp and the other a mollusk are required. One life cycle test is required with the technical grade active ingredient. The life cycle test is required to be conducted with the more sensitive freshwater or estuarine/marine crustacean species. If the life cycle test was conducted with a species different from those tested in the acute studies, then an acute test with the species used in the early life cycle test would also be required to allow calculation of an acute-to-chronic ratio for use in estimating chronic values for the most acutely sensitive crustacean species. There are instances where the acute mollusk results are more sensitive than the crustaceans but a mollusk life cycle test is not required for several reasons. First there is no standard life cycle test for mollusks. Second, the acute endpoints in the two mollusk guideline tests which the Agency uses do not correspond to those of the crustaceans such that acute-to-chronic ratios cannot be applied to the crustaceans to estimate chronic reproductive endpoints for them. If the acute mollusk study was the embryo-larval test, it is a sensitive early life stage test, and the NOAEC from the study is used as chronic measure for mollusks, this is also in-line with the Office of Water ambient water quality criteria development guidance. Acute testing with the end-use product for each of the three species tested with the technical grade active ingredient is additionally required if an ingredient in the end-use product enhances the toxicity of the active ingredient, or if the expected environmental concentration in surface water is greater than or equal to half the acute endpoint value for that species, or if the 7Q10 upper 10^{th} percentile concentration exceeds the acute concentration of concern for the species greater than or equal to 4 days.
30	For this cooling water case chronic benthic sediment testing with the technical active ingredient is required for two freshwater species one, an amphipod and the other, a chironomid. Additionally, if the label does not prohibit discharge of the cooling water or cooling water effluent to estuarine/marine surface waters, one chronic sediment test with an estuarine/marine amphipod species is required. Sediment testing is required because the active ingredient is expected to partition to sediment, that is the Kow is greater than or equal to 1000.

	Only chronic testing is required in this example because the active ingredient is known to be stable that is, its half-life >10 days, and therefore no subchronic testing is required. The half- life and sediment fate studies and whether or not the active ingredient is a known reproductive toxicant determines whether a chronic or subchronic testing is conducted. If the active is stable, like in this example, or is a known reproductive toxicant then life cycle testing would be required. If the active was not stable the short-term subchronic test is required. In the case where short-term testing is conducted, additional life cycle testing would be required where the estimated environmental concentration in sediment is greater than or equal to 0.1 times the LC_{50} or EC_{50} from the short-term subchronic test.
31	For the cooling water system use pattern the data requirements for non-target fish include for the technical grade active ingredient: two freshwater acute tests, one with a cold water species and one with a warm water species. One estuarine/marine acute test, if the label does not prohibit discharge of cooling water or cooling water effluent to estuarine/marine surface waters. And thirdly an early life stage test with one species, the more sensitive of the freshwater or estuarine/marine species tested. If the early life stage test is conducted with a species different from the acutes, an acute test using the early life stage species is also required to allow calculation of an acute-to-chronic ratio for use in estimating a chronic value for the most acutely sensitive fish species. If the antimicrobial is a known reproductive physiological toxicant, instead of an early life stage test full life cycle testing is required. This is because early life stage tests, while good surrogates for full life cycle tests where the mode of action does not affect reproductive physiology will underestimate chronic toxicity if it is a reproductive toxicant. Reproductive physiological endpoints include measures like fertility, fecundity such as the number of eggs produced, changes in sex ratio all of which cannot be measured in an ELS test. Additionally, in this case instead of just one species, two species one for freshwater and one for the estuarine/marine are required if the label does not specifically prohibit cooling water or cooling water effluent discharge to estuarine/marine surface waters. There will also be cases where the fish full life cycle testing may be required in addition to ELS testing. Full life cycle testing is conditionally required in addition to an ELS test if either of the two following conditions occur. First the estimated environmental concentration is greater than or equal to 0.1 times the Early Life Stage NOAEC; or two the 7Q10 upper 10^{th} percentile surface water concentration exceeds 0.1 times the ELS NOAEC more than 20 days. I also want to note that sometimes a full fish life cycle test for a species other than those used in acute tests are submitted. This is not unusual, especially for fish. For example, a rainbow trout which is a standard cold water test species requires several years to mature so this species is not practical to use in a full life cycle test. A species that has a shorter life cycle is more practical but such a species may not be as sensitive as the species used in acute testing. Species can differ in sensitivity, and if a relatively insensitive species is used for the chronic testing as compared to the acute test the resulting chronic value can lead to having acute values being lower than chronic values or if not lower not representative of the true chronic toxicity of more sensitive species this potentially results in major

	underestimation of chronic risks. Therefore if the life cycle test is conducted with species different from those tested in the acute studies, an acute test with the species used in the chronic test, would also be required so that an acute to chronic ratio can be calculated and used in estimating chronic values for the most acutely sensitive fish species. Acute testing with the end-use product for a freshwater fish species and one estuarine/marine species is additionally required if an ingredient in the end-use product enhances the toxicity of the active ingredient, or if the expected environmental concentration of the active ingredient in surface water is greater than or equal to half the acute endpoint value of the active ingredient for that species, or if the 7Q10 upper 10^{th} percentile concentration exceeds the acute concentration of concern for the species greater than or equal to 4 days. Simulated or aquatic field testing for effects to nontarget animals like the aquatic field testing for nontarget plants is a higher tier test and is used to support registration of an end use product. Just like with aquatic plants, aquatic field testing for aquatic animals is conditionally required on a case-by-case basis and would be specifically designed to refine exposure estimates, magnitude of impacts to the nontarget aquatic animal community in the environment, and to refine estimates of risk. Study objectives, study design, and protocols must be approved by the Agency prior to the initiation of such studies.
32	For the cooling water system use pattern two bioconcentration studies, one with a fish and one with an oyster, with the active ingredient are required for this example because the active ingredient is stable, it has a Kow of greater than 1,000 and cooling water or cooling water effluent will be discharged to surface waters. In these studies fish will primarily uptake the chemical across the gill. Oysters, which are filter feeders, will assimilate the chemical from across their gills but also from the water they filter through their bodies to feed, and from the chemical sorbed to particulates in the water or sorbed to the algae they feed upon throughout the study. A food chain transfer study is a higher tier study, and is required on a case-by-case basis. In a food chain transfer study two or more aquatic trophic levels are present, and the ability of the substance to transfer and increase in concentration from one trophic level to the next is evaluated.
33	The data requirements I just went through as I indicated at the start were based on several assumptions about the physical/chemical properties of the active ingredient and its fate and exposure. Be sure and consult the table notes in the Part 158 Subpart W tables for determining specific data requirements for an active ingredient or end-use product. There are circumstances where differences in the physical/chemical properties, fate, or exposure conditions will require less data then what I just presented. For example, if the active ingredient and its major degradates did not partition to sediment as determined by the Kow, Koc, and Kd values, then no sediment testing would be required. In my examples I touched upon where data would not be needed if label language prohibited cooling water or cooling water effluent discharge to estuarine/marine surface waters. However, if the reversal was true, where the label prohibited cooling water discharge to freshwater, some of the freshwater data requirements would be waived.

	There are also circumstances where differences in the physical/chemical properties, fate, or exposure conditions will require more data or alternative types of data than the example I provided. For example where the active ingredient is not stable but is expected to form a major degradate which is stable. In this case, except maybe for a spill, environmental exposures are expected to be to the major degradate. In this case testing of the degradate would be more applicable for a risk assessment instead of the active ingredient for a number of the data requirements. There would still be data requirements for the active ingredient to address hazard labeling. Another example where additional data might be needed is where the pKa (the acid dissociation constant) of the active ingredient is in the environmentally relevant pH range. This is important because it means under certain pH conditions the chemical may be more bioavailable or toxic than under other pH conditions. In this case aquatic tests are required to be conducted under pH conditions which result in exposure to the most bioavailable form. To refine risk and mitigation, some of the aquatic tests should be conducted at more than one pH such that results bracket the pKa to provide a quantifiable relationship between pH and toxicity. This concludes the ecological data requirements for the cooling water system use pattern.
34	Now for a brief overview of how the dietary exposure assessment occurs. Risk is a function of hazard and exposure for this assessment and per part 158W, residue chemistry data are required for uses that may result in residues in potable water and fish. A screening level dietary exposure assessment is conducted relying on both environmental fate data and modeling. Its exposure is modeled using the dietary exposure evaluation model food commodity intake database or DEEM- FCID. Acute, chronic, and cancer assessments can be conducted. Nine subpopulations of interest are looked at. The general US Population, All Infants (<1 year), Children from age 1-2, Children 3-5, Children 6-12, Youth 13-19, Adults 20-49, Adults 50+, and Females 13-49. In the model consumption data from the 2003-2008 USDA What We Eat In America (WWEIA) survey that was conducted as part of the National Health and Nutrition Examination Survey (NHANES) is where data are taken and is nationally representative/statistically-based. Data is collected on a two-year continuous basis (~10,000 individuals, ~7,000 foods). Outputs are based on the percentage of the population adjusted dose or % PAD. This screening level assessment often does not show risks of concern. Based on that, specific residue data that I identified at the beginning may not be necessary to make a safety finding.
35	In regards to the dietary exposure assessment for drinking water and fish. For the drinking water the estimated drinking water concentrations (EDWCs) are used as inputs into DEEM and FCID. These are based upon two possibilities. The first is E-FAST and here surface water concentration based on the 30Q5 flow value is used to represent acute exposure and the harmonic mean flow value is used to represent chronic exposure. In some cases we also use End-of-pipe. These EDWCs are incorporated in DEEM-FCID into the food categories “water, direct, all sources” and “water, indirect, all sources.” For a recent case in order to be conservative, the end-of-pipe EDWC was used for the dietary exposure assessment and no risks of concern were identified for any sub-populations. Regarding fish, residues in fish

	can also be a concern for subsistence and recreational fishermen. This was pointed out in an earlier slide at the beginning of this presentations where there were fishermen standing around fishing adjacent cooling water discharge. Right now OPP Science Policy Council is currently evaluating an OPP-wide method for addressing possible exposures from fish consumption. If drinking water is the only source of exposure, no additional food forms are included in the assessments.
36	And that brings us to the end of the presentation, this last slide shows references that were sighted throughout the slides. And thank you for listening. I hope this helps you understand how AD handles the cooling water system use pattern.
37	