

US EPA ARCHIVE DOCUMENT

# **Registration Review Proposed Process**

## **Antimicrobial Pesticide Case Study**

PPDC Workgroup Meeting

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September 28, 2004

# Antimicrobial Pesticide Case Background

## Regulatory History

- First Registered: Mid-1980s
- RED: Mid 1990s, Pre-FQPA
- Pesticide Type:
  - Disinfectant
  - Algaecide
  - Bacteriostat regulator
  - Microbiocide/Microbiostat
  - Fungicide/Fungistat

# Antimicrobial Pesticide Case Background

## Use Profile

- **Indirect food uses:** Pulp/paper, dishwashing liquids (products touch food-contact surfaces); has FDA 409 clearance
- **Non-food indoor uses:** Cleaners, laundry detergents, textiles/fabrics, consumer/institutional products, paints, oil field systems, air washer systems, air conditioning/humidifying systems, cooling water systems, papermills, absorbent clays, metal working fluids, printing inks, adhesives
- **Outdoor uses:** Open industrial waste water systems, sewage settling ponds, sewage systems, ground wood/saw dust (as an absorbent)

# Antimicrobial Pesticide Case Background

## Last Major Assessments

- Registration Eligibility Decision (RED): Mid 1990s, Pre-FQPA
  - Toxicology Assessment (complete database)
  - Occupational Assessment (complete assessment at time, not all application methods evaluated, exposure database has significant limitations)
  - Residential Assessment (very limited, children not assessed, not all uses evaluated; lacked residential Standard Operating Procedures)

# Antimicrobial Pesticide Case Background

## Last Major Assessments Cont.

- Ecological Toxicity Assessment (hazard only, no plant data or chronic fish or invertebrate data)
- Environmental Fate Assessment
- Ecological risks not estimated (no Risk Quotients or levels of concern estimated; not standard practice at that time)
- No dietary, drinking water or aggregate assessments (no SOP's at that time)
- Recent Heating Ventilation and Air-Conditioning (HVAC) Assessment
  - Occupational Assessment
  - Residential Assessment

# Antimicrobial Pesticide Case Background

## Hazard Profile For Human Health

- High to moderate toxicity for acute oral, dermal, eye and skin irritation
- Severe gastrointestinal irritant following repeated oral exposure
- Developmental and reproductive effects only in the presence of maternal toxicity
- Negative for genotoxicity
- No evidence of carcinogenicity in two chronic rodent studies
- No reported human incidence data

# Antimicrobial Pesticide Case Background

## Occupational/Residential Exposure & Risks

- No risks of concern for all worker scenarios in RED after mitigation measures
- No risks of concern for residential handlers of paints or adhesives using a paintbrush
- No risks of concern from HVAC use



# Antimicrobial Pesticide Case Background

## Environmental Fate

- Stable to hydrolysis under normal conditions; may rapidly hydrolyze at warmer temperature and/or high pH
- Parent compound expected to have a relatively short half-life in the environment (photoreactive in water)
- The major degradate has a much longer half-life than the parent raising chronic concerns
- Unlikely to bioaccumulate

# Antimicrobial Pesticide Case Background

## Hazard Profile for Ecological Effects, Exposure, & Risk

- Only have acute studies
- Practically non-toxic to slightly toxic to birds
- Slightly to moderately toxic to freshwater fish and terrestrial invertebrates
- Moderately to highly toxic to estuarine/marine invertebrates
- Slightly toxic to estuarine/marine fish

# Antimicrobial Pesticide Case Background

## Hazard Profile for Ecological Effects, Exposure, & Risk (cont.)

- Exposure to non-target aquatic organisms is expected from industrial discharges to surface water
- Discharges may adversely affect aquatic life. Chronic effects to invertebrates are also possible due to slow degradation of degradates
- In the RED, deferred to Office of Water, since aquatic environments are regulated under National Pollution Discharge Elimination System (NPDES) permitting program (current practice in mid-1990s).

# PPDC Workgroup Response

Discussion

Opinion:

- Easy Off?
- Need New Risk Assessment(s)?
- Need New Risk Assessment(s), New Data?