

US EPA ARCHIVE DOCUMENT

Registration Review Process Proposed

Conventional Pesticide Case Study

PPDC Workgroup Meeting

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Conventional Pesticide Case Background

Regulatory History

- First registered: late 1980's

Use Profile

- Post emergence herbicide
- Acts through foliar uptake
- Controls wide range of broadleaf weeds in cereal crops
- Also has non-food uses
- Applied by air and ground equipment

Conventional Pesticide Case Background

Human Health Risk Assessment Status

- Recent dietary risk assessment
- Recent aggregate food & water assessment
- No residential uses – no assessment needed
- Last occupational assessment at time of first registration

Conventional Pesticide Case Background

Hazard Profile For Human Health

- Low to moderate acute toxicity via the oral, inhalation, and dermal routes of exposure
- It is a skin sensitizer and a mild eye irritant
- Repeated dose oral toxicity studies resulted primarily in decreased body weights and body weight gains accompanied by decreased food consumption
- No evidence for significant toxicity to specific target organs

Conventional Pesticide Case Background

Hazard Profile For Human Health (cont.)

- No evidence of neurotoxicity or neuropathy from available studies
- Developmental and reproductive toxicity studies indicated no increased susceptibility of offspring
- Based on carcinogenicity studies, the chemical is classified as Group C (possible human carcinogen)
- Negative for mutagenicity
- Complete toxicology data base

Conventional Pesticide Case Background

FQPA Factor for Human Health

- The Special FQPA default safety factor (10x) is reduced to 1x since there is no indication of increased susceptibility in developmental toxicity studies in rats and rabbits and rat reproduction studies, and conservative exposure estimates are unlikely to underestimate risk.

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Human Health Risk Assessment Profile:

Occupational and Residential Exposure and Risk

- Most recent occupational risk assessment conducted during initial registration of chemical (not included in recent assessment).
- No residential uses

Dietary Exposure and Risks

- Tox studies suggest an acute dietary risk assessment is unnecessary.
- Chronic dietary exposure estimates are <1% of the dose that would be of concern.
- Dietary assessment is considered protective of potential cancer concerns.

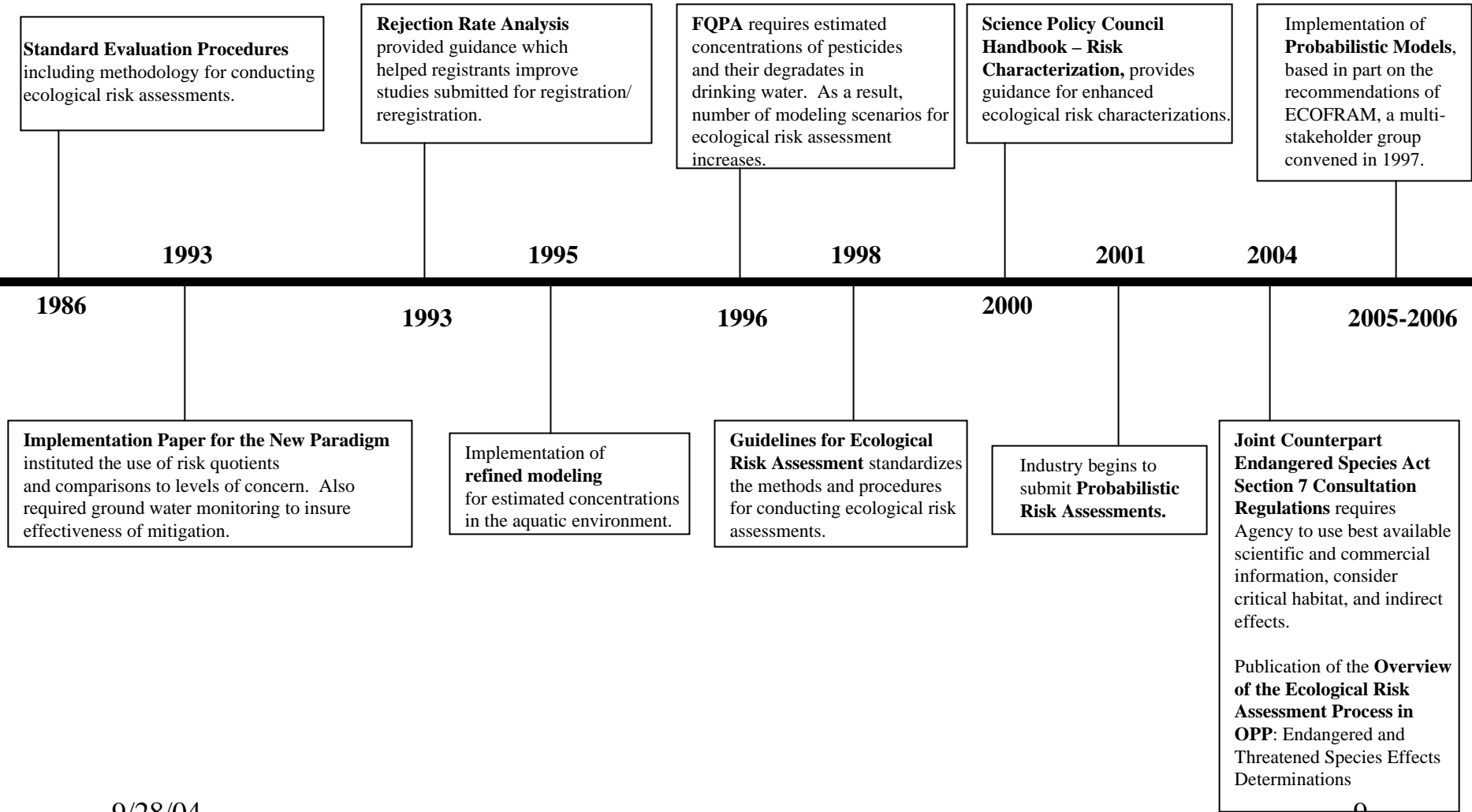
Conventional Pesticide Case Background

Human Health Risk Assessment Profile (cont.)

Drinking Water and Aggregate Risk

- Drinking water risk assessment completed recently.
- Aggregate risk assessment completed recently
- Food and water chronic exposures are <1% of the dose that would be of concern for all population subgroups.

Major Milestones in Ecological Risk Assessments and Drinking Water Exposure Assessments Conducted in OPP 1984 – Present and Future



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Ecological Effects Risk Assessment

- Ecotoxicity and environmental fate assessments were completed in late 1980's
- More recently, a drinking water exposure assessment was conducted for a tolerance reassessment decision
- No new uses added since the initial registration

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Stressor-Response Profile For Ecological Effects

- Practically non-toxic to birds on an acute and dietary basis
- Practically non-toxic to both warmwater and coldwater fish
- Practically non-toxic to aquatic invertebrates

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Status of Ecotoxicity Studies

- Studies submitted since registration include:
 - Avian reproduction
 - Seed germination/seedling emergence
 - Vegetative vigor
 - Aquatic plant growth
- Avian reproduction and aquatic plant studies have been screened
- Terrestrial plant data have been reviewed, but not yet incorporated into a risk assessment

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Environmental Exposure Profile

- Primary routes of dissipation are hydrolysis and microbial degradation
- Half-lives are less than one week in acidic environments and 1-4 weeks under more alkaline conditions
- High mobility in soil based on laboratory studies
- Little mobility observed in field studies
- Volatilization and bioaccumulation are not important pathways

PPDC Workgroup Response

Discussion

Opinion:

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