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CONTINUING USES FOR CREOSOTE: Influencing factors and responses (Presentation outline)

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1. **CONTINUING USES FOR CREOSOTE** are to preserve wood

2. **CONTINUING USES FOR CREOSOTE**

Past usage
↓
Continuing usage
↓
Future usage

3. **PAST USAGE OF CREOSOTE TREATED WOOD**

Commercial Building Construction
Marine Structures
Timber Bridges
Foundation Piling
Home and Farm
Building interiors, food
contact, animal husbandry-cribbing
Utility Line Transmission
Railroad Crossties

4. **FACTORS THAT INFLUENCE CHEMICAL PRODUCT USE**

- Product price/performance → Deselection
- Regulatory initiative → Use restrictions
- Regulatory initiative → Deselection
- Unwarranted claims of adverse health or environmental effects → Deselection

5. **REGULATORY INITIATIVES AND UNWARRANTED CLAIMS OF ADVERSE EFFECTS ARE USUALLY ENVIRONMENTAL OR HEALTH-ISSUE BASED**

Environmental and health-issue based concerns are subject to regulatory action that increasingly involves risk-based management.

Pesticides
Risk Assessment
Risk Mitigation
Changes in use pattern
Possible loss of uses

6. 1986 REGULATORY ACTION TO MITIGATE RISK

- Institute creosote wood treating worker exposure control requirements (mainly PPE)
- Eliminate certain farm and home uses of creosote treated wood
- Classify creosote as a restricted–use pesticide

7. PAST USAGE OF CREOSOTE TREATED WOOD

Commercial Building Construction
Marine Structures
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8. CONTINUING USES FOR CREOSOTE ARE TO PRESERVE WOOD FOR:

Construction
Commercial Structures
Marine Structures
Timber Bridges
Utility Line Transmission
Railroad Crossties

9. EPA PESTICIDE INITIATIVES

- Creosote Data Call-In and Reregistration Standard, 1986 (CC I)
- Creosote Data Call-In and Reregistration Standard, 1988 (CC II)
- PMRA Re-Evaluation of Heavy Duty Wood Preservatives, 1998 (CITW & CCII)
- Draft Preliminary Risk Assessment and Science Chapters, January 2003 (CCII)
- PMRA & EPA Preliminary Risk Assessment and Science Chapters, December, 2003 (Creosote Council III)

10. RISK ASSESSMENT

EXPOSURE + HAZARD = RISK

Exposure assessments can be for occupational, residential, children, environmental or other routes of contact

Hazard assessment is for potential adverse effects to humans, domestic animals, wildlife and the environment

11. PMRA & EPA's JANUARY, 2003 DRAFT CREOSOTE PRELIMINARY RISK ASSESSMENTS

- Occupational only
- Wood treatment was the only occupation
- Initially considered 11 wood treating application scenarios (DRAFT Assessment)
- Deterministic assessment
  "snapshot approach"
  All input parameters were considered to be a single, same value for all times
- Estimated very high cancer rates and non-cancer morbidity in all wood-treating workers

12. PMRA & EPA's December, 2003 CREOSOTE PRELIMINARY RISK ASSESSMENTS

- Occupational only
- Wood treatment was the only occupation
- Initially considered 1 wood treating application scenario
- Deterministic assessment
  "snapshot approach"
  All input parameters were considered to be a single, same value for all times
- Risk based on assessment of single component of creosote instead of whole creosote
- Estimated high cancer rates and non-cancer morbidity in all wood-treating workers

13. THE RATIONALE FOR CHANGE IN JANUARY 2003 DRAFT RISK ASSESSMENTS OF WORKER RISKS were almost entirely due to the registrants' voluntary cancellation of non-pressure uses.

14. CREOSOTE VOLUNTARY USE CANCELLATIONS

- All non-pressure treatment uses
  Spray application
  Mop or brush-on application
  Thermal treatment application
- Effective December 31, 2004

- After 2004 existing stocks already in hands of dealers or users can be used until stocks depleted

15. CCIII's PROBABILISTIC RISK ASSESSMENTS

- Occupational only
- Wood treatment was the only occupation
- Initially considered 1 wood treating application scenario
- Probabilistc assessment
  "Distributional approach"
  Input parameters were evaluated as a set, or "distribution" of values for across time
- Cancer risk and dermal risk based on assessment of whole creosote; inhalation non-cancer based on naphthalene
- Estimated lower cancer rates and non-cancer morbidity in all wood-treating workers

16. PROBABILISTIC RISK ASSESSMENT

- Probabilistic methodology is EPA's preferred approach to risk assessment (US EPA Risk Assessment Guidelines, 1977; US EPA OPPTS, 2000) "EPA expects distributional analysis to be used to estimate acute population risk"
- Methods characterize variability and uncertainty associated with the required input parameters

17. DIFFERENCES IN APPROACHES TO RISK ASSESMENT

Cancer Risk Assessment

PMRA/EPA – All risk based on BaP only
PMRA/EPA – Deterministic methodology
PMRA/EPA - 50% BaP dermal penetration factor

CCIII – All risk based on assessment of creosote as an entity
CCIII – Probabilistic methodology
CCIII – 0.22% creosote dermal penetration factor

18. DIFFERENCES IN APPROACHES TO RISK ASSESMENT

Non-Cancer Risk Assessment

PMRA/EPA – All risk based on creosote components
PMRA/EPA – Deterministic methodology

CCIII – Dermal risk based on assessment of creosote as an entity;
- Inhalation risk based on naphthalene equivalents exposure

CCIII – Probabilistic methodology

19. RESULTS

Endpoint Assessment	PMRA/EPA	CCIII
Cancer	**1.7 X 10-2 1.8X 10-4**	**Mean Risk = 3.9 – 8.8 X 10-5 95th %-ile = 1.5 – 3.1 X 10-4**
Non-cancer	**All MOE's <100**	**All HI >1.00**

20. CANCER RISK INTERPRETATION

- Calculated risks fall within range of acceptable occupational risk
- The upper-bound cancer risk estimate set forth in the risk assessment suggests that, even using the most conservative assumptions, less than one additional cancer case (0.06 – 0.19) would be expected to occur even following a lifetime of work pressure-treating wood with creosote.
- Non-treating workers who contact creosote as a result of working with treated wood are likely to receive less exposure to creosote than treaters, so risk will be commensurately reduced.

21. NON-CANCER RISK INTERPRETATION

- The estimates of hazard generally fall below the acceptable level of 1.0 as a Hazard Index (HI);
- The only HI greater than 1.0 was the result of dermal exposure
- Dermal exposure (dermal dose) was heavily influenced by the inclusion in the data of two potentially outlier points that were much greater than all other dermal data points
- Appropriate workplace practices can mitigate this type of exposure

22. ENVIRONMENTAL RISKS

- EPA was criticized for their environmental risk analysis
- EPA approach was based on literature values for components of creosote
- CCIII continues to sponsor the work of Dr. Kenn Brooks on environmental fate and effects assessment of creosote and creosote-treated wood

23. FUTURE USAGE OF CREOSOTE

- Possibility of additional changes in pressure treating work practices to further reduce worker exposure
- Continued use of creosote-treated wood products in the present markets

- Possible oversight of after-market uses on creosote treated wood

24. CREOSOTE COUNCIL

- Coopers Creek Chemical Corp.
- KMG-Bernuth, Inc.
- Koppers, Inc.
- RailWorks, Inc.
- Rutgers Chemicals AG

25. CREOSOTE COUNCIL RESPONSES

- Compliance with data production requirements (16 years; >$4,000,000)
- Error Correction comments as well as comprehensive comments on content to draft PRA
- Voluntary cancellation of non-pressure treating uses of creosote
- Additional comprehensive comments on PRA
- Submit Probabilistic Risk Assessments

26. CREOSOTE COUNCIL COMMENTS TO DOCKET

- EPA public docket contains EPA documents as well as public comments on the EPA's assessments
- Registrant & technical information on the pesticide products
- Science Chapters, including exposure, toxicology, human & environmental effects
- Risk assessments