

SEAUPG 2004 Conference - Baton Rouge Presented By Earl W. Arp, Ph.D.

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bitumen: (n)
asphalt

Preparing our industry
for the IARC Monograph

SEAUPG
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Statement of the Problem

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The International Agency for Research on Cancer (IARC) has identified bitumen (asphalt) as a high priority agent for cancer classification review.

This review is expected by **2007/08**.




Statement of the Problem

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The **last full IARC review** of bitumen was conducted in **1985**.

At that time there was **inadequate evidence** that bitumens were carcinogenic to humans (Group 3) but sufficient evidence of carcinogenicity in animals exposed repeatedly to (solvent) extracts of certain bitumens (2B).




Statement of the Problem

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Since 1985, **three key studies** related to asphalt and cancer have been published and each study produced results that **suggest a cancer risk** associated with asphalt exposure.


However, two of these **have been challenged** by industry scientists as flawed and unreliable for classification purposes.



Statement of the Problem

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In the **third study**, IARC researchers were unable to adequately control for potential **confounding exposures** (i.e. smoking and coal tar), so a follow-up investigation is now underway.




Statement of the Problem

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Despite this, **government agencies and others continue to cite these studies** in official publications.

In order to effectively counter these reports, publication of industry-sponsored findings in the peer-reviewed literature and **new original research is critical**.



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Statement of the Problem

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Several attempts by U.S. agencies to regulate asphalt exposure as a carcinogenic risk have failed.

Currently, **no regulatory agency** or consensus standards body in the U. S. classifies asphalt as a cancer causing agent.

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Statement of the Problem

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The Asphalt Institute has identified the IARC monograph review as an

urgent industry priority

and the time is now to complete research and enter it into the scientific literature.

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What is the IARC Monograph Program?

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As part of the World Health Organization, the IARC Monographs series **publishes authoritative independent assessments** by international experts of the carcinogenic risks posed to humans by a variety of agents, mixtures and exposures.

The Monographs are **used widely** by research scientists, public health authorities and national and international regulatory authorities.

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IARC Evaluations classified by group

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- 1 The agent (mixture) is carcinogenic to humans.
- 2A The agent (mixture) is probably carcinogenic to humans.
- 2B The agent (mixture) is possibly carcinogenic to humans.
- 3 The agent (mixture, or exposure circumstance) is not classifiable as to carcinogenicity in humans.
- 4 The agent (mixture, exposure circumstance) is probably not carcinogenic to humans.

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Characteristics of IARC Monograph

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It's All About Science

IARC **only considers the peer-reviewed** scientific literature and government reports in arriving at its determinations.

In relative order of importance, human data > animal data > short term test data, such as mutagenicity.

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Characteristics of IARC Monograph

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It's All About Cancer

The potential for an agent to cause cancer in humans is the **sole interest of the IARC** in its monograph program. Other health endpoints and mitigating circumstances are secondary to carcinogenic potential as judged by the data.

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Characteristics of IARC Monograph

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It's All About Hazard

The **potential to cause cancer** as evidenced by the data is the guiding principal. One solid study demonstrating excess cancer can **outweigh multiple studies** suggesting no effect (strength of evidence); the potency and risk of a cancer-causing agent is left for others to complete.



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Use of IARC Monographs

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IARC cancer classifications can trigger regulatory action since they are **considered "authoritative" by agencies** such as: OSHA, the National Toxicology Program (NTP), NIOSH and California's Proposition 65 Program.

IARC Monographs have also been the scientific **basis** in the past for **European Union classification** decisions for petroleum products.



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Potential Industry Impact

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The following is a list of possible ramifications of an IARC reclassification of interest to manufacturers and users of asphalt products.

- Toxic tort
- Emissions controls
- Workers compensation
- Groundwater contamination
- Clean-up standards
- Product labeling
- Competitive marketing
- Substitute products
- Drinking water systems
- Community activists
- Plant sitings
- Workplace controls
- Hazardous waste classification
- Automatic listings (California Proposition 65, NIOSH, NTP, WHMIS - in Canada)



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Our Objective

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Fill critical scientific data gaps and publish all relevant findings for incorporation in the Monograph review process.



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Industry Preparation Plans

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European-Based Studies

- **IARC Nested Case Control Study** - a multi-country epidemiology study primarily focusing on what caused elevated lung cancer deaths found during their initial investigation.
- **Fraunhofer Study** - an animal asphalt fume inhalation study of lung cancer potential
- **BGFA Study** - to evaluate the predictive power of biomarkers by linking findings from the Fraunhofer Study to exposures in active paving crews



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Industry Preparation Plans

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Domestic Studies

APEC & AREC Skin Painting Studies-evaluate cancer hazard posed by asphalt fume.

Completes the industry's long-standing **critique** of the NIOSH animal studies.

All resulting data from these studies are intended to be **published for incorporation into the IARC evaluation**; these data are expected to be crucial to the final IARC determination.



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Industry Preparation Plans

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- **APEC Skin Penetration Study**-evaluate the rate of absorption of PAC's from asphalt across the intact skin.
- **APEC and AREC Studies of Confounders**-highlight prior exposures to potentially hazardous agents that may have existed in the workplaces of yesteryear.
- **Comprehensive Set of Scientific Reference Materials**
-for use with bodies interested in classification or regulation of asphalt (bitumen) aerosol and vapors.

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Industry Preparation Plans

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- **International Symposium – Health Effects of Occupational Exposure to Bitumen Aerosols and Vapor –**
- improved understanding of the asphalt industry;
- awareness of key issues regarding existing health studies;
- elaborate role of potential confounders in past investigations;
- facilitate publication of new and previously unpublished research.

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Industry Preparation Plans

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- **National Toxicology Program** -announced intent to consider asphalt fume for listing in the next Report on Carcinogens-
 - Potential Impact in U.S. ~ = IARC Classification;
 - Detailed Review Process over Two Year Period;
 - Initial Comments Filed
 - Industry, IARC, Fraunhofer Institute
 - Updated Status via FR Notice Expected Early 2005

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AI HS&E Partnerships & Priorities

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- **Domestic**
 - Asphalt Institute HS&E Committee
 - Asphalt Paving Environmental Council (NAPA-SAPA)
 - Asphalt Roofing Environmental Council (ARMA-NRCA)
- **Global**
 - EUROBITUME
 - Global Paving Alliance (AI-EB-EAPA-NAPA-others)
 - Global Roofing Alliance (AI-EB-BWA-ARMA-NRCA)
- **Immediate Priorities**
 - IARC: Global Issue of the Decade
 - NTP: U.S. Issue of High Importance

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Concluding Remarks

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- The **Global Asphalt Industry** is Confronted with Significant **Challenges** and Opportunities
 - Some of Which Will Have Lasting Influence
- All Challenges **Cannot Be Met** by **Single** Group
 - Success Depends on Common Goals and Strategies, Coordinated Programs and Joint Activities
- **Asphalt Institute** is **Committed** to the **Global Network of Partnerships** Working Together in Preparation for the IARC Review
 - Confident that **Together** we can Manage Tomorrow's Challenges Successfully

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?? QUESTIONS ??

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About the Asphalt Institute

The Asphalt Institute is the international trade association of **75** petroleum asphalt/bitumen producers, manufacturers and affiliated business.

Founded in 1919, the Institute's members **represent 90% of the liquid asphalt** produced in North America and a growing percentage internationally.

About the Asphalt Institute

AI promotes petroleum asphalt as a **safe, cost effective and environmentally friendly** construction material for highways, streets, and roofing systems. This is pursued through a program of scientific research and technological developments.

Through its various committees and partnerships, the Asphalt Institute serves its Members as a **center of excellence for health, safety, and environmental matters.**

AI's HSE program is often cited by members as a **top reason** for their Institute membership.