

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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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.

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.

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.

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.

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.

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.