Health and safety –
Latest findings
Knut Soraas
Director General Eurobitume
European Mastic Asphalt Association
General Meeting
Marseille 1st October 2004
Presentation Outline

- Introduction
- Important work and studies
- IARC Monograph
- REACH
A license to operate

- Our products and the way they are applied must be safe to the individual both in situ and in the workplace, and safe to the environment

Product stewardship

--> Worker protection

--> regulations
Industry Goals and Objectives

- Provide relevant information to promote the safe use of bitumen
- Provide data to answer key health and regulatory questions
- Provide data that is accepted by the broad scientific community
Important work and studies
Joint HSE group

Deliverables:
• FAQ Mastic asphalt – two versions
• SDS Mastic asphalt
• Safe Handling of Mastic Asphalt

New:
• Exposure Reduction
• IARC Monograph Chapter 1 material
Europe Classification of Bitumen

- EU regulators [1993] deferred classification of bitumen, awaiting outcome of WHO (IARC) epi-study

- German regulators - AGS - deferred a “local” classification of bitumen pending outcome of animal inhalation studies
Closure on Cancer Question By Providing High Quality Data for Review by IARC and other Groups

- **Human epi-study IARC NCC**
  - Does exposure to bitumen cause lung cancer in humans? Identify effects of confounding factors from Phase I. Phase II started 1st June 2004

- **Animal 2 year study Fraunhofer**

- **Animal mechanistic study Fraunhofer**
  - Clarify possible mechanisms of action and provide data on possible biological exposure markers.

- **Human mechanistic studies BGFA**
  - Link mechanistic work in animals with human exposure data
IARC Monograph
The IARC Monograph program

• IARC Monographs have been the scientific basis in the past for EU classification decisions for Petroleum Products

• IARC Monographs are important outside EU: OSHA (USA) views IARC determination as conclusive

• Bitumen a high priority item in IARC program, next monograph for bitumen assumed to take place 2007

N.B. IARC is part of WHO
The IARC Monograph Process

• Date of the official review selected well in advance and posted on the IARC website.

• Group of scientists knowledgeable in the subject matter to be reviewed selected by IARC approximately 6 months prior to the meeting.

• Industry usually allowed one or more observers at the review. They participate fully but do not vote.

• Drafts of the various chapters are finalized and a classification reached by simple majority vote.
The IARC Monograph Review

- One global review
- For all sections of the Monograph other than Chapter 1 (Production, Use and Occurrence) only peer reviewed scientific literature is considered. This is a very firm rule.

- Industry is asked to provide information to complete Chapter 1 - need not be peer reviewed.

- As the focus of the Monographs is human health, epidemiology data are deemed most significant.

- Publishing Monograph
  1. Industry description; “Chapter 1”
  2. Exposure data
  3. References of published evidence
  4. Cancer classification assessment
Monograph preparations

- Ch 1, Industry Description
  - Changes over time
  - Regional differences

- Bibliography (on epidemiology, toxicology, exposure, mechanistics)
  - Gaps identification and filling with new data/papers
    - New research
    - Publish unpublished data
    - Reviews of existing papers

- Communication

- Industry is preparing on a global basis, Eurobitume has the leading role
  - Eurobitume, EAPA, BWA, EMAA
  - AI, NAPA, ARMA, NRCA
Ch 1 – Bitumen Manufacturing and Use (schematic)

Intermediate blended products
- Soft grades
- CB / Fluxed
- Emuls.
- PmB
- Paints

Application
- Paving *) (EAPA, NAPA, +AAPA)
- Roofing *) (BWA, ARMA, NRCA)
- Other Waterproofing, membranes
- Mastic *) (EMAA, +??)
- Other

*: Inclusion of Regional specifics foreseen to be required.

Additives
- Emulsifiers / Polymers / Adhesion Agents / Fluxes / Solvents / Filler / RAP / TLA / Coal Tar…

Bitumen Preparations and Derivatives

Bitumen Substance

Intermediate blended products

Nine EINECS Entries:
- Pen grade (EB, Al, +AAPA)
- Oxidised (EB, Al, +AAPA)
- Soft Grades (EB, Al, +AAPA)

Note: Inclusion of Regional specifics may be required.

Bitumen Manufacturing (refineries)
EMAA & Eurobitume joint HSE group tasks

- Chapter 1
  - EMAA: Description of practices, before and now
    - Products and formulations/composition, applications
    - Exposure data

- Bibliography: Consolidated literature list / Gaps
  - EMAA: Any available published / unpublished studies or data?

- Joint HSE group has started this work
  - Part of the industry Global Monograph Preparation Program
### IARC Monograph Timeline

#### Preliminary

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**IARC Monograph Preparation**

**IARC Monograph**
REACH
REACH proposal

- Registration
- Evaluation
- Authorisation and Restriction of Chemicals
- Replaces about 40 existing Community Directives and Regulations on chemicals by a single regulation with one consistent approach
REACH

• Maintain EU Chemical Industry competitiveness as well as protection of human health and environment
• Reverses the burden of proof, from authorities to industry, in order to adequately control risks
  – Industry to ensure that human health and the environment are not adversely affected
Thank you!