

# Health and safety – Latest findings

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# Presentation Outline

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- Introduction
- Important work and studies
- IARC Monograph
- REACH

PRACTICAL SOLUTIONS

# A license to operate

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- 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

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- 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

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# Important work and studies

# Joint HSE group

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## 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

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- 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

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# Closure on Cancer Question By Providing High Quality Data for Review by IARC and other Groups

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- 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 1<sup>st</sup> June 2004
- Animal 2 year study Fraunhofer
  - Does exposure to bitumen fume cause cancer in animals? Identify dose response relationship, and threshold level for health effect. Started March 2003.
- 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

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# IARC Monograph

# The IARC Monograph program

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- 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

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- 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

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- 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

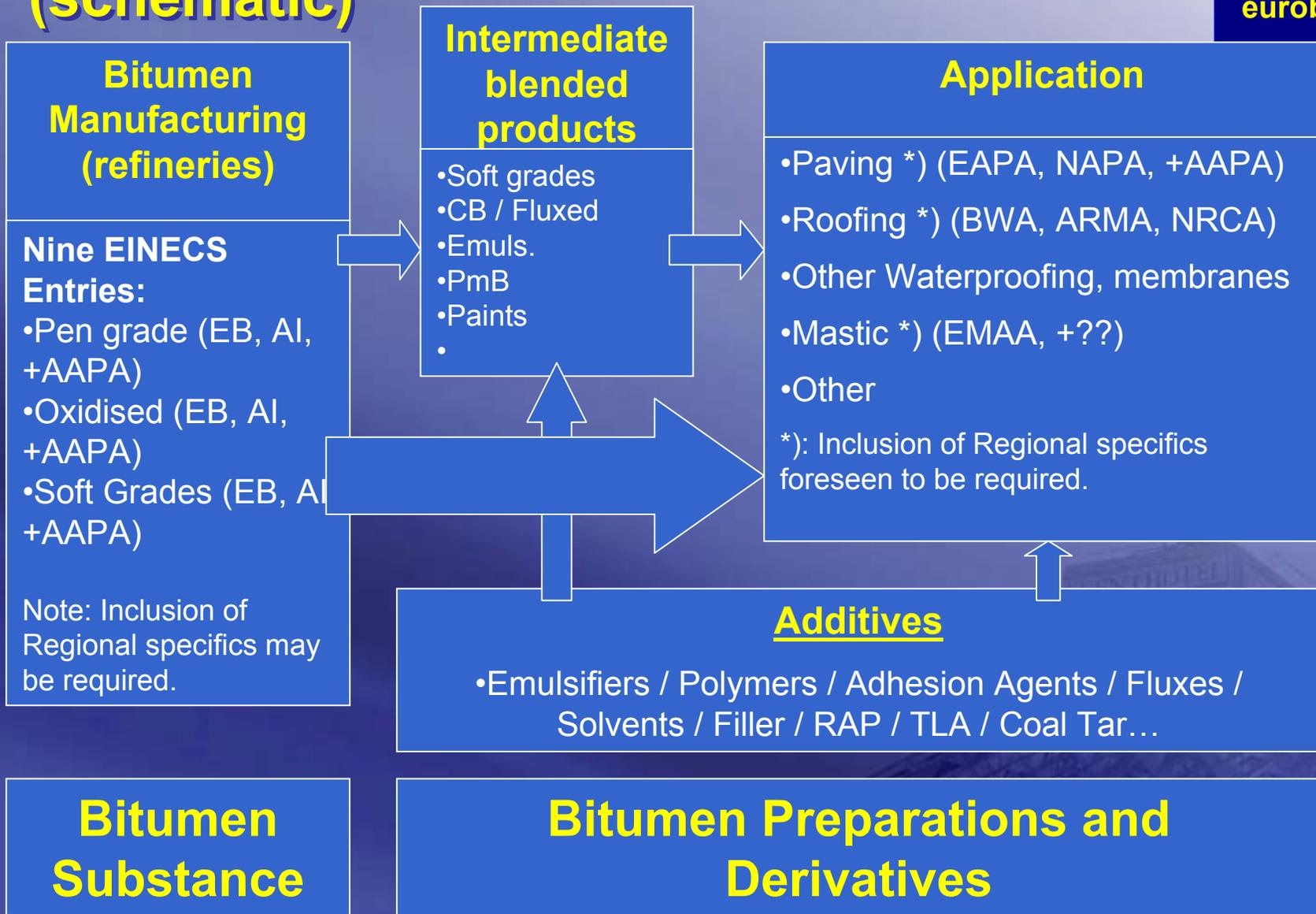
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- Ch 1, Industry Description
  - Changes over time
  - Regional differences
- Bibliography (on epidemiology, toxicology, exposure, mechanistics)
  - Gaps identification and filling with new data/papers
    - New research
    - Publish unpublished data
    - 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

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# Ch 1 – Bitumen Manufacturing and Use (schematic)

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# IARC Monograph preparations

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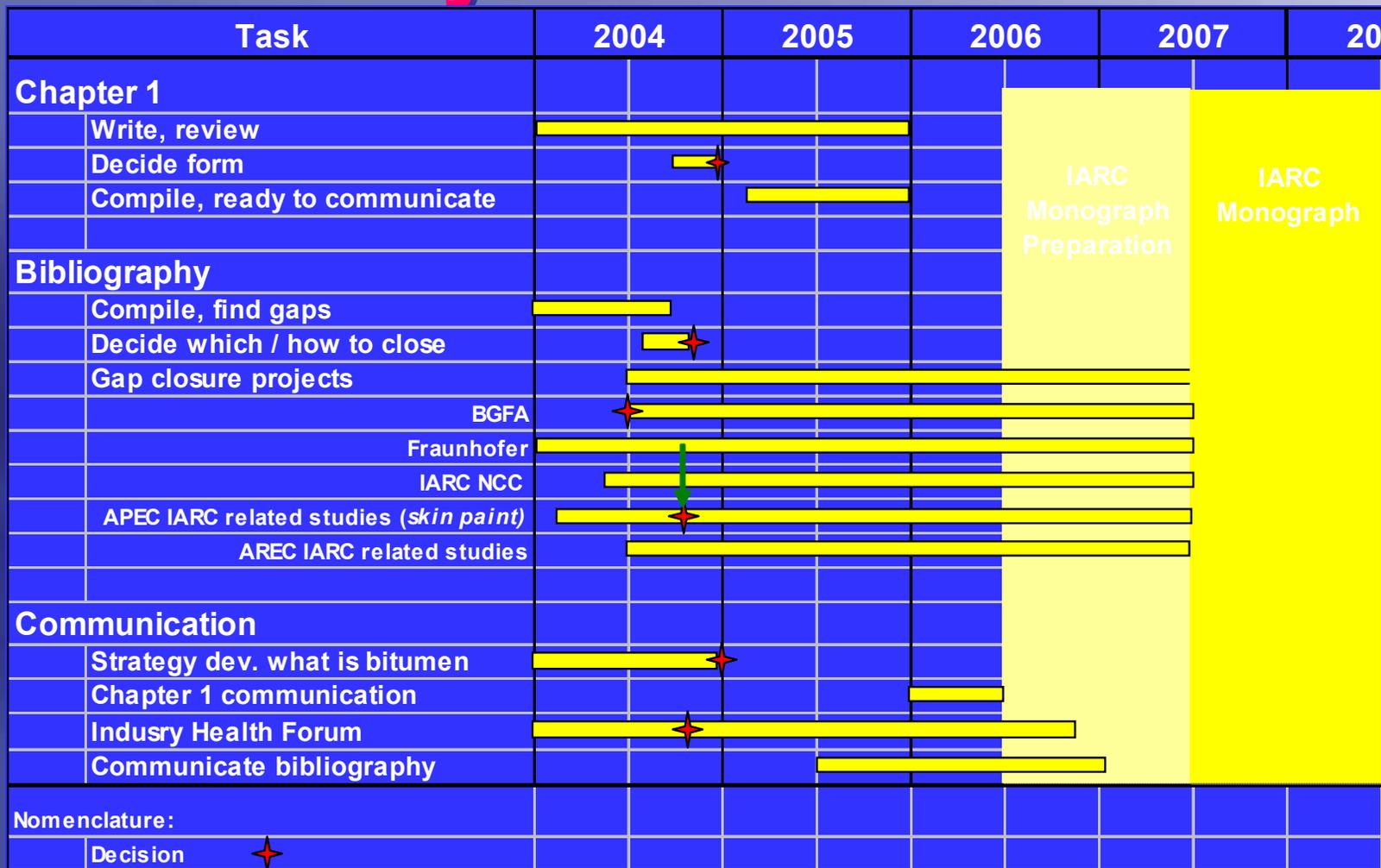
## EMAA & Eurobitume joint HSE group tasks

- 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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# REACH

# REACH proposal

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- 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

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# REACH

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- 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

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**Thank you!**