

# Proposal to Streamline Several Sections of Cancer Hazard Identification Documents

**Carcinogen Identification Committee Meeting**  
**February 27, 2024**

**Cancer Toxicology and Epidemiology Section**  
**Reproductive and Cancer Hazard Assessment Branch**  
**Office of Environmental Health Hazard Assessment, CalEPA**



**CalEPA**  
California Environmental  
Protection Agency

# Outline

- Goals of the Proposal and today's discussion
- HID Sections included in the Proposal
  - *Introduction*
  - *Carcinogenicity Studies in Humans*
  - *Carcinogenicity Studies in Animals*

# Goals

- Goal of the Proposal
  - Streamline three sections of the HID
    - Introduction
    - Carcinogenicity studies in humans
    - Carcinogenicity studies in animals
  - Focus on the most informative studies, limit the scope of discussion of the less informative studies
- Goal for today's discussion
  - Receive input on the Proposal

# Structure of the Proposal

- For the Introduction section, the Proposal includes
  - Proposed changes
  - Examples of proposed changes
- For the carcinogenicity studies in humans and animals sections, the Proposal includes
  - General considerations of informativeness
  - Proposed changes
  - Proposed organization
  - Examples of proposed changes

# Changes to the *Introduction* of HID

- Chemical Identity No Changes
- Production, Sources, and Uses Limit to 1-2 paragraphs
- Occurrence and Exposure Limit to 1-2 paragraphs
- Reviews by Other Health Agencies No Changes

# Changes to the *Carcinogenicity Studies in Humans* Section

- Most informative studies No changes: provide text and tables
- Less informative studies Briefly summarize, discuss limitations. No detailed description or table
- Least informative studies and cancer sites with very limited data Mention and list in the bibliography

# Considerations of Informativeness of Epidemiologic Studies

- Factors inherent to specific **study designs**
- **Sensitivity and ability** to detect a true association
  - Presence or absence of **biases** (e.g., selection and attrition bias, exposure measurement error and misclassification, outcome misclassification, potential for confounding, analysis bias)
  - **Other factors** (e.g., sample size, exposure contrast, sufficient follow-up time)

# Changes to the *Carcinogenicity Studies in Animals* Section

- Most informative studies

No changes: provide text and tables

- Less informative studies

Briefly summarize key findings. No detailed description or tables.

- Least informative studies

Mention and list in the bibliography



# Considerations of informativeness of animal carcinogenicity studies

## Most informative

- Animal cancer bioassays
- Exceptionally, sub-chronic or short-term studies, when adequately designed and there is evidence that the carcinogenicity of the chemical has a short latency period

## Less informative

- Studies using genetically modified animal models, xenograft and regenerated organs using normal cells, and tumor initiation-promotion studies

## Least informative

- Co-carcinogenicity studies, and xenograft studies using human cancer cells

# Q&A Break