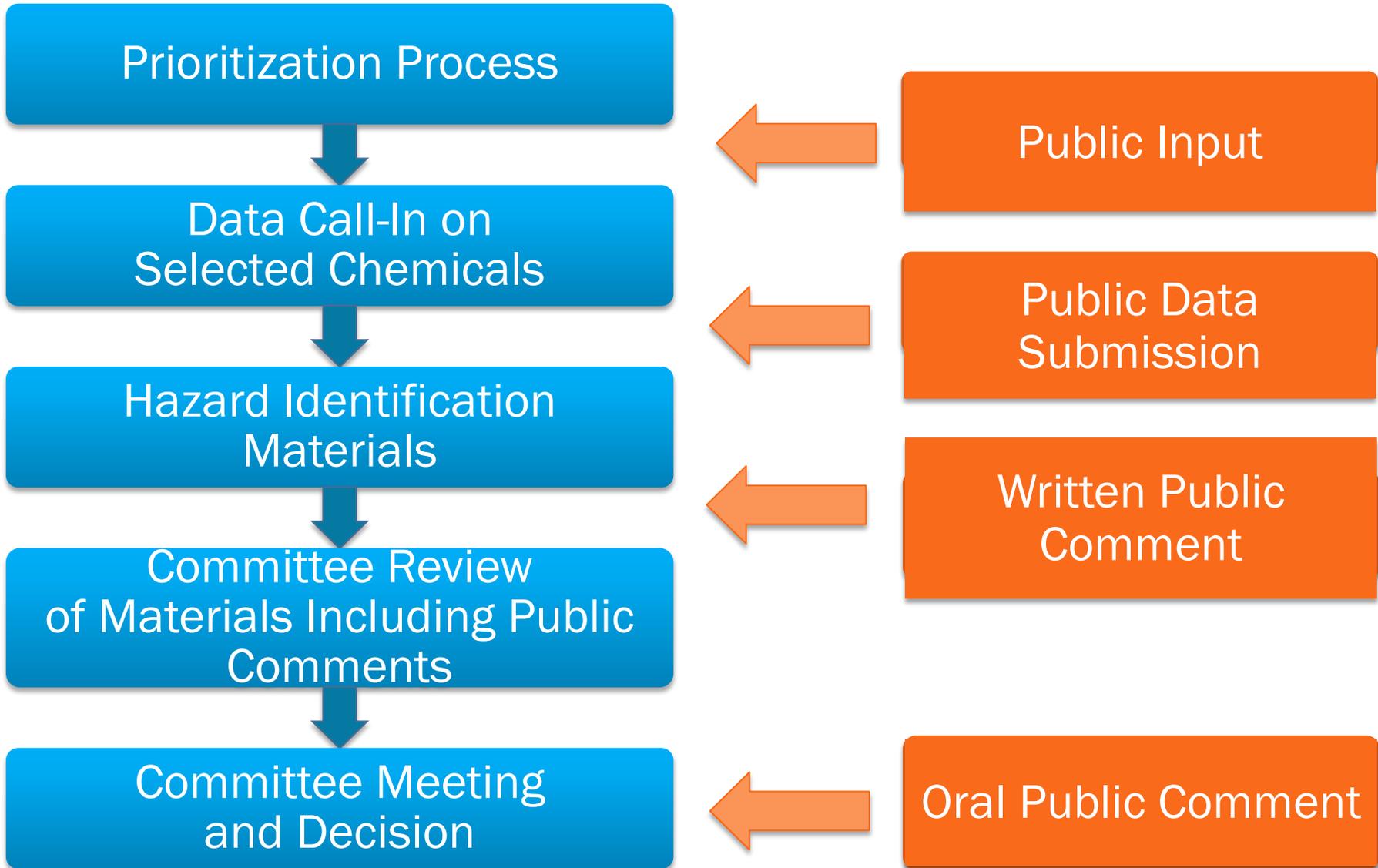


DEVELOPMENTAL AND REPRODUCTIVE TOXICANT (DART) IDENTIFICATION COMMITTEE: THE “STATE’S QUALIFIED EXPERTS” (CONTINUED)

AN ADVISORY BODY TO THE GOVERNOR AND
THE OFFICE OF ENVIRONMENTAL HEALTH
HAZARD ASSESSMENT (OEHHA)



DEVELOPMENT OF HAZARD IDENTIFICATION MATERIALS FOR THE DART IC



Development of Hazard Identification Materials

To support Committee deliberation.

Topics covered:

Chemical Identity, occurrence and use

Male Reproductive Toxicity

Female Reproductive Toxicity

Developmental Toxicity



Development of Hazard Identification Materials (continued)

Lines of Evidence:

Human studies

Animal studies

Mechanistic and other relevant data

(Pharmacokinetics, Metabolism, Genotoxicity,
Pathology, Structure-Activity Comparisons, etc.)



Hazard Identification Materials Formats

- Summary and review of evidence* by OEHHA (e.g., Xylene)
- Brief summary by OEHHA and other entities (e.g., National Academy of Sciences), study reports, and/or other scientific publications (e.g., Bisphenol A)

*All scientific publications used in the reviews are generally sent to the committee member as part of the Hazard Identification Materials



Relationship between Maternal Toxicity and Developmental Outcome

U.S. EPA (1991) Guidelines for Developmental Toxicity Risk Assessment. “Agents that produce developmental toxicity at a dose that is not toxic to the maternal animal are especially of concern because the developing organism is affected but toxicity is not apparent in the adult. However, **the more common situation is when adverse developmental effects are produced only at doses that cause minimal maternal toxicity** [marginal but significantly reduced body weight, reduced weight gain, or specific organ toxicity, and at the most no more than 10% mortality]; **in these cases, the developmental effects are still considered to represent developmental toxicity and should not be discounted as being secondary to maternal toxicity.** At doses causing excessive maternal toxicity (that is, significantly greater than the minimal toxic dose), information on developmental effects may be difficult to interpret and of limited value.”

United Nations Economic Commission for Europe Globally Harmonized System of Classification and Labeling of Chemicals (Section 3.6.2.4.2, 2009) “Developmental effects, which occur even in the presence of maternal toxicity are considered to be evidence of developmental toxicity, unless it can be unequivocally demonstrated on a case by case basis that the developmental effects are secondary to maternal toxicity.”



DART IC Deliberations

To aid committee determinations on whether a chemical has been

“clearly shown, through scientifically valid testing according to generally accepted principles, to cause reproductive toxicity,”

the committee receives:

Hazard identification materials

- Information compiled and prepared by OEHHA
- All public comments
- Other information committee members request OEHHA to obtain or prepare for them



QUESTIONS?

