NTP's Process On EO Has Not Enabled A Scientific Dialogue On Key Questions Related To Classification Of EO

- EOIC's comments present issues on the scientific frontier as to the relevance of cytogenetic data in cancer classification.
- NTP should encourage debate on how genetic toxicity data are used in cancer classification.
- EOIC is unable to engage in dialogue on a question of this complexity in 5 minutes presentations -- especially when there is no question and answer opportunity.

Specific Concerns With The NTP Process

- The background documentation that led to the proposed (re)classification is not available for comment until late stages of the process.
- The background document for EO does not respond to the detailed comments that EOIC provided in March.
- The five-minute opportunity for comment before BSC is inadequate, both because the time allotted is insufficient to address complex subject matter and because there is no question-and-answer or meaningful dialogue.
  - -- The BSC does not have adequate time to review commenters' responses to the Background Documentation.
- While we recognize that the BSC review is not the last stage in the process, the next stage--review by the NTP Director--also lacks opportunity for dialogue on scientific issues.

NTP Classification Decisions Are Agency "Rules"

- As a federal agency, NTP is subject to the Administrative Procedure Act. In Synthetic Organic Chemical Manufacturers Ass'n. (SOCMA) v. HHS, 720 F. Supp. 1244 (W.D. La. 1989), chemical companies challenged the substance of certain cancer listing decisions.
- The SOCMA v. HHS decision is significant for purposes of evaluating NTP's notice-and-comment obligations because the court finds that the APA is fully applicable to NTP listing decisions. The listings constitute a "rule" and as such are subject to judicial review.
  - -- The Court stated: "The Annual Report was intended to offer the Secretary's judgment as to carcinogenicity for reference by a broad range of regulatory agencies and to play an important role in setting the regulatory agenda. It fits squarely within the type of decision that Congress intended to be reviewable under the APA."
  - -- NTP Classification Criteria "constitute a 'rule' as defined in § 551(4), subject to judicial review pursuant to § 702."
- NTP like other agencies must provide a meaningful opportunity for public comment in its rulemaking.

Stakeholder Participation Helps Produce Decisions Based on Sound Science

- Notice and comment is not some hyper-technical legal requirement imposed to complicate agency decision-making.
- According to the Ommen Commission on Risk Assessment (1997): "Experience increasingly shows that risk management decisions that are made in collaboration with stakeholders are more effective and more durable. Stakeholders bring to the table important information, knowledge, expertise, and insights for crafting workable solutions. Stakeholders are more likely to accept and implement a risk management decision they have participated in shaping. . . ."
- "Stakeholder collaboration . . . facilitates an exchange of information and ideas that is essential for enabling all parties to make informed decisions about reducing risks. Collaboration does not require consensus, but it does require that all parties listen to, consider, and respect each other's opinions, ideas, and contributions."
- Members of the Ommen Commission: Gilbert Omenn (chair), Alan Kessler, Norman Anderson, John Doull, Peter Chin, Bernard Goldstein, Prof. Joshua Lederberg, Sheila McGuire and Virginia Weldon, David Rall, formerly Director of NIEHS and NTP.

EOIC Recommendations

- EOIC requests an on-the-record meeting to explore novel issues presented by use of cytogenetic data in cancer classification.
  - -- Engage in a meaningful exchange on genetic toxicity issue
  - -- Take the time to consider in press Preston research only recently provided to NTP to allow scientific information to receive adequate review
- Avoid rush to judgment
- Until this meaningful dialogue occurs, defer EO from 9th carcinogen list