Comments on the NTP's Report on Carcinogens (RoC) Process

Richard A. Becker, Ph.D., D.A.B.T.
American Chemistry Council

January 2004

Recommendations

- Strengthen the scientific quality
- Enhance public participation processes in the development of RoC actions
- Clarify listing/delisting criteria used for the RoC

Scientific Quality

- The foundation of RoC listings and delistings
  - comprehensive and thorough review and interpretation of the best available science
  - scientific experts need to be involved
  - conducted in a manner that fosters scientific dialog
  - transparent decision making, open meetings and stakeholder involvement
- Any changes to the RoC contemplated by NTP should be focused on ensuring these fundamental principles are enhanced
- NTP's efforts to revise the RoC process will be advanced by activities to address Data Quality and Peer Review directives of OMB

Public & Stakeholder Participation

- Open & transparent process
- Adequate time to engage
- Opportunity for meaningful input at appropriate points
- Recognition that comments & interchange is considered fully

ACC's Recommendations

- NTP consider adapting and building on the interactive scientific model put into practice in the CERHR process

- Adaptation of the CERHR process:
  - Comprehensive & thorough background document
  - Participation in drafting/writing document by subject-matter experts
  - Opportunity for meaningful scientific input early on in the process: latest studies, mode of action data, etc.

— Process —

NTP Center for the Evaluation of Risks to Human Reproduction

Chemical Nomination and Selection

Open nomination process

Nominations reviewed by CC

Chemicals recommended

Approval, NTP, Assoc. Director

Public comment

CC Recommends chemicals for review

Approval, NTP, Assoc. Director

Public comment

Expert Panel Review

CC Recommends Expert Panel

Approval, NTP, Assoc. Director

Meeting Announcement; Public comment

Draft report

Expert Panel meeting; public comment

Expert Panel Report

Public comment

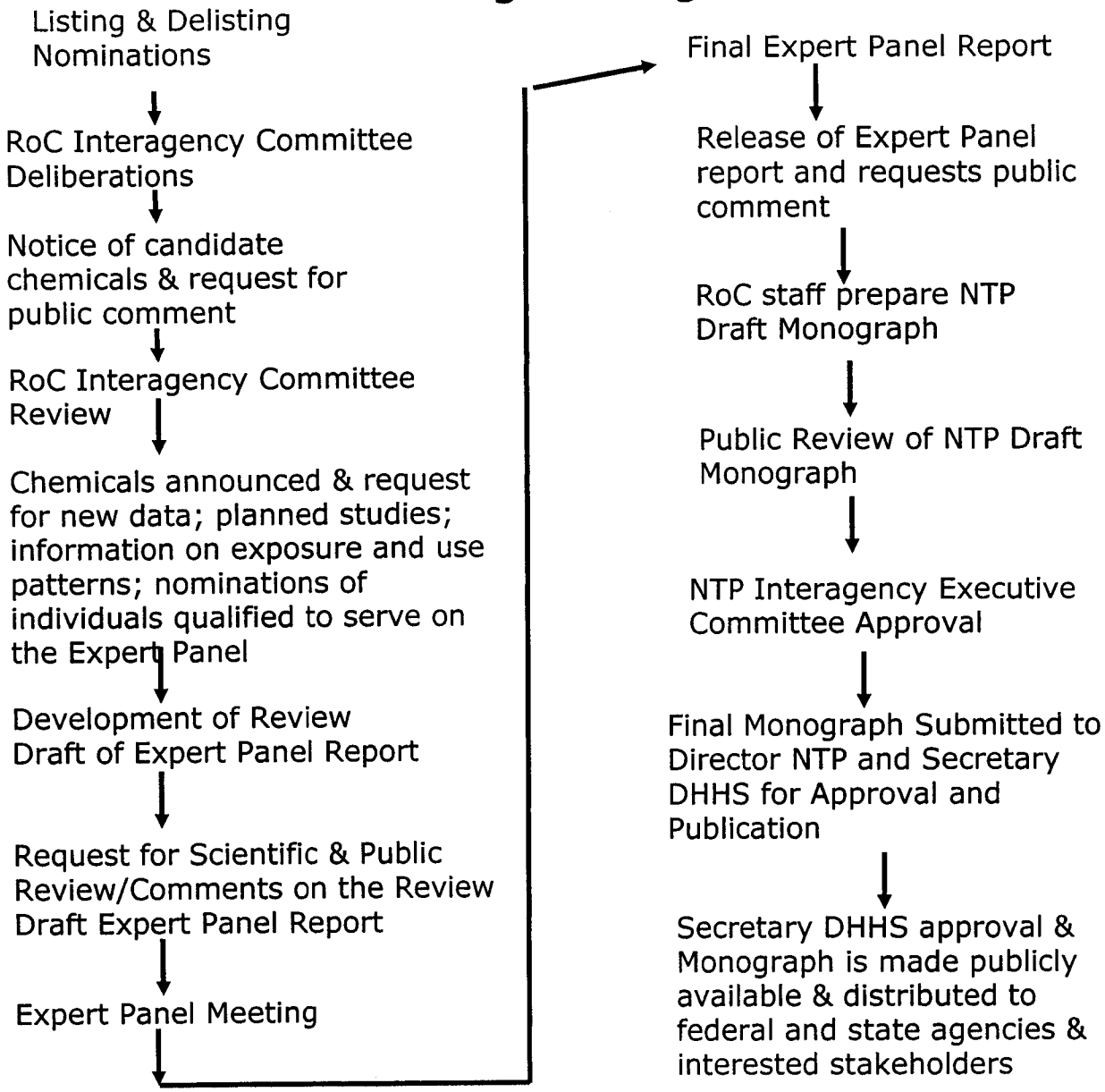
NTP Transmittal

NTP Center Report
- Background Information
- Expert Panel Conclusions
- New data
- NTP position
- Public comments

CC Review

NTP Center Report Transmitted
- Federal agencies
- State agencies
- Public
- Scientific community

Recommended Process NTP Consider for Strengthening the RoC



Criteria for Listing/Delisting

- "Known to be a human carcinogen" -- determination <u>should only be made</u> if there is sufficient evidence of carcinogenicity from epidemiological or clinical studies that indicate a causal relationship between exposure to the agent and human cancer.
- A clear distinction between "known to be a human carcinogen" and "reasonably anticipated to be a human carcinogen" is sound public policy.
- Mechanistic or other scientific information should be used in reaching a determination of "reasonably anticipated to be (or not to be) a human carcinogen"