

Report on Carcinogens Concepts

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NTP Board of Scientific Counselors Meeting
April 16 – 18, 2014



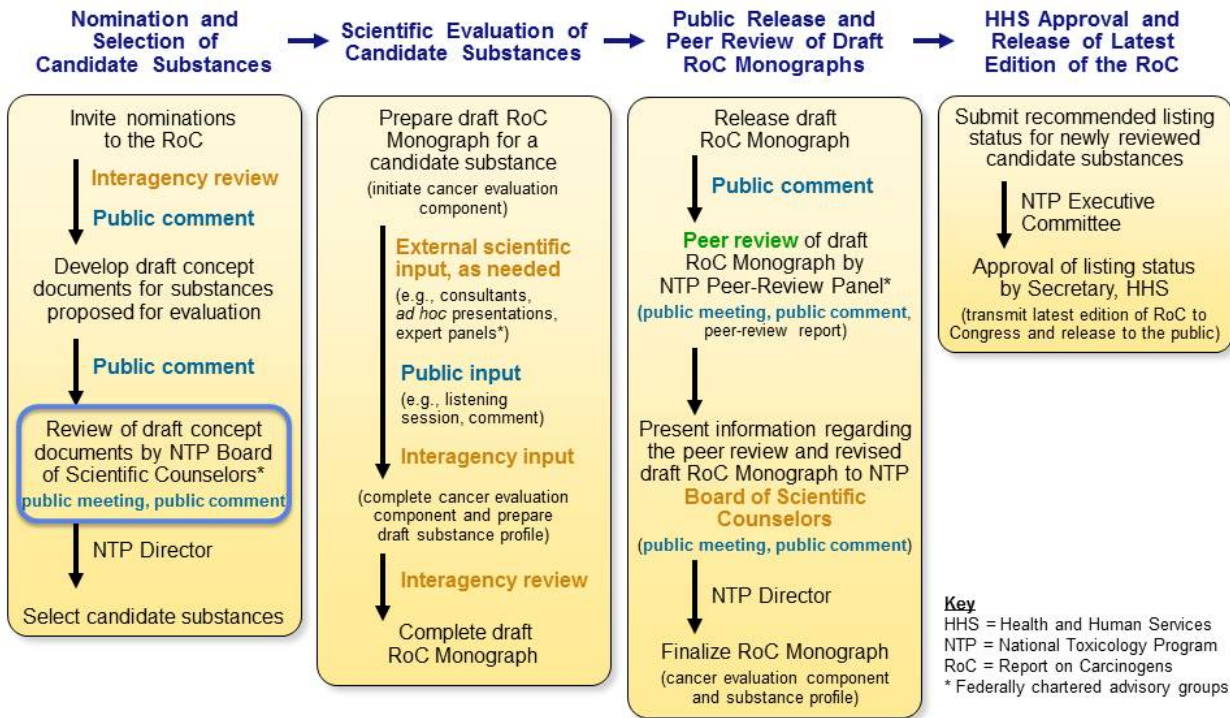
The Report on Carcinogens (RoC) is congressionally mandated

- Public Health Services Act, Section 301(b)(4) (1978, amended 1993).
 - Directs HHS Secretary to publish a list of carcinogens.
- The National Toxicology Program (NTP) prepares the RoC for the Secretary.
- Identifies substances that pose a cancer hazard for people in the United States.
 - Lists substances as “*known*” or “*reasonably anticipated human carcinogens*”.
- Each edition of the report is cumulative.
 - Most recent edition, 12th RoC, was published in June 2011.

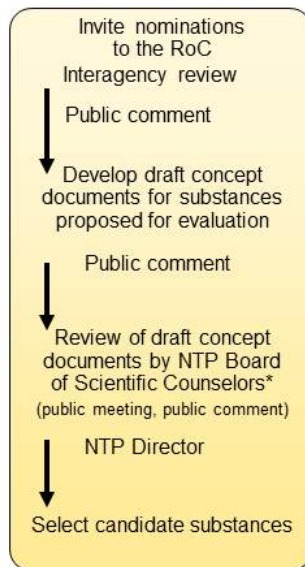


<http://ntp.niehs.nih.gov/go/roc>

Process for preparation of the RoC

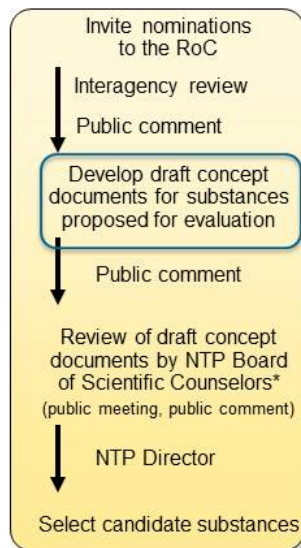


Rolling process for selecting nominations for formal review



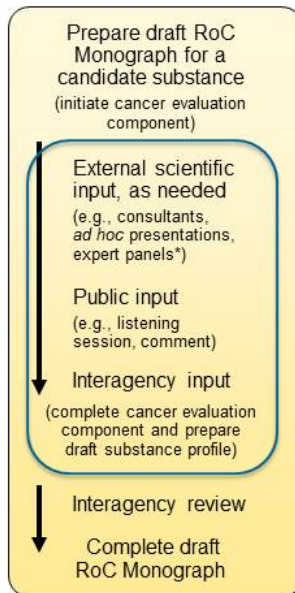
- On an ongoing basis the NTP invites nominations and solicits comments or information on those nominated substances.
- The NTP uses this information and input from its interagency partners to identify substances to propose for formal review.
- For each substance proposed for review, the NTP prepares a draft concept document.
- The NTP invites comment on the draft concept document.

Draft concept document



- Objectives:
 - Rationale for reviewing the proposed candidate substance.
 - Proposed approach for conducting the cancer evaluation.
- Types of Information:
 - Overview of human exposure data.
 - Overview of the extent and nature of the carcinogenicity information.
 - **Not** a review or assessment of the data
 - Key scientific questions and issues based on current knowledge.
 - Preliminary literature search strategy.

ORoC will use a variety of mechanisms to obtain scientific and public inputs



- Technical advisors (individual level).
 - External or internal to the government.
 - Expertise on substance and/or relevant disciplines.
 - Provide early input in identifying literature and issues and comment on draft monograph.
- Information group (non-FACA).
 - Individuals assembled to exchange information, usually about a specific issue.
 - Provide comment as individuals.
- *Ad-hoc* presentations (e.g., public web-based symposiums).
 - Invited presentations on specific issue(s).
 - Focused discussions led by technical advisors.

ORoC establishes a website for each candidate substance

Pentachlorophenol



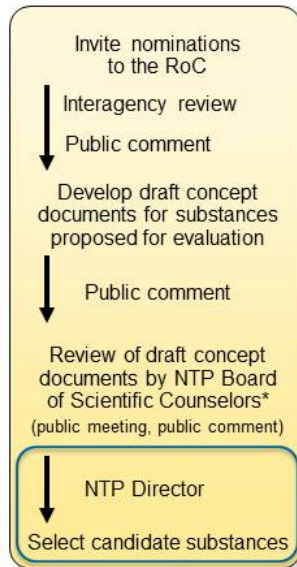
<http://ntp.niehs.nih.gov/go/37897>

Status: Candidate Substance

- Background
 - CAS # 87-86-5
 - General biocide that has been used extensively as a fungicide, bactericide, herbicide and insecticide by agriculture and other industries. In 1987, over-the-counter use was banned and other uses restricted. Currently, pentachlorophenol is defined in the United States as a 'heavy duty' wood preservative that is used primarily in the treatment of utility poles and cross arms.
- RoC documents related to the scientific review of pentachlorophenol
 - Federal Register Notice - Jan. 19, 2012 requesting public comment on nominated substances
 - Concept Document
 - Federal Register Notice – October 17 2012 requesting Nominations of Scientific Experts
 - Protocol: Evaluation of human cancer studies (August 15, 2013)
 - Protocol: Evaluation of cancer studies in experimental animals (November 2, 2012) - Protocol Update (August 15, 2013)
 - Preliminary literature search and identified citations (August 15, 2013)
 - Draft RoC Monograph *(Updated 8/30/2013 with revised cover)*
 - Revised Draft RoC Monograph *(March 14, 2014)*
 - NTP Board of Scientific Counselors, Meeting April 16 – 18, 2014
 - Final RoC Monograph
- Public Comments
- Meetings, Webinars and Listening Sessions
 - Webinar (April 11, 2013) - Human cancer studies on exposure to pentachlorophenol (PCP): Differentiating potential cancer effects of PCP exposure from effects due to occupational co-exposures or PCP contaminants
 - Meeting: Peer Review of Draft Report on Carcinogens Monographs for *ortho*-Toluidine and Pentachlorophenol
- **INPUT – provide information** *(such as citations or new studies, scientific issues, nomination of experts or to comment on RoC documents)*

NTP will communicate via the NTP list serve (<http://ntp.niehs.nih.gov/go/getnews>) when new information is added or current information is updated on this page.

Next steps



- NTP considers comments on draft concepts from the Board of Scientific Counselors and public.
 - NTP Director finalizes the list of candidate substances.
 - Office of the RoC (ORoC) finalizes the concept documents.
- ORoC establishes a webpage for each candidate substance and posts relevant materials.
- ORoC initiates scientific evaluation of the candidate substances including development of the draft RoC monographs.