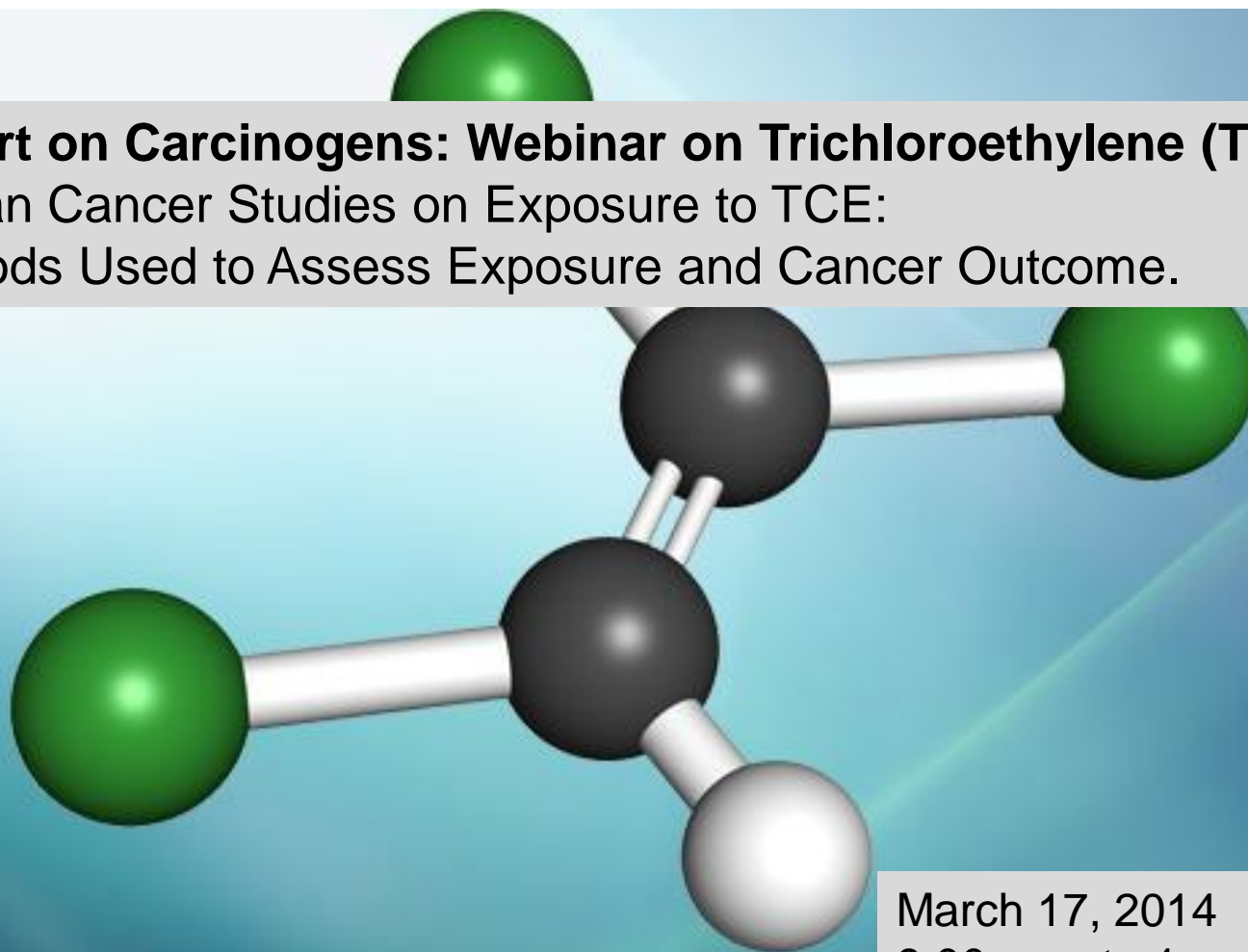




NTP

National Toxicology Program

Report on Carcinogens: Webinar on Trichloroethylene (TCE)
Human Cancer Studies on Exposure to TCE:
Methods Used to Assess Exposure and Cancer Outcome.



March 17, 2014
9:00 a.m. to 1 p.m EDT



Trichloroethylene (TCE) Webinar Agenda

Welcome and Introduction: Mary Wolfe/Ruth Lunn, NTP

Webinar Agenda and Logistics: Cheryl Siegel Scott, U.S. EPA

Seminar Presentations: Cheryl Siegel Scott

- **Methods Used to Assess TCE Exposure Levels, Duration, and Probability in Epidemiologic Studies.**
 - Patricia Stewart, PhD, Stewart Exposure Assessments, LLC
- **Methods Used to Classify Cancer Outcomes – Specifically Lymphohematopoietic Cancers.**
 - Bernard D. Goldstein, MD, Professor Emeritus, University of Pittsburgh
- **Use of Exposure and Outcome Assessments in the Epidemiologic Studies.**
 - Mark Purdue, PhD, National Cancer Institute

Discussion: Neela Guha, International Agency for Research on Cancer

- Topic-Specific Questions
- Public-Initiated Questions

Draft Protocol for Preparing the Draft RoC Monograph on TCE: Ruth Lunn

Next Steps/Closing Remarks: Ruth Lunn/Mary Wolfe

NTP Selected TCE as a Candidate Substance

- TCE is a chlorinated alkene used primarily as a metal degreaser.
- Occupational and environmental exposure.
 - TCE is ubiquitous in the atmosphere, soil, ground, surface and drinking water, and in food.
- Currently listed in the Report on Carcinogens (RoC) as *reasonably anticipated to be a human carcinogen*.
- Adequate database of cancer studies published since the last RoC review.
- Review for possible change in listing status in the RoC.

Process for Preparation of the Report on Carcinogens (RoC)

Nomination and Selection of Candidate Substances



Scientific Evaluation of Candidate Substances



Public Release and Peer Review of Draft RoC Monographs



HHS Approval and Release of Latest Edition of the RoC

Invite nominations to the RoC

Interagency review

Public comment

Develop draft concept documents for substances proposed for evaluation

Public comment

Review of draft concept documents by NTP Board of Scientific Counselors*
(public meeting, public comment)

NTP Director

Select candidate substances

Prepare draft RoC Monograph for a candidate substance
(initiate cancer evaluation component)

External scientific input, as needed
(e.g., consultants, ad hoc presentations, expert panels*)

Public input
(e.g., listening session, comment)

Interagency input

(complete cancer evaluation component and prepare draft substance profile)

Interagency review

Complete draft RoC Monograph

Release draft RoC Monograph

Public comment

Peer review of draft RoC Monograph by NTP Peer-Review Panel*
(public meeting, public comment, peer-review report)

Present information regarding the peer review and revised draft RoC Monograph to NTP Board of Scientific Counselors (BSC)
(public meeting, public comment)

NTP Director

Finalize RoC Monograph
(cancer evaluation component and substance profile)

Submit recommended listing status for newly reviewed candidate substances

NTP Executive Committee

Approval of listing status by Secretary, HHS
(transmit latest edition of RoC to Congress and release to the public)

Key

HHS = Health and Human Services

NTP = National Toxicology Program

* Federally chartered advisory groups

TCE Webinar: Purpose





- To obtain scientific and public input on:
 - Issues related to the assessment of information (exposure and endpoint) in the epidemiologic studies of exposure to TCE.
 - Protocol for preparing the draft RoC monograph on TCE.
- Input from the webinar will be used to inform the RoC cancer evaluation of TCE.

Trichloroethylene



<http://ntp.niehs.nih.gov/go/37899>

Status: Candidate Substance

- Background
 - CAS # 79-01-6
 - Halogenated alkene used mainly as an intermediate for hydrofluorocarbon production (67%) and as a degreaser for metal parts (30%). It is a major ingredient in many consumer products and has been found in food and drinking water, and the environment (ambient air, ground and tap water).
 - Currently listed as *Reasonably Anticipated to be a Human Carcinogen* in the 12th RoC.
- RoC documents related to the scientific review of trichloroethylene
 - [Federal Register Notice \(January 19, 2012\)](#)  requesting public comment on nominated substances
 - [Revised Concept Document](#)  (December 31, 2013)
 - [Protocol: Methods for preparing the draft RoC monograph on TCE](#)  (December 31, 2013)
 - Preliminary literature search and identified citations
 - Draft RoC Monograph
 - Final RoC Monograph
- [Public Comments](#)
- Meetings, Webinars and Listening Sessions
 - [Federal Register Notice \(Nov. 12, 2013\)](#)  - requesting nominations of speakers for a proposed TCE webinar
 - [Webinar \(March 17, 2014\)](#) - "Human Cancer Studies on Exposure to Trichloroethylene (TCE): Methods Used to Assess Exposure and Cancer Outcomes"
- **INPUT – provide information** (*such as citations or new studies, scientific issues, nomination of experts, or 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.

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Webinar Logistics: Opportunities for Public Participation

- Seminar presentations: Question and Answers
 - The public may ask **clarifying** questions following each presentation.
- Topic-specific questions
 - The Discussion Leader (Dr. Guha) will ask the speakers a series of questions on four topics and will facilitate the discussion.
 - Following the last question for each topic, the public can ask a question or make a comment that is related to each topic.
- Public-initiated questions/topics
 - The public can ask a question or make a comment on any topic related to the webinar.
- Draft Protocol
 - Following the presentation, the public can ask a question or make a comment on the draft protocol for preparing the draft RoC monograph on TCE.

Webinar Logistics: How to Participate?

- Media for participating
 - Operator assisted call: Dial 1-866-952-1907 (toll-free) or 1-785-424-1826 for U.S. participants.
 - Email: ntpMeetings@niehs.nih.gov for International participants.
- Methods for participating
 - Moderator or Discussion Leader will ask for questions or comments during the question and answer periods and discussion sessions.
 - If you have a question, dial the number above; the operator will inform you when it is your turn to speak.
 - State your name and affiliation before asking your question.
 - Hang up the phone after your question has been addressed.
 - Dial *0 if you need to contact the operator while you are on hold.
- Please use your computer audio during the speaker presentations and when you are not making a comment.