DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Draft Report on Carcinogens
Monograph on Antimony Trioxide;
Availability of Document; Request for Comments; Notice of Peer-Review Meeting

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Toxicology Program (NTP) announces a meeting to peer review the Draft Report on Carcinogens (RoC) Monograph on Antimony Trioxide. The Office of the Report on Carcinogens, Division of the National Toxicology Program (DNTP), National Institute of Environmental Health Sciences (NIEHS) prepared the monograph. This peer-review meeting is by webcast only and is open to the public. Registration is requested for oral comment and is required to access the webcast. Information about the meeting and registration is available at https://ntp.niehs.nih.gov/go/38853.

DATES: Meeting: January 24, 2018, 8:30 a.m. to adjournment at approximately 4:00 p.m. Eastern Standard Time (EST). The meeting may end sooner or later than 4:00 p.m. EST.


Written Public Comment Submissions: Deadline is January 10, 2018.

Registration for Oral Comments: Deadline is January 10, 2018.

Registration to View Webcast: Deadline is January 24, 2018.

Registration to view the meeting webcast is required.

ADDRESSES:
Meeting Location: Webcast.
Meeting Web page: The draft monograph, preliminary agenda, registration, and other meeting materials will be available at https://ntp.niehs.nih.gov/go/38853.

Webcast: The URL for viewing the peer-review meeting webcast will be provided to registrants.

FOR FURTHER INFORMATION CONTACT: Canden Byrd, ICF, 2635 Meridian Parkway, Suite 200, Durham, NC, USA 27713. Phone: (919) 293–1660, Fax: (919) 293–1645, Email: canden.byrd@icf.com.

SUPPLEMENTARY INFORMATION:

Background: The RoC is a congressionally mandated, science-based, public health report that identifies agents, substances, mixtures, or exposures (collectively called “substances”) in our environment that pose a cancer hazard for people in the United States. NTP prepares the RoC on behalf of the Secretary of Health and Human Services.

NTP follows an established, four-part process for preparing the RoC (https://ntp.niehs.nih.gov/pubhealth/roc/process/index.html). For each substance selected for review, a draft RoC monograph is prepared that presents (1) information on human exposure to the substance; (2) an assessment of the evidence from cancer studies in humans and experimental animals, mechanisms of carcinogenicity, and other data relevant for evaluating the substance’s potential carcinogenicity; and (3) NTP’s preliminary RoC listing recommendation. The draft monograph also contains a draft profile that provides NTP’s preliminary listing recommendation for the substance and a summary of the scientific evidence considered key to reaching that recommendation.

Antimony trioxide was selected for review following solicitation of public comment, review by the NTP Board of Scientific Counselors on December 14–15, 2016, and approval by the NTP Director (https://ntp.niehs.nih.gov/go/9741).

Antimony trioxide is the most commercially significant form of antimony and is a high-production-volume chemical with a production volume exceeding one million pounds per year. Its major industrial use is as a synergist with halogenated flame-retardants in textiles, plastics, and rubber. The main exposures to antimony trioxide are from inhalation of airborne solid dust and for workers in facilities producing or using antimony trioxide. Exposures of the public to antimony trioxide are primarily from environmental exposures secondary to human activities. Antimony trioxide can form in the product life cycle of other antimony compounds, such as during the use of automobile brake containing antimony trisulfate, which can oxidize into antimony trioxide. The draft RoC monograph includes a cancer hazard assessment for antimony trioxide.

Meeting and Registration: The meeting is open to the public with time set aside for oral public comment. Registration to view the webcast is by January 24, 2018, at https://ntp.niehs.nih.gov/go/38853. Registration is required to view the webcast; the URL for the webcast will be provided in the email confirming registration.

Individuals with disabilities who need accommodation to view the webcast should contact Canden Byrd by phone: (919) 293–1660 or email: canden.byrd@icf.com. TTY users should contact the Federal TTY Relay Service at (800) 877–8339. Requests should be made at least five business days in advance of the event.

Meeting Materials: The draft monograph and preliminary agenda will be available on the NTP Web site at https://ntp.niehs.nih.gov/go/38853. The draft monograph should be available by November 30, 2017. Additional information will be posted when available or may be requested in hardcopy, contact Canden Byrd by phone: (919) 293–1660 or email: canden.byrd@icf.com.

Following the meeting, a report of the peer review will be prepared and made available on the NTP Web site. Individuals are encouraged to access the meeting Web page to stay abreast of the most current information regarding the meeting.

Request for Comments: NTP invites written and oral public comments on the draft monograph. The deadline for submission of written comments is January 10, 2018, to enable review by the peer-review panel and NTP staff prior to the meeting. Registration to provide oral comments is on or before January 10, 2018, at https://ntp.niehs.nih.gov/go/38853. Written public comments and any other correspondence on the draft monograph should be sent to Canden Byrd by email: canden.byrd@icf.com. Persons submitting written comments should include name, affiliation, mailing address, phone, email, and sponsoring organization (if any). Written comments received in response to this notice will be posted on the NTP Web site, and the submitter will be identified by name, affiliation, and sponsoring organization (if any). Guidelines for public comments are available at https://ntp.niehs.nih.gov/ntp/aboutntp/guidelines_public_comments_508.pdf.

Oral public comment at this meeting is welcome, with time set aside on January 24 for the presentation of oral remarks on the draft monograph. Public comments will be presented by teleconference line. Fifty (50) lines will be available for this call; availability is on a first-come, first-served basis. The lines will be open from 8:30 a.m. until
adjournment at approximately 4:00 p.m.
EST on January 24, 2018 (meeting may
end sooner or later than 4:00 p.m. EST).
Oral comments will be received only
during the formal public comment
periods indicated on the preliminary
agenda. The access number for the
teleconference line will be provided to
registrants by email prior to the meeting.
Each organization is allowed one time
slot. At least 7 minutes will be allotted
to each time slot, and if time permits,
the allotment may be extended to 10
minutes at the discretion of the chair.
Please note: The time per speaker may
be decreased if the number of
commenters exceeds the total time
allotted for public remarks. If the time
per speaker changes, commenters
should send a copy of their
slides and/or statement or talking points
to Can den Byrd by email: can den. byrd@icf.com
by January 10, 2018. If possible, oral public
commenters should send a copy of their
slides and/or statement or talking points
to Can den Byrd by email: can den. byrd@icf.com
by January 10, 2018. Written
statements may supplement and may
expand the oral presentation.

Background Information on the RoC:
Published biennially, each edition of
the RoC is cumulative and consists of
substances newly reviewed in addition
to those listed in previous editions. For
each listed substance, the RoC contains
a substance profile, which provides
information on cancer studies that
support the listing—including those in
humans and animals and studies on
possible mechanisms of action,
information about potential sources of
exposure to humans, and current
Federal regulations to limit exposures.
The 14th RoC, the latest edition, was
published on November 3, 2016

Background Information on NTP Peer-
Review Panels: NTP panels are
technical, scientific advisory bodies
established on an “as needed” basis to
provide independent scientific peer
review and advise NTP on agents of
public health concern, new/revised
toxicological test methods, or other
issues. These panels help ensure
transparent, unbiased, and scientifically
rigorous input to the program for its use
in making credible decisions about
human hazard, setting research and
testing priorities, and providing
information to regulatory agencies about
alternative methods for toxicity
screening or nominations of
scientific experts for upcoming
panels. Scientists interested in serving
on an NTP panel should provide their
current curriculum vitae to Can den
Byrd by email: can den. byrd@icf.com.
The authority for NTP panels is
provided by 42 U.S.C. 217a; section 222
of the Public Health Service Act, as
amended. The panel is governed by the
Federal Advisory Committee Act, as
amended (5 U.S.C. Appendix 2), which
sets forth standards for the formation
and use of advisory committees.

Dated: November 1, 2017.
John R. Bucher,
Associate Director, National Toxicology
Program.

FOR ADDITIONAL INFORMATION:
To request more information on the
proposed project or to obtain a copy of the
data collection plans and
instruments, contact: Dr. Jennifer
Guimond, Project Clearance Liaison,
Office of Science Policy, Reporting, and
Program Analysis, Eunice Kennedy
Shriver National Institute of Child
Health and Human Development,
National Institutes of Health, 31 Center
Drive, Room 2A18, Bethesda, Maryland,
20892 or call non-toll-free number (301)
496–1877 or Email your request,
including your address to:
Jennifer.guimond@nih.gov.

SUPPLEMENTARY INFORMATION:
This proposed information collection was
previously published in the Federal
Register on August 28, 2017, page 40778
(82 FR 40778) and allowed 60 days for
public comment. No public comments
were received. The purpose of this
notice is to allow an additional 30 days for
public comment.

The Eunice Kennedy Shriver National
Institute of Child Health and Human
Development (NICHD), National
Institutes of Health, may not conduct or
sponsor, and the respondent is not
required to respond to, an information
collection that has been extended,
revised, or implemented on or after
October 1, 1995, unless it displays a
currently valid OMB control number.

In compliance with section
3507(a)(1)(D) of the Paperwork
Reduction Act of 1995, the National
Institutes of Health (NIH) has submitted
to the Office of Management and Budget
(OMB) a request for review and
approval of the information collection
listed below.

Proposed Collection: Generic
Clearance for the Collection of
Qualitative Feedback on Agency Service Delivery
(Eunice Kennedy Shriver National
Institute of Child Health and Human
Development)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the
Paperwork Reduction Act of 1995, the
National Institutes of Health (NIH) has
submitted to the Office of Management
and Budget (OMB) a request for review and
approval of the information collection
listed below.

DATES: Comments regarding this
information collection are best assured
of having their full effect if received
within 30-days of the date of this
publication.

ADDRESS: Written comments and/or
suggestions regarding the item(s)
contained in this notice, especially
regarding the estimated public burden
and associated response time, should be
directed to the Office of Management and
Budget, Office of Regulatory Affairs,
OIRA_submission@omb.eop.gov or by
fax to 202–395–6974, Attention: Desk
Officer for NIH.

FOR FURTHER INFORMATION CONTACT:
To request more information on the
proposed project or to obtain a copy of the
data collection plans and
instruments, contact: Dr. Jennifer
Guimond, Project Clearance Liaison,
Office of Science Policy, Reporting, and
Program Analysis, Eunice Kennedy
Shriver National Institute of Child
Health and Human Development,