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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Draft Report on Carcinogens Monograph on *Helicobacter pylori*: Chronic Infection;
Availability of Document; Request for Comments

AGENCY: National Institutes of Health, HHS

ACTION: Notice.

SUMMARY: The National Toxicology Program (NTP) announces the availability of the Draft Report on Carcinogens (RoC) Monograph on *Helicobacter pylori*: Chronic Infection for public comment. The Office of the Report on Carcinogens (ORoC), Division of the National Toxicology Program (DNTP), National Institute of Environmental Health Sciences (NIEHS) prepared the monograph.

DATES: Document Availability: The draft monograph should be available by May 11, 2018, at <https://ntp.niehs.nih.gov/go/845046>.

Written Public Comments Submission: Deadline is June 1, 2018.

ADDRESSES: Written public comments should be submitted electronically at <https://ntp.niehs.nih.gov/go/845046>.

FOR FURTHER INFORMATION CONTACT: NTP Meetings Staff, 2635 Meridian Parkway, Suite 200, Durham, NC, USA 27713. Phone: (919) 293-1660, Fax: (919) 293-1645, Email: NTP-Meetings@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 a four-part process using established listing criteria to evaluate substances for possible listing in the RoC and prepare the report (<https://ntp.niehs.nih.gov/go/rocprocess>). 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. This information is presented in the substance profile in the *Helicobacter pylori* (*H. pylori*) monograph. The monograph also includes a summary of strategies to prevent *H. pylori*-associated cancers.

H. pylori was selected for review following solicitation of public comment, review by the NTP Board of Scientific Counselors on April 11, 2016, and approval by the NTP Director (<https://ntp.niehs.nih.gov/go/9741>). Information on the NTP review of *H.*

pylori is available at <https://ntp.niehs.nih.gov/go/791433>. *H. pylori* is a gram-negative, multi-flagellated bacterium that colonizes the luminal mucosal surface of the body (corpus) and lower portion (antrum) of the stomach; if untreated, the infection usually lasts for the individual's lifetime. Chronic infection can cause gastritis and peptic ulcers. The bacterium is spread by person-to-person contact, especially among family members. Risk factors for *H. pylori* infection include age, race or ethnicity (minority), socioeconomic status (low family income and lower education level), and crowded housing.

Request for Comments: NTP invites written public comments on the draft monograph. The deadline for submission of written comments is June 1, 2018. Written public comments should be submitted electronically at <https://ntp.niehs.nih.gov/go/845046>. Any other correspondence should be sent to NTP Meetings Staff by email: NTP-Meetings@icf.com. Persons submitting written comments should include their name, affiliation (if applicable), phone, email, and sponsoring organization (if any) with the document. Written comments received in response to this notice will be posted on the NTP website (<https://ntp.niehs.nih.gov/go/845046>), with the submitter identified by name, affiliation, and/or sponsoring organization. Following the public comment period, the draft monograph will undergo external peer review by letter. Comments that address scientific or technical issues will be shared with external scientists for their consideration during the peer review. Guidelines for public comments are at http://ntp.niehs.nih.gov/ntp/about_ntp/guidelines_publiccomments_508.pdf.

Background Information on RoC: Each edition of the RoC is cumulative and consists of substances newly reviewed in addition to those listed in previous editions. The Secretary of Health and Human Services approves new listings. 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, informational 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 (available at <http://ntp.niehs.nih.gov/go/roc>).

Dated: May 2, 2018.

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