DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Toxicology Program (NTP); Report on Carcinogens (RoC) Center: Request for Public Comments on the RoC Expert Panel's Recommendation on Listing Status for Formaldehyde and the Scientific Justification for the Recommendation

AGENCY: National Institute of Environmental Health Sciences (NIEHS); National Institutes of Health (NIH).

ACTION: Request for comments.

SUMMARY: The NTP invites public comment on the recommendation from an expert panel on the listing status for formaldehyde in the 12th RoC and the scientific justification for the recommendation. The recommendation and scientific justification for formaldehyde are available electronically in Part B of the Expert Panel Report (*http://ntp.niehs.nih.gov/go/29682* Formaldehyde, Expert Panel Report Part B) or in printed text from the RoC Center (see **FOR FURTHER INFORMATION CONTACT** below). The RoC Center convened a ten-member expert panel of scientists, plus four technical scientific experts, from the public and private sectors on November 2–4, 2009, in Research Triangle Park, NC. The panel was asked (1) to apply the RoC listing criteria to the relevant scientific evidence and make a recommendation regarding listing status (*i.e., known to be a human carcinogen, reasonably anticipated to be a human carcinogen,* or not to list) for formaldehyde in the 12th RoC and (2) to provide the scientific justification for their recommendation.

DATES: The Expert Panel Report (Part B) for formaldehyde will be available for public comment by December 18, 2009. Written comments should be submitted by February 8, 2010.

ADDRESSES: Comments should be sent to Dr. Ruth Lunn, Director, RoC Center [NIEHS, P.O. Box 12233, MD K2–14, Research Triangle Park, NC 27709; FAX: 919–541–0144; or *lunn@niehs.nih.gov.* Courier address: NIEHS, Room 2006, 530 Davis Drive, Morrisville, NC 27560].

FOR FURTHER INFORMATION CONTACT: Dr. Ruth Lunn, RoC Center, 919–316–4637 or *lunn@niehs.nih.gov.*

SUPPLEMENTARY INFORMATION:

Background

Formaldehyde is a high-production chemical that has a wide array of uses. The predominant use of formaldehyde in the United States is in the production of industrial resins (mainly urea, phenol, polyacetal, and melamine resins) that are used primarily to manufacture products such as adhesives and binders for wood products. Other uses include as a chemical intermediate, in agriculture (for example as a fumigant), in the production of paraformaldehyde and chelating agents, embalming and fixative or preservative in the medical and research fields, and as a preservative in numerous consumer products such as cleaning agents and cosmetic products. The predominant use of formaldehyde in the United States is in the production of industrial resins (mainly urea, phenol, polyacetal, and melamine resins) that are used to manufacture products such as adhesives and binders for wood products, pulp and paper, plastics, synthetic fibers, in textile finishing and other products. Formaldehyde has been detected in indoor and outdoor air, surface water and groundwater, soil and food products and is generally considered to be ubiquitous in the environment. Formaldehyde (gas) is currently listed in the 11th RoC as *reasonably anticipated to be a human carcinogen,* and was nominated for reclassification of its listing status in the 12th RoC.

The NTP announced the RoC review process for the 12th RoC on April 16, 2007, in the **Federal Register** (72 FR 18999, available at *http://ntp.niehs.nih.gov/go/15208*). As part of this process, the NTP announced availability of the draft background document for formaldehyde, invited public comments on the draft background document, and announced the formaldehyde expert panel meeting (74 FR 15983, *http://ntp.niehs.nih.gov/go/29682*). On November 2–4, 2009, the RoC Center convened a ten-member expert panel of scientists from the public and private sectors to evaluate formaldehyde for possible listing in the 12th RoC. Four additional, non-voting, expert scientists were also in attendance to respond to technical concerns from the panel. The expert panel met in a public forum at the Hilton Raleigh-Durham Airport Hotel at Research Triangle Park, NC. The panel was charged to peer review the draft background document for formaldehyde and then to make a recommendation on its listing status in the 12th RoC and to provide a scientific justification for that recommendation. Details about the meeting, including public comments received and the expert panel reports, are available on the RoC Web site (*http://ntp.niehs.nih.gov/go/29682*). The expert panel report for formaldehyde contains two parts: Part A has the peer-review comments on the draft background document and Part B has the recommendation on listing status and its scientific justification. The expert panel recommended that formaldehyde be listed in the 12th RoC as *known to be a human carcinogen.*

Request for Comments

The RoC Center invites written public comments on the expert panel's recommendation on listing status for formaldehyde and the scientific justification for the recommendation. All comments received will be posted on the RoC Web site and the commenter identified by name, affiliation, and sponsoring organization, if applicable. Persons submitting written comments are asked to include their name and contact information (affiliation, mailing address, telephone and facsimile numbers, e-mail, and sponsoring organization, if any) and send them to Dr. Lunn (see **ADDRESSES** above). The deadline for submission of written comments is February 8, 2010.

Next Steps

The RoC Center is in the process of finalizing the background document for formaldehyde based upon the expert panel's peer review comments and public comments on the draft document. Persons can register free-of-charge with the NTP listserv (*http://ntp.niehs.nih.gov/go/231*) to receive notification when the final background document is posted on the RoC Web site. As part of the RoC review process, two government groups will also conduct reviews of formaldehyde; these meetings are not open to the public. Upon completion of these reviews, the NTP will (1) draft a substance profile for formaldehyde that contains its listing recommendation for the 12th RoC and the scientific information supporting that recommendation, (2) solicit public comment on the draft substance profile, and (3) convene a meeting of the NTP Board of Scientific Counselors to peer review the draft substance profile.

Background Information on the RoC

The RoC is a Congressionally mandated document that identifies and discusses agents, substances, mixtures, or exposure circumstances (collectively referred to as ''substances'') that may pose a hazard to human health by virtue of their carcinogenicity. The RoC follows a formal, multi-step process for review and evaluation of selected chemicals. Substances are listed in the report as either *known or reasonably anticipated human carcinogens.* The NTP prepares the RoC on behalf of the

Secretary of Health and Human Services. Information about the RoC and the review process is available on its Web site (*http://ntp.niehs.nih.gov/go/roc*) or by contacting Dr. Lunn (see **FOR FURTHER INFORMATION CONTACT** above).

Dated: December 9, 2009.

John R. Bucher,

Associate Director, National Toxicology Program.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Notice of Re-Designation of the Service Delivery Area for the Cowlitz Indian Tribe

AGENCY: Indian Health Service.

ACTION: Notice.

SUMMARY: This Notice advises the public that the Indian Health Service (IHS) proposes to expand the geographic boundaries of the Service Delivery Area (SDA) for the Cowlitz Indian Tribe. The Cowlitz SDA currently is comprised of Clark, Cowlitz, King, Lewis, Pierce, Skamania, and Thurston in the State of Washington. These counties were designated as the Tribe's SDA in 67 FR 46329. It is proposed that Columbia County, Oregon, and Wahkiakum and Kittitas Counties, Washington be added to the existing SDA.

DATES: This notice is effective 30 days after date of publication in the **Federal Register**.

ADDRESSES: Comments may be mailed to Betty Gould, Regulations Officer, Indian Health Service, Suite 450, 12300 Twinbrook Parkway, Rockville, Maryland 20852. Comments will be made available for public inspection at this address from 8:30 a.m. to 5:00 p.m. Monday–Friday beginning approximately 2 weeks after publication of this notice.

FOR FURTHER INFORMATION CONTACT: Carl Harper, Director, Office of Resource Access and Partnerships, Indian Health Service, Suite 360, 12300 Twinbrook Parkway, Rockville, Maryland 20852. Telephone 301/443–2694 (This is not a toll free number).

SUPPLEMENTARY INFORMATION: The IHS currently provides services under regulations in effect on September 15, 1987 and IHS republished at 42 CFR part 136, subparts A–C. Subpart C defines a Contract Health Service Delivery Area (CHSDA) as the geographic area within which CHS will be made available by the IHS to members of an identified Indian community who reside in the area. Residence with a CHSDA or SDA by a person who is within the scope of the Indian health program, as set forth in 42 CFR 136.12, creates no legal entitlement to contract health services but only potential eligibility for services. Services needed but not available at a IHS/Tribal facility are provided under the CHS program depending on the availability of funds, the person's relative medical priority, and the actual availability and accessibility of alternate resources in accordance with the regulations.

As applicable to the Tribes, these regulations provide that, unless otherwise designated, a CHSDA shall consist of a county which includes all or part of a reservation and any county or counties which have a common boundary with the reservation (42 CFR 136.22(a)(6) (2007). The regulations also provide that after consultation with the Tribal governing body or bodies of those reservations included in the CHSDA, the Secretary may, from time to time, re-designate areas within the United States for inclusion in or exclusion from a CHDSA. The regulations require that certain criteria must be considered before any re-designation is made. The criteria are as follows:

(1) The number of Indians residing in the area proposed to be so included or excluded;

(2) Whether the Tribal governing body has determined that Indians residing in the area near the reservation are socially and economically affiliated with the Tribes;

(3) The geographic proximity to the reservation of the area whose inclusion or exclusion is being considered; and

(4) The level of funding which would be available for the provision of contract health services.

Additionally, the regulations require that any re-designation of a CHSDA must be made in accordance with the Administrative Procedures Act (5 U.S.C. 553). In compliance with this requirement, we are publishing this proposal and requesting public comment.

The purpose of this FR notice is to notify the public of the request of the Cowlitz Indian Tribe to expand their SDA as presented in their 08–3 Tribal resolution dated January 5, 2008, and 08–56 Tribal resolution, dated December 06, 2008. The Tribe's request will expand their current SDA which incorporates Cowlitz, Clark, Skamania, King, Pierce, Thurston and Lewis Counties in the State of Washington, to include Columbia County in the State of Oregon, and Kittitas and Wahkiakum Counties in the State of Washington.

Under 42 CFR 136.23 those otherwise eligible Indians who do not reside on a reservation but reside within a CHSDA must be either members of the Tribe or maintain close economic and social ties with the Tribe. In this case, the Tribe estimates the current eligible population will be increased by 35 individuals' enrolled Cowlitz members who are actively involved with the Tribe, but not eligible for health services.

In applying the aforementioned CHSDA re-designation criteria required by operative regulations (43 FR 35654), the following findings are made:

1. Columbia County, Oregon is contiguous with Clark County in the state of Washington. Kittitas County is contiguous to King County and Wahkiakum County is contiguous to Lewis in the State of Washington.

2. These three counties are not part of any other Tribes CHSDA.

3. It is important for the Cowlitz Indian Tribe to be able to deliver health care services to enrolled members residing in these three counties. The Tribe believes eligible Tribal members living in the counties proposed for expansion should also be eligible for CHS.

4. Most of the 35 Tribal members use the Cowlitz Clinic in Longview, Washington for their health care needs. It is estimated that members have a 40 minute drive to receive their health care. These Tribal members do not currently receive care under the CHS program.

5. The financial resources required to meet the immediate needs of the Tribal members residing in the three counties will not be substantial as the Tribe will use existing Federal allocations for contract health funds.

Since CHS is a critical component of the Tribes' overall health care system for its members, the Tribe feels that the members residing in the three counties should be included within the SDA for the Tribe.

Accordingly, after considering the Tribes' request in light of the criteria specified in the regulations, the IHS is proposing to re-designate the SDA for the Tribe to consist of Columbia County in the State of Oregon and Kittitas and Wahkiakum Counties in the State of Washington.

This notice does not contain reporting or recordkeeping requirements subject to prior approval by the Office of Management and Budget under the Paperwork Reduction Act of 1980.