

Dated: April 3, 2009.

Edwin L. Walker,

Acting Assistant Secretary for Aging.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number NIOSH-161]

Request for Information on Carbon Nanotubes (CNTs) Including Single-Walled Carbon Nanotubes (SWCNTs) and Multi-Walled Carbon Nanotubes (MWCNTs)

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of public comment period.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) intends to evaluate the scientific data on carbon nanotubes (CNTs) and develop appropriate communication documents, such as an Alert and/or Current Intelligence Bulletin, which will convey the potential health risks and recommend measures for the safe handling of these materials. NIOSH has developed guidelines for managing the potential health concerns associated with occupational exposures to engineered nanoparticles [see: <http://www.cdc.gov/niosh/topics/nanotech/safenano/>] which will provide the framework for developing specific recommendations for CNTs.

NIOSH is requesting information on the following: (1) Published and unpublished reports and findings from *in vitro* and *in vivo* toxicity studies with CNTs, (2) information on possible health effects observed in workers exposed to CNTs, (3) information on workplaces and products in which CNTs can be found, (4) description of work tasks and scenarios with a potential for exposure, (5) workplace exposure data, and (6) information on control measures (e.g., engineering controls, work practices, personal protective equipment) that are being used in workplaces where potential exposures to CNTs occur.

Public Comment Period: Comments must be received by May 15, 2009.

ADDRESSES: You may submit comments, identified by docket number NIOSH-161, by any of the following methods:

- *Mail:* NIOSH Docket Office, Robert A. Taft Laboratories, MS-C34, 4676 Columbia Parkway, Cincinnati, OH 45226.

- *Facsimile:* (513) 533-8285.

- *E-mail:* nioshdocket@cdc.gov.

All information received in response to this notice will be available for public examination and copying at the NIOSH Docket Office, 4676 Columbia Parkway, Cincinnati, Ohio 45226. A complete electronic docket containing all comments submitted will be available on the NIOSH Web page at <http://www.cdc.gov/niosh/docket>, and comments will be available in writing by request. NIOSH includes all comments received without change in the docket, including any personal information provided.

FOR FURTHER INFORMATION CONTACT:

Ralph D. Zumwalde, NIOSH, Robert A. Taft Laboratories, MS-C32, 4676 Columbia Parkway, Cincinnati, OH 45226, telephone (513) 533-8320.

SUPPLEMENTARY INFORMATION:

Nanotechnology is generally defined as the intentional manipulation of matter to form novel structures with one or more dimension or features less than 100 nanometers (nm). Nanotechnology involves a wide range of chemistries and almost unlimited types of structures that have highly unpredictable interactions with biological systems. Carbon nanotubes (CNTs) are a type of nanomaterial comprised of a sheet of graphite (a hexagonal lattice of carbon) rolled into a cylinder that can have a length-to-width ratio greater than 1,000. Carbon nanotubes are produced having a single cylinder carbon wall (single-walled carbon nanotubes [SWCNT]) or having multiple walls-cylinders nested within other cylinders (multi-walled carbon nanotubes [MWCNT]). CNTs range in diameter from about 1-2 nanometers for SWCNTs to dozens of nanometers for MWCNTs with lengths extending into the micrometer range.

There are several major techniques used in the synthesis of CNTs. The arc-evaporation technique involves passing a current of about 50 A between two graphite electrodes in an atmosphere of helium in the presence of metal catalysts (Co, Ni). The second method is chemical vapor deposition, where nanotubes are formed by decomposition of a carbon-containing gas with use of nano-sized catalytic particles usually Fe, Co, Yt or Ni. The advantage of catalytic synthesis over arc-evaporation is the ability to scale-up for volume production. The third method for

making CNTs, laser ablation, involves employment of a powerful laser to vaporize metal (Co and Ni)-graphite targets. Of the three major processes, chemical vapor deposition is the most prominent one that is currently used for CNT production.

Due to their unique physical and chemical properties, CNTs have sparked much research into developing novel applications. CNTs are ideal non-biodegradable materials; they are stronger than steel, flexible, lightweight, heat resistant, and have high electrical conductivity. The market for CNTs is estimated to grow substantially over the next decade. They are currently used in a variety of applications including: Electronics, reinforced plastics, micro-fabrication conjugated polymer activators, biosensors, enhanced electron/scanning microscopy imaging techniques, and in pharmaceutical/biomedical devices for drug delivery and medical diagnostics. Estimates of the number of workers potentially exposed to CNTs are unavailable due to limited exposure data and its relatively recent introduction into domestic commerce.

The toxic nature of SWCNTs and MWCNTs in humans is not known. Recently published *in vitro* and *in vivo* studies with some SWCNTs and MWCNTs describe adverse effects including their ability to be cytotoxic when tested in various cell cultures, and cause acute inflammation and early onset of fibrosis when delivered to the lungs of mice by pharyngeal aspiration or inhalation. No occupational exposure limits for CNTs have been established by NIOSH or the Occupational Safety and Health Administration (OSHA).

NIOSH seeks to obtain materials, including published and unpublished reports and research findings, to evaluate the possible health risks of occupational exposure to CNTs. Examples of requested information include, but not limited to, the following: (1) Identification of industries or occupations in which exposures to CNTs may occur.

(2) Trends in the production and use of CNTs.

(3) Description of work tasks and scenarios with a potential for exposure to CNTs.

(4) Workplace exposure measurement data in various types of industries and jobs.

(5) Case reports or other health information demonstrating potential health effects in workers exposed to CNTs.

(6) Research findings from *in vitro* and *in vivo* toxicity studies.

(7) Information on control measures (e.g., engineering controls, work practices, PPE) being taken to minimize worker exposure to CNTs.

Dated: March 31, 2009.

James D. Seligman,

Chief Information Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Criteria for Vaccination Requirements for U.S. Immigration Purposes

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC) is seeking public comment on a set of proposed criteria to be used in determining which vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) for the general United States population should be required for immigrants seeking admission into the United States or seeking adjustment of status to that of an alien lawfully admitted for permanent residence. Under section 212 of the Immigration and Nationality Act (INA) (8 U.S.C. 1182), an alien who seeks admission as an immigrant, or who seeks adjustment of status to one lawfully admitted for permanent residence, must present documentation for having received vaccination for "vaccine-preventable diseases, which shall include at least the following diseases: mumps, measles, rubella, polio, tetanus and diphtheria toxoids, pertussis, *Haemophilus influenzae* type B and hepatitis B, and any other vaccinations against vaccine-preventable diseases recommended by the Advisory Committee on Immunization Practices." Because the INA explicitly requires vaccinations for some vaccine-preventable diseases (mumps, measles, rubella, polio, tetanus and diphtheria toxoids, pertussis, *Haemophilus influenzae* type B and hepatitis B), CDC will continue to require those vaccinations for immigrants seeking admission into the United States or seeking to adjust their status to that of legal permanent resident. CDC has developed specific criteria to determine which other vaccinations recommended by ACIP for the general population will be required

for such immigrants. Through this notice, CDC proposes to begin use of the following criteria:

1. The vaccine must be an age-appropriate vaccine as recommended by ACIP for the general U.S. population, and

2. At least one of the following:

a. The vaccine must protect against a disease that has the potential to cause an outbreak.¹

b. The vaccine must protect against a disease that has been eliminated in the United States, or is in the process for elimination in the United States.

The evolution of vaccine development has progressed to include those targeting specific groups and chronic morbidity and mortality. Therefore, CDC is now developing specific criteria to be applied against each vaccine in lieu of requiring all ACIP recommended vaccines for immigration purposes. CDC has taken a scientific, evidence-based, public health approach in developing these criteria, and has considered the unique characteristics of the time and place of the medical screening process for U.S. immigration purposes.

Using specific scientific-based criteria to determine the relevant vaccines required for U.S. immigration purposes will ensure CDC decision-making regarding vaccination requirements is grounded in public health necessity and need in light of a growing list of vaccines for infectious and non-infectious diseases.

After consideration of public comments received through this notice, as well as those received during an ACIP meeting held at CDC February 25-26, 2009, CDC will publish a notice regarding implementation of the final criteria for determining which vaccines recommended by ACIP for the U.S. population will be required for immigrants in accordance with section 212(a)(1)(A)(ii) of the Immigration and Nationality Act, Section 212 (8 U.S.C. 1182(a)(1)(A)(ii)).

CDC will continue to work closely with the Department of Homeland Security and the Department of State in the implementation of the vaccination requirements for U.S. immigration purposes.

DATES: Written comments must be received on or before May 8, 2009. Comments received after April 8, 2009 will be considered to the extent possible.

¹ For purposes of this Notice, "potential to cause an outbreak" means the occurrence of more cases of disease than could be anticipated in a given area or among a specific group of people over a particular period of time. In general, and as observed through previous experience, an outbreak is associated with a public health response.

ADDRESSES: You may submit written comments to the following address: Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, Attn: Immigration Vaccination Requirements, 1600 Clifton Road, NE., MS E-03, Atlanta, Georgia, 30333.

You may also submit written comments via e-mail to DGMQpubliccomments@cdc.gov.

FOR FURTHER INFORMATION CONTACT:

David M. McAdam, Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, 1600 Clifton Road, NE., MS E-03, Atlanta, Georgia 30333; telephone 404-498-1600.

SUPPLEMENTARY INFORMATION:

Background

Medical examinations for immigration purposes are authorized under section 232 of the Immigration and Nationality Act (INA) (8 U.S.C. 1222) Under sections 212(a)(1) and 232 of the INA (8 U.S.C. 1182(a)(1) and 1222), and section 325 of the Public Health Service Act (42 U.S.C. 252), the Department of Health and Human Services (HHS) establishes requirements for the medical examination. The Secretary of HHS has delegated this authority to the Centers for Disease Control and Prevention (CDC), and it is administered by CDC's Division of Global Migration and Quarantine (DGMQ). These requirements are codified in 42 CFR part 34, Medical Examination of Aliens. Panel physicians and civil surgeons, through contractual agreements and by designations with the Department of State and the Department of Homeland Security, respectively, conduct the medical examinations in accordance with these regulations and as provided for in Technical Instructions (TIs) issued by CDC/DGMQ. The vaccination requirements for U.S. immigration purposes are listed in the Technical Instructions ([see http://www.cdc.gov/ncidod/dq/technica.htm](http://www.cdc.gov/ncidod/dq/technica.htm)).

Under section 212(a)(1)(A)(ii) of the Immigration and Nationality Act (8 U.S.C. 1182(a)(1)(A)(ii)), an alien who seeks admission as an immigrant, or who seeks adjustment of status to one lawfully admitted for permanent residence, must present documentation for having received vaccination for "vaccine-preventable diseases, which shall include at least the following diseases: mumps, measles, rubella, polio, tetanus and diphtheria toxoids, pertussis, *Haemophilus influenzae* type B and hepatitis B, and any other