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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[CDC-2013-0023; Docket Number NIOSH 240-A]

Draft Current Intelligence Bulletin "Update of NIOSH Carcinogen Classification and Target Risk Level Policy for Chemical Hazards in the Workplace"

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 Draft Document Available for Public Comment and Public Meeting

Summary: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) announces the availability of the following draft document for public comment entitled "Current Intelligence Bulletin: Update of NIOSH Carcinogen Classification and Target Risk Level Policy for Chemical Hazards in the Workplace." To view the notice, document and related materials, visit

<http://www.regulations.gov> and enter CDC-2013-0023 in the search

field and click "Search." Additional information is also located at the following web site:

<http://www.cdc.gov/niosh/topics/cancer/policy.html>. Comments may be provided to the NIOSH docket, as well as given orally at the following meeting.

Public Comment Period: Comments must be received by [insert date 90-days after FRN publishes].

Public Meeting Time and Date: December 16, 2013, 9 a.m. - 4 p.m., Eastern Time. Please note that public comments may end before the time indicated, following the last call for comments. Members of the public who wish to provide public comments should plan to attend the meeting at the start time listed.

Place: Surface Transportation Board Hearing Room, Patriots Plaza One, 395 E Street SW, 1st Floor, Room 120, Washington, DC 20201.

Status: The meeting is open to the public, limited only by the space available. The meeting space accommodates approximately 150 people. In addition, there will be an audio conference for those who cannot attend in person. There is no registration fee to attend this public meeting. However, those wishing to attend

are encouraged to register by December 3, 2013 with the NIOSH Docket Office at 513/533-8611 or e-mail niocindocket@cdc.gov.

Security Considerations: Due to mandatory security clearance procedures at the Patriots Plaza Building, in-person attendees must present valid government-issued picture identification to security personnel upon entering the building and go through an airport-type security check.

Non-US citizens: Because of CDC Security Regulations, any non-U.S. citizen wishing to attend this meeting must provide the following information in writing to the NIOSH Docket Officer at the address below no later than November 22, 2013 to allow time for mandatory CDC facility security clearance procedures to be completed.

1. Name:
2. Gender:
3. Date of Birth:
4. Place of birth (city, province, state, country):
5. Citizenship:
6. Passport Number:
7. Date of Passport Issue:
8. Date of Passport Expiration:
9. Type of Visa:

10. U.S. Naturalization Number (if a naturalized citizen):
11. U.S. Naturalization Date (if a naturalized citizen):
12. Visitor's Organization:
13. Organization Address:
14. Organization Telephone Number:
15. Visitor's Position/Title within the Organization:

This information will be transmitted to the CDC Security Office for approval. Visitors will be notified as soon as approval has been obtained. Non-U.S. citizens are encouraged to participate in the audio conferencing due to the extra clearance involved with in-person attendance.

Attendee and Speaker Registration: Attendees are encouraged to sign up by December 3, 2013 with the NIOSH Docket Office.

Individuals wishing to speak during the meeting may sign up when registering with the NIOSH Docket Office no later than December 3, at 513/533-8611 or by email at nioshdocket@cdc.gov. Those who have not signed up to present in advance may be allowed to present at the meeting if time allows.

Persons wanting to provide oral comments will be permitted up to 20 minutes. If additional time becomes available, presenters will be notified. Oral comments given at the meeting must also

be submitted to the docket in writing in order to be considered by the Agency.

Priority for attendance will be given to those providing oral comments. Other requests to attend the meeting will then be accommodated on a first-come basis. Unreserved walk-in attendees will not be admitted due to security clearance requirements.

Purpose of Meeting: To discuss and obtain comments on the draft document, "Current Intelligence Bulletin: Update of NIOSH Carcinogen Classification and Target Risk Level Policy for Chemical Hazards in the Workplace." Special emphasis will be placed on discussion of the following:

Overall questions

- 1) Are the proposed carcinogen policies consistent with the current scientific knowledge of toxicology, risk assessment, industrial hygiene, and occupational cancer? If not, provide specific information and references that should be considered.
- 2) Is there additional scientific information related to the issues of the proposed NIOSH carcinogen policies that should be considered for inclusion? If so, provide information and specify

references for consideration. Is there any discussion in the document that should be omitted?

3) Is the proposed carcinogen classification policy explained in a clear and transparent manner? Is the basis for the proposed policy adequately explained? If not, specify (section, page, and line number) where clarification is needed.

4) Are there issues relevant to the classification of occupational carcinogens that have not been adequately addressed in this proposed policy? If so, provide information and specify references for consideration.

5) NIOSH adapted the OSHA Hazard Communication Table Relating Approximate Equivalences among IARC, NTP RoC, and GHS Carcinogenicity Classifications (Appendix F, Part D, OSHA Globally Harmonized System for Hazard Communication) to provide a simple, systematic method of determining GHS cancer hazard categories. However, NIOSH has further considered the GHS carcinogen categories 1B and 2 because NTP classification *reasonably anticipated to be a human carcinogen* and IARC classification 2B have criteria that overlap the two GHS categories. NIOSH has reviewed the criteria for GHS classification and has determined that chemicals classified by

NTP as *reasonably anticipated* and chemicals classified as IARC 2B "that have sufficient evidence from animal data" meet the criteria for GHS Carcinogen Category 1B. Chemicals classified by NTP as *reasonably anticipated* and chemicals classified by IARC as 2B "that have limited evidence from animal data" meet the criteria for GHS Carcinogen Category 2. NIOSH is requesting comments on the validity of the NIOSH Correspondence table (Table 2) and its usefulness as a guide to determine GHS hazard categories.

6) Is the proposed target risk level policy explained in a clear and transparent manner? Is the basis for the proposed policy adequately explained? If not, specify (section, page, and line number) where clarification is needed.

7) An analytical feasibility (AF) notation will be used to identify those RELs that are established to reflect the limitations of the sampling and analytical method (i.e., AF) and not the target risk level of 1 in 1,000. Is this notation adequately explained?

8) Is the proposed analytical feasibility and technical achievability policy explained in a clear and transparent manner? Is the basis for the proposed policy adequately

explained? If not, specify (section, page, and line number) where clarification is needed.

Written comments will be accepted at the meeting. Written comments may also be submitted by any of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>.
Follow the instructions for submitting comments.
- *Mail*: NIOSH Docket Office, Robert A. Taft Laboratories,
4676 Columbia Parkway, MS C-34, Cincinnati, Ohio 45226.

All material submitted to the Agency should reference the agency name and docket number [CDC-2013-0023; NIOSH 240-A]. All electronic comments should be formatted as Microsoft Word. Please make reference to CDC-2013-0023 and Docket Number NIOSH 240-A.

Transcript: A transcript will be prepared and posted to NIOSH Docket within 30 days after the meeting. Each person making a comment will be asked to give his or her name and affiliation, and all comments (including their name and affiliation) are considered to be in the public domain, and the transcript will be archived in the NIOSH Docket and posted on a public Web site.

All information received in response to this notice will be available for public examination and copying at the NIOSH Docket Office, Room 111, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

Background: This draft NIOSH document provides an update of the NIOSH Carcinogen Classification and relevant Recommended Exposure Limit (REL) policies. The proposed update of policies is prompted by comments from the public and stakeholders and recent developments in how the carcinogenic risk to substances is assessed. NIOSH stakeholders have recently expressed concerns about limitations in the NIOSH approach to classifying and controlling carcinogens. A major limitation identified is use of the term "Potential Occupational Carcinogen" which dates to the OSHA hazard classification for carcinogens outlined in 29 CFR 1990.103 (see below). The adjective "potential" conveys uncertainty that is not warranted with many carcinogens such as asbestos, benzene, and others.

Further, the existing NIOSH carcinogen policy does not allow for classification on the basis of the magnitude and sufficiency of the scientific evidence. In contrast, other organizations such as the National Toxicology Program (NTP), the International Agency for Research on Cancer (IARC) and the Environmental

Protection Agency (EPA) have differential classification systems with categories that reflect the weight of scientific evidence.

Coincident with NIOSH recognition of this language limitation was international recognition of the need for more efficient and faster classification of substances and the consideration of alternative substances that are less toxic and more environmentally sustainable.

In August 2011, NIOSH published in the Federal Register its intent to review and request for information regarding its approach to classifying carcinogens and establishing recommended exposure limits for occupational exposures to hazards associated with cancer. The initial comment period of September 22, 2011 was subsequently extended until December 30, 2011. On December 12, 2011, a public meeting was held at the Hubert H. Humphrey Building in Washington, DC to engage stakeholders and members of the public in discussions of the relevant issues pertaining to the NIOSH assessment. Input received from the public and stakeholders during this process was considered and is reflected in the draft document now available for public review. To view this docket's previous information go to:

<http://www.cdc.gov/niosh/docket/archive/docket240.html>.

The purpose of the public review of the draft document is to obtain comments on whether NIOSH has adequately explained the basis for its revised policies on classifying chemicals as carcinogens and deriving RELs that are transparent, consistent, and that contribute to the effective risk management of chemical carcinogens in the workplace.

Contact Persons For Technical Information: T.J. Lentz, telephone (513) 533-8260, or Faye Rice, telephone (513) 533-8335, NIOSH, MS-C32, Robert A. Taft Laboratories, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

Dated: November 8, 2013.

John Howard

Director, National Institute for Occupational Safety and Health

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