

sectors to provide an inter-sector perspective of the structure and progress of NORA to date. This is also an opportunity to obtain feedback on how to ensure that NORA realizes its full impact potential. We are interested in your comments on NORA processes; activities and accomplishments; and opportunities for adjustments for the future.

Public Comment Period: Comments must be received by August 31, 2011.

ADDRESSES: Written comments may be submitted to the NIOSH Docket Office, Robert A. Taft Laboratories, 4676 Columbia Parkway, MS-C34, Cincinnati, Ohio 45226. All material submitted should reference docket number NIOSH-244 and must be submitted by *August 31, 2011* to be considered by the Agency. All electronic comments should be formatted in Microsoft Word. In addition, comments may be sent via e-mail to nioshdocket@cdc.gov or by facsimile to (513) 533-8285. 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 electronic docket, including any personal information.

FOR FURTHER INFORMATION CONTACT: Chia Chang, NIOSH, telephone (202) 245-0625, NORAmiddecade@cdc.gov.

Dated: July 13, 2011.

John Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2011-18753 Filed 7-22-11; 8:45 am]

BILLING CODE 4163-19-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number NIOSH-245]

Notice of Public Meeting on the NIOSH Document Titled: "Criteria for a Recommended Standard: Occupational Exposure to Diacetyl and 2,3-pentanedione"

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

ACTION: Notice of public meeting.

SUMMARY: The National Institute for Occupational Safety and Health

(NIOSH) of the Centers for Disease Control and Prevention (CDC) will hold a public meeting to discuss and obtain comments on the draft document, "Criteria for a Recommended Standard: Occupational Exposure to Diacetyl and 2,3-pentanedione". A copy of the draft document will be posted on the Internet at <http://www.cdc.gov/niosh/docket/review/docket245/default.html> for Docket number NIOSH-245 on August 12, 2011. This notice serves as advance notice of the meeting and public comment period.

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DATES AND TIME: August 26, 2011, 8 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 comments should plan to attend the meeting at the start time listed.

ADDRESSES: Omni Shoreham, 2500 Calvert, Street NW. (at Connecticut Avenue) Washington, DC 20008.

Status: The meeting is open to the public limited only by the space available. The meeting room accommodates 150 people. To pre-register for the meeting, interested parties should contact the NIOSH Docket Office at nioshdocket@cdc.gov or by fax at (513) 533-8285. Due to limited space, notification of intent to attend the meeting must be made to the NIOSH Docket Office no later than August 19, 2011. 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.

Speaker Registration: Persons wanting to provide oral comments on the draft document should contact the NIOSH Docket Office at nioshdocket@cdc.gov or by fax at (513) 533-8285. Presenters will be permitted approximately 10 minutes, and will be informed if additional time becomes available. All requests to present should contain the name, address, telephone number, and relevant business affiliations of the presenter, and the topic of the presentation. Oral comments made at the public meeting must also be submitted to the NIOSH Docket Office

in writing in order to be considered by the Agency.

Agenda: The meeting will begin with an introduction and presentation by Federal officials, followed by presentations from attendees who register to speak. Each speaker will be limited to ten minutes. If all pre-registered presentations are complete before the end time, there will be an open session to receive comments from anyone who has not signed up on the speaker registration list who may wish to speak. Open session comments will also be limited to 10 minutes per speaker. After the last speaker or at 4 p.m., whichever occurs first, the meeting will be adjourned.

SUPPLEMENTARY INFORMATION:

I. Matters To Be Discussed

At the public meeting, special emphasis will be placed on the following topics:

1. Hazard identification, risk estimation, and discussion of health effects for diacetyl and 2,3-pentanedione;
2. Basis of the Recommended Exposure Limit for diacetyl and 2,3-pentanedione;
3. Workplaces and occupations where exposure to diacetyl and 2,3-pentanedione occur;
4. Current exposure measurement methods;
5. Current strategies for controlling occupational exposure to diacetyl and 2,3-pentanedione: *e.g.*, engineering controls, work practices, medical surveillance, and personal protective equipment;
6. Oral comments provided to NIOSH on the draft criteria document.

II. Transcripts

Transcripts will be prepared and posted to NIOSH Docket number 245 approximately 30 days after the meeting. If a person making a comment gives his or her name, no attempt will be made to redact that name. NIOSH will take reasonable steps to ensure that individuals making public comments are aware of the fact that their comments (including their name, if provided) will appear in a transcript of the meeting posted on a public Web site. Such reasonable steps include: (a) A statement read at the start of the meeting stating that transcripts will be posted and names of speakers will not be redacted; and (b) A printed copy of the statement mentioned in (a) above will be displayed on the table where individuals sign up to make public comments. If individuals in making a statement reveal personal information (*e.g.*, medical information) about

themselves, that information will not usually be redacted. The CDC Freedom of Information Act coordinator will, however, review such revelations in accordance with the Freedom of Information Act and if deemed appropriate, will redact such information. Disclosures of information concerning third parties will be redacted.

III. Public Comment Period

Written comments on the document will be accepted until October 14, 2011 in accordance with the instructions below. All material submitted to NIOSH should reference Docket Number NIOSH-245. All electronic comments should be formatted as Microsoft Word or pdf files and make reference to docket number NIOSH-245. To submit comments, please use one of these options:

- Present oral comments at the public meeting and provide a written copy of comments to the NIOSH Docket Office.
- Send NIOSH comments using the online form at <http://www.cdc.gov/niosh/docket/review/docket245/comments.html>.
- Send comments by e-mail to nioshdocket@cdc.gov?subject=245.
- Facsimile: (513) 533-8285.
- Mail: NIOSH Docket Office, Robert A. Taft Laboratories, MS-C34 4676 Columbia Parkway, Cincinnati, Ohio 45226.

All information received in response to this notice will be available for public examination and copying at, NIOSH Docket Office, 4676 Columbia Parkway, Room 111, Cincinnati, Ohio 45226. A complete electronic docket containing all comments submitted will be available on the NIOSH docket home 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.

CONTACT PERSON FOR MORE INFORMATION: Lauralynn Taylor McKernan, ScD, CIH, NIOSH, 4676 Columbia Parkway, MS-C32, Cincinnati, OH 45226, telephone (513) 533-8542, fax (513) 533-8230, E-mail LMcKernan@cdc.gov.

Dated: July 19, 2011.

John Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2011-18755 Filed 7-22-11; 8:45 am]

BILLING CODE 4163-19-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of Biotechnology Activities; Recombinant DNA Research: Action Under the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)

AGENCY: National Institutes of Health, PHS, Department of Health and Human Services.

ACTION: Proposed Minor Action under the *NIH Guidelines*.

SUMMARY: The Office of Biotechnology Activities (OBA) is updating Appendix B of the *NIH Guidelines* by specifying the risk group (RG) classification for several common attenuated strains of bacteria and viruses that are frequently used in recombinant DNA research. OBA is also adding the risk group for several viruses not previously listed in Appendix B. The *NIH Guidelines* provide guidance to investigators and local Institutional Biosafety Committees (IBCs) for setting containment for recombinant DNA research. Section II-A, Risk Assessment, instructs investigators and IBCs to make an initial risk assessment based on the RG of the agent (see Appendix B, Classification of Human Etiologic Agents on the Basis of Hazard). The RG of the agent often establishes the minimum containment level required for experiments subject to the *NIH Guidelines*.

The classification of agents into various RG categories is based largely on their ability to cause human disease and the availability of treatments for that disease. For the most part, the organisms listed in Appendix B are wild-type, non-attenuated strains and a distinction is not made between the RG classification for the wild-type organism and a corresponding attenuated strain. A few attenuated strains of organisms are classified in Appendix B at a lower RG than that of the parental organism. However, there are a number of additional, well-established attenuated strains employed in research subject to the *NIH Guidelines* that are not specifically listed and thus by default are included in the same RG as the wild-type organism. Therefore, the biosafety level (BL) specified for research subject to the *NIH Guidelines* may be identical for experimentation with either the attenuated or the wild-type strain. OBA has therefore conducted an evaluation of certain attenuated strains, focusing on those for which a risk assessment had been undertaken and containment recommendations determined in the

Centers for Disease Control and Prevention (CDC)/NIH publication *Biosafety in Microbiological and Biomedical Laboratories (BMBL)* (5th edition). Specifying the risk groups for these attenuated strains in Appendix B of the *NIH Guidelines* will lead to more uniform containment recommendations that are commensurate with the biosafety risk. In addition, OBA has identified several RG3 viruses that are not currently specified in Appendix B or are currently specified as a member of a family of viruses otherwise classified as RG2. Therefore, Appendix B is being updated to address these viruses as well.

In addition to considering the risk assessment articulated in the BMBL, OBA also consulted with members of the NIH Recombinant DNA Advisory Committee (RAC) as well as other subject matter experts from NIH, CDC, and academia. Of note, the RAC discussed the appropriate containment for two attenuated strains of *Yersinia pestis* (*lcr*⁻ and *pgm*⁻ mutants) at its June 16, 2010, meeting when the committee considered which antibiotic markers could be used in these strains without requiring RAC review under Section III-A-1-a. (A webcast of that discussion is available at http://oba.od.nih.gov/rdna_rac/rac_past_meetings_2010.html.) The RAC recommendations regarding containment for work with these attenuated strains of *Yersinia pestis* are being implemented by amending Appendix B to indicate that these specific strains are RG2 organisms rather than RG3 organisms.

This update does not include all attenuated strains identified in the BMBL. OBA has tried to select attenuated strains commonly used in recombinant DNA research. OBA has also not modified the RG for viruses for which the *NIH Guidelines* already provides specific containment recommendations. For example, human immunodeficiency virus (HIV) is currently classified as a RG3 virus in Appendix B of the *NIH Guidelines*. However, Section II-A-3 makes specific recommendations regarding when BL2 is acceptable for research with HIV and OBA's guidance titled *Biosafety Considerations for Research with Lentiviral Vectors* (see http://oba.od.nih.gov/rdna_rac/rac_guidance_lentivirus.html) provides additional containment recommendations for lentiviral vectors derived from HIV.

Revision of Appendix B is considered a Minor Action under Section IV-C-3 of the *NIH Guidelines* and therefore can be implemented by OBA after consultation