

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, MS-C34, 4676 Columbia Parkway, Cincinnati, OH 45226.

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

- *Email:* [nioshdocket@cdc.gov](mailto: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. For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> or <http://www.cdc.gov/niosh/docket/review/docket255/default.html>. NIOSH includes all comments received without change in the docket, including any personal information provided. All electronic comments should be formatted as Microsoft Word. All material submitted to the Agency should reference docket number NIOSH-255 and must be submitted by May 29, 2012 to be considered by the Agency.

*Background:* This report details the results of a cooperative study between the National Institute for Occupational Safety and Health (NIOSH) and the Mine Safety and Health Administration (MSHA) investigating the ability of the Coal Dust Explosibility Meter (CDEM) to accurately predict the explosibility of samples of coal and rock dust mixtures collected from underground coal mines in the U.S. The CDEM, which gives instantaneous results in real time, represents a new way for miners and operators to assess the relative hazard of dust accumulations in their mines and the effectiveness of their rock dusting practices. The intention of the device is to assist mine operators in complying with the (MSHA) final rule 30 CFR 75.403, requiring that the incombustible content of combined coal dust, rock dust, and other dust be at least 80% in underground areas of bituminous coal mines.

This study was completed in 2010, and involved field use of the CDEM within MSHA's 10 bituminous coal districts. As part of their routine dust compliance surveys in these districts, MSHA inspectors collected sample coal and rock dust mixtures, field testing these samples for explosibility with the CDEM. Samples were then sent to the MSHA laboratory at Mt. Hope, WV, for parallel testing, first using a drying oven to determine the surface moisture followed by traditional low temperature ashing (LTA) method. The LTA method

determines explosibility of a coal and rock dust sample in a laboratory by heating the mixture to burn off the combustible material. The results, when combined with the surface moisture, are reported as total incombustible content (TIC). If the TIC is  $\geq 80\%$ , the sample is deemed to be nonexplosible and compliant with 30 CFR 75.403.

The CDEM utilizes a different approach, using optical reflectance to determine the ratio of rock dust to coal dust in a mixture. The CDEM offers real-time measurements of the explosion propagation hazard within a coal mine entry, allowing for immediate identification and mitigation of the problem.

The conclusions of this study support the field use of the CDEM to measure the explosibility of coal and rock dust mixtures, to more effectively improve the onsite adequacy of rock dusting for explosion prevention.

**FOR FURTHER INFORMATION CONTACT:** Dr. Jeff Kohler, NIOSH, Associate Director for Mining, 626 Cochran Mill Road, Pittsburgh, PA 15236, telephone (412) 386-5301, email [jkohler@cdc.gov](mailto:jkohler@cdc.gov).

*Reference:* Web address for this publication: [http://www.cdc.gov/niosh/docket/review/docket255/pdfs/CDEM\\_IC\\_Final\\_May01.pdf](http://www.cdc.gov/niosh/docket/review/docket255/pdfs/CDEM_IC_Final_May01.pdf).

Dated: May 9, 2012.

**John Howard,**

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

[FR Doc. 2012-11695 Filed 5-14-12; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### **Announcement of an Opportunity for Manufacturers and Designers of Closed Circuit Escape Respirators To Participate in Performance Testing Within a Correlation Test Program Offered by the National Institute for Occupational Safety and Health**

**AGENCY:** The 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.

**SUMMARY:** The purpose of this notice is to announce a Correlation Test Program offered by NIOSH through its National Personal Protective Technology Laboratory (NPPTL) and provide

information on how interested parties can obtain the Standard Test Procedures. The Correlation Test Program is the result of HHS publishing a final rule (<http://www.gpo.gov/fdsys/pkg/FR-2012-03-08/pdf/2012-4691.pdf>), *Approval Tests and Standards for Closed-Circuit Escape Respirators (CCERs)* on March 8th 2012. This final rule revised and updated the requirements for testing and certification of CCERs and introduced the use of an Automated Breathing and Metabolic Simulator to be used during testing as part of the approval process.

The Correlation Testing Program will consist of two tests:

- Performance Tests of As-Received and Environmentally Treated Closed-Circuit Respirators; and
- Capacity Tests of As-Received and Environmentally Treated Closed-Circuit Escape Respirators.

The Standard Test Procedures for the Correlation Testing Program, and for the other CCER performance requirements, are available from NIOSH for review. These procedures are subject to modification as they are incorporated into the certification program.

All correlation testing conducted in this program will be done free of charge. This program was designed to enable potential CCER applicants to correlate or calibrate their own automated breathing and metabolic simulator to the automated breathing and metabolic simulator that will be used by NPPTL as part of the CCER approval process.

NPPTL will not make any performance-related judgments as to the ability of any tested units meeting the new approval requirements. Data obtained from testing will be provided only to the applicant. Testing results may be provided to the public; however, product or applicant identity will not be disclosed. Test results from the Correlation Test Program are not applicable as pre-test data for a respirator approval application.

**DATES:** The CCER Correlation Test Program shall be in effect until November 15, 2012.

**FOR FURTHER INFORMATION CONTACT:** For additional information concerning the application requirements and process, Jeff Peterson, telephone (412) 386-4018, email [JPeterson@cdc.gov](mailto:JPeterson@cdc.gov). For information concerning details and copies of the Standard Test Procedures, Tim Rehak, telephone (412) 386-6866, email [TRehak@cdc.gov](mailto:TRehak@cdc.gov).

Dated: May 9, 2012.

**John Howard,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0438]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of FDA's procedures for early food safety evaluation of new non-pesticidal proteins produced by new plant varieties intended for food use, including bioengineered food plants; new Form FDA 3666, which may be submitted electronically via the Electronic Submission Gateway (ESG); and the guidance document entitled, "Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use."

**DATES:** Submit either electronic or written comments on the collection of information by July 16, 2012.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

#### FOR FURTHER INFORMATION CONTACT:

Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400T, Rockville, MD 20850, 301-796-5733, [domini.bean@fda.hhs.gov](mailto:domini.bean@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

#### Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use (OMB Control Number 0910-0583)—Revision

##### I. Background

Since May 29, 1992, when FDA issued a policy statement on foods derived from new plant varieties, FDA has encouraged developers of new plant varieties, including those varieties that are developed through biotechnology, to consult with FDA early in the development process to discuss possible scientific and regulatory issues that might arise (57 FR 22984). The guidance entitled, "Recommendations for the

Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use," continues to foster early communication by encouraging developers to submit to FDA their evaluation of the food safety of their new protein. Such communication helps to ensure that any potential food safety issues regarding a new protein in a new plant variety are resolved early in development, prior to any possible inadvertent introduction into the food supply of material from that plant variety.

FDA believes that any food safety concern related to such material entering the food supply would be limited to the potential that a new protein in food from the plant variety could cause an allergic reaction in susceptible individuals or could be a toxin. The guidance describes the procedures for early food safety evaluation of new proteins in new plant varieties, including bioengineered food plants, and the procedures for communicating with FDA about the safety evaluation.

FDA has recently developed a form that interested persons may use to transmit their submission to the Office of Food Additive Safety in the Center for Food Safety and Applied Nutrition. New Form FDA 3666, a draft of which is available at <http://www.fda.gov/downloads/Food/GuidanceCompliance/RegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/RegulatorySubmissions/UCM199325.pdf>, is entitled, "Early Food Safety Evaluation of a New Non-Pesticidal Protein Produced by a New Plant Variety (New Protein Consultation)" and may be used in lieu of a cover letter for a New Protein Consultation (NPC). Form FDA 3666 prompts a submitter to include certain elements of a NPC in a standard format and helps the respondent organize their submission to focus on the information needed for FDA's safety review. The form, and elements that would be prepared as attachments to the form, may be submitted in electronic format via the Electronic Submission Gateway (ESG), or may be submitted in paper format, or as electronic files on physical media with paper signature page. The information is used by FDA to evaluate the food safety of a specific new protein produced by a new plant variety.

##### II. NPC Information Submitted on Form FDA 3666

The NPC submitted to FDA includes the following information on Form FDA 3666 and in attachments to the form: