

and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Office of Food Safety, Center for Food Safety and Applied Nutrition (HFS-300), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT:

Jenny Scott, Center for Food Safety and Applied Nutrition (HFS-300), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2166.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry entitled “Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities.” We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of the FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations.

Section 103(c) of the FDA Food Safety Modernization Act (FSMA) directed us to conduct rulemaking to clarify the on-farm activities that would, in part, determine when an establishment is required to register with us as a “facility,” or is not required to register with us because the establishment is a “farm.” To do so, we conducted rulemaking to revise and add farm-related definitions to our existing regulation for Registration of Food Facilities in the same rulemaking documents that we issued to establish our regulation entitled “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food” in part 117 (21 CFR part 117). (See the final rule at 80 FR 55908, September 17, 2015). For the purposes of the draft guidance, we call that rulemaking “the farm definition rulemaking.” The farm definition rulemaking revised the “farm” definition to provide for two types of farms: (1) Primary production farms and (2) secondary activities farms. The farm definition rulemaking also revised three definitions associated with

the “farm” definition (*i.e.*, the definitions of “packing,” “holding,” and “manufacturing/processing”) and added more examples of activities in each of these definitions. The farm definition rulemaking also established a new definition associated with the “farm” definition (*i.e.*, the definition of “harvesting”) and included examples of harvesting activities in the definition. During the farm definition rulemaking, several comments asked us to classify specific on-farm activities as harvesting, packing, holding, or manufacturing/processing so that an operation that conducts these activities on a farm can determine whether conducting that specific activity is within, or outside, the “farm” definition. Some comments asked us to make a table of activities prominently available on our Internet site for easy access whenever the public seeks out information regarding regulations to which these activities apply. (See 80 FR 55908 at 55920.) To address these comments, we announced our intent to issue a draft guidance with our current thinking on the classification of activities as “harvesting,” “packing,” “holding,” or “manufacturing/processing” (80 FR 55908 at 55921). The draft guidance that we are making available implements that stated intent.

The draft guidance provides examples of activities classified as “harvesting,” “packing,” “holding,” or “manufacturing/processing,” as well as activities classified in more than one way. We note that the list of examples of activities classified as “holding” in the draft guidance does not include “repacking and blast freezing . . . when product is not exposed to the environment,” despite our statement in the farm definition rulemaking that such activities would be considered practical necessities for distribution and therefore “holding.” See 80 FR 55908 at 55934 (Comment/Response 44). We made similar statements in a related rulemaking to establish our regulation entitled “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals” in part 507 (21 CFR part 507) (80 FR 56170, September 17, 2015). See 80 FR 56170 at 56192 (Comment/Response 39). Our prior statements were incorrect and we hereby withdraw them. Neither “repacking” nor “blast freezing” should be considered a “holding” activity. We have thought more about what should be considered a “practical necessity” and are explaining our thinking more in the draft guidance.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 1, subpart H have been approved under OMB control number 0910-0502. The collections of information in part 117 have been approved under OMB control number 0910-0751. The collections of information in 21 CFR part 507 have been approved under OMB control number 0910-0789. The collections of information in 21 CFR part 112 have been approved under OMB control number 0910-0816. The collections of information in 21 CFR part 121 have been approved under OMB control number 0910-0812.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/ForIndustry/ColorAdditives/GuidanceComplianceRegulatoryInformation/ucm153033.htm> or <http://www.regulations.gov>. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: August 19, 2016.

Jeremy Sharp,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2016-20301 Filed 8-24-16; 8:45 am]

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DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Parts 56 and 57

[Docket No. MSHA-2014-0030]

RIN 1219-AB87

Examinations of Working Places in Metal and Nonmetal Mines

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Proposed rule; extension of comment period; close of record.

SUMMARY: In response to stakeholder requests, the Mine Safety and Health Administration (MSHA) is extending the comment period for Agency’s proposed rule on Examinations of Working Places in Metal and Nonmetal Mines. The document also clarifies and seeks additional comments on selected proposed provisions.

DATES: The comment period for the proposed rule published on June 8, 2016 (81 FR 36818), is extended. Comments must be received or postmarked by midnight Eastern Daylight Savings Time on September 30, 2016.

ADDRESSES: Submit comments and informational materials, identified by RIN 1219-AB87 or Docket No. MSHA-2014-0030, by one of the following methods listed below:

- *Federal E-Rulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- *Email:* zzMSHA-comments@dol.gov.

- *Mail:* MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Suite 4E401, Arlington, Virginia 22202-5452.

- *Hand Delivery or Courier:* 201 12th Street South, Suite 4E401, Arlington, Virginia, between 9:00 a.m. and 5:00 p.m. Monday through Friday, except Federal holidays. Sign in at the receptionist's desk on the 4th floor East, Suite 4E401.

- *Fax:* 202-693-9441.

Instructions: All submissions for the proposed rule must include RIN 1219-AB87 or Docket No. MSHA-2014-0030. MSHA posts all comments without change, including any personal information provided. Access comments electronically on <http://www.regulations.gov> and on MSHA's Web site at <https://www.msha.gov/regulations/rulemaking>.

Docket: The proposed rule for Examinations of Working Places in Metal and Nonmetal Mines was published on June 8, 2016 (81 FR 36818). The document is available on <https://www.regulations.gov> and on MSHA's Web site at <https://www.msha.gov/regulations/rulemaking/examinations-working-places-metal-and-nonmetal-mines>. Review comments in person at the Office of Standards, Regulations, and Variances, 201 12th Street South, Suite 4E401, Arlington, Virginia 22202-5452. Sign in at the receptionist's desk on the 4th floor East, Suite 4E401.

Email Notification: To subscribe to receive email notification when MSHA publishes rulemaking documents in the **Federal Register**, go to <https://www.msha.gov>.

FOR FURTHER INFORMATION CONTACT: Sheila A. McConnell, Director, Office of Standards, Regulations, and Variances, MSHA, at mcconnell.sheila.a@dol.gov (email), 202-693-9440 (voice); or 202-693-9441 (facsimile). These are not toll-free numbers.

SUPPLEMENTARY INFORMATION:

Background

On June 8, 2016 (81 FR 36818), the Mine Safety and Health Administration (MSHA) published a proposed rule on Examinations of Working Places in Metal and Nonmetal (MNM) mines. The purpose of this proposed rule is to ensure that mine operators identify and correct conditions that may adversely affect miners' safety or health. MSHA conducted public hearings on the proposed rule on July 19, 21, 26, and August 4, 2016. In response to stakeholder requests, MSHA is providing additional time for interested parties to comment on the proposed rule. MSHA is extending the deadline for comments from September 6, 2016, to September 30, 2016.

I. Request for Comments and Close of Record

Under proposed §§ 56.18002(a)(1) and 57.18002(a)(1), MSHA proposed that metal and nonmetal mine operators promptly notify miners in any affected areas of any conditions found that may adversely affect safety or health and promptly initiate appropriate action to correct such conditions. MSHA received comments and testimony requesting that the Agency clarify the proposed requirement "to promptly notify miners." Upon consideration of such comments and testimony, MSHA clarifies that "to promptly notify miners" means any notification to the miners that alerts them to adverse conditions in their working place so that they can take necessary precautions to avoid an accident or injury before they begin work in that area. This notification could take any form that is effective to notify affected miners of the particular condition: Verbal notification, prominent warning signage, other written notification, etc. MSHA believes that, in most cases, verbal notification or descriptive warning signage would be needed to ensure that all affected miners received actual notification of the specific condition in question.

MSHA also clarifies that a "prompt" notification would occur before miners are potentially exposed to the condition; e.g., before miners begin work in the affected areas, or as soon as possible after work begins if the condition is discovered while they are working in an area. For example, this notification could occur when miners are given work-shift assignments. MSHA seeks comments on proposed §§ 56.18002(a)(1) and 57.18002(a)(1).

MSHA also clarifies that the proposed rule would not change existing standards regarding conditions that present imminent danger. Like the

existing rule, the proposed §§ 56.18002(a)(2) and 57.18002(a)(2) continue to require that conditions that may present an imminent danger which are noted by the person conducting the examination shall be brought to the immediate attention of the operator who shall withdraw all persons from the area affected (except persons referred to in section 104(c) of the Federal Mine Safety and Health Act of 1977) until the danger is abated.

As MSHA stated during the public hearings, the proposed rule would not change the existing definition of working place. Existing §§ 56.2 and 57.2 define "working place" as: "Any place in or about a mine where work is being performed." Regarding the timing of the examination, some commenters expressed concern that the proposed rule would require mine operators to conduct an examination of the entire mine before the start of each shift. It is not MSHA's intent for the mine operator to examine the entire mine before work begins. The proposal would require an examination of "each working place" "before work begins in an area." A "working place" is not the entire mine unless miners will be working in all areas of the mine. "Before work begins in an area" may or may not coincide with the start of any particular shift; it depends on when miners actually will be working in any particular working place. The proposed rule, like the existing rule, would require examinations in only those areas where work will be performed. As MSHA stated in the preamble, a "working place" applies to all locations at a mine where miners work in the extraction or milling processes. (81 FR 36821.) MSHA clarifies that consistent with the existing definition of "working place," this includes roads traveled to and from a work area.

MSHA further explained that a working place would not include roads not directly involved in the mining process, administrative office buildings, parking lots, lunchrooms, toilet facilities or inactive storage areas. Unless required by other standards, mine operators would only be required to examine isolated, abandoned, or idle areas of mines or mills when miners have to perform work in these areas during the shift.

In MSHA's June 8, 2016 **Federal Register** proposed rule (81 FR 36826), the introductory text of §§ 56.18002(b) and 57.18002(b) stated that the person conducting the examination would be required to sign and date the record before the end of the shift for which the examination was made. MSHA has received a number of comments and

heard testimony at the public hearings on stakeholder concerns that the proposed requirement to sign the examination record would increase the potential for liability of miners under section 110(c) of the Mine Act for those who conduct workplace examinations. MSHA notes that Mine Act liability as an “agent” of an operator under section 110(c) relates to the substantive duties and delegated responsibilities of the person in question. The proposed rule language would not change the qualification requirements for the “competent person” (although MSHA asked for comments on this issue). The proposal also would not change the substantive requirements either for the areas to be examined or the adverse conditions for which the examination would be made. While the degree of responsibility a particular person may have at any given mine may vary widely, the single act of printing one’s initials or name, as opposed to signing one’s name, adds no more and no less to the substantive duties and qualifications of the person who conducts the examination.

Nonetheless, some commenters were concerned that the signature requirement would discourage miners from conducting working place examinations and would have a negative impact on the quality of the examination. MSHA seeks comments on an alternative approach of simply requiring that the name of the competent person, rather than the signature, be included in the examination record.

MSHA received a number of comments and heard testimony at the public hearings seeking clarification on the recordkeeping requirements for adverse conditions found that are immediately corrected. Some commenters were concerned that recording every condition and every corrective action would be an excessive burden to mine operators, especially for small operators. As MSHA stated, the Agency believes that making and maintaining a record of adverse conditions found and corrective actions taken would help mine operators and miners and their representatives become more aware of potential dangers and more proactive in their approach to correcting these issues before they cause or contribute to an accident, injury, or fatality. (81 FR 36819). MSHA seeks information on how mine operators have used the examination record to identify and correct systemic adverse conditions that may contribute to an accident, injury, or fatality. In addition, MSHA seeks comment on possible limitations that would be placed on the

mine operators’ ability to use the examination record to identify and correct systemic adverse conditions if a record of an adverse condition that is immediately corrected is not made.

MSHA received a number of comments and heard testimony at the public hearings asking if MSHA would require the person conducting the working place examination to wait until the end of the shift to make the record. MSHA clarifies that the proposed rule would allow the competent person conducting the exam to make the record any time before the end of the shift.

II. Paperwork Reduction Act of 1995

MSHA’s proposed rule contains changes that would affect the burden in an existing OMB Control Number 1219–0089. MSHA, the Department of Labor, and the Office of Management and Budget are particularly interested in comments related to the recordkeeping requirement that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

MSHA solicits comments from the mining community on all aspects of the proposed rule. Commenters are requested to be specific in their comments and to provide sufficient detail in their responses to enable proper Agency review and consideration. All comments must be received by September 30, 2016.

Dated: August 17, 2016.

Joseph A. Main,

Assistant Secretary of Labor for Mine Safety and Health.

[FR Doc. 2016–20395 Filed 8–23–16; 8:45 am]

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DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Parts 57, 70, 72, and 75

[Docket No. MSHA–2014–0031]

RIN 1219–AB86

Exposure of Underground Miners to Diesel Exhaust

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Request for information; extension of comment period.

SUMMARY: In response to requests from the public, the Mine Safety and Health Administration (MSHA) is extending the comment period on the Agency’s request for information on Exposure of Underground Miners to Diesel Exhaust. This extension gives stakeholders additional time to evaluate the comments and testimony received thus far and submit information to the Agency.

DATES: The comment period for the request for information published on June 8, 2016 (81 FR 36826), is extended. Comments must be received by midnight Eastern Standard Time on November 30, 2016.

ADDRESSES: Submit comments and informational materials for the rulemaking record, identified by RIN 1219–AB86 or Docket No. MSHA–2014–0031, by one of the following methods:

- *Federal E-Rulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- *Email:* zzMSHA-comments@dol.gov.
- *Mail:* MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Suite 4E401, Arlington, Virginia 22202–5452.
- *Hand Delivery or Courier:* 201 12th Street South, Suite 4E401, Arlington, Virginia, between 9:00 a.m. and 5:00 p.m. Monday through Friday, except Federal holidays. Sign in at the receptionist’s desk on the 4th Floor East, Suite 4E401.

• *Fax:* 202–693–9441.
Instructions: All submissions must include “RIN 1219–AB86” or “Docket No. MSHA–2014–0031.” Do not include personal information that you do not want publicly disclosed; MSHA will post all comments without change to <http://www.regulations.gov> and <http://arlweb.msha.gov/currentcomments.asp>, including any personal information provided.

Docket: For access to the docket to read comments received, go to <http://>