

internalization of pathogens in citrus fruit. Is this assumption valid?

(2) Is internalization of pathogens into citrus fruit theoretically possible?

(3) If internationalization of pathogens into citrus fruit is theoretically possible, is such internalization likely to result in a public health risk?

(4) If internalization does occur and it results in a public health risk, are there techniques to assure that internalization of pathogens does not occur? What are they?

Second, comments to the proposed HACCP rule requested that FDA clarify at what point in the production process a processor should begin to measure attainment of the 5-log pathogen reduction. In light of the new data and information on pathogen internalization and survival, FDA's current view is that for any juice made from fruit for which there is a potential for pathogens to be internalized, measurement of the 5-log reduction must begin where preventive treatment has intimate contact with pathogens. This means that the 5-log reduction must be achieved after the juice has been extracted. Accordingly, in terms of the application of the 5-log reduction, FDA requests comment on the following:

(1) FDA's current view is that the 5-log pathogen reduction must begin where the preventative treatment has intimate contact with the pathogens. FDA is particularly interested in any data or other information about scientifically validated procedures for a 5-log reduction that address FDA's concerns about pathogen internalization and that begin earlier in the process than the juice expression step.

(2) The ability of processors to achieve the desired level of public health protection if processors: (a) Use cumulative steps that are separated in time or location, or (b) do not package product immediately after attaining the 5-log reduction.

(3) For firms producing fresh juice, the costs and economic feasibility of achieving a 5-log pathogen reduction using the approach reflected in FDA's current thinking.

(4) The benefits to processors of using this enhanced 5-log pathogen reduction approach in terms of improved shelf-life or other any benefit.

Third, FDA is aware that the majority of juice processors already apply some sort of heat treatment to the juice that they produce. Under a HACCP system, the application of heat is a critical control point (CCP) in terms of controlling microbiological hazards. FDA requests comments that describe the monitoring methods that juice processors currently use to assure that

the heat treatment is adequately delivered so as to control pathogens.

Fourth, FDA also specifically requests comment on several economic issues, as follows:

(1) The agency is aware that some consumers prefer to consume raw (i.e., unprocessed) juice. FDA requests comment from these consumers concerning how much they would be willing to pay for a gallon of raw juice. FDA also requests information from raw juice processors on the percent of annual profit that firms derive from the sale of raw juice.

(2) The agency developed a preliminary regulatory impact analysis and a small entity analysis that estimate benefits and costs associated with the HACCP proposal. These analyses were published in the **Federal Register** of May 1, 1998 (63 FR 24254). FDA requests comment on impacts, costs, and benefits on businesses with fewer than 500 employees.

(3) FDA requests comment on the ways in which processors that have already implemented HACCP have done so in a manner that is different from the provisions of the proposed rule.

Finally, as noted above, FDA has prepared a summary of certain data and information regarding internalization and survival of pathogens in produce. The agency has also prepared reports of the agency's recent research. FDA is announcing the availability of the following: (1) Two documents summarizing new data on internalization and survival of microorganisms in citrus (Refs. 1 and 2); and (2) a review of published and unpublished information on internalization and survival of microorganisms in fruits and vegetables (Ref. 3). FDA is also announcing the availability for public comment of the transcripts from a July 15 to 16, 1999, FDA-sponsored technical scientific workshop on apple cider.

To be considered, written comments must be received by January 24, 2000, by the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

### **III. References**

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons

between 9 a.m. and 4 p.m., Monday through Friday.

1. Walderhaug, M. O., S. Edelson-Mammel, A. DeJesus, B. S. Eblen, A. J. Miller, and R. L. Buchanan. "Preliminary Studies on the Potential for Infiltration, Growth and Survival of *Salmonella enterica* Serovar Hartford and *Escherichia coli* O157:H7 Within Oranges." U.S. Food and Drug Administration, November 8, 1999.

2. Merker, R., S. Edelson-Mammel, V. Davis, R. L. Buchanan. "Preliminary Experiments on the Effect of Temperature Differences on Dye Uptake by Oranges and Grapefruit. U.S. Food and Drug Administration, November 4, 1999.

3. Potential for Infiltration, Survival, and Growth of Human Pathogens within Fruits and Vegetables, U.S. Food and Drug Administration, November 3, 1999.

Dated: November 16, 1999.

**Margaret M. Dotzel,**

*Acting Associate Commissioner for Policy.*  
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**BILLING CODE 4160-01-F**

## **DEPARTMENT OF LABOR**

### **Mine Safety and Health Administration**

#### **30 CFR Parts 70, 71 and 90**

### **Proposed Program Policy Letter on Samples Used To Determine the Respirable Dust Level When Quartz Is Present**

**AGENCY:** Mine Safety and Health Administration, Labor.

**ACTION:** Request for comments.

**SUMMARY:** The Mine Safety and Health Administration (MSHA) requests comments on a draft Program Policy Letter (PPL) regarding the samples that are used to determine the reduced respirable coal mine dust standard when more than 5.0 percent of quartz is present in the mine atmosphere. Under the PPL, the samples used to determine a reduced standard would be MSHA samples exclusively rather than a combination of MSHA and mine operator samples. MSHA is publishing this Notice to afford an opportunity for interested persons to comment on the draft PPL before it is issued.

**DATES:** Submit comments on or before December 23, 1999.

**ADDRESSES:** Send comments on the proposed policy—

(1) By mail to MSHA, Office of Standards, Regulations, and Variances, 4015 Wilson Boulevard, Room 631, Arlington, VA 22203;

(2) By facsimile to MSHA, Office of Standards, Regulations, and Variances, 703-235-5551; or

(3) By electronic mail to comments@msha.gov. If possible, please

supplement written comments with computer files on disk; contact the Agency with any format questions.

**FOR FURTHER INFORMATION CONTACT:**  
Ronald J. Schell, Division of Health, Coal Mine Safety and Health, (703) 235-1358. You may obtain copies of this Notice in alternative formats by calling the MSHA Office of Standards, Regulations, and Variances at (703) 235-1910. The alternative formats available are large print or electronic file on a computer disk. The proposed rule also is available on the Internet at <http://www.msha.gov/REGSINFO.HTM>.

#### SUPPLEMENTARY INFORMATION:

##### I. Paperwork Reduction Act

The information collection requirements associated with transmitting mine operator quartz samples to us (MSHA) are approved by the Office of Management and Budget (OMB) under OMB control number 1219-0011. The Program Policy Letter (PPL) would reduce the number of mine operator samples submitted. The paperwork burden on the mine operators would be further reduced since mine operators would no longer be required to complete and submit the dust data cards that accompany quartz samples.

##### II. Background

We (MSHA) update our policies for enforcement of safety and health regulations through PPLs. PPLs explain or clarify how regulations work or apply in a particular situation. Once adopted, the policy statements are published in the MSHA Program Policy Manual and given wide distribution.

By this Notice, we are affording you the opportunity to comment on a draft PPL that would change the current policy for determining how the respirable coal mine dust standard is set when respirable dust samples indicate more than 5.0 percent quartz is present in the mine environment. Under this revised policy, only samples taken by MSHA, rather than a combination of MSHA and mine operator samples, would be used to establish the reduced standard due to the presence of quartz.

The text of the draft PPL follows the discussion of the draft policy below. We will consider all timely submitted comments before finalizing the PPL.

##### III. Discussion of Draft Policy

The standard set out in 30 CFR parts 70 and 71 requires that the average concentration of respirable coal mine dust be continuously maintained at or below 2.0 milligrams per cubic meter of air ( $2.0 \text{ mg/m}^3$ ). However, when the respirable dust in the mine atmosphere

of the active workings contains more than 5.0 percent quartz, the  $2.0 \text{ mg/m}^3$  standard must be lowered under a formula set forth in 30 CFR 70.101, 71.101 and 90.101.<sup>1</sup> That formula provides that the reduced standard be computed by dividing the percent of quartz into the number ten.

Under existing policy, MSHA samples can be averaged with mine operator samples to determine the percent of quartz in the mine environment. That policy is outlined in Chapter 1 of MSHA's Coal Mine Health Inspection Procedures Handbook. That policy provides that if an MSHA respirable dust sample indicates the presence of quartz in excess of 5.0 percent the mine operator is notified of the result and provided an opportunity to collect an optional respirable dust sample from the affected area or occupation. If the operator collects such a sample, and provided it has sufficient weight gain, the percent quartz in that sample is averaged with the results of the MSHA sample to determine the percent of quartz present in the mine environment. If no optional sample is submitted, the reduced standard is established based on the MSHA sample.

When an operator sample is submitted and the results of the MSHA and operator samples differ by more than  $\pm 2.0$  percent, the mine operator is provided the option of taking a second respirable coal mine dust sample. If the mine operator takes the second optional sample, the results are averaged with the results of the other two samples. When the average percent quartz in the three samples is greater than 5.0 percent, that average is used to compute the reduced respirable dust standard.

The current policy of allowing mine operators the option of taking up to two additional samples to determine the percent of quartz in the mine atmosphere began in 1986. The policy was implemented to address the concern of mine operators that reduced standards were being established based on a single MSHA sample which may not be representative of the level of quartz in the mine. During that time period, MSHA sampled each mechanized mining unit annually. Accordingly, operators were concerned that reduced standards were being established based on that single inspection and remained in place until MSHA conducted another inspection the following year. As a result, the current policy was put into effect to

allow mine operators to take up to two additional samples which would be averaged with the MSHA sample to determine the percent of quartz.

The report of the Secretary of Labor's Advisory Committee on the Elimination of Pneumoconiosis Among Coal Mine Workers, which was issued in October 1996, found that one of MSHA's highest priorities should be to restore confidence in the respirable coal mine dust sampling program. To achieve this objective, the Advisory Committee recommended that we assume responsibility for all compliance sampling from mine operators. We are working toward implementation of that recommendation. As part of our plan, we are proposing to issue this PPL which would establish MSHA sampling as the exclusive basis for determining the reduced standard, rather than using a combination of MSHA and mine operator sampling.

Under the proposed PPL, we would require three valid MSHA samples to set a reduced standard. In the near future, we intend to sample MMUs at underground coal mines each bimonthly period, and sample surface mines twice each year. When initial samples show potential overexposure to quartz, we will sample at a greater frequency to ensure that miners will be protected. This represents a significant increase in MSHA sampling that will allow us to determine the reduced standard based on multiple MSHA samples.

Since MSHA intends to sample at underground mines on a bimonthly basis and at each surface mine twice each year, the proposed PPL would continue to address the mine operators' previous concern that a reduced standard not be established on the results of a single MSHA sample. Instead, the standards would always be based on the average of three MSHA samples. This PPL would also address another concern of mine operators that their samples may be voided because there is insufficient weight gain on the filter to conduct a quartz analysis. Since MSHA cassettes are pre- and post-weighed, samples taken on these cassettes can be analyzed for quartz at a very low weight gain. Since all samples would be MSHA samples under this PPL, preweighed filters would be used in all instances.

As previously mentioned, the proposed PPL also addresses the recommendations of the Advisory Committee that compliance action be based solely on MSHA sampling results and reduces the burden and cost on mine operators to take and submit samples to MSHA. Under the PPL, we would average the percent of quartz

<sup>1</sup>Under MSHA regulations, the standard for intake air and for miners who have exercised rights under Part 90 is  $1.0 \text{ mg/m}^3$ . Those standards are also lowered if quartz exceeds 5.0 percent.

present in the three most recent MSHA respirable coal mine dust samples to determine the respirable coal mine dust standard when quartz is present. MSHA would also begin reporting quartz levels to the tenth of a percent (truncating to the tenth). This is the result of the improved accuracy of the quartz analysis system related to the use of respirable dust sampling filters pre-weighed to the thousandth of a milligram (0.001 mg).

While MSHA intends to use agency samples alone to establish reduced standards, we recognize that there will be a transition period at mines that currently have greater than 5.0 percent quartz in the mine atmosphere. The transition period will last until MSHA has taken three samples under this PPL. During this transition, on an entity (MMU, DA, or DWP) currently on a reduced standard, a new standard will be established by averaging the results of the first two MSHA samples taken under this PPL with the quartz level associated with the current reduced standard. Where we have taken fewer than two samples under this PPL, the existing reduced standard will continue to apply.

For example, assume an MMU has a reduced standard of 1.0 mg/m<sup>3</sup> with 10.0 percent of quartz. If our first sample under the new policy results in a quartz percentage of 7.2 percent, the existing 1.0 mg/m<sup>3</sup> would continue to apply. If the next MSHA sample indicates a quartz percentage of 16.1 percent quartz, the average quartz would be  $(10.0 + 7.2 + 16.1) \div 3$  or 11.1. This results in a 0.9 mg/m<sup>3</sup> reduced standard ( $10/11.1 = 0.9$ ).

For sampling entities (MMU, DWP, DA) not currently on a reduced standard, we would collect three separate samples and analyze them for quartz content to determine if a reduced standard was necessary.

#### **IV. Draft Program Policy Letter**

##### **Subject**

Change in the existing policy for 30 CFR 70.101, 71.101 and 90.101.

##### **Scope**

This Program Policy Letter (PPL) applies to mine operators, including independent contractors, and Mine Safety and Health Administration (MSHA) enforcement personnel.

##### **Purpose**

This PPL changes the way that a reduced standard is established when respirable coal mine dust samples contain quartz in excess of 5.0 percent in the mine environment. Only samples

taken by MSHA, rather than a combination of MSHA and mine operator samples, will be used to establish the reduction in the respirable coal mine dust standard due to the presence of quartz.

##### **Policy**

###### **Respirable Dust Standard When Quartz is Present.**

The lowering of the respirable dust standard when more than 5.0 percent of quartz is present will be based on the average percent of quartz in the three most recent MSHA respirable dust samples (Example 1). The standard at a sampling entity on a reduced standard on the effective date of the PPL will be based on the quartz level associated with the existing standard and the results of the first two MSHA samples taken under this PPL. Where we have taken fewer than two samples under this PPL, the existing reduced standard will continue to apply (Example 2).

*Example 1*—Mine “A” MMU 001–0 is on the 2.0 mg/m<sup>3</sup> standard. Our first sample under the new policy results in a quartz level of 10.2 percent, the existing 2.0 mg/m<sup>3</sup> would continue to apply. The next MSHA sample indicates a quartz level of 12.1 percent, the 2.0 mg/m<sup>3</sup> standard would continue to apply. The third MSHA sample indicates a quartz level of 11.3 percent. The new standard established would be based on  $(10.2 + 12.1 + 11.3) \div 3$  or 11.2 percent quartz. This results in a 0.9 mg/m<sup>3</sup> standard ( $10/11.2 = 0.9$ ).

*Example 2*—Mine “B” MMU 002–0 is on a reduced standard of 1.0 mg/m<sup>3</sup> with 10.0 percent of quartz. MSHA’s first sample results in a quartz percentage of 7.2 percent, the existing 1.0 mg/m<sup>3</sup> standard would continue to apply. The next MSHA sample indicates a quartz percentage of 16.1 percent. The new standard established would be based on  $(10.0 + 7.2 + 16.1) \div 3$  or 11.1 percent quartz. This results in a 0.9 mg/m<sup>3</sup> standard ( $10/11.1 = 0.9$ ).

##### **Effective Date of a New Reduced Standard**

a. A new lower standard due to quartz is effective seven days after the date that we mail the notice of the lower standard to the mine operator. This provides notice of the new reduced standard to the mine operator and allows changes in dust control to be made to achieve compliance prior to sampling.

b. A new higher standard for quartz is effective on the date that we mail the notice of the higher standard.

c. Where the effective date of the new standard for quartz occurs during the time that the mine operator is conducting required sampling for

respirable coal mine dust, the higher of the two standards will be effective during the required sampling. (The required samples are bimonthly sampling, requests from MSHA for five additional samples, and abatement samples.) The new standard will be effective when the required sampling is completed, with one exception. When abatement sampling shows continued noncompliance, the new standard becomes effective before any additional sampling is conducted.

*Example*—A mechanized mining unit (MMU) has a standard of 2.0 mg/m<sup>3</sup>. A new lower standard of 1.7 mg/m<sup>3</sup> is in the process of being set. However, the mine operator has taken at least one bimonthly sample before the effective date of the change. The higher standard (2.0 mg/m<sup>3</sup>) applies. The new lower standard (1.7 mg/m<sup>3</sup>) becomes effective at the completion of the bimonthly sampling requirement.

*Example*—We request a mine operator to submit five additional samples for a designated area. The existing standard is 1.7 mg/m<sup>3</sup>. A new higher standard of 2.0 mg/m<sup>3</sup> is in the process of being set. However, the mine operator has taken at least one additional sample before being notified of the change.

The higher standard (2.0 mg/m<sup>3</sup>) applies. The new higher standard (2.0 mg/m<sup>3</sup>) becomes effective on the date of the mailing.

##### **Effective Date**

After considering comments from the public and making appropriate revisions, we anticipate that this PPL would take effect 30 days from the date of publication of the final PPL and would be incorporated into MSHA’s Program Policy Manual.

**Authority:** Section 103(a) of the Federal Mine Safety and Health Act of 1977.

Dated: November 16, 1999.

**J. Davitt McAtee,**

*Assistant Secretary for Mine Safety and Health.*

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#### **ENVIRONMENTAL PROTECTION AGENCY**

#### **40 CFR Parts 49 and 52**

[TRI-FIP-003b; FRL-6479-9]

**Source Specific Federal Implementation Plan for Tri-Cities Landfill; Salt River Pima-Maricopa Indian Community**

**AGENCY:** Environmental Protection Agency (EPA).