

TABLE 2—E.O. 13771 SUMMARY (IN \$ MILLIONS 2016 DOLLARS) OVER AN INFINITE TIME HORIZON—Continued

	Primary (7%)	Lower bound (7%)	Upper bound (7%)	Primary (3%)	Lower bound (3%)	Upper bound (3%)
Annualized Costs .....	0.0124	0.0091	0.0157	0.0053	0.0039	0.0067
Annualized Cost Savings .....	0	0	0	0	0	0
Annualized Net Costs .....	0.0124	0.0091	0.0157	0.0053	0.0039	0.0067

**VIII. Analysis of Environmental Impact**

We have determined under 21 CFR 25.32(m) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

**IX. Paperwork Reduction Act of 1995**

FDA tentatively concludes that this proposed rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

**X. Federalism**

We have analyzed this proposed rule in accordance with the principles set forth in E.O. 13132. We have determined that this rule has federalism impacts as it amends the standard of quality regulations for bottled water. The existing standard of quality is not new and already preempts state laws because it is within the scope of section 403A of the FD&C Act, an express preemption provision.

**XI. Consultation and Coordination With Indian Tribal Governments**

We have analyzed this proposed rule in accordance with the principles set forth in E.O. 13175. We have tentatively determined that the rule does not contain policies that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. We invite comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

**XII. References**

The following references are on display in the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. FDA has verified the website addresses, as of the date this document publishes in the **Federal**

**Register**, but websites are subject to change over time.

- Rodwan, J.G. Jr., “Bottled Water. U.S. and International Developments & Statistics,” ([https://www.bottledwater.org/public/BMC2017\\_BWR\\_StatsArticle.pdf](https://www.bottledwater.org/public/BMC2017_BWR_StatsArticle.pdf)), *Bottled Water Reporter*, pp. 12–20, July/August, 2018.
- FDA, “Letter to Manufacturers, Distributors, or Importers of Bottled Water with an Update on Fluoride Added to Bottled Water,” (<https://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/bottledwatercarbonatedsoftdrinks/ucm444373.htm>), April 27, 2015
- FDA Memorandum, “Teleconference Related to Fluoride in Bottled Water,” 2016.
- FDA, “Proposed Rule to Revise the Allowable Level of Fluoride in Bottled Water to which Fluoride Has Been Added, Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis,” (<https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm>).

**List of Subjects in 21 CFR Part 165**

Beverages, Bottled water, Food grades and standards, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, we propose that 21 CFR part 165 be amended as follows:

**PART 165—BEVERAGES**

- 1. The authority citation for part 165 continues to read as follows:

**Authority:** 21 U.S.C. 321, 341, 343, 343–1, 348, 349, 371, 379e.

- 2. Revise § 165.110(b)(4)(ii)(C) and (D) to read as follows:

**§ 165.110 Bottled water.**

\* \* \* \* \*

- (b) \* \* \*
- (4) \* \* \*
- (ii) \* \* \*

(C) Bottled water packaged in the United States to which fluoride is added must not contain fluoride in excess of 0.7 milligram per liter.

(D) Imported bottled water to which fluoride is added must not contain

fluoride in excess of 0.7 milligram per liter.

\* \* \* \* \*

Dated: March 26, 2019.

**Scott Gottlieb,**

*Commissioner of Food and Drugs.*

[FR Doc. 2019–06201 Filed 4–2–19; 8:45 am]

**BILLING CODE 4164–01–P**

**DEPARTMENT OF THE INTERIOR**

**Office of Surface Mining Reclamation and Enforcement**

**30 CFR Part 935**

[SATS No. OH–260–FOR; Docket ID: OSM–2018–0001; S1D1S SS08011000 SX064A000 190S180110; S2D2S SS08011000 SX064A000 19XS501520]

**Ohio Regulatory Program**

**AGENCY:** Office of Surface Mining Reclamation and Enforcement, Interior.

**ACTION:** Proposed rule; public comment period and opportunity for public hearing on proposed amendment.

**SUMMARY:** We, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are announcing receipt of a proposed amendment to the Ohio regulatory program (the Ohio program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Through this proposed amendment, Ohio seeks to revise its program to require permit applications to list all unabated “violation notices,” as that term is defined in the approved program. This change is necessary to be consistent with the Federal regulations. This document gives the times and locations that the Ohio program and this proposed amendment to that program are available for your inspection, the comment period during which you may submit written comments on the amendment, and the procedures that we will follow for the public hearing, if one is requested.

**DATES:** We will accept written comments on this amendment until 4:00 p.m., Eastern Daylight Time (e.d.t.), May 3, 2019. If requested, we will hold a public hearing on the amendment on April 29, 2019. We will accept requests

to speak at a hearing until 4:00 p.m., e.d.t. on April 18, 2019.

**ADDRESSES:** You may submit comments, identified by SATS No. OH-260-FOR, by any of the following methods:

- *Mail/Hand Delivery:* Mr. Ben Owens, Field Office Director, Pittsburgh Field Office, Office of Surface Mining Reclamation and Enforcement, 3 Parkway Center, Pittsburgh, Pa 15220.
- *Fax:* (412) 937-2177.

- *Federal eRulemaking Portal:* The amendment has been assigned the Docket ID OSM-2018-0001. If you would like to submit comments go to <http://www.regulations.gov>. Follow the instructions for submitting comments.

*Instructions:* All submissions received must include the agency name and docket number for this rulemaking. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Public Comment Procedures" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

*Docket:* For access to the docket to review copies of the Ohio program, this amendment, a listing of any scheduled public hearings, and all written comments received in response to this document, you must go to the address listed below during normal business hours, Monday through Friday, excluding holidays. You may receive one free copy of the amendment by contacting OSMRE's Pittsburgh Field Office or the full text of the program amendment is available for you to read at [www.regulations.gov](http://www.regulations.gov).

Mr. Ben Owens, Field Office Director, Pittsburgh Field Office, Office of Surface Mining Reclamation and Enforcement, 3 Parkway Center, Pittsburgh, Pa 15220, Telephone: (412) 937-2827, Email: [bowens@osmre.gov](mailto:bowens@osmre.gov).

In addition, you may review a copy of the amendment during regular business hours at the following location: Mr. Lanny E. Erdos, Chief, Ohio Department of Natural Resources, Division of Mineral Resources Management, 2045 Morse Road, Building H2, Telephone: (614) 265-6893, Email: [lanny.erdos@dnr.state.oh.us](mailto:lanny.erdos@dnr.state.oh.us).

**FOR FURTHER INFORMATION CONTACT:** Mr. Ben Owens, Field Office Director, Pittsburgh Field Office, 3 Parkway Center, Pittsburgh, Pa. 15220. Telephone: (412) 937-2827, email: [bowens@osmre.gov](mailto:bowens@osmre.gov).

#### **SUPPLEMENTARY INFORMATION:**

- I. Background on the Ohio Program
- II. Description of the Proposed Amendment
- III. Public Comment Procedures
- IV. Procedural Determinations

### **I. Background on the Ohio Program**

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its program includes, among other things, state laws and regulations that govern surface coal mining and reclamation operations in accordance with the Act and consistent with the Federal regulations. See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Ohio program on August 16, 1982. You can find background information on the Ohio program, including the Secretary's findings, the disposition of comments, and conditions of approval of the Ohio program in the August 10, 1982, **Federal Register** (47 FR 34717). You can also find later actions concerning the Ohio program and program amendments at 30 CFR 935.10, State Regulatory Program Approval; and 935.11, Conditions of State Regulatory Program Approval; and 935.15, Approval of Ohio Regulatory Program Amendments.

### **II. Description of the Proposed Amendment**

By letter dated November 20, 2017 (Administrative Record No. OH-2196-01), Ohio sent OSMRE an amendment that includes statutory changes to its Ohio Revised Code (ORC) as well as regulatory changes to its Ohio Administrative Code (OAC) under SMCRA (30 U.S.C. 1235). Ohio is submitting these changes in response to a required amendment found at 30 CFR 935.16 (a). In an October 19, 2015 **Federal Register** notice (80 FR 63125), OSRME required Ohio to amend its program to require permit applications to list all unabated "violation notices," as that term is defined in the Ohio approved program. This change is necessary to be consistent with the Federal regulation at § 778.14(c).

The full text of the program amendment is available for you to read at the locations listed above under **ADDRESSES** or at [www.regulations.gov](http://www.regulations.gov).

### **III. Public Comment Procedures**

Under the provisions of 30 CFR 732.17(h), we are seeking your comments on whether the amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If we approve the amendment, it will become part of the State program.

#### *Electric or Written Comments*

If you submit written or electronic comments on the proposed rule, they should be specific, confined to issues

pertinent to the proposed regulations, and explain the reason for any recommended change(s). We appreciate any and all comments, but those most useful and likely to influence decisions on the final regulations will be those that either involve personal experience or include citations to and analyses of SMCRA, its legislative history, its implementing regulations, case law, other pertinent State or Federal laws or regulations, technical literature, or other relevant publications.

We cannot ensure that comments received after the close of the comment period (see **DATES**) or sent to an address other than those listed (see **ADDRESSES**) will be included in the docket for this rulemaking and considered.

#### *Public Availability of Comments*

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

#### *Public Hearing*

If you wish to speak at the public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT** by 4:00 p.m., e.d.t. on April 18, 2019. If you are disabled and need reasonable accommodations to attend a public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT**. We will arrange the location and time of the hearing with those persons requesting the hearing. If no one requests an opportunity to speak, we will not hold a hearing.

To assist the transcriber and ensure an accurate record, we request, if possible, that each person who speaks at the public hearing provide us with a written copy of his or her comments. The public hearing will continue on the specified date until everyone scheduled to speak has been given an opportunity to be heard. If you are in the audience and have not been scheduled to speak and wish to do so, you will be allowed to speak after those who have been scheduled. We will end the hearing after everyone scheduled to speak, and others present in the audience who wish to speak, have been heard.

#### *Public Meeting*

If only one person requests an opportunity to speak, we may hold a public meeting rather than a public

hearing. If you wish to meet with us to discuss the amendment, please request a meeting by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**. All such meetings are open to the public and, if possible, we will post notices of meetings at the locations listed under **ADDRESSES**. We will make a written summary of each meeting a part of the administrative record.

#### IV. Procedural Determinations

##### *Executive Order 12866—Regulatory Planning and Review*

Pursuant to Office of Management and Budget (OMB) Guidance and dated October 12, 1993, the approval of state program amendments is exempted from OMB review under Executive Order 12866.

##### *Other Laws and Executive Orders Affecting Rulemaking*

When a state submits a program amendment to OSMRE for review, our regulations at 30 CFR 732.17(h) require us to publish a notice in the **Federal Register** indicating receipt of the proposed amendment, its text or a summary of its terms, and an opportunity for public comment. We conclude our review of the proposed amendment after the close of the public comment period and determine whether the amendment should be approved, approved in part, or not approved. At that time, we will also make the determinations and certifications required by the various laws and executive orders governing the rulemaking process and include them in the final rule.

##### **List of Subjects in 30 CFR Part 935**

Intergovernmental relations, Surface mining, Underground mining.

Dated: October 11, 2018.

**Thomas D. Shope,**  
*Regional Director.*

**Editorial note:** This document was received for publication by the Office of the Federal Register on March 29, 2019.

[FR Doc. 2019-06492 Filed 4-2-19; 8:45 am]

**BILLING CODE 4310-05-P**

## DEPARTMENT OF INTERIOR

### Office of Surface Mining Reclamation and Enforcement

#### 30 CFR Part 938

[SATS No. PA-168-FOR; Docket ID: OSM-2017-0010; S1D1S SS08011000 SX064A000 190S180110; S2D2S SS08011000 SX064A000 19XS501520]

#### Pennsylvania Regulatory Program

**AGENCY:** Office of Surface Mining Reclamation and Enforcement (OSMRE), Interior.

**ACTION:** Proposed rule; public comment period and opportunity for public hearing on proposed amendment.

**SUMMARY:** We, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are announcing receipt of a proposed amendment to the Pennsylvania program under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Through this proposed amendment, Pennsylvania seeks to revise its regulatory program regulations that involve remining operations with pollutional discharges. This document gives the times and locations that the Pennsylvania program and this proposed amendment to that program are available for your inspection, the comment period during which you may submit written comments on the amendment, and the procedures that we will follow for the public hearing, if one is requested.

**DATES:** We will accept written comments on this amendment until 4 p.m., Eastern Standard Time (e.s.t.), May 3, 2019. If requested, we will hold a public hearing on the amendment on April 29, 2019. We will accept requests to speak at a hearing until 4 p.m., e.s.t. on April 18, 2019.

**ADDRESSES:** You may submit comments, identified by SATS No. PA-168-FOR; Docket ID: OSM-2017-0010, by any of the following methods:

- *Mail/Hand Delivery:* Mr. Ben Owens, Field Office Director, Pittsburgh Field Office, Office of Surface Mining Reclamation and Enforcement, 3 Parkway Center, Pittsburgh, PA 15220.
- *Fax No.:* 412-937-2177.
- *Federal eRulemaking Portal:* The amendment has been assigned the Docket ID OSM-2016-0012. If you would like to submit comments go to <http://www.regulations.gov>. Follow the instructions for submitting comments.

*Instructions:* All submissions received must include the agency name and docket number for this rulemaking. For detailed instructions on submitting

comments and additional information on the rulemaking process, see the "Public Comment Procedures" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

*Docket:* For access to the docket to review copies of the Pennsylvania program, this amendment, a listing of any scheduled public hearings, and all written comments received in response to this document, you must go to the address listed below during normal business hours, Monday through Friday, excluding holidays. You may receive one free copy of the amendment by contacting OSMRE's Pittsburgh Field Office or the full text of the program amendment is available for you to read at [www.regulations.gov](http://www.regulations.gov).

Mr. Ben Owens, Field Office Director, Pittsburgh Field Office, Office of Surface Mining Reclamation and Enforcement, 3 Parkway Center, Pittsburgh, PA 15220, Telephone: (412) 937-2827, Email: [bowens@osmre.gov](mailto:bowens@osmre.gov).

In addition, you may review a copy of the amendment during regular business hours at the following location: Thomas Callaghan, P.G., Director, Bureau of Mining and Reclamation, Pennsylvania Department of Environmental Protection, Rachel Carson State Office Building, P.O. Box 8461, Harrisburg, PA 17105-8461, Telephone: (717) 787-5015, Email: [tcallaghan@pa.gov](mailto:tcallaghan@pa.gov).

**FOR FURTHER INFORMATION CONTACT:** Mr. Ben Owens, Field Office Director, Pittsburgh Field Office, Office of Surface Mining Reclamation and Enforcement, 3 Parkway Center, Pittsburgh, PA 15220, Telephone: (412) 937-2827, Email: [bowens@osmre.gov](mailto:bowens@osmre.gov).

#### **SUPPLEMENTARY INFORMATION:**

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#### **I. Background on the Pennsylvania Program**

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its State program includes, among other things, State laws and regulations that govern surface coal mining and reclamation operations in accordance with the Act and consistent with the Federal regulations. See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Pennsylvania program on July 30, 1982. You can find background information on the Pennsylvania program, including