

## APPENDIX—REGULATORY REVIEW MODIFIED TEN-YEAR SCHEDULE—Continued

16 CFR Part	Topic	Year to review
698 .....	Model Forms and Disclosures .....	2020.
803 .....	[Hart-Scott-Rodino Antitrust Improvements Act] Transmittal Rules .....	2020.

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**SUSQUEHANNA RIVER BASIN COMMISSION****18 CFR Part 806****Review and Approval of Projects****AGENCY:** Susquehanna River Basin Commission.**ACTION:** Notice of proposed rulemaking and public hearing.

**SUMMARY:** This document contains proposed rules that would amend the project review regulations of the Susquehanna River Basin Commission (Commission) to: Include definitions for new terms that are used in the proposed rulemaking; provide for administrative approval of interbasin transfers of flowback and production fluids between drilling pad sites that are isolated from the waters of the basin; provide for administrative approval of out-of-basin transfers of flowback or produced fluids from a Commission approved hydrocarbon development project to an out-of-basin treatment or disposal facility; insert language authorizing “renewal” of expiring approvals, including Approvals by Rule (ABRs); delete specific references to geologic formations that may be the subject of natural gas development using hydrofracture stimulation and replace with a generic category—“unconventional natural gas development;” broaden the scope of ABRs issued to include hydrocarbon development of any kind utilizing the waters of the basin, not just unconventional natural gas well development; memorialize the current practice of requiring post-hydrofracture reporting; standardize at 15 years the term of ABR approvals for both gas and non-gas projects; and provide further procedures for the approval of water sources utilized at projects subject to the ABR process.

**DATES:** Comments on these proposed rules may be submitted to the Commission on or before August 23, 2011. The Commission has scheduled two public hearings on the proposed rules, to be held August 2, 2011, in Harrisburg, Pennsylvania, and August 4,

2011, in Binghamton, New York. The locations of the public hearings are listed in the addresses section of this notice.

**ADDRESSES:** Comments may be mailed to: Mr. Richard A. Cairo, Susquehanna River Basin Commission, 1721 N. Front Street, Harrisburg, PA 17102-2391, or by e-mail to [rcairo@srbc.net](mailto:rcairo@srbc.net).

The public hearings will be held on Tuesday, August 2, 2011, at 10 a.m., at the Rachel Carson State Office Building, 400 Market Street, Harrisburg, PA 17101, and on Thursday, August 4, 2011 at 7 p.m., at the Holiday Inn Binghamton Downtown, 2-8 Hawley Street, Binghamton, New York 13901. Those wishing to testify are asked to notify the Commission in advance, if possible, at the regular or electronic addresses given below.

**FOR FURTHER INFORMATION CONTACT:** Richard A. Cairo, General Counsel, telephone: 717-238-0423, ext. 306; fax: 717-238-2436; e-mail: [rcairo@srbc.net](mailto:rcairo@srbc.net). Also, for further information on the proposed rulemaking, visit the Commission’s Web site at <http://www.srbc.net>.

**SUPPLEMENTARY INFORMATION:****Background and Purpose of Amendments**

The basic purpose of the regulatory amendments set forth in this proposed rulemaking is to make further modifications to the Commission’s project review regulations, most of which relate to the approval of hydrocarbon development projects.

New terms are used in these amendments that require further definition in 18 CFR 806.3. These include definitions for the terms flowback, formation fluids, hydrocarbon development, hydrocarbon water storage facility, production fluids, tophole water, and unconventional natural gas development.

In order to encourage the reuse of least quality water instead of fresh water for hydraulic fracturing by unconventional natural gas development, the Commission proposes to add paragraph (a)(3)(iv) to § 806.4, which would provide for administrative approval of diversions involving flowback or production fluids from hydrocarbon development projects being transferred across the basin

boundary from one drilling pad site to another drilling pad site, provided this water is handled in a manner that isolates it from the waters of the basin. Such diversions would be approved administratively under the provisions of § 806.22(f), rather than § 806.4. This change would incorporate into the regulation a policy adopted by the Commission on March 10, 2011.

To encourage reuse, treatment and proper disposal, paragraph (a)(3)(v) of § 806.4 would also be added, which would provide for diversions involving flowback or production fluids transferred to an out-of-basin treatment or disposal facility operating under separate governmental approval to be subject to administrative approval under the provisions of § 806.22(f), rather than being subject to docket approval under § 806.4.

Currently, § 806.4(a)(8) states that natural gas well development projects targeting the Marcellus and Utica shale formation, or any other shale formations identified in an Executive Director determination, involving a withdrawal, diversion or consumptive use of water in any quantity, must be approved by the Commission. Rather than attempting to name every possible geologic formation that may be the subject of development using hydrofracture stimulation (beyond Marcellus and Utica and the additional formations referenced in the Executive Director’s recent Notice of Determination issued on April 21, 2011), the specific formation references would be deleted and replaced with a generic category—“unconventional natural gas development,” which relates to the extraction of gaseous hydrocarbons from low permeability geologic formations utilizing enhanced drilling, stimulation and recovery techniques. The “gallon one” regulatory threshold currently applicable under the regulations to gas well development in the specifically named formations would instead be extended to this broader category.

Language is inserted into §§ 806.13 and 14 authorizing “renewal” of expiring approvals, including Approvals by Rule (ABRs). Currently, the regulations have no specific reference to a “renewal” process for expiring approvals. Renewals are also provided for in additions to § 806.22(e)(6) and (f)(9).

Adjustments are made to § 806.15—Notice of Application to account for changes and additions to § 806.22(f) described below relating to source registrations and administrative approvals of sources.

Currently, § 806.22(f) establishes an ABR process for consumptive use approvals related to natural gas well development. The Commission proposes to broaden the scope of ABRs issued under § 806.22(f) to include hydrocarbon development of any kind utilizing the waters of the basin, not just unconventional natural gas well development. Rather than requiring such projects to go through review and docket approval under § 806.4, they would be regulated under the administrative ABR process for consumptive use approvals, which has become a very effective mechanism for managing this type of activity. The inclusion of “unconventional natural gas well development” as a subcategory of hydrocarbon development retains coverage of well development using unconventional stimulation or recovery techniques such as hydraulic fracturing under the ABR process.

Proposed § 806.22(f)(4) would clarify that post-hydrofracture reporting is intended to be included in the metering, daily use monitoring and quarterly reporting requirement specified in § 806.30. This would memorialize an ongoing practice of the Commission.

Proposed § 806.22(f)(8) would broaden the certification provided by project sponsors on their compliance with state and federal laws to include “re-use” as well as treatment and disposal of flowback and production fluids.

Revised § 806.22(f)(9) would extend the concept of “renewal” to an existing ABR, where it is not explicitly mentioned in the current regulations.

The current regulations only provide a 4-year duration for natural gas development project ABRs. This relatively short approval term was implemented to give the Commission a near-term opportunity to evaluate the use of an administrative approval process for natural gas-related consumptive use activity. Revised § 806.22(f)(10) would extend the term of an approval by rule from 4 years to 15 years from the date of notification by the Executive Director, reflecting the knowledge and experience gained by the Commission in reviewing natural gas development projects. A 15-year term is the standard approval term for all other ABRs.

Water source approvals under the hydrocarbon development ABR program are restructured in three ways. First,

language would be inserted in § 806.22(f)(11) to identify water sources that are authorized for use by operation of the rule, rather than by separate approval. These sources would continue to be subject to tracking, recordkeeping and reporting requirements. The existing provisions of § 806.22(f)(12) would be split apart, resulting in revised language and the creation of a new § 806.22(f)(13). As revised, § 806.22(f)(12) sets out the registration procedure for hydrocarbon developers to use a source of water approved by the Commission pursuant to § 806.4(a) and issued to persons other than the project sponsor. The new § 806.22(f)(13) authorizes approvals for sources, including, but not limited to public water supplies, wastewater, and hydrocarbon water storage facilities not otherwise associated with docket approvals issued by the Commission or ABRs issued by the Executive Director. By issuing approvals for such hydrocarbon water storage facilities, a tracking mechanism would be created authorizing use of these sources by operation of the rule, rather than needing individual registrations or approvals. Such an approach provides the necessary management controls.

#### List of Subjects in 18 CFR Part 806

Administrative practice and procedure, Water resources.

Accordingly, for the reasons set forth in the preamble, the Susquehanna River Basin Commission proposes to amend 18 CFR Part 806 as follows:

### PART 806—REVIEW AND APPROVAL OF PROJECTS

#### Subpart A—General Provisions

1. The authority citation for Part 806 continues to read as follows:

**Authority:** Secs. 3.4, 3.5(5), 3.8, 3.10 and 15.2, Pub. L. 91–575, 84 Stat. 1509 *et seq.*

2. Amend § 806.3 by adding definitions for “Flowback”, “Formation fluids”, “Hydrocarbon development”, “Production fluids”, “Project”, “Tophole water”, and “Unconventional natural gas development” to read as follows:

#### § 806.3 Definitions.

\* \* \* \* \*

**Flowback.** The return flow of water and formation fluids recovered from the well bore of an unconventional natural gas or hydrocarbon development well within 30 days following the release of pressures induced as part of the hydraulic fracture stimulation of a target geologic formation, or until the well is

placed into production, whichever occurs first.

**Formation fluids.** Fluids in a liquid or gaseous physical state, present within the pore spaces, fractures, faults, vugs, caverns, or any other spaces of formations, whether or not naturally occurring or injected therein.

\* \* \* \* \*

**Hydrocarbon development.** Activity associated with the siting, drilling, casing, cementing, stimulation and completion of wells, including but not limited to unconventional natural gas development wells, undertaken for the purpose of extraction of liquid or gaseous hydrocarbon from geologic formations.

**Hydrocarbon water storage facility.** An engineered barrier or structure, including but not limited to tanks, pits or impoundments, constructed for the purpose of storing water, flowback or production fluids for use in hydrocarbon development.

\* \* \* \* \*

**Production fluids.** Water or formation fluids recovered at the wellhead of a producing hydrocarbon well as a by-product of the production activity.

**Project.** Any work, service, activity, or facility undertaken, which is separately planned, financed or identified by the Commission, or any separate facility undertaken or to be undertaken by the Commission or otherwise within a specified area, for the conservation, utilization, control, development, or management of water resources, which can be established and utilized independently, or as an addition to an existing facility, and can be considered as a separate entity for purposes of evaluation. For purposes of hydrocarbon development activity, the project shall be considered to be the drilling pad upon which one or more exploratory or production wells are undertaken, and all water-related appurtenant facilities and activities related thereto.

\* \* \* \* \*

**Tophole water.** Groundwater that is encountered collected at the surface during drilling operations undertaken in conjunction with hydrocarbon development.

**Unconventional natural gas development.** Activity associated with the siting, drilling, casing, cementing, stimulation and completion of wells undertaken for the purpose of extraction of gaseous hydrocarbons from low permeability geologic formations utilizing enhanced drilling, stimulation or recovery techniques.

\* \* \* \* \*

3. In § 806.4, revise paragraph (a)(3) introductory text, add paragraphs

(a)(3)(v) and (a)(3)(vi), and revise paragraph (a)(8), as follows:

**§ 806.4 Projects Requiring Review and Approval.**

(a) \* \* \*

(3) Diversions. Except with respect to agricultural water use projects not subject to the requirements of paragraph (a)(1) of this section, the projects described in paragraphs (3)(i) through (3)(iv) below shall require an application to be submitted in accordance with § 806.13, and shall be subject to the standards set forth in § 806.24. The project sponsors of out-of-basin diversions shall also comply with all applicable requirements of this part relating to consumptive uses and withdrawals. The projects identified in paragraphs (3)(v) and (3)(vi) below shall be subject to regulation pursuant to § 806.22(f).

\* \* \* \* \*

(v) The interbasin diversion of any flowback or production fluids from hydrocarbon development projects from one drilling pad site to another drilling pad site for use in hydrofracture stimulation, and handled in such a manner as to isolate it from the waters of the basin, shall not be subject to separate review and approval as a diversion under this paragraph if the generating or receiving pad site is subject to an Approval by Rule issued pursuant to § 806.22(f).

(vi) The out-of-basin diversion of flowback or production fluids from a hydrocarbon development project for which an Approval by Rule has been issued pursuant to § 806.22(f), to an out-of-basin treatment or disposal facility authorized under separate governmental approval to accept the same, shall not be subject to separate review and approval as a diversion under this paragraph.

\* \* \* \* \*

(8) Any unconventional natural gas development project in the basin involving a withdrawal, diversion or consumptive use, regardless of the quantity.

\* \* \* \* \*

**Subpart B—Application Procedure**

4. Revise § 806.13, as follows:

**§ 806.13 Submission of Application.**

Project sponsors of projects subject to review and approval of the Commission under §§ 806.4, 806.5 or 806.6, or project sponsors seeking renewal of an existing approval of the Commission, shall submit an application and applicable fee to the Commission, in accordance with this subpart.

5. In § 806.14, revise paragraph (a), as follows:

**§ 806.14 Contents of Application.**

(a) Except with respect to applications to renew an existing Commission approval, applications shall include, but not be limited to, the following information and, where applicable, shall be submitted on forms and in the manner prescribed by the Commission. Renewal applications shall include such information that the Commission determines to be necessary for the review of same, and shall likewise be submitted on forms and in the manner prescribed by the Commission.

\* \* \* \* \*

6. In § 806.15, revise paragraphs (d), (e) and (f) and add paragraph (g), as follows:

**§ 806.15 Notice of Application.**

\* \* \* \* \*

(d) For applications submitted under § 806.22(f)(13) for a public water supply source, the newspaper notice requirement contained in paragraph (a) of this section shall be satisfied by publication in a newspaper of general circulation in the area served by the public water supply.

(e) For applications submitted under § 806.22(f)(13) for a wastewater discharge source, the newspaper notice requirement contained in paragraph (a) of this section shall be satisfied by publication in a newspaper of general circulation in each area within which the water obtained from such source will be used for natural gas development.

(f) For applications submitted under § 806.22(f)(13) for a hydrocarbon water storage facility, the newspaper notice requirement contained in paragraph (a) of this section shall be satisfied by publication in a newspaper of general circulation in the area in which the project is located.

(g) The project sponsor shall provide the Commission with a copy of the United States Postal Service return receipt for the notifications to agencies of member States, municipalities and county planning agencies required under paragraph (a) of this section. The project sponsor shall also provide certification on a form provided by the Commission that it has published the newspaper notice(s) required by this section and made the landowner notifications as required under paragraph (b) of this section, if applicable. Until these items are provided to the Commission, processing of the application will not proceed. The project sponsor shall maintain all proofs of notice required hereunder for the

duration of the approval related to such notices.

**Subpart C—Standards for Review and Approval**

7. In § 806.22, revise paragraphs (e)(1), (e)(6), (f), (f)(1), (f)(4), (f)(8), (f)(9), (f)(10), (f)(11), and (f)(12), and add paragraph (f)(13), to read as follows:

**§ 806.22 Standards for consumptive uses of water.**

\* \* \* \* \*

(e) \* \* \*

(1) Except with respect to projects involving hydrocarbon development subject to the provisions of paragraph (f) of this section, any project whose sole source of water for consumptive use is a public water supply, may be approved by the Executive Director under this paragraph (e) in accordance with the following, unless the Executive Director determines that the project cannot be adequately regulated under this approval by rule.

\* \* \* \* \*

(6) The Executive Director may grant, deny, suspend, rescind, modify or condition an approval to operate under this approval by rule, or renew an existing approval by rule previously granted hereunder, and will notify the project sponsor of such determination, including the quantity of consumptive use approved.

\* \* \* \* \*

(f) Approval by rule for consumptive use related to unconventional natural gas and other hydrocarbon development.

(1) Any unconventional natural gas development project, or any hydrocarbon development project subject to review and approval under §§ 806.4, 806.5, or 806.6 of this part, shall be subject to review and approval by the Executive Director under this paragraph (f) regardless of the source or sources of water being used consumptively.

\* \* \* \* \*

(4) The project sponsor shall comply with metering, daily use monitoring and quarterly reporting as specified in § 806.30, or as otherwise required by the approval by rule. Daily use monitoring shall include amounts delivered or withdrawn per source, per day, and amounts used per gas well, per day, for well drilling, hydrofracture stimulation, hydrostatic testing, and dust control. The foregoing shall apply to all water, including stimulation additives, flowback and production fluids, utilized by the project. The project sponsor shall also submit a post-hydrofracture report

in a form and manner as prescribed by the Commission.

\* \* \* \* \*

(6) Any flowback or production fluids utilized by the project sponsor for hydrofracture stimulation undertaken at the project shall be separately accounted for, but shall not be included in the daily consumptive use amount calculated for the project, or be subject to the mitigation requirements of § 806.22(b).

\* \* \* \* \*

(8) The project sponsor shall certify to the Commission that all flowback and production fluids have been re-used or treated and disposed of in accordance with applicable state and federal law.

(9) The Executive Director may grant, deny, suspend, rescind, modify or condition an approval to operate under this approval by rule, or renew an existing approval by rule granted hereunder, and will notify the project sponsor of such determination, including the sources and quantity of consumptive use approved. The issuance of any approval hereunder shall not be construed to waive or exempt the project sponsor from obtaining Commission approval for any water withdrawals or diversions subject to review pursuant to § 806.4(a). Any sources of water approved pursuant to this section shall be further subject to any approval or authorization required by the member State.

(10) An approval by rule shall be effective upon written notification from the Executive Director to the project sponsor and shall expire 15 years from the date of such notification.

(11) A project sponsor issued an approval by rule pursuant to paragraph (f)(9) of this section may utilize any of the following water sources at the drilling pad site:

(i) Water sources approved for use by the project sponsor for unconventional natural gas development, or hydrocarbon development, whichever is applicable, pursuant to § 806.4 or this section.

(ii) Tophole water encountered during the drilling process.

(iii) Precipitation or stormwater collected on the drilling pad site.

(iv) Flowback or production fluids obtained from a hydrocarbon water storage facility, provided it is used for hydrofracture stimulation only, and is handled in such a manner as to isolate it from the waters of the basin.

(v) Water obtained from a hydrocarbon water storage facility associated with an approval issued by the Commission pursuant to § 806.4(a) or by the Executive Director pursuant to this section.

(12) A project sponsor issued an approval by rule pursuant to paragraph (f)(9) of this section may utilize a source of water approved by the Commission pursuant to § 806.4(a) and issued to persons other than the project sponsor, provided any such source is approved for use in unconventional natural gas development, or hydrocarbon development, whichever is applicable, the project sponsor has an agreement for its use, and at least 10 days prior to use, the project sponsor registers such source with the Commission on a form and in a manner as prescribed by the Commission. The project sponsor shall also provide a copy of same to the appropriate agency of the member State. The project sponsor shall record on a daily basis, and report quarterly on a form and in a manner prescribed by the Commission, the quantity of water obtained from any source registered hereunder.

(13) A project sponsor issued an approval by rule pursuant to paragraph (f)(9) of this section may also utilize other sources of water, including but not limited to, public water supply, wastewater discharge, or a hydrocarbon water storage facility not otherwise associated with an approval issued by the Commission pursuant to § 806.4(a) or an approval by rule issued pursuant to paragraph (f)(9) of this section, provided such sources are first approved by the Executive Director. Any request for approval shall be submitted on a form and in a manner as prescribed by the Commission, shall satisfy the notice requirements set forth in § 806.15, and shall be subject to review pursuant to the standards set forth in subpart C of this part. Any approval issued hereunder shall be subject to such monitoring and reporting requirements as may be contained therein.

Dated: July 1, 2011.

**Thomas W. Beauduy,**

*Deputy Executive Director.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 16 and 118

[Docket No. FDA-2011-D-0398]

#### Guidance for Industry: Questions and Answers Regarding the Final Rule, Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation; Availability

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

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled “Guidance for Industry: Questions and Answers Regarding the Final Rule, Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation” (the draft guidance). The draft guidance provides guidance to egg producers and other persons who are covered by FDA’s final rule entitled “Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation” (the final rule). The draft guidance contains questions FDA has received on the final rule since its publication and responses to those questions.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on the draft guidance before it begins work on the final version of the guidance, submit electronic or written comments on the draft guidance by September 12, 2011.

**ADDRESSES:** Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written requests for single copies of the draft guidance to the Division of Plant and Dairy Food Safety/Office of Food Safety, Center for Food Safety and Applied Nutrition (HFS-315), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or fax your request to 301-436-2632. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.