

in a form and manner as prescribed by the Commission.

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(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).

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(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.

FOR FURTHER INFORMATION CONTACT:

Nancy Bufano, Center for Food Safety and Applied Nutrition (HFS-316), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1493.

SUPPLEMENTARY INFORMATION:**I. Background**

In the **Federal Register** of July 9, 2009 (74 FR 33030), FDA issued a final rule requiring shell egg producers to implement measures to prevent *Salmonella* Enteritidis (SE) from contaminating eggs on the farm and from further growth during storage and transportation, and requiring these producers to maintain records concerning their compliance with the final rule and to register with FDA. This final rule became effective September 8, 2009, with a compliance date of July 9, 2010, for producers with 50,000 or more laying hens. For producers with fewer than 50,000, but at least 3,000 laying hens, the compliance date is July 9, 2012. The compliance date for persons who must comply with only the refrigeration requirements was July 9, 2010.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on how to interpret the requirements in the final rule, including questions and answers on compliance dates; coverage; definitions; SE prevention measures; sampling and testing for SE; registration; and compliance and enforcement. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

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 118.5, 118.6, 118.10, and 118.11 have been approved under OMB control number 0910-0660.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to

send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at <http://www.fda.gov/RegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: July 7, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 52**

[EPA-R03-OAR-2011-0092; FRL-9437-1]

Approval and Promulgation of Air Quality Implementation Plans; West Virginia; Regional Haze State Implementation Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing a limited approval and a limited disapproval of a revision to the West Virginia State Implementation Plan (SIP) submitted by the State of West Virginia through the West Virginia Department of Environmental Protection (WVDEP) on June 18, 2008, that addresses regional haze for the first implementation period. This revision addresses the requirements of the Clean Air Act (CAA) and EPA's rules that require states to prevent any future, and remedy any existing, anthropogenic impairment of visibility in mandatory Class I areas caused by emissions of air pollutants from numerous sources located over a wide geographic area (also referred to as the "regional haze program"). States are required to assure reasonable progress toward the national goal of achieving natural visibility conditions in Class I areas. EPA is proposing a limited approval of this SIP revision to implement the regional haze requirements for West Virginia on the basis that the revision, as a whole, strengthens the West Virginia SIP. Also in this action, EPA is proposing a limited disapproval of this same SIP revision because of the deficiencies in

the State's June 2008 regional haze SIP submittal arising from the remand by the U.S. Court of Appeals for the District of Columbia (D.C. Circuit) to EPA of the Clean Air Interstate Rule (CAIR). EPA is also proposing to approve this revision as meeting the requirements of 110(a)(2)(D)(i)(II) and 110(a)(2)(J), relating to visibility protection for the 1997 8-Hour Ozone National Ambient Air Quality Standard (NAAQS) and the 1997 and 2006 fine particulate matter (PM_{2.5}) NAAQS.

DATES: Comments must be received on or before August 12, 2011.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA-R03-OAR-2011-0092 by one of the following methods

A. <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

B. *E-mail:*
fernandez.cristina@epa.gov.

C. *Mail:* EPA-R03-OAR-2011-0092, Cristina Fernandez, Associate Director, Office of Air Program Planning, Mailcode 3AP30, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery:* At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA-R03-OAR-2011-0092. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through <http://www.regulations.gov> or e-mail. The <http://www.regulations.gov> website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through <http://www.regulations.gov>, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in