

**DELAWARE RIVER BASIN
COMMISSION****18 CFR Parts 410 and 440****Importations of Water Into and
Exportations of Water From the
Delaware River Basin; Discharges of
Wastewater From High Volume
Hydraulic Fracturing and Related
Activities**

AGENCY: Delaware River Basin
Commission.

ACTION: Final rule.

SUMMARY: The Commission is amending its Comprehensive Plan and the Delaware River Basin Water Code concerning importations of water into and exportations of water from the Delaware River Basin; its Special Regulations—High Volume Hydraulic Fracturing, to prohibit discharges to waters or land within the basin of wastewater from high volume hydraulic fracturing (“HVHF”) and HVHF-related activities; and its Water Quality Regulations, to facilitate the implementation in state-issued permits of the prohibition on such discharges.

DATES: This final rule is effective March 6, 2023. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of March 6, 2023.

FOR FURTHER INFORMATION CONTACT: Pamela M. Bush, Esquire, Commission Secretary and Assistant General Counsel, at pam.bush@drbc.gov (preferred) or 609–477–7203.

SUPPLEMENTARY INFORMATION: The Delaware River Basin Commission (“DRBC” or “Commission”) is a Federal-interstate compact agency charged with managing the water resources of the Delaware River Basin on a regional basis without regard to political boundaries. Its members are the governors of the four basin states—Delaware, New Jersey, New York, and Pennsylvania—and the Division Engineer, North Atlantic Division, U.S. Army Corps of Engineers, representing the Federal Government.

Background

By a Resolution for the Minutes on February 25, 2021, the DRBC Commissioners directed the Executive Director to prepare and publish for public comment a set of amendments to the Comprehensive Plan and implementing regulations to update the Commission’s policies and provisions concerning inter-basin transfers of water and wastewater from and into the basin and to “include in the draft regulations such other proposed amendments . . .

as [the Executive Director, in consultation with the Commissioners] deem necessary or appropriate.” The directive followed the Commission’s decision not to include in its final rule adopted in 2021, portions of a proposed rule published in the *Federal Register* in January 2018 that concerned the exportation of water to support high volume hydraulic fracturing (“HVHF”) and the importation, treatment, and discharge of “produced water” and “CWT wastewater” (with accompanying definitions).¹ In accordance with the Commission’s February 25, 2021 directive, the Commission published a new proposed rule on November 22, 2021 (86 FR 66250). The draft regulations appeared on the Commission’s website on October 28, 2021,² and notice of the proposed amendments appeared in the Delaware Register of Regulations, 25 Del. Reg. 548, 559, on December 1, 2021, the New Jersey Register, 53 N.J.R. 1994, on December 6, 2021, the New York Register on November 17, 2021, p. 2, and the Pennsylvania Bulletin, 51 Pa. B. 7471, on December 4, 2021.

Opportunity for public input on the proposed rules was provided during a comment period that ran from October 28, 2021, through February 28, 2022. In addition to accepting written comments, the Commission accepted oral comment at five hearings conducted via Zoom and telephone. The fifth hearing included toll-free telephone access and real-time English-to-Spanish and Spanish-to-English professional translation, which allowed attendees to listen and participate in either English or Spanish. The Commission received a total of 2,461 public comment submissions, consisting of 2,388 in writing and 73 oral comments. Notably, in many cases, a single written submission consisted of comments with multiple signatories or parts, and many similar or identical comments were separately submitted by multiple commenters using form letters or template language provided by organizations.

The Commission reviewed the statements, consultant reports, scientific literature and other materials submitted by commenters. The staff, in consultation with the Commissioners, prepared a Comment and Response Document summarizing the comments on the proposed rule and setting forth

¹ See 86 FR 20628 (April 21, 2021) and 83 FR 1586, pp. 1589, 1591 (January 12, 2018).

² By a Resolution for the Minutes dated September 9, 2021, the DRBC Commissioners extended from September 30, 2021 to November 30, 2021 the date by which draft regulations would be published.

the Commission’s responses and revisions in detail. By Resolution No. 2022–04 on December 7, 2022, the Commission adopted the Comment and Response Document simultaneously with its adoption of the final rule.

Changes From the Proposed Rule

Incorporation by reference: The final rule incorporates by reference into the Code of Federal Regulations the Commission’s Water Quality Regulations and the Delaware River Basin Water Code (the “Water Code”) as amended by the Commission on December 7, 2022. For a discussion of the amendments, including changes from those proposed in October and November 2021, see “Additional Materials” below. The Water Code and Water Quality Regulations are reasonably available to regulated and other interested parties through the Commission’s website, www.drbc.gov.

Special Regulations—High Volume Hydraulic Fracturing: The final rule includes the addition of two words to section (1) of the proposed definition of “Wastewater from HVHF and HVHF-related activities” in § 440.2 of the Special Regulations. The words “or” and “containing” are added to clarify that the definition refers to wastewater, brine, or sludge *containing* (as opposed to constituting) the various listed contaminants. The final rule also includes a new defined term—“Discharge of wastewater from HVHF and HVHF-related activities”—to make the meaning and intended effect of the rules more explicit. Additional non-substantive changes were made to conform proposed rule text in § 440.2 to Code of Federal Regulations standards.

Summary of Material Incorporated by Reference

The Delaware River Basin Water Code consists of four articles applicable to public and private water projects and programs within the Delaware River Basin. Article I sets forth general policies of the Commission with respect to the planning of Federal, state and local projects, the Commission’s comprehensive plan, and projects subject to the Commission’s review. Article II sets forth measures for the conservation, development and utilization of the water resources of the basin, including the management of shared water resources during drought, provisions relating to inter-basin transfers of water, metering and reporting of withdrawals, and water audit requirements. Article III establishes water quality standards, including uses and quality objectives for surface and ground waters. Article IV

contains rules relating to application of water quality standards within the basin.

The Water Quality Regulations apply to all public and private entities that discharge waste to waters of the Delaware River Basin and are comprised of four articles. Article I sets forth general purposes of the Water Quality Regulations, as well as definitions applicable to the Water Quality Regulations. Article II concerns interstate cooperation among the signatories to the Delaware River Basin Compact. Article III sets forth water quality standards and guidelines for the Delaware River Basin. Article IV contains rules relating to application of water quality standards within the basin.

Activities Prohibited and Activities Not Regulated by the Final Rule

Many commenters urged the Commission to prohibit activities that would be prohibited by the proposed (now final) prohibition at 18 CFR 440.4. The final rule at § 440.4(b) prohibits the discharge of wastewater “from high volume hydraulic fracturing and HVHF-related activities to waters or land within the basin.” The terms “Discharge of wastewater from HVHF and HVHF-related activities,” “HVHF-related activities,” and “wastewater from HVHF and HVHF-related activities” all are defined in detail in § 440.2. Activities about which multiple commenters expressed concern, which are *prohibited by the final rule* include (but are not necessarily limited to) the following:

- discharge of HVHF wastewater to waters or land within the basin;
- road spreading of HVHF wastewater;
- injection of HVHF wastewater into deep wells within the basin;
- disposal of HVHF wastewater in basin landfills;
- discharge of leachate from any landfill in the basin that accepts HVHF waste after the effective date of the final regulations, including after treatment at an onsite or off-site leachate or wastewater treatment plant; and
- spills and leaks during transport, transfer, or storage of HVHF wastewater within the basin if not fully captured by a containment system in place throughout the duration of the spill or leak and thereafter promptly removed or remediated.

Other commenters urged the Commission to prohibit activities that are beyond the scope of the proposed rule. As explained in detail in the Commission’s Comment and Response document, *the final rule does not:*

- regulate air emissions from HVHF activities;
- regulate the transportation and storage of HVHF materials, which are regulated under detailed state and Federal programs focused on these activities;
- categorically prohibit the transfer of HVHF wastewater into the basin when no resulting discharge is proposed;
- categorically prohibit the transfer of water from the basin if it would be used to support HVHF (or any other specified activity). However, the rule does limit the circumstances under which transfers of water from the basin will be considered and provides for an evaluation of such proposals based on factors designed to ensure no harm to the basin’s water resources or the health and safety of the basin community; or
- prohibit road spreading of wastewater from *conventional* drilling activities, an activity not within the scope of DRBC’s proposed rulemaking. The Commission will continue to coordinate with the basin states to review the scientific evidence regarding harm to water resources caused by road spreading of conventional oil and gas production wastewater and may in the future consider whether additional regulation of the practice is needed in the basin.

Additional Materials

Additional materials can be found on the Commission’s website, www.drbc.gov, at https://www.nj.gov/drbc/about/regulations/final-rule_import-export-hvhf-discharge.html. These include links to Resolution No. 2022–04 of December 7, 2022 adopting the final rule; the Commission’s Comment and Response Document; mark-ups comparing the final to the proposed rule text for Section 2.30 of the Water Code and for the Commission’s Special Regulations at 18 CFR part 440; mark-ups comparing the amended to the existing rule text for 18 CFR part 440 and the Commission’s Water Quality Regulations; and clean drafts of the amended and existing Section 2.30 of the Water Code for comparison.

The Commission’s notice of proposed rulemaking, proposed rule text, written comments received, and transcripts of public hearings can be found on the Commission’s website at https://www.state.nj.us/drbc/meetings/proposed/notice_import-export-rules.html.

List of Subjects in 18 CFR Parts 410 and 440

Incorporation by reference, Natural gas, Wastewater discharge, Water pollution control, Water resources.

For the reasons set forth in the preamble, the Delaware River Basin Commission amends 18 CFR chapter III as follows:

PART 410—BASIN REGULATIONS; WATER CODE AND ADMINISTRATIVE MANUAL—PART III WATER QUALITY REGULATIONS

- 1. The authority citation for part 410 continues to read as follows:

Authority: Delaware River Basin Compact, 75 Stat. 688.

- 2. Amend § 410.1 by revising paragraph (c) to read as follows:

§ 410.1 Basin regulations—Water Code and Administrative Manual—Part III Water Quality Regulations.

* * * * *

(c) Work, services, activities and facilities affecting the conservation, utilization, control, development or management of water resources within the Delaware River Basin are subject to regulations contained within the Delaware River Basin Water Code with Amendments through December 7, 2022 and the Administrative Manual—Part III Water Quality Regulations with Amendments through December 7, 2022. Both the Delaware River Basin Water Code and the Administrative Manual—Part III Water Quality Regulations are incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain or inspect this material at the Delaware River Basin Commission (DRBC), 25 Cosey Road, West Trenton, New Jersey 08628–0360, 609–883–9500, www.drbc.gov.

You may inspect this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations.html or email fr.inspection@nara.gov.

PART 440—HIGH VOLUME HYDRAULIC FRACTURING

- 3. The authority citation for part 440 continues to read as follows:

Authority: Delaware River Basin Compact (75 Stat. 688).

- 4. Amend § 440.1 by revising paragraph (d) to read as follows:

§ 440.1 Purpose, authority, and relationship to other requirements.

* * * * *

(d) *Relationship to other Commission requirements.* The provisions of this part are in addition to all applicable requirements in other Commission regulations, dockets, permits, and determinations.

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■ 5. Amend § 440.2 by revising the introductory text, adding, in alphabetical order, the definitions for “Discharge of wastewater from HVHF and HVHF-related activities,” “HVHF-related activities,” and “Wastewater from HVHF and HVHF-related activities,” and revising the definition of “Water resource(s)” to read as follows:

§ 440.2 Definitions.

For purposes of this part, the following terms and phrases have the meanings provided. Some definitions differ from those provided in regulations of one or more agencies of the Commission’s member states and the Federal Government. Other definitions are consistent with terms defined by the Delaware River Basin Compact.

* * * * *

Discharge of wastewater from HVHF and HVHF-related activities is an intentional or unintentional action or omission resulting in the releasing, spilling, leaking, pumping, pouring, emitting, emptying, spreading, spraying, injecting, leaching, dumping, or disposing of such wastewater to waters or land within the Basin, and including the abandonment or discarding of barrels, containers, and other receptacles containing such wastewater.

* * * * *

HVHF-related activities are:

(1) Construction of an oil or natural gas production well that is to be stimulated using HVHF as defined in this section;

(2) Chemical mixing or storage of proppant, chemicals and other additives to make fracturing fluid; and

(3) Management of wastewater from hydraulic fracturing, including storage, disposal, treatment, or reuse in hydraulic fracturing operations or other uses.

* * * * *

Wastewater from HVHF and HVHF-related activities is:

(1) Any wastewater, brine, or sludge containing chemicals, naturally occurring radioactive materials, heavy metals or other contaminants that have been used for or generated by high volume hydraulic fracturing or HVHF-related activities;

(2) Leachate from solid wastes associated with HVHF-related activities, except if the solid wastes were lawfully disposed of in a landfill within the Basin prior to March 6, 2023; and

(3) Any products, co-products, byproducts, or waste products resulting from the treatment, processing, or modification of the wastewater described in paragraphs (1) and (2) of this definition.

Water resource(s) is, in accordance with section 1.2(i) of the *Delaware River Basin Compact*, water and related natural resources in, on, under, or above the ground, including related uses of land, which are subject to beneficial use, ownership or control within the Delaware River Basin.

■ 6. Add § 440.4 to read as follows:

§ 440.4 Wastewater from high volume hydraulic fracturing and related activities.

(a) *Determination.* The Commission has determined that the discharge of wastewater from high volume hydraulic fracturing and HVHF-related activities poses significant, immediate and long-term risks to the development, conservation, utilization, management, and preservation of the Basin’s water resources. Controlling future pollution by prohibiting such discharge is required to effectuate the Comprehensive Plan, avoid injury to the waters of the Basin as contemplated by the Comprehensive Plan, and protect the public health and preserve the waters of the Basin for uses in accordance with the Comprehensive Plan.

(b) *Prohibition.* No person may discharge wastewater from high volume hydraulic fracturing or HVHF-related activities to waters or land within the Basin.

Dated: January 26, 2023.

Pamela M. Bush,

Commission Secretary and Assistant General Counsel.

[FR Doc. 2023–02125 Filed 2–1–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 864

[Docket No. FDA–2023–N–0062]

Medical Devices; Hematology and Pathology Devices; Classification of the Software Algorithm Device To Assist Users in Digital Pathology

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the software algorithm device to assist users in digital pathology into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the software algorithm device to assist users in digital pathology’s classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients’ access to beneficial innovative devices.

DATES: This order is effective February 2, 2023. The classification is applicable on September 21, 2021.

FOR FURTHER INFORMATION CONTACT: Arpita Roy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3319, Silver Spring, MD 20993–0002, 240–402–4807, Arpita.Roy@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the software algorithm device to assist users in digital pathology as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients’ access to beneficial innovation, in part by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as “postamendments devices” because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (see 21