

To: Jackson, Ryan[jackson.ryan@epa.gov]
From: Bloomberg BNA
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EHS Federal Regulatory Alert

November 28, 2017 - Number 227

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Summaries

AIR

Missouri SIP/2008 Ozone NAAQS Infrastructure Requirements

AIR

Notice of the EPA announces the withdrawal of an Oct. 6, 2017, direct final rule (82 FR 46679) that would have approved portions of revisions to the Missouri SIP regarding infrastructure requirements for the 2008 ozone NAAQS. The revisions address prevention of significant deterioration of air quality (prong 3). The agency took no action on significant contribution to nonattainment (prong 1) or interference with maintenance of the NAAQS (prong 2) because those elements were not addressed in the SIP revision submittal. The agency will act separately on proposed revisions concerning protection of visibility (prong 4). The withdrawal is in response to adverse comments. The agency will proceed with a final rule based on the related proposed rule (82 FR 46741; 10/06/2017). The withdrawal is effective Nov. 28, 2017. Contact: Tracey Casburn; EPA Region 7, Air Planning and Development Branch; 913-551-7016; casburn.tracey@epa.gov. Citations: 40 CFR 52.1320

82 FR 56172 (11/28/2017)

Regulatory Update

AIR

Missouri SIP/2010 SO2 NAAQS Infrastructure Requirements

AIR

Notice of the EPA announces the withdrawal of an Oct. 6, 2017, direct final rule (82 FR 46672) that would have approved portions of revisions to the Missouri SIP regarding infrastructure requirements for the 2010 sulfur dioxide (SO₂) NAAQS. The rule would have approved revisions concerning prevention of significant deterioration of air quality (prong 3). The agency took no action on revisions concerning significant contribution to nonattainment (prong 1), interference with maintenance of the NAAQS (prong 2), or certain requirements for designated nonattainment areas. Revisions concerning protection of visibility (prong 4) will be addressed in a separate rulemaking. The withdrawal is in response to adverse comments. The agency will proceed with a

final rule based on the related proposed rule (82 FR 46742; 10/06/2017). The withdrawal is effective Nov. 28, 2017. Contact: Tracey Casburn; EPA Region 7, Air Planning and Development Branch; 913-551-7016; casburn.tracey@epa.gov. Citations: 40 CFR 52.1320(e)

82 FR 56172 (11/28/2017)

Regulatory Update

AIR

Nebraska SIP/Operating Permits Program

AIR

Notice of the EPA announces the withdrawal of an Oct. 5, 2017, direct final rule (82 FR 46420) that would have approved portions of revisions to the Nebraska SIP, the operating permits program, and the Section 112(l) program. The revisions incorporate by reference the list of organic compounds that are exempt from the definition of volatile organic compound and update notification requirements for the operating permits program. The revisions also extend the process of off-permit changes to Class I operating permits. The withdrawal is in response to adverse comments. The agency will proceed with a final rule based on the related proposed rule (82 FR 46453; 10/05/2017). The withdrawal is effective Nov. 28, 2017. Contact: Greg Crable; EPA Region 7, Air Planning and Development Branch; 913-551-7391; crable.gregory@epa.gov. Citations: 40 CFR 52.1420; 70, Appendix A

82 FR 56173 (11/28/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Army Corps of Engineers Regulatory Review Report

GENERAL ENVIRONMENT AND SAFETY

Notice of the U.S. Army Corps of Engineers announces the availability of a report that assesses potential changes to regulations to reduce limitations on the development and use of domestic energy resources, including oil, natural gas, coal, nuclear energy, and renewable energy. The report, which is required by Executive Order 13783 on promoting energy independence and economic growth (82 FR 16093; 03/31/2017), proposes changes to nine nationwide permits that authorize activities under Section 10 of the Rivers and Harbors Act and Section 404 the Clean Water Act. The permits relate to maintenance, utility line activities, hydropower projects, surface coal mining, commercial and institutional developments, coal remining, underground coal mining, land-based renewable energy generation projects, and water-based renewable energy generation pilot projects. Contact: David Olson; USACE; 202-761-4922

82 FR 56192 (11/28/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

California/Pure Water San Diego Program, North City Project

GENERAL ENVIRONMENT AND SAFETY

Notice of the Bureau of Reclamation announces the availability of a draft environmental impact

statement regarding the North City Project in San Diego. The project is the first phase of the Pure Water San Diego Program, a water and wastewater facilities plan to produce potable water from recycled water via construction of new water and wastewater treatment facilities, pump stations, and pipelines. The proposed project involves expansion of the North City Water Reclamation Plant through construction of an adjacent North City Pure Water Facility with a purified water pipeline to Miramar Reservoir. The project also involves construction of the North City Renewable Energy Facility to receive landfill gas from the Miramar Landfill gas collection system via a gas pipeline. The notice specifies that a project alternative would involve the installation of a longer pipeline to deliver water to San Vicente Reservoir. Comments are due Jan. 8, 2018. Contact: Doug McPherson; Department of the Interior, Bureau of Reclamation; 951-695-5310; dmcperson@usbr.gov

82 FR 56264 (11/28/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Electric Utilities/Performance During Faults, Training for Personnel

GENERAL ENVIRONMENT AND SAFETY

Proposed rule of FERC would approve reliability standards PRC-027-1 (coordination of protection systems for performance during faults) and PER-006-1 (specific training for personnel) submitted by the North American Electric Reliability Corp. (NERC). The rule would maintain the coordination of protection systems installed to detect and isolate faults on bulk electric system elements and ensure that personnel are trained on specific topics essential to reliability to perform or support real-time operations of the bulk electric system. The commission proposes that NERC modify proposed reliability standard PRC-027-1 to require an initial protection system coordination study to ensure that applicable entities will perform a study demonstrating proper coordination of its protection systems. The rule also would approve associated violation risk factors, violation severity levels, implementation plans, and effective dates proposed by NERC and approve the retirement of reliability standard PRC-001-1.1(ii)(system protection coordination). In addition, the rule would approve new and revised definitions of "protection system coordination study," "operational planning analysis," and "real-time assessment." Comments are due Jan. 29, 2018. Contact: Juan Villar; FERC, Office of Electric Reliability; 772-678-6496; Juan.Villar@ferc.gov. Citations: 18 CFR 40

82 FR 56186 (11/28/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Energy Conservation Standards Program Design

GENERAL ENVIRONMENT AND SAFETY

Notice of the Energy Department, Office of Energy Efficiency and Renewable Energy, announces a request for information regarding the potential advantages and disadvantages of revising the U.S. Appliance and Equipment Energy Conservation Standards (ECS) program to include additional compliance flexibility. Feedback is requested on the possible design of such a program, with particular interest expressed for designs that incorporate market-based policy mechanisms, such as averaging, credit trading, or feebate programs. Feedback also is requested on possible economic efficiency gains, impacts on consumer and manufacturer costs and on energy savings, and suggestions for a pilot product category and/or phase-in of revisions across

the ECS program. In addition, the agency requests feedback on potential challenges with designing and implementing flexible program approaches as well as possible solutions. Comments are due Feb. 26, 2018. Contact: DOE, Office of Energy Efficiency and Renewable Energy; 202-287-1445; ProgramDesign2017STD0059@ee.doe.gov. Citations: 10 CFR 430

82 FR 56181 (11/28/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Lower Colorado River Multi-Species Conservation Program/Northern Mexican Gartersnake
GENERAL ENVIRONMENT AND SAFETY

Notice of the U.S. Fish and Wildlife Service announces the availability of a draft environmental assessment for a draft amendment to the existing Endangered Species Act permit for the Lower Colorado River Multi-Species Conservation Program (LCR MSCP) that would add the northern Mexican gartersnake as a covered species. The amendment would provide incidental take coverage to the gartersnake for activities associated with river operations and water and power delivery for the entire program area in Arizona, California, and Nevada. Contact: Steve Spangle; USFWS, Arizona Ecological Services Field Office; 602-242-0210; incomingzcorr@fws.gov

82 FR 56261 (11/28/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

New Mexico/Farmington District Resource Advisory Council
GENERAL ENVIRONMENT AND SAFETY

Notice of the Bureau of Land Management announces a meeting of the Farmington District, N.M., Resource Advisory Council and field trip to the Chockcherry Canyon in the Glade Run Recreation Area. The agenda includes updates on the Farmington resources management plan amendment and the land use planning in the Taos Field Office, updates on the Taos general recreation plan and the Farmington Glade Run recreation implementation plan, and an overview of fire and fuel plan treatments for the Farmington District. The agenda also includes a presentation of the BLM's role in the Four Corners Air Quality Group and the introduction of new RAC members and election of a new RAC chair. The meeting and field trip are scheduled for Jan. 30 and 31, 2018, respectively, in Farmington, N.M. Comments are due Jan. 29, 2017. Contact: Zach Stone; BLM, Farmington District Office; 505-564-7677; zstone@blm.gov

82 FR 56263 (11/28/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

New Mexico/Las Cruces District Resource Advisory Council Meeting
GENERAL ENVIRONMENT AND SAFETY

Notice of the Bureau of Land Management announces a meeting of the Las Cruces District, N.M., Resource Advisory Council and field trip to the northern Potrillo Mountains. The agenda includes updates on current and proposed lands including realty, planning, and energy projects in the

district; the Tri-County Supplemental Resource Management Plan; and the land-use planning process in the district. The field trip and meeting are scheduled for Jan. 30 and 31, 2018, respectively, in Las Cruces, N.M. Comments are due Jan. 29, 2018. Contact: Deborah Stevens; BLM, Las Cruces District; 575-525-4421

82 FR 56264 (11/28/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Regulatory Review Period/Rapivab

GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces a determination of the regulatory review period for the human drug product Rapivab (peramivir) in response to a patent term restoration application from BioCryst Pharmaceuticals Inc., of Durham, N.C. The product is indicated for the treatment of acute uncomplicated influenza in patients 18 years and older who have been symptomatic for no more than two days. Comments are due Jan. 29, 2018. Petitions for a determination of whether the applicant for extension acted with due diligence during the regulatory review period are due May 29, 2018. Contact: Beverly Friedman; FDA, Office of Regulatory Policy; 301-796-3600

82 FR 56244 (11/28/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Regulatory Review Period/Savaysa

GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces a determination of the regulatory review period for the human drug product Savaysa (edoxaban tosylate monohydrate) in response to a patent term restoration application from Daiichi Sankyo Co., of Tokyo. The product is indicated to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation and for the treatment of deep vein thrombosis and pulmonary embolism following five to 10 days of initial therapy with a parenteral anticoagulant. Comments are due Jan. 29, 2018. Petitions for a determination of whether the applicant for extension acted with due diligence during the regulatory review period are due May 29, 2018. Contact: Beverly Friedman; FDA, Office of Regulatory Policy; 301-796-3600

82 FR 56252 (11/28/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Regulatory Review Period/Senza Spinal Cord Stimulation System

GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces a determination of the regulatory review period for the medical device Senza spinal cord stimulation system in response to a patent term restoration application from Nevro Corp., of Redwood City, Calif. The product is indicated as an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with failed back surgery syndrome, intractable low-back pain, or leg pain. Comments

are due Jan. 29, 2018. Petitions for a determination of whether the applicant for extension acted with due diligence during the regulatory review period are due May 29, 2018. Contact: Beverly Friedman; FDA, Office of Regulatory Policy; 301-796-3600

82 FR 56250 (11/28/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Regulatory Review Period/Yondelis

GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces a determination of the regulatory review period for the human drug product Yondelis (trabectedin) in response to a patent term restoration application from Pharma Mar SA, of Madrid. The product is indicated for the treatment of patients with unresectable or metastatic liposarcoma or leiomyosarcoma who received a prior anthracycline-containing regimen. Comments are due Jan. 29, 2018. Petitions for a determination of whether the applicant for extension acted with due diligence during the regulatory review period are due May 29, 2018. Contact: Beverly Friedman; FDA, Office of Regulatory Policy; 301-796-3600

82 FR 56246 (11/28/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Regulatory Review Period/Zerbaxa

GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces a determination of the regulatory review period for the human drug product Zerbaxa (ceftolozane sulfate and tazobactam sodium) in response to patent term restoration applications from Astellas Pharma Inc., of Tokyo, and Wakunaga Pharmaceutical Co., of Osaka, Japan. The product is indicated for the treatment of complicated intra-abdominal infections, used in combination with metronidazole and for complicated urinary tract infections, including pyelonephritis. Comments are due Jan. 29, 2018. Petitions for a determination of whether the applicant for extension acted with due diligence during the regulatory review period are due May 29, 2018. Contact: Beverly Friedman; FDA, Office of Regulatory Policy; 301-796-3600

82 FR 56253 (11/28/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

U.S.-Chile Environmental Cooperation Agreement Work Program

GENERAL ENVIRONMENT AND SAFETY

Notice of the State Department requests comments and suggestions regarding items for inclusion in the 2018-2020 Work Program to be established by the U.S. and Chile pursuant to the U.S.-Chile Environmental Cooperation Agreement. Comments are due Dec. 6, 2017. Contact: Keri Holland; State Department; Bureau of Oceans and International Environmental and Scientific Affairs; 202-647-6777; HollandKJ@state.gov

82 FR 56321 (11/28/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Variant Classification and Interpretation in Precision Oncology Workshop

GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces a workshop to discuss precision oncology variant classification and interpretation to weigh evidence of sequencing results. The workshop is intended to collect input from internal and external experts in precision oncology to discuss how genetic sequencing data is best implemented in patient management so that regulatory strategies can be advanced to support the development of safe and effective precision-based drugs and devices for marketing. The workshop is scheduled for Jan. 29, 2018, in Silver Spring, Md. Contact: Hisani Madison; FDA, Center for Devices and Radiological Health; 240-402-6581; hisani.madison@fda.hhs.gov

82 FR 56245 (11/28/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

X-Ray Imaging Device Premarket Notifications/Pediatric Information

GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces the availability of a guidance for industry concerning pediatric information for X-ray imaging device premarket notifications. The guidance details what information should be included in premarket notification submissions and device labeling for X-ray imaging devices indicated for pediatric populations or general use X-ray imaging devices for which considerable pediatric application is anticipated. The guidance also provides recommendations for labeling, including the instructions for use. The guidance applies to both new devices and modifications of existing X-ray imaging devices that require submission of a new premarket notification, regardless of whether the device is a complete X-ray imaging system, a component part of an X-ray imaging device, or an accessory. Comments may be submitted at any time. Contact: Laurel Burk; FDA, Center for Devices and Radiological Health; 301-796-5933

82 FR 56248 (11/28/2017)

Regulatory Update

HAZARDOUS WASTE CLEANUP

Connecticut/Bridgeport Fire Superfund Site

HAZARDOUS WASTE CLEANUP

Notice of the EPA announces a proposed settlement agreement under CERCLA with Rowayton Trading Co., of Rowayton, Conn., regarding the Bridgeport Fire Superfund Site in Bridgeport, Conn. The agreement requires the settling party to pay \$50,000 to the Superfund and includes a covenant not to sue. Comments are due Dec. 28, 2017. Contact: Cynthia Lewis; EPA, Office of General Counsel; 617-918-1889; lewis.cindy@epa.gov

82 FR 56234 (11/28/2017)

Regulatory Update

HAZARDOUS WASTE CLEANUP

Kansas/CERCLA Stipulation and Order
HAZARDOUS WASTE CLEANUP

Notice of the Department of Justice announces a proposed stipulation and order in *In re Hawker Beechcraft Inc. (No. 12-11873 (SMB))*, lodged on Nov. 20, 2017, with the U.S. Bankruptcy Court for the Southern District of New York. The proposed stipulation and order addresses the recovery of past response costs under CERCLA incurred by the U.S. concerning contamination at the Tri-County Public Airport (TCPA) site in Morris County, Kansas. Under the stipulation and order, the defendants agree that the U.S. will have an allowed general unsecured claim of \$738,337 for response costs and agree that any claim for costs incurred on or after the petition date at the site and three other Kansas sites is not discharged or impaired. The defendants also agree that they will comply with CERCLA administrative orders related to the TCPA site. The U.S. agrees not to sue the parties for any pre-petition response costs at the four sites. Comments are due Dec. 28, 2017. Contact: DOJ, Environment and Natural Resources Division; 202-514-2701

82 FR 56269 (11/28/2017)

Regulatory Update

MINING

National Coal Council Charter Renewal
MINING

Notice of the Energy Department, Office of Fossil Energy, announces the renewal of the charter for the National Coal Council for two years. The council provides advice, information and recommendations to the secretary of Energy regarding coal policy issues. Members consist of representatives from the coal industry, including from large and small companies; commercial and residential consumers; and environmental, labor, research, and academic organizations. Contact: Daniel Matuszak; DOE; 202-287-6915; daniel.matuszak@hq.doe.gov

82 FR 56226 (11/28/2017)

Regulatory Update

OCCUPATIONAL SAFETY AND HEALTH

Nationally Recognized Testing Laboratories/Intertek
OCCUPATIONAL SAFETY AND HEALTH

Notice of OSHA announces a final decision to expand the scope of recognition for Intertek Testing Services NA, of Cortland, N.Y., as a nationally recognized testing laboratory. The expansion involves the addition of seven test standards to its scope of recognition. The decision is effective Nov. 28, 2017. Contact: Kevin Robinson; OSHA, Directorate of Technical Support and Emergency Management; 202-693-2110; robinson.kevin@dol.gov. Citations: 29 CFR 1910.7

82 FR 56270 (11/28/2017)

Regulatory Update

PESTICIDES

Pesticide Tolerance Exemption/Polyethyleneimine

PESTICIDES

Final rule of the EPA establishes an exemption from the requirement of a tolerance for residues of polyethyleneimine when used as an inert ingredient in a pesticide chemical formulation on growing crops and raw agricultural commodities after harvest. The rule is issued in response to a petition filed on behalf of BASF Corp., of Florham Park, NJ. The rule is effective Nov. 28, 2017. Objections and hearing requests are due Jan. 29, 2018. Contact: Michael Goodis; EPA, Office of Pesticide Programs; 703-305-7090; RDFRNotices@epa.gov. Citations: 40 CFR 180.910

82 FR 56173 (11/28/2017)

Regulatory Update

RADIATION

Missouri/Discovery Ridge Radioisotope Production Facility

RADIATION

Notice of the NRC announces a hearing to receive testimony and exhibits related to Northwest Medical Isotopes LLC's application for a permit to construct a radioisotope production facility at the Discovery Ridge Research Park in Columbia, Mo. The agenda includes presentations and discussions regarding safety and environmental matters related to the project. The commission previously issued a final environmental impact statement (82 FR 22858; 05/18/2017) recommending that the permit should be issued. The hearing is scheduled for Jan. 23, 2018, in Rockville, Md., and will continue on subsequent days if necessary. Documents and comments are due Jan. 2, 2018. Contact: Denise McGovern; NRC, Office of the Secretary; 301-415-0681; Denise.McGovern@nrc.gov. Citations: 10 CFR 50.35, 50.40, 50.50, 51.105

82 FR 56276 (11/28/2017)

Regulatory Update

WATER

Perchlorate in Drinking Water/Peer Review Meeting

WATER

Notice of the EPA announces a peer review meeting and final list of expert peer review panelists for review of scientific materials in the draft report on proposed approaches to inform the derivation of a maximum contaminant level goal for perchlorate in drinking water (82 FR 43354; 09/15/2017). The report describes revisions to the biologically based dose-response model and model report for perchlorate in drinking water following the first peer review in January 2017 (81 FR 87553; 12/05/2016). The notice also includes a list of the eight expert peer reviewers selected by the EPA's contractor Versar Inc. The meeting is scheduled for Jan. 29-30, 2018, in Arlington, Va. Contact: Samuel Hernandez; EPA, Office of Ground Water and Drinking Water; 202-564-1735; hernandez.samuel@epa.gov

82 FR 56235 (11/28/2017)

Regulatory Update

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