

**To:** Jackson, Ryan[jackson.ryan@epa.gov]  
**From:** Bloomberg BNA  
**Sent:** Wed 6/14/2017 12:40:57 PM  
**Subject:** June 14 -- EHS Federal Regulatory Alert



## **EHS Federal Regulatory Alert**

June 14, 2017 - Number 113

You can create a report customized by topic, jurisdiction, and date range by using the [Regulatory Summaries Report Tool](#). The report can be generated in Excel, Word, or PDF.

### Summaries

*AIR*

#### California SIP/Imperial County APCD New Source Review Permitting Program AIR

Final rule of the EPA amends regulations under 40 CFR 52.220 to approve revisions to the Imperial County Air Pollution Control District portion of the California SIP regarding the new source review permitting program. The rule approves revisions concerning application requirements and processing of applications. The rule also approves a technical correction concerning exemptions. A June 12, 2017, proposed rule (82 FR 26883) addresses revisions concerning new and modified stationary source review and would grant conditional approval pending the district's commitment to submit a SIP revision that regulates ammonia as a fine particulate matter (PM-2.5) precursor. The rule is effective July 14, 2017. Contact: Thien Nguyen; EPA Region 9; 415-947-4120; [nguyen.thien@epa.gov](mailto:nguyen.thien@epa.gov)

82 FR 27125 (06/14/2017)

#### Regulatory Update

*AIR*

#### New Mexico SIP/Regional Haze AIR

Final rule of the EPA amends regulations under 40 CFR 52.1620 to approve a revision to the New Mexico SIP. The revision includes a progress report concerning federal regional haze requirements and an adequacy determination for achieving reasonable progress goals regarding visibility improvement and emission reductions for Class I areas affected by sources in the state. The rule is effective July 14, 2017. Contact: James Grady; EPA Region 6; 214-665-6745; [grady.james@epa.gov](mailto:grady.james@epa.gov)

82 FR 27127 (06/14/2017)

#### Regulatory Update

**AIR**

**Oklahoma SIP/Infrastructure and Interstate Transport Requirements**

**AIR**

Final rule of the EPA amends regulations under 40 CFR 52 to partially approve and partially disapprove revisions to the Oklahoma SIP concerning infrastructure and interstate transport requirements for the 2012 fine particulate matter (PM-2.5) NAAQS. The rule approves revisions related to interference with prevention of significant deterioration. The rule disapproves interstate transport provisions for visibility protection (prong 4). The rule takes no action regarding 2010 sulfur dioxide or the 2012 PM-2.5 NAAQS, which will be addressed at a later date. The rule is effective July 14, 2017. Contact: Wendy Jacques; EPA Region 6; 214-665-7395; jacques.wendy@epa.gov

82 FR 27121 (06/14/2017)

**Regulatory Update**

**AIR**

**Risk Management Program/Accidental Release Prevention**

**AIR**

Final rule of the EPA further delays the effective date of a Jan. 13, 2017, final rule (82 FR 4594) that amends regulations under 40 CFR 68.3 through 68.210 (nonconsecutive) and adopts regulations under 40 CFR 68.59, 68.80, 68.93, 68.96, and 68.205 to revise accidental release prevention requirements under the Risk Management Program (RMP). The rule requires all facilities with Program 2 or 3 processes to conduct a root cause analysis as part of an incident investigation of a catastrophic release or possible catastrophic release and to contract with an independent third-party to perform a compliance audit after a reportable release. The rule also requires owners or operators of Program 3 facilities in North American Industrial Classification System codes 322, 324, and 325 to conduct a safer technology and alternative analysis as part of their process hazard analysis and to evaluate the feasibility of any inherently safer technology (IST) identified. In addition, the rule requires owners or operators of Program 2 or 3 facilities to coordinate with the local emergency response agencies at least once per year, to conduct notification exercises annually, and to conduct a full field exercise at least once every five years and one tabletop exercise annually in the other years. Finally, the rule requires all facilities to provide basic chemical hazard information to the public; to provide local emergency response agencies with summaries of their activities on compliance audits, emergency response exercises, accident history and investigation reports, and any ISTs implemented at the facility; and to hold a public meeting for the local community within a specified time frame after an RMP reportable accident. The EPA previously delayed (82 FR 13968; 03/16/2017) the effective date of the final rule until June 19, 2017, and now further delays the effective date until Feb. 19, 2019. Petitions for judicial review are due Aug. 14, 2017. Contact: James Belke; EPA, Office of Land and Emergency Management; 202-564-8023; belke.jim@epa.gov

82 FR 27133 (06/14/2017)

**Regulatory Update**

**AIR**

**Texas SIP/Dallas-Fort Worth Ozone Nonattainment Area**

**AIR**

Direct final rule of the EPA amends regulations under 40 CFR 52.2270 to approve revisions to the Texas SIP regarding the 2008 8-hour ozone NAAQS for the Dallas/Fort Worth moderate ozone nonattainment area. The revisions concern requirements for vehicle inspection and maintenance and nonattainment new source review. The rule is effective Sept. 12, 2017, unless adverse comments are received by July 14, 2017. Contact: Carl Young; EPA Region 6; 214-665-6645; young.carl@epa.gov

82 FR 27122 (06/14/2017)

Regulatory Update

**AIR**

Texas SIP/Dallas-Fort Worth Ozone Nonattainment Area

**AIR**

Proposed rule of the EPA amends regulations under 40 CFR 52.2270 to approve revisions to the Texas SIP regarding the 2008 8-hour ozone NAAQS for the Dallas/Fort Worth moderate ozone nonattainment area. The revisions concern requirements for vehicle inspection and maintenance and nonattainment new source review. A concurrent direct final rule adopts the provisions, effective Sept. 12, 2017. Comments are due July 14, 2017. Contact: Carl Young; EPA Region 6; 214-665-6645; young.carl@epa.gov

82 FR 27221 (06/14/2017)

Regulatory Update

**AIR**

West Virginia SIP

**AIR**

Final rule of the EPA amends regulations under 40 CFR 52.2520 to update materials submitted by West Virginia that are incorporated by reference into their SIP. The rule affects SIP materials that are available for public inspection. The rule is effective June 14, 2017. Contact: Sheila Martinez; EPA Region 3; 215-814-2035; martinez.sheila@epa.gov

82 FR 27118 (06/14/2017)

Regulatory Update

**ENDANGERED SPECIES**

California/Long Wharf Maintenance and Efficiency Project

**ENDANGERED SPECIES**

Notice of the National Oceanic and Atmospheric Administration, National Marine Fisheries Service, announces the issuance of an incidental harassment authorization to Chevron, of San Ramon, Calif., for authorization to take marine mammals incidental to pile driving and removal associated with the Richmond Refinery Long Wharf Maintenance and Efficiency Project in San Francisco Bay, Calif. The authorization allows take in the form of Level B harassment of the harbor seal and the California gray sea lion. The authorization is effective Jan. 1, 2018, and

expires Dec. 31, 2018. Contact: Robert Pauline; NMFS, Office of Protected Resources; 301-427-8401

82 FR 27240 (06/14/2017)

Regulatory Update

**FOOD SAFETY**

Color Additive Certification Requests and Recordkeeping

**FOOD SAFETY**

Notice announces the intention of the Food and Drug Administration to seek OMB approval for a continuing information collection request regarding certification requests and recordkeeping for color additives manufactured for use in foods, drugs, cosmetics, or medical devices (21 CFR 80). The collection addresses the submission of data to the FDA including a manufacturer's name, address, color additive sample batch number and weight, storage information, intended use information, and a statement of the fee on a certification request to help the agency determine whether a color additive is safe for use and to assess a certification fee. Comments are due Aug. 14, 2017. Contact: JonnaLynn Capezzuto; FDA, Office of Operations; 301-796-3794

82 FR 27259 (06/14/2017)

Regulatory Update

**FOOD SAFETY**

Recordkeeping Requirements for Food Facilities

**FOOD SAFETY**

Notice announces the intention of the Food and Drug Administration to seek OMB approval for a continuing information collection request concerning recordkeeping and records access requirements for food facilities (21 CFR 1.337, 1.345, and 1.352). The collection addresses requirements for persons who manufacture, process, pack, hold, receive, distribute, transport, or import food to establish and maintain records identifying the immediate previous sources and immediate subsequent recipients of food to enable response to contamination. Comments are due Aug. 14, 2017. Contact: JonnaLynn Capezzuto; FDA, Office of Operations; 301-796-3794

82 FR 27263 (06/14/2017)

Regulatory Update

**GENERAL ENVIRONMENT AND SAFETY**

Abuse-Deterrent Opioid Formulation Impact Workshop

**GENERAL ENVIRONMENT AND SAFETY**

Notice of the Food and Drug Administration announces a workshop to discuss data and methods for evaluating the impact of opioid formulations with properties designed to deter abuse in the postmarket setting. The workshop will address ways to improve the analysis and interpretation of existing data and opportunities and challenges for collecting and/or linking additional data to improve national surveillance and research capabilities on the subject. The notice specifies that, to supplement the workshop, the FDA is making available an issues paper which summarizes key methodological issues and outlines the issues for discussion during the workshop, including

enhancing existing resources, applying new methodology, and creating new resources. The workshop is scheduled for July 10-11, 2017, in Silver Spring, Md. Comments are due Sept. 11, 2017. Contact: Cynthia Kornegay; FDA; 301-796-0187; Cynthia.Kornegay@fda.hhs.gov

82 FR 27271 (06/14/2017)

Regulatory Update

**GENERAL ENVIRONMENT AND SAFETY**

Device Good Manufacturing Practice Advisory Committee

**GENERAL ENVIRONMENT AND SAFETY**

Notice of the Food and Drug Administration seeks nominations for nonvoting industry representatives on the Device Good Manufacturing Practice Advisory Committee. The agency also seeks to identify industry organizations interested in participating in the selection of nonvoting industry representatives. The committee makes recommendations regarding proposed regulations relating to good manufacturing practices governing the methods used in, and the facilities and controls used for, the manufacture, packaging, storage, installation, and servicing of devices. The committee also makes recommendations on proposed guidelines for the medical device industry in meeting the good manufacturing practice requirements and advises the agency regarding manufacturer petitions for exemptions or variances from good manufacturing practice regulations. Statements of interest and nominations are due July 14, 2017. Contact: Margaret Ames; FDA, Center for Devices and Radiological Health; 301-796-5960; margaret.ames@fda.hhs.gov

82 FR 27265 (06/14/2017)

Regulatory Update

**GENERAL ENVIRONMENT AND SAFETY**

Disclosures in Professional and Consumer Prescription Drug Promotion

**GENERAL ENVIRONMENT AND SAFETY**

Notice announces the intention of the Food and Drug Administration to seek OMB approval for a new information collection request concerning disclosures in prescription drug promotion. The collection addresses a study of the effectiveness of clear and conspicuous disclosures in both health care professional and consumer prescription drug promotion, including disclosures regarding scope of treatment, ease of use, and statistical significance. The study will include eye-tracking studies and questionnaires conducted with health care professionals and consumers recruited from internet panels. Comments are due Aug. 14, 2017. Contact: Jonnalynn Capezzuto; FDA, Office of Operations; 301-796-3794; PRASstaff@fda.hhs.gov

82 FR 27268 (06/14/2017)

Regulatory Update

**GENERAL ENVIRONMENT AND SAFETY**

Drug Regulatory Review Period/Hetlioz

**GENERAL ENVIRONMENT AND SAFETY**

Notice of the Food and Drug Administration announces a determination of the regulatory review

period for the human drug product Hetlioz (tasimelteon) in response to an application submitted by Vanda Pharmaceuticals Inc., of Washington, D.C. The notice specifies that the product is indicated for the treatment of non-24-hour sleep-wake disorder. Comments are due Aug. 14, 2017. Petitions for a determination of whether the applicant for extension acted with due diligence during the regulatory review period are due Dec. 11, 2017. Contact: Beverly Friedman; FDA, Office of Regulatory Policy; 301-796-3600

82 FR 27261 (06/14/2017)

Regulatory Update

**GENERAL ENVIRONMENT AND SAFETY**

Drug Regulatory Review Period/NeuroPace RNS System

**GENERAL ENVIRONMENT AND SAFETY**

Notice of the Food and Drug Administration announces a determination of the regulatory review period for the NeuroPace RNS® System medical device in response to an application submitted by NeuroPace Inc., of Mountain View, Calif. The notice specifies that the device is indicated as an adjunctive therapy in reducing the frequency of seizures in individuals 18 years of age or older with partial onset seizures who have undergone diagnostic testing that localized no more than two epileptogenic foci, are refractory to two or more antiepileptic medications, and currently have frequent and disabling seizures. Comments are due Aug. 14, 2017. Petitions for a determination of whether the applicant for extension acted with due diligence during the regulatory review period are due Dec. 11, 2017. Contact: Beverly Friedman; FDA, Office of Regulatory Policy; 301-796-3600

82 FR 27266 (06/14/2017)

Regulatory Update

**GENERAL ENVIRONMENT AND SAFETY**

Vermont Yankee Nuclear Power Station

**GENERAL ENVIRONMENT AND SAFETY**

Notice of the Nuclear Regulatory Commission announces the issuance of an exemption in response to a request from the Entergy Nuclear Operations Inc., of Buchanan, N.Y., for the Vermont Yankee Nuclear Power Station, in Vernon, Vt. The exemption allows Entergy to load certain lower enriched fuel assemblies with higher enriched fuel assemblies in the same HI-STORM 100 multipurpose canister using Certificate of Compliance No. 1014, Amendment No. 10. Contact: Yen-Ju Chen; NRC, Office of Nuclear Material Safety and Safeguards; 301-415-1018; Yen-Ju.Chen@nrc.gov

82 FR 27297 (06/14/2017)

Regulatory Update

**GENERAL ENVIRONMENT AND SAFETY**

Virginia/North Anna Power Station Unit 3

**GENERAL ENVIRONMENT AND SAFETY**

Notice of the Nuclear Regulatory Commission announces the issuance of combined license no.

NPF-103 to Virginia Electric and Power Co., doing business as Dominion Virginia Power, for North Anna Unit 3 at the North Anna Power Station in Louisa County, Va. The notice also announces the availability of a summary record of decision, a final environmental impact statement, a final safety evaluation report, and the commission's memorandum and order. The combined licenses are effective June 2, 2017. Contact: James Shea; NRC, Office of New Reactors; 301-415-1388; James.Shea@nrc.gov

82 FR 27296 (06/14/2017)

Regulatory Update

**GENERAL ENVIRONMENT AND SAFETY**

Washington State/Colville Indian Reservation

**GENERAL ENVIRONMENT AND SAFETY**

Notice of the Bureau of Indian Affairs, in cooperation with the Confederated Tribes of the Colville Reservation and the EPA, announces the availability of a draft programmatic environmental impact statement (DEIS) for the 2015 Colville Reservation integrated resource management plan. The plan specifies management goals and objectives for the commercial forest, rangeland, and agricultural lands of the reservation located in north central Washington state. The document addresses five management alternatives, including the preferred alternative of enhancing and improving the current reservation management strategy. Comments are due 45 days after the EPA publishes a notice of availability of the DEIS in the Federal Register. Contact: Debra Wulff; BIA, Colville Agency; 509-634-2316; debra.wulff@bia.gov

82 FR 27278 (06/14/2017)

Regulatory Update

**PESTICIDES**

Bed Bug Pesticide Products Test Guidance

**PESTICIDES**

Notice of the EPA announces the availability of final test guidelines under OCSP Series 810.3900 regarding laboratory product performance testing methods for bed bug products. The guidance applies to liquids, aerosols, fogs and impregnated fabrics that are intended to attract, repel, or kill the common bed bug. The guidance does not apply to repellent products applied to human skin or products that are exempted from FIFRA registration. The document is part of a series of test guidelines issued by the Office of Chemical Safety and Pollution Prevention (OCSP) for use in testing chemical substances under TSCA, FIFRA, and the Federal Food, Drug, and Cosmetic Act. Contact: Michael Goodis; EPA, Office of Pesticide Programs; 703-305-7090; RDFRNotices@epa.gov

82 FR 27254 (06/14/2017)

Regulatory Update

**PESTICIDES**

EPA Human Studies Review Board Meetings

**PESTICIDES**

Notice of the EPA, Office of the Science Advisor, announces two meetings of the Human Studies Review Board, which advises the agency on the ethical and scientific reviews of research with human subjects. The first meeting will address the field evaluation of three topically applied insect repellent products containing IR3535 against mosquitoes in Florida. The second meeting will include the review and finalization of the board's draft final report from the first meeting. The first meeting is scheduled for July 26, 2107, via webinar. The second meeting is scheduled for Sept. 15, 2017, via teleconference. Comments are due July 19, 2017, and Sept. 8, 2017, respectively. Contact: Jim Downing; EPA, Office of the Science Advisor; 202-564-2468; [downing.jim@epa.gov](mailto:downing.jim@epa.gov)

82 FR 27255 (06/14/2017)

Regulatory Update

**PESTICIDES**

Pesticide Tolerances/Isofetamid

**PESTICIDES**

Final rule of the EPA amends regulations under 40 CFR 180.681 to establish tolerances for residues of the fungicide isofetamid in or on multiple commodities. The rule also removes the existing time-limited tolerances for residues in or on caneberry subgroup 13-07A and bushberry subgroup 13-07B. The rule is issued in response to a petition by ISK Biosciences Corp., of Concord, Ohio. The rule is effective June 14, 2017. Objections and hearing requests are due Aug. 14, 2017. Contact: Michael Goodis; EPA, Office of Pesticide Programs; 703-305-7090; [RDFRNotices@epa.gov](mailto:RDFRNotices@epa.gov)

82 FR 27149 (06/14/2017)

Regulatory Update

**PESTICIDES**

Pesticide Tolerances/Spirotetramat

**PESTICIDES**

Final rule of the EPA amends regulations under 40 CFR 180.641 to establish tolerances for residues of the insecticide spirotetramat and its metabolites in or on sugar beet molasses at 0.30 parts per million (ppm), sugar beet roots at 0.15 ppm, carrot roots at 0.15 ppm, the stone fruit group 12-12 at 4.5 ppm, and the nut tree group 14-12 at 0.25 ppm. The rule also removes existing tolerances for the stone fruit group 12 and the nut tree group 14, which are superseded by the new tolerances. The rule is in response to petitions filed by Bayer CropScience LP, of Research Triangle Park, N.C., and IR-4 Project Headquarters, of Princeton, N.J. The rule is effective June 14, 2017. Objections and hearing requests are due Aug. 14, 2017. Contact: Michael Goodis; EPA, Office of Pesticide Programs; 703-305-7090; [RDFRNotices@epa.gov](mailto:RDFRNotices@epa.gov)

82 FR 27144 (06/14/2017)

Regulatory Update

**RADIATION**

ACRS Advanced Power Reactor 1400 Subcommittee Meeting

**RADIATION**

Notice of the Nuclear Regulatory Commission announces a meeting of the Advisory Committee on Reactor Safeguards Subcommittee on Advanced Power Reactor 1400 (APR1400). The agenda includes presentations by NRC staff and Korea Hydro & Nuclear Power Co., of Gyeongju, South Korea, concerning Chapters 7 and 18 of the APR1400 Design Control Document on instrumentation and controls, and human factors engineering. The meeting is scheduled for June 20-21, 2017, in Rockville, Md. Comments are due June 20, 2017. Contact: Christopher Brown; NRC, Advisory Committee on Reactor Safeguards; 301-415-7111; Christopher.Brown@nrc.gov

82 FR 27295 (06/14/2017)

Regulatory Update

**RADIATION**

Nondiscrimination in NRC Programs

**RADIATION**

Notice announces the intention of the Nuclear Regulatory Commission to seek OMB approval for a continuing information collection request concerning nondiscrimination in federally assisted commission programs (10 CFR 4.331). The collection addresses compliance and pre-award reviews and other similar procedures that permit investigation and correction of violations by recipients of federal financial assistance (Forms 781 and 782). Comments are due Aug. 14, 2017. Contact: David Cullison; NRC; 301-415-2084; INFOCOLLECTS.Resource@nrc.gov

82 FR 27291 (06/14/2017)

Regulatory Update

**WATER**

Effluent Limitations and Standards for Dental Facilities

**WATER**

Final rule of the EPA adopts regulations under 40 CFR 441.10, 441.20, 441.30, 441.40, and 441.50 concerning the dental office point source category. The rule establishes pretreatment standards for discharges of mercury from dental offices into municipal sewage treatment plants and requires dental offices to use amalgam separators. The rule also incorporates best management practices recommended by the American Dental Association and addresses oversight and reporting requirements for general pretreatment. The rule is effective July 14, 2017. Contact: Karen Milam; EPA, Office of Water; 202-566-1915; milam.karen@epa.gov

82 FR 27154 (06/14/2017)

Regulatory Update

**WATER**

Louisiana/Lower Mississippi River Anchorages

**WATER**

Interim rule of the U.S. Coast Guard amends regulations under 33 CFR 110.195 to modify and establish anchorages for the Lower Mississippi River below Baton Rouge, La. The rule establishes the Point Michel and Plaquemines Point anchorages and increases the size of the

existing Cedar Grove and White Castle anchorages to address increased waterway congestion. The rule is effective June 14, 2017. Comments are due Oct. 12, 2017. Contact: Howard Vacco; USCG Sector New Orleans, Waterways Management Division; 504-365-2281; howard.k.vacco@uscg.mil

82 FR 27112 (06/14/2017)

Regulatory Update

**WATER**

Minnesota/Cross-Media Electronic Reporting

**WATER**

Notice of the EPA announces the approval of a request from Minnesota concerning cross-media electronic reporting requirements. The approval authorizes the state to revise its EPA-authorized programs to allow electronic reporting under its national primary drinking water regulations implementation program (40 CFR 142). The approval is effective July 14, 2017, if no hearing requests are received by that date. Contact: Karen Seeh; EPA, Office of Environmental Information; 202-566-1175; seeh.karen@epa.gov

82 FR 27253 (06/14/2017)

Regulatory Update

[Privacy Policy](#) | [Terms of Service](#) | [Manage Your Email](#) | [Contact Us](#)

1801 South Bell Street, Arlington, VA 22202  
Copyright © 2017 [The Bureau of National Affairs, Inc.](#) .  
EHS Federal Regulatory Alert