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**From:** Bloomberg BNA  
**Sent:** Tue 9/12/2017 12:13:52 PM  
**Subject:** Sep. 12 -- EHS Federal Regulatory Alert



## **EHS Federal Regulatory Alert**

September 12, 2017 - Number 175

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### Summaries

*AIR*

California SIP/Placer and Ventura County Air Pollution Control Districts

**AIR**

Proposed rule of the EPA would approve revisions to the Placer and Ventura County air pollution control districts (APCD) portions of the California SIP. The rule would approve a Placer County APCD rule concerning emissions of nitrogen oxides from incinerators. The rule also would approve a Ventura County APCD rule addressing previously unregulated types of fuel burning equipment, including kilns, dryers, and ovens. Comments are due Oct. 12, 2017. Contact: Kevin Gong; EPA Region 9; 415-972-3073; Gong.Kevin@epa.gov. Citations: 40 CFR 52

82 FR 42765 (09/12/2017)

Regulatory Update

*AIR*

Delaware SIP/2008 Eight-Hour Ozone NAAQS

**AIR**

Proposed rule of the EPA would approve a revision to the Delaware SIP regarding reasonably available control technology (RACT) requirements under the 2008 eight-hour ozone NAAQS. The revision includes a certification that for certain categories of sources, previously adopted nitrogen oxide (NOx) and volatile organic compound (VOC) RACT controls approved under the 1979 one-hour and 1997 eight-hour ozone NAAQS are based on the currently available technically and economically feasible controls and continue to represent RACT for implementation of the 2008 eight-hour ozone NAAQS. The revision also addresses the adoption of new or more stringent standards or controls that represent RACT control levels for certain categories of sources. In addition, the revision includes a negative declaration that control technique guidelines (CTG) or non-CTG major sources of VOC and NOx sources do not exist in the state. A revision relating to startup, shutdown, and maintenance will be addressed in a separate action. Comments are due Oct. 12, 2017. Contact: Leslie Doherty; EPA Region 3; 215- 814-3409; jones.leslie@epa.gov. Citations: 40 CFR 52

82 FR 42767 (09/12/2017)

Regulatory Update

**AIR**

Idaho SIP/PM-2.5 NAAQS Infrastructure Requirements

**AIR**

Proposed rule of the EPA would approve revisions to the Idaho SIP regarding the infrastructure requirements for the 2012 annual fine particulate matter (PM-2.5) NAAQS. The rule would not approve or disapprove state provisions regarding excess emissions during startup, shutdown, or malfunction of operations at a facility or any provisions involving state director discretion or variance. Comments are due Oct. 12, 2017. Contact: Matthew Jentgen; EPA Region 10, Air Planning Unit; 206-553-0340; jentgen.matthew@epa.gov. Citations: 40 CFR 52

82 FR 42772 (09/12/2017)

Regulatory Update

**AIR**

Kentucky SIP/Ambient Air Quality Standards

**AIR**

Final rule of the EPA approves revisions to the Kentucky SIP that update the state's ambient air quality standards to reflect the historical and current NAAQS for carbon monoxide, lead, nitrogen dioxide, ozone, particulate matter (PM-10 and PM-2.5), and sulfur dioxide. The revisions also update and reformat an ambient air quality standards table. The rule does not approve revisions regarding state air quality standards for hydrogen sulfide, fluorides, and odor. The rule is effective Oct. 12, 2017. Contact: Madolyn Sanchez; EPA Region 4, Air Planning and Implementation Branch; 404-562-9644; sanchez.madolyn@epa.gov. Citations: 40 CFR 52.920

82 FR 42746 (09/12/2017)

Regulatory Update

**AIR**

Montana FIP/Regional Haze

**AIR**

Final rule of the EPA revises the Montana regional haze federal implementation plan (FIP). The revisions increase the best available retrofit technology (BART) nitrogen oxides emission limit for the Trident cement kiln in Three Forks to 7.6 pounds per ton clinker as a 30-day rolling average. The revisions also correct the reasonable progress determination for the Blaine County #1 Compressor Station and the instructions for compliance determinations for particulate matter BART emission limits at electrical generating units and cement kilns. Portions of the FIP addressing the Colstrip and Corette power plants that have been vacated and remanded by the appeals court will be addressed in a separate action. The rule is effective Oct. 12, 2017. Contact: Jaslyn Dobrahner; EPA Region 8, Air Program; 303-312-6252; dobrahner.jaslyn@epa.gov. Citations: 40 CFR 52.1396

82 FR 42738 (09/12/2017)

Regulatory Update

**AIR**

West Virginia/Clean Air Act Consent Decree

**AIR**

Notice of the Department of Justice announces a proposed modification to a consent decree in *United States v. Bayer CropScience LP* (Civil Action No. 2:15-cv-13331), lodged on Aug. 31, 2017, with the U.S. District Court for the Southern District of West Virginia. The original consent decree (80 FR 57873; 09/25/2015) addressed alleged violations of the Clean Air Act related to a 2008 explosion at a methomyl production unit in Institute, W.Va., and required the defendant to pay a civil penalty of \$975,000; to perform injunctive relief to reduce the likelihood of future accidents at the Institute plant and several other chemical processing plants; and to perform supplemental environmental projects valued collectively at \$4.23 million. The proposed modification would replace one of the supplemental environmental projects that involved expanding a wastewater sump with another project to purchase emergency response equipment, reducing the total cost of the supplemental environmental projects to \$3.05 million. Comments are due Oct. 12, 2017. Contact: DOJ, Environment and Natural Resources Division; 202-514-2701

82 FR 42838 (09/12/2017)

Regulatory Update

**GENERAL ENVIRONMENT AND SAFETY**

Age, Race and Ethnicity Data in Medical Device Clinical Studies

**GENERAL ENVIRONMENT AND SAFETY**

Notice of the FDA announces the availability of a final guidance for industry concerning the evaluation and reporting of age, race, and ethnicity data in medical device clinical studies. The guidance is intended to encourage the collection and consideration of age, race, ethnicity, and associated covariates during the study design stage; to provide recommended analyses of study subgroup data with a framework for considering demographic data when interpreting overall study outcomes; and to specify the FDA's recommendations for reporting age, race, and ethnicity-specific information in summaries and labeling for approved or cleared medical devices. The guidance also extends the policy established in the agency's guidance for evaluation of sex-specific data in medical device clinical studies to additional demographic subgroups. Comments may be submitted at any time. Contact: Katheryn O'Callaghan; FDA, Center for Devices and Radiological Health; 301-796-6349

82 FR 42819 (09/12/2017)

Regulatory Update

**GENERAL ENVIRONMENT AND SAFETY**

International Drug Scheduling

**GENERAL ENVIRONMENT AND SAFETY**

Notice of the FDA announces an extension of the comment period regarding an Aug. 14, 2017, notice (82 FR 37866) relating to the abuse potential, actual abuse, medical usefulness, trafficking,

and impact of scheduling changes on availability for medical use of 17 drug substances, including various synthetic opioids and cannabinoids. Comments received will be considered in preparing a response from the U.S. to the World Health Organization (WHO) regarding the abuse liability and diversion of the drugs. WHO will use the information to consider whether to recommend that certain international restrictions be placed on the drugs during the meeting of its 39th Expert Committee on Drug Dependence, scheduled for Nov. 6-10, 2017, in Geneva. Comments now are due Sept. 20, 2017. Contact: James Hunter; FDA, Center for Drug Evaluation and Research; 301-796-3156; james.hunter@fda.hhs.gov

82 FR 42818 (09/12/2017)

Regulatory Update

**GENERAL ENVIRONMENT AND SAFETY**

Oral Rabies Vaccine Trial

**GENERAL ENVIRONMENT AND SAFETY**

Notice of the Animal and Plant Health Inspection Service announces the availability of a supplemental environmental assessment and finding of no significant impact for an oral rabies vaccination (ORV) field trial in New Hampshire, New York, Ohio, Vermont, and West Virginia. The supplemental assessment analyzed potential effects of the ORV for wildlife in the specified states and the geographic shift of the ORV zone in Ohio and the addition of 17 counties in West Virginia so that baits could be applied to the western edge of the ORV zone in West Virginia. The finding of no significant impact is based on the EA and the 2013, 2015, and 2017 supplements to the EA and reflects the agency's determination that the distribution of the experimental wildlife rabies vaccine will not have a significant impact on the quality of the human environment. Contact: Richard Chipman; APHIS; 603-223-9623; richard.b.chipman@aphis.usda.gov

82 FR 42781 (09/12/2017)

Regulatory Update

**GENERAL ENVIRONMENT AND SAFETY**

Oregon Air National Guard Military Airspace Expansion

**GENERAL ENVIRONMENT AND SAFETY**

Notice of the Department of the Air Force announces the availability of the record of decision (ROD) that approves modifications to existing airspace and the establishment of new airspace in Nevada, Oregon, and Washington to support the Oregon Air National Guard's F-15 training operations and to implement practicable mitigation. The ROD is based on the May 19, 2017, final environmental impact statement (82 FR 22997). Contact: Kevin Marek; National Guard Bureau; 240-612-8855

82 FR 42803 (09/12/2017)

Regulatory Update

**GENERAL ENVIRONMENT AND SAFETY**

Petition for Enforcement Action/Defective Safety Components and Falsified Quality Assurance

**GENERAL ENVIRONMENT AND SAFETY**

Notice of the NRC announces the receipt of a petition from Paul Gunter, on behalf of Beyond Nuclear and representing numerous public interest groups, requesting that the NRC take action on licensees of plants that currently rely on potentially defective safety-related components and potentially falsified quality assurance documentation supplied by AREVA-Le Creusot Forge and its subcontractor, Japan Casting and Forging Corp. The petitioner provided expert review that identified significant irregularities and anomalies in the manufacturing process and quality assurance documentation of large reactor components manufactured by the AREVA-Le Creusot Forge for French reactors and reactors in other countries. Supplements to the petition are also being considered in evaluating the petitioners' request for enforcement action. The request for enforcement action meets the criteria for review under the 10 CFR 2.206 process, but the request concerning potentially falsified quality assurance documentation will be referred to another NRC process for appropriate action. Contact: Merrilee Banic; NRC, Office of Nuclear Reactor Regulation; 301-415-2771; Merrilee.Banic@nrc.gov. Citations: 10 CFR 2.206

82 FR 42857 (09/12/2017)

Regulatory Update

**GENERAL ENVIRONMENT AND SAFETY**

Premarket Approval Application Critical to Quality Pilot Program

**GENERAL ENVIRONMENT AND SAFETY**

Notice of the FDA announces the Premarket Approval Application (PMA) Critical to Quality pilot program, a voluntary program for early evaluation of device design and manufacturing process quality information. The program allows qualifying PMA applicants to engage the FDA on development of critical to quality controls for their devices and forego the standard PMA preapproval inspection. The FDA would instead focus on applicants' implementation of controls during a post-market inspection, including design, manufacturing, and quality assurance practices identified by applicants. Program participation criteria and procedures are provided. The program will run from Sept. 29, 2017, through Dec. 31, 2018. Contact: Bleta Vuniqui; FDA, Center for Devices and Radiological Health; 301-796-5497; Bleta.Vuniqui@fda.hhs.gov

82 FR 42815 (09/12/2017)

Regulatory Update

**GENERAL ENVIRONMENT AND SAFETY**

Tennessee Valley Authority/Reservoir Land Management Plans

**GENERAL ENVIRONMENT AND SAFETY**

Notice of the Tennessee Valley Authority announces the adoption of reservoir land management plans for eight TVA reservoirs, including Chickamauga, Fort Loudoun, Great Falls, Nickajack, and Normandy in Tennessee; Wheeler and Wilson in Alabama; and Kentucky in Kentucky and Tennessee. The TVA also is incorporating the information from the plans into its comprehensive valleywide land plan. The TVA is implementing the preferred alternative identified in the final environmental impact statement (82 FR 33911; 07/21/2017) that provides for allocation of land in the eight reservoirs into broad land use categories or zones, including project operations (Zone 2), sensitive resource management (Zone 3), natural resource conservation (Zone 4), industrial (Zone 5), developed recreation (Zone 6), and shoreline access (Zone 7). Contact: Kelly Baxter; TVA; 865-632-2444; krbaxter@tva.gov

82 FR 42872 (09/12/2017)

Regulatory Update

**OCCUPATIONAL SAFETY AND HEALTH**

Examinations of Working Places in Metal and Nonmetal Mines

**OCCUPATIONAL SAFETY AND HEALTH**

Proposed rule of the Mine Safety and Health Administration would further delay until March 2, 2018, the effective date of a Jan. 23, 2017, final rule (82 FR 7680) that updated standards for the examination of working places in metal and nonmetal mines. The rule requires operators to promptly notify miners of any conditions found that may adversely affect their safety or health, and requires operators to promptly take corrective action. The rule also requires the examination record to include the name of the examiner, examination date, location of areas examined, a description of adverse conditions found, and the date of corrective action. In addition, the rule requires operators to make the examination record available to authorized representatives of the secretary of Labor and miners' representatives and to provide a copy upon request. MSHA previously delayed the effective date to assure that mine operators and miners affected by the rule have the required training and compliance assistance (82 FR 15173; 03/27/2017) and to allow additional time for the agency to provide stakeholders training and compliance assistance (82 FR 23139; 05/22/2017). The current action would allow additional time for MSHA to provide stakeholders training and compliance assistance and provide more time to train inspectors. A concurrent proposed rule would make limited changes to the final rule concerning working place examinations and reopens the comment period and announces a series of hearings concerning the limited changes. Comments on the delay of effective date are due Sept. 26, 2017. Contact: Sheila McConnell; MSHA, Office of Standards, Regulations, and Variances; 202-693-9440; mcconnell.sheila.a@dol.gov. 30 CFR 56.18002, 57.18002

82 FR 42765 (09/12/2017)

Regulatory Update

**OCCUPATIONAL SAFETY AND HEALTH**

Examinations of Working Places in Metal and Nonmetal Mines

**OCCUPATIONAL SAFETY AND HEALTH**

Proposed rule of the Mine Safety and Health Administration would modify a Jan. 23, 2017, final rule (82 FR 7680) that updated standards for the examination of working places in metal and nonmetal mines. The rule requires operators to promptly notify miners of any conditions found that may adversely affect their safety or health, and requires operators to promptly take corrective action. The rule also requires the examination record to include the name of the examiner, examination date, location of areas examined, a description of adverse conditions found, and the date of corrective action. In addition, the rule requires operators to make the examination record available to authorized representatives of the secretary of Labor and miners' representatives and to provide a copy upon request. The changes would clarify that working place examinations must be conducted before work begins or as miners begin work and specifies the adverse conditions and related corrective actions that must be included in the working place examination record. MSHA previously delayed the effective date to assure that mine operators and miners affected by the rule have the required training and compliance assistance (82 FR 15173; 03/27/2017) and to allow additional time for the agency to provide stakeholders training and compliance assistance (82 FR 23139; 05/22/2017). A concurrent proposed rule would delay until March 2, 2018, the effective date of the rule to allow MSHA more

time to provide stakeholders training and compliance assistance and provide more time to train inspectors. Hearings are scheduled for Oct. 24, 26, 31, and Nov. 2, 2017, in Arlington, Va.; Salt Lake City; Birmingham, Ala.; and Pittsburgh, respectively. Comments are due Nov. 13, 2017. Contact: Sheila McConnell; MSHA, Office of Standards, Regulations, and Variances; 202-693-9440; mcconnell.sheila.a@dol.gov. 30 CFR 56.18002, 57.18002

82 FR 42757 (09/12/2017)

Regulatory Update

**OCCUPATIONAL SAFETY AND HEALTH**

Mine Safety/Hoist Operator Physical Fitness

**OCCUPATIONAL SAFETY AND HEALTH**

Notice of the Mine Safety and Health Administration announces the submission of a continuing information collection request to the OMB regarding physical fitness requirements of hoist operators. The collection addresses requirements for the examination and certification of hoist operators' fitness by a qualified licensed physician within 12 months preceding hoisting duties. Comments are due Oct. 12, 2017. Contact: Michel Smyth; Labor Department; 202-693-4129; DOL\_PRA\_PUBLIC@dol.gov. Citations: 30 CFR 56.19057, 57.19057

82 FR 42838 (09/12/2017)

Regulatory Update

**OIL AND GAS INDUSTRY**

Onshore Oil and Gas Leases on Federal and Indian Lands

**OIL AND GAS INDUSTRY**

Notice announces the intention of the Bureau of Land Management to seek OMB approval for a revised information collection request regarding the authorization and management of onshore oil and gas leases on federal and Indian lands, except for the Osage Tribe (Forms 3160-3, 3160-4, 3160-5, and 3160-6). The revisions address the addition of standards concerning operations, site security, and measurement of oil. The revisions also address the removal of the gas flaring collection activity and the continuation of the collection activity regarding hydraulic fracturing, which will be addressed in a future rulemaking. Comments are due Nov. 13, 2017. Contact: Subijoy Dutta; BLM; 202-912-7152; sdutta@blm.gov. Citations: 43 CFR 3160, 3164.1, 3170

82 FR 42832 (09/12/2017)

Regulatory Update

**TOXIC SUBSTANCES**

Schedule I Controlled Substances/Synthetic Opioids

**TOXIC SUBSTANCES**

Notice announces the intention of the Drug Enforcement Administration to issue a temporary order to place the synthetic opioids ortho-fluorofentanyl, tetrahydrofentanyl, and methoxyacetyl fentanyl in to Schedule I under the Controlled Substances Act. The action is necessary due to the high potential for abuse of such substances. A temporary scheduling order will be published in the Federal Register and will not be issued prior to Oct. 12, 2017. Contact:

Michael Lewis; DEA, Office of Diversion Control; 202-598-6812. Citations: 21 CFR 1308.11

82 FR 42754 (09/12/2017)

Regulatory Update

**WATER**

Georgia/CWA, RCRA Consent Decree

**WATER**

Notice of the Department of Justice announces a proposed consent decree in *United States v. Woco Pep Oil Inc.* (Civil Action No. 1:17-cv-3249), lodged on Aug. 28, 2017, with the U.S. District Court for the Northern District of Georgia. The consent decree addresses claims under the CWA and RCRA and requires the defendant to pay a civil penalty of \$24,000, to be divided evenly between the state of Georgia and the U.S. The consent decree also requires the defendant to perform a supplemental environmental project and to install advanced technology to improve leak detection at its facilities. Comments are due Oct. 12, 2017. Contact: Henry Friedman; DOJ; 202-514-2701

82 FR 42837 (09/12/2017)

Regulatory Update

**WATER**

New York Clean Water Act Section 303(d) List

**WATER**

Notice of the EPA announces the reopening of the comment period for an Aug. 9, 2017, notice (82 FR 37214) regarding the agency's proposal to include certain water quality limited segments and associated pollutants in New York's 2016 list of waters under Section 303(d) of the Clean Water Act. On July 21, 2017, the agency approved the state's list with respect to the 792 waterbody/pollutant combinations requiring total maximum daily loads but disapproved the state's decision not to include 71 other combinations. The agency is extending the comment period in response to stakeholder requests. Comments now are due Oct. 12, 2017. Contact: Aimee Boucher; EPA Region 2; 212-637-3837; boucher.aimee@epa.gov

82 FR 42808 (09/12/2017)

Regulatory Update

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