

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

July 27, 2017 - Number 143

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Summaries

AIR
Harley-Davidson Inc. Clean Air Act Consent Decree
AIR

Notice of the Justice Department announces a proposed consent decree in *United States v. Harley-Davidson Inc.* (Civil Action No. 1:16-cv-01687), lodged July 20, 2017, with the U.S. District Court for the District of Columbia. The consent decree addresses a complaint alleging that the defendants violated the Clean Air Act prohibitions on the manufacture or sale of devices that defeat the functioning of motorcycle certified emissions control systems and on tampering with such systems in connection with the manufacture and sale of over 339,392 aftermarket devices, known as “super tuners.” The consent decree also addresses the alleged manufacture and sale of over 12,000 motorcycles from model years 2006, 2007, and 2008 that were not certified by the EPA. The consent decree requires the defendants to pay a \$12 million civil penalty; to stop selling illegal tuners by Aug. 23, 2016; and to offer to buy back and destroy all such tuners in stock at Harley-Davidson dealerships. The consent decree also requires the defendants to obtain executive orders from the California Air Resources Board for any future tuner sales and conduct related emission testing, to label uncertified super tuners sold outside the U.S., and to ensure that all future motorcycle models intended for sale in the U.S. are certified by the EPA. The consent decree is identical to an Aug. 24, 2016, consent decree (81 FR 57936) except that the requirement for defendants to pay for a specified mitigation project has been removed due to questions over the legality of the project. Comments are due Aug. 28, 2017. Contact: DOJ, Environment and Natural Resources Division; 202-514-2701

82 FR 34977 (07/27/2017)

Regulatory Update

AIR
NESHAP for Wool Fiberglass Manufacturing
AIR

Direct final rule of the EPA revises the NESHAP for flame attenuation lines in the wool fiberglass

manufacturing industry. The revision provides affected sources an additional year to comply with the emission limits for flame attenuation lines, now requiring compliance by July 31, 2018. The extension provides owners and operators of flame attenuation lines subject to the emission limits for formaldehyde, phenol, and methanol a total of three years to demonstrate compliance with the limits established in a July 29, 2015, final rule (80 FR 45280). The extension is due to new and corrected data submitted by Johns-Manville Corp., of Denver, regarding the final stack test emissions methodology and test data on low-pull flame attenuation lines. The rule is effective Oct. 25, 2017, unless significant adverse comments are received by Aug. 28, 2017, or a hearing is requested by Aug. 3, 2017. Contact: Brian Storey; EPA, Office of Air Quality Planning and Standards; 919-541-1103; storey.brian@epa.gov. Citations: 40 CFR 63, Subpart NNN, Table 2

82 FR 34858 (07/27/2017)

Regulatory Update

AIR

NESHAP for Wool Fiberglass Manufacturing

AIR

Proposed rule of the EPA would revise the NESHAP for flame attenuation lines in the wool fiberglass manufacturing industry. The revision would provide affected sources an additional year to comply with the emission limits for flame attenuation lines, requiring compliance by July 31, 2018. The extension would provide owners and operators of flame attenuation lines subject to the emission limits for formaldehyde, phenol, and methanol a total of three years to demonstrate compliance with the limits established in a July 29, 2015, final rule (80 FR 45280). The extension is due to new and corrected data submitted by Johns-Manville Corp., of Denver, regarding the final stack test emissions methodology and test data on low-pull flame attenuation lines. A concurrent direct final rule adopts the provisions, effective Oct. 25, 2017. Hearing requests are due Aug. 3, 2017. Comments are due Aug. 28, 2017. Contact: Brian Storey; EPA, Office of Air Quality Planning and Standards; 919-541-1103; storey.brian@epa.gov. Citations: 40 CFR 63, Subpart NNN, Table 2

82 FR 34910 (07/27/2017)

Regulatory Update

ENDANGERED SPECIES

California/Chinook Salmon, Steelhead Enhancement Permit

ENDANGERED SPECIES

Notice of the National Marine Fisheries Service announces the receipt of an application from the U.S. Fish and Wildlife Service to renew for five years a permit to enhance the propagation and survival of anadromous fish. The FWS requests authorization to take threatened California Central Valley steelhead and threatened Central Valley spring-run Chinook salmon during hatchery and monitoring activities associated with the San Joaquin River Restoration Program (SJRRP) and the SJRRP's Salmon Conservation and Research Program. The application includes a new request to collect Central Valley spring-run Chinook salmon from Butte Creek to use as broodstock, which was not authorized by previous permits. Comments are due Aug. 28, 2017. Contact: Jeff Abrams; NOAA; 916-930-3714; Jeff.Abrams@noaa.gov

82 FR 34931 (07/27/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Classification of Assayed Quality Control Material for Microbiology Assays

GENERAL ENVIRONMENT AND SAFETY

Final rule of the FDA codifies a final order to classify assayed quality control material for clinical microbiology assays into class II (special controls). The device is indicated for use in a test system to estimate test precision or detect systematic analytical deviations that may arise from reagent or analytical instrument variation, and consists of single or multiple microbiological analytes intended for use with either qualitative or quantitative assays. The classification was applicable March 28, 2016. The order is effective July 27, 2017. Contact: Ryan Lubert; FDA, Center for Devices and Radiological Health; 240-402-6357; ryan.lubert@fda.hhs.gov. Citations: 21 CFR 866.3920

82 FR 34848 (07/27/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Classification of Balloon Aortic Valvuloplasty Catheters

GENERAL ENVIRONMENT AND SAFETY

Final rule of the FDA codifies a final order to classify the balloon aortic valvuloplasty catheter into class II (special controls). The device is a catheter with a balloon at the distal end of the shaft that is intended to treat stenosis in the aortic valve when the balloon is expanded. The classification was applicable June 11, 2012. The order is effective July 27, 2017. Contact: Nicole Ibrahim; FDA, Center for Devices and Radiological Health; 301-796-5171; nicole.ibrahim@fda.hhs.gov. Citations: 21 CFR 870.1255

82 FR 34850 (07/27/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Environmental Financial Advisory Board Meeting

GENERAL ENVIRONMENT AND SAFETY

Notice of the EPA announces a meeting of the Environmental Financial Advisory Board to discuss proposed legislation; EPA priorities; and activities, progress, and preliminary recommendations concerning board work projects. The meeting also will include consideration of requests for assistance from EPA program offices and discussion of environmental finance issues related to decentralized wastewater systems, lead risk reduction, public private partnerships, and domestic recycling programs. The meeting is scheduled for Aug. 22-23, 2017, in Overland Park, Kan. Contact: Sandra Williams; EPA; 202-564-4999; williams.sandra@epa.gov

82 FR 34942 (07/27/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY
FDA Oncology Center of Excellence
GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces the reorganization of the Office of Medical Products and Tobacco to reflect creation of the Oncology Center of Excellence. The center leads the clinical portion of medical oncology and malignant hematology applications involving drugs, biologics, and devices. The center also works with existing centers and FDA oncology staff to harmonize cancer-specific regulatory approaches and coordinate oncology-specific regulatory science initiatives and outreach. The reorganization was effective Dec. 22, 2016. Contact: Rachel Sherman; FDA, Office of Medical Products and Tobacco; 240-402-4474

82 FR 34956 (07/27/2017)

Regulatory Update

HAZARDOUS MATERIALS TRANSPORTATION
Crash Preventability Demonstration Program
HAZARDOUS MATERIALS TRANSPORTATION

Notice of the Federal Motor Carrier Safety Administration announces that the Crash Preventability Demonstration Program will begin accepting requests for data review (RDRs) to evaluate the preventability of certain categories of crashes through the agency's national data correction system, DataQs. Crashes that will be reviewed under the RDR process include when commercial motor vehicles (CMVs) are struck by a motorist under the influence, struck by a motorist driving the wrong way, or struck while the CMV was legally stopped or parked, including when the vehicle was unattended. Submissions should include law enforcement reports and documentation that a crash was not preventable. RDRs will be accepted beginning Aug. 1, 2017, for crashes that occur on or after June 1, 2017. Contact: Catterson Oh; FMCSA, Compliance Division; 202-366-6160; Catterson.Oh@dot.gov. Citations: 49 CFR 385 and 390

82 FR 35045 (07/27/2017)

Regulatory Update

HAZARDOUS MATERIALS TRANSPORTATION
Medical Qualification Requirements
HAZARDOUS MATERIALS TRANSPORTATION

Notice announces the intention of the Federal Motor Carrier Safety Administration to seek OMB approval for a revised information collection request regarding commercial motor vehicle driver medical qualification requirements. The collection concerns health information submitted by health care professionals treating drivers, including information regarding treatment of diabetes mellitus. The information is used to determine and certify medical fitness of drivers who operate commercial motor vehicles in interstate commerce for nonexcepted industries. The revision is due to an anticipated final rule that would eliminate the blanket prohibition against insulin-dependent diabetic individuals' operation of commercial motor vehicles in interstate commerce. The revision would replace the requirement for written notification from the treating clinician with the insulin-treated diabetes mellitus assessment form. Comments are due Sept. 25, 2017. Contact: Christine Hydock; FMCSA, Medical Programs Division; 202-366-4001; FMCSAmedical.@dot.gov. Citations: 49 CFR 391

82 FR 35041 (07/27/2017)

Regulatory Update

HAZARDOUS MATERIALS TRANSPORTATION
Motor Carriers of Passengers Annual Report
HAZARDOUS MATERIALS TRANSPORTATION

Notice of the Federal Motor Carrier Safety Administration announces the submission of a continuing information collection request to the OMB regarding the annual report of Class I motor carriers of passengers (Form MP-1). The form addresses financial, operating, equipment, and employment data from individual motor carriers of passengers. Comments are due Aug. 28, 2017. Contact: Vivian Oliver; FMCSA, Office of Registration and Safety Information; 202-366-2974; vivian.oliver@dot.gov. Citations: 49 CFR 369.4

82 FR 35027 (07/27/2017)

Regulatory Update

HAZARDOUS WASTE CLEANUP
California/Rockets, Fireworks, and Flares Superfund Site
HAZARDOUS WASTE CLEANUP

Notice of the Justice Department announces a proposed consent decree in the City of Colton v. American Promotional Events Inc. (Civil Action No. CV 09-01864) lodged on July 18, 2017, with the U.S. District Court for the Central District of California. The consent decree resolves claims under CERCLA for the recovery of response costs in connection with cleanup actions at the Rockets, Fireworks, and Flares Superfund Site, formerly the B.F. Goodrich Superfund Site, in San Bernardino County, Calif. The proposed consent decree requires the Estate of Wong to pay \$5.9 million, which will be allocated as established by a 2013 consent decree between the U.S. and B.F. Goodrich Corp (77 FR 64353). Comments are due Aug. 28, 2017. Contact: DOJ, Environment and Natural Resources Division; 202-514-2701; pubcomment-ees.enrd@usdoj.gov

82 FR 34978 (07/27/2017)

Regulatory Update

HAZARDOUS WASTE CLEANUP
Irma King Trust/EPA CERCLA Consent Agreement
HAZARDOUS WASTE CLEANUP

Notice of the EPA announces a proposed administrative settlement with Irma King Trust for alleged violations of CERCLA at the San Fernando Valley Area 2 Superfund Site. The agreement requires the respondent to pay \$30,000 for past and future response costs that the EPA has incurred or will incur at the site. The settlement includes a covenant not to sue. Comments are due Aug. 28, 2017. Contact: Tessa Berman; EPA Region 9, Office of Regional Counsel; 415-972-3472; berman.tessa@epa.gov

82 FR 34944 (07/27/2017)

Regulatory Update

OCCUPATIONAL SAFETY AND HEALTH

Nationally Recognized Testing Laboratories/TUVRNA

OCCUPATIONAL SAFETY AND HEALTH

Notice of OSHA announces the receipt of and the preliminary finding to grant an application from TUV Rheinland of North America Inc. (TUVRNA), of Newtown, Conn., for expansion and reduction of its scope of recognition as a nationally recognized testing laboratory. The expansion involves the addition of the test standard for electric vehicle charging system equipment to its scope of recognition. The reduction involves the removal of the standard for intrinsically safe apparatus and associated apparatus for use in Class I, II, III Division 1, Hazardous (Classified) Location. Comments are due Aug. 11, 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 34980 (07/27/2017)

Regulatory Update

PESTICIDES

Pesticide Product Registrations

PESTICIDES

Notice of the EPA announces the receipt of five applications to register new uses for pesticide products containing currently registered active ingredients. The applications, submitted by Syngenta Crop Protection LLC, FMC Corp., and Nufarm Americas Inc., are for one fungicide, two insecticides, one herbicide, and one bactericide/fungicide proposed for use on various agricultural products and as a termiticide. Comments are due Aug. 28, 2017. Contact: Michael Goodis; EPA, Office of Pesticide Programs; 703-305-7090; RDFRNotices@epa.gov

82 FR 34941 (07/27/2017)

Regulatory Update

PESTICIDES

Pesticide Tolerance/Ametoctradin

PESTICIDES

Final rule of the EPA increases the tolerance for residues of the fungicide ametoctradin in or on dried cone hops to 100 parts per million. The rule is issued in response to a petition filed by BASF Corp., of Research Triangle Park, N.C. The rule is effective July 27, 2017. Objections and hearing requests are due Sept. 25, 2017. Contact: Michael Goodis; EPA, Office of Pesticide Programs; 703-305-7090; RDFRNotices@epa.gov. Citations: 40 CFR 180.663

82 FR 34875 (07/27/2017)

Regulatory Update

PESTICIDES

Pesticide Tolerance/Fenpyroximate

PESTICIDES

Final rule of the EPA increases tolerances for residues of the insecticide fenpyroximate in or on citrus, dried pulp to 4.0 parts per million (ppm); citrus, oil to 15 ppm; and fruit, citrus, group 10-10 to 1.0 ppm. The rule is issued in response to a petition filed by Nichino America Inc., of Wilmington, Del. The final tolerances match the petitioned tolerances, except for the tolerance on citrus oil, which the EPA set at 15 ppm rather than the petitioned 14 ppm. The rule is effective July 27, 2017. Objections and hearing requests are due Sept. 25, 2017. Contact: Michael Goodis; EPA, Office of Pesticide Programs; 703-305-7090; RDRNotices@epa.gov. Citations: 40 CFR 180.566

82 FR 34870 (07/27/2017)

Regulatory Update

PESTICIDES

Pesticide Tolerances/Tolpyralate

PESTICIDES

Final rule of the EPA establishes a tolerances for residues of the herbicide tolpyralate in or on field corn, popcorn, and sweet corn of 0.01 parts per million. The rule is issued in response to a petition filed by ISK Biosciences Corp., of Concord, Ohio. The rule is effective July 27, 2017. Objections and hearing requests are due Sept. 25, 2017. Contact: Michael Goodis; EPA, Office of Pesticide Programs; 703-305-7090; RDRNotices@epa.gov. Citations: 40 CFR 180.696

82 FR 34877 (07/27/2017)

Regulatory Update

RADIATION

Florida/Turkey Point Site

RADIATION

Notice of the NRC announces a hearing to convene an evidentiary session to receive testimony and exhibits regarding the application from Florida Power and Light Co., of Juno Beach, Fla., for combined licenses to construct and operate Units 6 and 7 at the Turkey Point site in Miami-Dade County, Fla. The hearing is scheduled for Oct. 5, 2017, in Rockville, Md. Comments are due Aug. 30, 2017. Contact: Denise McGovern; NRC; 301-415-0681; Denise.McGovern@nrc.gov. Citations: 10 CFR 51.107 and 52.97

82 FR 34995 (07/27/2017)

Regulatory Update

RADIATION

Licenses and Radiation Safety Requirements for Irradiators

RADIATION

Notice announces the intention of the NRC to seek OMB approval for a continuing information collection request concerning licenses and radiation safety requirements for irradiators. The collection addresses application, reporting, and recordkeeping requirements for licensee

possession and use of source or byproduct material. Comments are due Sept. 25, 2017. Contact: David Cullison; NRC; 301-415-2084; INFOCOLLECTS.Resource@NRC.GOV. Citations: 10 CFR 36

82 FR 34994 (07/27/2017)

Regulatory Update

RADIATION

Nuclear Fuel Data Survey

RADIATION

Notice announces the intention of the Energy Information Administration to seek OMB approval for a revised information collection request regarding the nuclear fuel data survey (Form GC-859). The collection gathers data on spent nuclear fuel (SNF) from all utilities that operate commercial nuclear reactors and from all others that possess irradiated fuel from commercial nuclear reactors. The collection supports research objectives of developing a range of options and supporting analyses to facilitate informed choices about how best to manage SNF. The revisions add voluntary reporting of assembly burnup data and require reporting of discharged fuel that is shipped or transferred to other storage sites. The revisions also seek information for consolidated, reconstituted, reconstructed fuel assemblies and dry cask loading pattern maps with orientation details. Requests for several other data points are deleted. Comments are due Sept. 25, 2017. Contact: Marta Gospodarczyk; DOE, Office of Electricity, Coal, Nuclear, and Renewables Analysis; 202-586-0527; marta.gospodarczyk@eia.gov

82 FR 34940 (07/27/2017)

Regulatory Update

TOXIC SUBSTANCES

CFATS/Chemical-Terrorism Vulnerability Information

TOXIC SUBSTANCES

Notice of the Department of Homeland Security, National Protection and Programs Directorate, announces the submission of a revised information collection request to the OMB regarding the Chemical Facility Anti-Terrorism Standards (CFATS), which govern the security at covered chemical facilities that have been determined to be at high risk for terrorist attack. The revised collection removes five of the six previously approved instruments designed to manage the Chemical-Terrorism Vulnerability Information (CVI) program. The agency determined the removed instruments were rarely used and that such information is more likely to be collected from specific entities during the course of investigations. Comments are due Aug. 28, 2017. Contact: DHS; 866-323-2957; cfats@dhs.gov. Citations: 6 CFR 27

82 FR 34969 (07/27/2017)

Regulatory Update

TOXIC SUBSTANCES

Chemical Facility Anti-Terrorism Standards

TOXIC SUBSTANCES

Notice of the Department of Homeland Security, National Protection and Programs Directorate,

announces the submission of a revised information collection request regarding the Chemical Facility Anti-Terrorism Standards (CFATS). The CFATS governs the security at covered chemical facilities that have been determined to be at high risk for terrorist attack. The revised collection addresses information necessary to implement CFATS through portions of the Chemical Security Assessment Tool (CSAT). The revised collection also renames two previously approved instruments to clarify the functional purpose of both instruments, modifies the request for redetermination instrument to allow facilities to select from a list of possible reasons to support a request for redetermination, and adds the declaration of reporting status instrument to allow a chemical facility to notify DHS that it is not required to register in CSAT or submit a Top-Screen. Comments are due Aug. 28, 2017. Contact: DHS; 866-323-2957; cfats@dhs.gov. Citations: 6 CFR 27

82 FR 34967 (07/27/2017)

Regulatory Update

TOXIC SUBSTANCES
TSCA Statements of Findings
TOXIC SUBSTANCES

Notice of the EPA announces the availability of seven statements of findings that a new chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment. The notice specifies that the statements apply to premanufacture notices, microbial commercial activity notices, and significant new use notices submitted to the EPA under TSCA Section 5(a) from May 1-31, 2017. Contact: Greg Schweer; EPA, Office of Pollution Prevention and Toxics; 202-564-8469; schweer.greg@epa.gov

82 FR 34942 (07/27/2017)

Regulatory Update

WATER
Alternative Testing Methods for Drinking Water Contaminants
WATER

Final rule of the EPA approves 17 alternative testing methods for measuring the levels of contaminants in drinking water and determining compliance with national primary drinking water standards. The rule is effective July 27, 2017. Contact: Glynda Smith; EPA, Office of Ground Water and Drinking Water; 513-569-7652; smith.glynda@epa.gov. Citations: 40 CFR 141, Subpart C, Appendix A

82 FR 34861 (07/27/2017)

Regulatory Update

WATER
Definition of Waters of the U.S. Under the CWA
WATER

Proposed rule of the U.S. Army Corps of Engineers and the EPA would reinstate the definition of "waters of the United States" that existed prior to a June 29, 2015, final rule (80 FR 37054) that

clarified the scope of such waters that are protected under the Clean Water Act, and therefore are within U.S. regulatory jurisdiction, in light of U.S. Supreme Court decisions in 2001 and 2006. The rule is issued in response to a stay of the final rule by the U.S. Court of Appeals for the Sixth Circuit and Executive Order 13778 (82 FR 12497; 03/03/2017) that directed the agencies to review the final rule for consistency with certain policies and to issue a proposed rule amending or rescinding the final rule. The current action is the first of a two-step process for the substantive reevaluation of the definition of “waters of the United States.” Comments are due Aug. 28, 2017. Contact: Donna Downing; EPA, Office of Water; 202-566-2428; CWAwotus@epa.gov. Citations: 33 CFR 328.3 through 40 CFR 401.11 (nonconsecutive)

82 FR 34899 (07/27/2017)

Regulatory Update

WATER

Towing Vessels/Navigation Safety Information, Emergency Instructions

WATER

Notice announces the intention of the U.S. Coast Guard to submit a continuing information collection request to the OMB regarding navigation safety information and emergency instructions for certain towing vessels. The collection addresses requirements that mariners have adequate equipment, charts, maps, and other publications. The collection also addresses requirements for inspected towing vessels, under which a muster list and emergency instructions provide effective plans and references for crew to follow in emergency situations. Comments are due Sept. 25, 2017. Contact: Anthony Smith; USCG; 202-475-3532. Citations: 33 CFR 164, 46 CFR 199.80

82 FR 34960 (07/27/2017)

Regulatory Update

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