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From: Bloomberg BNA
Sent: Thur 8/3/2017 12:39:42 PM
Subject: Aug. 03 -- EHS Federal Regulatory Alert



EHS Federal Regulatory Alert

August 03, 2017 - Number 148

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Summaries

AIR

Harcros Chemicals/Clean Air Act Consent Decree

AIR

Notice of the Justice Department announces a proposed consent decree in *United States v. Harcros Chemicals Inc.* (Civil Action No. 2:17-cv-2432), lodged June 26, 2017, with the U.S. District Court for the District of Kansas. The consent decree would resolve claims regarding alleged Clean Air Act violations in connection with three of Harcros' chemical manufacturing, repacking, blending, storage, and distribution facilities in Bessemer, Ala.; Kansas City, Kan.; and Shreveport, La. The consent decree would provide injunctive relief regarding those facilities and 26 additional facilities in various states by requiring Harcros to pay a civil penalty of \$950,000 for the alleged violations and for violations expected to be uncovered at the other facilities. The defendant also would be required to audit its facilities for compliance with CAA Section 112(r), to correct any discovered violations of the requirements, and to perform a supplemental environmental project to enhance its fire-prevention capability at eight of its facilities. Comments are due Sept. 5, 2017. Contact: DOJ, Environment and Natural Resources Division; 202-514-2701

82 FR 36157 (08/03/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Biologics Patent Infringement Complaint

GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces that an applicant for a proposed biosimilar product has notified the agency that a patent infringement action has been filed in connection with the applicant's biologics license application. Contact: Daniel Orr; FDA, Center for Drug Evaluation and Research; 240-402-0979; daniel.orr@fda.hhs.gov

82 FR 36149 (08/03/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Drug Product Labeling/Child-Resistant Packaging Statements Guidance

GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces the availability of a draft guidance for industry regarding child-resistant packaging statements in drug product labeling. The guidance is intended to assist applicants, manufacturers, packagers, and distributors that include such statements in prescription and over-the-counter human drug product labeling and addresses information that should be included to avoid misleading statements. Comments are due Oct. 2, 2017. Contact: Richard Lostritto; FDA, Center for Drug Evaluation and Research; 301-796-1697. Citations: 16 CFR 1700

82 FR 36148 (08/03/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Minnesota, North Dakota/Valley Expansion Project

GENERAL ENVIRONMENT AND SAFETY

Notice of FERC announces the schedule of environmental review for the Valley Expansion Project in Clay County, Minn., and Barnes, Burleigh, Cass, and Stutsman counties in North Dakota. The project, proposed by WBI Energy Transmission Inc., of Bismarck, N.D., involves the construction, operation and maintenance of interconnect facilities with Viking Gas Transmission, including 38 miles of pipeline, a 2,600 horsepower electric compressor station, two replacement town border stations, and a regulator station. The issuance of the environmental assessment is scheduled for Sept. 20, 2017, and the 90-day federal authorization decision is due Dec. 19, 2017. Contact: FERC, Office of External Affairs; 866-208-3372; FERCOOnlineSupport@ferc.gov

82 FR 36131 (08/03/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Mountaineer Xpress and Gulf Xpress Projects

GENERAL ENVIRONMENT AND SAFETY

Notice of FERC announces the availability of the final environmental impact statement for the Mountaineer XPress Project and the Gulf XPress Project proposed by Columbia Gas Transmission LLC and Columbia Gulf Transmission LLC, respectively. The Mountaineer XPress Project involves the construction and operation of approximately 170 miles of pipeline and modification to or construction of three compressor stations in West Virginia, for the transportation of up to 2.7 million dekatherms per day (Dth/d) of natural gas. The Gulf XPress Project involves the construction and operation of seven new compressor stations and upgrades at an existing compressor station and meter station in Kentucky, Mississippi and Tennessee to allow for an additional 860,000 Dth/d of natural gas delivery to the Gulf Coast region. The agency concludes that approval of the proposed projects would result in some adverse and significant environmental impacts, however, if the projects are constructed and operated in accordance with mitigation measures discussed in the EIS and agency recommendations, the impacts would be

reduced to acceptable levels. Contact: FERC, Office of External Affairs; 866-208-3372; FERCOOnlineSupport@ferc.gov

82 FR 36130 (08/03/2017)

Regulatory Update

GENERAL ENVIRONMENT AND SAFETY

Withdrawal of Approval of New and Abbreviated New Drug Applications

GENERAL ENVIRONMENT AND SAFETY

Notice of the FDA announces the withdrawal of approval of three new drug applications and one abbreviated new drug application held by B. Braun Medical Inc., of Bethlehem, Pa. The applicant requested the withdrawal because the drug products are no longer marketed. The withdrawal is effective Sept. 5, 2017. Contact: Valerie Butler; FDA, Center for Biologics Evaluation and Research; 240-402-7911. Citations: 21 CFR 314.150

82 FR 36150 (08/03/2017)

Regulatory Update

HAZARDOUS MATERIALS TRANSPORTATION

Commercial Driver's License Standards Regulatory Guidance

HAZARDOUS MATERIALS TRANSPORTATION

Notice of the Federal Motor Carrier Safety Administration announces the availability of regulatory guidance clarifying that state driver licensing agencies may agree to facilitate the commercial learner's permit (CLP) application process and to administer the commercial driver's license (CDL) general knowledge test to individuals who do not live in the state. The guidance specifies that licensing agencies are authorized to perform such functions if the agency administering the general knowledge test transmits the test results to the applicant's state of domicile and the state agrees to accept the results and issue the CLP. The agency states that the guidance is consistent with an Oct. 13, 2016, final rule (81 FR 70634) regarding military personnel applying for a CLP or CDL. The guidance is applicable Aug. 3, 2017, and expires Aug. 3, 2022. Contact: Nikki McDavid; FMCSA, Office of Safety Programs; 202-366-0831; nikki.mcdavid@dot.gov. Citations: 49 CFR 383.73

82 FR 36101 (08/03/2017)

Regulatory Update

HAZARDOUS WASTE CLEANUP

National Priorities List/General Superfund Sites

HAZARDOUS WASTE CLEANUP

Final rule of the EPA adds seven sites to the General Superfund section of the National Priorities List: the Post and Lumber Preserving Co. site in Quincy, Fla.; the Microfab Inc. site in Amesbury, Mass.; the Old HWY 275 and North 288th Street site in Valley, Neb.; the Saint-Gobain Performance Plastics site in Hoosick Falls, N.Y.; the Battery Recycling Co. site in Bo. Cambalache, P.R.; the Former Custom Cleaners site in Memphis, Tenn.; and the Highway 18 Ground Water site in Kermit, Texas. The rule does not finalize the proposed addition of the Anaconda Copper Mine

site, in Yerington, Nev., to the NPL. The rule is effective Sept. 5, 2017. Contact: Terry Jeng; EPA, Office of Superfund Remediation and Technology Innovation; 703-603-8852; jeng.terry@epa.gov. Citations: 40 CFR 300

82 FR 36095 (08/03/2017)

Regulatory Update

HAZARDOUS WASTE CLEANUP

National Priorities List/Proposed General Superfund Sites

HAZARDOUS WASTE CLEANUP

Proposed rule of the EPA would add four sites to the General Superfund section of the National Priorities List: the Newark South Ground Water Plume site in Newark, Del.; the American Creosote DeRidder site in DeRidder, La.; the Mississippi Phosphates Corp. site in Pascagoula, Miss.; and the Eagle Industries site in Midwest City, Okla. The agency also is withdrawing its previous proposal to add the Burlington Northern Livingston Shop Complex site in Livingston, Mont. Comments are due Oct. 2, 2017. Contact: Terry Jeng; EPA, Office of Superfund Remediation and Technology Innovation; 703-603-8852; jeng.terry@epa.gov. Citations: 40 CFR 300

82 FR 36106 (08/03/2017)

Regulatory Update

PESTICIDES

FIFRA Scientific Advisory Panel Meeting/Endocrine Disruption

PESTICIDES

Notice of the EPA announces changes to the comment periods for a previously announced meeting of the Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (82 FR 26097; 06/06/2017) to consider and review scientific issues concerning the continuing development of alternative high-throughput screens to determine endocrine disruption. The meeting will include review of the agency's proposed high-throughput computational model of androgen receptor pathway activity and discussion of development of a high-throughput model of steroidogenesis and of a proposed adverse outcome pathway-based framework for screening chemicals for potential thyroid disruption. The meeting is scheduled for Nov. 28-30, 2017, in Arlington, Va., and via webcast. A list of prospective ad hoc panelists for the meeting will be posted on the agency's website by Aug. 22, 2017, and comments on the nominees are due Sept. 7, 2017. All other comments now are due Oct. 16, 2017. Contact: Todd Peterson; EPA, Office of Science Coordination and Policy; 202-564-6428; peterson.todd@epa.gov

82 FR 36137 (08/03/2017)

Regulatory Update

PESTICIDES

Pesticide Registration Cancellations

PESTICIDES

Notice of the EPA announces corrections to a Nov. 22, 2016, notice of receipt (81 FR 83833) and

an April 10, 2017, cancellation order (82 FR 17253) regarding requests from 11 registrants to voluntarily cancel 17 pesticide product registrations and to amend five registrations to terminate uses. The corrections revise the registration number for Curacron 8E to 100-669. Contact: Christina Scheltema; EPA, Office of Pesticide Programs; 703-308-2201; scheltema.christina@epa.gov

82 FR 36136 (08/03/2017)

Regulatory Update

PESTICIDES

Pesticide Registration Cancellations

PESTICIDES

Notice of the EPA announces the receipt of requests from registrants to voluntarily cancel 221 pesticide product registrations. The notice lists the registration numbers, product names, chemical names, and registrants. The agency intends to issue an order canceling all of the affected registrations unless there are substantive comments that warrant further review or the registrants withdraw their requests. Comments are due Jan. 30, 2018. Contact: Michael Yanchulis; EPA, Office of Pesticide Programs; 703-347-0237; yanchulis.michael@epa.gov

82 FR 36138 (08/03/2017)

Regulatory Update

PESTICIDES

Pesticide Registration Review/Draft Risk Assessments

PESTICIDES

Notice of the EPA announces the availability of draft human health and ecological risk assessments for the registration review of benfluralin, bromuconazole, carbaryl, clodinafop-propargyl, deltamethrin, diflufenzopyr, esfenvalerate, lufenuron, and mepiquat chloride/mepiquat pentaborate under FIFRA Section 3(g) and the procedural regulations for registration review. Comments are due Oct. 2, 2017. Contact: Dana Friedman; EPA, Office of Pesticide Programs; 703-347-8827; friedman.dana@epa.gov. Citations: 40 CFR 155, Subpart C

82 FR 36135 (08/03/2017)

Regulatory Update

PESTICIDES

Pesticide Tolerances/Cyclaniliprole

PESTICIDES

Final rule of the EPA establishes tolerances for residues of the insecticide cyclaniliprole in or on almond hulls at 6 parts per million; wet apple pomace at 0.5 ppm; cattle meat, goat meat, horse meat, and sheep meat at 0.01 ppm; nut tree group 14-12 at 0.03 ppm; and tea at 50 ppm. The rule also establishes tolerances in or on cattle fat, cattle meat byproducts, goat fat, goat meat byproducts, horse fat, horse meat byproducts, milk, sheep fat, and sheep meat byproducts at 0.015 ppm. In addition, the rule establishes tolerances in or on pome fruit group 11-10 at 0.3 ppm; small vine-climbing fruit subgroup 13-07F, except fuzzy kiwifruit, at 0.8 ppm; stone fruit group 12-

12 at 1 ppm; brassica head and stem group 5-16 at 1 ppm; cucurbit group 9 at 0.15 ppm; fruiting vegetable group 8-10 at 0.2 ppm; and leafy vegetable group 4-16 at 15 ppm. Finally, the rule establishes an exemption from the requirement of a tolerance for indirect or inadvertent residues. The rule is issued in response to a petition filed by ISK Biosciences Corp, of Concord, Ohio. The rule is effective Aug. 3, 2017. Objections and hearing requests are due Oct. 2, 2017. Contact: Michael Goodis; EPA, Office of Pesticide Programs; 703-305-7090; RDFRNotices@epa.gov. Citations: 40 CFR 180.694; 180.1344

82 FR 36090 (08/03/2017)

Regulatory Update

PESTICIDES

Pesticide Tolerances/Ethaboxam

PESTICIDES

Final rule of the EPA establishes tolerances for residues of the fungicide ethaboxam in or on ginseng at 0.1 parts per million; grape at 6 ppm; pepper/eggplant subgroup 8-10B at 0.9 ppm; cucurbit vegetables, group 9 at 0.3 ppm; and tuberous and corm vegetables, subgroup 1C at 0.01 ppm. The rule is issued in response to a petition filed by Valent USA Corp., of Walnut Creek, Calif. The rule is effective Aug. 3, 2017. Objections and hearing requests are due Oct. 2, 2017. Contact: Michael Goodis; EPA, Office of Pesticide Programs; 703-305-7090; RDFRNotices@epa.gov. Citations: 40 CFR 180.622

82 FR 36086 (08/03/2017)

Regulatory Update

RADIATION

Commercial Power Reactor Operator Licensing Examination Data

RADIATION

Notice of the NRC announces the submission of a continuing information collection request to the OMB regarding operator licensing examination data (Form 536). The collection addresses the voluntary submission of projected numbers of candidates for initial operator licensing examinations, estimated dates of the examinations, and the source of the examinations (NRC or facility) by commercial power reactor licensees and applicants for an operating license. Comments are due Sept. 5, 2017. Contact: David Cullison; NRC, Office of Information Services; 301-415-2084; INFOCOLLECTS.Resource@NRC.GOV. Citations: 10 CFR 50, 10 CFR 52

82 FR 36161 (08/03/2017)

Regulatory Update

TOXIC SUBSTANCES

Science Advisory Committee on Chemicals Nominations

TOXIC SUBSTANCES

Notice of the EPA announces an additional 64 candidates under consideration for appointment to the Science Advisory Committee on Chemicals (SACC). The committee provides advice and recommendations on the scientific basis for risk assessments, methodologies, and pollution

prevention measures or approaches. A Dec. 9, 2016, notice (81 FR 89092) provided a list of 29 candidates under consideration for appointment to the SACC. The EPA intends to further consider the 29 candidates in addition the newly identified 64 candidates. Comments are due Sept. 5, 2017. Contact: Tamue Gibson; EPA, Office of Science Coordination and Policy; 202-564-7642; gibson.tamue@epa.gov

82 FR 36132 (08/03/2017)

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