

# VEOLIA NORTH AMERICA - INDUSTRIAL BUSINESS REGULATORY UPDATE - August 2016

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The information contained herein is provided by Veolia North America for general informational purposes only. This information should not be construed as legal advice or a legal opinion on any specific facts or circumstances. If you should have any questions, please contact Tom Baker, Veolia Director Environment & Transportation at tom.baker@veolia.com.

### A. EPA Awards Grants to Advance Air Monitoring Technology; Notice

On August 8, 2016, the Environmental Protection Agency (EPA) announced that they had awarded \$4.5 Million in federal grant funding to six research organizations to work with local communities to explore data quality, durability, and uses for low-cost air pollution sensor technology.

On August 30, 2016, EPA announced the Smart City Air Challenge which is offering \$40,000 to two communities to help them develop and implement plans for collecting and sharing data from air quality sensors.

# 1. Research Organization Grants

These research grants were awarded to explore how air monitoring data can be effectively gathered and used by communities to better understand the public's exposure to air pollution. These grants were funded through the Science to Achieve Results (STAR) program. The grants were awarded to:

- Kansas State University for an evaluation of community-led research including air pollution monitoring in four diverse communities in Chicago using low cost portable air pollution sensors;
- b. Massachusetts Institute of Technology for the creation of a network of air pollution sensors that will improve the estimates of residents' exposures to volcanic emissions from the Kilauea (Hawaii) volcano and the impacts on human health and agricultural crops:
- c. South Coast Air Quality Management District that will provide local California communities with the knowledge necessary to select, use, and maintain low cost sensors and correctly interpret sensor data:
- d. University of Washington that will use low cost air particle sensors in student directed studies to assess heavy wood smoke impacts in rural communities;
- e. Research Triangle Institute will conduct a project that will create a framework to empower, support, and guide communities to design and conduct air quality monitoring studies using low cost sensors to address specific air quality concerns;
- f. Carnegie Mellon University will research the accuracy of air pollution sensors and the potential usefulness of that data.

#### 2. Smart City Air Challenge

EPA is offering up to \$40,000 apiece to two communities to help them develop and implement plans for collecting and sharing data from air quality sensors. The communities would install hundreds of air quality sensors and manage the resulting data. The communities would also work with the public to crowd source the air quality data and share it with the public online. The prize money is intended to serve as seed money and communities will need to partner with other parties, such as sensor manufacturers, data management companies, and universities.

EPA believes these studies will allow them to learn how communities collect, store and manage large amounts of data and understand the quality of data communities collect using low cost sensors. They will also see how communities transfer data from sensors to databases and visualize results.

#### Links

The link below provides access to EPA's Air Research Grants website.

https://www.epa.gov/research-grants/air-research-grants

The link below provides access to EPA's Smart City Air Challenge website.

https://www.challenge.gov/challenge/smart-city-air-challenge/

#### B. EPA Mercury Compounds; Prohibition of Export; Notice

On August 26, 2016, EPA published a list of mercury compounds that are prohibited from exportation (81 FR 58926-58927).

#### **Summary**

The Toxic Substances Control Act (TSCA) was amended by the enactment of the Frank R Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act (the ACT). The Act was enacted on June 22, 2016, and one element of the Act required EPA to publish a list of mercury compounds that are prohibited from exportation no later than 90 days after the enactment of the Act.

Beginning on January 1, 2020, the following chemicals will be prohibited from exportation:

- 1. Mercury (I) Chloride or Calomel
- 2. Mercury (II) Oxide
- 3. Mercury (II) Sulfate
- 4. Mercury (II) Nitrate
- 5. Mercury Sulfide or Cinnabar

#### **Exemption**

Mercury compounds exported to member countries of the Organization for Economic Co-operation and Development (OECD) for environmentally sound disposal are exempt from the export ban. The mercury compounds cannot be recovered, recycled, or reclaimed for use, after export.

#### **Effective Date**

The mercury compound export ban will become effective on January 1, 2020.

#### Link

The link below will allow you to view/print this notice.

https://www.gpo.gov/fdsys/pkg/FR-2016-08-26/pdf/2016-20534.pdf

# C. EPA Spring 2016 Semi-Annual Regulatory Agenda; Notice

On May 18, 2016, EPA published the Spring 2016 Semi-Annual Regulatory Agenda as part of the 2016 Spring Unified Agenda and Regulatory Plan.

# Summary

EPA publishes a semi-annual regulatory agenda twice per year. The semi-annual regulatory agenda describes a broad universe of regulatory activities that are under development or review including the following waste-related topics:

# Office of Land and Emergency Management - Final Rule Stage

- 1. Management Standards for Hazardous Waste Pharmaceuticals
- 2. Hazardous Waste Generator Improvements Rule
- 3. Hazardous Waste Export-Import Revisions Rule
- 4. Hazardous Chemical Reporting; Community Right-to-Know; Revisions to Hazard Categories and Minor Corrections
- 5. Modernization of the Accidental Release Prevention Regulations under the Clean Air Act

#### Office of Land and Emergency Management – Proposed Rule Stage

- 1. User Fee Schedule for Electronic Hazardous Waste Manifest
- 2. Non-Hazardous Secondary Materials Additions to List of Categorical Non-Waste Fuels; Other Treated Railroad Ties and Used Oil

# Office of Land and Emergency Management – Long-Term Actions

1. Financial Responsibility Requirements under CERCLA Section 108(b) for Facilities in the Chemical, Petroleum and Electric Power Industries

#### Link

The link below will allow you to view/print the Spring 2016 Semi-Annual Regulatory Agenda.

http://www.reginfo.gov/public/do/eAgendaMain

# D. DOT/PHMSA Hazardous Materials: FAST Act Requirements for Flammable Liquids and Rail Tank Cars; Final Rule

On August 15, 2016, the Department of Transportation, Pipeline and Hazardous Materials Safety Administration (PHMSA) published a final rule (81 FR 53935-53957) to codify in the Hazardous Materials Regulations certain mandates and minimum requirements of the FAST Act.

# **Summary**

On May 8, 2015, PHMSA and the Federal Railroad Administration (FRA) published the HM-251 final rule amending the Hazardous Materials Regulations (HMR) by defining certain trains transporting large volumes of Class 3 flammable liquids as "high hazard flammable trains" (HHFT) and imposed certain operation restrictions, such as speed restrictions, braking systems and routing. The HM-251 final rule also adopted requirements in the HMR for sampling and testing programs to ensure the proper classification of unrefined petroleum-based products transported under the HMR. Lastly, the rule codified new tank car design standards, namely the DOT Specification 117 (DOT-117), DOT Specification 117P (DOT-117P) and DOT Specification 117R (DOT-117R) and established a phase-out schedule for existing DOT Specification 111 tank cars by requiring the use of either a DOT-117, 117P, or 117R tank car by certain dates for the transport of Class 3 flammable liquids in an HHFT.

On December 4, 2015, President Obama signed legislation entitled "Fixing America's Surface Transportation Act of 2015" (FAST Act). The FAST Act includes the "Hazardous Materials Transportation Safety Improvement Act of 2015" and instructs the Secretary of Transportation to make specific regulatory amendments to the tank car design standards and the phase out schedule codified in the HM-251 final rule. The FAST Act mandates a commodity-specific phase-out of all DOT-111 tank cards used to transport Class 3 flammable liquids regardless if the train is an HHFT and requires that all tank cars used to transport Class 3 flammable liquids meet the DOT-117, 117P, or 117R requirements.

PHMSA is issuing this final rule to mandate a revised phase-out schedule for all DOT Specification 111 tank cars used to transport unrefined petroleum products (e.g., petroleum crude oil), ethanol, and other Class 3 liquids. The FAST Act also requires that each tank car built to meet the DOT-117 Specification and each non-jacketed tank car retrofitted to meet the DOT-117R Specification be equipped with a thermal protection blanket that is at least one-half inch thick and meet existing thermal protection standards. Further, the FAST Act mandates minimum top fittings protection requirements for tank cars retrofitted to meet the DOT-117R Specification.

#### **Effective Date**

This final rule became effective on the date of publication, August 15, 2016.

#### Link

The link below will allow you to view/print this final rule.

https://www.gpo.gov/fdsys/pkg/FR-2016-08-15/pdf/2016-19406.pdf

# E. DOT Technical Amendment; Amendment to the Definition of "Service Agent" in the DOT Drug and Alcohol Testing Regulations; Final Rule

On August 8, 2016, the Department of Transportation (DOT) published a final rule (81 FR 52364-52365) amending the DOT regulations to conform to recent legislation that changed the definition of the term "service agent" in the DOT drug and alcohol testing regulations. The final rule revises the definition of "service agent" to include all entities that provide services for DOT mandated drug and alcohol programs.

# **Background**

Service agents have played an integral role in many DOT-regulated employers' drug and alcohol testing programs. Many employers use their service agents as advisors and rely on their services to maintain compliance with DOT regulations. Service agents who are focused on compliance typically increase efficiencies and contribute to the safety of the travelling public.

For more than sixteen years, the term "service agent" has been defined as, "any person or entity, other than an employee of the employer, who provides services specified under this part to employers and/or employees in connection with DOT drug and alcohol testing requirements. This includes, but is not limited to, collectors Breath Alcohol Technicians (BATs), Saliva Testing Technicians (STTs), laboratories, Medical Review Officers (MROs), substance abuse professionals, and Consortia/Third Party Administrators (C/TPAs). To act as service agents, persons and organizations must meet the qualifications set forth in applicable sections of this part. Service agents are not employers for purposes of this part." (49 CFR 40.3)

In addition, over the years, the service agent industry has grown and it provides many services to DOT-regulated employers. As the sophistication of the drug and alcohol testing industry has grown, FMCSA has seen service agents offer auditing services to DOT-regulated employers. Given the fact that additional services have been offered to employers related to DOT's drug and alcohol program, the types of providers that fall into the definition of service agent have evolved.

# **Summary**

In this new rule, FMCSA is deleting from the current definition of "service agent" the phrases "specified under this part" and "set forth in application sections of this part" (both of which refer to 49 CFR Part 40). FMCSA has also inserted the language "if applicable" to the definition because the Agency believes that it is important to continue to note that if a DOT regulation requires specific qualifications, then the service agent must comply. In so doing, FMCSA is conforming to MAP-21 and clarifying that the expanding range of drug and alcohol program services has been included in this definition. The new definition is:

Service Agent – Any person or entity, other than an employee of the employer, who provides services to employers and/or employees in connection with DOT drug and alcohol testing requirements. This includes, but is not limited to, collectors, BAT and STTs, laboratories, MROs, substance abuse professionals, and C/TPAs. To act as service agents, persons and organizations must meet DOT qualifications, if applicable. Service Agents are not employers for purposes of this part.

#### **Effective Date**

This rule became effective on the date of publication, August 8, 2016.

#### Link

The link below will allow you to view/print this final rule.

https://www.gpo.gov/fdsys/pkg/FR-2016-08-08/pdf/2016-18328.pdf

#### F. DOT/FMCSA National Hazardous Materials Route Registry Revisions and Procedures; Notice

On August 8, 2016, the Department of Transportation, Federal Motor Carrier Safety Administration (FMCSA) published a notice (81 FR 52518-52521) providing the most current revisions to the National Hazardous Materials Route Registry (NHMRR) and procedures to facility the update of the NHMRR by State and Tribal government routing agencies. The NHMRR is a listing, as reported by States and Tribal governments, of all designated and restricted road and preferred highway routes for the transportation of highway route controlled quantities (HRCQ) of Class 7 radioactive materials (RAM) and non-radioactive hazardous materials (NRHMs).

# **Background**

Paragraphs (a)(2) and (b) of section 5112 of title 49, United States Code (U.S.C.) permit States and Tribal governments to designate and limit highway routes of which HRCQ/RAM and NRHM may be transported, provided that the State or Tribal government complies with standards prescribed by the Secretary of Transportation (the Secretary) and meets publication requirements in section 5112(c). To establish standards under paragraph (b), the Secretary must consult with the States, and, under section 5112(c), coordinate with the States to publish periodically a list of currently effective HRCQ/RAM and NRHM highway routing designations and restrictions. The requirements that States and Tribal governments must follow to establish, maintain, or enforce routing designations for the transport of placardable quantities of NRHM are set forth in 49 CFR 397, Subpart C. 49 CFR 397, Subpart D sets out the requirements for designating preferred routes for HRCQ/RAM shipments as an alternative, or in addition, to Interstate System Highways. For HRCQ/RAM shipments 49 CFR 397.101 defines a preferred route as an Interstate Highway for which no alternative route is designated by the State; a route specifically designated by the State; or both.

Currently, 49 CFR 397, Subpart C (Routing of NRHM) and Subpart D (Routing of Class 7 RAM) address the routing requirements and procedures that State and Tribal government are required to follow. 49 CFR 397.73 establishes public information and reporting requirements for NRHM. States or Tribal governments are required to furnish information regarding any new or changed routes to FMCSA within 60 days after establishment. Under 49 CFR 397.103, a State routing designation for HRCQ/RAM routes (preferred routes) as an alternative, or in addition, to an Interstate System Highway, is effective when the authorized routing agency provides FMCSA with written notification, FMCSA acknowledges receipt in writing, and the route is published in FMCSA's Hazardous Material Route Registry. This notice serves only to provide the most current updates to the NHMRR, and to communicate to States and Tribal government routing agencies procedures to facilitate timely reporting and efficient update of the NHMRR as required by 49 U.S.C. 5112 and 49 CFR 397; it does not establish any new public information and/or reporting requirements.

# **Procedural Changes**

Section 33013 of the Moving Ahead for Progress in the 21<sup>st</sup> Century Act of 2012 (MAP-21) amended 49 U.S.C. 5112(c), which addresses the form, manner, and timetable for State and Tribal Governments to issue and update routing information for commercial motor vehicles transporting hazardous material in commerce for which DOT regulations require placarding of the vehicle. In October 2014, FMCSA

published a Technical Amendments Rule that included amendments to 49 CFR 397.69 to address section 33013 of the statute. Among the amendments was a State reporting requirement to include the name of the agency responsible for the highway route designations, and another to clarify that any State or Tribal government designated route is effective only after publication in the NHMRR. This notice further addresses the form and manner for updating this information by establishing a procedure for updating the NHMRR in accordance with the statute and regulations.

### Updates to the NHMRR

The most up-to-date version of the NHMRR, was published in the Federal Register on April 29, 2015 (80 FR 23860) and can be accessed on the internet at:

http://www.fmcsa.dot.gov/regulations/hazardous-materials/national-hazardous-materials-route-registery. Further, this Web page provides a link to <a href="http://www.fmcsa/dot.gov/regulations/hazardous-materials/national-hazardous-materials-route-registry-state">http://www.fmcsa/dot.gov/regulations/hazardous-materials-route-registry-state</a> which provides the Route Registry listing of each individual State and Tribal government as well as information on the official routing agency. This information, available for use by the routing agencies as well as the general public, is presented, in three formats; a spreadsheet, a PDF file, and as available, an interactive map. In addition, FMCSA has established an internet mailbox at <a href="https://www.fmcsa/dot.gov/regulations/hazardous-materials-route-registry-state">https://www.fmcsa/dot.gov/regulations/hazardous-materials-route-registry-state</a> which provides the Route Registry listing of each individual State and Tribal government as well as information on the official routing agency. This information, available for use by the routing agencies as well as the general public, is presented, in three formats; a spreadsheet, a PDF file, and as available, an interactive map. In addition, FMCSA has established an internet mailbox at <a href="mailto:https://mww.fmcsa/dot.gov">https://mww.fmcsa/dot.gov</a> to facilitate communication with routing agencies.

While the route designation reporting requirements of 49 CFR 397.73 and 397.103 do not provide a specific procedure to follow whenever there is a change in routing designations, the FMCSA is providing the following procedure to facilitate State and Tribal government routing agencies in updating their Route Registry listing.

# **Revisions to the National Hazardous Materials Route Registry**

Since FMCSA published the NHMRR on April 29, 2015, the State of California has notified the FMCSA of revisions to their Route Registry.

In accordance with the requirements of 49 CFR 397.73 and 397.103, the Route Registry listings for the State of California, as published in Tables 16 and 17 are being revised. The revised tables reflect the most current Route Registry listings for the State of California and supersede and replace the corresponding tables in the April 29, 2015 notice. The changes to the listings contained in the tables are reflected in the information posted on the internet at <a href="http://www.fmcsa.dot.gov/regulations/hazardous-materials/national-hazardous-materials-route-registry">http://www.fmcsa.dot.gov/regulations/hazardous-materials/national-hazardous-materials-route-registry</a>.

No other States submitted changes.

#### **Effective Date**

These National Hazardous Materials Route Registry Revisions and Procedures became effective on August 8, 2016.

#### Link

The link below will allow you to view/print this notice.

https://www.gpo.gov/fdsys/pkg/FR-2016-08-08/pdf/2016-18729.pdf

#### G. DOT/FMCSA/PHMSA Spring 2016 Semi-Annual Regulatory Agenda; Notice

On May 18, 2016, the Department of Transportation, Federal Motor Carrier Safety Administration (FMCSA) and Pipeline and Hazardous Materials Safety Administration (PHMSA) published the Spring 2016 Semi-Annual Regulatory Agenda as part of the 2016 Spring Unified Agenda and Regulatory Plan.

#### **Summary**

FMCSA and PHMSA publish a semi-annual regulatory agenda twice per year. The semi-annual regulatory agenda describes a broad universe of regulatory activities that are under development or review including the following commercial motor vehicle and hazardous materials transportation related topics:

# Federal Motor Carrier Safety Administration – Final Rule Stage

- 1. Commercial Drivers' License Drug and Alcohol Clearinghouse (MAP-21)
- 2. Parts and Accessories Necessary for Safe Operation; Inspection, Repair, and Maintenance; General Amendments (RRR)
- 3. Driving of Commercial Motor Vehicles: Use of Seat Belts
- 4. Federal Civil Penalties Inflation Adjustment of 2015

# Federal Motor Carrier Safety Administration – Proposed Rule Stage

1. MAP-21 Enhancements and other Updates to the Unified Registration System

# Federal Motor Carrier Safety Administration – Long-Term Actions

1. Evaluation of Safety-Sensitive Personnel for Moderate-to-Severe Obstructive Sleep Apnea

#### Pipeline and Hazardous Materials Safety Administration – Final Rule Stage

- 1. Hazardous Materials: Miscellaneous Amendments RRR
- 2. Hazardous Materials: FAST Act Requirements for Flammable Liquids and Rail Tank Cars
- 3. Hazardous Materials: Revised Lithium Battery Provisions
- 4. Hazardous Materials: Revision of Maximum and Minimum Civil Penalties

# Pipeline and Hazardous Materials Safety Administration – Proposed Rule Stage

- 1. Hazardous Materials: Adoption of American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code Section XII and the National Board Boiler and Pressure Vessel Inspectors Code
- 2. Hazardous Materials: Miscellaneous Pressure Vessel Requirements DOT Specification Cylinders RRR
- 3. Hazardous Materials: Review and Update of Rail Carrier Regulations in Part 174 RRR
- 4. Hazardous Materials: Oil Spill Response Plans and Information Sharing for High-Hazard Flammable Trains
- 5. Hazardous Materials: Response to Petitions for Rulemaking
- 6. Hazardous Materials: Harmonization with International Standards RRR
- 7. Hazardous Materials: Revisions to Hazardous Materials Emergency Preparedness Grants Requirements RRR
- 8. Hazardous Materials: Real-Time Emergency Response Information by Rail
- 9. Hazardous Materials: Revision of the Requirements for Carriage by Aircraft RRR

# Link

The link below will allow you to view/print the Spring 2016 Semi-Annual Regulatory Agenda.

http://www.reginfo.gov/public/do/eAgendaMain

#### H. OSHA Process Safety Management Guidance Products Available for Public Review; Notice

On August 23, 2016, the Occupational Safety and Health Administration (OSHA) distributed an email notifying interested parties that three draft guidance documents for specific process safety management (PSM) covered industries were available for review and comment.

#### **Summary**

As part of the action items listed in the Actions to Improve Chemical Facility Safety and Security – A Shared Commitment report to the president, OSHA committed to developing three guidance documents. The guidance documents are:

- 1. Process Safety Management Explosive and Pyrotechnics Manufacturing Guidelines for Compliance
- 2. Process Safety Management Small Business Guidelines for Compliance
- 3. Process Safety Management Storage Facilities Guidelines for Compliance

The documents don't appear to present proposed regulatory changes, but are limited to additions to OSHA guidance regarding documents applicability and enforcement. The only section applicable to Veolia are in the storage facilities guidance document. The one revision that would impact Veolia is a new OSHA enforcement clarification memo regarding the applicability of the PSM standards to mixtures. The OSHA enforcement clarification memo nullifies former interpretations regarding "commercial grade" or "chemical grade" materials and references the EPA Risk Management Plan (RMP) "1% test rule." The 1% rule essentially states that if a mixture contains greater than 1% of any chemical listed in Appendix A the PSM requirements apply to the management of that chemical.

#### **Comments Due**

Comments on these proposed guidelines must be submitted to OSHA on or before September 23, 2016. OSHA has established a docket (OSHA-2016-0021) for the submission of comments.

#### Link

Docket OSHA-2016-0021 can be found in the following link.

https://www.regulations.gov/docket?D=OSHA-2016-0021

The link below will allow you to view/print the OSHA enforcement clarification memo.

https://www.osha.gov/pls/oshaweb/owadisp.show\_document?p\_table=INTERPRETATIONS&0\_id=30848

# I. OSHA Spring 2016 Semi-Annual Regulatory Agenda; Notice

On May 18, 2016, the Occupational Safety and Health Administration (OSHA) published the Spring 2016 Semi-Annual Regulatory Agenda as part of the 2016 Spring Unified Agenda and Regulatory Plan.

#### **Summary**

OSHA publishes a semi-annual regulatory agenda twice per year. The semi-annual regulatory agenda describes a broad universe of regulatory activities that are under development or review. The Spring 2016 Semi-Annual Regulatory Agenda includes the following OSHA topics:

# Occupational Safety and Health Administration – Final Rule Stage

- 1. Walking Working Surfaces and Personal Fall Protection Systems (Slips, Trips, and Fall Protection)
- 2. Clarification of Employer's Continuing Obligation to Make and Maintain Accurate Records of Each Recordable Injury and Illness
- 3. Rules of Agency Practice and Procedure Concerning OSHA Access to Employee Medical Records

# Occupational Safety and Health Administration - Proposed Rule Stage

- 1. Occupational Exposure to Beryllium
- 2. Infectious Diseases

- 3. Standards Improvement Project IV
- 4. Quantitative Fit Testing Protocol: Amendment to the Final Rule on Respiratory Protection

# Occupational Safety and Health Administration – Long-Term Actions

- 1. Bloodborne Pathogens
- 2. Combustible Dust
- 3. Preventing Backover Injuries and Fatalities
- 4. Chemical Management and Permissible Exposure Limits (PELs)
- 5. Process Safety Management and Prevention of Major Chemical Accidents
- 6. Emergency Response and Preparedness
- 7. Powered Industrial Trucks
- 8. Lock-out/Tag-out Update
- 9. Revocation of Obsolete Permissible Exposure Limits (PELs)
- 10. 1-Bromopropane (1-BP) Standard
- 11. Occupational Exposure to Styrene
- 12. Blood Lead Level for Medical Removal
- 13. Updating Requirements for the Selection, Fit Testing, and Use of Hearing Protection Devices

#### Link

The link below will allow you to view/print the Spring 2016 Semi-Annual Regulatory Agenda.

http://www.reginfo.gov/public/do/eAgendaMain

#### J. DHS Transportation Worker Identification Credential (TWIC) – Reader Requirements; Final Rule

On August 23, 2016, The Department of Homeland Security (DHS) published a final rule (81 FR 57651-57713) requiring owners and operators of certain vessels and facilities regulated by the Coast Guard to conduct electronic inspections of Transportation Worker Identification Credentials (TWICs) as an access control measure.

#### **Summary**

In this final rule the U.S. Coast Guard has amended regulations under 33 CFR 101, 103, 104, 105, and 106 to require owners and operators of certain high-risk vessels and facilities subject to maritime security requirements under the Maritime Transportation Security Act to use electronic readers designed to work with the Transportation Worker Identification Credentials (TWICs) as an access control measure. The rule requires Risk Group A owners and operators to perform electronic TWIC authentications to prevent unescorted access to secure areas by uncredentialed persons. The rule also specifies that the authentications will include a verification of the TWIC credential, a match of the credential against an up-to-date list maintained by the Transportation Safety Administration (TSA) and a biometric identify confirmation (i.e., fingerprint) with a biometric template stored on the credential. In addition, the rule sets forth related recordkeeping and security plan amendment requirements and specifies related exemptions.

#### **Effective Date**

This rule became effective on the date of publication, August 23, 2016.

#### Link

The link below will allow you to view/print this final rule.

https://www.gpo.gov/fdsys/pkg/FR-2016-08-23/pdf/2016-19383.pdf

# K. DOJ/DEA Schedules of Controlled Substances: Placement of Thiafentanil into Schedule II; Interim Final Rule with Request for Comments

On August 26, 2016, the Department of Justice, Drug Enforcement Agency (DEA) published an interim final rule (81 FR 58834-58840) placing the substance thiafentanil (4-(methoxycarbonyl)-4-(N-phenmethoxyacetamido)-1-[2-(thienyl)ethyl]piperidine), including its isomers, esters, ethers, salts and salts of isomers, esters and ethers into schedule II of the Controlled Substances Act.

#### **Summary**

Thiafentanil is a synthetic analogue of fentanyl and is structurally related to other fentanyl-like opioids such as sufentanil and carfentanil, both Schedule II substances. It acts as a potent  $\mu$ -opioid receptor agonist and produces strong morphine-like effects in animals. Because thiafentanil shares chemical and pharmacological similarities with Schedule II fentanyl and its analogues, the abuse potential is considered similar to that of schedule II opioid substances. After reviewing all scientific data and medical evaluations and the scheduling recommendation provided by HHS, DEA has concluded that thiafentanil including its isomers, esters, ethers, salts and salts of isomers, esters, and ethers warrant control in Schedule II of the Controlled Substances Act.

#### **Effective Date**

This interim final rule became effective on August 26, 2016.

#### **Comments Due**

Comments on this interim final rule must be received by DEA on or before September 26, 2016.

# Link

The link below will allow you to view/print the interim final rule.

https://www.gpo.gov/fdsys/pkg/FR-2016-08-26/pdf/2016-20463.pdf

# L. DHHS/CDC Multi-Agency Informational Meeting Concerning Compliance with the Federal Select Agent Program; Public Webcast

On August 30, 2016, the Department of Health and Human Services, Centers for Disease Control and Prevention (CDC) published a notice (81 FR 59631-59632) of a public webcast regarding the Federal Select Agent Program.

#### **Summary**

The public webcast is an opportunity for the affected community (i.e., registered entity responsible officials, alternate responsible officials, and entity owners) to obtain specific regulatory guidance and information concerning biosafety, security, and incident response issues related to the Federal Select Agent Program. Representatives from the Federal Select Agent Program will participate on the webcast to address questions and concerns from participants.

#### **Webcast Date**

The webcast will be conducted on November 9, 2015 from Noon to 4:00 PM Eastern Time.

#### Registration

To participate in the webcast you must complete an online registration by November 4, 2016.

#### Links

The link below will allow you to register for the webcast.

http://www.selectagents.gov

The link below will allow you to view/print the notice of the webcast.

https://www.gpo.gov/fdsys/pkg/FR-2016-08-30/pdf/2016-20710.pdf

# M. DoT/TTB Reclassification of Specially Denatured Spirits and Completely Denatured Alcohol Formulas and Related Amendments; Final Rule

On August 30, 2016, the Department of the Treasury, Alcohol and Tobacco Tax and Trade Bureau (TTB) published a final rule (81 FR 59445-59464) amending regulations regarding denatured alcohol and products made with industrial alcohol by eliminating outdated specially denatured spirits formulas from the regulations, reclassifying some specially denatures spirits formulas as completely denatured alcohol formulas, and issuing some new general-use formulas for manufacturing products with specially denatured spirits.

# **Background**

On June 27, 2013, TTB published Notice No. 136 (78 FR 38638) proposing several changes to the regulations to ease burdens on industry and TTB, as well as other improvements and clarifications. The changes proposed by TTB were:

- 1. The removal of 16 Specially Denatured Alcohol (S.D.A.) formulas, because they were no longer in use:
- 2. Reclassification of two (2) S.D.A formulas to Completely Denatured Alcohol (C.D.A.) because it is very difficult to separate the denaturant from the alcohol in the formulation;
- A new multi-purpose general-use formula was proposed for appropriate articles made with one or more of 15 S.D.A. formulations:
- 4. TTB proposed three S.D.A. formulations that would be allowed to be used as ingredients in certain general-use formulas;
- 5. The creation of a general-use formula for duplicating fluids and ink solvents;
- 6. Amend the proprietary solvents general-use formula to allow the use of S.D.A. 3-C in the manufacture of proprietary solvents;
- 7. Remove the use of benzene as a denaturant;
- 8. Clarify that the destruction of recovered material that is not sufficiently denatured to meet the formula specifications of an article must be done by the original manufacturer, a distilled spirits plant, or a facility that possess an S.D.S. dealer's permit.

#### **Summary**

In this final rule TTB is finalizing the revisions as published in the June 2013 Notice No. 136 with minor revisions.

#### **Effective Date**

This final rule will become effective on October 31, 2016.

#### Link

The link below will allow you to view/print the final rule.

https://www.gpo.gov/fdsys/pkg/FR-2016-08-30/pdf/2016-20712.pdf