



## VEOLIA NORTH AMERICA - INDUSTRIAL BUSINESS REGULATORY UPDATE - August 2014

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**A. EPA Grants Final Approval for Electric Utilities to Dispose PCB Remediation Wastes Containing <50 ppm PCBs in Non-TSCA Regulated Landfills**

On June 10, 2014, the Environmental Protection Agency (EPA) issued a final 40 CFR 761.61(c) risk-based disposal approval that allows electric utilities to dispose of polychlorinated biphenyl (PCB) remediation wastes containing <50 ppm PCBs in Non-Toxic Substances Control Act (TSCA) Landfills.

**Background**

On April 4, 2012, the Utility Solid Waste Activities Group (USWAG) submitted a national risk-based disposal approval application in accordance with 40 CFR 761.61(c) to EPA. The request was for approval for the disposal of PCB remediation wastes generated at secure utility facilities containing “as-found” PCB concentrations of less than 50 ppm as well as PCB remediation wastes with non-porous surfaces having surface contamination less than 100 micrograms per square centimeter ( $\mu\text{g}/\text{cm}^2$ ) in non-TSCA approved landfills (e.g., municipal solid waste landfills).

On September 25, 2013, EPA issued a “Draft Risk Based Approval to Dispose of Polychlorinated Biphenyl (PCB) Remediation Waste” for public comment. After reviewing the comments EPA issued the final risk-based disposal approval to USWAG members. The final approval includes some changes in response to public comments.

**Conditions for Use of Approval**

At least two (2) days prior to the first shipment of PCB remediation wastes to a Non-TSCA Landfill the utility must post prominently on their website a copy of EPA’s June 10, 2014 approval letter and a notice to the public that the approval allows the utility to dispose PCB remediation wastes with as-found concentrations of less than 50 ppm PCBs in Non-TSCA approved landfills. The notice must also include utility contact information and remain posted on the utilities website until this approval expires.

The utility must also submit a notification to the EPA Regional PCB coordinator, the Office of Resource Conservation and Recovery (ORCR) Cleanup Programs Branch Chief, and the local government official by certified mail or e-mail at least two (2) days before the first shipment of wastes. The notification is required each time that the utility disposes of PCB Remediation Waste using this approval.

The notification must contain the following information:

1. USWAG member name and address;
2. EPA ID number of the utility site (if applicable);
3. Name and contact information (phone and e-mail address);
4. Name and contact information (phone, e-mail, and address) of the primary utility recordkeeping contact, if different from 3 above;
5. Site location (street address, city, county, state, and zip code; latitude/longitude coordinates may be used if the site does not have a street address);
6. Date waste was determined to be PCB remediation waste;
7. Size of site area containing the PCB remediation waste;
8. Description of the waste, including maximum as-found PCB concentration and estimated quantity to be disposed of under this Approval; and
9. Name, location, and type of facility where the waste will be disposed.

For each disposal conducted under this approval, the utility must provide written notice to the disposal facility stating that it will ship PCB remediation waste with as-found PCB concentrations of <50 ppm PCBs to the disposal facility.

The utility must maintain records of the PCB remediation waste disposed under this approval for at least five (5) years following the removal and disposal of the waste.

### Approved Disposal Facilities

Under this approval, PCB remediation wastes with as-found concentrations of PCBs < 50 ppm may be disposed in the following facilities:

1. Facilities licensed, permitted, or registered by a state to manage municipal solid waste under 40 CFR Part 258;
2. Facilities licensed, permitted, or registered by a state to manage non-municipal non-hazardous waste under 40 CFR 257.5-257.30; and
3. Hazardous waste landfills.

### USWAG Members

This approval is only applicable to USWAG member companies. A list of USWAG member companies is listed in Appendix II of the Approval. A link to the Approval is included in the Links Section below.

### Effective Date

This approval became effective on June 10, 2014, and will expire five years from the date of signature. In order to continue operating under this Approval a renewal application must be submitted to EPA at least 90 days prior to the expiration date of the approval.

### Link

The link below will allow you to view/print the final approval letter which includes the conditions and a list of USWAG member companies.

[http://www.epa.gov/epawaste/hazard/tsd/pcbs/pdf/USWAG\\_61c\\_FINAL\\_061014.pdf](http://www.epa.gov/epawaste/hazard/tsd/pcbs/pdf/USWAG_61c_FINAL_061014.pdf)

## B. DOT/PHMSA Hazardous Materials: Transportation of Lithium Batteries; Final Rule

On August 6, 2014, the Department of Transportation, Pipeline and Hazardous Materials Safety Administration (PHMSA) published a final rule (79 FR 46011-46040) in consultation with the Federal Aviation Administration (FAA) modifying the requirements governing the transportation of lithium cells and batteries.

### Summary

This final rule revises hazard communication and packaging provisions for lithium batteries and harmonizes the Hazardous Materials Regulations (HMR) with applicable provisions of the United Nations (UN) Model Regulations, the International Civil Aviation Organization's Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO Technical Instructions), and the International Maritime Dangerous Goods (IMDG) Code.

The following revisions are included in this final rule:

1. Replaces equivalent lithium content with Watt-hours for lithium ion cells and batteries;
2. Adopts separate shipping descriptions for lithium metal batteries and lithium ion batteries;
3. Revises provisions for the transport of small and medium lithium cells and batteries including cells and batteries packed with, or contained in, equipment;
4. Revises the requirements for the transport of lithium batteries for disposal or recycling;
5. Harmonizes the provisions for the transport of low production and prototype lithium cells and batteries with the ICAO Technical Instructions and the IMDG Code; and
6. Adopts new provisions for the transport of damaged, defective, and recalled lithium batteries.

The provisions of this final rule are consistent with Section 828 of the “FAA Modernization and Reform Act of 2012,” which prohibits DOT from issuing or enforcing any regulations or other requirement regarding the air transportation of lithium cells or batteries if the requirement is more stringent than the requirements of the ICAO Technical Instructions.

#### **Effective Date**

Voluntary compliance with these amendments is authorized on August 6, 2014 and mandatory compliance begins on February 6, 2015.

#### **Link**

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

<http://www.gpo.gov/fdsys/pkg/FR-2014-08-06/pdf/2014-18146.pdf>

### **C. DOT/PHMSA Hazardous Materials: Enhanced Tank Car Standards and Operational Controls for High-Hazard Flammable Trains; Notice of Proposed Rulemaking**

On August 1, 2014, the Department of Transportation, Pipeline and Hazardous Materials Safety Administration (PHMSA) published a notice of proposed rulemaking (79 FR 45015-45079) that would implement new operational requirements for certain trains transporting a large volume of Class 3 flammable liquids; improvements in tank car standards; and revisions to the general requirements for offerors to ensure proper classification and characterization of mined gases and liquids.

#### **Summary**

The proposed revisions are designed to lessen the frequency and consequences of train accidents/incidents involving certain trains transporting a large volume of flammable liquids. The growing reliance on trains to transport large volumes of flammable liquids poses a significant risk to life, property, and the environment.

Proposed revisions to the Hazardous Materials Regulations (HMR) include:

1. The term “High-hazard flammable train” (HHFT) would be defined as a train carrying 20 or more tank carloads of flammable liquids (including crude oil and ethanol);
2. Classification and characterization of mined gases and liquids would be improved by requiring written sampling and testing programs. Offerors would be required to certify that a sampling and testing program is in place, document the program, and make program information available to DOT personnel upon request;
3. Carriers would be required to perform a routing analysis for HHFTs that would consider safety and security factors and to select a route based on their findings of the analysis;
4. For trains containing one million gallons of Bakken crude oil, carriers would be required to notify State Emergency Response Commissions (SERCs) or other appropriate state delegated entities about the operation of these trains through their states;
5. Enhanced braking would be required for HHFTs;
6. New standards would apply to tank cars constructed after October 1, 2015 that are used to transport flammable liquids as part of a HHFT;
7. Existing tank cars that are used to transport flammable liquids as part of a HHFT would be retrofitted to meet the selected option for performance requirements. Those not retrofitted would be retired, repurposed, or operated under speed restrictions for up to five years, based on packing group assignment of the flammable liquids being shipped by rail.

## Comments Due

Comments on this advance notice of proposed rulemaking must be received by PHMSA on or before September 30, 2014.

## Link

The link below will allow you to view/print this advance notice of proposed rulemaking.

<http://www.gpo.gov/fdsys/pkg/FR-2014-08-01/pdf/2014-17764.pdf>

## D. DOT/PHMSA Hazardous Materials: Failure to Pay Civil Penalties; Final Rule

On August 7, 2014, the Department of Transportation, Pipeline and Hazardous Materials Safety Administration (PHMSA) published a final rule (79 FR 46194-46200) prohibiting a person who fails to pay a civil penalty or fails to abide by a payment agreement from performing activities regulated by the Hazardous Materials Regulations (HMR) until the payment is made.

## Summary

In response to a statute adopted in the MAP-21, PHMSA is adopting a new Subpart E to Part 109 setting forth procedures to require a person who is delinquent in paying civil penalties to cease regulated hazardous materials operations until payment has been made or an acceptable payment plan has been arranged. PHMSA is also adding procedural requirements to ensure that a person subject to the prohibition is notified in writing and given an opportunity to respond before being required to cease hazardous materials operations.

Under the provisions of this rule, the agency that issued the final order outlining the terms and outcome of an enforcement action will send the respondent a Cessation of Operations Order (COO) if payment has not been received within 45 calendar days after the payment due date or a payment plan installment date as specified in the final order. The COO would notify the respondent that it must cease hazardous materials operations on the 91<sup>st</sup> calendar day after failing to make payment in accordance with the agency's final order or payment plan arrangement, unless payment is made. A respondent will be allowed to appeal the COO within 20 days of receipt of the order according to the procedures set forth by the agency issuing the COO.

In accordance with MAP-21, the prohibition on hazardous materials operations shall not apply to a person unable to pay civil penalties because such person is a debtor in a case under Chapter 11 of the Bankruptcy Code. Such a person must provide the enforcing agency with the following information about its bankruptcy proceeding:

1. The chapter of the Bankruptcy Code under which the bankruptcy proceeding is filed (i.e., Chapter 7 or 11);
2. The bankruptcy case number;
3. The court in which the bankruptcy proceeding is filed; and
4. Any other information requested by the agency to determine a debtor's bankruptcy status.

This information will enable the agency to verify debtor status and to work with the bankruptcy court, if needed, to assess the debtor's ability to pay penalties when determining whether to prohibit hazardous materials operations.

PHMSA, FAA, FMCSA, and FRA caution regulated entities not to construe the right to appeal a COO as an opportunity to re-argue the merits of the penalty assessment. Regulated entities have had ample opportunity to address the merits of any proposed penalty assessment at earlier stages in the enforcement process. The only information sufficient to prevent the prohibition on hazardous materials

operations after nonpayment of penalties would be proof of payment, proof of bankruptcy debtor status and an ability to pay, or an Emergency Stay issued by a Federal District Court with jurisdiction over these matters. Additionally, at the discretion of the agency, upon appeal by the respondent, the agency can rescind the COO if an agreeable payment plan has been arranged. Persons that continue to conduct regulated activities in violation of the COO will be subject to additional penalties, including criminal prosecution pursuant to 49 U.S.C. 5124.

**Effective Date**

This final rule will become effective on September 8, 2014.

**Link**

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

<http://www.gpo.gov/fdsys/pkg/FR-2014-08-07/pdf/2014-18617.pdf>

**E. DOT/PHMSA Hazardous Materials: Special Permit and Approvals Standard Operating Procedures and Evaluation Process; Notice of Proposed Rulemaking**

On August 12, 2014, the Department of Transportation, Pipeline and Hazardous Materials Safety Administration (PHMSA) published a notice of proposed rulemaking (79 FR 47047-47063) that would revise the hazardous materials regulations to include the standard operating procedures and criteria used to evaluate applications for special permits and approvals.

**Background**

On July 6, 2012, President Obama signed the Moving Ahead for Progress in the 21<sup>st</sup> Century Act (MAP-21), which includes the Hazardous Materials Transportation Safety Improvement Act of 2012 (HMTSIA). In the HMTSIA, Congress directed PHMSA to issue a rulemaking to require: (1) standard operating procedures (SOPs) to support the administration of special permits and approval programs; and (2) objective criteria to support the evaluation of special permits and approval applications.

**Summary**

In this notice of proposed rulemaking (NPRM), PHMSA is proposing to revise 40 CFR 105.5, 107.1, 107.113, 107.117; add a new Appendix A (Standard Operating Procedures for Special Permits and Approvals) to 49 CFR Part 107; and revise 49 CFR 171.8 to incorporate the existing procedures for processing special permits and approval applications.

Appendix A to Part 107 includes the following table outlining the “Special Permit and Approval Evaluation Review Process.”

<b>Special Permit</b>	<b>Non-Classification Approval</b>	<b>Classification Approval</b>	<b>Registration Approval</b>
1. Completeness	1. Completeness	1. Completeness	1. Completeness
2. Publication			
3. Evaluation	2. Evaluation	2. Evaluation	2. Evaluation
a. Technical	a. Technical	a. Technical	a. Fitness Only
b. Fitness	b. Fitness		
4. Disposition	3. Disposition	3. Disposition	3. Disposition
a. Approval	a. Approval	a. Approval	a. Approval
b. Denial	b. Denial	b. Denial	b. Denial
5. Reconsideration	4. Reconsideration	4. Reconsideration	4. Reconsideration

## Comments Due

Comments on this NPRM must be submitted to PHMSA by October 14, 2014.

## Link

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

<http://www.gpo.gov/fdsys/pkg/FR-2014-08-12/pdf/2014-18925.pdf>

## F. DOT/PHMSA Hazardous Materials: Reverse Logistics (RRR); Notice of Proposed Rulemaking

On August 11, 2014, the Department of Transportation, Pipeline and Hazardous Materials Safety Administration (PHMSA) published a notice of proposed rulemaking (79 FR 46748-46758) that would revise the Hazardous Materials Regulations (HMR) applicable to return shipments of certain hazardous materials by motor vehicle.

### Summary

This notice of proposed rulemaking (NPRM) proposes to create a new section in the HMR with provisions tailored to the unique characteristics of reverse logistics. By creating an exception from existing regulations for certain reverse logistics shipments, this NPRM offers opportunities for reduced compliance costs among hazardous materials (hazmat) shippers and carriers, without any decrease in safety. In addition, PHMSA is addressing a reverse logistics issue related to the transportation of used automobile batteries to recycling centers. This change to the HMR will reduce the burden on the regulated community when consolidating shipments of lead acid batteries for recycling.

PHMSA is proposing the following changes in this NPRM:

#### 1. Define the Term “Reverse Logistics” in 49 CFR 171.8

“Reverse Logistics” is the process of moving goods from their final destination for the purpose of capturing value, recall, replacement, proper disposal, or similar reason.

#### 2. Applicability and Hazard Classes

Reverse logistics shipments would be limited to transportation by motor vehicle only and would not be subject to any other requirements of the HMR unless otherwise specified.

Reverse logistics shipments would be limited to only the following hazard classes: 1.4 (ammunition), 2.1, 2.2, 3, 4.1, 5.1, 5.2, 6.1, 6.2, 8, and 9 and in quantities as specified in a new 49 CFR 173.157(a).

#### 3. Packaging

The packaging requirements for the reverse logistics exception would be included in 49 CFR 173.157(b). PHMSA believes the proposed set of packaging standards under this NPRM would ensure a consistent and safe packaging requirement for low hazard items.

#### 4. Hazard Communication

PHMSA is proposing hazard communication requirements for packagings shipped under the reverse logistics exception.



5. Training

Employees shipping hazardous materials under the reverse logistics exception would not be required to be fully trained under 49 CFR Part 172, Subpart H. Relief from hazardous materials training for employees preparing reverse logistics shipments would be added to a new paragraph 49 CFR 173.157(d).

6. Exceptions and Segregation Requirements – 49 CFR 173.157(e)

PHMSA is proposing to adopt the following segregation requirements and authorize the following exceptions to hazardous materials shipped under the reverse logistics exception:

- a. A reverse logistics material may be transported by motor vehicle under the provisions of this section with other hazardous materials without affecting its eligibility for exceptions provided by this section.
- b. Hazardous materials that may react dangerously with one another may not be transported in the same outer packaging.
- c. Different hazard classes of materials in reverse logistics may be transported in the same cargo transport unit provided that they are adequately separated to prevent commingling of materials that may result in a dangerous reaction in the event of an accidental release during transport.
- d. Shipments made under this section are subject to the incident reporting requirements in 49 CFR 171.15.

7. Battery Recycling

PHMSA is proposing to revise 49 CFR 173.159(e) to allow for the pick-up of used automotive lead-acid batteries from multiple retail locations for the purposes of recycling subject to the following conditions:

- a. Any other material loaded in the same vehicle must be blocked, braced, or otherwise secured to prevent contact with or damage to the batteries. In addition, pallets used should be built as to not cause damage to another pallet in transportation.
- b. A carrier may accept shipments of lead acid batteries from multiple locations for the purpose of consolidating shipments of lead acid batteries for recycling.
- c. Class 8 lead acid batteries are the only hazardous material authorized on the transport vehicle under this section.
- d. Shipments made under this section are subject to the incident reporting requirements in 49 CFR 171.15.

**Comments Due**

Comments on this NPRM must be received by PHMSA by October 10, 2014.

**Link**

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

<http://www.gpo.gov/fdsys/pkg/FR-2014-08-11/pdf/2014-18741.pdf>

**G. DOT/PHMSA Hazardous Materials: Harmonization with International Standards (RRR); Advance Notice of Proposed Rulemaking**

On August 25, 2014, the Department of Transportation, Pipeline and Hazardous Materials Safety Administration (PHMSA) published a notice of proposed rulemaking (79 FR 50741-50834) to amend the Hazardous Materials Regulations (HMR) to maintain alignment with international standards by



incorporating various amendments, including changes to proper shipping names, hazard classes, packing groups, special provisions, packaging authorizations, air transport quantity limitations, and vessel stowage requirements.

## Summary

Following are some of the proposed revisions included in the NPRM:

### 1. Incorporation of Revised Standards

PHMSA is proposing to incorporate by reference the newest versions of various international hazardous materials standards. Included in these standards are: the 2015-2016 International Civil Aviation Organization Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO TI); Amendment 37-14 of the International Maritime Dangerous Goods Code (IMDG Code); the 18<sup>th</sup> Revised Edition of the United Nations Recommendations on the Transport of Dangerous Goods Code (UN Model Regulations); and the International Atomic Energy Agency (IAEA) Safety Standards for Protecting People and the Environment, Regulations for the Safe Transport of Radioactive Material, No. SSR-6, 2012 Edition.

### 2. Revisions to the Hazardous Materials Table (HMT) Entries

Proposed amendments to the 49 CFR 172.101 HMT to add, revise, or remove certain proper shipping names, hazard classes, packing groups, special provisions, packaging authorizations, bulk packaging requirements, passenger and cargo aircraft maximum quantity limits. The proposed changes mirror changes in the Dangerous Goods list of the 18<sup>th</sup> Revised Edition of the UN Model Regulations, the IMDG Code, and the ICAO TI.

### 3. Exceptions for Marine Pollutants

The NPRM proposes an exception from the Hazardous Materials Regulations (HMR) for marine pollutants up to 5 liters (1.3 gallons) for liquids or 5 kilograms (11 pounds) for solids when these materials are packaged in accordance with the general packaging requirements of 49 CFR 173.24 and 173.24(a).

### 4. Modifications to the Marine Pollutant List

PHMSA is proposing modifications to the list of marine pollutants in 49 CFR 172.101, Appendix B based on changes to the IMDG Code and an evaluation of listed materials.

### 5. Minimum Size Requirements for OVERPACK and SALVAGE Markings

These proposed amendments would add minimum sizes for OVERPACK and SALVAGE markings, requiring these markings to be at least 12 millimeters (0.47 inches) high.

### 6. Revisions to Vessel Stowage Requirements

PHMSA is proposing to revise and add stowage codes listed in column 10 B of the HMT and segregation requirements in 49 CFR 176.83 based on changes to the IMDG Code.

In addition, this NPRM would increase the required segregation distances between Division 4.3 dangerous when wet materials and Class 3 flammable liquids and Division 2.1 flammable gases.

7. Addition of Entries for Adsorbed Gases in the HMT

Revisions to the HMT to include seventeen new entries for adsorbed gases based on revisions to the UN Model Regulations. These revisions would also add a definition for adsorbed gas, authorized packagings, and safety requirements that include filling limits.

8. Revisions to Lithium Battery Requirements

This NPRM would harmonize the PHMSA requirements with the latest version of the ICAO Technical instructions for the packing, labeling, and shipping paper revisions.

9. Revised Definition of Non-Bulk Packaging

Proposes adding a new paragraph to the non-bulk packaging definition to include bags and boxes conforming to the applicable requirements for specification packagings in 49 CFR 178 Subpart L if they have a maximum net mass of 400 kilograms (882 pounds) or less.

**Comments Due**

Comments on this NPRM must be received by PHMSA by October 24, 2014.

**Link**

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

<http://www.gpo.gov/fdsys/pkg/FR-2014-08-25/pdf/2014-19161.pdf>

**H. OSHA Improve Tracking of Workplace Injuries and Illnesses; Supplemental Notice of Proposed Rulemaking and Extension of Comment Period**

On August 14, 2014, the Occupational Safety and Health Administration (OSHA) published a supplemental notice of proposed rulemaking (79 FR 47605-47610) extending the comment period for the “Improve Tracking of Workplace Injuries and Illnesses” proposed rule (78 FR 67253) and seeking comment on whether the proposed rule could cause employers to under-record employees’ injuries and illnesses.

**Summary**

On November 8, 2013, OSHA published a proposed rule to amend workplace injury and illness data collection requirements that would add requirements for the electronic submission of injury and illness information to OSHA. On January 9 and 10, 2014, OSHA held a public meeting on the proposed rule. One topic that dominated the comments was that the proposal might create a motivation for employers to under-record injuries and illnesses, since the injury and illness data would become publically available on OSHA’s website.

In this supplemental notice of proposed rulemaking OSHA is seeking comment on whether the proposed rule should be amended to:

1. Require that employers inform their employees of their right to report injuries and illnesses;
2. Require that any injury and illness reporting requirements established by the employer be reasonable and not unduly burdensome; and
3. Prohibit employers from taking adverse action against employees for reporting injuries and illnesses.

In addition, OSHA is seeking any information on employer's practices or policies that might discourage injury and illness reporting by employees and includes the following questions in the supplemental notice of proposed rulemaking:

1. Are you aware of situations where employers have discouraged the reporting of injuries and illnesses?
2. Will the fact that employer injury and illness statistics will be publically available on the internet cause some employers to discourage their employees from reporting injuries and illnesses?
3. Are you aware of any studies or reports on practices that discourage injury and illness reporting?
4. Do you or does your employer currently inform employees of their right to report injuries and illnesses?
5. Are there any difficulties or barriers an employer might face in trying to provide such information to its employees?
6. How might an employer best provide this information: orally to the employee, through a written notice, posting, or in some other manner?
7. What procedures do you or does your employer have about the time and manner of reporting injuries and illnesses?
8. Are you aware of any examples of reporting requirements that you consider to be unreasonably burdensome and could discourage reporting?
9. How should OSHA clarify the requirement that reporting requirements are "reasonable and not unduly burdensome?"
10. Are you aware of employer practices or policies to take adverse action against persons who report injuries or illnesses?
11. Are you aware of any particular situations where an employee decided not to report an injury or illness to his or her employer because of a fear that the employer would take adverse action against the employee?
12. What kinds of adverse actions might lead an employee to decide not to report an injury or illness?
13. Are there any practices that OSHA should explicitly exclude under this provision to ensure that employers are able to run an effective workplace safety program?
14. What other actions can OSHA take to address the issue of employers who discourage employees from reporting injuries and illnesses?

#### **Comments Due**

Following the extension of the comment period, comments must now be submitted to OSHA by October 14, 2014.

#### **Link**

The link below will allow you to view/print this supplemental notice of proposed rulemaking.

<http://www.gpo.gov/fdsys/pkg/FR-2014-08-14/pdf/2014-19083.pdf>

### **I. DHS Chemical Facility Anti-Terrorism Standards; Advance Notice of Proposed Rulemaking**

On August 18, 2014, the Department of Homeland Security (DHS) published an advance notice of proposed rulemaking (79 FR 48693-48696) requesting comments from the regulated community on proposed modifications or improvements that could be made to the Chemical Facility Anti-Terrorism (CFATS) Standards.

#### **Background**

The CFATS program requires any chemical facility that possesses a Chemical of Interest (COI) at or above the applicable Screening Threshold Quantity (STQ) to complete and submit to DHS through the Chemical Security Assessment Tool (CSAT) a Top-Screen Analysis. Any facility determined to be high-

risk following DHS's review of the Top-Screen Analysis is assigned a preliminary risk-based tier (Tiers 1-4) and must submit a Security Vulnerability Assessment (SVA) to DHS. DHS then evaluates the SVA and makes a final determination regarding whether the facility is high-risk, and if so, which tier it should be assigned. Any facility that receives a final high-risk determination from DHS must submit, obtain DHS approval of, and implement a Site Security Plan (SSP).

### Summary

In this advance notice of proposed rulemaking (ANPRM) the DHS is seeking recommendations from the regulated community on modifications or improvements that could be made to the CFATS standard. Some of the topics DHS is seeking comment are include:

1. Improvements to the information submission processes (i.e., the Top-Screen, SVA, and SSP submissions) and associated schedules;
2. The means and methods by which facilities claim a statutorily exempt status and whether or not commenters think that deletions, additions or modification to the list of exempt facilities should be considered;
3. The use of ASPs in lieu of SVAs and, in particular, the current limitation on the use of ASPs in lieu of SVAs to Tier 4 facilities;
4. The scope, tier applicability and processes for submitting and reviewing SSPs and ASPs;
5. The processes for submitting and evaluating requests for redetermination by chemical facilities previously determined to be high-risk;
6. The issuance of orders and the regulatory enforcement process; and
7. The treatment of non-Traditional Chemical Facilities;

### Comments Due

Comments on this ANPRM must be submitted to DHS on or before October 17, 2014.

### Link

The link below will allow you to view/print this advance notice of proposed rulemaking.

<http://www.gpo.gov/fdsys/pkg/FR-2014-08-18/pdf/2014-19356.pdf>

## J. **DOJ/DEA Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products from Schedule III to Schedule II; Final Rule**

On August 22, 2014, the Department of Justice, Drug Enforcement Administration (DEA) published a final rule (79 FR 49661-49682) rescheduling hydrocodone combination products from schedule III to schedule II of the Controlled Substances Act (CSA).

### Summary

A drug may be transferred between schedules if the CSA receives a petition to reschedule the drug from an interested party. The DEA received a petition requesting that hydrocodone combination products (HCPs) be controlled in schedule II of the CSA. Based on a consideration of all comments, the scientific and medical evaluation and recommendation from the Department of Health and Human Services, and based on DEA's consideration their eight factor analysis, the DEA has determined that:

1. HCPs have a high potential for abuse. The abuse potential of HCPs is comparable to the schedule II controlled substance oxycodone;
2. HCPs have a currently accepted medical use in treatment in the United States.
3. Abuse of HCPs may lead to severe psychological or physical dependence.

Therefore, DEA is publishing this final rule subjecting hydrocodone combination products to all regulatory controls as Schedule II substances.

**Effective Date**

This final rule will become effective on October 6, 2014.

**Link**

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

<http://www.gpo.gov/fdsys/pkg/FR-2014-08-22/pdf/2014-19922.pdf>

**K. DOJ/DEA Schedules of Controlled Substances: Placement of Suvorexant into Schedule IV; Final Rule**

On August 28, 2014, the Department of Justice, Drug Enforcement Administration (DEA) published a final rule (79 FR 51243-51247) placing suvorexant [(7R)-4-(5-chloro-1,3-benzoxazol-2-yl)-7-methyl-1,4-diazepan-1-yl][5-methyl-2-(2H-1,2,4-triazol-2-yl)phenyl]methanone including its salts, isomers, and salts of isomers, into schedule IV of the Controlled Substances Act (CSA).

**Summary**

Suvorexant is a new chemical developed for the treatment of insomnia. Suvorexant acts by inhibiting the orexin 1 (OX1) and orexin 2 (OX2) receptors. Based on a consideration of all comments, the scientific and medical evaluation and recommendation from the Department of Health and Human Services, and based on DEA's consideration of their eight factor analysis, the DEA has determined that a potential for abuse of suvorexant exists. Therefore DEA is publishing this final rule subjecting suvorexant, its salts, isomers, and salts of isomers to all regulatory controls as Schedule IV substances.

**Effective Date**

This final rule will become effective on September 29, 2014.

**Link**

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

<http://www.gpo.gov/fdsys/pkg/FR-2014-08-28/pdf/2014-20515.pdf>