VEOLIA
ENVIRONMENTAL SERVICES

TECHNICAL SOLUTIONS
NORTH AMERICA

REGULATORY UPDATE – October 2012

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A. EPA Revised RCRA Hazardous Waste Pharmaceutical Rule under Development

The Environmental Protection Agency (EPA) is in the process of developing a new proposal to establish standards for the management and disposal of hazardous waste pharmaceuticals generated by healthcare facilities. The revised rule will be implemented under the Resource Conservation and Recovery Act (RCRA) and will only apply to pharmaceutical wastes that meet the definition of a RCRA Hazardous Waste and are generated by a healthcare facility. These Pharmaceutical wastes will NOT be regulated under the Universal Hazardous Waste Program. EPA will also review existing pharmaceuticals to determine if any meet the definition of a hazardous waste and establish a process for reviewing new pharmaceuticals moving forward.

Proposed Rule Publication Date

EPA anticipates that the proposed rule will be published and available for comment in August 2013.

Link

Below is a link to EPA's Management of Waste Pharmaceuticals website.

http://www.epa.gov/wastes/hazard/generation/pharmaceuticals.htm

B. Obama Signs the Hazardous Waste Electronic Manifest Establishment Act (S. 710)

On October 5, 2013, President Obama signed the Hazardous Waste Electronic Manifest Establishment Act (S. 710). This legislation will establish an electronic system to track hazardous waste shipments and replace the current system requiring hazardous waste handlers to file multiple paper copies of hazardous waste manifests. EPA must complete a rulemaking for the electronic waste manifest system, but EPA has stated that the proposed regulations have already been drafted. When the rulemaking has been completed, a contractor must be hired to develop he software and set up the system. This entire process could take up to three years to implement.

Link

The link below will allow you to view/print the Hazardous Waste Electronic Manifest Establishment Act (S. 710) that has been signed by the President.

http://www.gpo.gov/fdsys/pkg/BILLS-112s710enr/pdf/BILLS-112s710enr.pdf

C. EPA Recommendation on the Disposal of Household Pharmaceuticals Collected by Take-Back Events, Mail-Back, and Other Collection Programs; Guidance Memo

On September 26, 2012, Suzanne Rudzinski, Director, EPA Office of Resource Conservation and Recovery (ORCR) issued a memorandum to the RCRA Division Directors titled

"Recommendation on the Disposal of Household Pharmaceuticals Collected by Take-Back Events, Mail-Back, and Other Collection Programs."

The guidance in this memo establishes or reconfirms the following policies:

1. Consistent with the Drug Enforcement Administration (DEA) regulations, the ultimate users of pharmaceuticals may not deliver their unused pharmaceuticals that are DEA regulated controlled substances to any other person for the purpose of disposal other than by surrender to law enforcement, including DEA. This restriction will remain in effect until DEA finalizes and implements regulations for the Secure and Responsible Drug Disposal Act of 2010.

2. EPA is establishing combustion in a permitted hazardous waste incinerator or cement kiln as the recommended best practice for the destruction of collected household pharmaceuticals.

3. EPA recognizes that due to the limited number of permitted hazardous waste combustors, that it may be cost prohibitive to dispose of household pharmaceuticals at hazardous waste combustors, therefore, if this is not feasible, combustion by small or large municipal waste combustors, as a minimum standard, is acceptable to meet both DEA's goal of preventing the diversion of controlled substances and EPA's goal of protecting the environment.

Link

Below is a link to the full text of this Memorandum.

http://www.epa.gov/osw/hazard/generation/pharmaceuticals/pharms-take-back-disposal.pdf

D. DOT/FMCSA Rescission of 10-Day Agency Discretionary Period in Assigning Unsatisfactory Safety Ratings; Final Rule

On October 23, 2012, the Department of Transportation, Federal Motor Carrier Safety Administration (FMCSA) published a final rule (77 FR 64759-64762) amending the Federal Motor Carrier Safety Regulations to remove the provision indicating that the Agency will consider 10-day extension of the 45-day period after which passenger and hazardous materials carriers must cease operation after receiving a proposed unsatisfactory safety rating.

Summary

The FMCSA had discontinued this practice as a matter of policy and in this final rule is amending the regulations to be consistent with Agency policy and statutory language. FMCSA will continue to review requests for upgrades of proposed unsatisfactory safety ratings for such carriers, but will no longer grant extensions to the 45-day period.

The purpose of this final rule is to bring 49 CFR 385.17(f) into conformity with §31144(c)(4) by removing the provision allowing a 10-day extension of the effective date of a proposed

unsatisfactory rating for motor carriers transporting passengers or hazardous materials in quantities requiring placarding.

Effective Date

This final rule will become effective on November 23, 2012.

Link

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

http://www.gpo.gov/fdsys/pkg/FR-2012-10-23/pdf/2012-26044.pdf

E. DOT/PHMSA Shippers – General Requirements for Shipments and Packagings; Correction

On October 2, 2012, the Department of Transportation, Pipeline and Hazardous Materials Administration (PHMSA) published a correction to the general requirements for shipments and packagings for shippers.

Summary

In this federal register publication PHMSA is issuing the following corrections to the hazardous materials regulations (HMR).

1. **49 CFR 173.333 Assignment of packing group and hazard zones for Division 6.1 materials**

   Paragraph (e) is reassigned as paragraph (c) and revised to read: *Transitional provisions.* The criteria for packing group assignments in effect on December 31, 2006, may continue to be used until January 1, 2012.

2. **49 CFR 173.134 Class 6, Division 6.2 – Definitions and exceptions**

   Paragraph (c)(2) is corrected to read:

   (2) The following materials may be offered for transportation and transported as a regulated medical waste when packaged in a rigid non-bulk packaging conforming to the general packaging requirements of 49 CFR 173.24 and 173.24(a) and packaging requirements specified in 29 CFR 1910.1030 and transported by a private or contract carrier in a vehicle used exclusively to transport regulated medical waste:

   (i) Waste stock or culture of a Category B infectious substance;
   (ii) Plant and animal waste regulated by the Animal and Plant Health Inspection Service (APHIS);
   (iii) Waste pharmaceutical materials;

(iv) Laboratory and recyclable wastes;
(v) Infectious substances that have been treated to eliminate or neutralize pathogens;
(vi) Forensic materials being transported for final destruction;
(vii) Rejected or recalled health care products;
(viii) Documents intended for destruction in accordance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) requirements; and
(ix) Medical or clinical equipment and laboratory products provided they are properly packaged and secured against exposure or contamination. Sharps containers must be securely closed to prevent leaks or punctures.

Effective Date

These corrections became effective on the date of publication, October 2, 2012.

Link

The link below will allow you to view/print these corrections.

http://www.gpo.gov/fdsys/pkg/FR-2012-10-02/pdf/2012-24294.pdf

F. DOT/PHMSA Hazardous Materials: Incorporation of Certain Special Permits and Competent Authorities into Regulations; Notice of Proposed Rulemaking

On October 22, 2012, the Department of Transportation, Pipeline and Hazardous Materials Safety Administration (PHMSA) published a notice of proposed rulemaking (77 FR 64450-64461) that would amend the Hazardous Materials Regulations (HMR) by incorporating provisions contained in certain widely used or longstanding special permits and competent authority approvals that have established safety records into the HMR.

Summary

These proposed revisions are intended to provide wider access to the regulatory flexibility offered in special permits and approvals and eliminate the need for numerous renewal requests, reducing paperwork burdens, and facilitating commerce while maintaining an appropriate level of safety.

PHMSA is proposing to incorporate the provisions contained in the following special permits and approvals:

Special Permits

1. DOT-SP 9275 – Authorization for the transportation in commerce of certain limited quantities of liquids and solids containing ethyl alcohol and exempt these shipments from the provisions of the HMR.

2. DOT-SP 11263 – Authorization for the transportation of Class 9 solid coal pitch compounds in non-specification open-top or closed-top sift proof metal cans or fiber drums.

3. DOT-SP 11836 – Authorization for the transportation in commerce of UN1H1 and UN6HA1 drums containing ammonia solutions that do not meet certain requirements contained in 49 CFR 173.24 and 173.24a.

4. DOT-SP 13124 – Authorization for the transportation of ammonia solutions in UN1H1 and UN6HA1 drums by private or contract carrier.

5. DOT-SP 12134 – Authorization for the exceptions for spent bleaching earth (Division 4.2 PG III).

6. DOT-SP 12825 – Authorization for the transportation of Life-saving appliances, self-inflating, that contain non-specification steel cylinders between a vessel and an authorized facility for servicing.

7. DOT-SP 14479 – Authorization for the use of alternative shipping names and marking requirements for regulated medical wastes.

8. Special Permits for Harmonization with the "FAA Modernization and Reform Act of 2012" – PHMSA is adding an exception to the HMR for Oxygen cylinders and other Oxidizing cylinders transported aboard aircraft within the state of Alaska. This language will make several existing special permits no longer necessary. This includes the following special permits: 14903, 14908, 15062, 15075, 15076, 15077, 15078, 15079, 15092, 15094, 15095, and 15143.

Competent Authority Approvals

1. CA2005120010 – Authorization to manufacture, mark, and sell UN4G combination packagings with outer fiberboard boxes and with inner fiberboard components that have basis weights that very by not more than plus or minus 5% from the measured basis weight in the initial design qualification test report.

2. CA20060660005 – Authorization to manufacture, mark, and sell UN5M1 and UN5M2 multi-wall paper bags with individual paper wall basis weights that very by plus or minus 5% from the nominal basis weights reported in the initial design qualification test report.

3. CA2006060006 – Authorization to manufacture, mark, and sell UN4G combination packagings with outer fiberboard components that have individual containerboard basis weights that very by plus or minus 5% from the nominal basis weight reported in the initial design.

4. CA2006010012 – Authorization to manufacture, mark, and sell UN4G combination packagings with outer fiberboard boxes and with inner fiberboard components that have

individual containerboard basis weight that vary by plus or minus 5% from the nominal basis weight reported in the initial design qualification test report.

PHMSA is also proposing to revise this section to allow for approval holders applying for a timely renewal to continue using their approval after the expiration date if they apply within 60 days of the expiration dates.

Comments Due

Comments on this notice of proposed rulemaking must be submitted to PHMSA on or before December 21, 2012.

Link

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

http://www.gpo.gov/fdsys/pkg/FR-2012-10-22/pdf/2012-25853.pdf

G. DOT/STB Civil Monetary Penalty Inflation Adjustment Rule; Final Rule

On October 22, 2012, the Department of Transportation, Surface Transportation Board (STB) published a final rule (77 FR 64431-64434) adjusting the civil monetary penalties for inflation pursuant to the Debt Collection Improvement Act of 1996.

Summary

Prior to the issuance of this final rule, the STB penalties have not been adjusted for inflation since 1996. Following are some of the civil penalty adjustments that could potentially impact Veolia.

U.S. Code Citation	Civil Monetary Penalty Description	Maximum Penalty Amount 1996	Adjusted Maximum Civil Penalty Amount
49 U.S.C. 14901(b)	Maximum penalty for each violation of the hazardous waste rules under section 3001 of the Solid Waste Disposal Act	$20,000	$22,000
49 U.S.C. 14901(e)	Minimum penalty for each violation of a transportation rule	$2,000	$2,200
49 U.S.C. 14901(e)(2)	Minimum penalty for each additional violation	$5,000	$5,500
49 U.S.C. 14907	Maximum penalty for recordkeeping/reporting violations	$5.000	$5,500

Effective Date

This final rule became effective on the date of publication, October 22, 2012.

Link

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

http://www.gpo.gov/fdsys/pkg/FR-2012-10-22/pdf/2012-25773.pdf

H. DOT/PHMSA Hazardous Materials: Minor Editorial Corrections and Clarifications (RRR); Final Rule

On October 5, 2012, the Department of Transportation, Pipeline and Hazardous Materials Safety Administration (PHMSA) published a final rule (77 FR 60935-60945) that corrects editiorial errors, makes minor regulatory changes, and in response to requests for clarification, improves the clarity of certain provisions in the Hazardous Materials Regulations.

Summary

Annually, PHMSA reviews the Hazardous Materials Regulations (HMR) to identify typographical errors, outdated addresses or other contact information and similar errors. In this final rule, PHMSA is correcting typographical errors, incorrect Code of Federal Regulations (CFR) references and citations, inconsistent use of terminology, misstatements of certain regulatory requirements, and inadvertent omissions of information. The amendments contained in this final rule are non-substantive changes and do not impose new requirements.

Effective Date

This final rule became effective on the date of publication, October 5, 2012.

Link

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

http://www.gpo.gov/fdsys/pkg/FR-2012-10-05/pdf/2012-24263.pdf

I. OSHA New State Activity Mandated Measures (SAMMs) Memorandum Issued

On October 11, 2012, the Occupational Safety and Health Administration (OSHA) director, Dr. David Michaels, issued a memorandum outlining new State Activity Mandated Measures (SAMMs) to the Agency's Regional Administrators.

Summary

SAMMs is a system for measuring how effectively States are enforcing workplace safety and health regulations. The updated measures focus on States' response times to complaints, how they assess penalties, and whether compliance officers are accompanied by workers during inspections. Other measurable in the revised SAMMs are:

1. Planned versus actual inspections;
2. Percent of inspections in the public sector;
3. Percent of inspections where establishments were found in compliance;
4. Average number of violations per inspection;
5. Average current serious penalty, with a breakout by total and size of employer;
6. Percent of high-hazard establishments inspected;
7. Percent of penalty retained after reductions;
8. Percent of fatalities responded to within one day;
9. Number of open, uncontested cases with incomplete abatement more than 60 days after citations were issued;
10. Average number of days between an inspection's opening conference and issuing citations;
11. Average number of work days to initiate complaint investigations;
12. Average number of work days to initiate complaint inspections;
13. Percent of imminent danger complaints and referrals responded to within one work day;
14. Number of inspections where entry was denied and entry was not obtained;
15. Percent of safety whistleblower investigations completed within 90 calendar days;
16. Average number of calendar days to complete a safety whistleblower investigation;
17. Percent of Safety whistleblower complaints determined to have merit; and
18. Percent of initial inspections with employee representation during the walk-around by inspectors or employer interviews.

Effective Date

The revised SAMMS system became effective on October 1, 2012.

J. DHHS Possession, Use, and Transfer of Select Agents and Toxins; Biennial Review; Final Rule

DoA Agricultural Bioterrorism Protection Act of 2002; Biennial Review and Republication of the Select Agency and Toxin List; Amendments to the Select Agent and Toxin Regulations; Final Rule

On October 5, 2012, the Department of Health and Human Services (HHS) and the Deparment of Agriculture, Animal and Plant Health Inspection Service (APHIS) published a final rules (77 FR 61083-61115 and 77 FR 61055-61081 respectively) removing or excluding select agents and toxins, adding 3 select agents, designating select agents and toxins as "Tier 1" agents, establishing new security requirements for entities possessing Tier 1 agents, and clarifying regulatory language concerning security, training, biosafety, and incident response.

Background

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Act) required the establishment of a list of biological agents and toxins that have the potential to pose a severe threat to public health and safety, animal or plant health, or animal or plant products. The Act also requires the list of select agents and toxins to be reviewed and republished on a biennial basis. This list was last republished in October 2008.

On July 2, 2010, President Obama signed Executive Order 13546: "Optimizing the Security of Biological Select Agents and Toxins in the United States" that directed HHS and APHIS to:

1. Designate a subset of select agents and toxins that present the greatest risk of deliberate misuse with the most significant potential for mass casualties or devastating effects on the economy, critical infrastructure, or public confidence (Tier 1 Chemicals);
2. Explore options for graded protection of Tier 1 agents and toxins to permit tailored risk management practices;
3. Consider reducing the number of agents and toxins on the Select Agents List;
4. Establish personnel reliability standards for individuals with access to Tier 1 select agents and toxins; and
5. Establish physical and information security standards for Tier 1 select agents and toxins.

On October 3, 2011, HHS (76 FR 61206) and APHIS (76 FR 61228) published proposed rules to amend and republish the list of select agents and toxins that have a potential to pose a severe threat to public health and safety, animal or plant health, or animal or plant products. In addition, APHIS held a public meeting to provide specific regulator guidance related to the Federal Select Agent Program on November 16, 2011.

Following a review of the comments received HHS and APHIS has published these final rules.

Summary

In this final rule HHS and APHIS have removed or excluded select agents, added select agents, and designated select agents as Tier 1 agents. Following is a list of the Tier 1 Chemicals

HHS Tier 1 Chemicals

- Ebola virus
- *Francisella tularensis*
- Marburg virus
- Variola major virus
- Variola minor virus
- *Yersinia pestis*
- Botulinum neurotoxin
- Botulinum neurotoxin producing species of *Clostridium*

APHIS Tier 1 Chemicals

- Foot-and-mouth disease virus
- Rinderpest virus

Crossover Tier 1 Chemicals

- *Bacillus anthracis*
- *Burkholderia mallei*
- *Burkholderia pseudomallei*

ADDITION OF SELECT AGENTS AND TOXINS

HHS has added three agents to the list of select agents and toxins. These materials are listed below:

- SARS-CoV virus
- Lujo virus
- Chapare virus

DELETION OF SELECT AGENTS AND TOXINS

Following are the agents deleted from the list of select agents and toxins:

HHS Agents Deleted

- Cercopithecine Herpesvirus 1 (Herpes B virus)
- *Clostridium perfringens* epsilon toxin
- *Coccidioides posadasii/Coccidioides immitis*
- Eastern Equine Encephalitis virus (South American type only)
- Flexal virus
- West African clade of Monkeypox virus
- *Rickettsia rickettsia*
- The non-short, Paralytic alpha conotoxins containing the following amino acid sequence $X_1CCX_2PACGX_3X_4X_5X_6CX_7$
- Shigatoxins
- Shiga-like ribosome inactivating proteins
- Staphylococcal Enterotoxins (non-A, non-B, non-C, non-D, and non-E subtypes)
- Tick-borne encephalitis complex viruses (Central European subtype)

APHIS Agents Deleted

- *Xylella fastidiosa*, citrus variegated chlorosis (CVC) strain
- Akabane virus
- Bluetongue Virus (exotic)

- Bovine Spongiform Encephalopathy Agent
- Camel Pox Virus
- *Ehrlichia Ruminantium* (Heartwater)
- Japanese Encephalitis Virus
- Malignant Catarrhal Fever Virus (Alcelaphine Herpesvirus Type 1)
- Menangle Virus
- Vesicular Stomatitis Virus (Exotic): Indiana Subtypes VSV-IN2, VSV-IN3

Overlap Agent Deleted

- Venezuelan Equine Encephalitis Virus (subtypes ID and IE)

AMENDMENTS

Following are some of the amendments included in the final rule:

1. Several Amended Definitions
2. Minimum Security Standards for Tier 1 Select Agents
    a. Security plan must be designed according to site-specific risk assessment and provide graded protection in accordance with the risk of the select agent or toxin
    b. Conduct complete inventory audits of select agents and toxins in long-term storage when specific events occur.
    c. Conduct a pre-access suitability assessment of persons who will have access to a Tier 1 select agent or toxin
    d. Training of employees with access to Tier 1 select agents and toxins on policies and procedures for reporting, evaluation, and corrective actions concerning the assessment of personnel suitability.
    e. Procedures that will limit access to a Tier 1 select agent or toxin to only those individuals who are approved by the HHS/APHIS Secretary or Administrator.
    f. A minimum of 3 security barriers where each security barrier adds to the delay in reaching secured areas where select agents and toxins are used or stored.
    g. Response time for security forces or local police must not exceed 15 minutes.
3. Additional Physical Security Measures for Variola Major and Minor Viruses
4. A Security Plan must be submitted for initial registrations, renewal registrations, or when requested.

Effective Date

By December 4, 2012, all entities that possess SARS, Chapare, and Lujo viruses must provide notice to the Centers for Disease Control regarding their possession of these viruses, and by April 3, all previously unregistered entities must meet all of the requirements of these final rules.

The remainder of the amendments will become effective on December 4, 2012.

Links

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

http://www.gpo.gov/fdsys/pkg/FR-2012-10-05/pdf/2012-24389.pdf

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

http://www.gpo.gov/fdsys/pkg/FR-2012-10-05/pdf/2012-24434.pdf

K. DOJ/DEA Schedules of Controlled Substances: Extension of Temporary Placement of Methylone into Schedule I of the Controlled Substances Act; Final Order

On October 18, 2012, the Department of Justice, Drug Enforcement Agency (DEA) published a final order (77 FR 64032-64033) extending the temporary scheduling of methylone (3,4-methylenedioxy-N-methylcathinone) including its salts, isomers, and salts of isomers into Schedule I of the Controlled Substances Act (CSA).

Summary

The temporary scheduling of methylone was scheduled to expire on October 20, 2012/ This final order extends the temporary scheduling of methylone to April 20, 2013, or until rulemaking proceedings are completed, whichever occurs first.

Effective Date

This final order became effective on October 18, 2012.

Link

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

http://www.gpo.gov/fdsys/pkg/FR-2012-10-18/pdf/2012-25510.pdf