Chemical & Material Risk Management Initiatives
REACH & Cr6+ Strategies
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   19a. **NAME OF RESPONSIBLE PERSON**
World-wide Trends

• **Use of Precautionary Principle**
  – Must understand health & environmental effects before using chemicals

• **Biomonitoring – What’s showing up in humans?**
  – Centers for Disease Control’s national biomonitoring & California voluntary program

• **Evolving Risk Assessment Science & Process**

• **Strict Chemical Management**
  – Cradle to grave

• **Green Chemistry**

• **International, Federal, & State Toxic Substances Laws**
  – Restrictions or banning of chemicals/materials (e.g., BPA)
  – California Green Chemistry Law
  – Minnesota “Toxic Free Kids Act”
  – Pending TSCA¹ reform

¹ Toxic Substances Control Act
Chemical & Material Risk Management
Directorate Portfolio

- Emerging Contaminants Program
- Green Chemistry & DoD Chemical Management Program
  - DoD REACH Strategic Plan signed in July 2010
- E.O. 13514 “Environmental, Energy, & Economic Performance”
  - Strategic Sustainability Performance Plan signed June 2010
- ESOH Policies & Procedures for DoD Acquisitions
  - Use of Life Cycle Assessment to inject sustainability considerations into acquisition process
What is an Emerging Contaminant?

• Chemicals & materials that have pathways to enter the environment and present potential unacceptable human health or environmental risks…

and either

• do not have peer-reviewed human health standards

or

• Standards/regulations are evolving due to new science, detection capabilities, or pathways.
EC “Scan-Watch-Action” Process

- Over-the-horizon
  - EC News
  - Possible DoD impacts
  - Phase I Assessment
  - Probable high DoD impacts
  - Phase II Assessment

- Review literature, periodicals, regulatory communications, etc.
- Monitor events; Conduct Phase I qualitative impact assessment
- Conduct Phase II quantitative impact assessment; develop & rank RMOs*

- Risk Management Options (RMOs) to ECGC
- Approved RMOs become Risk Management Actions (RMAs)
REACH

The European Union’s Regulation for “Registration, Evaluation, & Authorisation of Chemicals”
What is REACH?

- European Union’s massive chemical management regulation
- Enacted in June 2007 to replace some 40 pre-existing laws
  - Covers all 27 EU countries and some neighboring states
- Focuses on high-volume/exposure chemicals
- Will require application-specific authorization to use
  - Substances of Very High Concern (SVHCs)
    - Very persistent, very bio-accumulative (vPvB)
    - Carcinogens, mutagens and reproductive toxins
    - Risks must be adequately controlled OR benefits outweigh risks AND no alternatives exists
- Far more sweeping than EU’s Restriction of Hazardous Substances (RoHS)
  - 6 RoHS-regulated chemicals vs. ~30,000 REACH-registered chemical in ten years!
How Is REACH Being Implemented?

- The European Chemicals Agency (ECHA)
  - Formed by EU to manage REACH chemical data and collection

- Substance Information Exchange Forums (SIEFS)
  - Voluntary industry bodies created concerning specific chemicals to help gather and disseminate information

- Non-profit organizations (NGOs) and the public may request this information
Some Consequences of REACH

• REACH was enacted to
  – Provide better visibility and transparency of chemical exposure information to consumers
  – Decrease the use of toxic and hazardous chemicals in the EU
  – Shift the ‘Burden of Proof’ for the safety of materials to the manufacturer/supplier
  – Reduce future environmental and health damages due to chemical release and exposure

• ECHA registrations under REACH have skyrocketed from hundreds to thousands of chemicals within the past several months

• In 2011, ECHA expects to add 40 chemical bans

How will these developments impact chemical companies & defense industry?
What Is the Cost of REACH?
One industry estimate

If RoHS cost industry $1 dollar…

REACH will cost $12.
What About Defense Applications?

• Military Applications Were **Not** Considered
  – Yet there are very unique performance requirements for many defense materials

• Different EU Ministries of Defence (MODs) Have Different Opinions
  – REACH applies to
    - No military applications…
      - Some military applications…
        - All military applications

• No Blanket Military Exemption from REACH
  – Each Member State (MS) has the ability to issue narrow exemptions for military-unique products
# Potential Effects of REACH on DoD

<table>
<thead>
<tr>
<th>EXPECTED OUTCOMES ON COMMERCE</th>
<th>POTENTIAL IMPACTS TO DoD</th>
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<tr>
<td>Limiting/eliminating some chemical availability</td>
<td>Negative effects on U.S. military operations and maintenance in the EU</td>
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<td>Decreased material availability and increased costs for certain chemicals/articles</td>
<td>Disruption to defense supply chains outside the EU due to the global nature of supply</td>
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<td>Undisclosed substitution of chemicals in Commercial, Off-the-Shelf items</td>
<td>Failure or marginal performance of weapon systems or components of weapon systems</td>
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<td>Increased equipment costs passed on to foreign customers when substitute materials are available to satisfy individual country requirements</td>
<td>Increased equipment costs <em>eventually</em> passed on to DoD</td>
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<td>Different interpretations of REACH by each of the EU / participating states (30)</td>
<td>Disruption of U.S. and NATO interoperability (e.g., FMS)</td>
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<td>Accidental release of proprietary information</td>
<td>Accidental disclosure of classified or controlled unclassified information</td>
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<td>Accelerating the need to test and evaluate substitute materials</td>
<td>Increased DoD research and development costs</td>
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DoD Strategic Plan for REACH

- Signed out by Principal Deputy USD for AT&L\(^1\)
  - Cleared for public release
  - July 2010

- Defense Logistics Agency (DLA) has major role in identifying service-specific supply concerns

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\(^1\) Under Secretary of Defense for Acquisition, Technology and Logistics.
Goals of DoD’s REACH Strategic Plan

- Protecting the Availability of Substances of Significance to the DoD Mission
- Ensuring the Performance of Substitutes
- Guarding Against Disruptions to the Supply Chain
- Other Goals
  - Supporting defense exemptions
  - Minimizing negative impacts to Foreign Military Sales (FMS)
  - Capitalizing on Environment, Safety and Heath (EHS) improvements
  - Capitalizing on chemical management opportunities
  - Corroborating acquisition strategies
  - Planning for future regulations

A ‘Living Document’ in need of periodic updates
Nanomaterials

A class of materials (not individual chemicals) with at least one dimension between approximately 1 and 100 nanometers (nm)

Natural
- Natural Processes

Engineered
- Designed at nanoscale

Incidental
- Industrial Processes

Possess unique properties for both armament and personnel protection
Nanomaterials = EC Definition

- EU is regulating nanomaterials under REACH
  - Issued guidance for registrants to include information on nanomaterials in their dossiers submitted to ECHA
    - “No data, no market”
  - Issued labeling requirements for cosmetics, food additives, and other consumer products containing nanomaterials
- Individual countries are also reviewing their regulatory regimes for nanomaterials
DoD Hexavalent Chromium Minimization Strategy
Hexavalent Chromium (Cr6+) - Some Facts

- Cr6+ compounds are wonderful corrosion inhibitors

- Cr6+ compounds are highly toxic
  - We’ve learned how to use them safely
  - It can be expensive to control, store, dispose
  - Liability issues always loom

- National & international procedures and regulations are tightening

- There is a growing list of suitable substitutes for specific applications
Desired DoD Paradigm Shift

• Default use of Cr6+
• “Promotion” of substitutes
• Can result in business as usual

• Default use of substitutes
• Use of Cr6+ if no substitute can meet performance requirements
• Bias for change

Note: The required performance shouldn’t be based on Cr6+ but on a level of acceptable performance for the application
Three Part Cr6+ Strategy

Minimization Policy
Sets the Desired Course

Legacy Project
Minimizes Cr6+ in Existing Specs

Defense Federal Acquisition Rule
Minimizes Cr6+ in New Acquisitions
MEMORANDUM FOR SECRETARIES OF THE MILITARY DEPARTMENTS

SUBJECT: Minimizing the Use of Hexavalent Chromium (Cr⁶⁺)

Cr⁶⁺ is a significant chemical in numerous Department of Defense (DoD) weapons systems and platforms due to its corrosion protection properties. However, due to the serious human health and environmental risks related to its use, national and international restrictions and controls are increasing. These restrictions will continue to increase the regulatory burden and life cycle costs for DoD and decrease material availability. OSD, DoD Components, and industry have made substantial investments in finding suitable replacements for Cr⁶⁺ for many of the current DoD applications. In particular, a number of defense-related industries are minimizing or eliminating the use of Cr⁶⁺ where proven substitutes are available that provide acceptable performance for the application.

This is an extraordinary situation that requires DoD to go beyond established hazardous materials management processes. To more aggressively mitigate the unique risks to DoD operations posed by Cr⁶⁺, I direct the DoD Military Departments to take the following actions:

- Invest in appropriate research and development on substitutes.
- Ensure testing and qualification procedures are funded and conducted to qualify technically and economically suitable substitute materials and processes.
- Approve the use of alternatives where they can perform adequately for the intended application and operating environment. Where Cr⁶⁺ is produced as a by-product from use or manufacture of other acceptable chromium oxides, explore methods to minimize Cr⁶⁺ production.
- Update all relevant technical documents and specifications to authorize use of the qualified alternatives and, therefore, minimize the use of materials containing Cr⁶⁺.
- Document the system-specific Cr⁶⁺ risks and efforts to qualify less toxic alternatives in the Programmatic Environment, Safety, and Occupational Health Evaluations for the system. Analyses should include any cost/schedule risks and life cycle cost comparisons among alternatives. Life cycle comparisons should address material handling and disposal costs and system overhaul cycle times/costs due to any differences in corrosion protection.
- Share knowledge derived from research, development, testing and evaluations (RDT&E) and actual experiences with qualified alternatives.
Myth-busters

• The DoD policy **does not** ban the use of hexavalent chromium

• The policy **does** provide a strong forcing function to use substitutes...where they can meet performance requirements

• New systems...use **requires executive level approval**...must certify no acceptable substitute

• Legacy **systems**...evaluate substitutes during system **modifications** & maintenance, as practical
DFARs Clause
(Defense Federal Acquisition Regulations)

- **Purpose:** Implement the DoD policy and prevent unwanted/unknown hex chrome products from entering the system
- **DoD contracts/specs can’t result in:**
  - Deliverables with Cr6+ greater than 0.1% by weight
- **Exceptions:**
  - Legacy systems – those past Milestone A
    - But alternatives should be considered during system mods, overhauls, maintenance procedure updates
  - Sustainment contracts (parts, services) for systems where Cr6+ previously approved
  - Doesn’t include Cr6+ produced as a by-product of a process
Summary

• The DoD policy is proactive but practical
  – It strikes the right balance between mission performance & sustainable materials/processes

• The chemical management world is changing…those who adapt early will be stronger

Know what you are buying…know what’s in your products
Questions & Discussion

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Back-up Slides
# Important Dates

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| December 1, 2010 | By this date the following pre-registered 'phase-in' substances should have been registered when supplied at:
|               | ≥ 1000 tonnes per annum (tpa) or;                                           |
|               | ≥ 100 tpa and classified under CHIP as very toxic to aquatic organisms or;  |
|               | ≥ 1 tpa and classified under CHIP as Cat 1 or 2 carcinogens, mutagens or reproductive toxicants |
| June 1, 2013   | Deadline for registration of substances supplied at ≥ 100 tpa               |
| June 1, 2018   | Deadline for registration of substances supplied at ≥ 1 tpa                 |
Important Developments

• Imminent ‘improvements’ to Safety Data Sheets (SDSs), the EU equivalent of Material Safety Data Sheets (MSDSs)
  – Limits use of product to specified applications
  – More explicit ‘exposure scenarios’
• EUCOM reports transportation confusion and uncertainty
  – Even though transportation governed by Globally Harmonized System of Classification and Labelling of Chemicals (GHS) by 2012
• Eventual registration of products known as ‘articles’ that contain chemicals
  – Many may not have traditional SDSs and/or MSDSs
Limited Understanding of REACH By defense industrial suppliers

Percent of Personnel at Companies supplied the U.S. Military with **No** understanding of the REACH Regulation as it affects their companies

- Manufacturing Personnel: 43.1%
- Purchasing Personnel: 42.5%
- Senior Management: 29.7%
- Engineering Personnel: 28.6%
- Environment, Health & Safety Personnel: 3.4%


Demonstrates the need for more involvement of US firms in SIEF-like organizations for sharing information, etc.
Earlier Efforts to Promote Safe Handling of Nanomaterials

• Two Memoranda
  – Signed by USD(AT&L) in May 2008 to help manage chemical/material risks when uncertainty is very high
    • Greatest risk to DoD is to do nothing
  – Signed by DUSD(I&E) in October 2009 to create voluntary arrangement between DoD and the National Institute for Occupational Safety and Health (NIOSH)
    • Measure potential exposure to DoD research personnel
For More Information on REACH

• Website

• Legislation*

• Directive*

• See Also
  – 142-Page Comparative Analysis of Canadian, European Union and United States Policies

* Click on ‘EN’ for English versions.