



***Looking Deeper into  
Authorization and Restriction  
Impacts on the US***

**REACH Training Development  
Workshop  
October 15, 2009**

# The Authorization in REACH



- A list of **Substances of Very High Concern (SVHCs)** is being published and maintained by the European Chemicals Agency (ECHA)
  - The official listing of SVHCs is being maintained on the “Candidate List” of substances for Authorization
  - The first release of the Candidate List was published on October 28, 2008
  - The proposals for the 2<sup>nd</sup> Candidate List were posted September 1, 2009
  - Subsequent updates are expected on a regular basis
- The Candidate List will be evaluated periodically to determine if their continued use should require **Authorization**
  - And as a result, be included on the Annex XIV list for Authorization
- The EU wants to strongly restrict and control the use of SVHCs to protect human health and the environment

***SVHCs Must be Tracked to Ensure Compliance to Reporting and Authorization Requirements***

# The Authorization in REACH



- Process by which a substance is added to Annex XIV for Authorization:
  - Substance added to the Registry of Intentions as a proposed substance for the next update to the Candidate List as a SVHC
    - Note – The Registry of Intentions is also where substances are added prior to inclusion on Annex VI for labeling & classification, and Annex XVII for Restriction
  - Substance is added to the Candidate List as a SVHC
  - Substance is added from the Candidate List to the Priority List for proposed addition to Annex XIV
  - After a review period, substances on the Priority List are submitted to the European Commission for final approval & official addition to Annex XIV, requiring Authorization for continued use in the EU
- Once added to Annex XIV, Authorization from ECHA is required for continued use of the substance after a pre-defined sunset date
  - Along with Restriction, represents the highest measure of control for a substance under REACH

# Candidate List



## Current Candidate List for Substances of Very High Concern (SVHC)\*

Name of SVHC and CAS # listed below

Red = Proposed for Authorization

1. Anthracene – 120-12-7
2. **4,4'- Diaminodiphenylmethane – 101-77-9**
3. **Dibutyl phthalate – 84-74-2**
4. Cobalt dichloride – 7646-79-9
5. Diarsenic pentaoxide – 1303-28-2
6. Diarsenic trioxide – 1327-53-3
7. Sodium dichromate, dihydrate – 7789-12-0; 10588-01-9
8. **5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene) – 81-15-2**
9. **Bis (2-ethyl(hexyl)phthalate) (DEHP) – 117-81-7**
10. **Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified**  
→ ( $\alpha$  – HBCDD,  $\beta$ -HBCDD,  $\gamma$ -HBCDD)- 25637-99-4; 3194-55-6; (134237-51-7, 134237-50-6, 134237-52-8)
11. **Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins) – 85535-84-8**
12. Bis(tributyltin)oxide – 56-35-9
13. Lead hydrogen arsenate – 7784-40-9
14. Triethyl arsenate – 15606-95-8
15. **Benzyl butyl phthalate – 85-68-7**

\* = As of October 15, 2009

# Proposed Substances for 2<sup>nd</sup> Candidate List



## Proposal for 2<sup>nd</sup> Candidate List for Substances of Very High Concern (SVHC)\*

### Name of SVHC and CAS # listed below

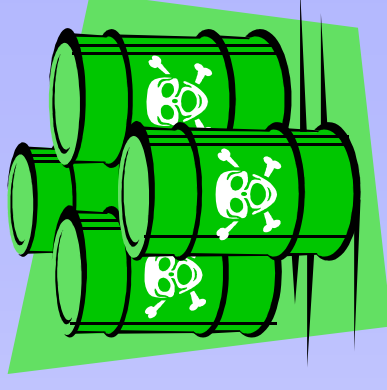
1. Anthracene oil – 90640-80-5
2. Anthracene oil, anthracene paste, distn. Lights – 91995-17-4
3. Anthracene oil, anthracene paste, anthracene fraction – 91995-15-2
4. Anthracene oil, anthracene-low – 90640-82-7
5. Anthracene oil, anthracene paste – 90640-81-6
6. Coal tar pitch, high temperature – 65996-93-2
7. Acrylamide – 79-06-1
8. Aluminosilicate, Refractory Ceramic Fibres
9. Zirconia Aluminosilicate, Refractory Ceramic Fibres
10. 2,4-Dinitrotoluene - 121-14-2
11. Diisobutyl phthalate – 84-69-5
12. Lead chromate – 7758-97-6
13. Lead chromate molybdate sulphate red (C.I. Pigment Red 104) – 12656-85-8
14. Lead sulfochromate yellow (C.I. Pigment Yellow 34) - 1344-37-2
15. Tris(2- chloroethyl)phosphate – 115-96-8

\* = As of October 15, 2009

# Criteria for Candidate List Substances



- Criteria for a Substance to be added to the Candidate List:
  - Carcinogens, Mutagens and Reproductive Toxins (CMRs)
  - Persistent, Bioaccumulative and Toxic (PBT)
  - very Persistent and very Bioaccumulative (vPvB)
  - There is "scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern"
  - Such substances are identified on a case-by-case basis
- Updates to the Candidate List of SVHCs overseen by ECHA
  - Additions to list are proposed by EU Member States through a "Registry of Intent", available to companies on the ECHA website



***List of SVHCs is Expected to Grow Dramatically***

# REACH Authorization in Brief



- Authorization will be required for Candidate List substances included in Annex XIV of REACH
- Applicants should investigate the possibility of substituting these substances with safer alternatives or technologies, and prepare substitution plans
  - May take years or decades to substitute some substances requiring Authorization
- Companies applying for Authorization may have to also demonstrate that risks associated with uses of these substances are adequately controlled or that the socio-economic benefits from their use outweigh the risks
- Applying for Authorization will be costly, and approval will not be automatic
  - Some uses will be denied and others restricted
- If granted, Authorizations will have an expiration date and require renewal
  - Implies that Authorization may not be a viable long-term solution

***Products Containing These Substances will face Increased Scrutiny from your Customers***

# Ranking for REACH Authorization Priorities

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- SVHCs will be introduced on the Candidate List over time
- According to Article 58(3), priority for inclusion in Annex XIV shall normally be given to substances with:
  - PBT or vPvB properties
  - Wide Dispersive Use
    - “Wide Dispersive Use” can refer to many small point sources or diffuse release, or activities which deliver uncontrolled exposure
  - High Volumes – the total annual tonnages are considered as:
    - Low volumes, if less than 10 t/y
    - *Relatively low* volumes, if 10 to 100 t/y
    - *Relatively high* volumes, if 100 to 1,000 t/y
    - High volumes, if 1,000 to 10,000 t/y
    - *Very high* volumes, if greater than 10,000 t/y

# Metals and Authorization



- Metals, and other substances in the periodic table, are naturally occurring in ores and will always exist
- It is more likely that a CMR metal will be restricted, with exemptions for certain uses (such as cadmium and lead)
- CMR metals are very unlikely to be priorities for Authorization
- However, metal compounds, especially organometal compounds, **are likely** to be subject to Authorization:
  - Where they are classified CMR category 1 or 2
  - Where they have high production volumes or dispersive uses
  - Where there is a strong political will to regulate
- Example: Hexavalent chrome compounds

***Could be of Particular Importance to Aerospace***

# Authorization and YOU



- **Imported Articles are not subject to Authorization**
  - However, you may still be impacted by products from your EU supply chain that are no longer available due to Authorization costs
- **Some SVHCs can not be removed from product designs quickly or easily:**
  - Aviation: Airworthiness / Certification
  - Availability of tested alternatives
  - Other existing contractual requirements
- **Manufacturers, importers, suppliers, and downstream users must work together to develop an approved alternative**

***Authorization Impacts may not be Direct,  
But They will be Felt Throughout the Industry***

# The Restriction in REACH



- Substances introduced onto Annex XVII of REACH are considered **Restricted** for a particular use within the EU
  - The use is important; unlike Authorization, substances that are added to Annex XVII are only Restricted for the use(s) identified
- Restricted substances are added to Annex XVII directly
  - Via a directive by the European Commission
- Restricted substances are **not** necessarily derived from the Candidate List of SVHCs
  - Implies there may not be advanced notice of a potential addition to Annex XVII on an official forum or list maintained by ECHA
- Initial Annex XVII list derived from heritage legislations
  - New substances beginning to be added to list in 2009

# Restriction and YOU



- **Imported Articles are subject to Restriction**
  - As opposed to Authorization, where they are exempt
- **Some Restricted substances may not be removed from product designs quickly, easily, or cheaply**
  - Sunset dates established to allow sufficient time for alternative substances to be utilized; may not always be enough time
- **Manufacturers, importers, suppliers, and downstream users must to work together to develop an approved alternative**
  - Restriction cannot be ignored, even if you do not sell into the EU
    - Suppliers may no longer be able to meet your demands for a product!

***There Is No Way Around Restriction!***

# What Actions Should I Take?



- Check to see if you have Candidate List or Restricted substances in your product
  - This includes component parts from your sub tier vendors
    - Where do the SVHCs come from?
    - Where do the products containing them go?
    - Are the products articles or substances/ preparations?
    - How much is imported?
      - For Authorization, you may be exempt if importing an article into the EU
- It can be expected that your customers in the EU and those supplying into the EU will start requesting this information
- To identify potential compliance issues and mitigate any disruptions

***REACH Requirements are in Effect  
Your Compliance Process Should be in Effect Too!***

# Questions

