Maintaining REACH SVHC Declarations

Compliance for Substances of Very High Concern

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Agenda

• Introduction
• REACH regulation
  - Article 33
  - Authorisation process
  - Definition of an article
  - Updating cycle
• SVHC declarations
  - Initial declaration
  - High risk SVHCs
  - Maintaining a REACH SVHC declaration
• Proposition 65
  - Overlap with REACH SVHC
  - Changes to Prop 65
• Q&A

Note - Presentation is only 50 minutes plus Q&A. Please submit questions so that we can address your specific issues.
Claigan Restricted Materials Services

• REACH
  - Product level REACH SVHC declarations
    • Engineering evaluation
    • Data gathering
    • Laboratory testing
• Related services
  - California Proposition 65
  - RoHS
    • Testing, data gathering, and technical files
  - Conflict minerals
    • World leader in due diligence and SEC disclosures
  - Global requirements
    • EU packaging directive, IATA lithium restrictions, EU battery directive, Health Canada (BPA), US FDA (latex), EU MDD (DEHP)
Overview - REACH Regulation

• Regulation (EC) No 1907/2006
  - concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
• Primarily concerned
  - Registration and safety of chemicals
• But does include requirements for articles
Article 33

• “Any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0,1 % weight by weight (w/w) shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.“

• This is for business to business sales

• Sales to a consumer are allowed 45 days to respond
  - But a sale of a consumer product to a business (retailer) do not benefit from the 45 day period
Authorisation Explained (Simplified)

1. **Substance** recommended by to become a candidate for authorisation by EU member state or ECHA

2. If unanimous agreement by EU member states that the substance qualifies as a cat 1 or 2 CMR, PBT, or vPvB

3. Substance recommended to become authorised by EU member state or ECHA

4. If approved by EU member states, the substance now requires authorisation to use

5. Substance, after a certain date, requires authorisation for use or addition to an article in the EU

Consultation by EU Member States (once every 6 months)

Proposal to add as candidate for authorisation

Addition to candidate for authorisation list (Now an SVHC)

Consultation by EU Member States

Addition to authorisation list

Substance requires authorisation
Definition of an Article

- Definition in dispute between EU member states
- Simplified definition
  - Any detachable physical item placed on the market in the EU
- Example (laptop)
  - Laptop
  - Detachable power cable
  - Laptop box (each packaging item is a separate article)
  - Mouse
  - Spare battery
  - Replacement motherboard
Update Cycle - SVHC List

- **Substance of Very High Concern**
  - The current list contains 151 substances (SVHCs)
  - Dec 2013 list

- **Update cycle**
  - New substances are added to the list every six months
  - ~17th to 20th of June and Dec of each year

- **New substances under consultation at the moment**
  - 1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear (DnHP variant)
  - Cadmium chloride
  - Sodium perborate; perboric acid, sodium salt
  - Sodium peroxometaborate
Creating an Initial SVHC Declaration

• Key items to account for in an initial declaration
  - What articles are require declaration?
  - What substances are likely to be in the article above 0.1% w/w?

• Substances and locations
  - How do I close the gaps?
  - Is there a way to declare materials in uncertain circumstances or declare them in a more general way?
What to Declare?

• Common focus of SVHC work for many companies
  - Main products they manufacture
    • Example - Benchtop analyzer
  - Every catalog component
    • Example - thick film resistors, ceramic capacitors, diodes, etc..
• In reality
  - SVHC primarily exist in accessories and consumables
    • Power cord, installation screw driver, lithium battery, probe
  - SVHC heavily biased towards custom components
    • Cables, probes, handles
Notable Declarable SVHCs in Articles

- **Phthalates** (DEHP, BBP, DBP, DnHP)
  - Plasticizers
  - Common between 5% to 30% w/w in
    - PVC, synthetic rubber, vinyl, sealants

- **1, 2-dimethoxyethane (EGDME)**
  - Common between 1% to 4% w/w in
    - Lithium manganese batteries

- **Cd**
  - Red dye in plastics
  - Brass
    - Cd content in not controlled in most brass alloys
  - Non-issue in RoHS compliance products
Phthalates

- DEHP, BBP, DBP is extraordinarily common in high concentrations in
  - cables
  - vinyl
  - strain relief
  - foam handles
- Supplier knowledge
  - Low to very low knowledge
  - Suppliers are incorrect in phthalate content in related materials
    - More than 50% of the time
    - (Based on laboratory testing by Claigan)
  - Worse in low cost products
    - both in terms of knowledge and change of contains DEHP
- Unless the supplier is extremely knowledgeable, assume they are incorrect regarding phthalate content
Industry Agreements / REACH Rules

• Not all materials are ‘created equal’
• Substances in polymers need to be declared
  - Such as PVC
• Substances in UVCB’s do not
  - Such as glass
• Example
  - PbO and B2O3 (not declarable in glass)
  - Glass is classified under REACH as an UVCB substance (substance of unknown or variable composition, complex reaction products or biological material) containing the elements silica, calcium, sodium, potassium, magnesium and other cations bonded together by oxygen. These elements are bonded into a non crystalline molecular structure with completely different properties in comparison to the starting raw materials. Glass does not contain the oxidized chemicals in the different raw materials. Therefore, as diboron trioxide and lead monoxide are not present in the glass in their molecular forms, there are no applicable obligations under the EU REACH regulation with regards to communication to customers and notification to ECHA for articles containing glass, due to the inclusion of diboron trioxide (EU 215-125-8) or lead monoxide (EN 215-267-0) in REACH Annex XIV.
Circuit Boards

- Primary sources of SVHCs on circuit boards
  - Diodes and thick film resistors
    - PbO
    - Not declarable (Pb in glass)
  - Button cell batteries
    - 1, 2-dimethoxyethane (EGDME)
  - Large aluminum capacitors with PVC sleeves
    - DEHP
- Very little risk of SVHC on circuit a board outside of the above
- As long as button cell batteries, and PVC sleeved aluminum capacitors are managed
  - Little risk in the circuit board
  - Significantly reduces data gathering / testing workload
Full Material Declaration

- **Full material declaration**
  - Not what you think it is
  - Declaration of all restricted substances in a part above 0.1%

- **Obvious issues**
  - Very difficult for complex components
  - Not generally available
  - No standard until recently

- **Fundamental issue**
  - Substances in polymers do not need to be declared on a safety data sheet
  - Examples
    - Stabilizers in plastics - example: Pb
    - Plasticizers in plastics - example: phthalates
    - Flame retardants in plastics - example: PBDE, HBCDD
  - Full material declaration provides no significant ‘future proofing’ for compliance
    - Example - BPA, antimony trioxide, Dec 2012 REACH SVHC list
Maintaining an SVHC Declaration

- SVHC list is updated every 6 months
  - Do you re-gather all of your SVHC data?
    - A lot of work
    - Most suppliers will not have an updated SVHC declaration

- Effective solution
  - Identify which of the new SVHCs
    - Are likely to be in any of your products above 0.1% w/w
  - Gather data for or test only the affected parts
  - Normally <1% of parts and materials
Review of Substances

- **Substance review**
  - What are the common uses of the new SVHC?
  - What materials contain those SVHCs?

- **Components review**
  - Which of my parts and materials
    - contain the identified materials that may contain SVHCs?
    - are large enough that the substance could be above 0.1% w/w in an article

- **Conduct data gathering or testing on those specific identified parts**

- **Note** - Many companies rely on specialist 3rd party companies to conduct the review above
  - Fairly inexpensive
Data Gathering or Testing of Key Substances

- **Data gathering**
  - For parts and components that may contain the new SVHC is sufficient mass
    - Data gathering from related suppliers is an option
    - Raw materials supplier
      - plastic compounder, paint manufacturer, etc...
      - generally good chance of having the information
    - Component suppliers
      - cable supplier, connector supplier
      - unlikely to have timely and correct data
    - Distributor
      - with some exceptions, extremely unlikely to have timely and correct data

- **Testing**
  - Often required for high risk materials
    - At least a sample
    - Normally a very small number of parts
  - Supplier knowledge is low and opportunity for error is very large for new SVHCs
OEM Products

- OEM products
  - Products that are designed and manufactured by another company
  - But sold under your brand

- Standard practice
  - Make disclosure of SVHC data part of the purchasing requirements / engineering specifications for OEM products
  - Select and test very high risk materials
    - Normally in parallel to another restricted materials verification
      - RoHS, prop 65, etc...

- OEM suppliers
  - Some provide very good SVHC declarations
    - And require little (if any) additional verification / testing
  - Many have no clue or want to charge you large $'s for the declaration
California Proposition 65

- Extremely high enforcement rate
  - 100 to 200 enforcements per month
- Substances have high overlap with REACH SVHC
  - Substances of highest enforcement for Prop 65
    - are mostly REACH SVHC or RoHS substances
    - Pb, Cd, Hg, DEHP, BBP, DBP.
  - But, Prop 65 does have a slightly larger number of high risk restricted substances
    - TDCPP, DIDP, DINP, Antimony Trioxide
- Common practice
  - Conduct compliance with Proposition 65 in parallel to compliance to EU REACH
  - Often requires specialized 3rd party support
    - But normally far more cost efficient
Change
US (California) - Proposition 65

- Proposed changes in consultation
  - Notification of authorities
  - Structure of warning
  - Mandatory communication of certain substances

- Timeline
  - Consultation and workshop in April
  - Rules to be finalized mid 2014
  - Updated rules to be adopted mid 2015
US (California) - Proposition 65
Notification of Authorities (Proposal)

- Within 30 days of placing a warning on a product
  - Authorities in California need to be notified
  - Notification can be individually or part of a group (authorized agent)

- Information to be included
  - The name and contact information for the person providing the warning.
  - The name and contact information for the manufacturer of any product the warning is intended to cover.
  - The specific products or category of products the warning is intended to cover, including barcodes, if any.
  - The type of occupational exposure to a listed chemical the warning is intended to cover, if any.
  - The type of environmental exposures the warning is intended to cover, if any, and the affected area.
  - The name of the chemical or chemicals for which the warning is being provided.
  - Whether the warning is being provided for cancer, or birth defects or other reproductive harm, or both.
  - The anticipated route, routes, or pathways of exposure to the listed chemical for which the warning is being provided.
  - Reasonably available information concerning the anticipated level of human exposure to the listed chemical, if known.
  - Information concerning actions a person can take to minimize or eliminate exposure to the listed chemical, if any.
  - Whether the warning is being provided in any language other than English and a copy of the translated warning, if any.
Warnings (if notified to the gov. of California) need to have 3 to 5 of the following elements

- Use of the signal word “WARNING”;
- Use of the word “expose” to be consistent with the language in the statute;
- The standard (Globally Harmonized System) pictogram for toxic hazards (only for consumer products other than foods, occupational and environmental warnings);
- Disclosure of the names of up to 12 commonly-known chemicals that require warnings, such as lead and mercury, in the text of the warning;
- A link to a new OEHHA website to allow the public to access more information relating to the warning, including additional chemicals, routes of exposure, and if applicable, any actions that individuals could take to reduce or avoid the exposure.
US (California) - Proposition 65

Mandatory Substances

- Substances that need to be identified on the warning
  - Acrylamide
  - Arsenic
  - Benzene
  - Cadmium
  - Chlorinated Tris (TDCPP)
  - 1,4-Dioxane
  - Formaldehyde
  - Lead
  - Mercury
  - Phthalates
  - Tobacco smoke
  - Toluene
Summary

- REACH SVHC
  - Identify the high risk materials
  - Identify the high risk articles
    - the power cable is higher risk than the laptop
  - Prosecute those high risk materials / articles
  - Assume that many suppliers will have no idea what they are doing

- Leverage
  - Related compliance work
    - Proposition 65
  - 3rd party specialized organization (such as Claigan)
    - easier, cheaper, more accurate
  - Procurement and engineering specifications
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Q&A
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