RoHS, RoHS II and Now RoHS III

Vinay Goyal

Disclaimer

- This presentation has nothing to do with my present or previous employers and their internal practices
- All the companies I worked for, or with, were successful companies in their respective fields
- Please seek professional advise from a consultant and/or legal counsel as applicable to your organization
On Saturday November 7, 2015:
I will be presenting on “Risk Management related to Product Environmental Compliance Requirements”
Today’s topic on RoHS:
Is a small and specific subset of “Global Product Environmental Requirements”
Growth of Product Environmental Requirements

Environmental Labels
First: for those who know enough about RoHS

I will address later to those who are new to RoHS

That is True ... RoHS3 is on its way.

This Directive adds four phthalates to the RoHS restricted substances, to be restricted in 2019
The four phthalates under added to “RoHS3”, are likely to be found in many soft rubber parts and PVC

- E.g. plastics, vinyl, labels, inks, synthetic rubber, epoxies, paints, sealing agents, coatings, adhesives and glues, polymers, polymer resistors, cables, wiring, handle grips, modeling clay, gaskets, rubber knobs and feet, and other materials

Where Used?

Challenges:

If you already have a RoHS program in place:

- You may have to either request all or selective suppliers whose product may containing these substances e.g. Rubber/Plastic material
- New written Declarations of Compliance
- Or an addendum to the previous Declaration

Update your compliance database for:

- Certificates
- Substance concentration

You may have to test your part(s) for the presence of phthalates and their concentration
The four phthalates CAS numbers, and common uses are:

- **Bis (2-ethylhexyl) phthalate (DEHP):** CAS # 117-81-7
  - Uses: used as plasticizer in manufacturing of articles made of PVC

- **Butyl benzyl phthalate (BBP):** CAS # 85-68-7
  - In addition to PVC plasticizer, used in adhesives and glues, vinyl floor coverings

- **Dibutyl phthalate (DBP):** CAS # 84-74-2
  - In addition to PVC plasticizer, used in printing inks, adhesives, sealants/grouting agents, nitrocellulose paints, film coatings and glass fibers

- **Diisobutyl phthalate (DIBP):** CAS # 84-69-5
  - In addition to PVC plasticizer, used in nitrocellulose plastic, paints, printing inks and adhesives, lacquer manufacturing
That is True ... RoHS3 is on its way.

- Challenge for those who have created Full Material Disclosure (FMD)
- The CAS numbers for these four phthalates are often buried in polymers, epoxies and PVC CAS numbers, so any CAS numbers for these materials will need to be expanded to the specific substances in these materials, or a written declaration will need to be supplemented in addition to the FMD

That is True ... RoHS3 is on its way.

- 2019 might seem like a long way off to meet these compliance deadlines, but think about companies are still struggling in managing their RoHS compliance after its first release in 2002 (RoHS1)
Especially those who are new to RoHS and recently joining the industry that is required to be RoHS compliant

RoHS

- It is a EU directive
  - RoHS I: Directive 2002/95/EC
  - RoHS II: Directive 2011/65/EU
  - RoHS III: TBD
- EU has three types of legislative acts
  - Directive
  - Regulation
  - Proclamation
RoHS

Rule # 1: (Continued)
- It may be directly applicable if:
  - Placing product on any EU member market
    - Currently 28 Countries
      - Recent survey showed that some customers in non-EU countries prefer to have RoHS compliant product over non-compliant product (though they do not have any national regulations)
  - Who is ultimately placing the product (or responsible)
    - Manufacturers in the EU
    - Importers in the EU
    - Customers, distributors, dealers, retailers, your office or warehouse
- Does not apply to Chemical Products
Rule # 1: (Continued)

It may be indirectly applicable if:

Your customer is integrating your part, sub-assembly or the product in its product that is within the scope of RoHS (placing on the market in EU market)

Rule # 2:

If it falls under the definition of Electrical and Electronic Equipment (EEE) in Directive Annex I

EEE: ‘electrical and electronic equipment’ or ‘EEE’ means equipment which is dependent on electric currents or electromagnetic fields in order to work properly and equipment for the generation, transfer and measurement of such currents and fields and designed for use with a voltage rating not exceeding 1,000 volts for alternating current and 1,500 volts for direct current;

‘Dependent: needing electric currents or electromagnetic fields to fulfill at least one intended function;’

‘Cables’ means all cables with a rated voltage of less than 250 volts that serve as a connection or an extension to connect EEE to the electrical outlet or to connect two or more EEE to each other
RoHS

Rule # 2: (Continued)

Correct Interpretation: Anything that is essential and integral part of the EEE

- Electrical, Electronic, Mechanical, Plastics, Cables, Wires, Nut, Bolt, Screw, Computer and Peripheral products, labels, Ink, paint, plating, varnish, etc.
- If one of the parts is not compliant, the entire product is considered non-compliant

Misconception:
- Applies to EEE and its electrical and electronic parts, assemblies only

Consumables:
- If contains electrical and electronic element

RoHS

Rule # 2: (Continued)

And falls in one of the EEE categories listed in Annex I
- Except Category 11
  - Category 1-7 and 10:
    - From July 1, 2006
  - Category 8: (Medical)
    - Medical: From July 22, 2014
    - IVD: From July 22, 2016
  - Category 9: (Monitoring and Control Devices)
    - Monitoring and Control: From July 22, 2014
    - Industrial Monitoring and Control: From July 22, 2017
  - Category 11: Enforcement date is July 22, 2019
RoHS

Rule # 3:
- If you have any of the restricted substances above the threshold limit
  - Lead (Pb): 0.1% or 1000 ppm
  - Mercury (Hg): 0.1% or 1000 ppm
  - Hexavalent Chromium (Cr6): 0.1% or 1000 ppm
  - Poly Brominated BiPhenyl Ether (PBB): 0.1% or 1000 ppm
  - Poly Brominated DiPhenyl Ether (PBDE): 0.1% or 1000 ppm
  - Cadmium (Cd): .01% or 100 ppm
- At homogenous Material Level:
  - ‘homogeneous material’ means one material of uniform composition throughout or a material, consisting of a combination of materials, that cannot be disjointed or separated into different materials by mechanical actions such as unscrewing, cutting, crushing, grinding and abrasive processes

Rule # 4:
- Exemptions:
  - Is your product/part RoHS exempts:
    - Fully or:
      - Example: equipment necessary for the protection of the essential interests of the security of Member States, including arms, munitions and war material intended for specifically military purposes
      - Equipment designed to be sent into space
      - Large-scale stationary industrial tools;
      - Means of transport for persons or goods
      - Active implantable medical devices;
      - Solar Panels
      - Solely for the purposes of research and development only made available on a business-to-business basis. (a few – not on production level)
RoHS

Rule # 4: (Continued)

- Partially
  - Typically for Parts (certain parts are RoHS compliant by exemption)
  - Exemptions can be requested 18 months prior to enforcement with solid justification e.g. lack of technology, reliability data, socio-economic reasons
- Expensive and tedious process
- Annex III (for all kinds of products), and
- Annex IV (specifically for Medical, IVD and Monitoring and Control EEE)
- Battery and Packaging are outside the scope of RoHS
- They are regulated by EU Battery Directive and EU Packaging Directive

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RoHS

Rule # 4: (Continued)

- Caution:
  - Make sure that exemption is not expired
  - Some exemptions have earlier sunset date
  - Exemption for commercial products
    - Expires on July 21, 2016
  - Exemption for Medical, IVD, Monitoring and Control
    - Expires 7 years after the RoHS enforcement date
RoHS

Rule # 4: (Continued)
- Category 1 to 7 and 10 (Directive annex I)
  - Expires on July 21, 2016 (unless someone applied for further exemption – extend exemption deadline)
- Category 8
  - Medical: July 22, 2014 + 7 Years = July 21, 2021
  - IVD: July 22, 2016 + 7 Years – July 21, 2023
- Category 9
  - Monitoring and Control: July 22, 2014 + 7 Years = July 22, 2021
  - Industrial

Other requirements

- Record retention:
  - Minimum 10 years
- Marking:
  - RoHS Directive is a CE Marking directive
    - Comply with requirements applicable to CE Marking,
    - Declaration of Conformity and
    - Technical File
    - If a product has a CE mark (complying with all applicable CE Marking directive requirements but not RoHS compliant on or before its applicable enforcement date, it cannot have the CE mark on the product and therefore cannot be placed on the EU market
      - CE Mark is like a Passport (Product must be fully compliant to all applicable CE Marking directives requirements)
Other requirements

- Enforcement Agency
- Competent Authorities in EU member countries
- Note: Not required Notified Body (NB) audit but you can chose to use NB.

Compliance Risk:

- If your product is not compliant:
  - Even one part
  - Your product is considered non-compliant
  - That means, you cannot place CE marking on your products
  - You cannot ship/place on the EU market
- Shipping a non compliant product or Falsifying data may cause
  - Fines,
  - Stop ship,
  - Bad press
  - Recall, rework,
  - Jail time.....Etc.
Questions

vinaygoyal@sbcglobal.net
714-876-4277