RoHS and REACH

Effects on Wire & Cable and Medical Devices Industries

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Content

- Overview of issues specific to these industries :
  - Wire & Cable
  - Medical devices

  - RoHS scope questions:
  - RoHS exemption requests; practical experience of the process
  - Key substance issues: obsolescence and management

Wire and Cable

- RoHS: Pb/Cd in PVC less of a problem?
- RoHS2: Understanding of cable categorisation
- RoHS2: Additional substances
- REACH: SVHCs

Recast scope

- *Cables*

- All separately sold cables with rated voltage <250V are in scope
  - Those connected to EEE are same status as EEE
  - Purpose designed cables depend on purpose
    - e.g. USB cable is category 3
  - Extension leads are in category 2 in some EU States but excluded from RoHS in others (e.g. UK)
    - Where currently excluded, these will enter scope July 2019
  - Wire and cable on reels
    - Will be in scope 2019 – this is not finished EEE so do not CE mark (FAQ unclear)

REACH and the RoHS2 additional substances study

- Likely outcome?
  - risk assessment of the 3 phthalates – possible restriction
- The future
  - more studies are very likely including overlapping substances
  - will increase pressure for wider removal of these substances from supply chain generally

REACH SVHCs relevant to cables

- *e.g. Plasticisers in PVC*

Substance	Annex XIV?	Sunset date
benzyl butyl phthalate (BBP)	21 Feb 2011	21 Feb 2015
di (2-ethylhexyl) phthalate (or bis(2-ethylhexyl) phthalate) (DEHP)	21 Feb 2011	21 Feb 2015
dibutyl phthalate (DBP)	21 Feb 2011	21 Feb 2015
di-isobutyl phthalate; diisobutyl phthalate; (DIBP)	18 Feb 2012	21 Feb 2015
1,2-benzenedicarboxylic acid, di-C6-8-branched alkylesters, C7-rich; Di-n-heptyl phthalate (DNHP or DIHP)	no	
1,2-benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DNHUP)	no	
bis(2-methoxyethyl) phthalate; 1,2-Benzenedicarboxylic acid, bis(2-methoxyethyl) ester	no	
di-n-pentylphthalate; dipentylphthalate (DNPP or DPP)	no	

REACH SVHCs relevant to cables

- *e.g. Stabilisers in PVC*

Substance	Annex XIV?	Sunset date
tris 2-chloroethyl phosphate (TCEP)	18 Feb 2012	21 Aug 2015
bisphenol A	not SVHC	
lead (II) carbonate basic	no	
pentalead tetraoxide sulphate	no	
dioxobis(stearato)trilead	no	
tetralead trioxide sulphate	no	
phthalato(2-dioxotrilead)	no	
lead cynamidate	no	
trilead dioxide phosphonate	no	
dibutyl tin dichloride; DBT	no	
fatty acids, C16-18, lead salts	no	
sulfurous acid, lead salt, dibasic	no	
tris 2-chloroethyl phosphate (TCEP)	no	

Medical Devices

- RoHS2: Reminder of Categories and timings
- RoHS2: Exclusions and ‘large scale’
- RoHS2: Progress on compliance, exemptions status and learning points
- REACH: Potential restriction of BPA
- REACH: Reagents

RoHS substance restrictions

- *Timetable*

- 2 Jan 2013
  - Conformity assessment of products already covered
- 22 July 2014
  - Medical devices - *Category 8*
  - Monitoring and control instruments - *Category 9*
- 22 July 2016
  - In Vitro Diagnostics (IVD)
- 22 July 2017
  - Industrial monitoring and control instruments* - *Category 9*
- 22 July 2019
  - Other equipment (subject to review) – *Category 11*

* includes both industrial AND professional units but they must be designed exclusively for this use

Do products need to comply?

- *"Large-scale" exclusion*

- Exclusions include
  - LSIT – large-scale stationary industrial tools
  - LSFI – large-scale fixed installations
  - Difference not clear. LSIT definition appears different to RoHS1 FAQ definition
- Large-scale defined
  - Can use one or more of several optional criteria
    - Size, Weight, Power consumption, Etc.
  - Note that most "equipment" is designed to be installed as part of LSIT or LSFI and will be excluded (by Article 2.4c) if it

    a. Is specifically designed and is to be installed .....

    And

    b. Can be replaced only by the same specifically designed equipment

Do products need to comply?

- *Scope – new exclusion Article 2.4c*

- Recast Directive does not apply to equipment which:
  - "Is specifically designed and is to be installed as part of another type of equipment that is excluded or does not fall within scope of this directive,
  - which can fulfil its function only if it is part of that equipment
  - and which can be replaced only by the same specifically designed equipment"
- This means that specifically designed equipment (e.g. lighting) installed into a type of excluded equipment, such as a LSFI is itself excluded but only if the equipment can be replaced only by the same specifically designed equipment
  - Note that "equipment" is not clearly defined by RoHS recast
  - Components do not need to comply if used in out of scope EEE (except separately sold cables)

Do products need to comply?

- *Impact of WEEE2 (2012/19/EU) FAQ*

- The draft WEEE FAQ also define LSIT and LSFI
  - Based on and refers to RoHS2 FAQ but elaborated
    - LSFIs tend to be tailor-made unique installations, whereas LSIT need not be unique or custom designed
    - Custom PCs designed specifically for use in LSFI/LSIR out of scope
    - Facility comprising items of independent equipment is not LSFI
    - “Rule of thumb” criteria to define the term ‘large’ for LSSIT:
      - minimum weight of 3 tons
      - dimension of at least 2.5 m x 2.5 m

Annex IV exemptions status

- Medical devices sector engaged well in ERA study for the European Commission (2006)
  - Requested, reviewed
  - 20 (covering Categories 8 and 9) were justified and were added to Annex IV
- Subsequently discovered more exemptions were needed
  - some single manufacturers,
  - some coordinated
  - in general well researched and presented
- Öko has reviewed these and recommended many to be granted >>

Annex IV exemption requests

- *Examples of review recommendations*

Applicant	Request	Expiry date
COCIR	Hexavalent chromium in alkali dispensers used to create photocathodes ... in X-ray image intensifiers ... and in spare parts for X-ray systems placed on the EU market before 1 Jan 2020	31 December 2019 (except in spare parts)
COCIR	Lead, cadmium and hexavalent chromium in reused spare parts, recovered from medical devices placed on the market before 22 July 2014 and used in category 8 equipment placed on the market before July 22 2021 ... (auditable closed-loop business-to-business)	21 July 2021
COCIR	Lead in solders on printed circuit boards of detectors and data acquisition units for Positron Emission Tomographs which are integrated into Magnetic Resonance Imaging equipment.	31 December 2019
COCIR	Lead in solders on populated printed circuit boards used in Directive 93/42/EEC class IIa and IIb mobile medical devices others than portable emergency defibrillators: ...	Class IIa: 30 June 2016 Class IIb: 31 December 2020
CELMA	Decorative lamps for lead and/or cadmium (2 requests)	Requests denied
ANIE	Mercury in cold cathode fluorescent lamps for luminous sign and general purpose lighting (2 requests)	Requests withdrawn by applicant
JBCE	Lead in micro-channel plates (MCPs	21 July 2021 for medical equipment 21 July 2023 for in-vitro diagnostics
Therakos Photopheresis	Lead as an activator in the fluorescent powder of discharge lamps when used for extracorporeal photopheresis lamps containing BSP (BaSi2O5:Pb) phosphors	22 July 2021

Annex IV exemption requests

- *Latest review recommendations (19 Sept 2013)*

Applicant	Request	Recommendation
TMC	Lead in glass of electronic components and fluorescent tubes, or in electronic ceramic parts (including dielectric ceramic capacitors) used in industrial monitoring & control instruments (only sub-category 9 industrial), exemption to expire in 2024.	Grant but with reduced scope and timescale
TMC	Lead used in compliant pin connector systems for use in industrial monitoring and control instruments (only sub-category 9 industrial), exemption to expire in 2024	Grant but possibly with reduced scope and timescale
TMC	Mercury in cold cathode fluorescent lamps (CCFL) for back-lighting liquid crystal displays not exceeding 5 mg per lamp used in industrial monitoring and control instruments (only sub-category 9 industrial)	Grant to 22/7/2017
JBCE	Lead in platinized platinum electrodes for measurement instruments	Grant
STIHL	Lead in solders for the ignition module and other electronic engine controls mounted directly on or close to the cylinder of hand-held engines (classes SH: 1, SH: 2, SH: 3 of 2002/88/EC)	Grant
ESF	Hand crafted luminous discharge tubes (HLDT) used for signs, decorative or general lighting and light-artwork (mercury)	Grant
GE	Lead in stacked area array electronics in ionizing radiation detectors for CT and X-ray systems	In progress

Annex IV exemptions

- *Current consultation*

- 5 requests including
  - "Lead in solders used in boards of heart-lung machines" exemption to expire in 2017
    - Conversion of old design

REACH

- *Potential restriction of BPA*

- Bisphenol A
  - used to make epoxy resins, polycarbonate and several other plastics, including PVC
  - has been found in end products, including electrical products, as an impurity
- Reclassification?
  - ECHA consulting until 1 October
  - Propose reproductive toxin category 2> reproductive toxin category 1B
  - BPA would meet criteria for an SVHC
    - authorisation?

REACH/Classification, Labelling & Packaging

- *Impact on reagents*

- Reagents
  - Low volume
  - Financially important
- Registration probably not necessary
  - However notification required if hazardous according to CLP irrespective of volume
- Could be subject to authorisation impacted if also used in large volume in other applications
  - Consider your inventory
  - Consider other uses and likelihood of this occurring
  - Note progress of Rolls-Royce request

AIMDD - MDD

- *Revision*

- Pressure to tighten substance requirements
  - Accelerated phase out of hazardous substances