Guidance on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (RoHS) Regulations 2012

Two Parts:
1. Products first placed on the market between 1 July 2006 and 1 January 2013
2. Businesses and individuals placing or making electrical and electronic equipment available on the UK market from 2 January 2013.
Products first placed on the market between 1 July 2006 and 1 January 2013, under the 2008 RoHS Regulations

- Explains the requirements of the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2008 (the RoHS Regulations)
- It is intended for businesses and individuals placing or making electrical and electronic equipment available on the UK market between 1 July 2006 and 1 January 2013
- It explains the requirements on business, how to comply with the law and provides sources of further information
Obligations

• Economic operators must be able to demonstrate compliance by submitting an EU Declaration of Conformity and technical documentation or other information to the market surveillance authority on request and must retain such documentation for a period of ten years after the EEE is placed on the market.

• In the UK responsibility for the enforcement of the RoHS Regulations lies with the Secretary of State for Business, Innovation & Skills, who has appointed the National Measurement Office (NMO), an executive agency of the Department, to act on his behalf.
RoHS 1

• My device was on the market between 1 July 2006 and 1 January 2013
  – Yes: RoHS 1 applies
  – No: RoHS 2 applies

• Yes, it was on the market before 1 January 2013 but we have modified it in some way
  – I would think RoHS 2 applies but I would put the question to the National Measurement Office
Businesses and individuals placing or making electrical and electronic equipment available on the UK market from 2 January 2013

- Updated 6 September 2013
- Explains the requirements of the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012 (the RoHS 2 Regulations)
- Placing or making electrical and electronic equipment available on the UK market from 2 January 2013
- It explains the requirements on business, how to comply with the law and provides sources of further information.
RoHS 2

• Economic operators may not place, or make available, EEE containing lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE), in amounts exceeding the established maximum concentration values, on the market.

• Finished EEE must be CE marked.

• With the exception of some categories (where certain parts of the regulation apply on special dates), EEE that was outside the scope of the 2008 Regulations does not need to comply with the new Regulations until 22 July 2019
RoHS 2: Category 8 Medical Devices

• Medical devices enter into scope on the following timetable:
  – From 22 July 2014: Medical devices
  – From 22 July 2016: In vitro diagnostic medical devices

• RoHS 2 does not apply to Active Implantable Medical Devices
Exemptions: Annexes III and IV of RoHS Directive

• Annex III: specific exemptions agreed for items in any category
• Annex IV: additional exemptions for Medical Devices
• What does it say in Commission Guidance Documents?
Is My Device Exempt?

1. Is my device covered by a Medical Device application listed in Annex IV?
   - Yes: My device is exempt
   - No: What about Annex III?

2. Is my device covered by an application listed in Annex III?
   - Yes: My device is exempt until the deadline stated
   - No: My device is not exempt: RoHS 2 applies