



RoHS, RoHS 2, and REACH An overview



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- About ERA
- RoHS
 - Brief overview of general provisions – products in scope, restricted substances, exemptions, etc.
 - Changes with RoHS 2
 - Related global requirements in brief
- Overview of REACH
 - Main requirements
 - CLP/GHS & MSDS
 - Recent developments
 - Related global requirements in brief



- Founded 1920, ~120 employees
- Independent specialist engineering technical services
 - power systems and earthing
 - forensic engineering
 - design and materials
 - electrical testing
 - EMC design/testing
 - system safety assessment
 - **regulatory compliance**



- We track regulatory issues



- We advise
 - industry
 - policy makers
 - EU
 - UK government
 - enforcement bodies



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ERA CONFERENCE 2013





RoHS

- overview and key obligations

- Restricts
 - lead, cadmium, mercury, hexavalent chromium, PBDE and PBB
- From use in
 - 8 categories of electrical equipment
- Applies to
 - Products placed on the EU market from 1 July 2006
- Exemptions provided
 - Periodically reviewed

1. Large household appliances
2. Small household appliances
3. IT, telecom
4. Consumer equipment
5. Lighting equipment (includes light bulbs and luminaires)
6. Electrical tools (except Large-Scale Industrial Tools)
7. Toys, leisure and sport
8. **Medical electronics**
9. **Monitoring and Control Instruments**
10. Automatic dispensers

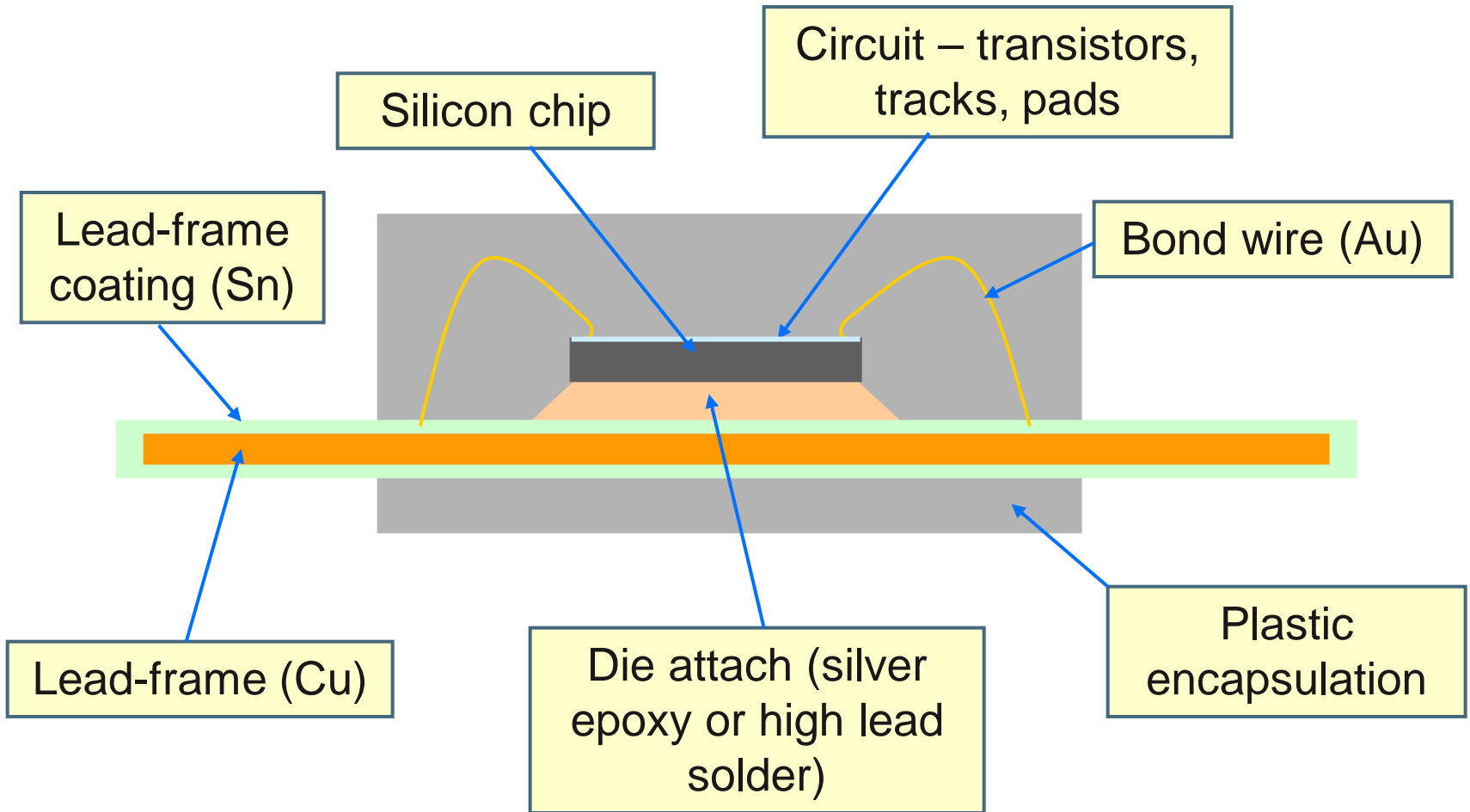
Compliance with RoHS

- *Maximum concentration values*

- Definition
 - Pb, Hg, Cr(VI), PBB and PBDE = 0.1% by weight of “homogeneous materials”
 - Cd = 0.01% by weight of “homogeneous materials”
- Homogeneous materials examples
 - Tin-plated coating
 - Plastic
 - Solder
- Homogeneous materials defined in EC guidance and in recast
 - Note that this is a definition only, not instructions for analysis

Compliance with RoHS

- *Homogeneous materials within IC*



- RoHS is a “single market” Directive
 - so requirements should be the same in all Member States
 - However, currently scope varies
 - Recast FAQ aims to avoid different interpretations
- Enforcement and penalties do vary
 - UK: From £5000 / offense (+costs) in UK (in magistrates court)
 - Unlimited fine in High Court
 - In some EU States - up to 3 years prison + several €millions fine



RoHS >>> RoHS2

- Scope, exclusions etc.
- Timings
- Compliance obligations and showing conformity
- Spare parts and consumables
- Revised exemption process
- Additional substances?

RoHS recast

- Comparison

RoHS (2002/95/EC)

Six restricted substances

Restriction on use of substances in products

8 Categories in scope

Exemptions annex

Self declaration

Applied to product placed on EU market from 1 July 2006

Informal collaboration by enforcement authorities

RoHS recast (2011/65/EU)

No change - but review within 3 years (HBCDD, DEHP, BBP, DBP).

No change yet

Open scope with exclusions >> Cat 8/9/11(other) included

Exemptions Annex III (existing)
Exemptions Annex IV (cat 8/9)

Conformity assessment (self)

Several dates >>

Formalised market surveillance

Substance restrictions and safety

- *RoHS Directive (2011/65/EC)*

- 2 Jan 2013
 - Conformity assessment of products already covered
 - 22 July 2014
 - Medical devices
 - Monitoring and control instruments
 - 22 July 2016
 - In Vitro Diagnostics (IVD)
 - 22 July 2017
 - Industrial monitoring and control instruments*
 - 22 July 2019
 - Other equipment (subject to review)
- * includes both industrial AND professional units but they must be designed exclusively for this use

- Equipment with any electrical function is in scope of recast
 - If excluded from RoHS1 this will be from 22 July 2019
 - Some Member States have always assumed that EEE with any electrical function is in scope (disagree with EC) but scope interpretations very variable
 - Petrol engine equipment & gas cookers have been excluded in most States
- New definition includes:
 - Gas, petrol and diesel powered tools such as gas cookers and petrol lawnmowers. - if they have any electrical function (electric clock, lamp, spark, etc.)
- Equipment brought into scope because of change of “dependent” definition is not necessarily in category 11
 - depends on main function of equipment

RoHS recast

- *Open scope - exclusions include*

- Military, national security & into space (satellites)
- Large-scale stationary industrial tools
- Large-scale fixed installations
- Means of transport (cars, trains, aircraft, etc.)
- PV panels used for power generation
- Non-road mobile machinery made available exclusively for professional use
- Active implanted medical devices (AIMD)
- Equipment constructed for R& D only – interpretation in FAQ guidance as prototypes

Do products need to comply?

- *exclusions*

- Large-scale fixed installations (LSFI)
 - “a large size combination of several types of apparatus and, where applicable, other devices, which are
 - assembled, installed by professionals and
 - intended to be used permanently in a pre-defined and dedicated location, and
 - to be de-installed by professionals”
 - Now includes building equipment, production lines, rail infrastructure, etc.
- Large-scale Stationary Industrial Tools (LSIT)
 - Defined in Article 3.3 of recast
 - Originally interpreted as production line, chemical plant, oil refinery, power stations, etc.
 - FAQ guidance states “Large-scale” can be based on size, power consumption or other criteria
 - Large-scale need not be as large as for LSFI
 - Must be a “tool” – now interpreted as large “tools”, e.g. CNC lathe, etc.

Do products need to comply?

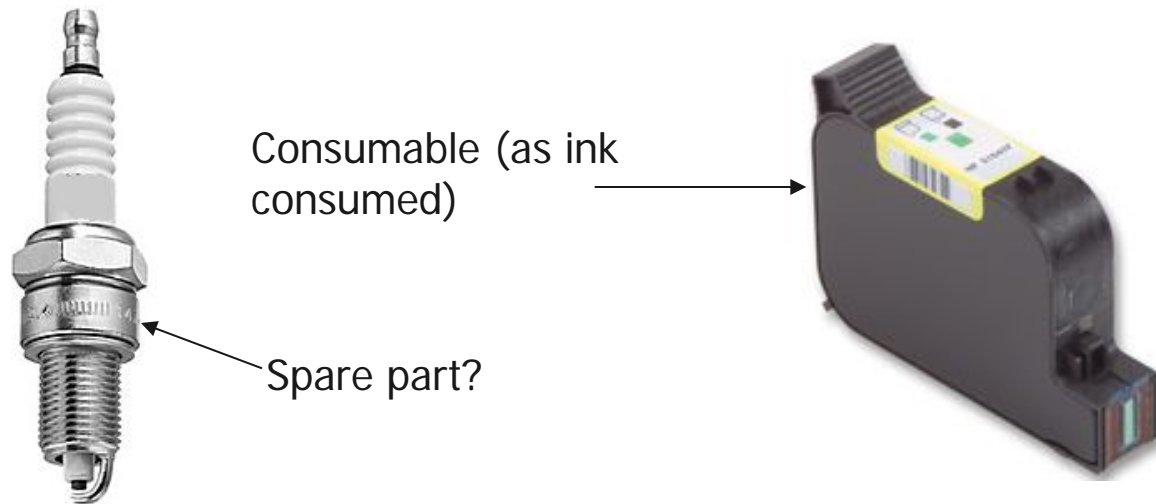
- *Spare parts*

- Categories 1 - 7 and 10
 - Restrictions do not apply to spare parts for the repair or reuse of EEE placed onto the market (POTM) before 1 July 2006
 - Newly included EEE
 - spare parts exemption applies only to EEE POTM before 1 July 2006 (**anomaly**)
- Category 8 & 9 EEE
 - non compliant spare may be used to repair EEE POTM before applicable deadline
- Spare parts are defined as “a separate part of an EEE...”
 - This implies components,
 - so EEE is not a spare part, although EEE may be excluded because of Art 2.4c (part of a equipment that is excluded or out of scope)
- Category 11 EEE
 - No spare part exemption (**anomaly?**)
- Exempt applications that expire
 - Recast allows “repair as produced”

- Need to document professional repairs to show that correct parts are used.
- So need to identify when EEE was placed on the market – e.g. by serial number
 - Unless only compliant spare parts are used

• Cd, penta- / octa-BDE in plastics already banned - can't be used in spare parts NOW as banned by REACH

- Consumables were excluded in original EC FAQ guidance – example of ink-jet cartridge was incorrect!
- Non-electrical consumables sold separately are excluded from RoHS, e.g. oil, air filters
- Electrical consumables sold to end users are in scope, e.g. ink jet cartridge (incorrectly excluded by EC FAQ), spark-plugs – consumables or spare parts?



- Accessories supplied with EEE are part of EEE and so should comply
- If sold with a product, then accessory has same status as product
 - e.g. carry case, cables, drill bits with electric drill
- Electrical accessories are in scope
 - category depends on main function
- Non-electrical accessories sold separately are excluded
 - e.g. separately sold drill bits



Minimum Concentration Values and homogeneous materials

- Still misunderstood by some producers (mainly in Asia)
- Difficulty with analysis of CrVI as wt %.
- Analysis of multi-layer thin coatings
- Difficulty with very small components
- Further guidance in recent EC impact assessment report (by ERA)

- Legal obligations
 - Ensure restricted substances are not present
 - Manufacturers must produce and maintain technical documents
 - CE mark finished EEE and provide DoC
 - Specific obligations in Article 7 – 10 (next slide)
- Use EU Harmonised standard EN50581 – technical documents
 - EN50581 explains how to comply with documentation requirements – more later

Requirement	Manufacturer	Authorised rep	Importer	Distributor
No RoHS substances	Ensure	No	Check	Check
Procedures to ensure ongoing conformity	Maintain	No	No	No
Conformity assessment	Perform	No	Check	No
Technical file	Compile and keep	Keep	Check	No
DoC	Provide and keep	Keep	Check and keep	Check
CE mark	Affix	Possible	Check	Check
Register of nonconforming /recalls	Maintain and inform	Possible	Maintain and inform	No
Product identification	Affix	Possible	Check	Check
Manufacturer identification	Affix own	Possible	Affix own	Check
If reason to think may contain RoHS substance > limit	Do not POTM. Withdraw or recall and inform MSA	Possible	Do not POTM. Withdraw or recall and inform MSA	Do not POTM. Withdraw or recall and inform MSA & mfr/importer
Request from MSA	Cooperate	Cooperate	Cooperate	Cooperate

- Note: Importer or distributor treated as manufacturer if they place on the market (POTM) under own name/trademark or modify EEE substantively

1. Supplier assessment
2. Requesting and checking supplier declarations
3. Assess likelihood of a RoHS substance
4. Technical documents - describe what you do, what you have done and why
 - Documents and procedures for these are recorded in the RoHS technical file
 - Module A of Annex II of 768/2008 describes generic conformity assessment procedure

Key elements of RoHS technical file

- Technical documentation shall include an adequate analysis and assessment of risk(s)
- Content
 - Description of product
 - General, description of function (identifies product, key to any scope arguments)
 - Exemptions used and rationale (NB watch for expiry)
 - Standards used (ERA suggestions)
 - Harmonised (EN50581)
 - Process level (PD IEC/TR 62476:2010 - framework for evaluation of products)
 - Disjointment (IEC/PAS 62596)
 - Test (IEC/EN 62321:2009 series)
 - Supplier compliance data
 - Declarations and other substantiating data (e.g. qualification)
 - Results of tests, analysis
 - Production control (e.g. change of supplier, qualification, audit) and recall

Criteria for a new exemption

RoHS	RoHS2
Scientifically or technically impractical	Scientifically or technically impractical
Substitutes have greater negative impact on health or environment	Substitutes have greater negative impact on health or environment (need LCA)
Cost is <u>NOT</u> a permitted criterion	Reliability
	Availability – used to determine expiry period only
	Socio-economic – used to determine expiry period (This is not “cost”)

Do products need to comply?

- *Exemptions*

- Overview
 - Currently 40 items listed in Annex III of RoHS
 - Annex has been amended many times
 - Some have expired
 - Some now applicable only to spare parts
 - Recast includes RoHS1 Annex as Annex III and a new Annex IV for categories 8 and 9 only

- Annex III applicable to all EEE
 - For cat 1 – 7 & 10 expire after up to 5 years (so by 21 July 2016)
 - For cat 8 & 9 expire 7 years after date product enters scope
- Annex IV applies only to cat 8 & 9 (last up to 7 years after entry into scope)
- Renewals
 - All exemptions will expire automatically unless renewed
 - Applications must be made at least 18 months before expiry to guarantee a decision before expiry date
 - Commission must decide on whether to renew at least 6 months before expiry (i.e. within 1 year of request)
 - If application rejected, a transition period of 12 – 18 months shall be permitted
- This fixed timescale does not apply to new requests
- New requests must include information in Annex V
- More on specific exemptions/exemption requests this afternoon

- Active enforcement in many EU States
- Formal RoHS Enforcement Network set up by recast
- Enforcement approaches
 - Authority inspectors will ask producers to see technical documents
 - If satisfied, will take no further action
 - Otherwise will ask for more information or may carry out analysis
 - Non-compliant EEE will be taken off the market
 - Fines may be imposed
 - Enforcers also buy / demand products for chemical analysis (1st screen by XRF)

- *UK and rest of EU details*

- Enforcement Authority in the UK is National Measurement Office (NMO) – formerly NWML www.rohs.gov.uk
- Enforcement >350 producers investigated (~250/year) – 60% too slow to provide documentation (>28 days)
 - ~ 50 Improvement Plans by mid 2010
 - 20 - 30 Compliance Notices by mid 2010
 - >3 “prosecutions”
 - Many instances where materials declarations not interpreted correctly
 - Several cases where products have been voluntarily withdrawn
 - One recent fine of £40,000 and many products have been removed from the market
- Enforcement action also in Denmark, Sweden, Finland, Ireland, Netherlands, etc.
 - Many product withdrawals and fines

- If you have put product on market and it is non-compliant you have committed an offence
- Due diligence provides a defence balancing the offence
- Only a few EU States recognise due diligence
 - In general, the size of fine depends on the severity of the offence

- RoHS – restricts 6 substances in a widening range of electrical and electronic equipment
 - but the intent is to increase the scope to more substances
- Process
 - Study for the European Commission
 - Proposal for amendment to the directive
 - Directive and transposition



Umweltbundesamt
(Austria)

Jan 2013 – Jan 2014

http://ec.europa.eu/environment/waste/rohs_eee/review/index_en.htm

- Substances
 - Required to consider 4 SVHCs
 - hexabromocyclododecane (HBCDD) – to be banned as a POP
 - dibutyl phthalate (DBP)
 - benzyl butyl phthalate (BBP)
 - bis-ethylhexyl phthalate (DEHP)
- Methodology
 - “shall be coherent with other legislation related to chemicals, in particular to the REACH Regulation (1907/2006), and shall take into account ... Annex XIV (substances subject to authorisation) and Annex XVII (substance restriction)

- Current status
 - pre-prioritisation methodology has been chosen by consultants
 - beginning to assess substances
- However
 - the pre-prioritisation phase does no more than select substances for further study
 - methodology document provided only very brief details of the most important phase of substance assessment
 - no reference to copious guidance produced by ECHA on substance assessment and the basis for restriction (e.g. Guidance for the preparation of an Annex XV dossier)

- *Global requirements*

- Largely derivative of EU RoHS
 - sometimes only cover metals
 - China remains a reporting and labelling requirement only