Using EN 50581 to manage compliance to the upcoming RoHS phthalate substance restrictions

7 April 2016, 2-3pm BST
Today’s webinar aims

• To explain what types of materials are at risk of containing the phthalates and how companies can use the EN 50581 standard to prioritise their compliance efforts on higher risk supplier parts. The webinar will also explain how companies can use EN 50581 to make self-declarations for parts which have no risk of containing the phthalates.

• Identifying which parts in your products contain the phthalates, finding alternatives and amending product specifications, and implementing these new manufacturing requirements with your supply chains, can take several years.

• Industry experience: Siemens, on its substance management challenges, its experience in using the EN 50581 standard, as well as recommendations to suppliers
Speakers

- Aidan Turnbull, Director, BOMcheck.net
- Johan Russinger, Senior Director, EHS, Siemens
- Chair: Leigh Stringer, Global Business Editor, Chemical Watch
Questions

Please submit questions during the webinar using your chat box

Any unanswered questions can be raised on the Chemical Watch LinkedIn page following the webinar:

www.chemicalwatch.com/linkedin
Using EN 50581 to manage compliance to the upcoming RoHS2 phthalate substance restrictions

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Agenda

1. Upcoming RoHS2 phthalate substance restrictions
2. Materials at risk of containing the new RoHS phthalates
3. Using EN 50581 to make self declarations for no risk parts
4. Siemens recommendations to suppliers
BOMcheck: Industry-lead shared web database for the electrotechnical industry

Launched in May 2008 by Siemens, Philips and GE Healthcare

- Industry Steering Group directs the development of new functions and features on BOMcheck
- Industry Substance List Working Group identifies and evaluates substance regulations

Owned and operated by thinkstep compliance limited

- Co-Chair of US Standard IPC 1752A for Materials Declarations
- European Regional Coordinator for International Standard IEC 62474 for Materials Declarations.
- Helped write EN 50581 Standard for RoHS2 Technical Documentation
2 million parts and 5,700 users including...
Guide to Using BOMcheck and EN 50581 for EU RoHS2 Technical Documentation

Reviewed by

- European Commission RoHS2 Working Group
- UK Government RoHS2 Regulators
- UK Government RoHS2 Enforcement Agency

Available free-of-charge at www.bomcheck.net/rohs

Guide to Using BOMcheck and EN 50581 to Comply with RoHS2 Technical Documentation Requirements
Directive 2011/65/EU (RoHS2) replaced Directive 2002/95/EC (RoHS1) and became EU Law on 21 July 2011
- Member State RoHS2 Regulations took effect from 2 January 2013

Continues to apply existing RoHS1 substance restrictions to electrical and electronic equipment in Category 1 – 7 and 10

Maximum concentration in any **homogenous material** in the part
- Cadmium/cadmium compounds: 0.01%
- Lead/lead compounds: 0.1%
- Hexavalent chromium compounds: 0.1%
- Mercury/mercury compounds: 0.1%
- Polybrominated biphenyls (PBB): 0.1%
- Polybrominated diphenyl ethers (PBDE): 0.1%
EU RoHS2 extends EU RoHS1 by adding...

- new product categories and compliance timelines
- new substance restrictions
- new CE marking requirements
- new Technical Documentation requirements
- new compliance assessment standard
New product categories and compliance timelines

Category 8: Medical Devices: **22 July 2014**
- In Vitro Diagnostic Medical Devices: **22 July 2016**
- Active Implantable Medical Devices: **Exempt until next review**

Category 9: Monitoring & Control Instruments: **22 July 2014**
- Industrial Monitoring & Control Instruments: **22 July 2017**

New Category 11: “**All Electrical and electronic equipment not covered by any other category**”: **22 July 2019**
New substance restrictions

RoHS2 Article 6: “amendment of the list of restricted substances shall be considered by 22 July 2014 and periodically thereafter”
- Austria Environment Agency report published January 2014

Directive 2015/863 published 4 June 2015 added four phthalates and maximum concentration 0.1% in any homogenous material
- Bis (2-ethylhexyl) phthalate (DEHP)
- Butyl benzyl phthalate (BBP)
- Dibutyl phthalate (DBP)
- Diisobutyl phthalate (DiBP)

All EEE except Category 8: Medical Devices and Category 9: Monitoring & Control Instruments: 22 July 2019
- Category 8: Medical devices and Category 9: Monitoring & Control Instruments: 22 July 2021
IPC 1752A standard manages supplier declarations against both EU RoHS lists

- **IPC 1752A standard provides two separate compliance lists**
  - Existing 6 RoHS substance restrictions: EUROHS-0508
  - Upcoming 4 RoHS substance restrictions: EUROHS-1506

- Suppliers can provide declarations against one list or both lists

- **Recommendation 1**: ask suppliers to provide declarations which comply with IPC 1752A format
  - Avoid cost of reviewing each declaration to check which list is referenced

- **Recommendation 2**: use an IPC 1725A software system which rolls up and reports BOM against each RoHS list separately
New Technical Documentation and CE marking requirements

RoHS2 Article 7: “Manufacturers shall draw up Technical Documentation, carry out internal production controls, provide EU Declaration of Conformity and affix CE Marking”

RoHS2 Article 18 refers Regulation 765/2008: “Market surveillance authorities shall perform documentary checks and, where appropriate, physical and laboratory checks”

Many products already CE marked for other Directives

- Continuing to CE mark product after compliance deadline means manufacturer is claiming the product now also complies with RoHS
- EU Declaration of Conformity must be expanded to include Directive 2011/65/EU after compliance deadline
RoHS 2 Article 16: “Equipment which has been assessed in accordance with EN 50581 shall be presumed to comply with RoHS2”

Companies who choose not to use EN 50581 are required to demonstrate how their Technical Documentation provides equivalent levels of evidence of compliance
Assess materials risk to decide supplier documentation requirements

The types of technical documents that are required for materials, parts and/or sub-assemblies shall be based on Manufacturer’s assessment of

- The probability of restricted substances being present in materials, parts or sub-assemblies, and
- The trustworthiness of the supplier

Documents for materials, parts, and/or sub-assemblies See 4.3.3

Supplier Declarations and/or Contractual Agreements
Material Declarations
Analytical Test Results

Evaluation of quality and trustworthiness See 4.3.4

Content of the Technical Documentation

- General description of the product
- Documents for materials, parts, and/or sub-assemblies
- Information showing the relationship between the documents and the corresponding materials, parts and/or sub-assemblies in the product
- List of harmonized standards and/or other technical specifications that have been used to establish the technical documents mentioned in 4.3, or to which such documents refer
Clause 4.3.2: Manufacturer can make self declaration where no risk is expected

“The types of technical documents that are required for materials, parts and/or sub-assemblies shall be based on the manufacturer’s assessment of

a) the probability of restricted substances being present in materials, parts or sub-assemblies, and

b) the trustworthiness of the supplier”

“When undertaking the assessment described in point a), the manufacturer may apply technical judgement, as some substances are unlikely to be contained in certain materials (e.g. organic substances in metals). Such technical judgement could be based on technical information available via the electrical/electronic industry, or a literature investigation of the materials/parts used in electrical/electronic products.”
Assessing supplier documentation requirements for low, medium and high risk parts

- **Type A**: Supplier declaration or material declaration required
- **Type B**: Material declaration required
- **Type C**: Material declaration and analytical test report required

<table>
<thead>
<tr>
<th>Probability that material, part and/or sub-assembly contains RoHS substances</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
</tr>
<tr>
<td>Trustworthiness of the supplier for RoHS conformity</td>
</tr>
<tr>
<td>Type A</td>
</tr>
</tbody>
</table>
Product Substance Risk Management:

Balancing technical and supplier risks that is As Low As Reasonably Practicable in line with EN 50581; Philips Healthcare approach

<table>
<thead>
<tr>
<th>Supplier Trust-worthiness</th>
<th>Product Substance Risk</th>
<th>Option</th>
<th>Evidence 1: Supplier- or Self-declaration 1)</th>
<th>Evidence 2: Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Low</td>
<td></td>
<td>in BOMCheck or other approved tool</td>
<td>No testing</td>
</tr>
<tr>
<td>A (high)</td>
<td>High</td>
<td>1</td>
<td>in BOMCheck or other approved tool</td>
<td>Random testing 2)</td>
</tr>
<tr>
<td>B (med)</td>
<td></td>
<td>1A</td>
<td>in BOMCheck or other approved tool</td>
<td>Recent analysis report 3) required from a certified lab</td>
</tr>
<tr>
<td>C (low)</td>
<td></td>
<td>2</td>
<td>in BOMCheck or other approved tool</td>
<td>Recent analysis report 3) required &amp; regular inspection 4)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3</td>
<td>in BOMCheck or other approved tool</td>
<td></td>
</tr>
</tbody>
</table>

1) **Self Declaration**: when fully or partly responsible for the design or when trustful components information(s) or when product substance risk is low

2) **Random Testing**: On full product, or on all high risk components of product

3) **Recent**: max. 12 months (or longer - in case evidence of no change is available)

4) **Regular inspection**: Risk based, either at manufacturer site or at incoming inspection minimal once per year
4 new RoHS phthalates are used as plasticizers in the electrotechnical industry

A plasticizer is an additive which makes a material more flexible, stretchable, bendable or workable

- Additive found in flexible (bendable) plastics, rubbers, epoxies, etc
- Additive found in flexible (stretchable) adhesives, sealants, lacquers, paints, printing inks etc

For example, PVC without any plasticizer is known as uPVC (unplasticized polyvinyl chloride) which is brittle and hard

- uPVC used in window frames and other rigid profile products
# Materials at **no risk** / **low risk** of containing phthalates

<table>
<thead>
<tr>
<th>No risk</th>
<th>Low risk</th>
</tr>
</thead>
</table>
| Metals, glass, ceramic | uPVC, other rigid plastics  
| Metal plating, solder               | Rigid adhesives (e.g. super glue)  
| Wood, paper, leather, textiles     | Rigid epoxies (e.g. rigid circuit boards)  
|                                | Hard paints and hard coatings  
|                                | Other inorganic materials                                                     |
## Materials at medium risk / high risk of containing phthalates

<table>
<thead>
<tr>
<th>Medium risk</th>
<th>High risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Sealants based on polysulfide, polyurethane foam or acrylic. Typical content 1 – 30%.</td>
<td>• Flexible PVC and other vinyl resins (e.g. coating cables and wires). Typical content 30-45%</td>
</tr>
<tr>
<td>• Flexible adhesives based on polyvinyl acetate (PVA) and polyacrylics. Typical content 1 – 5% but can be up to 10%</td>
<td>• Rubber including acrylobutadiene (NBR, Buna-n), styrene-butadiene (SBR, Buna-S) and polychloroprene rubber (neoprene). Typical content 10-20%</td>
</tr>
<tr>
<td>• Flexible paints based on polyurethane or polyacrylics (e.g. waterproof paint). Typical content 5% but can be up to 40%</td>
<td>• Cellulose ester plastics</td>
</tr>
<tr>
<td></td>
<td>• Plastic bags and films</td>
</tr>
<tr>
<td></td>
<td>• Flexible plastic and rubber tubing</td>
</tr>
</tbody>
</table>
Observations on phthalate use in the electrotechnical industry

- DEHP was the most commonly used phthalate and previously accounted for > 50% of all phthalate production
  - Low production costs and very good flexibility properties

- BBP is one of the most expensive phthalates and so other phthalates are used when possible

- DBP has very good low temperature flexibility in soft PVC

- DIBP is a specialist plasticiser which is used in combination with high molecular weight plasticizers. It is too volatile to be used by itself in PVC applications.
**Recommendation 3:** Start now by making self declarations for no-risk parts and sending parts list requests to suppliers for low, medium or high risk parts.
Business benefits of starting now: reduce costs of any necessary design changes or sourcing changes.

July 2019
Siemens Healthcare, Johann Russinger, Senior Director Global EHS

Preparing for Compliance to RoHS 2019/2021*
Siemens recommendations to suppliers

*2021 for Medical Devices, Monitoring & Control Instruments

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Content

- Siemens Healthcare Introduction
- Compliance – Challenges
- Experiences and Recommendations to Suppliers
Siemens Healthcare
A leading medical infrastructure company

**Key Financials**

<table>
<thead>
<tr>
<th></th>
<th>FY 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>New Orders</strong></td>
<td>€ 13.3bn</td>
</tr>
<tr>
<td><strong>Revenue</strong></td>
<td>€ 12.9bn</td>
</tr>
<tr>
<td><strong>Profit</strong></td>
<td>€ 2.2bn</td>
</tr>
<tr>
<td>in % of revenue</td>
<td>16.9%</td>
</tr>
<tr>
<td><strong>Underlying Profit</strong></td>
<td>€ 2.2bn</td>
</tr>
<tr>
<td>in % of revenue</td>
<td>16.9%</td>
</tr>
</tbody>
</table>

2) FY 2014 external revenue by location of customer
3) Commonwealth of Independent States

**Revenue by Region**

- **Germany**: 26%
- **Asia, Australia**: 6%
- **Europe, CIS, Africa, Middle East (Excl. Germany)**: 27%
- **Americas**: 40%

**Employees worldwide**

- FY 2011: 42,000
- FY 2012: 42,000
- FY 2013: 42,000
- FY 2014: 43,000
- FY 2015: 44,000

1) In FY 2015 adjusted for severance charges as well as other one-time effects

4) as of September 30, 2015
Siemens Healthcare
A leading medical infrastructure company

~43,000 employees worldwide

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Challenges in Substance Management
Siemens Healthcare has to fulfill the strictest requirements worldwide

**Complex Products**
- containing up to 5000 different purchased parts
- product lifetime up to 10 years
- in certain applications critical substances are required

**Large Supply Chain**
- several thousands of 1st tier-suppliers
- from small two person businesses to big corporations
- worldwide from Europe, Asia and America
- standard parts, specifically designed parts and complex components

**Global Market**
- with different substance restrictions and information requirements
- market-specific products are economically not profitable
- more and more new substance restrictions are on the horizon
Challenges in Substance Management
Complex supply chain - number of regulated substances is increasing continuously

- Permanent changes in regulations require constant actualization
  - Every six months new queries have to be communicated through the whole supply chain

- Each manufacturer is querying substances in a different way
  - Companies in the last year are receiving hundreds of different queries

- Many suppliers do not understand or even know the regulations
  - Only big companies have material-specialist and processes in place
  - Quality and trustworthiness of material information is very low

The manual collection of substance declarations is time consuming, expensive and error-prone
Challenges in Substance Management
Securing Compliance as a moving target

For example:
REACH candidate list with Substances of Very High Concern (SVHC) is continuously growing:

- 2010: 38 SVHCs
- 2012: 138 SVHCs
- Today: 168 SVHCs
- Possibly > 500 SVHCs

Substance information cannot be handled anymore by sending out letters to suppliers every 6 months.
Experience and Recommendations to Suppliers
Risk based approach according to EN 50581 and adequate measures
Experience and Recommendations to Suppliers
Risk based approach according to EN 50581 and adequate measures

Suppliers

No Hardware

Hardware (Manufacturing Business)

Low Risk*

Medium Risk* (majority)

High Risk*

No action needed

Purchasing contract terms and conditions

BOMcheck

BOMcheck + tests

Contract

Material Declaration

Analytical Tests

* Risk is defined by material- and supplier-risk evaluation matrix according to EN 50581
Experience and Recommendations to Suppliers
Examples on appliance of EN 50581

Example 1: Stainless steel spacers
Supplier: High trustworthiness
Material: No risk for existing RoHS substances
  No risk for the new RoHS substances

→ Purchasing contract terms and conditions

Example 2: Cables
Supplier: Medium trustworthiness
Material: High risk for existing RoHS substances (yellow colorants?)
  High risk for new RoHS substances (plasticizers?)

→ Material Declaration on BOMcheck + Analytical test report
Experience and Recommendations to Suppliers
Reduce time and costs by starting now! – Avoid expensive last minute design changes!

Start collecting and updating declarations from your suppliers now for the new RoHS substances
  → Make self declarations for no-risk parts
  → Send parts list requests to suppliers for low, medium or high risk parts
  → Ask suppliers to provide declarations

Implement EN 50581
  → Require standardized material declarations (e.g. IEC 62474 / IPC 1752A declarations) according to risk matrix
  → Ask your suppliers to implement EN 50581 (if not already done)
  → EN 50581 Guide available at www.bomcheck.net/rohs

Implement a robust process now
  → More substances will be added to RoHS and REACH
  → Implement a robust process now with your supply chain to reduce current and future costs and to keep on track with substance updates

Using BOMcheck saves time and cost
  → Standardized declarations in line with EN 50581
  → Keep up-to-date with new substance regulations around the world. Easy to update when new substances become regulated
  → Guidance reduces regulatory burden for REACH compliance (~ by 66%)
Thank you!

Johann Russinger
Senior Director Global EHS

Siemens Healthcare
HC QT EHS ST

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Thank you for attending

What did you think about the webinar? Please take part in our email survey (in your inbox now)

A downloadable recording of this presentation (with slides) will be available shortly.

If you have any questions, please contact Glen (glen@chemicalwatch.com)

NEXT

v Free webinar: The implementing regulation on joint submission and data sharing: Impact and Practical Advice, 15 April 2016

v Shanghai Chemicals Summit, 21–22 June 2016, Shanghai, China

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