



RISK MANAGEMENT STRATEGIES IN THE CONTEXT OF REGULATORY COMPLIANCE

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Content:

- ☐ Definitions
- ☐ General compliance risks
- ☐ RoHS risk assessment
- ☐ REACH risk assessment
- ☐ Summary

Definitions

What Is Risk Management?

❑ Risk is –

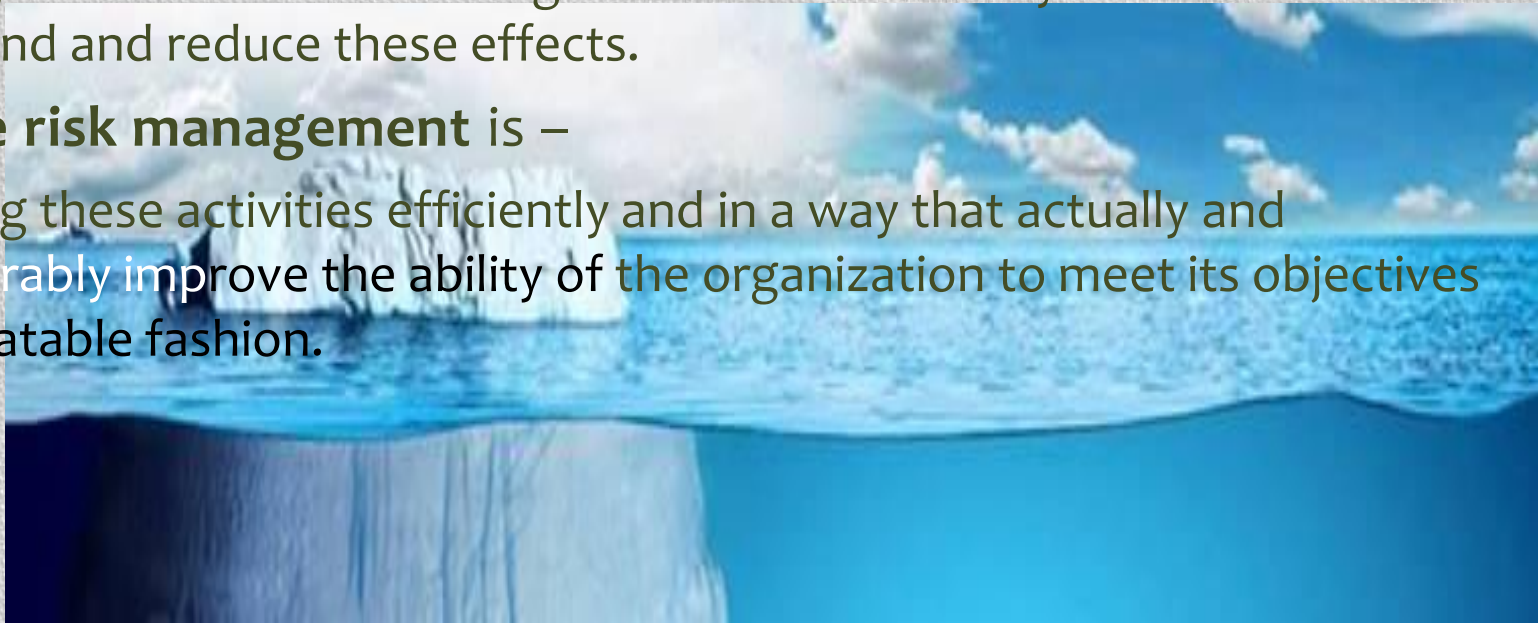
- The effect of uncertainty on the ability of organization to meet its objectives.

❑ Risk management is -

- The range of activities that an organization intentionally undertakes to understand and reduce these effects.

❑ Effective risk management is –

- Executing these activities efficiently and in a way that actually and demonstrably improve the ability of the organization to meet its objectives in a repeatable fashion.



Strategy, Risk Management, Compliance

- ❑ Separate disciplines
- ❑ Interrelated and must be considered together



Success at Both (Compliance & Risk Management)

- ❑ October 1911, two teams aimed to reach the South Pole
 - Team led by Scott - failure & death
 - Team led by Amundsen – victory, success & a hero's welcome

❑ What was the difference?

❑ SMaC Principle

- Specific
- Methodical
- Consistent

(twenty miles march)



Risk Radar Elements



General compliance risks

Hazard Compliance Requirements

❑ For new products, compliance starts with -

➤ Identifying applicable requirements

❑ Key items to identify

➤ What legislations are applicable to the product?

➤ What are those requirements?

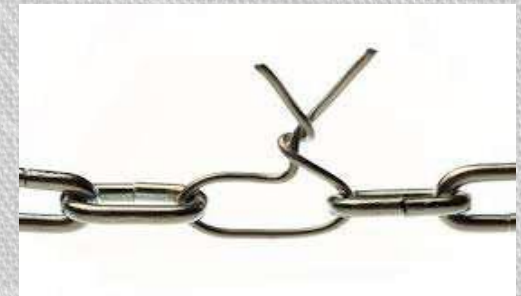
➤ What is the severity of those requirements? i.e.

✓ Restriction vs

✓ Disclosure vs

✓ Labelling

➤ And what are the outputs of those requirements?



Focus on Outputs

- ❑ Fundamental starting point of every restricted materials compliance requirement should be the outputs.
- ❑ Example - RoHS Recast (finished product)
 - Product compliant with the materials restrictions
 - CE marking compliance
 - ✓ CE mark
 - ✓ Declaration of Conformity
 - ✓ Technical file
- ❑ The more you can make them into a checklist, the better.



Risk Management

- ❑ Managing the risk is a mandatory part of Decision 768/2008 and RoHS Recast.
- ❑ Many options of risk management
 - High / low risk of suppliers
 - Supplier auditing
 - Product testing



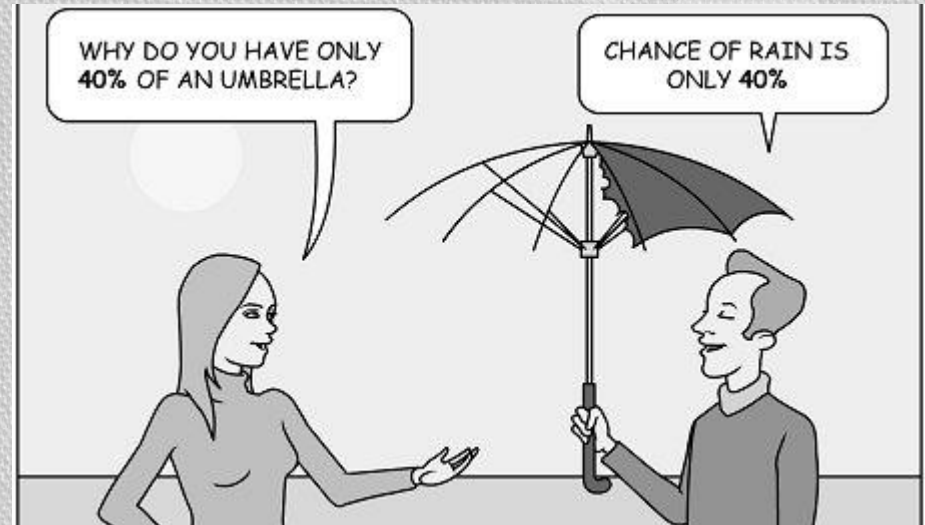
Testing of Sample Product

❑ Most effective method of risk management in terms of -

- time
- cost
- effectiveness

❑ Output

- If the product passes -
 - ✓ the compliance process works
 - ✓ due diligence is served
- If the product fails -
 - ✓ identify the cause of the failure and show solution



Brief Introduction to ISO 31000 – Risk management

- ❑ International non-certifiable standard providing principles, framework and process for managing risk.
- ❑ Not specific to any industry or sector.
- ❑ Able to be applied to any kind of risk and any kind of organization.
- ❑ Follows the Plan-Do-Check-Act cycle with the usual focus on continuous improvement.
- ❑ A standard that acts as an umbrella to other risk related standards of which there are many e.g. EHS, IT, BCP etc.



Creating the Future

☐ Standards: ISO 31000

- ISO 31000:2009, *Risk management — Principles and guidelines*
- IEC 31010:2009, *Risk management — Risk assessment techniques*
- ISO Guide 73:2009, *Risk management — Vocabulary*

☐ Technical Report — ISO

- ISO/TR 31004:2013, *Risk management — Guidance for the implementation of ISO 31000*

☐ Agree on definitions from the standard -

- Risk
- Residual Risk
- Risk Appetite etc.

☐ Create axioms that suit your organization.

Risk Assessment Methodologies

- ❑ ISO 31000 does not provide suggested risk assessment methodologies.
- ❑ It does reference the associated standard “Risk Assessment Techniques (ISO 31010).”



Risk Appetite vs. Risk Capacity

❑ Risk Appetite (ISO 31000)

- Amount and type of risk that an organization is willing to pursue or retain.

❑ Risk Capacity

- The maximum amount of risk which an organization is technically able to assume before breaching one or more of its contractual obligations, reputational and regulatory constraints.



Risk Assessment Method - Likelihood



5

Very Likely

4

Likely

3

Possible

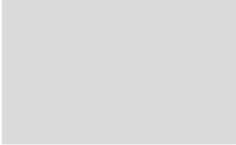
2

Unlikely

1

Very Unlikely

Risk Assessment Method - Consequence

	5	Very Severe
	4	Severe
	3	Moderate
	2	Minor
	1	Insignificant

Risk Level Calculation

			CONSEQUENCE				
			Minor	Moderate	Serious	Major	Catastrophic
			1	2	3	4	5
LIKLIHOOD	Rare	1					
	Unlikely	2					
	Likely	3					
	Expected	4					
	Certain	5					

Harm occurrence Likelihood levels

- Certain: will occur on every occasion
- Expected: is expected to occur in most circumstances (e.g. more than 2 times a year)
- Likely: could occur in many circumstances (e.g. probable to happen up to 2 times a year)
- Unlikely: could occur occasionally (e.g. possibility of happening once a year)
- Rare: not expected to happen, but is possible (even if no occurrence registered)

Harm severity levels

- Catastrophic: multiple deaths
- Major: possibility of death or major permanent loss of function (motor, sensory, physiologic, or intellectual)
- Serious: major injury / adverse health outcome (e.g. possibility of permanent lessening of bodily functioning)
- Moderate : moderate injury / adverse health outcome (e.g. increased length of stay)
- Minor: no or minor injury / adverse health outcome;

Estimated risk levels: **-Red: unacceptable risk** **-Yellow: tolerable risk** **-Green: acceptable risk**

Extract from Risk Register

Risk	Describe the Risk	Risk Owner - person or entity with the accountability to manage risk	Possible Cause(s) and/or Impact(s) of this Risk (brief narrative description)	Likelihood Rating	Consequence Rating	Risk = Likelihood x Consequence	Risk
							Very High 20-24
							High Risk 12-16
							Moderate Risk 5-10
							Low Risk 3-4
							Insignificant Risk 1-2
Finance	Failure to comply with financial regulations. Purchases can be made without authorisation.		Inexperienced staff. Lack of segregation of duties. Failure to obtain value for money - could cause reputational damage. Potential legal and disciplinary action.	3	3	9	

RoHS Risk Assessment

RoHS Compliance - IEC/PAS 62596:2013

Determination of certain substances in electrotechnical products

❑ Table B.1 - Probability of presence of restricted substances in materials and components used in electrotechnical products.

L = Low probability

M = Medium probability

H = High probability

N/A = Not applicable

➤ Use as guidance

➤ May not be with the current list of RoHS exemptions.

Components/ materials	Restricted substances ^a						Number of homogeneous materials ^b	Remarks
	Hg	Cd	Pb	Cr (VI)	PBBs	PBDEs		
Mechanical parts								
Framework – metal							1	Unpainted
Housing – plastic	L	L	L	L	L	M	1	
Power cord/cable	L	H	H	L	L	M	>1	
Thick film sensor	L	H	M	L	L	M	>1	
Heat sink	L	L	L	L	N/A	N/A	1	
Screw, washer, fastener – metal	L	M	M	H	N/A	N/A	1 and >1	Some are coated e.g. black and yellow chromate
Glass – CRT, lamp glass-to-metal seal	L	M	H	L	N/A	N/A	>1	Pb in glass could be exempted
Phosphorescent coating (e.g. CRT)	L	H	L	L	N/A	N/A	>1	
LCD panel/screen	H	L	H	H	L	L	>1	
Plasma panel/screen	H	L	H	H	L	L	>1	Pb in glass could be exempted
Lamps, back light	H	L	H	M	N/A	N/A	>1	Hg used in backlights could be exempted
Magnetic head	L	L	H	M	N/A	N/A	>1	
Printed wiring board (PWB)								
PWB substrate/laminate	L	L	L	L	L	N/A	>1	
Connector	M	L	H	L	L	H	>1	
Capacitor – electrolytic	L	M	H	L	L	M	>1	
Capacitor – chip-type	L	M	M	L	L	M	>1	
Resistor – IMT-type	L	M	H	L	L	L	>1	
Resistor – chip-type	L	H	M	L	L	L	>1	
Diode	L	M	M	L	L	L	>1	
Fuse	L	M	H	L	L	L	>1	
Solder (process and hand soldering)	L	M	H	L	N/A	N/A	1	
Glue (red and white)	L	L	M	L	M	M	1	Used to fix components
Component termination	L	H	H	L	N/A	N/A	1 and >1	

New Substance Restrictions

❑ 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)



❑ For all EEE except Category 8 (Medical Devices) and Category 9 (Monitoring & Control Instruments): Mandatory as of **22 July 2019**.

- Category 8 and Category 9: Mandatory as of **22 July 2021**.

Risk in New RoHS Phthalates

- ❑ 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.



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Risk Assessment

Materials at **no risk** / **low risk** of containing phthalates:

No Risk	• Metals, glass, ceramic • Metal plating, solder • Wood, paper, leather, textile
Low Risk	• uPVC, other rigid plastics • Rigid adhesives (e.g. super glue) • Hard paints and hard coatings • Other inorganic materials

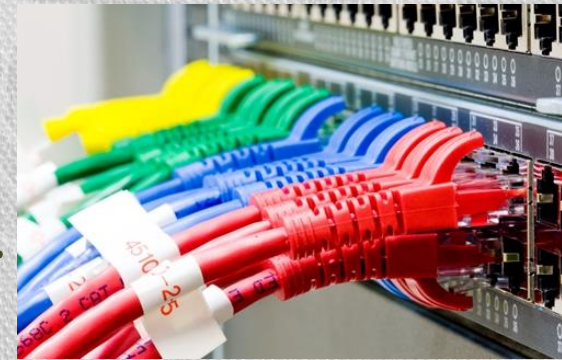
Risk Assessment – cont.

Materials at **medium** risk / **high** risk of containing phthalates:

Medium Risk	• Sealants based on polysulfide, polyurethane foam or acrylic. Typical content 1 – 30%. • Flexible adhesives based on polyvinyl acetate (PVA) and polyacrylics. Typical content 1 – 5% but can be up to 10%. • Flexible paints based on polyurethane or polyacrylics (e.g. waterproof paint). Typical content 5% but can be up to 40%.
High Risk	• Flexible PVC and other vinyl resins (e.g. coating cables and wires). Typical content 30-45%. • Rubber including acrylobutadiene (NBR, Buna-n), styrenebutadiene (SBR, Buna-S) and polychloroprene rubber (neoprene). Typical content 10-20%. • Cellulose ester plastics. • Plastic bags and films. • Flexible plastic and rubber tubing.

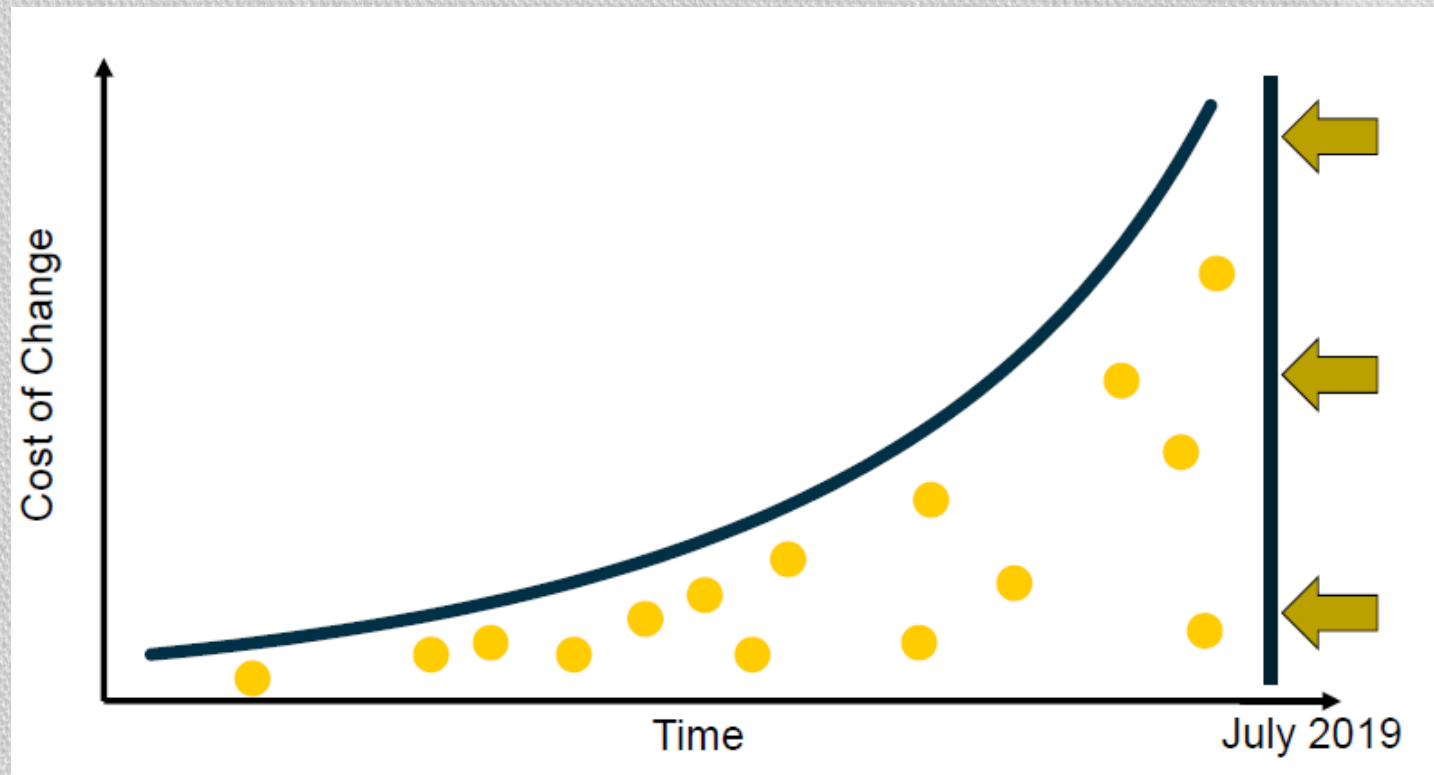
Observations on Phthalate Use in the Electrotechnical Industry

- ❑ **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 plasticizer which is used in combination with high molecular weight plasticizers. It is too volatile to be used by itself in PVC applications.



Business Benefits of Starting Now

Reduce costs of any necessary design changes or sourcing changes.



Assessing the Trustworthiness of the Supplier

- **Type A:** Supplier has a very good understanding of applicable environmental legislations, comprehensive and effective systems in place to ensure compliance, and requires selective analysis of high risk components /materials that it purchases from its suppliers.
- **Type B:** Supplier has a good understanding of applicable environmental legislations and has a system for ensuring compliance but may be lacking in some respect, e.g. does not require selective analysis of high risk components /materials that it purchases from its suppliers.
- **Type C:** Supplier does not understand applicable environmental legislations' requirements or does not have systems to ensure compliance and does not check declarations from its suppliers for incoming components/materials.

Types of Documents Required



❑ **Type A Supplier:** Supplier declaration and/or contractual agreement, or materials declaration is required for each material, part and/or sub-assembly.

❑ **Type B Supplier:**

- Materials declaration is required for each material, part and/or sub-assembly which has a medium or low probability of containing RoHS substances.
- Materials declaration and recent analytical test report are required for each material, part and/or sub-assembly that has a high probability of containing RoHS substances.

❑ **Type C Supplier:**

- Materials declaration is required for each material, part and/or sub-assembly which has a low probability of containing RoHS substances.
- Materials declaration and recent analytical test report are required for each material, part and/or sub-assembly that has a medium or high probability of containing RoHS substances.

Types of Documents Required – cont.

- Example of an assessment matrix to determine what types of documents are required for supplier parts for RoHS compliance:

Probability that material, part and/or sub-assembly contains RoHS substances		Low	Medium	High
Trustworthiness of the supplier for RoHS conformity	Type A	Supplier declaration or Material declaration required	Material declaration required	Material declaration required
	Type B	Material declaration required	Material declaration required	Material declaration and Analytical test report required
	Type C	Material declaration required	Material declaration and Analytical test report required	Material declaration and Analytical test report required

REACH Risk Assessment

SVHCs in Articles

- ❑ ECHA published draft of the updated version 4.0 of the *Guidance on requirements for substances in articles*, which account for the revised definition of “article” per the European Court of Justice.
- ❑ It seems that ECHA appears to be taking a very strict approach to interpretation, which would identify as an article any item – even those ultimately a part of a component – would be considered an article.
- ❑ While not exactly at the homogeneous level, this implies a whole new level of complexity that electronics manufacturers and the component supply chain will have to deal with.



Simplifies Data Collection

- ❑ Manufacturers no longer need to ask suppliers for the amount of the REACH Candidate List substance in the part because no need to calculate whether it is present $> 0.1\%$ by weight of the product.
 - Just need RCD (Regulatory Compliance Declaration) asking **Yes** or **No** if part includes any article which contains a REACH Candidate List substance above 0.1% by weight of that article.
- ❑ Must implement systems to collect any necessary information on safe use from suppliers whose parts include an article which contains $> 0.1\%$ of a REACH Candidate List substance by weight of the article.
 - However, very unusual in the electrotechnical industry as do not come into regular contact with humans during normal use.
 - in most cases manufacturers should expect the supplier to indicate that there is no safe use information which needs to be communicated, and so the manufacturer can communicate to their customer that there is no safe use information which needs to be communicated.

Practical Approach

- ❑ ECHA Guidance recommends that industry should -
 - Use sector knowledge to assess which REACH Candidate List substances are not found in supplied articles.
 - Establish supply chain communication standards and systems.
- ❑ Substance List Working Group works with IEC 62474 and IPC 1752A standards to implement recommendations for electrotechnical industry.
 - 173 SVHC.
 - **97 are not found** in electrotechnical equipment, **76 need investigation**.
 - Out of the 76, 14 are exotic substances; only 62 are commonly used in electrotechnical equipment.



REACH SVHC Opinion - In Practice

☐ Compliance change

- Grind testing of full products would no longer be feasible.
- Risk based engineering evaluation and testing would have more 'follow up' tests for specific materials.
 - ❖ Example - small PVC cable bundles that would normally be ignored for phthalates due to inconsequential size would need to be checked for phthalates.



Maintaining an SVHC Declaration

❑ SVHC list is updated every 6 months.

➤ Re-gather all your SVHC data?

✓ A lot of work

✓ Expensive

✓ Most suppliers don't have an updated SVHC declaration.

❑ Effective solution:

➤ Identify which of the new SVHCs are likely to be in any of your products above 0.1%.

➤ Gather data for or test only the affected parts.

➤ Normally <1% of parts and materials.



Phthalates

❑ DEHP, BBP, DBP is extraordinarily common in high concentrations in cables, vinyl, foam handles.



❑ Supplier knowledge is low/very low.

They are incorrect about their content in their product.

➤ The situation is worse in low cost products: Unless the supplier is extremely knowledgeable, assume they are incorrect regarding phthalate content!



Determining the Concentration of a Candidate List Substance in Electric Wire

- ❑ Insulated electric wire consists of core copper wire (article) covered with insulating PVC tube.
- ❑ The insulation PVC is produced through extrusion over the copper wire, and it has a function on its own and fulfils the definition of an article.
- ❑ The PVC mixture used in the coating contains 40% w/w of an SVHC used as a plasticizer – and hence in the insulator – is 40% w/w, i.e. above the 0.1% w/w threshold.
- ❑ The copper wire does not contain any SVHC.



Pb in PVC

❑ Pb as stabilizer in PVC for wiring

- In ~5% of wires tested

❑ Primarily (but not only)

- Hook up wire
- Cable bundles
- Shrink wrap



Cd in Surface Coating – Measurement Risk

❑ Increase in failures in 'RoHS' compliant fasteners for Cd in surface coatings

➤ Related to Cd contamination in 'Bright Nickel' coatings.

❑ Challenge

➤ EN/IEC 62321 standard does not have testing approach for Cd in surface coating.

➤ ICP (Inductively Coupled Plasma)

✓ The coating is ground up with the rest of the fastener creating deceptively low results.

➤ XRF

✓ The coating layer is observed but so thin that the measurement is inconsistent.

➤ HD XRF is a likely solution but not commonly available.



Summary

In Conclusion

- ❑ **Driver:** Decide on a standard to guide your business rather than legislation, compliance or risk.
- ❑ **Strategy:** Ensure your future development includes both Risk Management and Compliance from inception of new ideas and plans.
- ❑ **Definitions & Axioms:** Ensure key definitions from the standards become axioms, know and understood by all.
- ❑ **Method:** Study the different risk assessment methods and use ones to suit your organization.
- ❑ **Toolkit:** Develop a risk assessment toolkit that can be used and understood by all.



Thank you!

**Need further clarifications?
Need support in implementation?
Need general consultancy?**

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