

RoHS 2015/863 - Phthalate Compliance

Closing out compliance to phthalate restrictions

Presented by:
Bruce Calder
VP Consulting Services



Overview - Agenda - RoHS 3

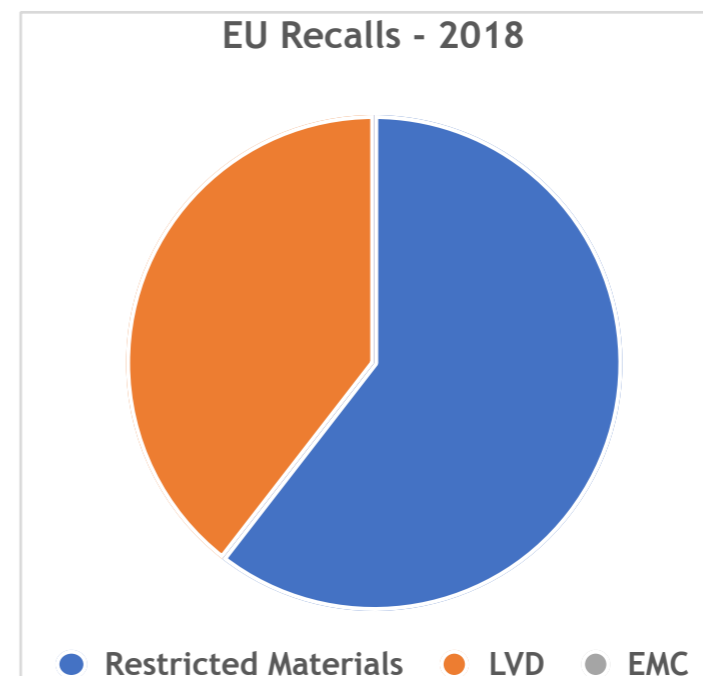
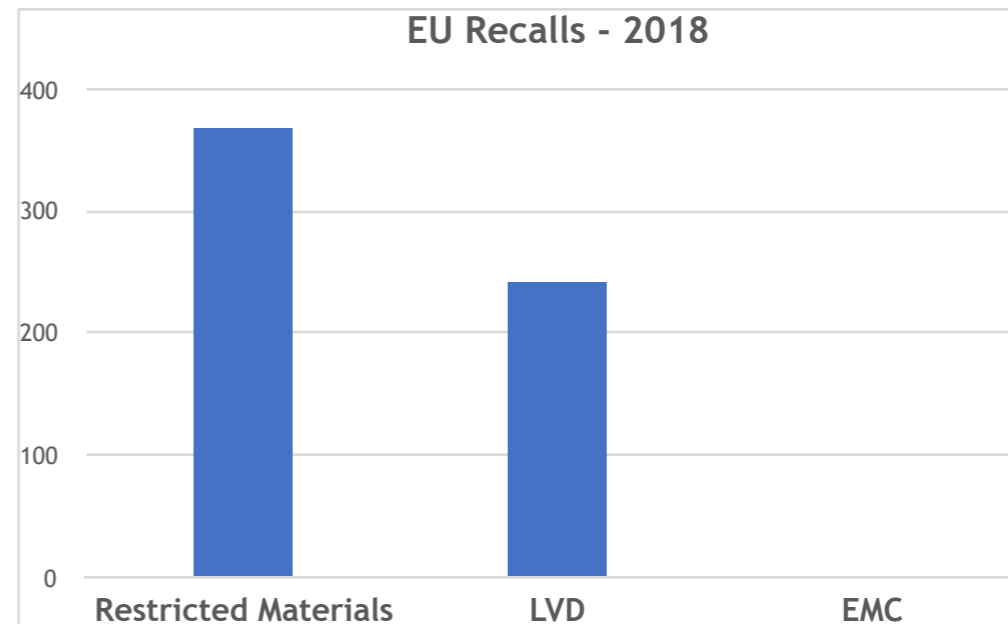
- Introduction
- EU Recalls - Restricted Materials
- What are orthophthalates?
 - Estrogenic endocrine disruptors
- High risk materials
- Compliance in Practice
 - CE marking
 - EN 63000 vs EN 50581
 - Manufacturer responsibility
 - Supplier declarations
 - Risk mitigation
- Common effective approaches
 - New and legacy products
- Approaches for large component / product range
- Summary
- Q&A



Webinar is 50 minutes with 10
minutes of Q&A
(hopefully)

EU Recalls - 2018

Regulation	Recalls
Restricted Materials	369
LVD	241
EMC	0



EU Recalls - 2018

- Recalls
 - Restricted materials - 369
 - Electrical Safety - 241
 - EMC - 0
- Key compliance note
 - From a recall perspective, restricted materials compliance should be given equivalent priority to electrical safety, and more than EMC compliance.

Laboratory and Consulting Services

- EU
 - RoHS 2
 - RoHS 3 (phthalates)
 - REACH SVHC
 - REACH Restrictions
 - EU POP
 - Swedish Flame Retardant Tax
 - EU Packaging Directive
 - WEEE Directive
 - EU Medical Device Regulation
- US
 - Prop 65
 - US Toxics in Packaging
 - iMERC (Hg)
- Canada
 - Canadian Prohibition
- China
 - China RoHS
- UAE
 - UAE RoHS
- Taiwan
 - Taiwan RoHS

Claigan Environmental - Difference

- Claigan's focus
 - Compliance
 - End Deliverables
- If a step or process does not contribute to compliance or end deliverables, then it needs to be justified

EU RoHS

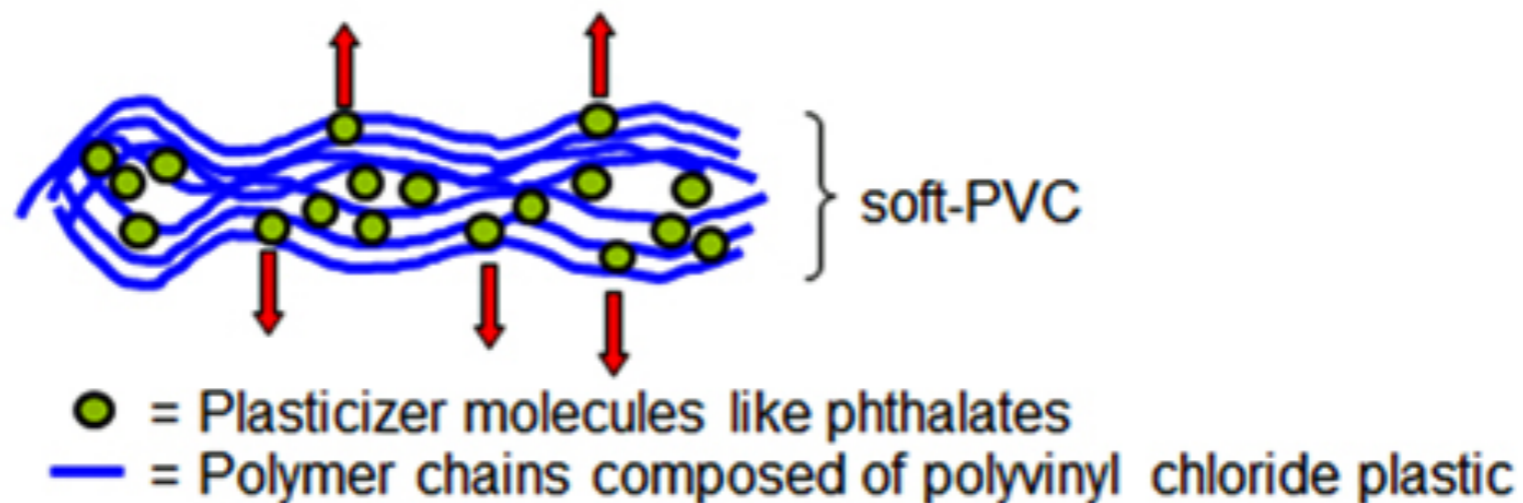
- CE marking directive
- EU RoHS 2 (2011/65/EU) - *Original*
 - Pb, Cd (100ppm), Hg, Cr6+, PBB, PBDE banned at 1,000 ppm
- EU RoHS 3 (phthalates) (2015/863) - *Amended*
 - DEHP, BBP, DBP, DIBP banned at 1,000 ppm
 - Deadline -
 - Most products - July 21 2019
 - Medical, IVD, monitoring and control - July 21 2021

Why were the phthalates added?

- RoHS is related to the safety of the recycling workers and their environment
 - Not related to consumer safety
- Low molecular weight phthalates
 - Category Ib Reproductive Toxins
 - Found to be in the blood stream of recycling workers, in the air / dust in the facilities, and in the environment surrounding the facility
 - Justified restrictions

Where are phthalates used?

- Rigid plastics
 - example - PVC
- Phthalates create flexibility
 - by getting in between the vinyl chloride strands and forcing them apart
 - leading to weaker forces of attraction
 - creating fluidity (flexibility)

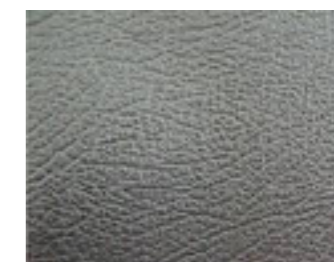


High Risk Materials

- Principal high risk materials
 - Flexible PVC
 - Neoprene
 - Nitrile rubber
 - SBR rubber
 - Adhesives
 - 'Toughened' or rubberized ABS
- Concentrations
 - 1,000 to 300,000 ppm

High Risk Components

- Typical high risk components
 - wires and cables
 - strain relief
 - o-rings, gaskets
 - sealed radial bearings
 - motor belts
 - stickers (PVC)
 - soft rubber components
 - synthetic leather
 - soft covers



Emerging Restricted Materials Trends

Historically, most regulated substances in electronics have been either

- *Carcinogens (ex. Cd)*
- *Reproductive toxins (ex. Phthalates)*

Endocrine Disruptors

Two major groups of endocrine disrupting chemicals

- *Estrogenic substances*
- *Thyroid disruptors*

Orthophthalates

- *Estrogenic endocrine disruptors*
- *Which leads to its classification as a Cat 1B Reproductive Toxin*

Endocrine Disruptors - Estrogenic

Estrogenic substances

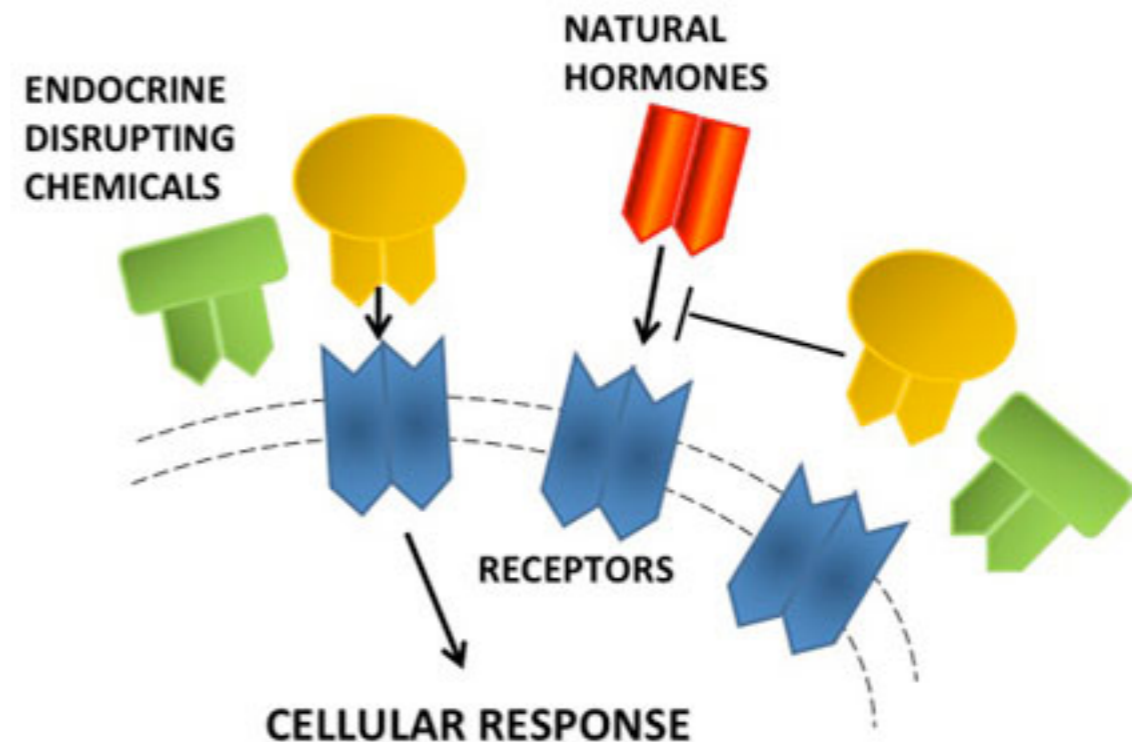
- *Have a chemical structure similar to estrogen*
- *Triggers the estrogen receptors to make a person or animal more female*

Outcomes

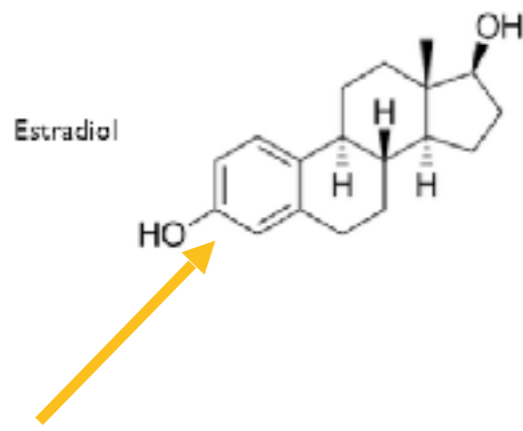
- *Males*
 - *Attention Deficit Hyperactive Disorder*
 - *Low sperm count (which leads to Cat 1B Repr. Toxin classification)*
- *Females*
 - *Hyper-ovarian growth (ovarian cysts)*

Endocrine Disruptors

- Estrogenic EDCs
 - Keys to a lock
- Summary
 - Estradiol-like structure allows them to ‘jimmy the lock’ of the estrogen receptors

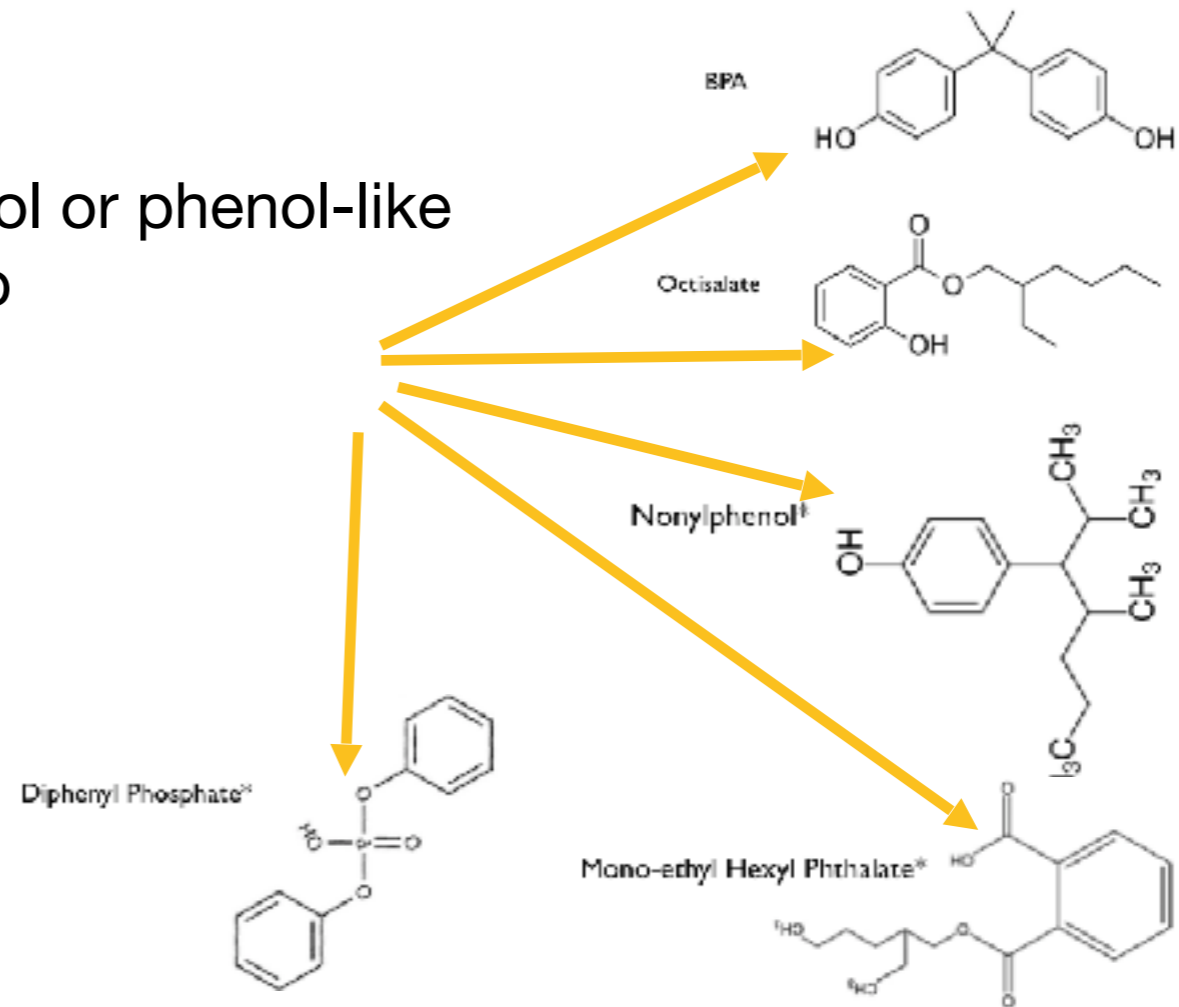


Endocrine Disruptors - Estrogenic - Examples



Key chemical group (phenol)

Phenol or phenol-like
group



Endocrine Disruptors - Estrogenic - Example Uses

Examples

Substance Group	Example	High Risk Materials
Low molecular weight orthophthalates	DEHP	PVC Polychloroprene (neoprene) Nitrile rubber Styrene butadiene rubber
Phenol ethoxylates	Octylphenol ethoxylate	Surfactant
Bisphenols	Bisphenol-A	PVC
Salicylates	Octisalate	Sunscreen
Phosphated phenols	Triphenyl phosphate	Flame retarded plastics
Benzidiols	Resorcinol	Ointments

CE Marking Conformity Assessment - RoHS

- EN 63000:2018 replaces EN 50581:2012
 - Based on IEC 63000:2016
- Key items
 - Basically same as previous EN 50581
 - To align with international standards
 - Implementation deadline (on CENELEC website) - 2019-06-07
- However, replacement of EN 50581 by EN 63000 has not been cleared through the EU Commission
 - So, according to the EU commission, EN 50581 is still the standard. Transition timeline 5 years.



New Standard for RoHS Technical File

- Key elements unchanged
- The manufacturer shall undertake the following four tasks:
 - determine the information needed (see 4.3.2);
 - collect the information (see 4.3.3);
 - evaluate the information with regard to its quality and trustworthiness and decide whether to include it in the technical documentation (see 4.3.4);
 - ensure that the technical documentation remains valid (see 4.3.5).

Recommended Approaches

- There is going to be confusion.
- Declaration of Conformity (DoC)
 - By July 2019, two options
 - Use both standards
 - EN 50581:2012 / EN 63000:2018
 - Stay with just EN 50581:2012
 - Supposedly there is a 5 year transition period
- Declaration
 - The standards are the same
 - Neither is incorrect
 - Best approach until clear guidance from EU Commission

Supplier Declarations (EN 63000 / 50581)

- Supplier declarations and/or contractual agreements, such as:
 - Supplier declarations, confirming that the restricted substance content of the specified material, part, or sub-assembly is within the permitted levels and identifying any exemptions that have been applied;
 - Signed contracts confirming that the manufacturer's specification for the maximum content of restricted substances in a material, part, or sub-assembly is fulfilled.
- Such declarations or agreements shall cover a specific material, part and/or sub-assembly, or a specific range of materials, parts and/or sub-assemblies.

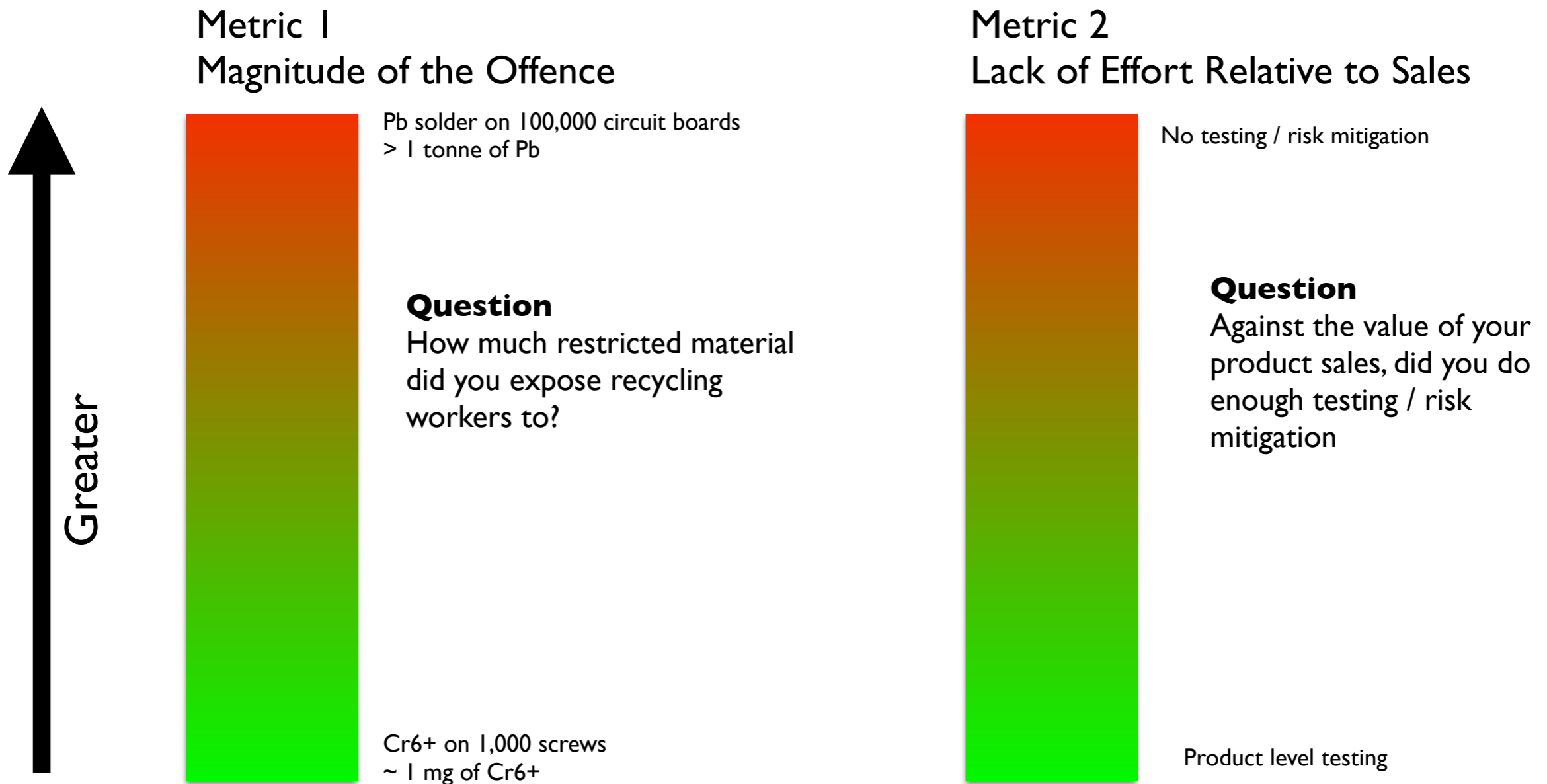
Supplier Specification

- Key note
 - If your supplier specification includes RoHS including 2015/863 phthalate restrictions,
 - And supplier agrees to it, that meets the documentation requirements of EN 50581 / EN 63000
 - In summary, CE marking documentation requirement is met if supplier agrees to specification including applicable RoHS requirements
- As long as risk is mitigated
 - Which is also true for RoHS CoCs

Enforcement in Practice

- Claigan has participated in a large number of restricted materials enforcement actions
 - RoHS, REACH, POP, Canadian Prohibition, Prop 65
- Consistent question from national authorities
 - Request for test reports for products
 - (unless self reported)

Enforcement Metrics



Risk Mitigation - Enforcement

- Very important question that occurs in every non-self reported enforcement action
- Considering the value of your sales in our jurisdiction,
 - Could you and should you have done more testing?
- Note - by value, not by volume.

Is CoC Data Gathering Successful?

- In making an RoHS compliant product?
 - Not usually.
- Risk mitigation
 - In 2018, >50% of finished electronic products that used after the fact data gathering as their primary compliance method failed RoHS 2 under testing
 - and initial results for RoHS 3 are worse

Best Compliance Approach

- Create restricted materials specification
 - Part of design not after the fact data gathering
 - Reference specification in designs and orders
 - Acquire confirmation at the supplier level
 - Create annual cycle to update specification
 - Add new requirements
 - Re-acquire supplier compliance
 - Same deadline / cycle every year
- Product testing
 - Test representative products to ensure specification is working

New Products

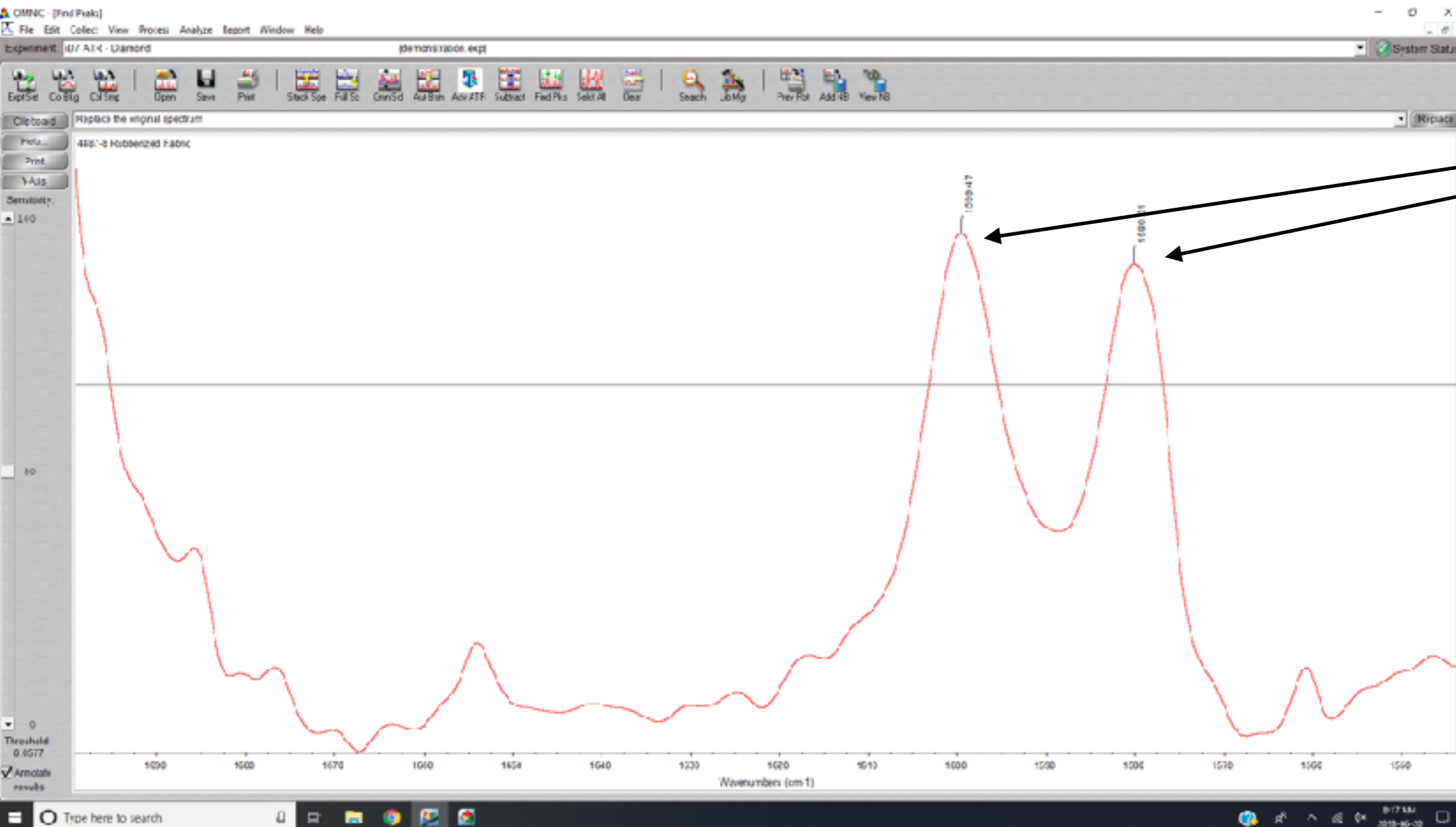
- Add to new product design process
 - Specification for designers to
 - Include in designs and specifications
 - Provide to suppliers
 - Use as guideline for choosing new parts and materials
- Add product test report as output in NPI process
 - At the same point in the NPI process as EMC testing, make a restricted materials test report necessary to reach manufacturing phase
 - A tangible output and gate will also make life easier for the product line manager

Legacy Products

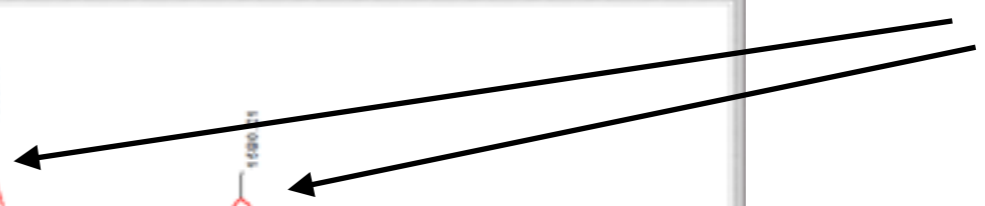
- Restricted materials specification
 - Create restricted materials specification
 - Provide to suppliers
 - Acquire confirmation at the supplier level
- Product testing
 - Test representative products to ensure process is working
 - Not all products, but enough to satisfy the question
 - “Against the value of your product sales, did you do enough testing / risk mitigation?”

Phthalate Screening - Large Scale or Closing Out the Project

- New screening technique validated for orthophthalates
 - RoHS 3, REACH SVHC, and Prop 65 phthalates
 - Fourier-transform infrared spectroscopy (FTIR) screening

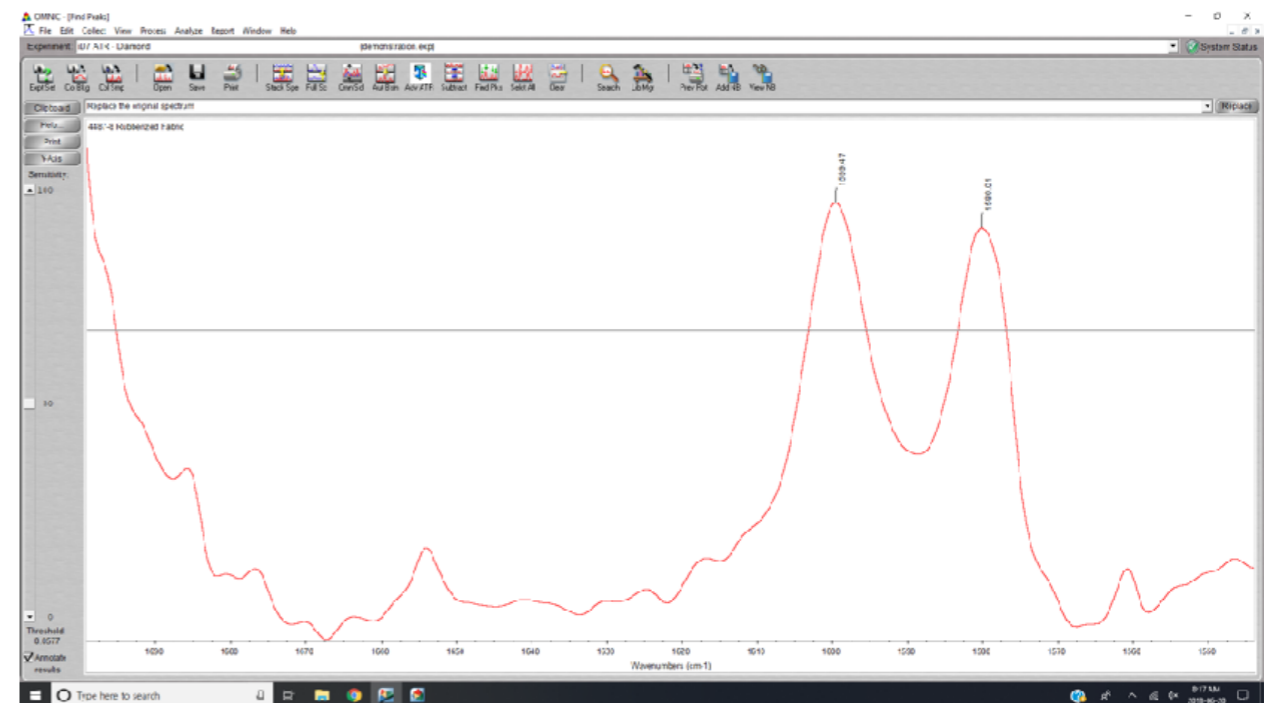


Orthophthalate peaks
(C=C bond in orthophthalate)



Phthalate Screening - Advantage

- Fast screening of presence of orthophthalates
 - Cannot distinguish which phthalate is present, but *if* a phthalate is present
 - Much faster / cheaper than digestion / GC-MS
 - Allows rapid screening of large number of components
 - Especially good for electronics (wires, gaskets, etc..)
 - Great for meeting last minute deadlines or as RoHS 3 risk mitigation
 - Can performed at your site

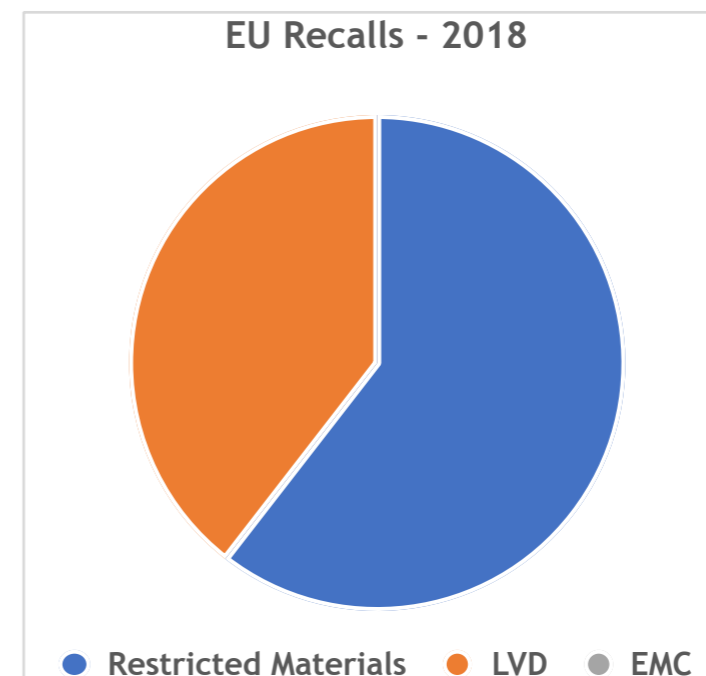
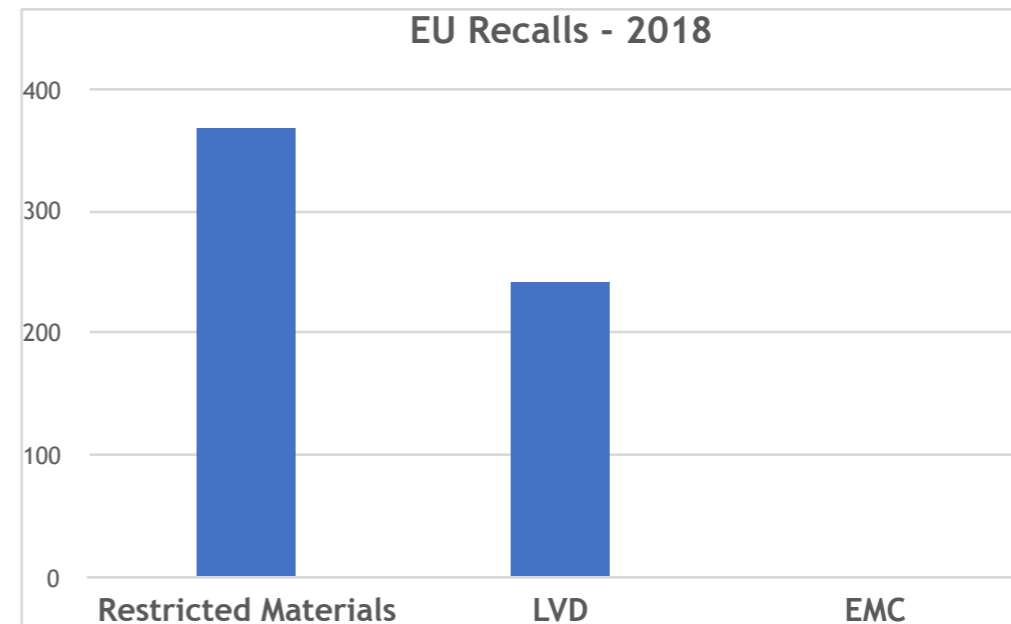


Summary

- Phthalates (DEHP, BBP, DBP, DIBP)
 - Common in PVC, neoprene, nitrile rubber, sbr rubber
- CE marking
 - Conformity assessment requirement
 - Either supplier documentation or testing
 - Risk mitigation required
 - Testing or other risk mitigation requested by national authorities
- Key question
 - “Against the value of your product sales, did you do enough testing / risk mitigation?”

EU Recalls - 2018

Regulation	Recalls
Restricted Materials	369
LVD	241
EMC	0



Phthalate Screening - Advantage

- Fast screening for presence of orthophthalates
 - Cannot distinguish which phthalate is present, but *if* a phthalate is present
 - Much faster / cheaper than digestion / GC-MS
 - Allows rapid screening of large number of components
 - Especially good for electronics (wires, gaskets, etc..)
 - Great for meeting last minute deadlines or as RoHS 3 risk mitigation
 - Can performed at your site

Q&A

