Focus on the European Union's REACH regulation and its implications for the Aerospace/Defense supply chain

Dr. Chris Robertson

Head of Regulatory Compliance, ERA Technology Ltd., UK

chris.robertson@era.co.uk, tel. +44 (0)1372 367204

Content

- About ERA
- Overview of REACH and key obligations
- Substances of Very High Concern (SVHCs)
  - tracking
  - authorisation process
  - restrictions
  - consultations and recent events
- Managing SVHC content information in the supply chain
- Relationship with the RoHS2 additional substances study (in brief)
- Key engagement fora

About ERA

- 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**

About ERA

- We track regulatory issues

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

REACH
- overview and key obligations

REACH overview
- Regulation 1907/2006

- **R**egistration
- **E**valuation
- **A**uthorisation of
- **Ch**emicals

Affects

- Chemical manufacturers
- Chemical importers
- Users of chemicals
- Distributors of chemicals
- Manufacturers and suppliers of hardware and components

REACH overview

- So what?

~~**Chemical manufacturers will deal with it – REACH has nothing to do with us**~~

REACH overview

- *Scope*

- Scope - almost everything
  - Substances

  - Mixtures of substances

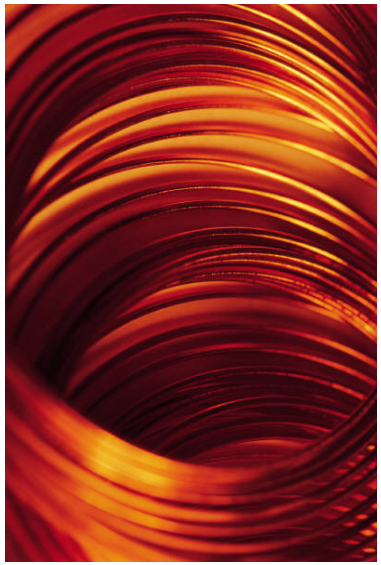
  - 'Articles'

REACH overview

- *What is an article?*

- “an object which during production is given a special shape, surface or design which determines its function to a greater degree than its chemical composition"

Ingots – are mixtures



This tube is an article as shape is more important

REACH overview

- *Obligations and impacts*

- Principal obligations
  - Registration of chemicals
  - Only use of certain chemicals where authorised
  - Substance restrictions
  - Providing information and safe use
- Impacts
  - Big increase in supply chain communications
  - Obsolescence of chemicals and products

REACH impact and obligations depend on your role

Role -1- "**Importer/mfr"** of substances/mixtures

Role -2- "**Downstream user**" of substances/mixtures

Role -3- "**Importer/manufacturer"** of articles

Role -4- "**Distributor**" of substances/mixtures

REACH - main requirements

Role -1-

"**Importer/mfr"** of substances/mixtures
registration, define and ensure safe use

Role -2-

"**Downstream user**" of substances/mixtures

Role -3-

"**Importer/manufacturer"** of articles

Role -4-

"**Distributor**" of substances/mixtures

Role
- 1 -

Importer/manufacturer of substances/mixtures

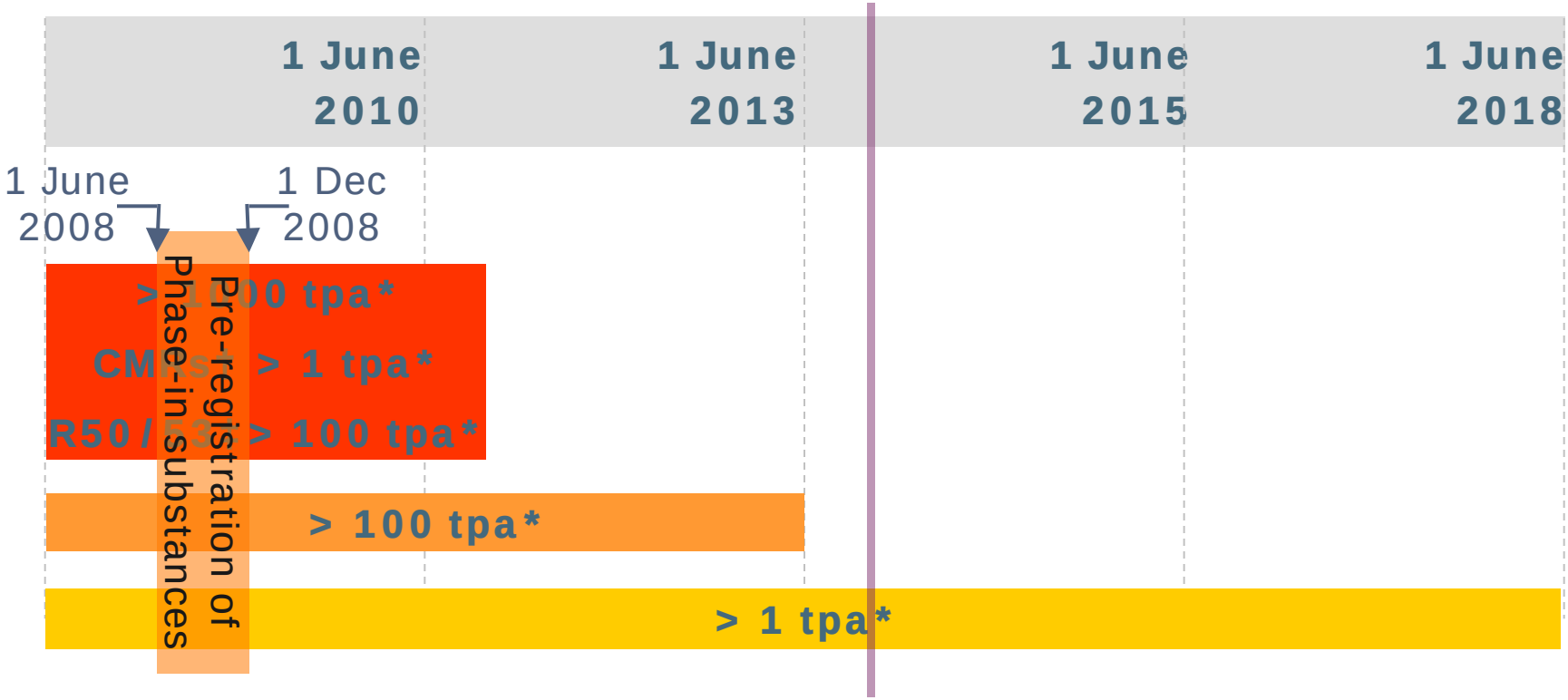
- Treated as the manufacturer unless non EU manufacturer appoints “only representative”
- Obligations
  - registration – see timeline – requires data submission
  - develop exposure scenarios
  - pass and accept data up and down supply chain

http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances

Role -1-

Timeline for registration

- *Phase-in (existing) substances*



* *substances produced/ imported per manufacturer or importer in volumes of*

† *carcinogen, mutagenic, toxic for reproduction, cat 1 or 2 according to Directive 67/548/EEC*

‡ *very toxic to aquatic organisms according to Directive 67/548/EEC*

REACH - main requirements

Role -1-

"**Importer/mfr"** of substances/mixtures

registration, define and ensure safe use

Role -2-

"**Downstream user**" of substances/mixtures

ensure safe use

Role -3-

"**Importer/manufacturer"** of articles

Role -4-

"**Distributor**" of substances/mixtures

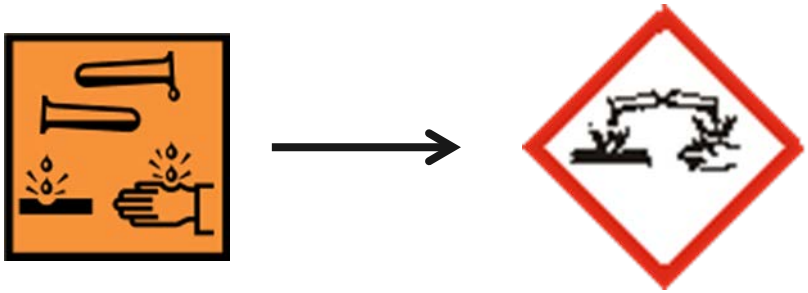
REACH overview

- *Use of chemicals*

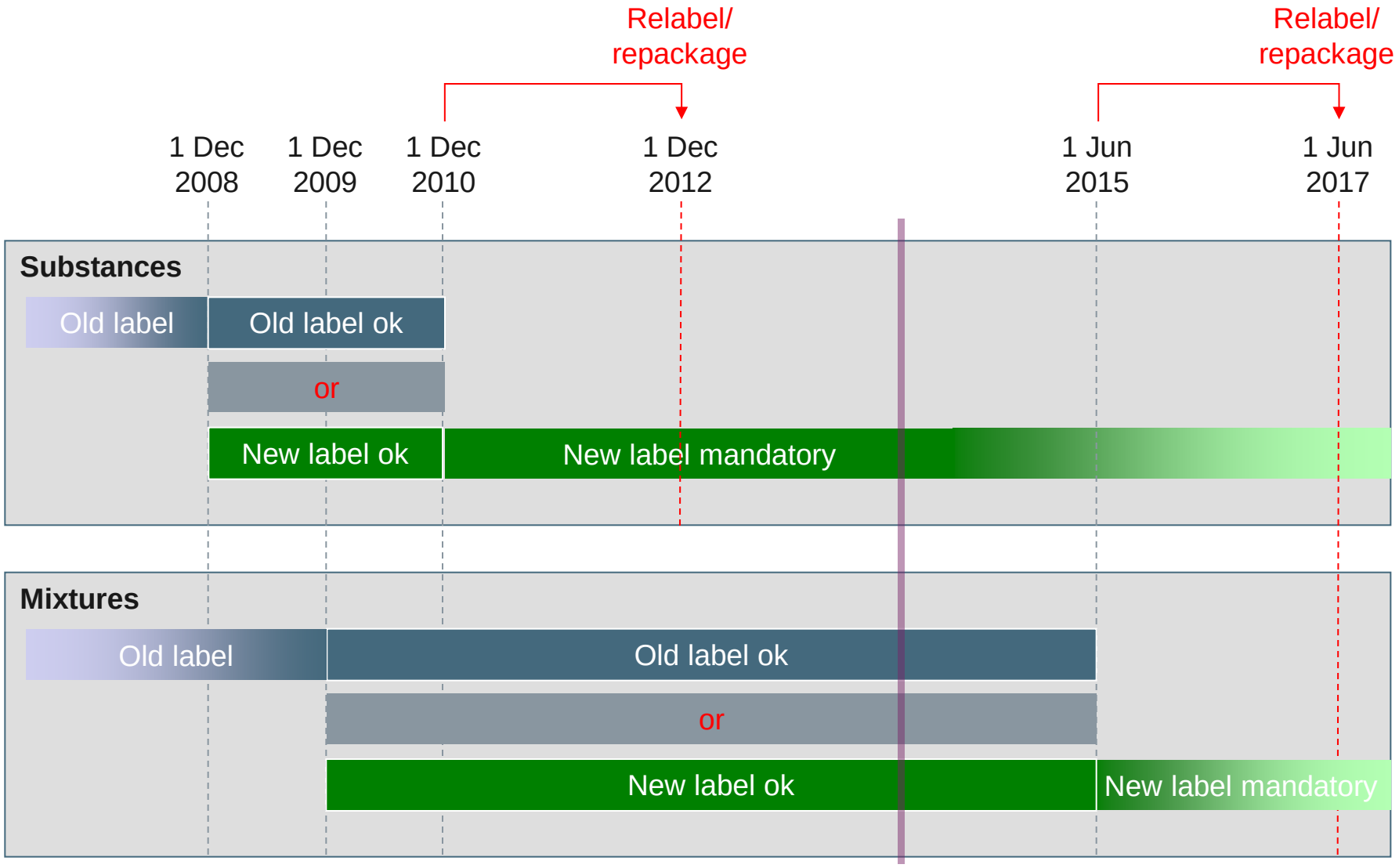
- Chemicals
  - paints, adhesives, solvent cleaners, solder paste, etc.
- Safety data sheet (SDS)
  - Must be supplied with all “dangerous” chemicals
    - New structure of SDS must be used
  - Use SDS to prepare safety assessment
  - SDS may include “exposure scenario” which will list all permitted “uses”. Chemicals are not permitted to be used in any other ways
    - “Uses” include storage, transfer between containers and waste disposal

Classification, Labelling and Packaging (CLP) Regulation 1275/2008

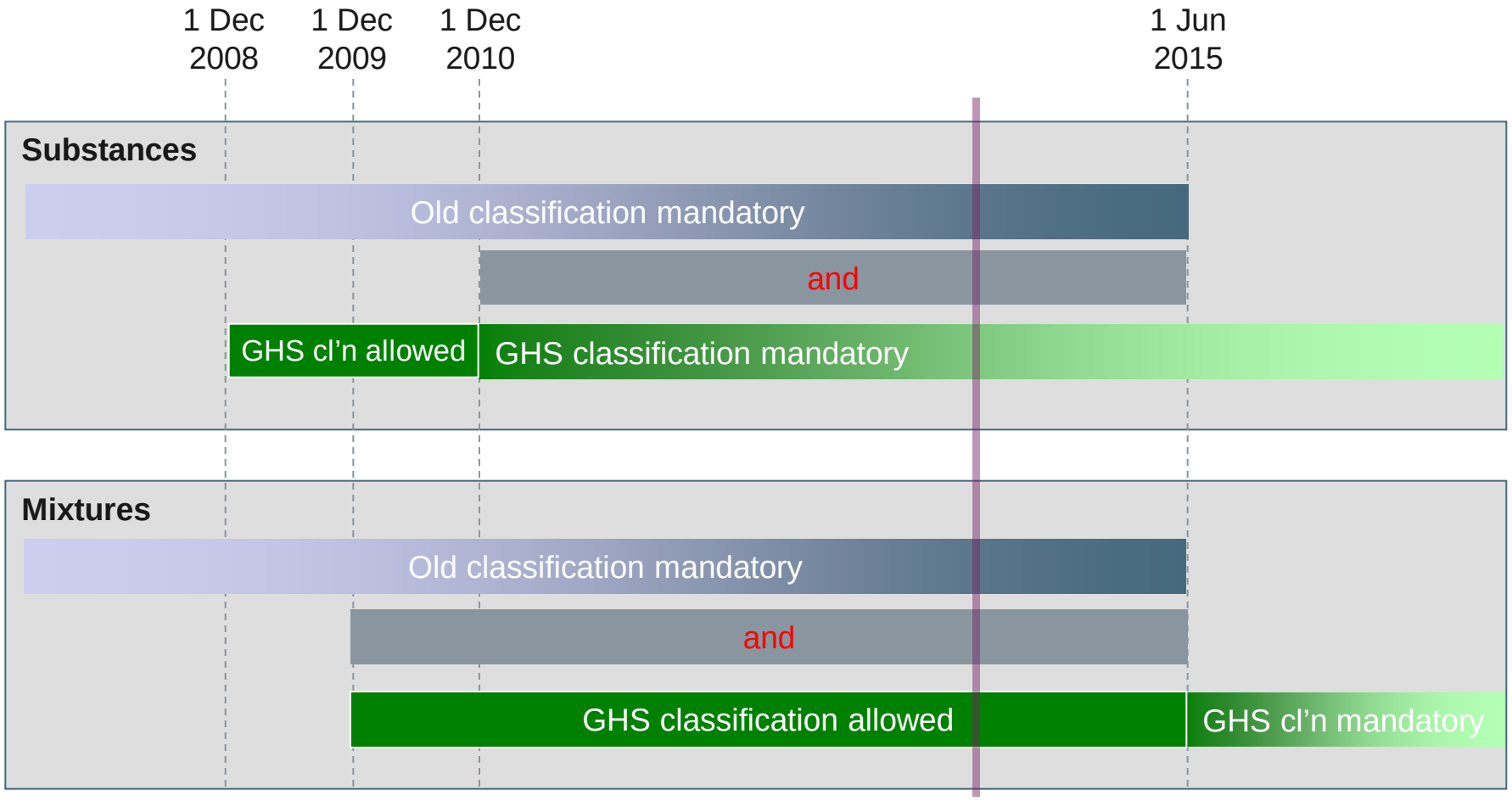
- Separate to REACH but closely linked
- Uses Globally Harmonised System (GHS) for hazard classification and labelling chemicals
  - New pictograms
  - Hazard and precautionary statements
  - Requires relabeling of chemical containers and changes to safety data sheets



GHS/CLP Labelling



GHS/CLP SDS Classification



REACH - main requirements

Role -1-

"**Importer/mfr"** of substances/mixtures

registration, define and ensure safe use

Role -2-

"**Downstream user**" of substances/mixtures

ensure safe use

Role -3-

"**Importer/manufacturer"** of articles

communicate safe use, avoid restricted substances

Role -4-

"**Distributor**" of substances/mixtures

REACH overview

- *SVHCs*

- **S**ubstances of **V**ery **H**igh **C**oncern
  - *Candidate list* of substances subject to authorisation for use
  - 144 substances (as at 20 June) - many more proposed
    - Examples: chromates, phthalates, cadmium, cadmium oxide
  - Obliges suppliers to
    - inform customers if an SVHC is present at >0.1% in an article
    - and provide safe use information if necessary for normal use of the article
- SVHCs added to Annex XIV (Authorisation)
  - After *sunset date* these chemicals cannot be used in the EU unless authorised for specific use
  - Does not apply to substances in articles imported into the EU

REACH overview

- *Substance restrictions*

- > 60 categories of substances listed in Annex XVII
  - Some are total bans on sale, use or import as chemicals or in articles – e.g. penta-BDE,
  - Some restrict supply to users – e.g. CMRs to consumers
  - Some restrict specified uses – e.g. SCCP in tyres
  - Some are process chemicals only
- More continuously added to list
  - e.g. cobalt compounds being considered

REACH - main requirements

Role -1-

"**Importer/mfr"** of substances/mixtures

registration, define and ensure safe use

Role -2-

"**Downstream user**" of substances/mixtures

ensure safe use

Role -3-

"**Importer/manufacturer"** of articles

communicate safe use, avoid restricted substances

Role -4-

"**Distributor**" of substances/mixtures

communicate up / down supply chain

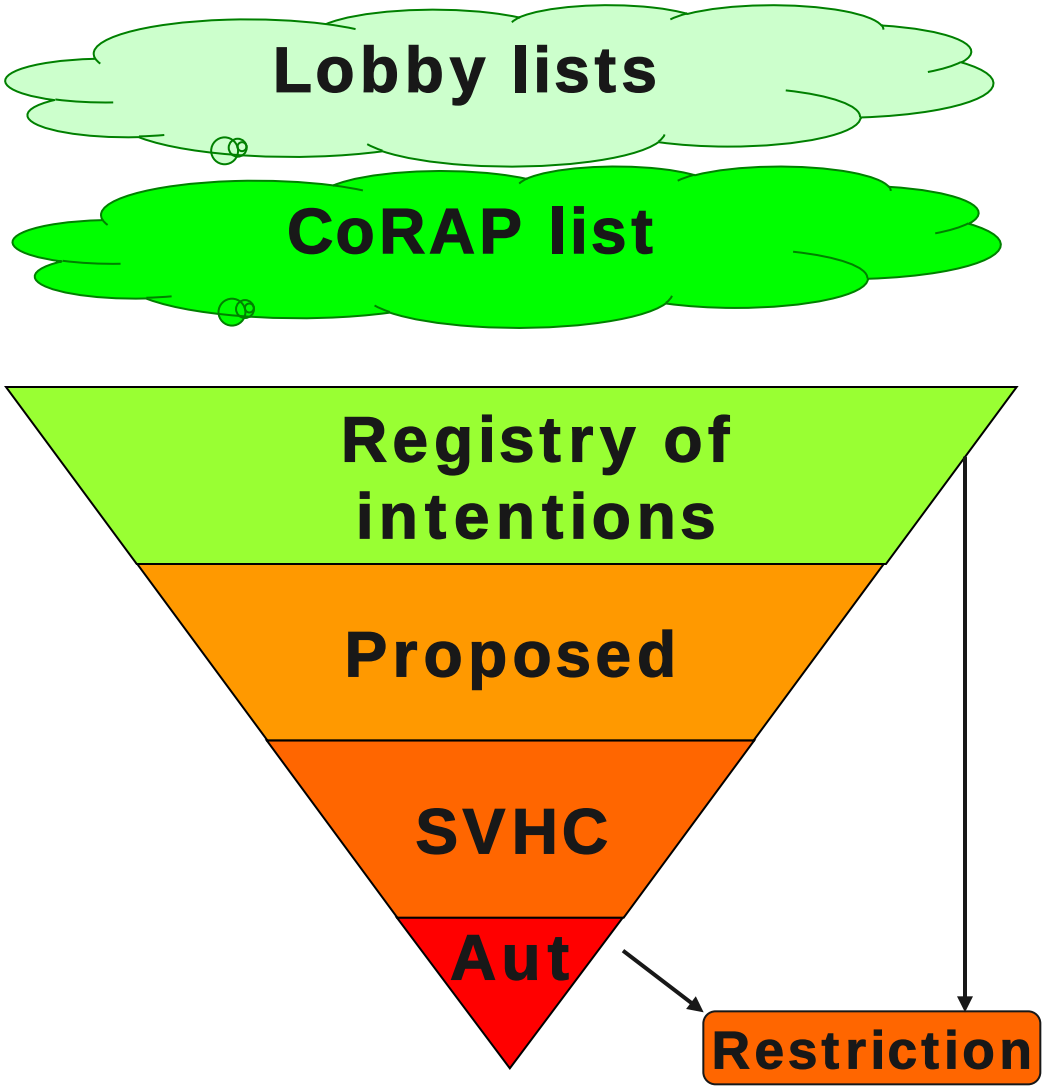
ENFORCEMENT

- REACH-EN-FORCE 1 (May 2009 to April 2011)
  - Focused on pre-registration and start of supply chain
  - ~2400 inspections in 26 countries
    - Significant deficiencies re. registration and SDS
- REACH-EN-FORCE-2 (May 2011 to March 2012)
  - Focused on downstream users who formulate mixtures
  - ~1200 inspections 29 states
    - More SDS available (86>>97%) and formats improved
    - 52% of SDS defective, 24% of labels did not correspond with SDS
- REACH-EN-FORCE-3 (Feb to August 2013 >?)
  - Focusing on registration obligations in general, Only Representatives obligations, Customs cooperation

Substances of Very High Concern (SVHCs)

- tracking
- authorisation process
- restrictions
- consultations and recent events

Authorisation and restriction – the process



Legal Requirements

None but increasing pressure on supply chain, from customers, NGOs and investors

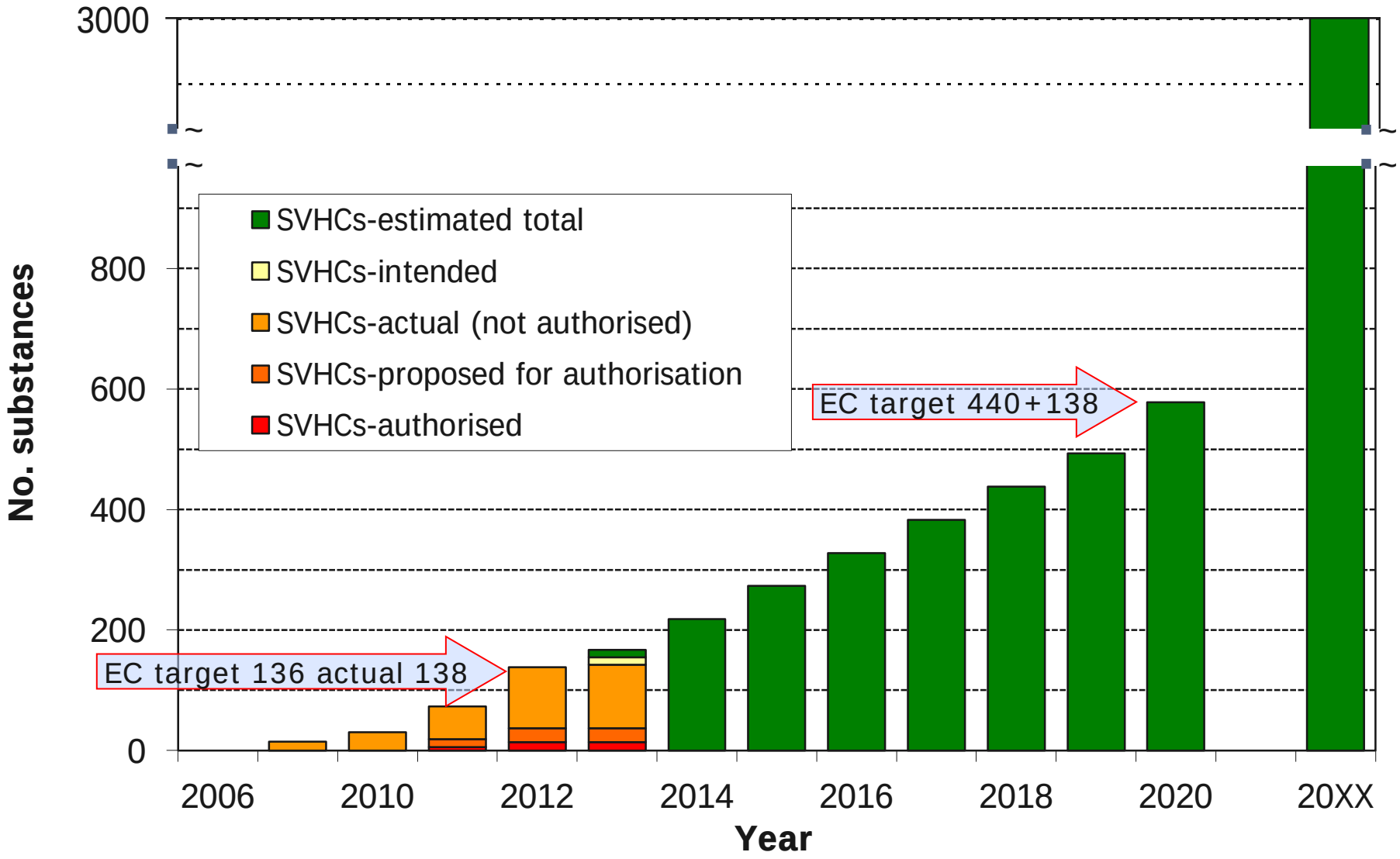
Provide data (+notification)

Only allowed in authorised "uses"

Role
- 3 -

Obligations regarding articles

- *Projected growth of SVHCs*



SVHCs – latest proposals

SVHC	Main uses
cadmium sulphide	Bright yellow and in photo-electronics (solar cells etc.)
di-n-hexylphthalate (DnHP/DHP)	Plasticiser in cellulose esters and PVC.
C.I. Direct Red 28	None known.
C.I. Direct Black 38	None known but has been used in plastics and textiles
ethylene thiourea	Unlikely (vulcanisation agent)
lead di(acetate)	Coatings and paints, thinners, paint removers. Fillers, putties, plasters
trixylyl phosphate (TXP)	Fire retardant for some plastics, FR in hydraulic fluids (e.g. for industrial generators)

SVHCs - Authorisation

- *Why is this important?*

- SVHCs placed on the Annex XIV list are not be allowed on the EU market (as chemicals) after a “sunset” date unless the “use” is authorised
  - This will directly affect:
    - Producers/importers of chemicals
    - Downstream users of chemicals
    - Producers of articles (if unable to use chemicals)
  - And indirectly:
    - The world market
- “Uses” include
  - storage, transfer between containers, processes and disposal
- But authorisation is not be required by importers and users of articles that contain these substances as integral parts which are made outside the EU

SVHCs
- Authorised and planned

- So far, 22 substances are listed in Annex XIV

Substance	Uses	Sunset date
DEHP	Plasticiser	21/02/2015
HBCDD	Flame retardant in HIPS	21/08/2015
MDA	Epoxy resin hardener	21/08/2014
Most chromates		21/09/2017
Sodium dichromate	Passivation, hard chromium plating	21/09/2017
Trichloroethylene	Metal degreasing	21/04/2016
(Cobalt compounds)	Surface treatment-hardening, anti-corrosion > being considered for restriction instead	

- More are proposed for inclusion – includes:
  - Refractory ceramic fibres – MAJOR substitution problem

The problem in practice -an example

- *hexavalent chromium*

- Many people asked “Is it is really a problem?”
  - “chromates won’t be authorised for several years”
  - “REACH allows authorised uses”
  - “what about getting a ‘defence exemption’ ”
  - “we can carry on manufacturing outside the EU”
- Yes, but...
  - Authorisation will not be granted if safer alternatives exist
  - Application for authorisation is expensive, manufacturers may not apply, especially for niche uses
  - Most EU States do not allow ‘defence exemptions’ – and they are few
  - Early obsolescence (globally) is a real possibility
  - Switching suppliers may require re-approval of products

Making a request for an authorised use

- *Experience so far*

- Early days
  - unclear process, strength of evidence?

- Just one request so far – Rolls-Royce
  - required for “processing of a stop-off formulation containing DEHP during the diffusion bonding and manufacture of aero engine fan blades”
  - stakeholder consultation closes October 9th, 2013

- What are the key lessons ...?

Making a request for an authorised use

- *Lessons so far*

- It costs and is very time consuming!
  - So don't do it unless absolutely necessary!
- Plan ahead
  - Difficult to understand
  - First application took 15 months (should shorten)
- Apply as high up the supply chain as possible
  - Authorisations apply downstream but only one step upstream
  - Ensure supply chain is on side
- Define the "use" simply and at as high a level as possible
  - Consistent with the similarity regarding substitution/alternatives
- Keep the arguments simple and clear

REACH Restrictions

- Annex XVII lists substance restrictions
  - Some are full bans such as pentabromodiphenyl ether
  - Some only affect supply to consumers
  - Some are application specific
- Examples that affect EEE
  - Cadmium in plastics (certain types), coatings and braze alloys – specified uses
  - Nickel – if in skin contact (based on test method)
  - Six plasticisers in children's products
  - Certain organo-tin compounds
  - Dimethylfumarate (biocide used in leather)

REACH restrictions

- *Cadmium*

- Cd in coatings and in plastics as pigment or stabiliser restricted in most applications since 1993
- Cd plating is allowed for “articles and components of the articles”
  - “used in …. aeronautical, aerospace … whose applications require high safety standards“
  - “electrical contacts in any sector of use, where that is necessary to ensure the reliability required of the apparatus on which they are installed”
- Cd in braze alloys restricted since 2010
  - allows “brazing fillers used in defence and aerospace applications and to brazing fillers used for safety reasons”

Managing SVHC content information in the supply chain

REACH

- *Article 33 declaration*

- **Duty to communicate information on substances in articles**

1. Any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0,1 % weight by weight (w/w) shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.

Role
- 3 -

Approaches to Article 33

Option	Pros	Cons
1 Full materials declaration	• Most comprehensive • Future proofing	• Most expensive • Not required • Suppliers unlikely to cooperate

Role
- 3 -

Approaches to Article 33

Option	Pros	Cons
1 Full materials declaration	• Most comprehensive • Future proofing	• Most expensive • Not required • Suppliers unlikely to cooperate
2 Demand declaration of all SVHCs	• Meets requirement (if you can get it)	• A blunt instrument • Will make your job more difficult

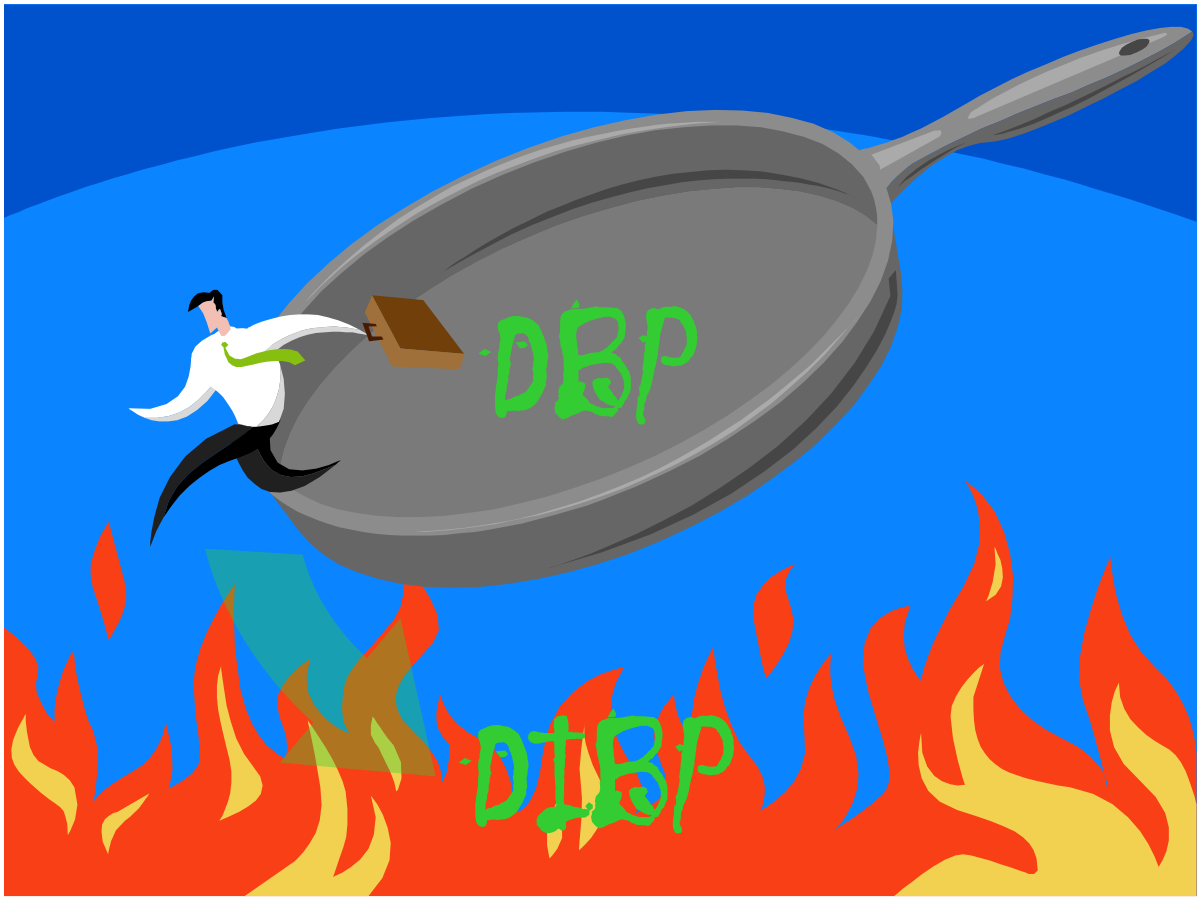
Role
- 3 -

Approaches to Article 33

Option	Pros	Cons
1 Full materials declaration	• Most comprehensive • Future proofing	• Most expensive • Not required • Suppliers unlikely to cooperate
2 Demand declaration of all SVHCs	• Meets requirement (if you can get it)	• A blunt instrument • Will make your job more difficult
3 Risk-based declaration	• Targets resource where most needed • Most likely to get data you need	• Rationale needs to be well defined and executed

REACH key issues
- Substance obsolescence

- Don’t get your fingers burnt!



Role
- 3 -

Obtaining Article 33 information

- *Risk based approach*

- For each item supplied
  - Step 1 – Assess what SVHCs could be present
    - Discount all other SVHCs
  - Step 2 – What SVHCs could be present above 0.1% by wt.?
    - Discount all other SVHCs
  - Step 3 – Ask supplier targeted questions on remaining SVHCs
    - Assess response critically (why should you believe them?)
  - Step 4 – Follow up supplier
    - Those who have not responded
  - Step 5 – If response inadequate choose next step
    - Change (or make plans to change) supplier
    - Chemical analysis
    - Accept? (note wording of Article 33)

SVHCs - examples

SVHC	Main uses
Chromates	**Passivation surface treatments**
Zinc chromate	**Primer (unlikely to exceed 0.1% of article)**
Bis–ethylhexyl phthalate (DEHP)	Plasticiser (most commonly used SVHC)
SCCP	Plasticiser and flame retardant (now classified as a POP so banned in EU)
Boric oxide	Flame retardant for paper (e.g. in instruction manuals)
PZT	Piezoelectric ceramic (e.g. in transducers)
MDA (methylene dianiline)	Epoxy hardener – not present in cured resin. Many resin suppliers have phased out MDA
2-ethoxyethanol; ethylene glycol monoethyl ether	Solvent so will not occur in articles
cadmium, cadmium oxide	high reliability coatings, contacts, specialist jointing

Business response
- Talk to your suppliers

- Use a phased approach

1. Who is responsible for REACH in your organisation?

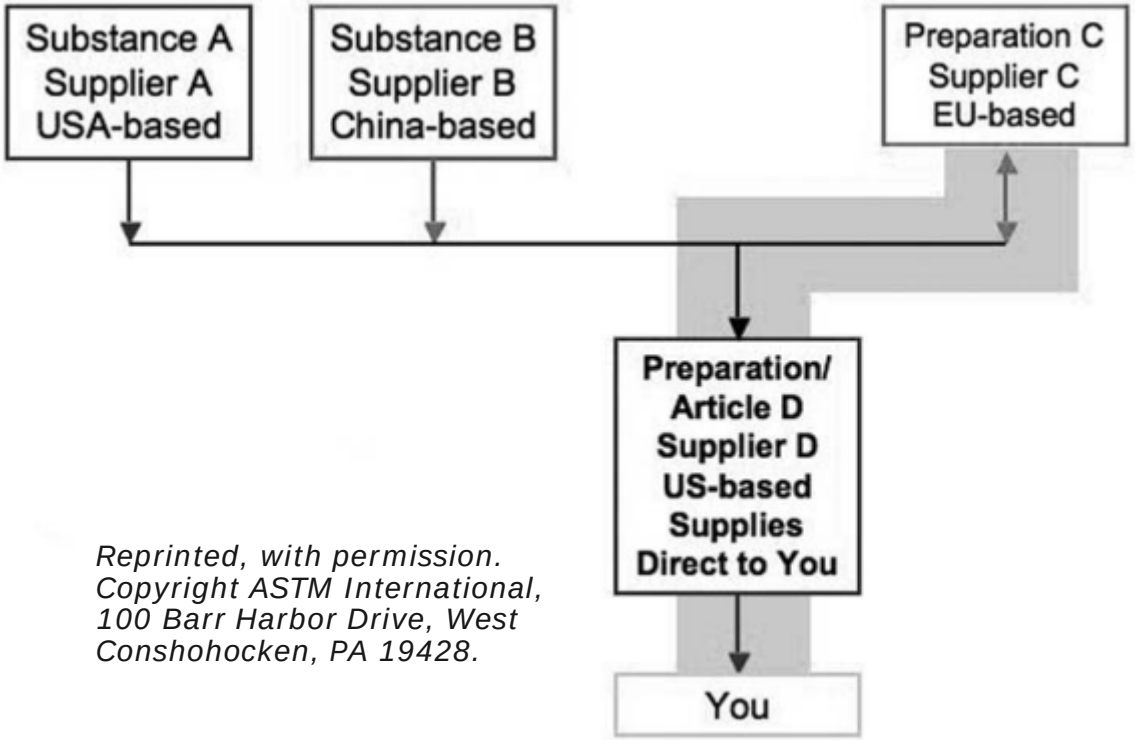
2. Ask some basic questions

    1. Do you understand your obligations under REACH?
    2. What are these obligations?
    3. What are you doing to address these?
    - Make clear their response may affect your relationship

3. Detailed dialogue >>>

Business response
- *Talk to your suppliers – useful tool*

- ASTM F2725-08, Standard Guide for REACH Supply Chain Information Exchange



Reprinted, with permission. Copyright ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428.

- A common approach to showing conformance
- Explains what needs to be done by each actor
- Charts process
- Questionnaires
- Worked examples

- Standard may be obtained from ASTM (www.astm.org)

REACH – final matters

- what to look out for
- RoHS2 vs. REACH

REACH – what to look out for

- *Reclassification*

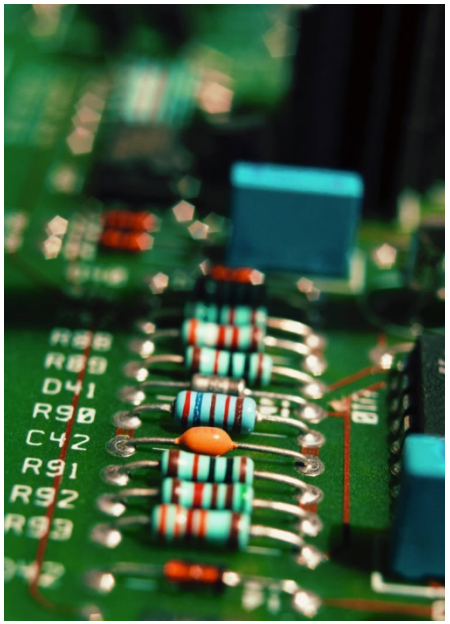
- New substance data
- Reclassification proposed
- Consequences
  - Becomes SVHC?
  - More stringent handling required? Training?
  - Revised exposure scenarios
  - Obsolescence
- Example – Nitric Acid
  - Proposed: Acute Toxic Category 1 by inhalation
  - Implications
    - Sites holding large quantities at high concentrations may be subject to Seveso III (control of major accidents)
    - Consumer: Child resistant fastenings, tactile warnings etc.
    - Review of handling procedures, documentation etc.

Role
- 3 -

0.1% SVHC limit

- *Current interpretation of articles*

Capacitors are articles



PCBs are articles

PC – another article

DEHP in PVC will exceed 0.1% in this cable but DEHP in wires of a PC may be <0.1% of article

REACH

- *Article 33 declaration*

- A potentially big problem!
  - Austria, Belgium, Denmark, France, Germany, Sweden insist that “0.1%” applies to each and every item once it becomes an article
  - Conflicts with official ECHA guidance and opinion of EC
  - Much more work to comply
    - No health or environmental benefit – because if there were an uncontrollable risk, the EC should introduce a restriction
  - Industry active in lobbying against this interpretation
  - France announced in 2012 that it will enforce their interpretation – but no legal action yet

REACH and the RoHS2 additional substances study

- 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
- Why is this relevant to REACH?
  - Substance overlap
  - Methodological link
  - Blacklist...?

Umweltbundesamt (Austria)

Jan 2013 – Jan 2014

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

REACH and the RoHS2 additional substances study

- 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)

REACH and the RoHS2 additional substances study

- 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)

REACH and the RoHS2 additional substances study

- Likely outcome?
  - risk assessment of the 3 phthalates – possible restriction
- The future
  - more studies are very likely including overlapping substances
  - will increase pressure for wider removal of these substances from supply chain generally

Key engagement fora

- *from "article" perspective*

Conclusions

- Number of supply chain and product related requirements continually increases
  - EU, US, Federal, national and worldwide
- Main types are:
  - Eco-design
  - Substance based (full/partial ban or information only)
  - End of life
  - Responsible sourcing - NEW
- Incorporate compliance within your existing processes
  - Should be proportionate, risk based and documented
  - Work with others where possible
  - Keep up to date

Thank you!

Dr Chris Robertson

Head of Regulatory Compliance

ERA Technology Limited

Cleeve Road, Leatherhead, Surrey KT22 7SA, UK

chris.robertson@era.co.uk • www.era.co.uk • tel: +44 (0) 1372 367204