Design Chain Solutions for Competitive Advantage: Your Environmental Solutions Resource

DIRECTIVE 2011/65/EU - REACH

What You Need to Know

DESIGN CHAIN ASSOCIATES

Ken Stanvick

SVP – Co Founder

Ken@designchainassociates.com

Agenda

- EU RoHS Today
- EU RoHS Recast
  - Scope
  - Definitions
  - Product Exclusions
  - Prevention
  - Inclusions/Exemptions
  - Review / Amendment of Restricted Substances
  - Obligations of Manufacturers
  - Authorised Representatives
  - Obligations of Importers

DESIGN CHAIN ASSOCIATES

Agenda

- EU RoHS Recast
  - Obligations of Distributors
  - Importers and Distributors Considered Manufacturers
  - Identification of Economic Operators
  - EC Declaration of Conformity
  - General Principles of the CE Marking
  - Rules and Conditions for Affixing the CE Marking
  - Presumption of Conformity
  - Future RoHS Review
  - Entry Into force & Transposition

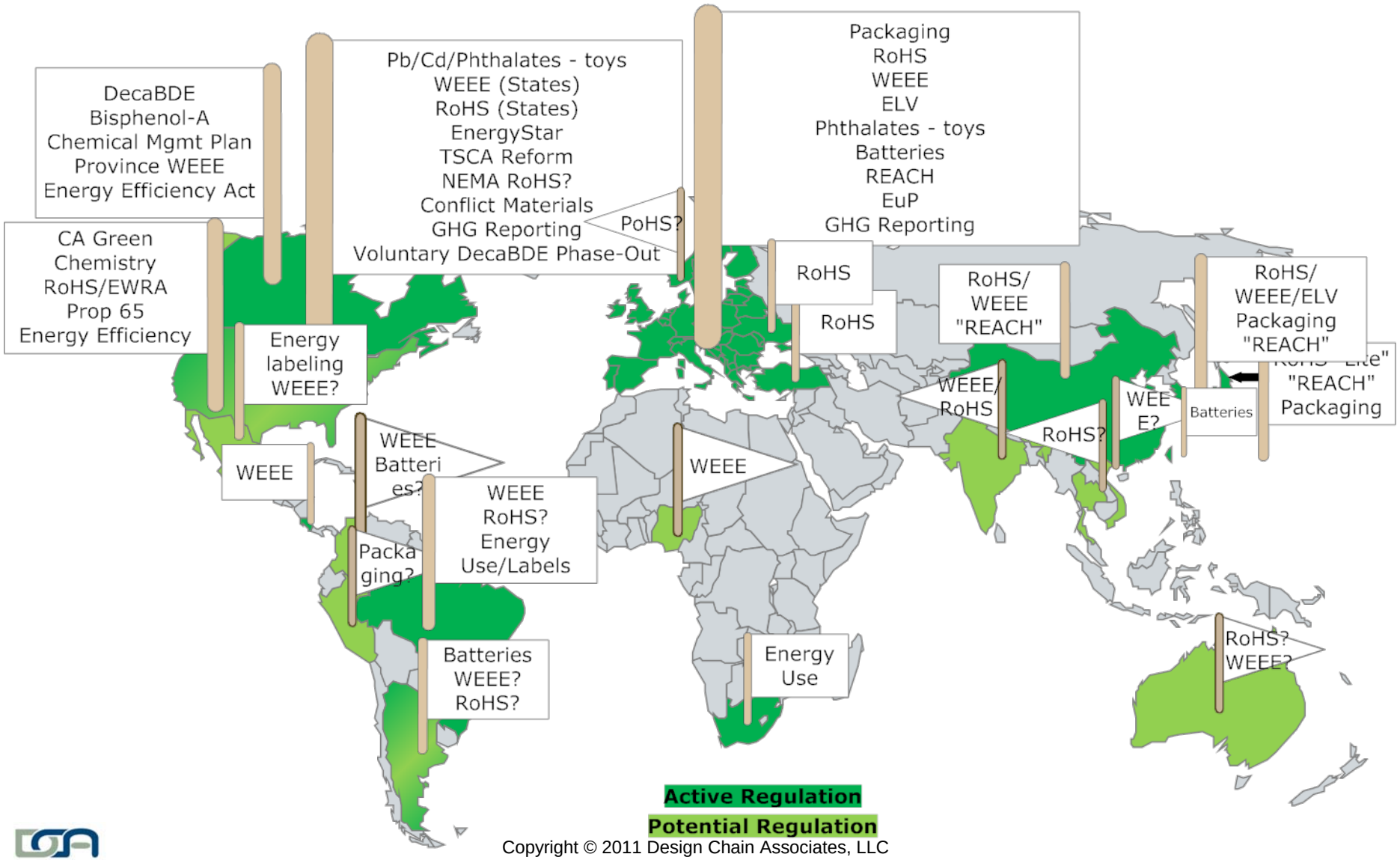
DESIGN CHAIN ASSOCIATES

Agenda

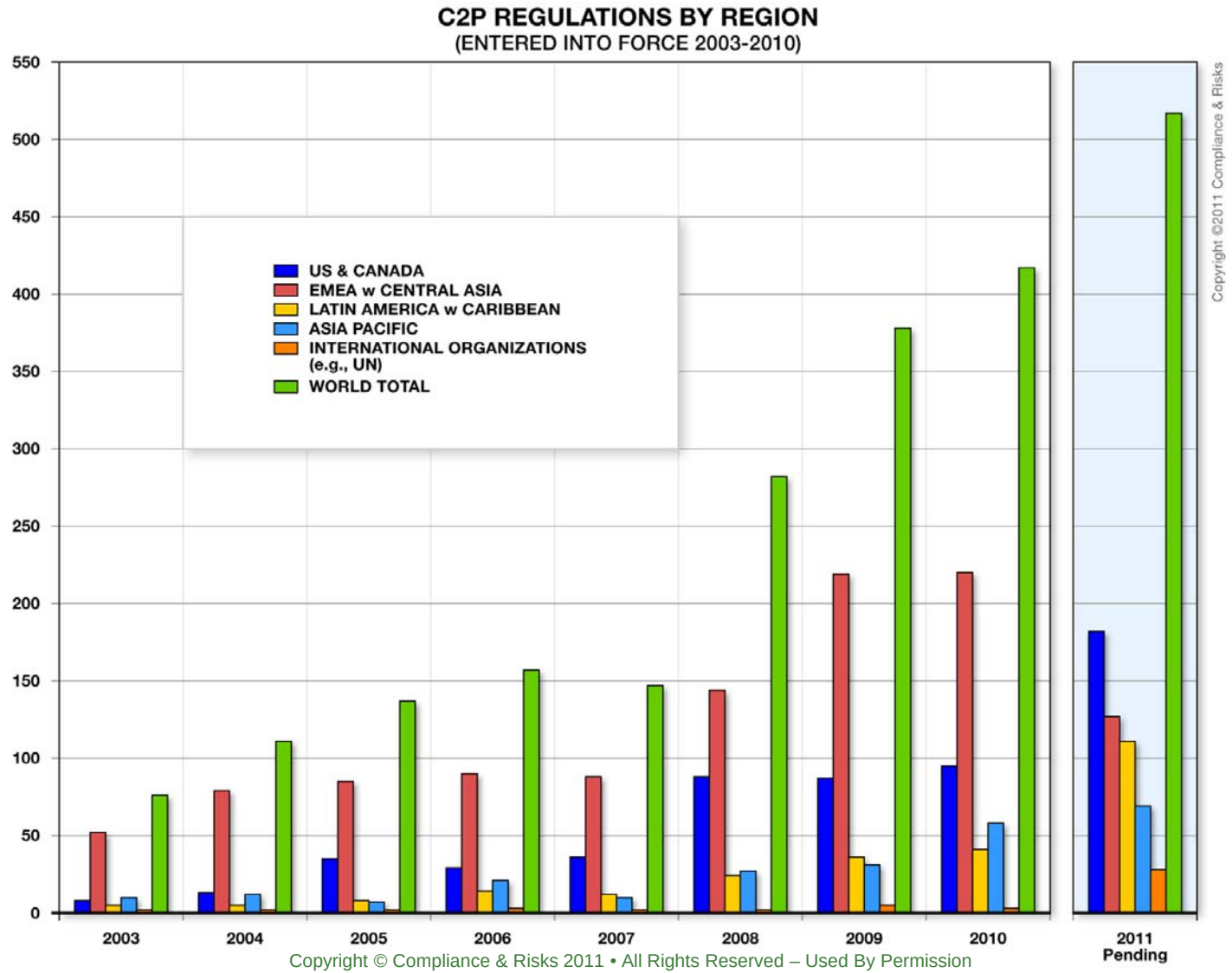
- CE Marking overview
  - Regulation (EC) No 768/2008
    - General Principles Article 1
    - Definitions Article R1
    - Obligations of Manufacturers Article R2
    - CONFORMITY ASSESSMENT PROCEDURES ANNEX II
      - Module A Internal production control
      - Technical documentation
      - Manufacturing
      - Conformity marking and declaration of conformity
      - Authorised representative
    - Affixing of the CE Marking
  - Guide to the implementation of directives based on the New Approach and the Global Approach
    - http://ec.europa.eu/enterprise/policies/single-market-goods/files/blue-guide/guidepublic_en.pdf
  - EU REACH Update

DESIGN CHAIN ASSOCIATES

INCOMPLETE Environmental Regulatory Landscape "Snapshot"



Growth in Environmental Regulations



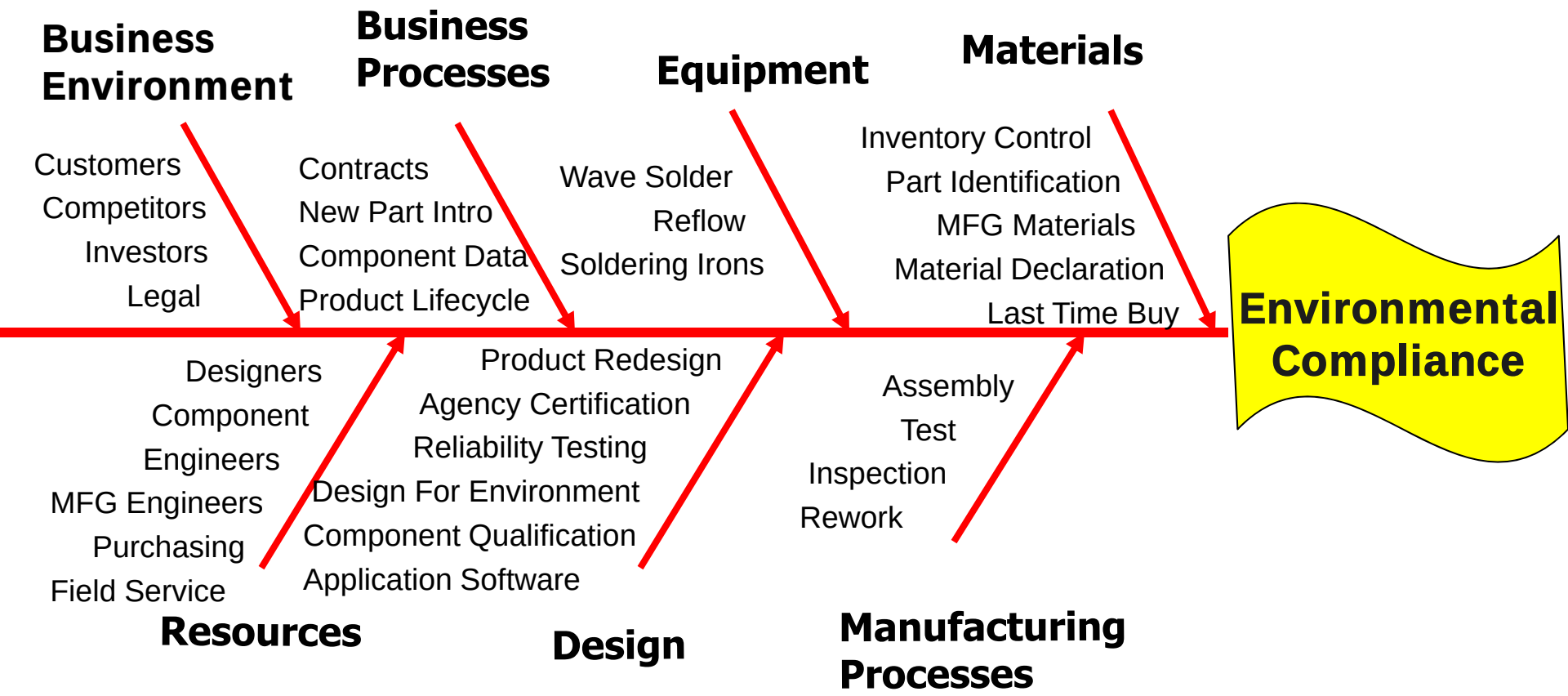
Environmental Compliance?

- Choosing the Wrong Supplier or Part Used to *Only* Have Cost, Quality and sometimes Production Consequences
- Now it ALSO has LEGAL and Revenue Consequences

Major Drivers

- Compliance Reporting
- Material Restrictions
- Material Content Disclosure
- Producer Responsibility – End of Life – WEEE
- ECO Friendly

Environmental Compliance Impact



RoHS Today –> RoHS Recast

RoHS Directive Today	RoHS Recast
Scope: 8 Categories	Scope: 11 Categories
"Primary Function"	"At Least One Intended Function"
No Reference to REACH	Review and Amendment of Annex II must be coherent with REACH
No Defined Maximum Validity Period For Exemptions	Defined Maximum Validity Period For Exemptions
No Defined Process For Renewing Exemptions	Defined Process For Renewing Exemptions
No CE Marking	CE Marking Required
No Signed Declaration Of Conformity Statement	Signed Declaration Of Conformity Statement Required
No Technical Document	Technical Document Required
Data Retention 4 Years (Guidance)	Data Retention 10 Years (Legislated)
No Defined Obligations For Manufactures, Distributors, Importers	Defined Obligations For Manufactures, Distributors, Importers

DESIGN CHAIN ASSOCIATES

RoHS Recast

DIRECTIVE 2011/65/EU

Date of entry into force

7/21/2011

Precautionary Principle

- The annexes to this Directive should be reviewed periodically to take into account, inter alia, Annexes XIV and XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the **R**egistration, **E**valuation, **A**uthorisation and Restriction of **Ch**emicals (REACH) and establishing a European Chemicals Agency. In particular, the risks to human health and the environment arising from the use of Hexabromocyclododecane (HBCDD), Bis (2-ethylhexyl) **phthalate (DEHP),** Butyl benzyl phthalate (BBP) and Dibutylphthalate (DBP) should be considered as a priority. With a view to further restriction of substances, the Commission should re-investigate the substances, which were subject to previous assessments, in accordance with the new criteria of this Directive as part of the first review.
  - Note – all are SVHCs under REACH and as such must be disclosed in articles containing SVHCs >0.1%W / W
- Link to DIRECTIVE 2011/65/EU
- http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:174:0088:0110:EN:PDF

DESIGN CHAIN ASSOCIATES

Precautionary Principle

- **Hexabromocyclododecane** (HBCD or HBCDD)
  - a brominated flame retardant
  - packaging material, video cassette recorder housing and electric and electronic equipment
- **Bis(2-ethylhexyl)phthalate**, **DEHP**
  - widely used as a plasticizer in manufacturing of articles made of PVC
  - as a dielectric fluid in capacitors
- **Benzylbutylphthalate** (**BBzP**), also called ***n*-butyl benzyl phthalate** (**BBP**) or **benzyl butyl phthalate**, is a phthalate
  - trade names e.g. Palatinol BB, Unimoll BB, Sicol 160, or Santicizer 160
  - widely used as a plasticizer in manufacturing of articles made of PVC
- **Dibutyl phthalate** (DBP)
  - widely used as a plasticizer in manufacturing of articles made of PVC
  - an additive to adhesives or printing inks

SCOPE

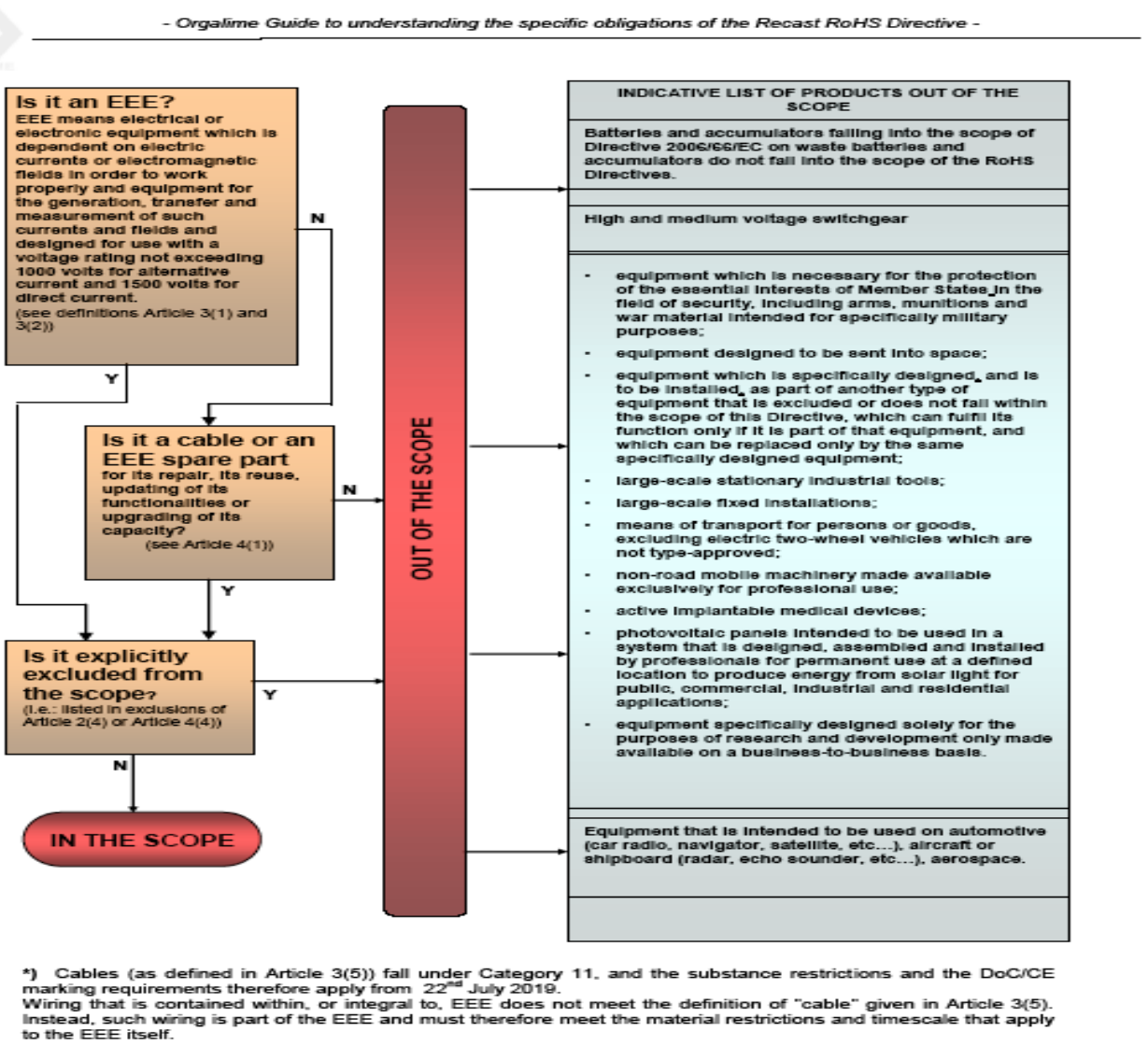
- RoHS Recast > DIRECTIVE 2011/65/EU
  - Article 2 Scope
    1. Large household appliances
    2. Small household appliances
    3. IT and telecommunications equipment
    4. Consumer equipment
    5. Lighting equipment
    6. Electrical and electronic tools (with the exception of large-scale stationary industrial tools)

SCOPE

- Article 2 Scope
  - 7. Toys, leisure and sports equipment
  - 8. **Medical devices**
    - ***three years* after the date of entry into force**
    - **in vitro medical devices**
      - **five years** after the date of entry into force
  - 9. **Monitoring and control instruments**
    - **three years** after the date of entry into force
    - **industrial monitoring and control instruments**
      - ***six years*** *after the date of entry into force*
  - 10. Automatic dispensers
  - 11. **Other electrical and electronic equipment** not covered by any of the categories above .
    - ***date of entry into force plus 8 years***

DESIGN CHAIN ASSOCIATES

RoHS Decision Tree for Products (Jan 3 2013)



*) Cables (as defined in Article 3(5)) fall under Category 11, and the substance restrictions and the DoC/CE marking requirements therefore apply from 22nd July 2019.
Wiring that is contained within, or integral to, EEE does not meet the definition of "cable" given in Article 3(5). Instead, such wiring is part of the EEE and must therefore meet the material restrictions and timescale that apply to the EEE itself.

http://publications.orgalime.org.

Definitions

- Article 3 Definitions : (selected examples)
  - 1) ‘electrical and electronic equipment’ or ‘EEE’ means equipment which is dependent on electric currents or electromagnetic fields in order to work properly and equipment for the generation, transfer and measurement of such currents and fields and designed for use with a voltage rating not exceeding 1 000 volts for alternating current and 1 500 volts for direct current;
  - (2) for the purposes of point 1, ‘dependent ‘ means, with regard to EEE, needing electric currents or electromagnetic fields to fulfil **at least one intended function;**

Definitions

- Article 3 Definitions : (selected examples)
  - "**large scale stationary industrial tools**" means a large size assembly of machines, equipment, and/or components, functioning together for a specific application, permanently installed and de-installed by professionals at a given place, and used and maintained by professionals in an industrial manufacturing facility or research and development facility;
  - "**large scale fixed installation**" means 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;

Definitions

- Article 3 Definitions : (selected examples)
  - "**cables**" means all cables with a rated voltage of less than 250V that serve as a connection or an extension to connect EEE to the electrical outlet or to connect two or more EEE to each other;
  - "**manufacturer**" means any natural or legal person who manufactures an EEE or who has an EEE designed or manufactured ***and markets it*** under his name or trademark;
  - "**distributor**" means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes an EEE available on the market;
  - "**importer**" means any natural or legal person established within the ***EU***, who places an EEE from a third country on the ***Union*** market;

DESIGN CHAIN ASSOCIATES

Definitions

- Article 3 Definitions : (selected examples)
  - "**economic operators**" means the manufacturer, the authorised representative, the importer and the distributor;
  - "**making available on the market**" means any supply of an EEE for distribution, consumption or use on the ***Union*** market in the course of a commercial activity, whether in return for payment or free of charge;
  - "**technical specification**" means a document that prescribes technical requirements to be fulfilled by a product, process or service;
  - "**authorised representative**" means any natural or legal person established within the ***Union*** who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;

Definitions

- Article 3 Definitions : (selected examples)
  - "**CE marking**" means a marking by which the manufacturer indicates that the product is in conformity with the applicable requirements set out in ***Union*** harmonisation legislation providing for its affixing;
  - "**conformity assessment**" means the process demonstrating whether the requirements of this Directive relating to an EEE, are met;
  - "**recall**" means any measure aimed at achieving the return of a product that has already been made available to the end user;

Definitions

- Article 3 Definitions : (selected examples)
  - "**industrial monitoring and control instruments**" mean monitoring and control instruments designed for exclusively industrial or professional use;
  - "**availability of a substitute**" means that the substitute can be manufactured and delivered within a reasonable period of time as compared with the time required for manufacturing and delivering the substances listed in Annex II

Definitions

- Article 3 Definitions : (selected examples)
  - “reliability of a substitute” means the probability that an EEE using a substitute will perform a required function without failure under a stated condition for a stated period of time;
  - “spare part” means a separate part of an EEE that can replace a part of an EEE. The EEE cannot function as intended without that part of the EEE. The functionality of EEE remains unchanged or is upgraded when the part is replaced by a spare part

DESIGN CHAIN ASSOCIATES

Product Exclusions

- This Directive does not apply to: (selected examples)
  - Equipment which is specifically designed **and to be installed** as part of another type of equipment that **is excluded or** does not fall within the scope of this Directive, **which** can fulfil its function only if it is part of that equipment**, and which can only be replaced by the same specifically designed equipment;**
  - Large-scale stationary industrial tools;
  - Large scale fixed installations;
  - Active implantable medical devices;

DESIGN CHAIN ASSOCIATES

Product Exclusions

- This Directive does not apply to: (selected examples)
  - **Photovoltaic panels** intended to be used in a system that is designed, assembled and installed by professionals for permanent use at a defined location to produce energy from solar light for public, commercial, industrial and residential applications;
  - Equipment specifically **designed solely for** the purposes of **research and development** only made available on a **business to business basis**.
  - Equipment which is necessary for the **protection of the essential interests of the security of Member States**, including arms, munitions and war material intended for specifically military purposes;

DESIGN CHAIN ASSOCIATES

Prevention

- Member States shall ensure that EEE ***placed on the market,*** including ***cables and*** spare parts for its repair***,*** its reuse***, updating of its functionalities or upgrading of its capacity,*** does not contain the substances listed in Annex II.
  - Paragraph 1 **shall apply to**
    - **medical devices and monitoring and control instruments** which are placed on the market from ***three years after the date of entry into force of this Directive***
    - **in vitro medical devices** which are placed on the market from ***five years after the date of entry into force of this Directive***
    - **industrial monitoring and control instruments** which are placed on the market from ***six years after the date of entry into force of this Directive***

Prevention

- Member States shall ensure that EEE ***placed on the market,*** including ***cables and*** spare parts for its repair***,*** its reuse***,*** ***updating of its functionalities or upgrading of its capacity,*** does not contain the substances listed in Annex II.
  - Paragraph 1 **shall not apply to** ***cables or*** spare parts for the repair, the reuse***, the updating of functionalities or upgrading of capacity*** of the following
    - **EEE** placed on the market **before** **1 July 2006**;
    - **medical devices** placed on the market **before** ***three years after the date of entry into force of this Directive***
    - **in vitro diagnostic medical devices** placed on the market **before** ***five years after the date of entry into force of this Directive***
    - **EEE** which **benefited from an exemption** and was **placed on the market** **before** that exemption expired *as far as that specific* **exemption is concerned**.

DESIGN CHAIN ASSOCIATES

Prevention

- Member States shall ensure that EEE ***placed on the market,*** including ***cables and*** spare parts for its repair**,** its reuse**, *updating of its functionalities or upgrading of its capacity,*** does not contain the substances listed in Annex II.
  - Paragraph 1 **shall not apply to** the re-use of spare parts recovered from EEE put on the market before 1 July 2006, under the condition that re-use takes place in auditable closed-loop business-to-business return systems, and that re-use of parts is notified to the consumer.

Inclusions / Exemptions

- ***For*** the purposes of adapting ***Annexes III and IV*** to scientific and technical progress, ***and in order to achieve the objectives set out in Article 1, the Commission shall*** adopt ***by means of individual delegated acts in accordance with Article 20 and subject to the conditions laid down in Articles 21 and 22 ,*** the following measures:
  - ***inclusion of*** materials and components of EEE ***for specific applications*** in Annexes III and IV ***on exemptions if such inclusion <u>does not weaken the environmental and health protection of Regulation (EC) No 1907/2006 (REACH)</u> and*** where any of the following conditions is fulfilled
    - their elimination or substitution via design changes or materials and components which do not require any of the materials or substances referred to in Article 4(1) **<u>is scientifically or technically impracticable</u>**;
    - the **<u>reliability</u>** of substitutes is not ensured

Inclusions / Exemptions

- ***inclusion of*** materials and components of EEE ***for specific applications*** in Annexes III and IV ***on exemptions if such inclusion does not weaken the environmental and health protection of Regulation (EC) No 1907/2006 and*** where any of the **following conditions is fulfilled**
  - the ***total* negative** environmental***,*** health ***and*** consumer safety impacts caused by substitution are likely to **outweigh** the ***total*** environmental, health ***and*** consumer safety **benefits** thereof;
  - The decision on inclusion of materials and components of EEE in Annexes III and IV on exemptions and the length of possible exemptions shall take into account the **availability of substitutes** and the **socio-economic impact** of substitution. Decisions on the length of possible exemptions shall take into account any potential **adverse impacts on innovation**. **Life-cycle thinking** on the overall impacts of the exemption shall apply, where relevant

DESIGN CHAIN ASSOCIATES

Inclusions / Exemptions

- Measures adopted in accordance with point (a) of paragraph 1 shall***, for categories 1 to 7, 10 and 11 of Annex I,*** have a validity period of up to five years ***and, for categories 8 and 9 of Annex I,*** **a validity period of up to seven years*****,*** to be decided on a case-by-case basis and which can be renewed.
  - For the exemptions listed in Annex III on,**date of entry into force*****,*** the maximum validity period, which can be **renewed**, shall, for categories 1 to 7 and 10 of Annex I***, be five years from the date of entry into force of this Directive*** and, for categories 8 and 9 of Annex I, ***seven years from the dates laid down in Article 4(3), unless a shorter period is specified.***
  - For the exemptions listed in Annex IV, **medical and monitoring**, on, date of entry into force***, the maximum validity period, which can be renewed, shall be seven years from the dates laid down in Article 4(3), unless a shorter period is specified***
    - Annex IV, Applications exempted from the ***restriction*** in Article 4(1) ***specific to medical devices*** and ***monitoring and control instruments***

DESIGN CHAIN ASSOCIATES

Inclusions / Exemptions

- **An application for granting, renewing or deleting** an exemption shall be made to the Commission in accordance with Annex V
  - Applications for exemptions, renewal of exemptions or, mutatis mutandis, for deleting an exemption may be submitted by a manufacturer, the authorised representative of a manufacturer, or any actor in the supply chain and shall include at least the following:
    - ✓ the name, address and contact details of the applicant;
    - ✓ information on the material or component and the specific uses of the substance in the material and component for which an exemption, or its deletion, is requested and its particular characteristics;
    - ✓ verifiable and referenced justification for an exemption, or its deletion, lished in Article 5;

1. ***Mutatis mutandis*** is a Latin phrase meaning "by changing those things which need to be changed" or more simply "the necessary changes having been made".
2. *en.wikipedia.org/wiki/**Mutatis_mutandis***

Inclusions / Exemptions

- **Applications for exemptions**, **renewal** of exemptions or, mutatis mutandis, for **deleting an exemption** may be submitted by a manufacturer, the authorised representative of a manufacturer, or any actor in the supply chain and shall include at least the following:
  - ✓ an analysis of possible alternative substances, materials or designs on a life-cycle basis, including, when available, information about independent research, peer-review studies and development activities by the applicant and an analysis of the availability of such alternatives;
  - ✓ information on the possible preparing for re-use, recycling of materials from waste EEE, the appropriate treatment provisions according to Annex II of Directive (…/…) of the European Parliament and of the Council on waste electrical and electronic equipment (WEEE);
  - ✓ other relevant information;

Inclusions / Exemptions

- **Applications for exemptions, renewal of exemptions** or, mutatis mutandis, for **deleting an exemption** may be submitted by a manufacturer, the authorised representative of a manufacturer, or any actor in the supply chain and shall include at least the following:
  - ✓ the proposed actions to develop, request the development and/or to apply possible alternatives including a timetable for such actions by the applicant;
  - ✓ where appropriate, an indication of the information which should be regarded as proprietary accompanied by verifiable justification;
  - ✓ when applying for an exemption, proposal for a precise and clear wording for the exemption
  - ✓ a summary of the application.

Inclusions / Exemptions

- An application for granting, renewing or deleting an exemption shall be made to the Commission in accordance with Annex V
  - The Commission shall:
    - ✓ acknowledge receipt of an application in writing within 15 days of its receipt. The acknowledgement shall state the date of receipt of the application;
    - ✓ inform without delay the Member States of the application and shall make the application and any supplementary information supplied by the applicant available to them;
    - ✓ make a summary of the application available to the public;
    - ✓ evaluate the application and its justification
  - An **application for renewal** shall be made **no later than** 18 months **before** an exemption expires.

DESIGN CHAIN ASSOCIATES

Inclusions / Exemptions

- The Commission shall decide on an application for renewal **no later than 6 months before** the expiry date of the existing exemption unless specific circumstances justify other deadlines. The existing exemption **shall in any case remain valid** until a decision on the renewal application is taken by the Commission.
  - In the event that the application for renewal **is rejected** or that an **exemption is deleted**, there shall be a **minimum period of 12 months** and **maximum period of 18 months** from the date the decision is taken **before the exemption expires**.
  - Before Annexes are amended, the Commission shall inter alia **consult economic operators**, **recyclers**, **treatment operators**, **environmental organisations** and **employee** and **consumer associations** and make the comments received **publicly available**.

Review / Amendment of Restricted Substances

- The review and amendment of the list of restricted substances in Annex II shall be coherent with other legislation related to chemicals, in particular Regulation (EC) No 1907/2006 (REACH) and shall take into account, inter alia, Annexes XIV and XVII to that Regulation. The review should use publicly available knowledge obtained from the application of such legislation
  - To review and amend Annex II, the Commission shall take special account of whether a substance, including **substances of very small size** or internal or surface structure, or a group of similar substances:
    - could have a negative impact during EEE waste management operations, including on the possibilities for preparing for the reuse of waste EEE or for recycling of materials from waste EEE;
    - could give rise, given its uses, to uncontrolled or diffuse release to the environment of the substance or could give rise to hazardous residues or transformation or degradation products through the preparing for re-use, recycling or other treatment of materials from waste EEE under current operational conditions;

DESIGN CHAIN ASSOCIATES

Review / Amendment of Restricted Substances

- With a view to achieving the objectives set out in Article 1 and taking account of the precautionary principle, a review, based on a thorough assessment, and amendment of the list of restricted substances in Annex II shall be considered by the Commission **before 3 years after the entry into force of this Directive** and periodically thereafter on its own initiative or following the submission of a proposal by a Member State containing the information referred to in paragraph 2

  - To review and amend Annex II, the Commission shall take special account of whether a substance, including substances of very small size (Nonomaterial?) or internal or surface structure, or a group of similar substances:

    - could lead to unacceptable exposure of workers involved in the waste EEE collection or treatment processes;

    - could be replaced by substitutes or alternative technologies which have less negative impacts.

DESIGN CHAIN ASSOCIATES

Review / Amendment of Restricted Substances

- The proposals to review and amend the list of restricted substances, or a group of similar substances, in Annex II shall contain at least the following information:
  - ✓ precise and clear wording of the proposal;
  - ✓ referenced and scientific evidence for the restriction;
  - ✓ information on the use of the substance or the group of similar substances in EEE;
  - ✓ information on detrimental effects and exposure in particular during waste EEE management operations;
  - ✓ information on possible substitutes and other alternatives, their availability and reliability;
  - ✓ justification for considering a Union-wide restriction as the most appropriate measure;
  - ✓ socio-economic assessment

DESIGN CHAIN ASSOCIATES

Obligations of Manufacturers

- Member States shall ensure that:
  - when placing ***EEE*** on the market, manufacturers ensure that they have been designed and manufactured in accordance with the requirements set out in Article 4(Prevention);
  - manufacturers draw up the required technical documentation and carry out the internal production control procedure in ***line with*** module A of Annex II to Decision No 768/2008/EC or have it carried out
    - Where compliance of EEE with the applicable requirements has been demonstrated by that procedure, manufacturers draw up an EC declaration of conformity and affix the CE marking ***on the finished product***.
    - Where other applicable Union legislation requires the application of a conformity assessment procedure which is at least as stringent, compliance with the requirements of Article 4(1) of this Directive may be demonstrated within the context of that procedure. A single technical documentation may be drawn up;

DESIGN CHAIN ASSOCIATES

Obligations of Manufacturers

- manufacturers keep the **technical documentation** and the **EC declaration of conformity** for **ten years** after the EEE has been placed on the market;
- manufacturers ensure that procedures are in place for **series production** to remain in conformity. Changes in product **design** or **characteristics** and changes in the harmonised **standards** or in **technical specifications** by reference to which conformity of EEE is declared shall be adequately taken into account;
- manufacturers keep a register of non-conforming EEE and product recalls, and keep distributors informed ***thereof***;

DESIGN CHAIN ASSOCIATES

Obligations of Manufacturers

- manufacturers ensure that their EEE **bear a type, batch or serial number or other element** allowing their identification, or, where the size or nature of the EEE does not allow it, that the required information is provided on the packaging or in a document accompanying the EEE;

- manufacturers **indicate their name, registered trade name or registered trade mark and the address** at which they can be contacted on the EEE or, where that is not possible, on its packaging or in a document accompanying the EEE. The address must indicate a single point at which the manufacturer can be contacted;

  - Where other applicable Union legislation contains provisions for the affixing of the manufacturer's name and address which are at least as stringent, those provisions shall apply;

DESIGN CHAIN ASSOCIATES

Obligations of Manufacturers

- manufacturers who consider or have reason to believe that a EEE which they have placed on the market is not in conformity with ***this Directive*** immediately take the necessary corrective measures to bring that EEE into conformity, to withdraw it or recall it, if appropriate ***and*** immediately inform the competent national authorities of the Member States in which they made the EEE available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken;

- manufacturers , further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of the EEE, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to ***ensure compliance with the provisions of this Directive of*** EEE which they have placed on the market.

DESIGN CHAIN ASSOCIATES

Authorised Representatives

- Member States shall ensure that:
  - a manufacturer ***has the possibility to*** appoint an authorised representative ***by written mandate***.
    - The obligations laid down in Article 7(a) and the drawing up of technical documentation shall not form part of the authorised representative's mandate;
      - "**authorised representative**" means any natural or legal person established within the ***Union*** who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;
    - an authorised representative ***performs*** the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:
      - ✓ keep the EC declaration of conformity and the technical documentation at the disposal of national surveillance authorities for **ten years** ***after the EEE has been placed on the market***;
      - ✓ further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of an EEE ***with this Directive***;
      - ✓ cooperate with the competent national authorities, at their request, on any action taken to ***ensure compliance with the provisions of this Directive of*** EEE covered by their mandate.

DESIGN CHAIN ASSOCIATES

Obligations of Importers

- importers place only compliant products on the ***Union*** market;
  - before placing an EEE on the market importers ensure that the appropriate conformity assessment procedure has been carried out by the manufacturer. ***Importers will further*** ensure that the manufacturer has drawn up the technical documentation, that the EEE bears the CE marking and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in Article 7(e) and (f).
    - ***manufacturers*** keep a register of non-conforming EEE and product recalls, and keep distributors informed ***thereof***
    - manufacturers ensure that their EEE bear a type, batch or serial number or other element allowing their identification, or, where the size or nature of the EEE does not allow it, that the required information is provided on the packaging or in a document accompanying the EEE
  - Where an importer considers or has reason to believe that an EEE is not in conformity with Article 4, he ***does*** not place the EEE on the market until it has been brought into conformity ***and*** inform the manufacturer and the **market surveillance authorities** to that effect;

DESIGN CHAIN ASSOCIATES

Obligations of Importers

- **importers indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the EEE** or, where that is not possible, on its packaging or in a document accompanying the EEE.
  - Where other applicable Union legislation contains provisions for the affixing of the importer's name and address which are at least as stringent, those provisions shall apply
- importers, in order to ensure compliance with the provisions of this Directive, keep a register of non-compliant EEE and EEE recalls, and keep distributors informed thereof;
- importers who consider or have reason to believe that an EEE which they have placed on the market is not in conformity with this Directive immediately take the corrective measures necessary to bring that EEE into conformity, to withdraw it or recall it, if appropriate ***and*** immediately inform the competent national authorities of the Member States in which they made the EEE available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken;

DESIGN CHAIN ASSOCIATES

Obligations of Importers

- importers keep, for ten years after the EEE has been placed on the market, a copy of the EC declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request;
- importers, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of an EEE **in a language** which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to ***ensure compliance with the provisions of this Directive of*** EEE which they have placed on the market.

Obligations of Distributors

- when making an EEE available on the market, distributors act with due care in relation to the requirements applicable in particular by verifying that the EEE bears the CE marking, that it is accompanied by the required documents **in a language which can be easily understood by consumers and other end-users** in the Member State in which the EEE is to be made available on the market, and that the manufacturer and the importer have complied with the requirements ***set out in Articles 7(f) and 7(g) and Article 9(c)***

  - **manufacturers** ensure that their EEE bear a type, batch or serial number or other element allowing their identification, or, where the size or nature of the EEE does not allow it, that the required information is provided on the packaging or in a document accompanying the EEE;

  - **manufacturers** indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the EEE or, where that is not possible, on its packaging or in a document accompanying the EEE. The address must indicate a single point at which the manufacturer can be contacted;

  - **importers** indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the EEE or, where that is not possible, on its packaging or in a document accompanying the EEE.

DESIGN CHAIN ASSOCIATES

Obligations of Distributors

- where a distributor considers or has reason to believe that an EEE is not in conformity with Article 4, he ***does*** not make the EEE available on the market until it has been brought into conformity***, and informs*** the manufacturer or the importer to that effect as well as the market surveillance authorities;

- distributors who consider or have reason to believe that an EEE which they have made available on the market is not in conformity with this Directive make sure that the corrective measures necessary to bring that EEE into conformity, to withdraw it or recall it, if appropriate, are taken ***and*** immediately inform the competent national authorities of the Member States in which they made the EEE available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken;

- distributors , further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of EEE. They cooperate with that authority, at its request, on any action taken to ***ensure compliance with the provisions of this Directive of the EEE*** which they have made available on the market.

Importers and Distributors Considered Manufacturers

- Cases in which obligations of manufacturers apply to importers and distributors
  - ***Member States shall ensure that an*** importer or distributor ***is*** considered a manufacturer for the purposes of this Directive and ***that*** he ***is*** subject to the obligations of the manufacturer under Article 7, where he places EEE on the market under his name or trademark or modifies EEE already placed on the market in such a way that compliance with the applicable requirements may be affected.

Identification of Economic Operators

- Member States shall ensure that economic operators on request, identify the following to the market surveillance authorities, for ten years
  - ✓ any economic operator who has supplied them with an EEE;
  - ✓ any economic operator to whom they have supplied an EEE.
    - "**economic operators**" means the manufacturer, the authorised representative, the importer and the distributor;

DESIGN CHAIN ASSOCIATES

EC Declaration of Conformity

- The EC declaration of conformity shall state that the fulfilment of requirements specified in Article 4 (Prevention) has been demonstrated.
- The EC declaration of conformity shall have the model structure and shall contain the elements specified in Annex VI and shall be updated. ***It shall be translated into the language or languages required by the Member State on the market of which the product is placed or made available.***
  - Where other applicable Union legislation requires the application of a conformity assessment procedure which is at least as stringent, compliance with the requirements of Article 4(1) of this Directive may be demonstrated within the context of that procedure. A single technical documentation may be drawn up
- By drawing up the EC declaration of conformity, the manufacturer shall assume responsibility for the compliance of the EEE ***with this Directive***.

DESIGN CHAIN ASSOCIATES

EC Declaration of Conformity

- EC DECLARATION OF CONFORMITY
  - ✓ No … (unique identification of the EEE)
  - ✓ Name and address of the manufacturer or his authorised representative:
  - ✓ This declaration of conformity is issued under the sole responsibility of the manufacturer (or installer):
  - ✓ Object of the declaration (identification of EEE allowing traceability. It may include a photograph, where appropriate):

EC Declaration of Conformity

- EC DECLARATION OF CONFORMITY
  - ✓ The object of the declaration described above is in conformity with Directive …/... on the restriction of the use of certain hazardous substances in electrical and electronic equipment
  - ✓ Where applicable, references to the relevant harmonised standards used or references to the ***technical*** specifications in relation to which conformity is declared:
  - ✓ Additional information:

Signed for and on behalf of: ……

(place and date of issue):

(name, function) (signature)

General Principles of the CE Marking

- The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.
  - The CE marking shall be affixed only by the manufacturer or his authorised representative.
  - The CE marking as presented in Annex II shall be affixed only to products to which its affixing is provided for by specific Community harmonisation legislation, and shall **not be affixed to any other product**.
  - By affixing or having affixed the CE marking, the manufacturer indicates that he takes responsibility for the conformity of the product with all applicable requirements set out in the relevant Community harmonisation legislation providing for its affixing.

DESIGN CHAIN ASSOCIATES

General Principles of the CE Marking

- The CE marking shall be the only marking which attests the conformity of the product with the applicable requirements of the relevant Community harmonisation legislation providing for its affixing.
- The affixing to a product of markings, signs or inscriptions which are likely to mislead third parties regarding the meaning or form of the CE marking shall be prohibited. Any other marking may be affixed to the product provided that the visibility, legibility and meaning of the CE marking is not thereby impaired.
- Without prejudice to Article 41, Member States shall ensure the correct implementation of the regime governing the CE marking and take appropriate action in the event of improper use of the marking. Member States shall also provide for penalties for infringements, which may include criminal sanctions for serious infringements. Those penalties shall be proportionate to the seriousness of the offence and constitute an effective deterrent against improper use

DESIGN CHAIN ASSOCIATES

Rules and Conditions for Affixing the CE Marking

- The CE marking shall be affixed visibly, legibly and indelibly to **the *finished* EEE or to its data plate**. Where that is not possible or not warranted on account of the nature of the EEE, it shall be **affixed to the packaging and to the accompanying documents**
- The CE marking shall be affixed before the EEE is placed on the market.
- Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and take appropriate action in the event of improper use of the marking. Member States shall also provide for penalties for infringements, which may include criminal sanctions for serious infringements. Those penalties shall be proportionate to the seriousness of the offence and constitute an effective deterrent against improper use.

Presumption of Conformity

- ***In the absence of evidence to the contrary,*** Member States shall presume electrical and electronic equipment bearing the CE marking as conforming to this Directive.
- ***Materials, components*** and ***EEE*** on which tests and measurements ***demonstrating compliance with the requirements of Article 4*** have been performed***, or which have been assessed,*** in accordance with harmonised standards, the references of which have been published in the Official Journal of the European Union, shall be presumed to comply with the requirements of this Directive

Future RoHS Review

- No later than 3 years after the date of entry into force of this Directive the Commission shall examine the need to amend the scope of this Directive in respect of the EEE referred to in Article 2, and shall present a report there on to the European Parliament and the Council accompanied by a legislative proposal, if appropriate, with respect to any additional exclusions related to that EEE.

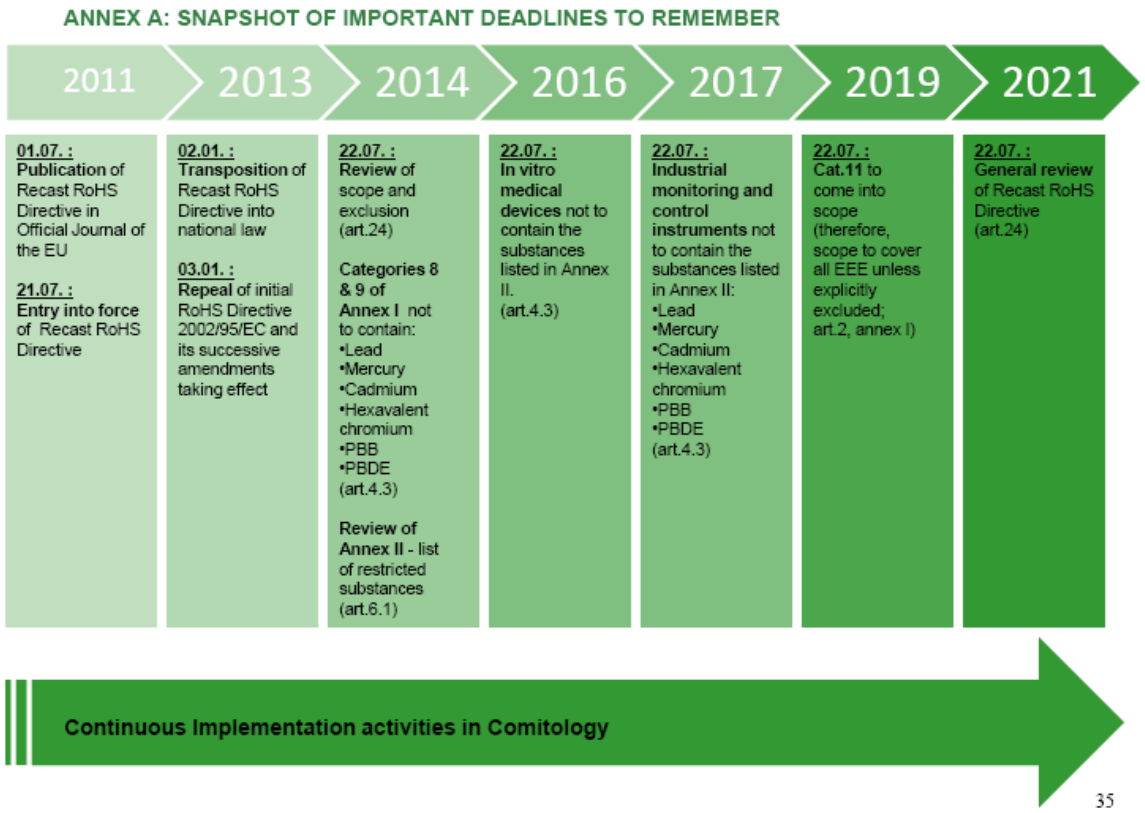
- No later than 10 years after the date of entry into force of this Directive the Commission shall carry out a general review of this Directive, and shall present a report to the European Parliament and the Council accompanied, if appropriate,by a legislative proposal.

DESIGN CHAIN ASSOCIATES

Entry Into force & Transposition

- This Directive shall enter into force on the 20th day following that of its publication in the Official Journal of the European Union.
  - July 21 2011
- Member States shall adopt and publish, by at the latest 18 months after the publication of this Directive, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions
  - Jan 3 2013

IMPORTANT DATES



- *Orgalime Guide to understanding the specific obligations of the Recast RoHS Directive*

Orgalime RoHS Guide http://publications.orgalime.org.

Regulation (EC) No 768/2008

- General Principles Article 1
  - Products placed on the Community market shall comply with all applicable legislation.
  - When placing products on the Community market, economic operators shall, in relation to their respective roles in the supply chain, be responsible for the compliance of their products with all applicable legislation
  - Economic operators shall be responsible for ensuring that all information they provide with regard to their products **is accurate, complete and in compliance with Community rules applicable.**
    - http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:218:0082:0128:en:PDF

Regulation (EC) No 768/2008

- Definitions Article R1
  - '**technical specification'** shall mean a document that prescribes technical requirements to be fulfilled by a product, process or service;
  - **'conformity assessment'** shall mean the process demonstrating whether specified requirements relating to a product, process, service, system, person or body have been fulfilled;
  - '**recall**' shall mean any measure aimed at achieving the return of a product that has already been made available to the end user;
  - '**withdrawal**' shall mean any measure aimed at preventing a product in the supply chain from being made available on the market;

Regulation (EC) No 768/2008

- Obligations of Manufacturers Article R2
  - Manufacturers shall draw up the required technical documentation and carry out the conformity assessment procedure applicable or have it carried out.
  - **Manufacturers shall ensure that procedures are in place for series production** to remain in conformity. Changes in product design or characteristics and changes in the harmonised standards or in technical specifications by reference to which conformity of a product is declared shall be adequately taken into account.
  - Manufacturers shall ensure that the product is accompanied by instructions and safety information in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.
  - Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of the product, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by products which they have placed on the market.

DESIGN CHAIN ASSOCIATES

Regulation (EC) No 768/2008

- CONFORMITY ASSESSMENT PROCEDURES ANNEX II
  - Module A Internal production control
    - **Internal production control** is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the products concerned satisfy the requirements of the legislative instrument that apply to them.
  - Technical documentation
    - The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the product's conformity to the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product. The technical documentation shall, wherever applicable, contain at least the following elements:

Regulation (EC) No 768/2008

- Technical documentation
  - ✓ a general description of the product
  - ✓ conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.
  - ✓ descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product
  - ✓ a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the Official Journal of the European Union, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the legislative instrument where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied
  - ✓ results of design calculations made, examinations carried out, etc
  - ✓ test reports

DESIGN CHAIN ASSOCIATES

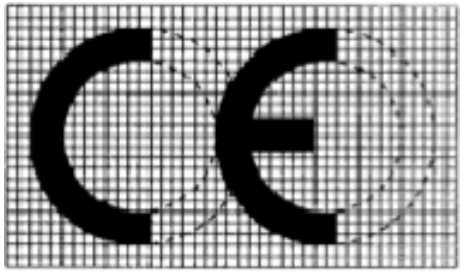
Regulation (EC) No 768/2008

- Manufacturing
  - The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured products with the technical documentation referred to in point 2 and with the requirements of the legislative instruments that apply to them.
- Conformity marking and declaration of conformity
  - The manufacturer shall affix the required conformity marking set out in the legislative instrument to each individual product that satisfies the applicable requirements of the legislative instrument
  - The manufacturer shall draw up a written declaration of conformity for a product model and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the product has been placed on the market. The declaration of conformity shall identify the product for which it has been drawn up.
  - A copy of the declaration of conformity shall be made available to the relevant authorities upon request.
- Authorised representative
  - The manufacturer's obligations, Conformity marking and declaration of conformity, may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate

DESIGN CHAIN ASSOCIATES

Affixing of the CE Marking

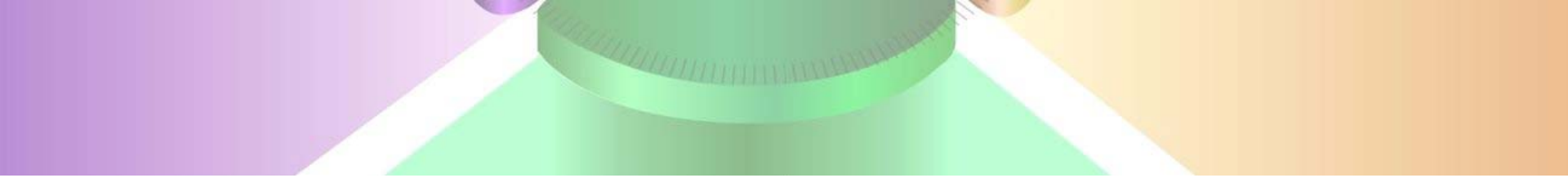
- The CE marking must be affixed by the manufacturer, or by the authorised representative established within the Community
- The CE marking must take the form below. If the CE marking is reduced or enlarged the proportions must be respected.



Affixing of the CE Marking

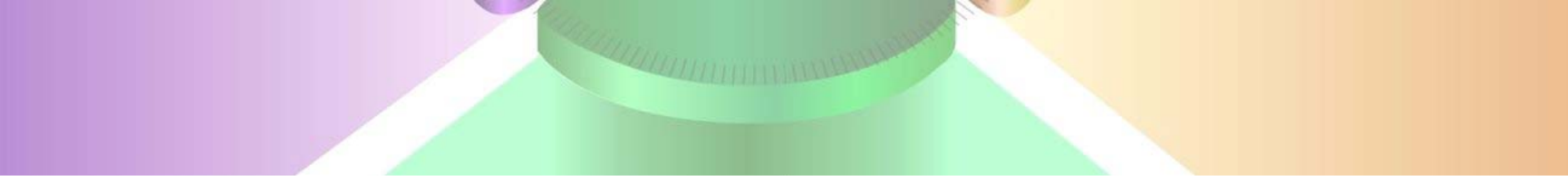
- The CE marking must be affixed visibly, legibly and indelibly to the product or to its data plate. However, where this is not possible or not warranted on account of the nature of the product, it must be affixed to the packaging, if any, and to the accompanying documents, where the directive concerned provides for such documents.
  - the requirement for visibility means that the CE marking must be easily accessible for all parties. It could, for instance, be affixed on the back or underside of a product. A minimum height of 5 mm is required to ensure that it is legible
  - It shall also be indelible so that it cannot be removed under normal circumstances without leaving noticeable traces (for example some product standards use a rub test with water and petroleum spirits). However, this does not mean that the CE marking must form an integral part of the product.
  - Additional information
    - Guide to the implementation of directives based on the New Approach and the Global Approach
      - http://ec.europa.eu/enterprise/policies/single-market-goods/files/blue-guide/guidepublic_en.pdf

DESIGN CHAIN ASSOCIATES



EU REACH Update

Registration, **E**valuation, **A**uthorization, and **R**estriction of **C**hemicals



The 0.1% w/w Limit Controversy

Nordic Council Report

- "REACH Trigger for Information on Substances of Very High Concern (SVHC)"
  - "As Assessment of the 0.1% Limit in Articles"
  - TemaNord 2010:514
- Based on disagreement with Commission Legal Service's definition of "article"
- Seeks to differentiate "complex article" comprised of other "articles" and influence the Guidance document
  - Examples provided of how many "tonnes" of SVHCs could be put on the market without disclosure triggers based on the current definition
- Would apply the 0.1% wt limit for candidate SVHC disclosure per Article 33 to components that are articles themselves
  - But *not* homogeneous materials, as in RoHS
- See http://www.norden.org

DESIGN CHAIN ASSOCIATES

Electronics Example: Current Interpretation

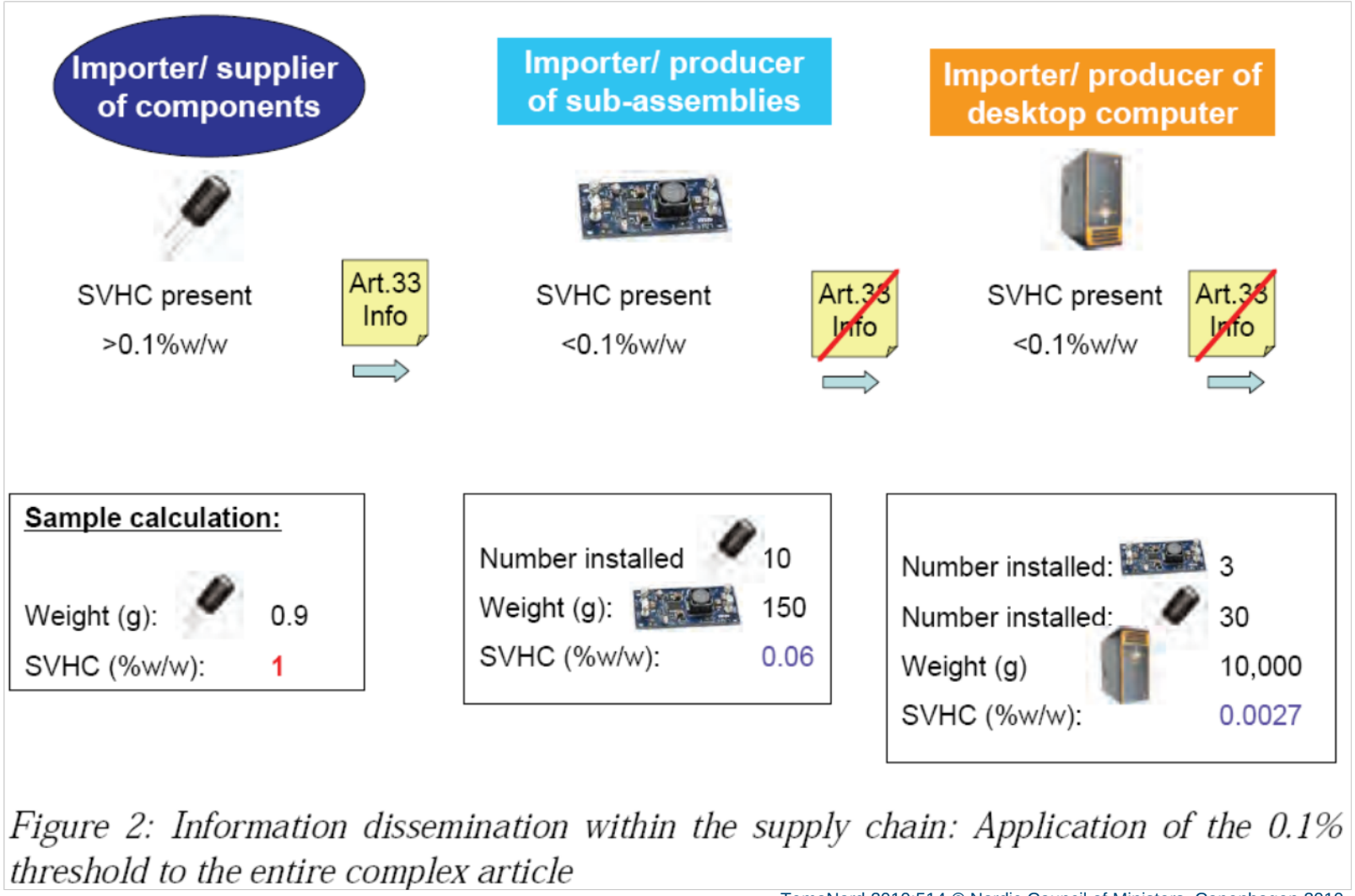


Figure 2: Information dissemination within the supply chain: Application of the 0.1% threshold to the entire complex article

TemaNord 2010:514 © Nordic Council of Ministers, Copenhagen 2010

Electronics Example: NC Preferred Interpretation

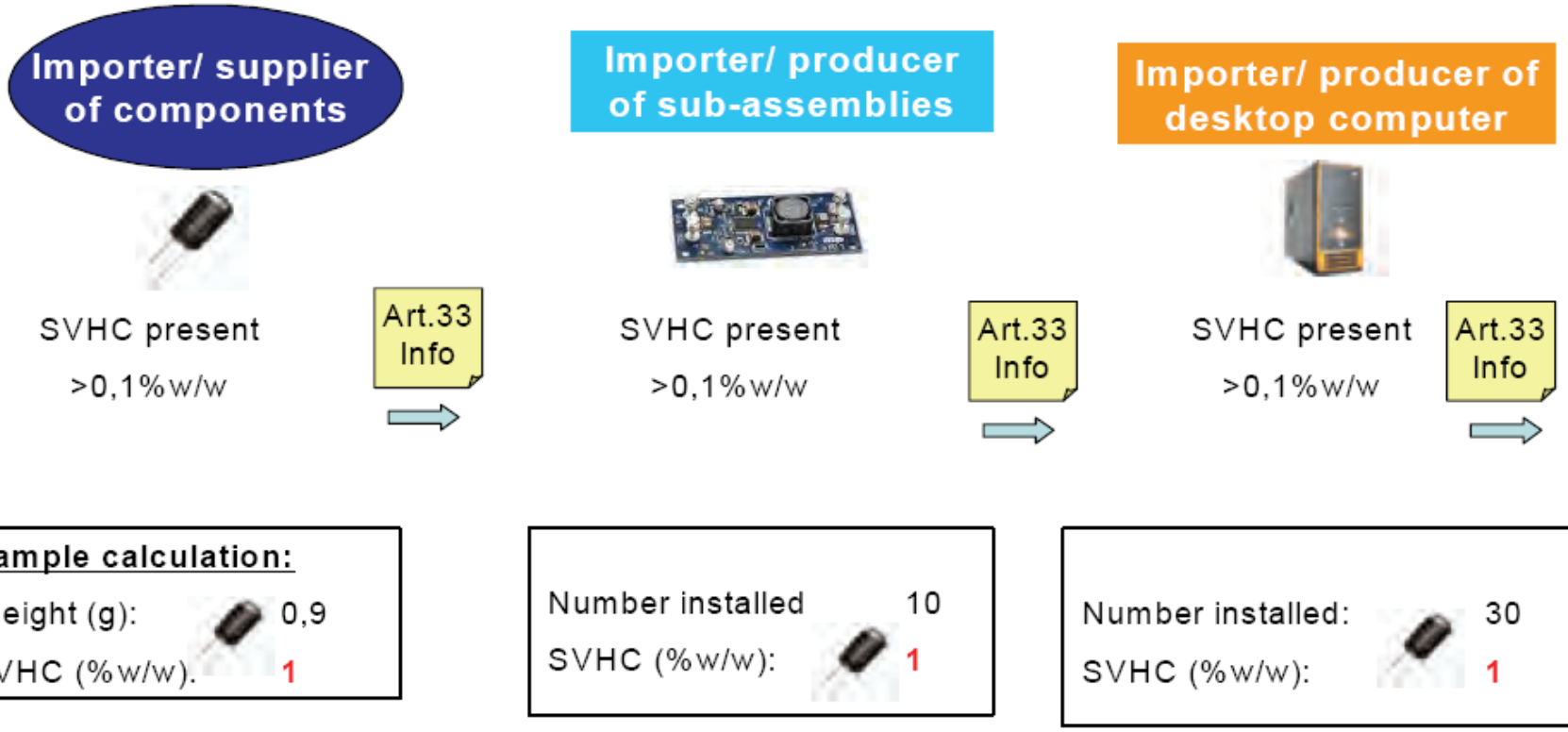


Figure 3: Information dissemination within the supply chain: Application of the 0.1% limit to parts or components

TemaNord 2010:514 © Nordic Council of Ministers, Copenhagen 2010

What's Next for 0.1%?

- Both sides of the argument were presented at the Feb 8-9 CARACAL meeting
- Commission Legal Service reiterated their interpretation: 0.1% applies to the entire article
- ECHA published the guidance in April as it is without the footnote referring to the dissenting views of six Member States
- In June, France unilaterally announced it will enforce the "once an article, always an article" approach

DESIGN CHAIN ASSOCIATES

Candidates for What?

- Candidates for prioritization and inclusion in the List of Substances Subject to Authorization
  - (Annex XIV of REACH)
- These are substances that have been identified as meeting the criteria for authorization
  - Defined in Article 57

Candidate List (Art. 59) History

List #	Date Proposed	End of 45 Day Technical Comment Period	Date of Publication (Article 33 In-Force)
1	1-Jun-2008	14-Aug-2008	28-Oct-2008
2	1-Sep-2009	15-Oct-2009	13-Jan-2010
3	8-Mar-2010	22-Apr-2010	18-Jun-2010
4	30-Aug-2010	14-Oct-2010	15-Dec-2010
5	21-Feb-2011	7-Apr-2011	20-Jun-2011
6	29-Aug-2011	13-Oct-2011	15-Dec-2011

Dates in RED are estimates

- **Additional Candidate Lists of SVHCs expected *twice a year***
- http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp

Candidate List Substances to Date

- 53 SVHCs Defined To Date
- http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp

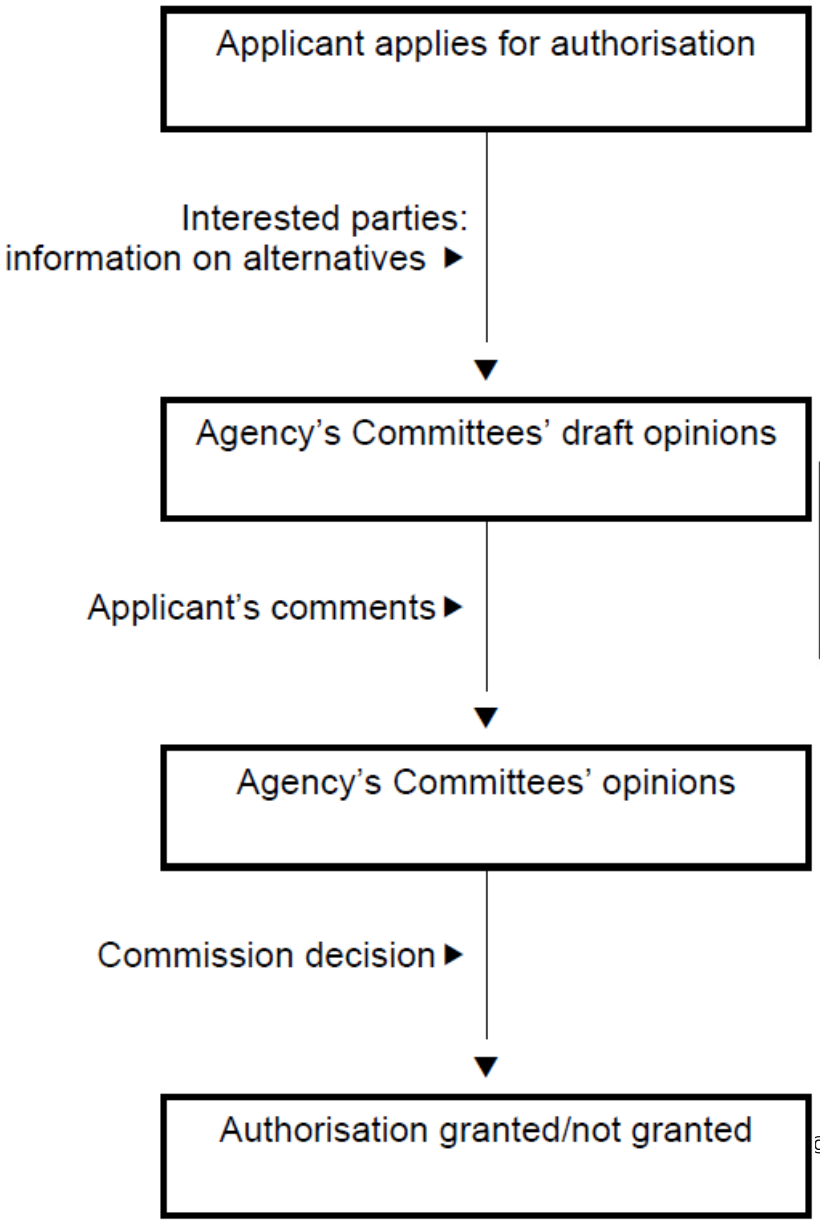
Group 1: 10/28/2008	Group 2: 1/14/2010	Group 3: 6/18/2010	Group 4: 12/15/2010	Group 5: 6/20/2011
Anthracene	2,4-Dinitrotoluene	Trichloroethylene	1,2,3-Trichlorobenzene	2-ethoxyethyl acetate
4,4'- Diaminodiphenylmethane (MDA)	Anthracene oil	Boric acid	1,2,4-Trichlorobenzene	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters
Dibutyl phthalate (DBP)	Anthracene oil, anthracene paste, distn. Lights	Disodium tetraborate, anhydrous	1,3,5-Trichlorobenzene	strontium chromate
Cobalt dichloride	Anthracene oil, anthracene paste, anthracene fraction	Tetraboron disodium heptaoxide, hydrate	Cobalt(II) sulphate	Hydrazine
Diarsenic pentaoxide	Anthracene oil, anthracene-low	Sodium chromate	Cobalt(II) dinitrate	1-methyl-2-pyrrolidone
Diarsenic trioxide	Anthracene oil, anthracene paste	Potassium chromate	Cobalt(II) carbonate	1,2,3-trichloropropane
Sodium dichromate, dihydrate	Diisobutyl phthalate (DIBP)	Ammonium dichromate	Cobalt(II) diacetate	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich
5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	Aluminosilicate, Refractory Ceramic Fibres	Potassium dichromate	2-Methoxyethanol	
Bis (2-ethyl(hexyl)phthalate) (DEHP)	Zirconia Aluminosilicate, Refractory Ceramic Fibres		2-Ethoxyethanol	
Hexabromocyclododecane	Lead chromate		Chromium trioxide	
Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	Lead chromate molybdate sulfate red (C.I. Pigment Red 104)		Acids generated from chromium trioxide and their oligomers: Chromic acid, Dichromic acid, Oligomers of chromic acid and	
Bis(tributyltin)oxide	Lead sulfochromate yellow (C.I. Pigment Yellow 34)			
Lead hydrogen arsenate	Acrylamide (added 3/30/2010)			
Triethyl arsenate	Tris(2-chloroethyl)phosphate (TCEP)			
Benzyl butyl phthalate (BBP)	Coal tar pitch, high temperature (CTPHT)			

Why These are Considered SVHCs

- CMRs: Carcinogenic, Mutagenic or toxic to Reproduction
  - DBP, DIBP:Reprotoxin - May cause harm to the fetus
  - DEHP: Reprotoxin - May impair fertility; May cause harm to the fetus
  - TCEP: Reprotoxin - May impair fertility
  - Boric Acid: Reprotoxin - May impair fertility; May cause harm to the fetus
- PBTs: Persistent, Bioaccumulative and Toxic
  - HBCD: PBT – Toxic to Daphnia (ecosystem “indicator species”), Very Bioaccumlative (vB), long half-life (>120 days) in soil; found in many places (can travel)
- vPvBs: Very Persistent or Very Bioaccumulative
  - SCCPs:PBT & vPvB - vP due to half life in fresh water/sediment > 180 days; vB in fish; Toxic to Daphnia magna
- Substances of equivalent level of concern
  - Some in group 4

DESIGN CHAIN ASSOCIATES

The Authorization Process



- ECHA Committees:
  - RA: Risk Assessment
  - SEA: Socio-Economic Analysis

Draft opinions
- RA Committee: risks to health and environment from use(s) of the Annex XIV substance applied for, risks arising from possible alternatives, and any information from third parties.
- SEA Committee: socio-economic factors, and the availability, suitability and technical feasibility of alternatives associated with the use(s) applied for, and any information from third parties.

art. 64.1 and 64.4

Annex XIV Substances #1

SVHC Authorization Status and Timetable: Group 1				
Substance name	**ECHA Recommendation Date**	**Date of Inclusion (DoI) in Annex XIV**	**Last Authorization Application Date**	**Sunset Date**
4,4'- Diaminodiphenylmethane (MDA)	1-Jun-2009	17-Feb-2011	21-Feb-2013	21-Aug-2014
Dibutyl phthalate (DBP)	1-Jun-2009	17-Feb-2011	21-Aug-2013	21-Feb-2015
5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	1-Jun-2009	17-Feb-2011	21-Feb-2013	21-Aug-2014
Bis (2-ethyl(hexyl)phthalate) (DEHP)	1-Jun-2009	17-Feb-2011	21-Aug-2013	21-Feb-2015
Hexabromocyclododecane (HBCDD)	1-Jun-2009	17-Feb-2011	21-Feb-2014	21-Aug-2015
Benzyl butyl phthalate (BBP)	1-Jun-2009	17-Feb-2011	21-Aug-2013	21-Feb-2015

- **Timetable**
  - 30 June 2010: Commission issues Draft Regulation updating Annex XIV to WTO
  - 30 Aug 2010: End of comment period
  - 17 Feb 2011: “Date of Inclusion” (application period begins) per Commission Regulation 143/2011

DESIGN CHAIN ASSOCIATES

Proposed Annex XIV Substances #2

Candidate SVHC Authorization Status: Group 2 (Proposed)				
Substance name	**EC Number**	**CAS Number**	**Last Auth Application Date**	**Proposed Sunset Date**
2,4 – Dinitrotoluene (2,4-DNT)	204-450-0	121-14-2	DoI+2 years	DoI+3.5 years
Diarsenic pentaoxide	215-116-9	1303-28-2	DoI+1.5 years	DoI+3 years
Diarsenic trioxide	215-481-4	1327-53-3	DoI+1.5 years	DoI+3 years
Diisobutyl phthalate (DIBP)	201-553-2	84-69-5	DoI+1year (min)	DoI+2.5 years (min)
Lead chromate	231-846-0	7758-97-6	DoI+1.75 years	DoI+3.25 years
Lead chromate molybdate sulfate red (C.I. Pigment Red 104)	235-759-9	12656-85-8	DoI+1.75 years	DoI+3.25 years
Lead sulfochromate yellow (C.I. Pigment Yellow 34)	215-693-7	1344-37-2	DoI+1.75 years	DoI+3.25 years
Tris (2-chloroethyl) phosphate (TCEP)	204-118-5	115-96-8	DoI+2 years	DoI+3.5 years

- Two from first SVHC list; remainder from second list
- Proposed by ECHA on 1 July 2010
- Comment period through 30 Sept 2010
- Submitted to EC 20 Dec 2010
- Anticipated DoI: November 2011

DESIGN CHAIN ASSOCIATES

Proposed Annex XIV Substances #3

Candidate SVHC Authorization Status: Group 3 (Proposed)		
Substance name	**EC Number**	**CAS Number**
Ammonium dichromate	232-143-1	7789-09-5
Chromic acid, Oligomers of chromic acid and dichromic acid, dichromic acid	231-801-5; 236-881-5	7738-94-5; 13530-68-2
Chromium trioxide	215-607-8	1333-82-0
Cobalt dichloride	231-589-4	7646-79-9
Cobalt(II) carbonate	208-169-4	513-79-1
Cobalt(II) diacetate	200-755-8	71-48-7
Cobalt(II) dinitrate	233-402-1	10141-05-6
Cobalt(II) sulphate	233-334-2	10124-43-3
Potassium chromate	232-140-5	7789-00-6
Potassium dichromate	231-906-6	7778-50-9
Sodium chromate	231-889-5	7775-11-3
Sodium dichromate	234-190-3	7789-12-0
Trichloroethylene	201-167-4	79-01-6

- 90 Day Comment Period opened 6/15/2011

http://echa.europa.eu/consultations/authorisation/draft_recommendations/recommendations_en.asp

DESIGN CHAIN ASSOCIATES

Authorization & Imported Articles

- Substances that are an integral part of imported articles are not subject to Authorization
- So you can import articles into the EU that incorporate authorized substances WITHOUT having an authorization in the supply chain
  - But they are subject to Restriction
- Imported products containing SVHCs on the Candidate List are still subject to notification (art 7.2) article 33-related communication, and to restrictions (Annex XVII)

Article 69 – Closing the Loophole

- The EC can request ECHA to produce an Annex XV Dossier on substances in articles
- If ECHA determines that risk is not “adequately controlled” they will produce a dossier after the Sunset Date
- If the Agency suggests restrictions as an appropriate response, the restriction process will begin
  - Member States can also initiate Annex XV Dossiers for similar purpose
  - Denmark has done so for 4 Phthalates – comments open now
- Buys time…sometimes

DESIGN CHAIN ASSOCIATES

Thank You For Your Attention

Questions ?