

RoHS and REACH



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Disclaimer

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This material represents the presenter's interpretation of these directives. Before acting on any of this information, you have to verify the accuracy of the author's interpretation with your own legal counsel.



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RoHS and REACH?

- **RoHS (Directive 2002/95/EC)**
 - Restriction of certain Hazardous Substances
- **REACH (Regulation (EC) No 1907/2006)**
 - Registration Evaluation Authorization and Restriction of Chemicals
- **Directive and Regulation**
 - In general, the difference between directives and regulations is that a directive requires individual Member States to transpose its requirements into national law to implement it whereas a regulation applies throughout the EU without more



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New RoHS will apply to –

EU Member Countries

- | | |
|---------------------------------------|---|
| • 1. Austria (became member in 1995) | • 15. Latvia (2004) |
| • 2. Belgium (Founder Member in 1957) | • 16. Lithuania (2004) |
| • 3. Bulgaria (2007) | • 17. Luxembourg (FM 1957) |
| • 4. Czech Republic (2004) | • 18. Malta (2004) |
| • 5. Cyprus (2004) | • 19. The Netherlands (FM 1957) |
| • 6. Denmark (1973) | • 20. Poland (2004) |
| • 7. Estonia (2004) | • 21. Portugal (1986) |
| • 8. Finland (1995) | • 22. Romania (2007) |
| • 9. France (FM 1957) | • 23. Slovakia (2004) |
| • 10. Germany (FM 1957) | • 24. Slovenia (2004) |
| • 11. Greece (1981) | • 25. Spain (1986) |
| • 12. Hungary (2004) | • 26. Sweden (1995) |
| • 13. Ireland (1973) | • 27. United Kingdom (Great Britain) (1973) |
| • 14. Italy, (FM 1957) | |



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New RoHS will apply to –

Certain Non – EU Member Countries

- | | |
|---|--|
| <ul style="list-style-type: none">• Three members of the European Free Trade Association (EFTA):• 1. Iceland• 2. Norway• 3. Liechtenstein• Although Switzerland is member of the EFTA, it does not take part in the European Economic Area (EEA = EU+EFTA). | <p>Turkey is neither member of the EU, nor is considered a part of the EFTA. However, Turkey has fully implemented many of the European CE marking directives. This means that for many products they also require CE Marking.</p> |
|---|--|



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Basic Principle

- Any member country before joining EU, must fulfill the economic and political conditions generally known as the **Copenhagen criteria**
 - A democratic,
 - Free market government together with the corresponding freedoms and institutions, and
 - Respect the rule of law.



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Who is responsible?

- Producer/Distributor/Importer in the EEA member country
 - Product under own brand name
 - Product manufactured by someone else
 - Placed product on the EU market on a professional basis



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Current RoHS



Current RoHS (EU)

- 10 categories
- Category 8 (Medical Devices) and Category 9 (Monitoring and Control) are outside the scope
- Effective from July 1, 2006
- Restricts 6 substances
 - at homogenous material level
- Self Certification
 - No special marking requirements
- Exemptions (39)



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Future RoHS (Recast)



Future RoHS (Recast)

- 11 categories and Category 8 and 9 will be within the scope
 - Inclusion of Category 11 – other Electrical and Electronic products that are not covered in original 10 categories
 - Category 8
 - Medical – effective 2014
 - In-Vitro Diagnostic (IVD) – effective 2016
 - Category 9
 - Monitoring and Control – effective 2014
 - Industrial Monitoring and Control – effective 2017
 - Category 11
 - Effective 2019



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Future RoHS (Recast)

- No new restricted substances but may be considered within next 3 years
- Exemption
 - **Specific** to Medical, and Monitoring and Control Equipment
 - Applies to these categories only and have a longer exemption period
 - **General**
 - Applies to all but few exemption have a longer exemption period for Medical, and Monitoring and Control Equipment



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Future RoHS (Recast)

- RoHS is going to be a CE marking Directive
 - CE declaration of conformity
 - CE Marking
 - Mandatory recall and withdrawal of non-compliant products
 - Manufacturers, importers and distributors have legal obligation to report non-compliant product to national authorities



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Declaration of Conformity

- Manufacturers are required to
 - Ensure that products are designed and manufactured according to the materials restrictions of RoHS
 - Draw up the required technical documentation and carry out the internal production control procedures in line with the module A of Annex II
 - Draw up EC declaration of conformity and affix CE marking on the finished product



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Declaration of Conformity

- Manufacturers are required to
 - Ensure that procedure are in place for series production to remain conformity
 - Ensure ability to adapt changes to future restrictions
 - Keep the EC declaration of conformity and technical documentation at the disposal of national surveillance authorities for 10 Years after the EEE has been placed on the market



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Decision NO 768/2008/EC

- New common framework for marketing of products and repeals council decision 93/465/EEC
- Provides reference provisions, definitions and general obligations for economic operators and a range of conformity assessment procedures.
- Lays down the rules for CE marking
- Provides the framework for the conformity assessment procedures and technical files requirements for range of EU directives including RoHS



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Declaration of Conformity

- Required to be translated into the languages required by the Member States into which the product is placed on the market or made available
- Conformity includes all parts, material, processes
 - All parts that essential and integral part of the equipment
 - Electrical, electronic, mechanical, marking, labels, accessories etc EXCEPT "Consumables"



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REACH



- REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT
- AND OF THE COUNCIL

REACH

- **Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), and**
- **Establishing a European Chemicals Agency (ECHA)**
- Other REACH type regulations
 - Japan REACH
 - China REACH
 - California Green Chemistry Initiative
 - CEPA (Canadian Environmental Protection Act)
 - Many more.....



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What is REACH

- The new EU Chemicals policy
- It is a regulation (not a directive)
- This is considered one of the most complex regulation issued by the European Union
 - Over 800 pages
 - Over 10 guidance documents
- Industry to provide chemical safety information to a new European Chemical Agency
 - **Responsibility shifted from Government to Producers**



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Applies to

- European Union (EU) Chemical (chemical substances)
 - Importers
 - Manufacturers of chemicals
 - Articles (Hardware) designed to emit substances



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What is SVHC

- **SVHC – Substances of Very High Concern**
 - Carcinogenic, Mutagenic, Toxic for Reproduction (CMRs) category 1 and 2
 - Persistent, bioaccumulative and toxic (PBT)
 - Very persistent and very bioaccumulative (vPvBs) according to given criteria, and/or
 - Anything above and beyond -
 - Where there is scientific evidence of probable serious effects to humans or the environment (e.g. endocrine disruptors) which will be identified on a case-by-case basis



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What is SVHC

- **Estimated 1500-2000 substances will go on SVHC list**
 - **Published regularly**
 - Dec 2008 Published 1st list of Substances of Very High Concern (SVHC) – 15 substances
 - Sep 2009 Published 2nd list of SVHC – 14 additional substances
 - As of today There are 46 substance
 - Next 12 months Could be over 100 substances



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What is SVHC

- **Part 1 – Disclosure**
- **Part 2 – Authorization**



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Disclosure

- Upon request from a user
 - If your product contains SVHC > .1% weight by weight, requires disclosure and safety information
 - If the SVHC exceeds 1 ton/yr/legal entity, it must be registered by Nov 30, 2010 or
 - As soon as it exceeds 1 ton limit anytime after Nov 30, 2010
 - Constantly keep updating the disclosure documents to your customers



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Disclosure

- It appears that REACH applies to
 - Importers and Manufacturers of chemicals and Articles (Hardware designed to emit substances) and
 - Not to anyone outside the EU member countries
 - But, if someone is importing your product, he/she will request the substance and safety information from manufacturer/supplier outside of the EU in order to meet his/her local regulatory obligations



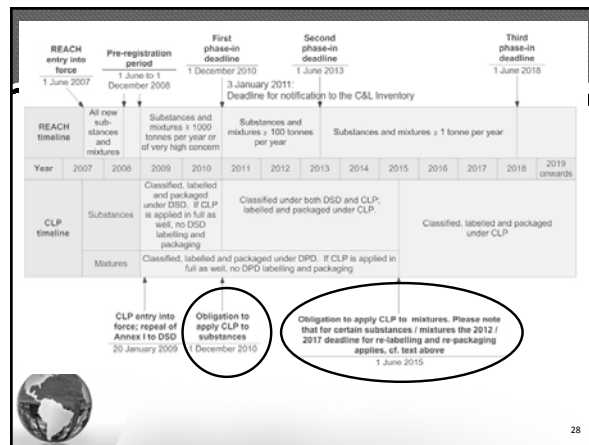
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Authorization

- If SVHC goes on the article XIV (14) list, it will require authorization for use
 - Authorization is same as exemption
 - Proactive
 - Based on compelling justification
 - No safe alternate
 - Business application
 - Socio-economic reason
 - Lack of reliability data
 - Could be restricted or banned
 - In all or specific business applications



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Current REACH status

Pre Registration:

Disclosure (pre-registration) in European Chemical Agency dossier if total substance in all product exceeds > 1 ton per year per legal entity

- | | |
|---------------|--|
| • June 1 2008 | } Pre-Registration began
Pre-Registration closed
List of Pre-registered substances published |
| • Nov 30 2008 | |
| • Dec 2008 | |

If a company imports or manufactures > 1 ton and pre-registers by November 30, 2008:

- It can continue using that chemical without registration until 2018
- Pre-registration is free except administrative cost
- "Registration" requires testing and safety information
 - Is a very expensive process



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As a result

60,000 companies have pre-registered about 140,000 substances

Estimated there are over 100,000 substances in commerce and majority of them do not have safety assessment information



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Pre Registration

- Why 1 ton limit?
 - Registration deadlines are as follows: On or before
 - 30 Nov 2010 > 1000 ton
 - 31 May 2013 > 100 ton
 - 31 May 2018 > 1 ton



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Pre Registration

- If the deadline for pre-registration is not met?
 - If a company fails (or does not wish) to pre-register within the applicable deadline (i.e. in most cases November 30, 2008):
 - It will have to suspend its activities involving the substances concerned and "register" them without delay.
 - All manufacturing, placing on the market and use of such substances between the start of the pre-registration deadline (i.e. in most cases 1 June 2008) and the date of suspension of activities may be subject to penalties according to national law.



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Pre Registration

- First-time Manufacturers or Importers or exceeding 1 ton limit
 - A substance importer or manufactured in quantities of 1 ton or more for the first time after 1 December 2008.
 - Must pre-register
 - Within six month after its manufacturing or import exceeds the one-ton threshold
 - At least 12 months before the relevant deadline for registration.



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CEPA and California Green Chemistry

- Canadian Environmental Protection Act
 - Register challenge substances (over 200) if imported > 100 Kg per year or manufactured in Canada > 1000 Kg
- California Green Chemistry
 - Not enough details
 - Pretty much similar requirements
 - Moving from cradle to grave to cradle to cradle
 - Must be recovered and recycled



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CLP

The CLP Regulation stands for Regulation (EC) No 1272/2008 on Classification, Labeling and Packaging of substances and mixtures



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CLP

- Complements the REACH Regulation and
- Replaces the current system contained in
 - The Dangerous Substances Directive (67/548/EEC) and
 - The Dangerous Preparations Directive (1999/45/EC)



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What is CLP

- CLP is about the hazards of chemical substances and mixtures and how to inform others about them.
- Identify Hazard classification as per the Global Harmonization System (GHS) so that workers and consumers know about its effects before they handle it.



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What is CLP

- Regularly report to ECHA (European Chemical Agency) database (central inventory)
 - Contains basic classification and labeling information on notified and registered substances.
 - Substances subject to registration under REACH and placed on the market
 - Substances classified as hazardous under CLP and placed on the market, irrespective of the tonnage.
 - Substances classified as hazardous under CLP and present in a mixture above the concentration limits specified in Annex I of CLP or as specified in DPD, which results in the classification of the mixture as hazardous, and the mixture is placed on the market.



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What is CLP

- Under REACH pre-registration over 60,000 manufacturers and importers have already registered more than 140,000 substances with the European Chemicals Agency (ECHA)
 - Pure Substances
 - The deadline for classifying was December 3, 2010 with 30 day grace period Jan 3, 2011
 - Mixtures
 - The deadline for classifying is 31 May 2015.



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Summary about REACH and CLP

1. SVHC over .1% by weight require disclosure and safety information within 45 day
2. If SVHC or any substance exceeds > 1 ton/year/legal entity, requires disclosure in ECHA database
3. SVHC list is constantly changing so be ready to update your disclosure report (e.g. Safety Data Sheet – SDS)
4. Plan to join the consortium with other companies for safety test prior to applicable registration timeline (>1000 tons, >100 tons, > 1 ton etc)
5. If any substance goes on Annex XIV (authorization) list, be ready to apply for exemption based on compelling justification



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Summary about REACH and CLP

6. Pure substance and Mixture substance reporting to ECHA and labeling as per CLP requirements and timeline
7. Any new substances in your product that are considered hazardous and have threshold limit, requires disclosure in ECHA database



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On watch

- RoHS
 - China RoHS, California RoHS, Japan RoHS, Korea RoHS, Norwegian RoHS, etc...
- REACH
 - Canadian Environmental Protection Act (CEPA), California Green Chemistry, Japan REACH, China REACH etc



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Thank you !!!!



Questions



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