

INTRODUCTION

REACH Compliance for Importers / Retailers



Delhi, 6.11.08

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INTRODUCTION



- **Registration, Evaluation, Authorisation and Restriction of Chemicals**
- **In force since 01.06.07**
- **850 Pages of EU Legislation**
- **Covers both Human Health and Environmental Issues**
- **Non Compliance can mean goods will be banned from EU market**

INTRODUCTION



- REACH is applicable to :
 - Chemical Substances
 - Chemical Preparations (Cocktails)
 - Chemical Substances in Articles

INTRODUCTION

REACH requires :

(under certain given circumstances)

- **A “registration process”
(including Pre-registration**
- **A “notification” process**
- **A “communication” information
sharing process**



INTRODUCTION



An importer based in the EU may :

- **Have obligations to “Register” chemicals contained in products he/she imports**
- **Have obligations to “notify” about chemicals in products**
- **Have obligations to “provide” accurate information to customers about chemicals in products**

INTRODUCTION



- **European Chemicals Agency (ECHA) is responsible for all aspects of REACH**
- **REACH is about products and international Supply Chain Management**
- **A big “RSL” with added complications**

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INTRODUCTION

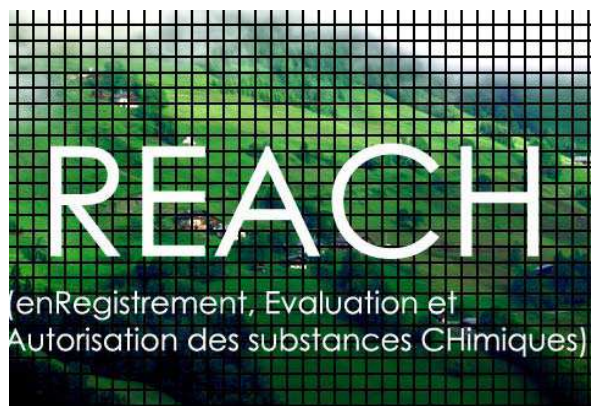
Main Objectives of REACH

- Create a single system to regulate chemicals in the EU
- Improve the protection of human health and the environment from risks that can be posed by chemicals
- Importers are given the responsibility of knowing that chemicals in products are safe



REQUIREMENTS

- REACH (substances in articles) requires three main actions :
 - Registration
 - Notification
 - Information / communication



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REQUIREMENTS

- **Substances in Articles**

- If release of a substance “is intended under normal and reasonable foreseeable conditions of use
- “if more than 1000 kg per year per legal entity of the same substance is contained in the product range
- The substance(s) must be registered with the European Chemical Agency (ECHA)



REQUIREMENTS

- What is an article ?

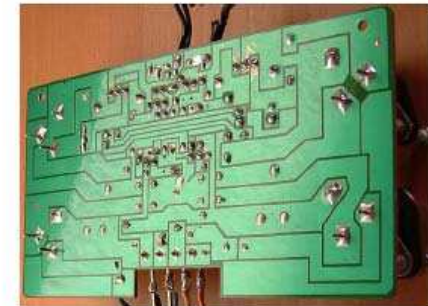
REACH Article 3.3 :

Article: means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition



REQUIREMENTS

Articles



REGISTRATION (Pre-registration)

Register Now!

**Registration
(Pre-registration)
of substances in Articles**

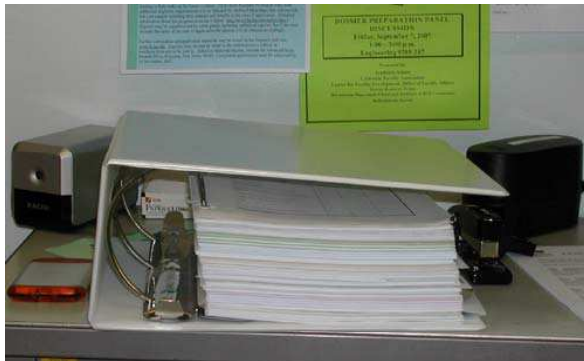


REGISTRATION (Pre-registration)



Registration procedures will require the submission of a complete technical dossier with :

- Your identity and contact information
- The identity of the substance and its use
- Imported tonnage per year (indicating the registration deadline) and exposure information
- Classification and labeling of the substance



REGISTRATION (Pre-registration)



- Guidance on its safe use
- Study summaries of the information on the intrinsic properties of the substance
- An indication as to whether the information has been reviewed by an assessor
- Proposals for further testing if relevant
- A chemical safety report (for substances in volumes exceeding 10 tons per year)

REGISTRATION (Pre-registration)



- “Registration” of a chemical substance contained in an article is required :
- When release of the substance from the article or articles is intentional
- When more than 1000 kg per substance, per year and per legal entity is imported (the actual amount imported rather than released is the important issue)

REGISTRATION (Pre-registration)

Intentional release
(under normal or reasonable foreseeable conditions of use)



- Release related to a quality/function is intentional
- Release related to an accessory quality/function is intentional
- Release caused by wear and tear in general not considered intentional release
- Release caused by accidents are generally not intended (even if they may be reasonably foreseeable)

REGISTRATION (Pre-registration)



**ENVIRONMENTAL
HAZARD**

- **Registration deadlines :**
- **01.12.2010**
 - **when 1000 tons are exceeded**
 - **when 100 tons of chemicals that are very toxic to aquatic organisms are exceeded**
 - **when 1 ton of chemicals that are carcinogenic, mutagenic, or toxic for reproduction is exceeded**

REGISTRATION (Pre-registration)

- 06.06.2013
 - when 100 tons are exceeded
- 06.06.2018
 - when 1 ton is exceeded



However these deadlines only apply if pre-registration has been correctly completed

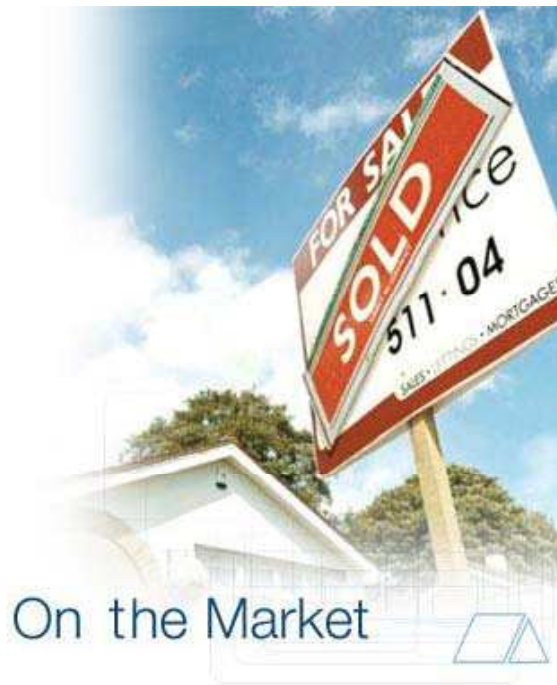
REGISTRATION (Pre-registration)



- Pre-registration requires importers to inform the ECHA of imports that will be subject to REACH
- Pre-registration can be carried out between 01.06.08 and 01.12.08
- Ignoring pre-registration opportunities would mean that all substances imported and subject to REACH would have to be fully registered immediately

REGISTRATION (Pre-registration)

This would be very costly and time consuming and would mean that articles could not be “placed on the market” until registration is complete



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REGISTRATION (Pre-registration)

identity



- **Pre-registration requires that :**
 - **Importer identity and contact information**
 - **Name of substance**
 - **Einecs and Cas numbers of the substance**
 - **Importers tonnage and expected registration deadline**
- are submitted to the ECHA by 01.12.08**

NOTIFICATION

Notification

The ECHA has to be notified by the EU importer if :

- A Substance of Very High Concern (SVHC) listed on the ECHA “candidate list” is present in an article above a concentration of 1000 ppm
- More than 1 ton per year is imported – in articles where 1000 ppm is exceeded



NOTIFICATION

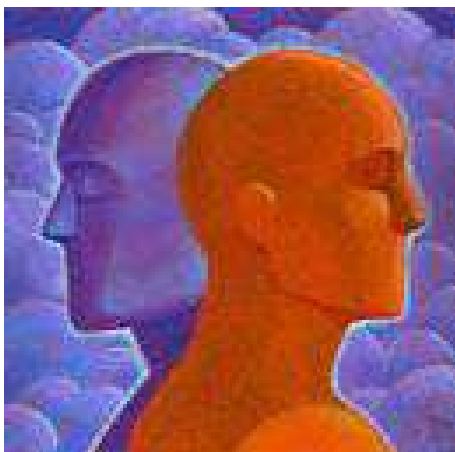
Substances of Very High Concern :

- Category 1 or 2 carcinogens
- Category 1 or 2 mutagens
- Category 1 or 2 toxic for reproduction
- Persistent, Bio accumulative and Toxic (PBT)
- Very persistent, very Bioaccumulative (vPvB)
- Substances pose serious effects to human health and/or environment



NOTIFICATION

- **Candidate list :**



- **Prepared by ECHA and based on individual member states requirements**
- **Expected by end 2008 / early 2009**

NOTIFICATION



SVHC LIST



| Substances | CAS No. / EC No. | SVHC Classification | Application |
|---|---------------------------|---------------------|--|
| Cobalt dichloride | 7646-79-9 / 231-589-4 | Cat. 1 & 2 CMR | Drying agents such as silica gel |
| Sodium dichromate dehydrate | 7789-12-0 / Not Available | Cat. 1 & 2 CMR | Metal finishing, leather tanning, textile dyeing, wood preservatives |
| Diarsenic pentaoxide | 1303-28-2 / 215-116-9 | Cat. 1 & 2 CMR | Fungicides, herbicides, insecticides |
| Diarsenic trioxide | 1327-53-3 / 215-481-4 | Cat. 1 & 2 CMR | Herbicides, insecticides |
| Lead hydrogen arsenate | 7784-40-9 / 232-064-2 | Cat. 1 & 2 CMR | Insecticides |
| Triethyl arsenate | 15606-95-8 / 427-700-2 | Cat. 1 & 2 CMR | Wood preservatives |
| Dibutyl phthalate | 84-74-2 / 201-557-4 | Cat. 1 & 2 CMR | Plasticizers, additive to adhesives or printing inks |
| Bis (2-ethyl(hexyl)phthalate) (DEHP) | 117-81-7 / 204-211-0 | Cat. 1 & 2 CMR | PVC Plasticizers, hydraulic fluid and dielectric fluid in capacitors |
| Benzyl butyl phthalate | 85-68-7 / 201-622-7 | Cat. 1 & 2 CMR | Plasticizer for vinyl foams, floor tiles, synthetic leathers |
| Anthracene | 120-12-7 / 204-371-1 | PBT | Dyes, insecticides, wood preservatives |
| Bis(tributyltin) oxide | 56-35-9 / 200-268-0 | PBT | Wood preservatives |
| 5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene) | 81-15-2 / 201-329-4 | vPvB | Fragrance, cosmetic products |
| Cyclododecane | 294-62-2 / 206-33-9 | PBT | Perfume fixative and enhancer |
| Hexabromocyclododecane (HBCDD) | 25637-99-4 / 247-148-4 | PBT | Flame retardants |
| Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins) | 85535-84-8 / 287-476-5 | PBT | Lubricants for metal processing, rubber and leather coating, glues |
| 4,4'- Diaminodiphenylmethane | 101-77-9 / 202-974-4 | Cat. 1 & 2 CMR | Azo colorants, epoxy resin hardener for rubber |

Abbreviations

- Cat. 1 & 2 CMR: Category 1 & 2 carcinogen, mutagen, & toxic for reproduction
- ECHA: European Chemical Agency
- PBT: Persistent Bioaccumulative Toxic
- REACH: Registration, Evaluation, Authorization and Restriction of Chemicals
- SVHC: Substances of Very Concern
- vPvB: very Persistent very Bioaccumulative

INFORMATION DUTY

Information duty :

Information on certain “Substances of Very High Concern” has to be passed down the supply chain from the importer to the retailer

If asked by an end-consumer, the retailer must provide such information, free of charge, and within 45 days



INFORMATION DUTY



This end-consumer right is most likely to be used by NGOS and consumer watchdog groups to raise public awareness of potential harmful chemicals in articles



INFORMATION DUTY



Date

Dear Sir/Madam

In accordance with the new European regulation on Chemicals, REACH, I am writing to ask you to inform me about the presence in the product XX or its packaging of any chemical from the group of "substances of very high concern" as specified by REACH.

Should any of these substances be present in the product XX or its packaging, I wish to be informed about the name of this substance, and receive sufficient information on how I can protect myself and the environment from it.

I would be grateful to receive this information within 45 days as required by REACH.

I would also be grateful if you would inform me about steps you are taking to provide products intended for the same use but which do not contain such potentially hazardous chemicals.

Yours faithfully,

SAMPLE LETTER FOR CONSUMER
TO REQUEST INFORMATION ABOUT
SUBSTANCES IN AN ARTICLE.

cc: European Chemicals Agency - P.O.Box 400,
00120 Helsinki, Finland, phone: +358-9-686180
email: info@echa.europa.eu, www.echa.europa.eu
(visiting address: Annankatu 18, 00120 Helsinki)
Your national consumer and/or environmental organisation.



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INFORMATION DUTY



- “Information duty” applies to SVHC’s in articles not preparations
- All SVHC’s above a concentration of 0.1 % in weight
- Applies as soon as the first candidate list is published

INFORMATION DUTY



- **What actions have importers taken :**
 - **Inventory checks for preparations and articles**
 - **Data gathering from the supply chain**
 - **Pre-registration if applicable**
 - **Substituting SVHC's for safer alternatives**

INFORMATION DUTY

REACH SIN* List 1.0



REACH SIN* List 1.0 (*Substitute It Now)

| Equivalent level of concern | | | |
|--|-----------|---|-----------------------------|
| CAS# | EC# | Name | Reason for inclusion |
| 1 95-50-1 | 202-425-9 | 1,2-DCBNonbenzene | Equivalent level of concern |
| 2 95-54-4 | 202-479-0 | 4-tert-butylphenol | Equivalent level of concern |
| 3 9002-93-1, 9035-19-5, 99997-00-6 | | 4-tert-octylphenylethoxysulfate | Equivalent level of concern |
| 4 52-53-5 | 205-533-3 | Arsine | Equivalent level of concern |
| 5 1303-64-4 | 215-175-0 | Arsimony trioxide | Equivalent level of concern |
| 6 119461-9 | 204-337-6 | Benzo[a]phenanthrene | Equivalent level of concern |
| 7 80-45-7 | 201-248-8 | Bisphenol A | Equivalent level of concern |
| 8 11653-19-6 | 214-804-9 | Deca-brominated diphenyl ether (Deca-BDE) | Equivalent level of concern |
| 9 1003-53-5, 77-58-7 | | Diethyltin | Equivalent level of concern |
| 10 28553-12-0, 88915-46-0 | 249-079-6 | Di-terphenyl phthalate (DTPP) | Equivalent level of concern |
| 11 50-00-0 | 200-001-8 | Formaldehyde | Equivalent level of concern |
| 12 1222-26-5 | 214-546-9 | Gaucheide | Equivalent level of concern |
| 13 1104-44-3 | 203-777-4 | Hexane | Equivalent level of concern |
| 14 91-20-3 | 202-045-5 | Naphthalene | Equivalent level of concern |
| 15 26194-52-3, 104-40-5, 90491-04-2 | 248-572-0 | Nonylphenol | Equivalent level of concern |
| 16 90784-95-0, 26021-38-3, 66412-54-4, 127067-67-0, 37336-87-1 | 500-024-6 | Nonylphenol ethoxylate | Equivalent level of concern |
| 17 566-67-2 | 209-136-7 | Octamethylcyclotrisiloxane | Equivalent level of concern |
| 18 140-66-8, 27185-28-0 | 205-425-2 | Octylphenol | Equivalent level of concern |
| 19 62449-39-0 | 264-150-0 | Heptalin waxes and Hydrocarbon waxes, chloro- | Equivalent level of concern |
| 20 1783-23-1 | 217-179-8 | Perfluorooctanesulfonate (PFOS) | Equivalent level of concern |
| 21 4151-50-2 | 223-980-3 | Perfluorooctane sulfonamide (PFOSA) | Equivalent level of concern |
| 22 335-67-1 | | PFQA | Equivalent level of concern |
| 23 100-42-5 | 202-051-5 | Styrene | Equivalent level of concern |
| 24 70-34-7 | 201-236-9 | Tetrahydrophthalic Anhydride (THPA) | Equivalent level of concern |
| 25 78-08-3 | 201-075-4 | Tetrahydrofuran | Equivalent level of concern |
| 26 21145-77-7, 1805-02-1 | 244-240-6 | Tonalide | Equivalent level of concern |
| 27 56573-86-4, 1461-22-9, 688-73-3 | | Tributyltin | Equivalent level of concern |
| 28 3393-34-5 | 225-182-2 | Tricresol | Equivalent level of concern |
| 29 2279-75-7, 1067-29-4 | | Trinonylphenol (TNP) | Equivalent level of concern |
| 30 668-34-6, 659-58-7, 76-57-6, 900-95-8 | | Triphenyltin (TPT) | Equivalent level of concern |
| PBT / vPvB | | | |
| CAS# | EC# | Name | Reason for inclusion |
| 1 87-61-2 | 201-751-1 | 1,2,3-Trichlorobenzene | PBT |
| 2 120-42-1 | 204-425-0 | 1,2,4-Trichlorobenzene | PBT |
| 3 85536-84-8 | 201-478-5 | Alkanes, C10-13, chloro-, SCCP | PBT |
| 4 2944-23-7 | 205-033-8 | Cyclohexane | PBT |
| 5 32536-52-0 | 251-087-9 | Diphenyl ether, octadecano derivative | PBT/ Classified CMR |
| 6 28537-06-4 | 247-140-4 | Heptamethylcyclododecane | PBT |
| 7 87-68-3 | 201-725-5 | Hexachlorobutadiene-1,3-diene | PBT/vPvB |
| 8 149-58-9 | 206-107-8 | perfluorooctanesulfonate | PBT/vPvB |
| 9 75-14-1 | 200-507-0 | Tetramethyllead | PBT |
| 10 85-36-9 | 203-086-0 | Triphenyltin chloride (TBTCl) | PBT |
| 11 90540-80-5 | 252-502-7 | Anthracene oil | PBT/ Classified CMR |
| 12 90540-81-6 | 252-502-2 | Anthracene oil, anthracene paste | PBT/ Classified CMR |
| 13 91098-15-2 | 255-275-9 | Anthracene oil, anthracene paste, anthracene fraction | PBT/ Classified CMR |
| 14 91098-17-4 | 255-275-5 | Anthracene oil, anthracene paste, dist. Lights | PBT/ Classified CMR |
| 15 90540-80-7 | 252-504-8 | Anthracene oil, anthracene oil | PBT/ Classified CMR |
| 16 120125-7 | 254-371-1 | Anthracene, pure | PBT |
| 17 81-15-2 | 201-329-4 | Musk Xylene | PBT |

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INFORMATION DUTY

- Where is full information available



<http://echa.europa.eu/>



ECHA website - European Chemicals Agency.url

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Many thanks

