

ABCs of GHS and REACH

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What is the GHS?



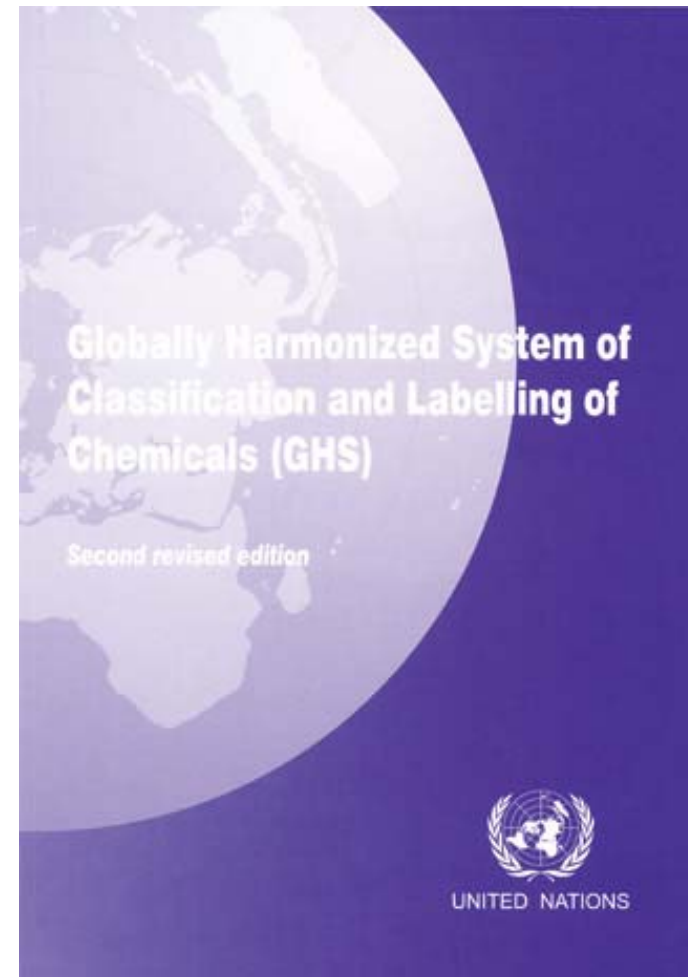
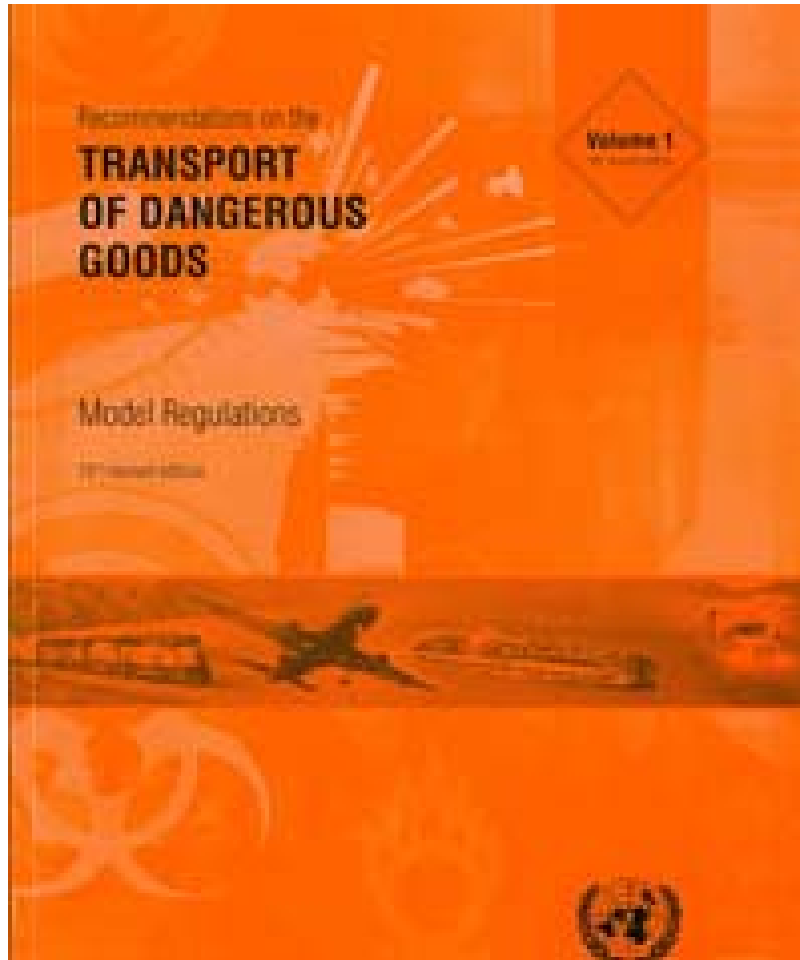
- Globally Harmonized System for Classification and Labelling of Chemicals
- A common and coherent United Nations approach to defining and classifying intrinsic hazards of chemical substances and mixtures, and conveying information about those hazards on labels and Safety Data Sheets (SDS)
- Criteria for hazard classification and hazard communication (Labels and SDSs) are harmonized and standardized.
- One system for workers, consumers, transport workers, and emergency responders.
- Provides the underlying infrastructure for establishment of national, comprehensive chemical safety programs.

Why GHS?



- Target: Establish consistent infrastructure to control chemical exposure and protect people and the environment
 - Streamlined hazard communication requirements
 - Consistent classification and labeling content
- Countries can choose to implement GHS in its entirety or implement only certain parts (“building block” approach)

The UN Purple Book:



The UN Purple Book:



- The UN Committee of Experts for the Transport of Dangerous Goods and the Globally Harmonized System for Classification and Labeling of Chemicals formally adopted GHS in December 2002.
- The GHS/UN document is a living document and is updated every 2 years
 - First edition was published in 2003
 - First revision published in 2005
 - Second revision in July 2007
 - Third revision was just published
- National implementations to stay aligned with revisions

The UN Approach to GHS



- Harmonized classifications

PHYSICAL HAZARDS

Explosives
Flammable Gases/Aerosols
Oxidizing Gases
Gases under Pressure
Flammable Liquids/Solids
Self-Reactive Substances
Pyrophoric Liquids/Solids
Self-Heating Substances
Substances which on contact
with water emit flammable
gases
Oxidizing Liquids/Solids
Organic Peroxides
Substances corrosive to metal

HEALTH HAZARDS

Acute toxicity
Skin corrosion/irritation
Severe eye damage/eye irritation
Respiratory sensitizer
Skin sensitizer
Germ cell mutagenicity
Carcinogenicity
Toxic to reproduction
STOT – Single/Repeat
Exposure
Aspiration hazard

ENVIRONMENTAL HAZARDS

Hazardous to the aquatic
environment (acute/chronic)

Hazardous to the Ozone Layer

Classification Principles



Based on the intrinsic hazards and a tiered approach

Use test data for the mixture, when available

If not ↓

Use “bridging” principles, if applicable

- Dilution
- Batching
- Concentration of Highly Toxic Mixtures
- Interpolation within One Toxic Category
- Substantially Similar Mixtures
- Aerosols

If not ↓

Estimate (calculate) hazard(s) based on the known ingredient information

GHS Calculation Types



Health and Environment

End Point	Calculation Type		
	Simple Threshold	Proportional Equation	Summation Methods
Acute Toxicity		√	
Skin Corrosion/Irritation	√ ¹		√
Serious Eye Damage/Irritation	√ ¹		√
Sensitization	√		
Mutagenicity	√		
Carcinogenicity	√		
Reproductive Toxicity	√		
Target Organ Toxicity			√
Aspiration			√ ²
Environmental <ul style="list-style-type: none"> • Acute Additivity Method • Acute Summation Method • Chronic Summation Method 		√	√ √

1. Only if Additivity does not apply
2. In conjunction with the viscosity of the mixture

Labels: Pre and Post-GHS

【산업안전보건법 제41조 규정에 의한 경고표지】
혼합물 A

고인화성물질 **독성물질, 변이원, 생물독성물질, 생식독성물질** **자극성물질**

유해물질에 따른 조치사항

- 취급장소에는 화재취약기구를 가동할 것
- 취급시 방독마스크, 보호안경, 보호의, 보호장갑 등 개인보호구를 착용할 것
- 위험의 증폭을 예방하기 위하여 흡입장, 분말소화기, 분말이산화탄소 소화기를 사용할 것

대전광역시 유성구 문지동 산업안전보건연구원
기타 자세한 사항은 물질안전보건자료(MSDS)를 참조할 것



디트리에틸 납 (Cas No. 78-30-2)

위험

유해범위 등급	상기한 지정적인 피해와 잠재적인 유해성 증진되면 지정적인 피해에 직간접 노출된 후에 심한 자극을 일으킬 수 있음 피해 또는 건강상의 조난을 일으킬 것으로 예상되는 경우 1등급의 유해성에 2등급을 할당 상위급의 자극을 일으킬 수 있음(피해 또는 유해성) 또는 (상위급에 손상을 일으킬 수 있음)에 따른 유해성 증가(피해) 발생에 의해 수생생물에 1등급이 있을
예방조치 등급	· 모든 작업 내역에서 흡입을 예방하기 위하여 적절한 호흡 보호구를 착용할 것 · 작업으로 야생의 야생, 보호장갑 보호복 착용, 안전보호구 착용할 것 · 즉시 의료기관이나 병원 방문하도록 의뢰 받거나 지체하지 않도록 함 · 2등급 이상은 흡입을 예방하기 위하여 흡입장 착용할 것 · 유해 물질의 발생을 예방하기 위하여 흡입장 착용할 것 · 작업장에서의 흡입을 예방하기 위하여 적절한 분말소화기를 사용할 것 · 흡입을 예방하기 위하여 흡입장 착용할 것 · 흡입을 예방하기 위하여 흡입장 착용할 것 · 흡입을 예방하기 위하여 흡입장 착용할 것

대전광역시 유성구 문지동 산업안전보건연구원 (000-000-0000)

Pre-GHS system

- Chemical name
- 7 Pictograms
- Classification (i.e: "Mixture A")
- Cautions/measures

GHS System

- Product information
- Pictograms
- Signal word
- Precautionary Statements
- Hazardous Statements
- Supplier information

GHS Label Example

• Label for “Benzopyrene” – CAS 50328


UN Version

Show GHS Label in : Japanese


Show GHS Label in : Korean

Benzopyrene

Danger



H350: May cause cancer (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard).




H340: May cause genetic defects (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard).

H360: May damage fertility or the unborn child (state specific effect if known) (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard).

H315: Causes skin irritation.

H400: Very toxic to aquatic life.

H410: Very toxic to aquatic life with long lasting effects.



H373: May cause damage to organs (or state all organs affected, if known) through prolonged or repeated exposure (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard).

P201: Obtain special instructions before use.

P202: Do not handle until all safety precautions have been read and understood.

P281: Use personal protective equipment as required.

P308+P313: IF exposed or concerned: Get medical advice/attention.

P405: Store locked up.

P501: Dispose of contents/container to

GHS Label

ベンゾピレン

危険



H350: 発がんのおそれ (他の経路からの暴露が有害でないことが決定的に証明されている場合、有害な暴露経路を記載)



H340: 遺伝性疾患のおそれ (他の経路からの暴露が有害でないことが決定的に証明されている場合、有害な暴露経路を記載)

H360: 生殖能または胎児への悪影響のおそれ (もし判れば影響の内容を記載する) または (他の経路からの暴露が有害でないことが決定的に証明されている場合、有害な暴露経路を記載)

H315: 皮膚刺激

H400: 水生生物に非常に強い毒性

H410: 長期的影響により水生生物に非常に強い毒性



H373: 長期にわたるまたは反復暴露による臓器の障害のおそれ (もし判れば影響を受ける全ての臓器を記載する) (他の経路からの暴露が有害でないことが決定的に証明されている場合、有害な暴露経路を記載)

P201: 使用前に取扱説明書入手すること。

P202: すべての安全注意を読み理解するまで取扱わないこと。

P281: 指定された個人用保護具を使用すること。

P308+P313: 暴露または暴露の懸念がある場合：医師の診断/手当てを受けること。

P405: 施錠して保管すること。

P501: 内容物/容器を (国際/国/都道府県/市町村の規則に従って) ... に廃棄すること。

GHS Label

벤조피렌

위험



H350: 암을 일으킬 수 있음. <만일 다른 노출 경로가 위험할 경우 이는 것이 단정적으로 증명된 경우라면 노출 경로를 정확히 명시해야 한다>.



H340: 유전적 결함을 일으킬 수 있음. <만일 다른 노출 경로가 위험할 경우 이는 것이 단정적으로 증명된 경우라면 노출 경로를 정확히 명시해야 한다>.

H360: 태아 또는 생식능력에 손상 일으킬 수 있음. <특별한 효과가 나타난 것일 경우 정확히 명시해야 함> <만일 다른 노출 경로가 위험할 경우 이는 것이 단정적으로 증명된 경우라면 노출 경로를 정확히 명시해야 한다>.

H315: 피부에 자극을 일으킴.

H400: 수생생물에 매우 유독함.

H410: 장기적인 영향에 의해 수생생물에게 고독성이 있음.



H373: 장기간이나 반복되는 노출을 통해서 장기에 손상 일으킬 수 있음. <모든 안전 예방조치 문구를 읽고 이해하기 전에는 취급하지 마시오.> <만일 다른 노출 경로가 위험할 경우 이는 것이 단정적으로 증명된 경우라면 노출 경로를 정확히 명시해야 한다>.

P201: 사용 전 취급 설명서를 확보하십시오.

P202: 모든 안전 예방조치 문구를 읽고 이해하기 전에는 취급하지 마시오.

P281: 적절한 개인 보호구를 착용하십시오.

P308+P313: 노출 또는 접촉이 우려되면 의학적인 조언·주의를 받으시오.

P405: 밀봉하여 저장하십시오.

P501: (관련 법규에 명시된 내용에 따라) 내용물·용기를 폐기하십시오.

Safety Data Sheet



- Based on 16 section SDS format
- Section 2: Hazard Identification
 - includes the GHS classification as well as the GHS label elements
- Country specific SDS regulatory requirements still need to be considered



GHS - Common Trends



- Adoption of UN classification criteria, labeling and SDS building blocks
- Provision of lists of classified substances (NZ, JP, KR, EU)
- Transitional Periods - examples:
 - Korea
 - July 1, 2008 to July 1, 2011 – substances and July 1, 2013 – mixtures
 - European Union
 - Dec. 1, 2010 for substances
 - June 1, 2015 for mixtures

GHS Around the Globe



- Global companies that use and manufacture chemicals will benefit from GHS as the basic principles for classification and labeling of chemicals are getting harmonized, YET:
 - **National implementations differ**
 - Some national authorities have published mandatory lists of GHS classifications
 - Some have kept part of their previous classification and labeling requirements
 - GHS and its revisions are not implemented at the same time
- Companies have to decide how to meet these different requirements where the GHS classification and the labeling of a chemical substance or mixture may vary from country to country

REACH



- Regulation (EC) No 1907/2006 of the European Parliament and of the Council, concerning the **Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)**
 - establishing a European Chemicals Agency (ECHA), amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC
- Entered into force June 1, 2007

Previous Legislature



- Regulation (EC) No 793/93
 - Distinction between so called “existing” and “new” chemicals based on cut-off date of 1981
- Lack of publicly available information on “existing” chemicals (about 100,000 as of 1981)
- No obligations on downstream users (industrial users and formulators)

REACH Basics



- **Scope:**
Manufacture, import, placing on market and use of substances (on their own, in preparations or in articles)
- **Two roles:**
 - **Manufacturer/Importer (M/I):** for the chemicals the European company produces or imports (into EU)
 - **Downstream User (DU):** for the chemicals the European company buys from an EU supplier
- **Impacts every company doing business in or exporting to Europe**

REACH – Key Elements



Key elements:

Title II: Registration of substances

Title III: Data sharing

Title IV: Information in the supply chain

Title V: Downstream users

Title VI: Evaluation

Title VII: Authorisation

Title VIII: Restrictions in marketing and use

Title XIV: Enforcement

REACH - Exemptions



Substance group	Title II Registration	Title IV SDS	Title V DU	Title VI Evaluation	Title VII Authorisation
Radioactive substances	Exempted	Exempted	Exempted	Exempted	Exempted
Under customs supervision and intended for re-exportation, or in transit	Exempted	Exempted	Exempted	Exempted	Exempted
Non-isolated intermediates	Exempted	Exempted	Exempted	Exempted	Exempted
Carriage of dangerous substances according to ADR, RID, IMDG or IATA	Exempted	Exempted	Exempted	Exempted	Exempted
Waste	Exempted	Exempted	Exempted	Exempted	Exempted
Certain substances in the interests of defence	Exempted	Exempted	Exempted	Exempted	Exempted
In medicinal products	Exempted	1)	Exempted	Exempted	Exempted
Food additives & Flavourings in food and feedingstuffs	Exempted	1)	Exempted	Exempted	Exempted
In Cosmetic or n medical devices		1)			
Annex IV or Annex V	Exempted		Exempted	Exempted	
Re-imported substances	Exempted		Exempted	Exempted	
Re-imported substances & Substances which have been registered and which are recovered	Exempted		Exempted	Exempted	
On-site isolated intermediates and transported isolated intermediates	"Light" registration				Exempted
Pesticides & Biocides	Exempted				
On ELINCS	2)				
Polymers	Exempted 3)			Exempted	
Product and process oriented research and development (PPORD)	4)				

- 1) Exempted in the finished state, intended for the final user 2) Exempted from registration by the notifier.
 3) The monomer substances might have to be registered see Title II, article 6.3 4) Exempted for up to 5 years

REACH – Registration



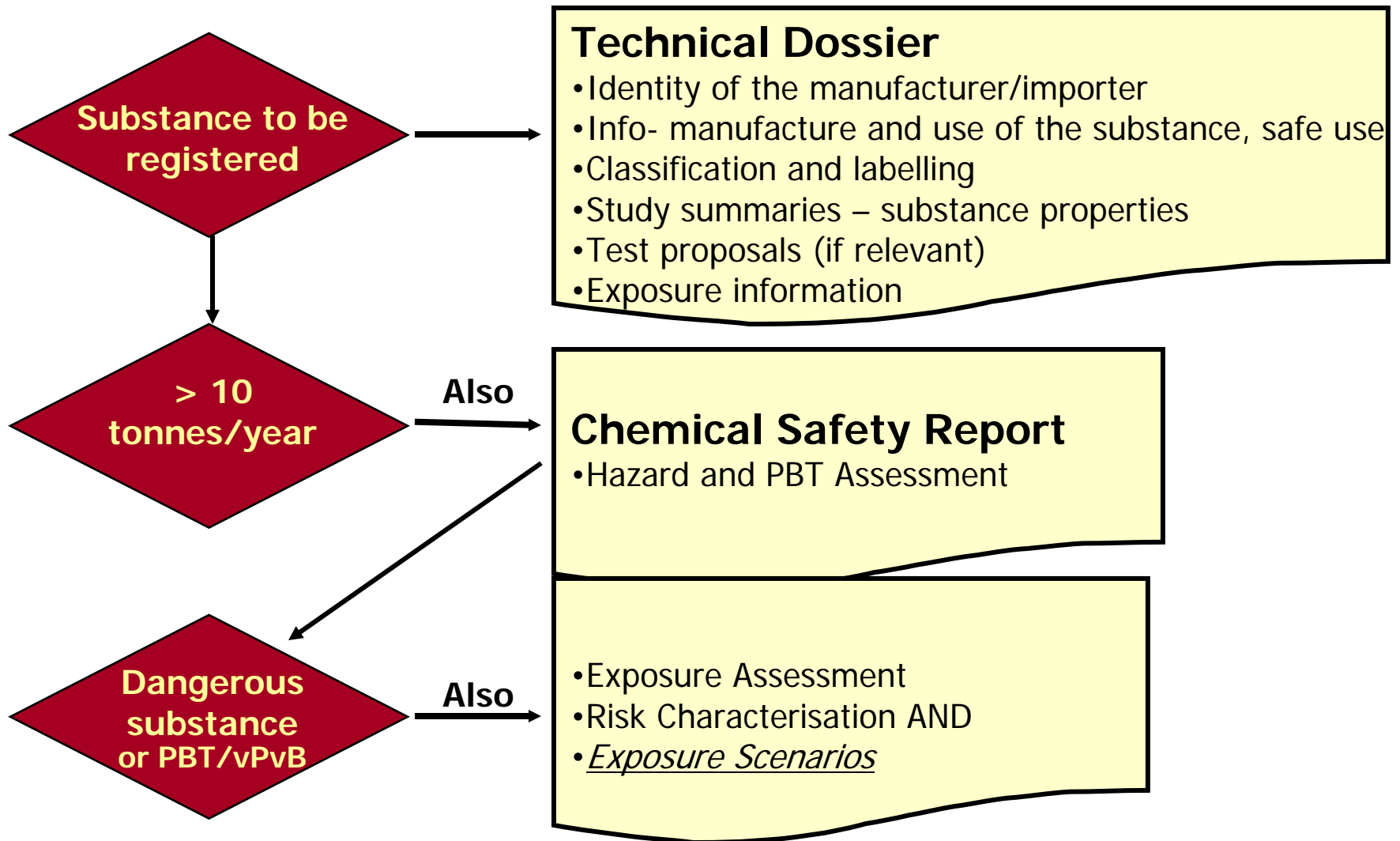
- Registration of manufactured/imported chemical substances > 1 tonne/year - various dead-lines over an 11 years period
 - May also apply to substances in articles
- Registration requirements started June 1, 2008
- Only EU companies can register
- Non-EU companies can choose to use an Only Representative
- One Substance Information Exchange Forum (SIEF) for each pre-registered substance with the same identity
- Joint submission of:
 - Classification and Labeling (must)
 - Study Summaries (must)
 - Robust study summaries and proposal of testing where listed in the relevant annexes (must)
 - Guidance of safe use of the substance (may)
 - Chemical Safety Report when required (may)
- **SIEFs shall remain operational until 1 June 2018**

REACH - Registration



- “Phase-in substances” pre-registered before December 2008 are subject to the following deadlines:
 - **December 2010:**
 - All substances >1000 tonnes
 - Carcinogens, Mutagens, Toxic to Reproduction (CMR cat. 1 or 2) >1 tonne
 - Very toxic to aquatic organisms (R50/53)> 100 tonnes
 - **June 2013:**
 - Substances 100 - 1000 tonnes
 - **June 2018:**
 - Substances 1 - 100 tonne
- Late pre-registration does not apply to companies that failed to meet the pre-registration deadline of December 1, 2008 for substances.
- These companies cannot continue producing or importing the substances until they have submitted a full registration dossier.

Registration Dossier



REACH - Registration (cont'd)



What should non – EU manufacturers do?

- Be sure to have good records of which substances are exported into EU and in what amounts
 - Also in articles
- Collect and evaluate available data
- Consider how/if to get involved in the registration work
- Follow the work in the SIEFs
- Consider if an only representative should be engaged

REACH – Information in the Supply Chain



- Safety Data Sheets are still regulated by REACH
 - Art 31 is updated to include all chemicals classified under 1272/2008 (CLP)
 - Annex II is in the process of being updated
- Additional/new requirements to the EU SDS under REACH:
 - Certain information must be included now
 - Certain information must be added once/if the substances in the product are registered
 - Exposure scenarios (ES) to be attached

REACH – Information in the Supply Chain



What should non – EU manufacturers do?

- Be sure their products are supplied in Europe with a compliant SDS (and label)
 - REACH compliant
 - Including proper declaration of ingredients
 - GHS compliant
 - Including national regulations
 - In the proper languages
 - Kept up to date

REACH - Authorisation



- Candidate list - Substances of Very High Concern (SVHC)
 - Available on the ECHA web site
- Substances on the Candidate List may subsequently become subject to authorization (Annex XIV) by decision of the European Commission
 - Continued use of substances included in Annex XIV requires that after the “sunset date” the use has been authorised
 - First issue of Annex XIV is June 2009
- Substances of very high concern (SVHC)
 - CMRs (carcinogens, mutagens and reproductive toxins – categories 1 or 2)
 - PBTs (persistent, bioaccumulative and toxic substances)
 - vPvBS (very persistent & very bioaccumulative substances)
 - Some substances of concern → irreversible serious effects on humans & the environment (e.g. endocrine disruptors)

REACH – Authorisation (cont'd)



What should non – EU manufacturers do?

- Track and understand which substances are considered SVHCs
- Understand if any candidate substances are in your products
- Prepare to re-formulate – consider substitution
- First substances:
 - 4,4'- Diaminodiphenylmethane (MDA) (Carc)
 - Dibutyl phthalate (DBP) (Rep)
 - 5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene) (vPvB)
 - Bis (2-ethylhexyl)phthalate (DEHP)
 - Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified (PBT)
 - Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins) (PBT & vPvB)
 - Benzyl butyl phthalate (BBP) (Rep)

REACH – Restrictions



Title VIII: Restrictions in marketing and use

- A substance on its own, in a preparation or in an article, for which Annex XVII contains a restriction shall not be manufactured, placed on the market or used unless it complies with the conditions of that restriction.
- Example:

'53. 2-(2-methoxyethoxy)
ethanol (DEGME)
CAS No: 111-77-3
Einesc No: 203-906-6

Shall not be placed on the market after 27 June 2010, for supply to the general public, as a constituent of paints, paint strippers, cleaning agents, self-shining emulsions or floor sealants in concentrations equal to or greater than 0,1 % by mass.

REACH - Enforcement



Press Release:

ECHA/PR/09/05

Helsinki, 30 April 2009

FIRST COORDINATED REACH ENFORCEMENT PROJECT STARTED

REACH-EN-FORCE-1, a joint REACH enforcement project, has started across Europe. National inspectors are checking pre-registrations, registrations and – where applicable – the provisions for Safety Data Sheets. The Forum for Exchange of Information on Enforcement, meeting for the fourth time this week in Helsinki, reviewed the start of the project and agreed on the further steps.

The enforcement project of the Forum enforces the core principle of REACH: *no data, no market*. Inspectors in the participating countries will focus on the phase-in substances (existing substances) and check through inspections whether companies have submitted a pre-registration or a registration and, where necessary, whether a Safety Data Sheet has been supplied.

The project will thus give a first impression of the level of compliance by manufacturers and importers (including only representatives) with REACH in the European Union and European Economic Area. At the same time, the capacity of the enforcement authorities to enforce REACH will be enhanced.

Thank you for your attention!

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