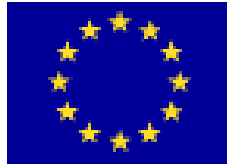


EU New Chemical policy

■ REACH

■ Regulation (EC)
No 1907/2006



欧盟新化学品政策

■ REACH

■ 法规 (EC) No 1907/2006



What is REACH?

- Create a single system to regulate chemicals in EU

The four key elements of REACH

Registration

- Substance ≥ 1 t/yr
- Sub. in preparation ≥ 1 t/yr
- Sub. in Article (intended release) ≥ 1 t/yr

Authorisation

SVHC-
manufacturing and use is only allowed
when authorisation is granted

Evaluation

- Dossier evaluation
- Substance evaluation

Restriction

Repeal 76/769/EEC restricts dangerous
substances on its own, in preparation
and in article

Substances
Substances



什么是REACH?

- 建立一个单一系统监管在欧盟境内的所有化学物质

REACH的四个主要元素

注册

- 物质 ≥ 1 吨/每年
- 配制品中的物质 ≥ 1 吨/每年
- 物品中的物质 (有意释放) ≥ 1 吨/每年

评估

- 技术档案评估
- 物质评估

授权

高关注物质-
只有在已授权的情况下，
才可制造或使用高关注物质

限制

废除指令76/769/EEC，
取而代之限制危险物质
以及配制品和物品中的危险物质

物质
物质



Glossary

Substance
Substance

Chemical elements and its compounds



Preparation
Preparation

Mixture of substances



Article
Article

Its shape determines its function to a greater degree than its chemical composition





词汇

物质
物质

化学物质及其化合物



混合物质

配制品
配制品



物品的功能主要取决于物品的形状而非化学成分

物品
物品



REACH

Main Objectives:

- To ensure a **high level of protection** of health and the environment
- **Put articles under regulation**
- Encourage **data sharing** and reduce animal testing
- Safeguarding innovation and competitiveness



REACH

主旨:

- 高度保护人类健康和环境
- 把物品纳入规管范围
- 鼓励数据共享和减少动物测试
- 保留研发空间以及保持欧盟化工业的竞争力





Penalties for Non-compliance

- Member States (MS) shall lay down their own provisions on penalties
- MS shall ensure they are implemented
- The penalties provided for must be effective, proportionate and dissuasive.
- MS shall notify the Commission regarding the provisions on penalties **no later than 1 December 2008**





违规惩罚

- 欧盟成员国必须厘定一套自己的罚则
- 成员国必须切实执行条款
- 罚则须行之有效，适当和劝阻式的
- 成员国必须在**2008年12月1号前**通告欧盟委员会有关罚则的详细内容



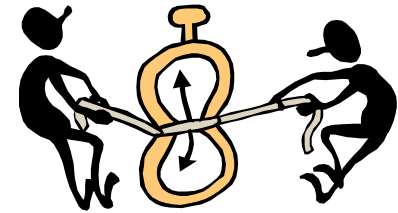
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REACH implementation process



Jun 1, 2007	REACH "ENTERS into FORCE"
Jun 1, 2008	European Chemical Agency fully operative
	Pre-registration of EXISTING substances (PHASE IN)
	Registration of NEW substances (NON PHASE IN)
Nov 30, 2008	Pre-registration ends

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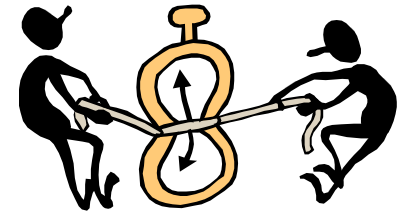


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REACH 实施时间表



2007年6月1号	REACH 正式生效
2008年6月1号	欧盟化学品局全面运作
	阶段性物质预注册开始
	非阶段性物质注册开始
2008年11月30号	预注册截止日期



Pre-registration



First Impact

- Pre-Registration necessary for substances:
 - on their own
 - in Preparations
 - In Articles *if* substance intended to be released

- Purpose
 - To facilitate data sharing
 - To reduce testing on vertebrate animals
 - To reduce costs to industry



预注册

首要事项

- 预注册范围：
 - 物质本身
 - 配制品中的物质
 - 物品中的有意释放的物质
- 预注册目的：
 - 方便数据共享
 - 减少脊椎动物测试
 - 减低注册或相关费用





Pre-registration

- 1 June 2008 to 1 December 2008
- For existing substances
- 1000 kg per manufacturer / importer
- Release from an article is intentional



预注册

- 2008年6月1号至2008年12月1号
- 只适合于阶段性物质
- 1000 千克 / 制造商或进口商
- 物质在物品中属于有意释放



Pre-registration

- Name of the substance
- Eines and CAS number
- Name / Address of pre-registrant
- Contact Person



预注册

- 物质名称
- EINECS号 and CAS号
- 预注册者姓名和地址
- 联络人



Pre-registration

How

- Pre-registration / registration shall be made via internet
- Two systems IUCLID 5 / REACH IT
- Provided free by ECHA



预注册

如何预注册

- 必须使用互联网预注册 / 注册
- 两个系统 IUCLID 5 / REACH IT
- 由欧盟化学品局人员设计，并免费提供于相关人士使用



Pre-registration

IMPORTANT

Failure to pre-register a substance means:

Until full registration has taken place, that substance cannot be put on the market.



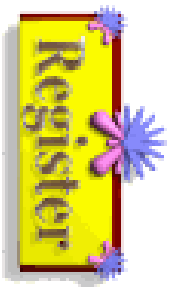
预注册

注意

如未能在规定时间内预注册：

只有在完成注册的情况下，物质才能投放于市场上。

Registration



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注册






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Registration

Substances	Sub. in Preparation	Sub. in Article
<p>Chemicals</p> 	<p>Glue</p> 	<p>T-shirt</p> 
<p>Registration required if sub.</p> <p style="color: purple; text-align: center;">≥ 1 t/a per manufacturer or importer</p>	<p>Registration required if sub. in preparation</p> <p style="color: purple; text-align: center;">≥ 1 t/a per manufacturer or importer</p>	<p>Registration required if sub. in Article is <u style="color: red;">intended to be released</u>,</p> <p style="text-align: center;">and</p> <p style="color: purple; text-align: center;">≥ 1 t/a per manufacturer or importer for that specific use</p>

注册

物质	配制品中的物质	物品中的物质
<p>化学品</p> 	<p>胶水</p> 	<p>汗衫</p> 
<p>物质的注册条件</p> <p>按制造商或进口商计</p> <p>≥ 1 吨/每年</p>	<p>配制品中物质的注册条件</p> <p>按制造商或进口商计</p> <p>≥ 1 吨/每年</p>	<p>物品中物质的注册条件</p> <p>物质有意释放</p> <p>以及</p> <p>按制造商或进口商计</p> <p>≥ 1 吨/每年</p>

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Substance & Substance in preparation Registration

Art 6(1)

- Manufacturer or importer of a substance, either on its own or in preparation, **in quantities \geq 1 t/a** shall submit a registration



物质以及配制品中的物质 注册

第 6条(1)

- 若物质本身或配制品中物质的数量大于或等于1吨/每年，制造商或进口商必须为该物质进行注册



Substance in Article Registration

Art 7(1)

- Any producer or importer of **articles** shall submit a **REGISTRATION** to the Agency for any substance contained in those articles, if both the following conditions are met:
 - (a) the substance is present in those articles in quantities **totalling over 1 tonne** per producer or importer per year;
 - (b) the substance is **INTENDED TO BE RELEASED under normal or reasonably foreseeable conditions of use.**

物品中的物质 注册

第 7条(1)

- 如果以下两个条件都符合，任何制造商或进口商必须为其物品中的物质向欧盟化学品局提交注册：
 - (1) 按制造商或进口商计，物质在物品中的数量大于或等于1吨/每年；
 - (2) 在正常和可合理遇见的使用情况下，物品中的物质是有意释放的。

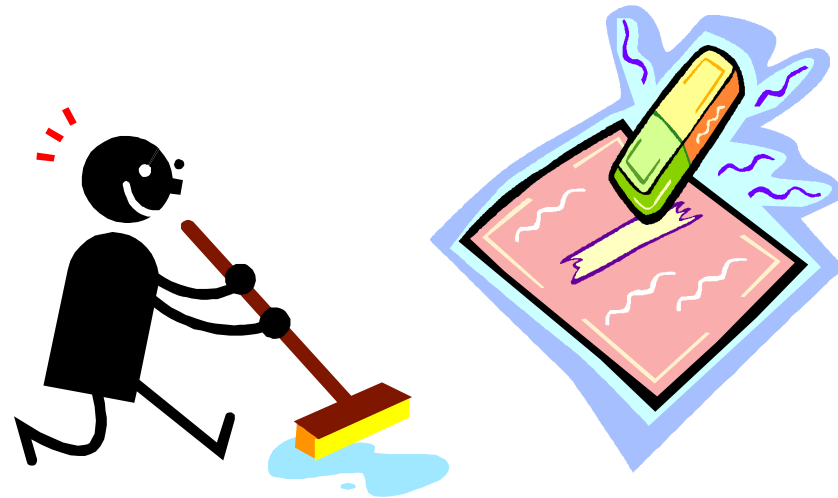




Substances intended to be released



Markers



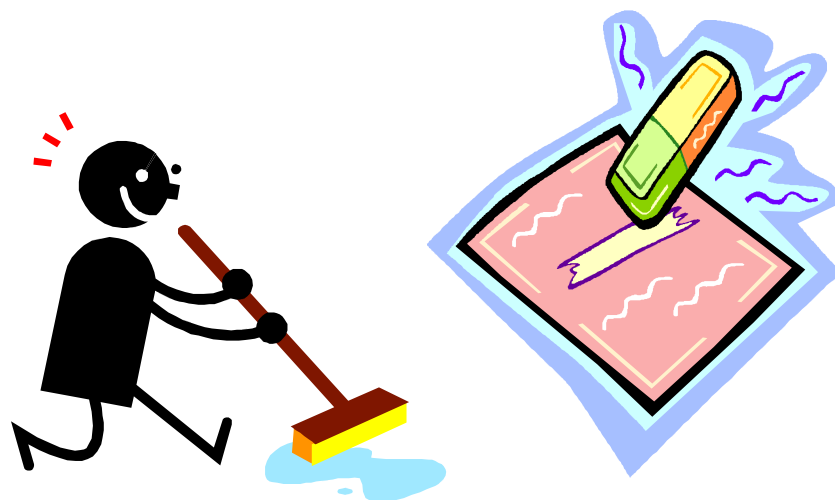
Textiles
impregnated
With polish

Scented
Eraser

未有确实定义的产品



记号笔



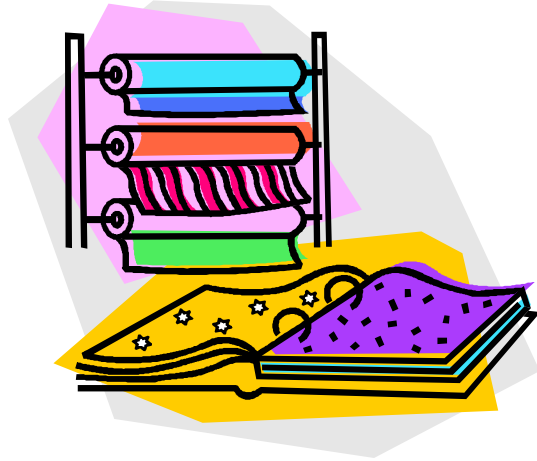
含擦亮剂的
纺织品

有香味的橡皮





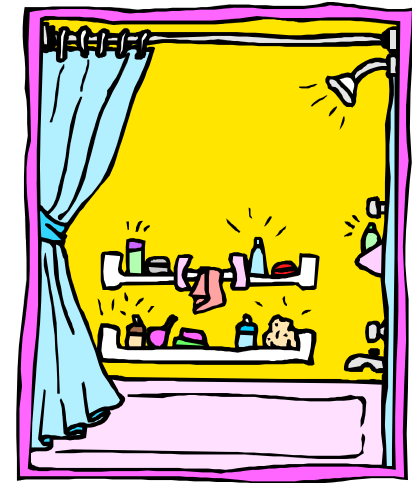
Substances not intended to be released



Clothes
(aromatic amines)



Tyres
(PAH)



Shower curtain
(Phthalates)



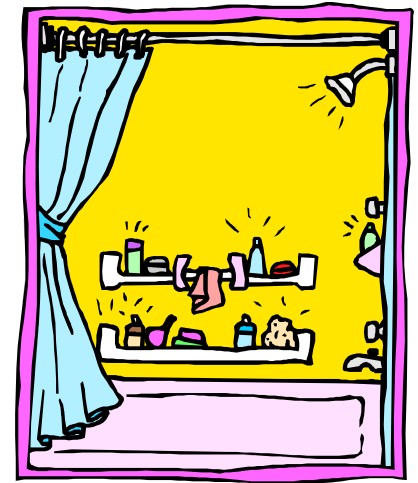
无意释放的物质



成衣
(芳香胺)



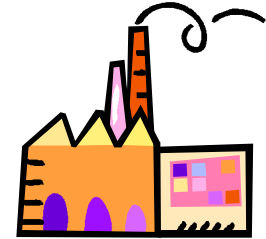
轮胎
(多環芳香族碳氫化合物)



浴帘
(邻本二甲酸盐)

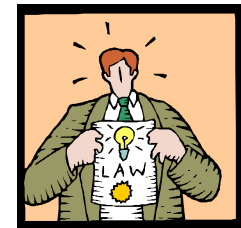


EU Manufacturer / Importer



- **Manufacturer:** means any natural or legal person **established within the Community** who manufactures a substance within the Community;
- **Importer:** means any natural or legal person **established within the Community** who is responsible for import

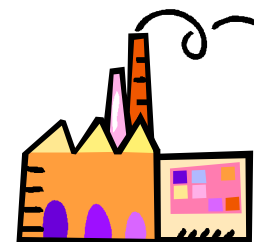
Non-EU manufacturer / importer



- Appoint an **ONLY REPRESENTATIVE** by mutual agreement
- To fulfill obligations on your behalf
- Shall inform along the supplier chain regarding the appointment

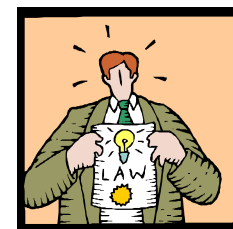


欧盟制造商 / 进口商



- **制造商**: 指任何在欧共同体内制造物质，并在欧共同体确立的自然人或法人
- **进口商**: 指任何负责进口，并在欧共同体确立的自然人或法人

非欧盟制造商 / 进口商



- 在双方协议的基础上，委任一个**唯一代理**
- 助你履行相关责任
- 你必须通知供应链中各成员关于是次委任



Registration:

BUT !!!

- Manufacturers / Importers of articles
 - Do not need to register substances
 - If the substance is already registered by another party for that use

注册:

然而 !!!

■ 物品的制造商或进口商

- 无须为其物质注册
- 如该物质已经由其他自然人或法人注册



Authorisation



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Authorisation



- Included chemicals:
 - **Cat 1 & 2 CMR, PBT, vPvB and substance with similar effects**
- Authorisation procedure consists of two steps:
 - a decision is taken via comitology as to which substances on the candidate list will be included in the system, which will be exempted and which deadlines will have to be met
 - **apply for an authorization with an analysis of possible substitutes**
- **Authorisation will be granted** if the applicant demonstrate the risk from the use of the substance is **adequately controlled**
- Or authorisation may be granted if **socioeconomic benefits outweigh the risks in the absence of suitable alternative**



授权



■ 范围:

- 第一及第二类致癌，致诱变或致生殖毒物 (CMR)，持久积累毒物(PBT), 非常持久及非常积累物质(vPvB) 和有同等危害的物质

■ 授权程序:

- 欧盟委员会会通过开会决定，从高关注物质候选名单中挑选哪些落入授权清单，列出豁免条款和使用期限。
- 申请授权时要附带一份替代物质的研究报告

■ 申请人若能证实物质的使用有足够的监管，或者

■ 在没有替代物质或技术的情况下，社会经济利益大于该物质所带来的危险，申请将会被接纳。



Restriction



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限制



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Restriction

- Provide a procedure to **regulate** that the manufacture, placing on the market or use of **certain dangerous substances**
- These dangerous substances shall be either **subject to conditions or prohibited**
- **Act as a safety net** to manage Community wide risks that are otherwise not adequately controlled.



限制

- 提供一个程序管理有害化学品的制造，使用和销售。
- 条文禁止或有条件下限制有害化学品的制造，使用和销售。
- 这法规在欧共体内作为一个安全网，堵塞法律漏洞。



Restriction

Art 67(1)

- A **substances** on its own, in **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.



限制

第 67条(1)

- 除非能满足附录XVII所厘定的限制要求，否则，物质本身、在配制品或物品中的物质将不能生产，使用或销售。





Restriction Examples



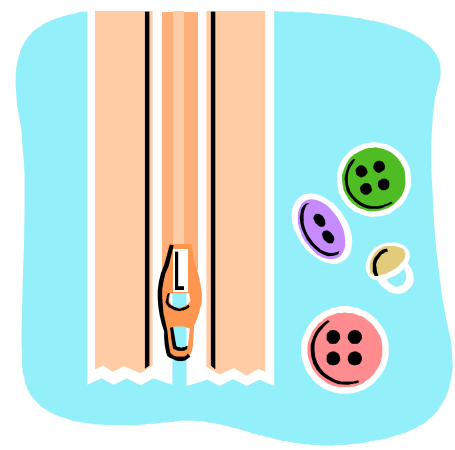
Textiles

Aromatic amines
Limit: 30 ppm



Plastic eyelet

Cadmium
Limit: 0.01% by mass



Metal button

Nickel release
Limit:
0.5 µg/cm²/week

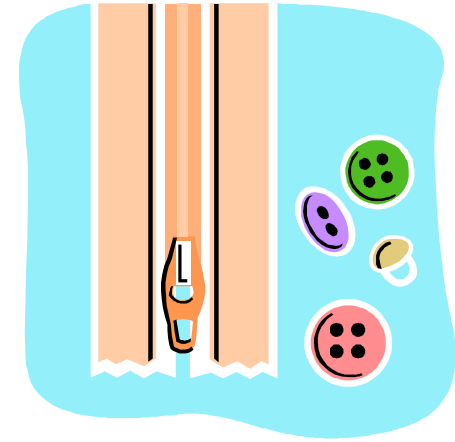


限制例子



纺织品
芳香胺

含量上限: 30 ppm



金属钮扣
镍释放

含量上限:
 $0.5 \mu\text{g}/\text{cm}^2/\text{week}$



塑料带眼
镉

含量上限: 0.01% 按重量计

Notification

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通报

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CAUTION

请注意！

Notification



Art 7(2)

- Any producer or importer of articles shall **NOTIFY** the Agency, if both the following conditions are met :
- (a) a substance on the candidate list (SVHC) is present in those articles in quantities **totalling over 1 tonne** per producer or importer per year;
- (b) the substance is present in those articles **above a concentration of 0.1% weight by weight (w/w)**.



通报



第7条(2)

- 如果以下两个条件同时符合，任何制造商或进口商必须**通报欧盟化学品局**有关高关注物质的信息：
- (1) 按制造商或进口商计，物品中高关注物质的**总量大于或等于1吨/每年**；以及
- (b) 该高关注物质在物品中的**含量大于或等于0.1% (按重量计)**。





Substance of very high concern (SVHC)

- Category 1 or 2 carcinogens
- Category 1 or 2 mutagens
- Category 1 or 2 toxic for reproduction
- Persistent, bioaccumulative and toxic (PBT)
- Very persistent and very bioaccumulative (vPvB)
- Substances pose serious effects to human health or the environment (e.g. endocrine disruptor)



高关注物质 (SVHC)

- 第一类或第二类致癌物质 (C)
- 第一类或第二类致诱变物质 (M)
- 第一类或第二类致生殖毒物 (R)
- 持久积累毒物 (PBT)
- 非常持久及非常积累物质 (vPvB)
- 有同等危害的物质 (例子：破坏内分泌的物质)





Possible consequences



Article 7(5)

- The Agency may require producers or importers of articles to submit a **REGISTRATION**, if all the following conditions are met:
 - a) the substance is present in those articles > 1 t/a
 - b) the Agency suspects that:
 - (i) **the substance is released from the articles**, and
 - (ii) the release of the substance from the articles presents a risk to human health or the environment;
 - c) The substance does not registered before because of the intended released requirement

后果



第7条(5)

- 如以下所有条件同时符合，欧盟化学品局有可能要求制造商或进口商为该物质**注册**：
 - a) 物质数量大于 1 吨/每年
 - b) 欧盟化学品局怀疑：
 - (i) 物质会从物品中释放出来；
 - (ii) 物质的释放会危害人体健康和环境
 - c) 该物质未有因有意释放而被注册



Information in the supply chain

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供应链中的资源传递

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Communicate information on substances in articles

NEW!



Article 33

1. Any supplier of an article containing a

SVHC in conc. > 0.1% (w/w)

- ✓ Shall provide the **recipient of the article** with sufficient information to allow safe use of the article
2. Provide such information to **consumer** on request
 - The information shall be provided **Free of charge within 45 days**

传递物品中物质的信息

新!

第33条

1. 任何供应商，物品中

高关注物质含量 > 0.1% (按重量计)

✓ 必须为买家提供足够的物品安全使用指引

2. 在消费者的要求下

■ 供应商必须在**45天内免费提供相关的安全使用指引**





Communicate information on substances in articles

- Information on SVHCs **must** be provided to **consumers** if requested
- **Obligation begins** as soon as official list of SVHC is published (candidate list): End 2008 / Early 2009



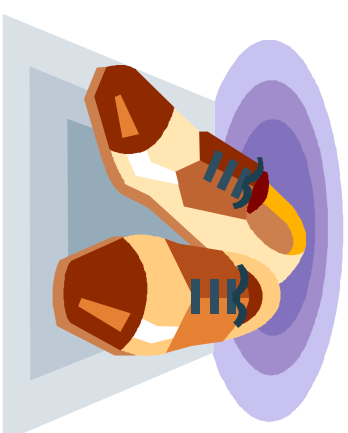
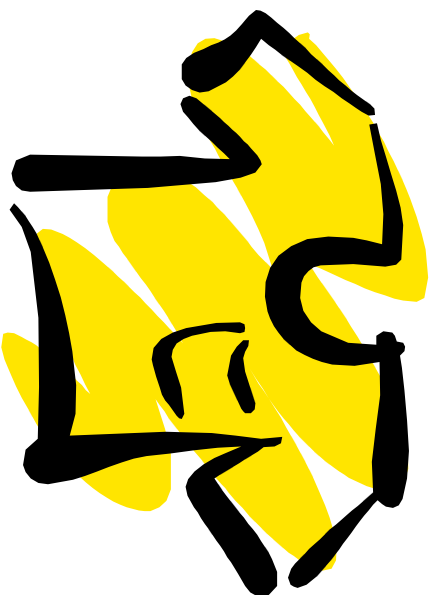
传递物品中物质的信息

- 若消费者有所要求，有关物品中高关注物质的讯息是必须提供的。
- 当高关注物质候选名单公布时，供应商就要切实履行其责任。
- 高关注物质的候选名单公布时间大概在2008年年底至2009年年头



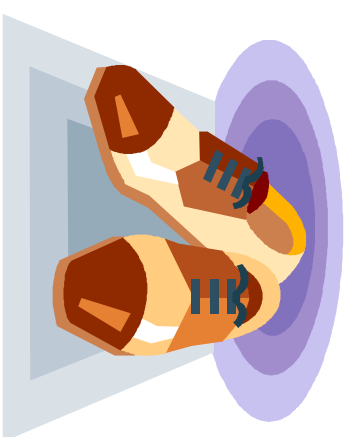
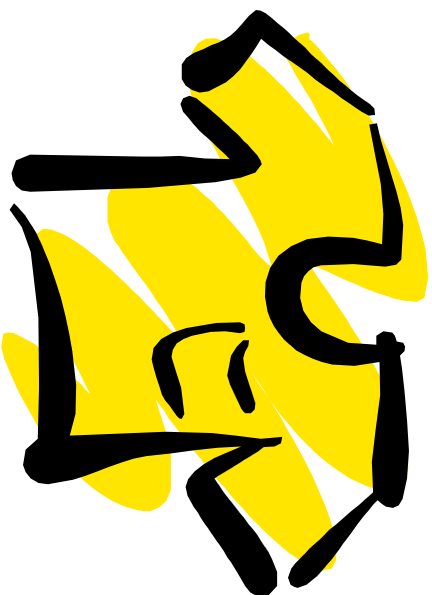
Any impact ?

What should we prepare ?





影响何在？ 应该如何准备？





Textiles and footwear

- Should I care about REACH ?



- Why?
 - A. Restriction requirement (repeal 76/769/EEC: Azo dyes, nickel release....)
 - B. Pre-registration of any substance intended to be released (very few in textiles/footwear, e.g., scents; infused deodorants; possibly overdyed denim)
 - C. Notification → May lead to registration
 - D. Information in the supply chain
 - E. Authorisation

纺织品及鞋类产品

- REACH对我有没有影响呢？ **是有影响的**
- 为什么？
 - A. 限制要求 (废除指令76/769/EEC: 代而管制偶氮染料，镍等的有害物质)
 - B. 有意释放物质的预注册(对纺织品及鞋类产品的影响比较少，例子有香味，除臭剂，或许包括染料过多的牛仔布)
 - C. 通报 → 有可能要申请**授权**
 - D. 供应链中的资讯传递
 - E. 授权



A. Restriction

- REACH will repeal 76/769/EEC in 1 Jun 2009
- Change “may not” to “shall not”
- More stringent requirements allow till 2013, list will be published in 2009



Textiles

Aromatic amines

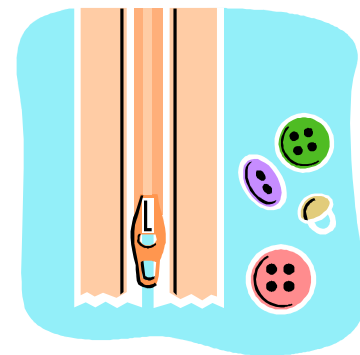
Limit: 30 ppm



Plastic eyelet

Cadmium

Limit: 0.01% by mass



Metal button

Nickel release

Limit :
0.5 $\mu\text{g}/\text{cm}^2/\text{week}$





A. 限制

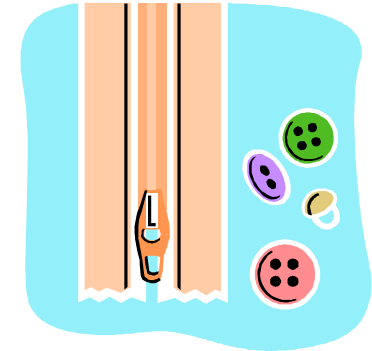
- REACH 将会在2009年6月1号废除指令76/769/EEC
- 更改了条款字眼，由‘不可’ 改为 ‘不准’
- 成员国原有更严格的条例会有效至2013年，条例清单将于2009年公布。



**纺织品
芳香胺**
含量上限: 30 ppm



**塑料带眼
镉**
含量上限: 0.01% (按重量计)



**金属钮扣
镍释放**
含量上限:
0.5 $\mu\text{g}/\text{cm}^2/\text{week}$



A. Restriction

- Against 76/769/EEC till 2009
- Limit value similar in REACH means they remain the same



Target compound analysis

- ✓ Azo dyes
- ✓ Cadmium
- ✓ Chromium VI
- ✓ Flame retardants
- ✓ Nickel release
- ✓ PCP



Source management

- ✓ Review MSDS
- ✓ Internal / External audit



A. 限制

- 受指令76/769/EEC规管直至2009年
- 含量限制基本上没有改动



定量分析

- ✓ 偶氮染料
- ✓ 镉
- ✓ 六价铬
- ✓ 阻燃剂
- ✓ 镍释放
- ✓ 五氯苯酚



源头管理

- ✓ 检阅化学品技术说明书 (SDS)
- ✓ 定期内部/请第三方作系统检查



C. Notification

Notify the European Chemical Agency

- Present of SVHC
- SVHC > 0.1% weight by weight
- SVHC > 1 t/yr

Information required:

- Identity and contact details of producer and importer
- Identity of the substance
- Classification of substance
- Brief description of the use of substance in the article
- Tonnage range of the substance

Starting ??

Article
Article



Possible outcome

Registration



C. 通报

通报欧盟化学品局

- 物品中含有高关注物质
- 在物品中含量 > 0.1% (按重量计)
- 按制造商或进口商计总量 > 1 吨/每年

通报所需资料：

- 制造商或进口商资料和联络详情
- 物质资料
- 物质危险分类
- 简单描述物质在物品中的功用
- 吨位范围

Starting ??

物品



可能后果

注册



Substances of Very High Concern (SVHC)

Type	Abbreviation	Examples	Status
Category 1 & 2 Carcinogen, Mutagen, & Toxic to Reproduction	Cat. 1 & 2 CMR	Cadmium Sulfate, Benzene	> 1100 types
Persistent Bioaccumulative & Toxic	PBT	Mercury, Polychlorinate d Biphenyls	Not published yet
very Persistent very Bioaccumulative	vPvB	Hexachlorobu ta-1,3-diene, Pentachlorobe nzenethiol	Not published yet

+

Substances of Equivalent Level of Concern



高关注物质

种类	缩写	例子	数量
第一类和第二类 致癌， 致诱变， 致生殖毒物	Cat. 1 & 2 CMR	硫酸镉, 苯	> 1100 种
持久积累毒物	PBT	汞, 多氯联苯	尚未公布
非常持久和非常积累物质	vPvB	六氯-1, 3-丁二烯, 五氯苯硫酚	尚未公布

+

有同等危害的物质

AFIRM RSL WORKING GROUP



NORDSTROM



D. Information in the supply chain
Shall provide information to the recipient

To allow safe use

- Present of SVHC
- SVHC > 0.1% weight by weight
- ~~■ SVHC > 1 t/yr~~



Within 45 days for consumer



D. 供应链中的资讯传递

须提供买家

安全使用指引

- 物品中含有高关注物质
- 高关注物质 > 0.1% 按重量计
- ~~■ 高关注物质 > 1 吨/每年~~



在45天内提供有关资料给消费者

AFIRM RSL WORKING GROUP



NORDSTROM



D. Information in the supply chain



Screen for SVHC

✓ Look for substitution



Prepare

REACH

format

SDS

to allow safe use

Material Safety Data Sheet
according to 1907/2006/EC, Article 31

Printing date: 07.06.2007

Page: 1/7

Revision: 05.06.2007

1 Identification of the substance/preparation and of the company/undertaking

Product details:

- Trade name: Correction Fluid - Pilot Test
- Article number: No. 125
- Registration number: Not available
- Application of the substance / the preparation (function):
- Manufacturer/Supplier: ABC Company, 1-2/F, ABC Building, No. 1 ABC Road, Hong Kong, Tel: 1234 5678, Fax: 1234 5677, e-mail: xxx@abc.com
- Further information obtainable from: ABC Company
- Information in case of emergency: Mr. ABC, Tel: 9876 5432
- Reference Number: 12345678AB

2 Hazards identification

Hazard description:

X: Harmful, F: Highly flammable, N: Dangerous for the environment

Information concerning particular hazards for human and environment:

The product has to be labelled also to the calculation procedure of the "General Classification guideline for preparations of the EU" in the later valid version.

- R 11 - Highly flammable
- R 26 - Irritating to skin
- R 51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
- R 65 - Harmful, may cause long damage if swallowed.
- R 67 - Vapour may cause drowsiness and dizziness.

Classification system:

The classification is according to the latest edition of the EU-Directive, and extended by company and literature data.

3 Composition/information on ingredients

Chemical characterization

Descriptive:

Mixture of substances listed below with unspecified additions.

For the meaning of the limited data phrases refer to section 16

Dangerous components:

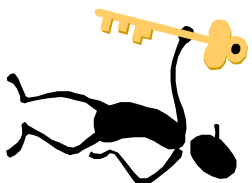
CAS: 108-67-2	methylcyclohexane	Xn, Xi, F, N, R 11-36, S131-05-67	14,0%
EINECS: 203-624-1			
EU Number: 001-019-007			
Non-dangerous components:			
CAS: 14431-67-7	nitroacetone diiside		49,3%
EINECS: 236-075-3			
CAS: 9894-02-4	Acrylyl Acryl		1,53%
CAS: 471-34-1	nitroacetone		0,5%
EINECS: 207-439-0			

12.06.07 09:27:27



AFIRM RSL WORKING GROUP

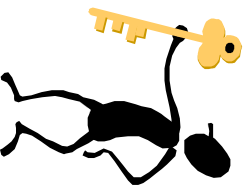
NORDSTROM



D. 供应链中的资讯传递

高关注物质筛分测试

✓ 寻找替代品



准备REACH

格式的安全

技术说明书

安全使用指引

Product code: 0013007
Material Safety Data Sheet according to 2007/2008/EC Article 31

Page: 1/1
Revision: 01/2010/07

1 Identification of the substance/preparation and of the company/fund/labeling

Preparation name: Concrete Road - Pink Peel
Trade name: Concrete Road - Pink Peel
Industry number: 261 721
This preparation is suitable for use on concrete surfaces for the renovation of the preparation (sawing).
Manufacturer/Supplier: ABC Company
Address: 1234 ABC Road, Hong Kong
TEL: 1234 5678
Fax: 1234 5679
e-mail: xyz@abc.com
Further information obtainable from: ABC Company
Agreement on use of emergency: M: 123 456
Reference Number: 123456789

2 Hazard identification

Hazard description: H314: Causes severe skin burns and eye damage.
H335: Irritates the respiratory system.
Agreement concerning pictograms: See Annex and agreement.
The product: Not to be labeled due to the exclusion procedure of the "General Classification guideline" for R+ (1).
R+ (1): Highly flammable (see Annex and agreement).
R+ (2): Irritating to skin.
R+ (3): Irritating to eyes.
R+ (4): Toxic to aquatic organisms; may cause long-term adverse effects in the aquatic environment.
R+ (5): Hazardous for ozone layer depletion.
Classification system: The classification is according to the latest edition of the GHS-GH, and provided by supplier and distributor.
0000

3 Composition/formulation and ingredients

Chemical composition:
Mixture of substances (not alone with other substances).
Information concerning: See Annex and agreement.

CSL 100-672	See Annex and agreement	See Annex and agreement	See Annex and agreement	See Annex and agreement	See Annex and agreement
ENRCS 200-654.1	See Annex and agreement	See Annex and agreement	See Annex and agreement	See Annex and agreement	See Annex and agreement
EP Number: 001-018-000	See Annex and agreement	See Annex and agreement	See Annex and agreement	See Annex and agreement	See Annex and agreement
Non-Aqueous component:	See Annex and agreement	See Annex and agreement	See Annex and agreement	See Annex and agreement	See Annex and agreement
CSL 7-1281-02-7	See Annex and agreement	See Annex and agreement	See Annex and agreement	See Annex and agreement	See Annex and agreement
ENRCS 200-654.1	See Annex and agreement	See Annex and agreement	See Annex and agreement	See Annex and agreement	See Annex and agreement
CSL 271-441	See Annex and agreement	See Annex and agreement	See Annex and agreement	See Annex and agreement	See Annex and agreement
ENRCS 200-654.0	See Annex and agreement	See Annex and agreement	See Annex and agreement	See Annex and agreement	See Annex and agreement



E. Authorisation

- SVHC present in Article
- SVHC included in the Authorisation list



Annex XIV

Shall apply for authorization

- ✓ Cat 1 & 2 CMR, PBT, vPvB
- ✓ Substances identified during registration



SVHC Candidate list



Prioritization of sub. for Authorisation (Annex XIV)



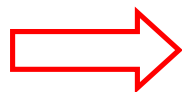


E. 授权

- 物品含有高关注物质
- 授权清单中包括该高关注物质

须申请授权

- ✓ Cat 1 & 2 CMR, PBT, vPvB
- ✓ 有同等危害的物质





E. Authorisation



Screen for SVHC

✓ Look for substitution



Prepare substitution plan

- ✓ Identify SVHC
- ✓ Confirm the source of SVHC
- ✓ Take corrective actions / Search for possible alternatives
- ✓ Consider compatibility of the alternative
- ✓ Trial run
- ✓ Decide whether to substitute



E. 授权



高关注物质筛分测试

✓ 寻找替代品



准备替代品研究计划

- ✓ 确认高关注物质
- ✓ 找出源头
- ✓ 更改技术或更换供应商 / 研发替代品
- ✓ 考虑替代品是否适用于现有生产程序
- ✓ 尝试是用替代物质进行生产
- ✓ 确定是否取代



What are the Frequently Asked Questions For Brands/Retailers?

- Is the product we import an article or a preparation?
- Does that article have an intended release?
- Is it possible that the article contains SVHC's?



给品牌持有者或零售商的 常见问题

- 我们所制造的产品是属于物品或配制品呢？
- 物品中的物质是否属于有意释放？
- 物品中会否含有高关注物质？



FAQ - preparations

■ What is a “preparation” ?

Mixtures or solutions composed of two or more substances (e.g. cosmetics).

To comply with REACH, importers need to obtain:

- *composition of the product they import, i.e. names (CAS numbers)*
- *quantities of all substances present in the preparation.*

常见问题-配制品

■ 什么是“配制品”？

混合物或由两种以上物质组成的溶液。（如化妆品等）

为符合法规要求，进口商需要收集以下资料：

- 所进口产品的化学成分（即化学物质名称和CAS号）
- 配制品中各种化学成分的重量百分比





FAQ - articles

- What is an “article” ?

Objects which during production are given a special shape, surface or design, which determines its function to a greater degree, than does its chemical composition.

常见问题-物品

- 什么是“物品”？

物件在生产的过程中被赋予特定的形状，外观或设计，该物件的功能主要取决于其形状，外观或设计而非其化学成分。





Pre-registration and registration

■ What needs to be registered ?

Substances intended to be released from an article, under certain conditions, require registration, e.g. garments containing anti-perspiration agents.

To comply with REACH, importers need to obtain from their suppliers:

- *composition of products they import, i.e. the name (CAS number) of substances intended to be released*
- *quantities present in the article*

预注册和注册

■ 注册所需资料？

在某种情况下，物品中有意释放的物质须要注册。（例如成衣中的止汗剂）

为符合法规要求，进口商需要向供应商收集以下资料：

- 进口产品的化学成分（即有意释放物质的名称和CAS号）
- 该物质在物品中的数量





FAQ : Notification of Substances of Very High Concern (SVHC)

- What is an SVHC ?

All substances which will be included on a list known as the "candidate list."

First version of the list may be published by end of 2008 on Website of European Chemicals Agency.

To comply with REACH, importers must be informed on Substances of Very High Concern present in articles in concentrations above 0,1 % - wt by wt (1000 mg /kg)



常见问题：高关注物质的通报

■ 什么是高关注物质？

系指所有落入高关注物质候选名单的物质

第一份候选名单将于2008年年底，在欧盟化学品局网站公布。

假若物品中的高关注物质含量重量比大于0.1%（1000毫克/每千克），为符合法规要求，进口商有必要知道相关资料。



Substances of Very High Concern (SVHC)

Type	Abbreviation	Examples	Status
Category 1 & 2 Carcinogen, Mutagen, & Toxic to Reproduction	Cat. 1 & 2 CMR	Cadmium Sulfate, Benzene	> 1100 types
Persistent Bioaccumulative & Toxic	PBT	Mercury, Polychlorinate d Biphenyls	Not published yet
very Persistent very Bioaccumulative	vPvB	Hexachlorobu ta-1,3-diene, Pentachlorobe nzenethiol	Not published yet

+

Substances of Equivalent Level of Concern



高关注物质

种类	缩写	例子	数量
第一类和第二类 致癌， 致诱变， 致生殖毒物	Cat. 1 & 2 CMR	硫酸镉, 苯	> 1100 种
持久积累毒物	PBT	汞, 多氯联苯	尚未公布
非常持久和非常积累物质	vPvB	六氯-1, 3-丁二烯, 五氯苯硫酚	尚未公布

+

有同等危害的物质