



Schweizerische Eidgenossenschaft
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Swiss Confederation

Federal Department of Home Affairs FDHA
Federal Office of Public Health FOPH
Consumer Protection Directorate

REACH

Federation of Hong Kong Industries
17th January, 2008

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Market Control and Advice



This presentation

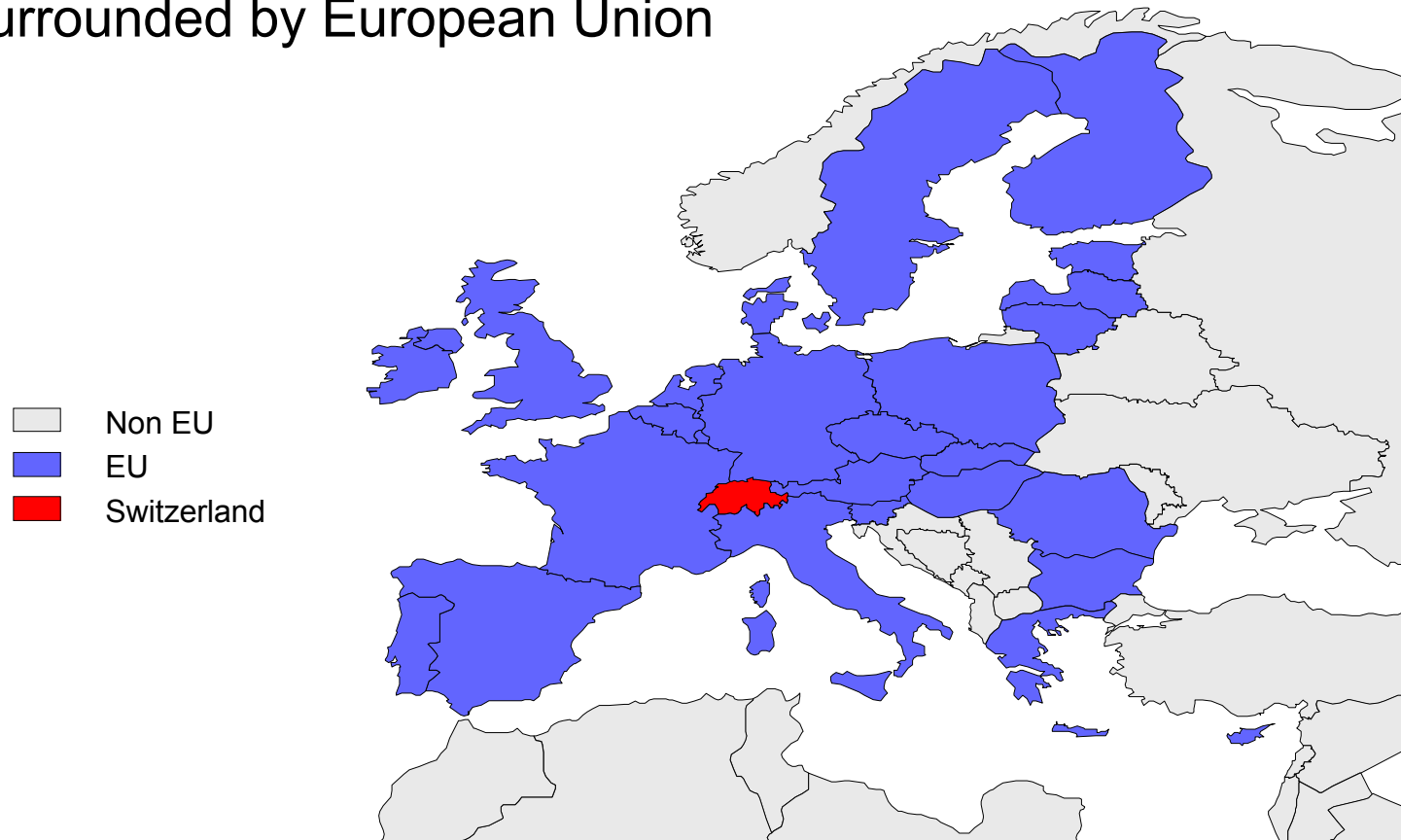
- Introduction
- REACH: The scope
- REACH: What's new?
- What does REACH cover? Exemptions
- REACH and articles
- REACH and information
- REACH: consequential effects
- How to prepare for REACH
- Case study textiles and REACH



Introduction

Situation of Switzerland

- Not member of European Union
- Surrounded by European Union



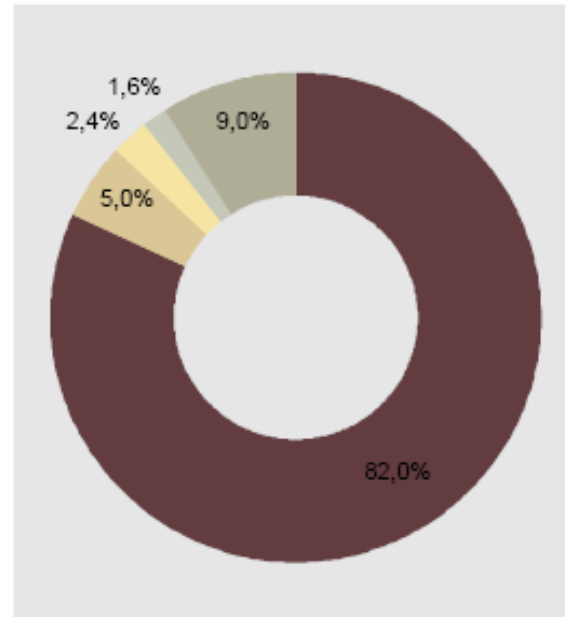


Some facts and figures

	EU	Switzerland
States	27	1
Languages	23	4
People	500 Mio	7.5 Mio

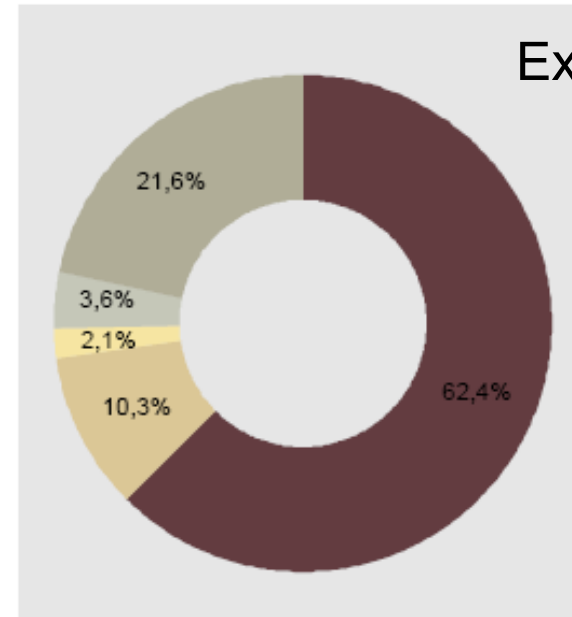
Einfuhren: 165 Mrd. CHF
(davon aus der EU: 135 Mrd.)

Imports



Ausfuhren: 177 Mrd. CHF
(davon in die EU: 110 Mrd.)

Exports



■ EU/EFTA ■ USA ■ China ■ Japan ■ Übrige



23 Languages....





Reaction on REACH

- Switzerland is outside REACH
- Swiss authorities are modifying Swiss laws that products fulfilling the terms of REACH can be placed on the market without changes.
- Information meetings for industry
- Observation of the implementation process of REACH in the EU



REACH: The scope

R egistration

E valuation

A uthorisation and restriction of

CH emicals



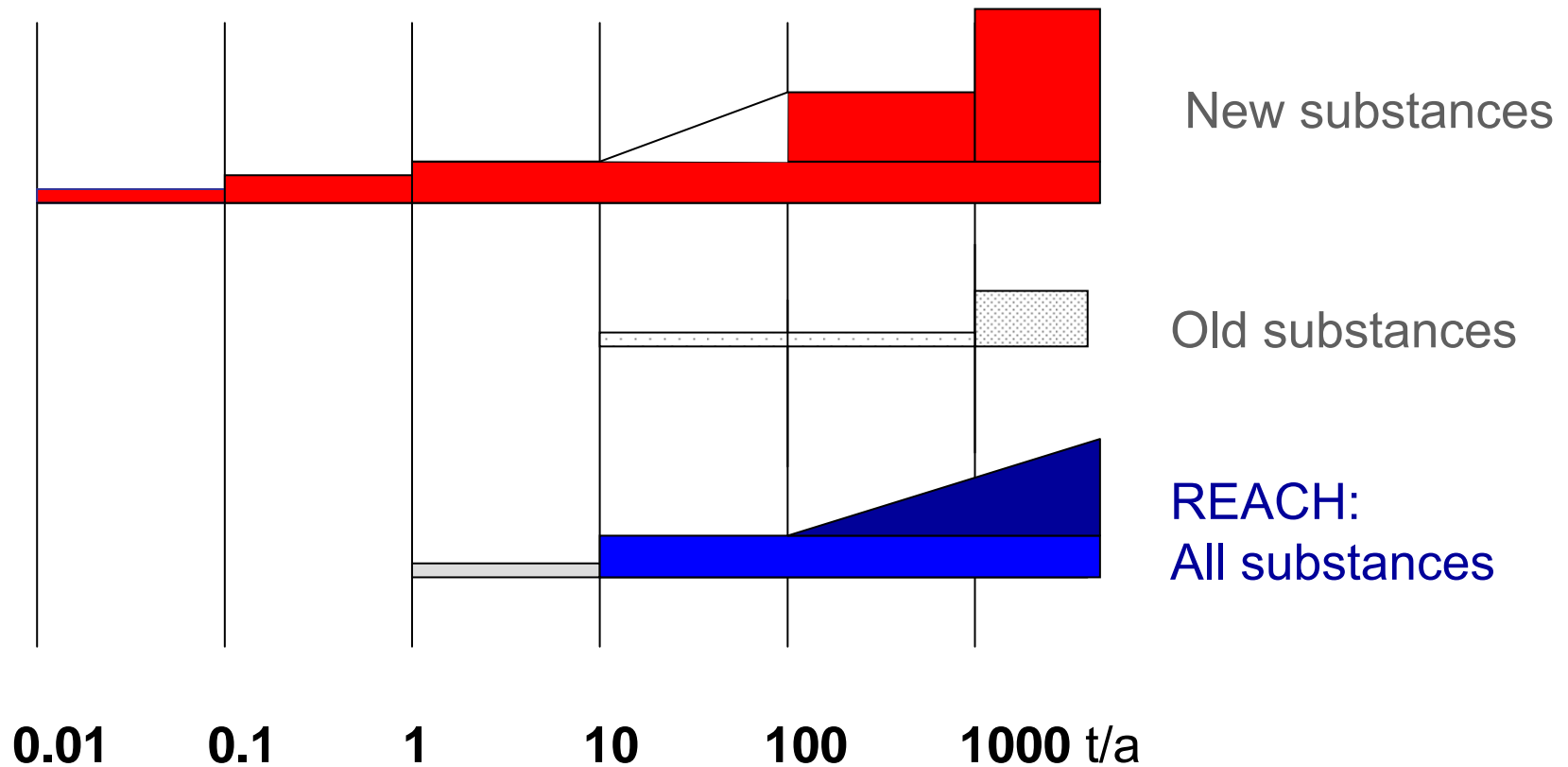
REACH: The motivation for REACH

- Only limited information on hazards and risks to human health and environment available
- Increasing public concern over risks of chemicals
- Different requirements for “old” and “new” chemicals
- No results under old chemicals regulation

⇒ Same requirements for all chemicals



Comparison of the data requirements for chemicals





REACH: Key objectives

- Protection of the environment
- Protection of the human health
- Health and safety at work
- Consumer health and safety
- Economic effects (harmonisation of the market)



REACH: What's new?

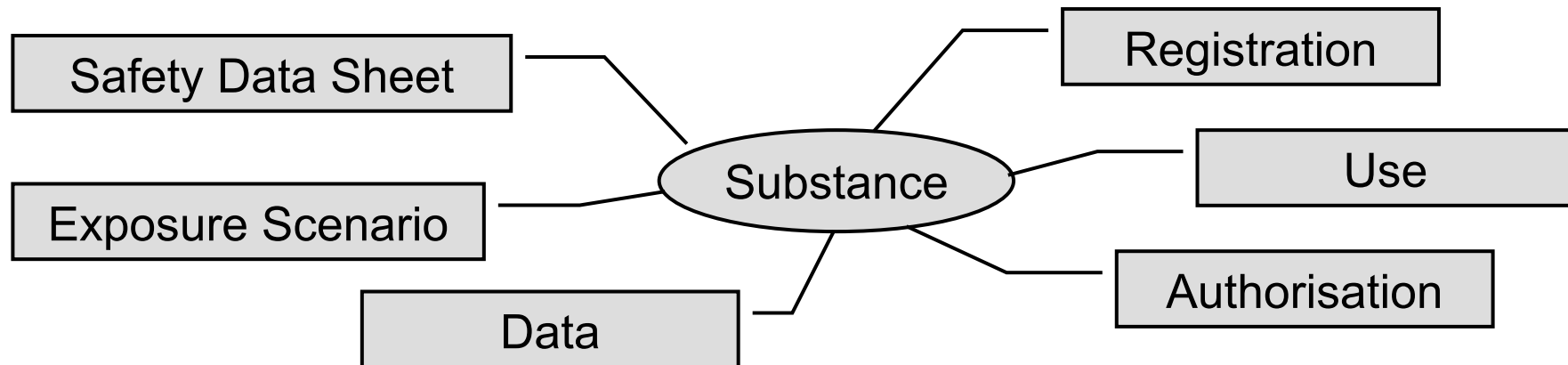
- Reversal of duties: Industry has to prove the safety of substances
- No data no market: Only registered substances are allowed to be used
- Obligation to share data among producers of the same substances
- Information down and up the supply chain: Down stream user information (and provision of information to the consumers)
- Substitution of substances of very high concern (SVHC): Have to be replaced by suitable alternatives where viable



REACH: What is covered? (1)

■ Substances

- Substances are the central element of REACH
- Substances have to be registered (REACH)
- The use(s) of the substances have to be also registered and authorized





REACH: What is covered? (2)

- Preparations (mixtures of substances)
- Articles (conditions!)

- General condition:
over 1 t/a
in articles when intended to release (e.g. printer cartridge) or
when SVHC over 0.1% w/w
[SVHC substances of very high concern: CMR 1/2; PBT; vPvB]
- Special condition:
EChA has the power to require registration



REACH: Exemptions

- Medicinal products
- Food or feeding stuffs
- Cosmetics
- Polymers
- Substances listed in Annex IV
- Substances listed in Annex V



REACH: The players

- **EChA: European Chemicals Agency** (in Helsinki)
manages the registration, evaluation, authorisation and restriction processes under REACH
- **Competent Authorities** of the member states
enforcement of REACH, inspections, check of compliance with REACH
- **Only representative**
The only representative will have to fulfil the registration obligations of importers

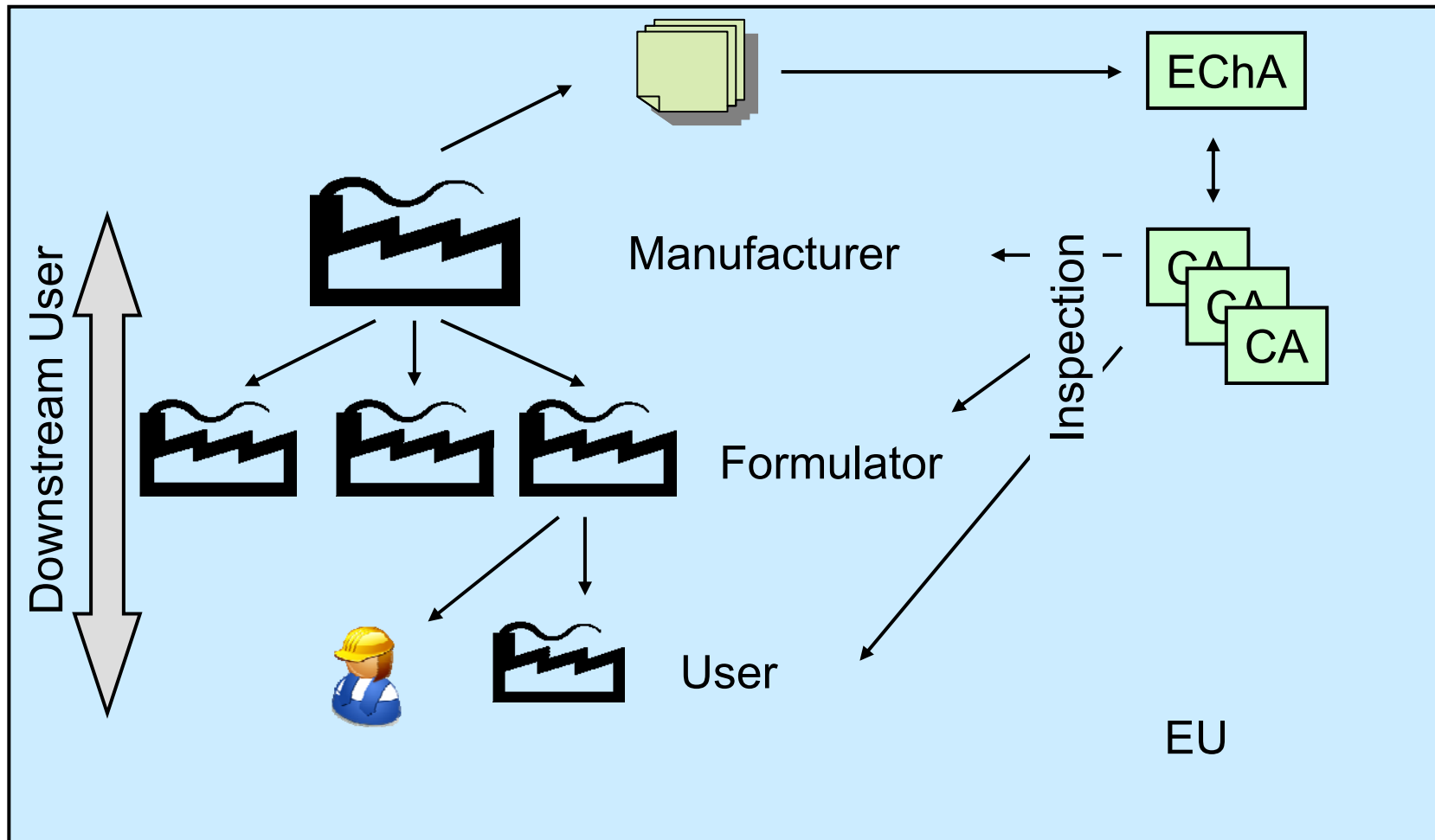


REACH: The players

- **Manufacturers**
Producer of substances
- **Importer**
A business located in the EU that imports substances, articles, preparations from outside the EU
- **Downstream user**
A user of a substance (or preparation) in industrial activities or for professional activities
- **Distributor**
A party that only stores substances, preparations or articles and places them on the market for third parties

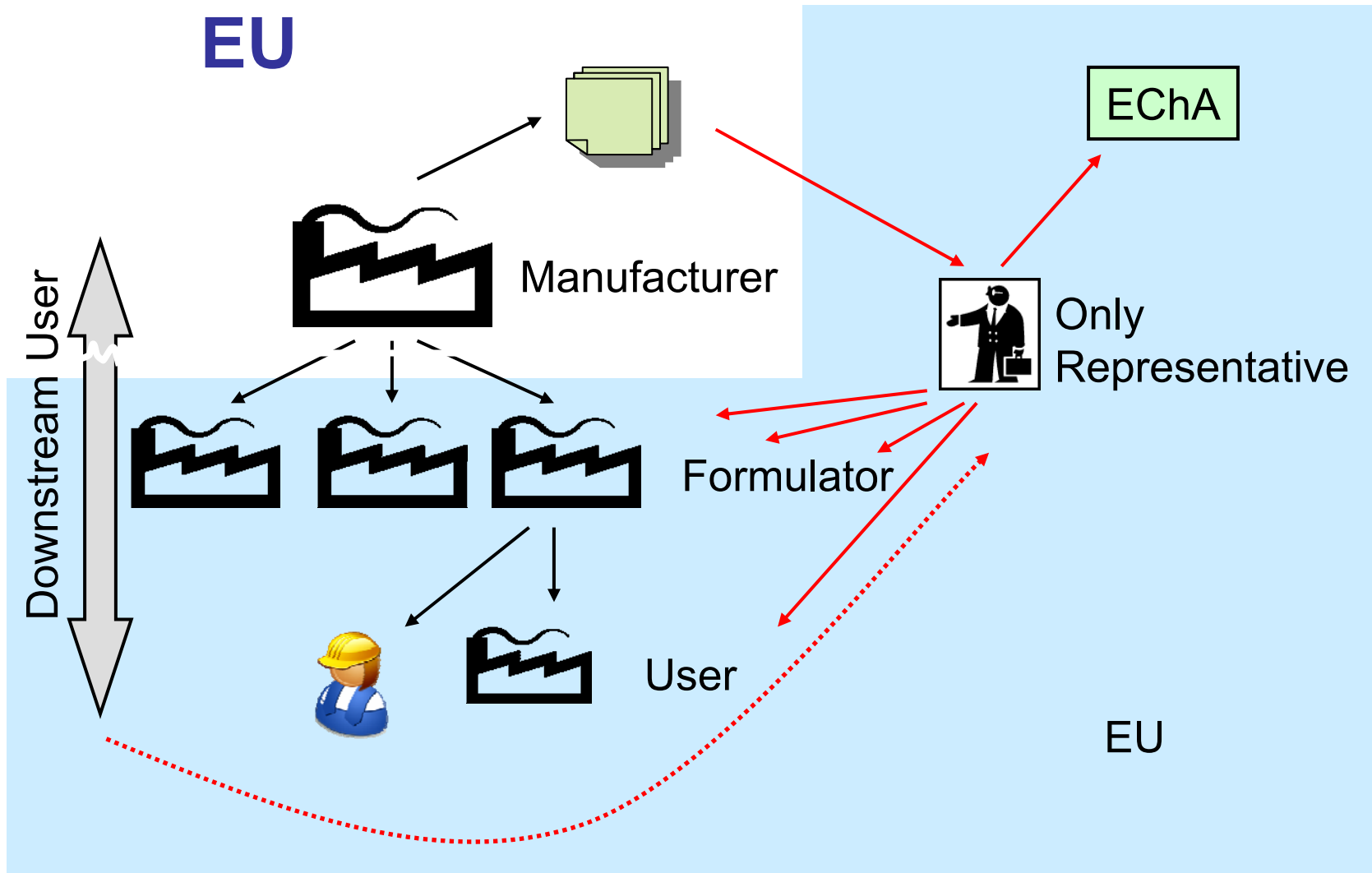


Communication within the EU





Communication when importing to the EU





REACH: Registration

- Duty on all 'legal or natural persons' established in the Community, and placing ≥ 1 t/a substance on the market in the European Union
 - Manufacturers (of chemicals)
 - Producers (of some articles)
 - Importers (of either chemicals or some articles)
- Compile a dossier of required information
- Submit this dossier to the EChA in Helsinki (with a fee)
- 2 week turn-around for EChA to supply Registration number
- No data, no market!

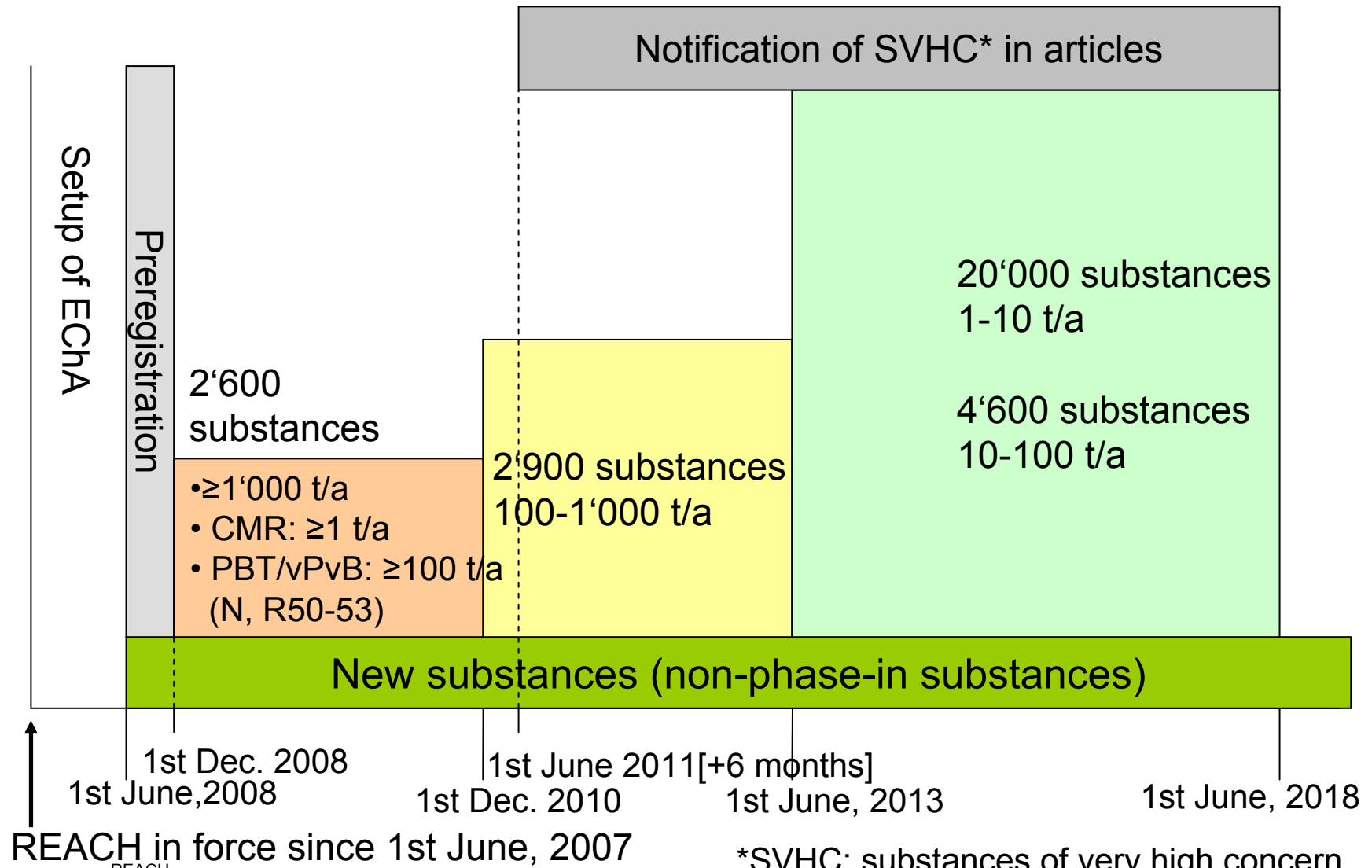


REACH: Registration

- For substances ≥ 10 t/a, conduct a 'Chemical Safety Assessment' and ...
- ... submit the resulting 'Chemical Safety Report' to EChA, including (with exceptions):
 - exposure scenarios, and
 - risk management measures
- 'One Substance, One Registration' ... multiple registrants/lead registrant
- Substance Information Exchange Fora (SIEF), and data sharing
- But long 'phase-in' (assuming pre-registered)
- Reduced requirements for substances in articles



Registration: Time frame





Registration: Important to remember

- One substance, one registration ⇒ preregistration to build SIEF
- Preregistration from 1st June, 2008 till 1st December 2008
- Registration always with intended uses
- Registration only possible by persons inside EU



REACH and articles

REACH article 7.1 Registration of substances in articles

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 one tonne per producer or importer per year;
- (b) the substance is intended to be released under normal or reasonably foreseeable conditions of use.



REACH and articles

But:

- Not all substances in articles need to be registered
- Substances in articles may be subject to reduced information requirements
- Substances of very high concern (SVHC) in articles are subject to notification
- Article 7.6 exemption where uses already registered



REACH and articles

Producer or importer to notify EChA if a substance in an article meets the criteria as a 'Substance of Very High Concern' (SVHC – Article 57), and if both the following conditions are met:

- (a) the substance is present in those articles in quantities totalling over one 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).



Obligation to inform

REACH title IV: Information in the supply chain

- Safety data sheet (SDS)
- Registry number
- Authorisation details
- Restrictions
- Duty to communicate substances in articles
- Duty to communicate information up the supply chain



REACH: consequential effects

- Availability of substances: 2%-30% of substances will vanish (due to high registration costs, not registered uses, lack of authorisation, constraints, reject of authorisation)
- New formulation of preparations (due to lack of substances)
- New production of articles (due to lack of substances)
- Higher prices of substances, preparations and articles



How to prepare to REACH

Just one thing you need:
Information!



Preliminary remarks

- Just try to act and think as you would produce in EU.
- Do you know the requirements your importer has in the EU?
What is his sight? What information does he need?
- Do you denominate an only representative?



Case study textiles: Introduction

Basic questions:

- Substances? Preparations? Articles?
- Which role do you have?
- How do you get your products in the EU on the market? Who sells them?
- What obligation do you have (respectively should be fulfilled by someone)?
- What information do you have to pass on?



Case study textiles: Type of object

Normally textiles are articles

(shape is normally more important than its chemical composition and there is normally no intended release of substances)

⇒ Above 1 t/a and above 0.1%w/w of SVHC

⇒ What chemicals do you use (or have been used) to produce them? Identify your chemicals (substances and preparations)



Identify your chemicals

Inventory of substances/preparations:

Chemical name of substance/preparation	
CAS-Nr.	
Brand name of raw material	
Supplier name of raw material	
EU sourcing	
SDS	
CEM/PBT/vPvB/Endocrine (SVHC)	
Classification	
Alternative	
Critical	
Annual tonnage/supplier	
Amount/concentration in product	
Brand name of product	
Comments	




How to go on

- Do you know the concentration of the chemicals in your textiles?
- Do you know the total amount of your exports (above 1 t/a)?
- Is any substance classified as SVHC?
- Is any substance not allowed for textiles? ⇒ Check Appendixes XVII (restrictions on manufacture, placing on the market and use of substances and preparations) and XIV (authorisation for use of substances in articles) and check authorisation of the substance(s) for allowed use(s).




Appendices XIV and XVII

- <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:396:0001:0849:EN:PDF>

L 396/386  Official Journal of the European Union 30.12.2006

ANNEX XIV

LIST OF SUBSTANCES SUBJECT TO AUTHORISATION

30.12.2006  Official Journal of the European Union L 396/385

ANNEX XVII

RESTRICTIONS ON THE MANUFACTURE, PLACING ON THE MARKET
AND USE OF CERTAIN DANGEROUS SUBSTANCES,
PREPARATIONS AND ARTICLES

Designation of the substance, of the groups of substances or of the preparation	Conditions of restriction
1. Polychlorinated terphenyls (PCTs) - Preparations, including waste oils, with a PCT content higher than 0,005 % by weight.	1. Shall not be used. However, the following use of equipment, installations and fluids which were in service on 30 June 1986 shall continue to be permitted until they are disposed of or reach the end of their service life: (a) closed-system electrical equipment transformers, resistors and inductors; (b) large condensers (\geq 1 kg total weight); (c) small condensers; (d) heat-transmitting fluids in closed-circuit heat-transfer installations; (e) hydraulic fluids for underground mining equipment.



Further obligations

- Comply with classification and labelling
- Inquiry obligation (45 day delay for answering consumer requests)
- Pre-registration if necessary
- Prepare to notify substances



Documents

- Safety data sheets (SDS)
Commonly used for chemicals; however for articles not needed
- Exposure scenario (ES)
*Gives information about risk management measures (RMM).
Implement the appropriate RMM.*

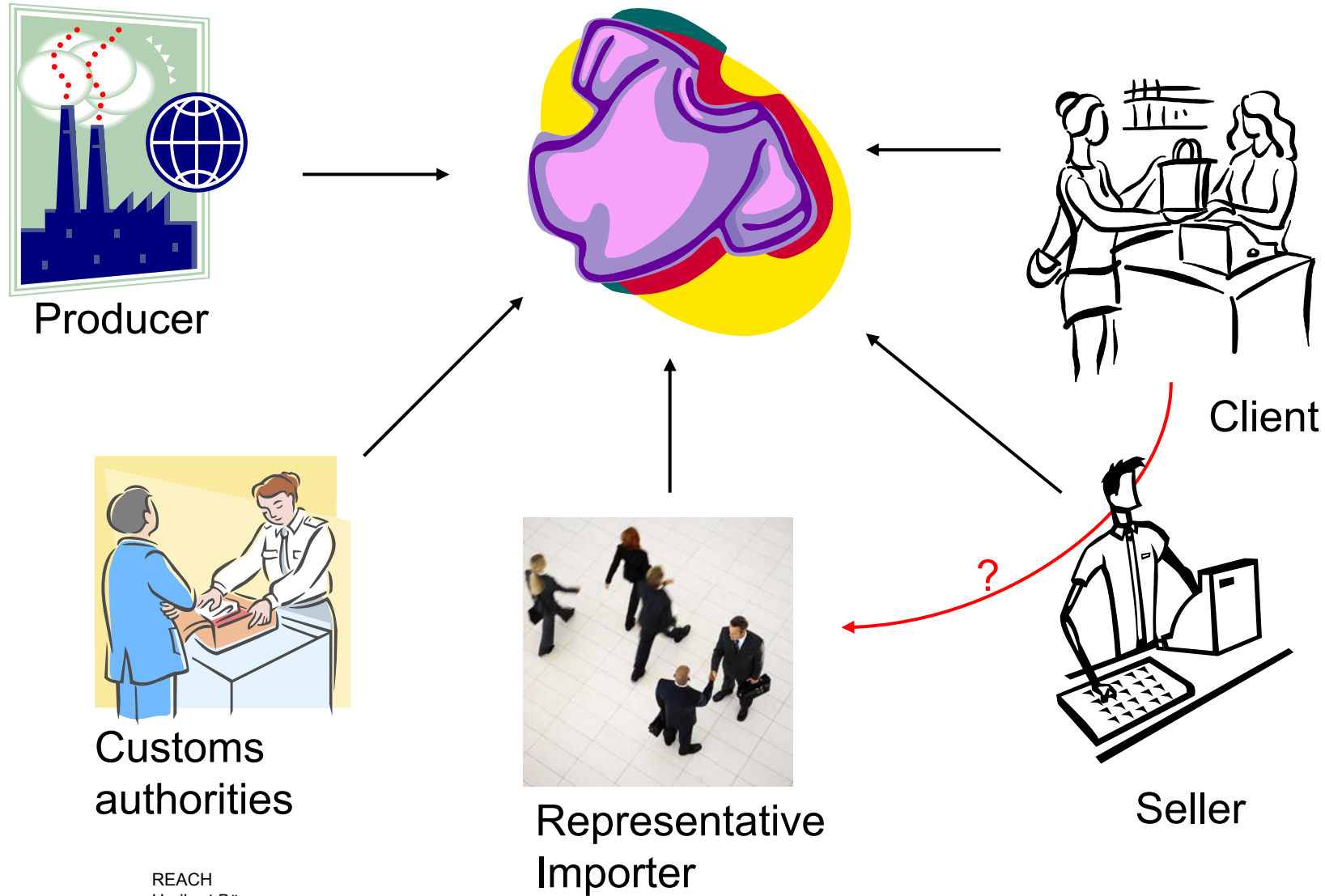


Case study textiles: other regulations concerning textiles

- Colorants
Some azo dyes are cancerogenic ⇒ website of the the german BAUA has a positive list: www.baua.de ⇒ search for textiles ⇒ “recommendable new substances: colorants”
- Nickel
No bleaching of nickel
- Lead
Case study
- Biocides
Check appendices for allowed biocides!



Case study textiles: What's the view?





Thank you for your attention!