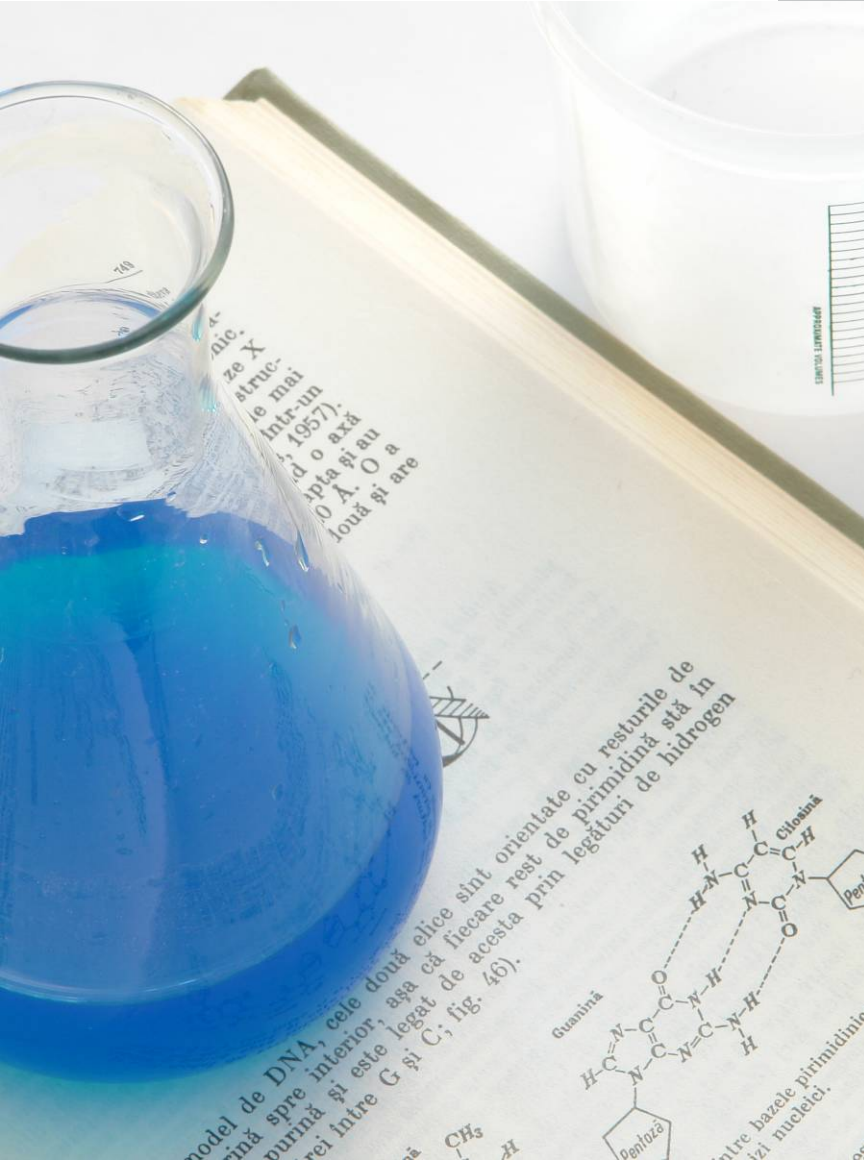




European
Commission



REACH – Textiles and leather articles

*2nd Meeting of the Working group on
EU-Ukraine industrial cooperation (focus
on Textile) - 4th December 2017*

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DG GROW
UNIT D1 REACH**

Outline

- REACH
 - ✓ Registration
 - ✓ Authorisation
 - ✓ Restrictions
- Enforcement

REACH – Cornerstone of chemicals policy in EU

➔ Regulation (EC) No 1907/2006 of the EP and of the Council of 18 December 2006 concerning:

- Registration
- Evaluation
- Authorisation and Restriction of CHemicals

Preparatory work started in 2001...
... entered into force on 1 June 2007

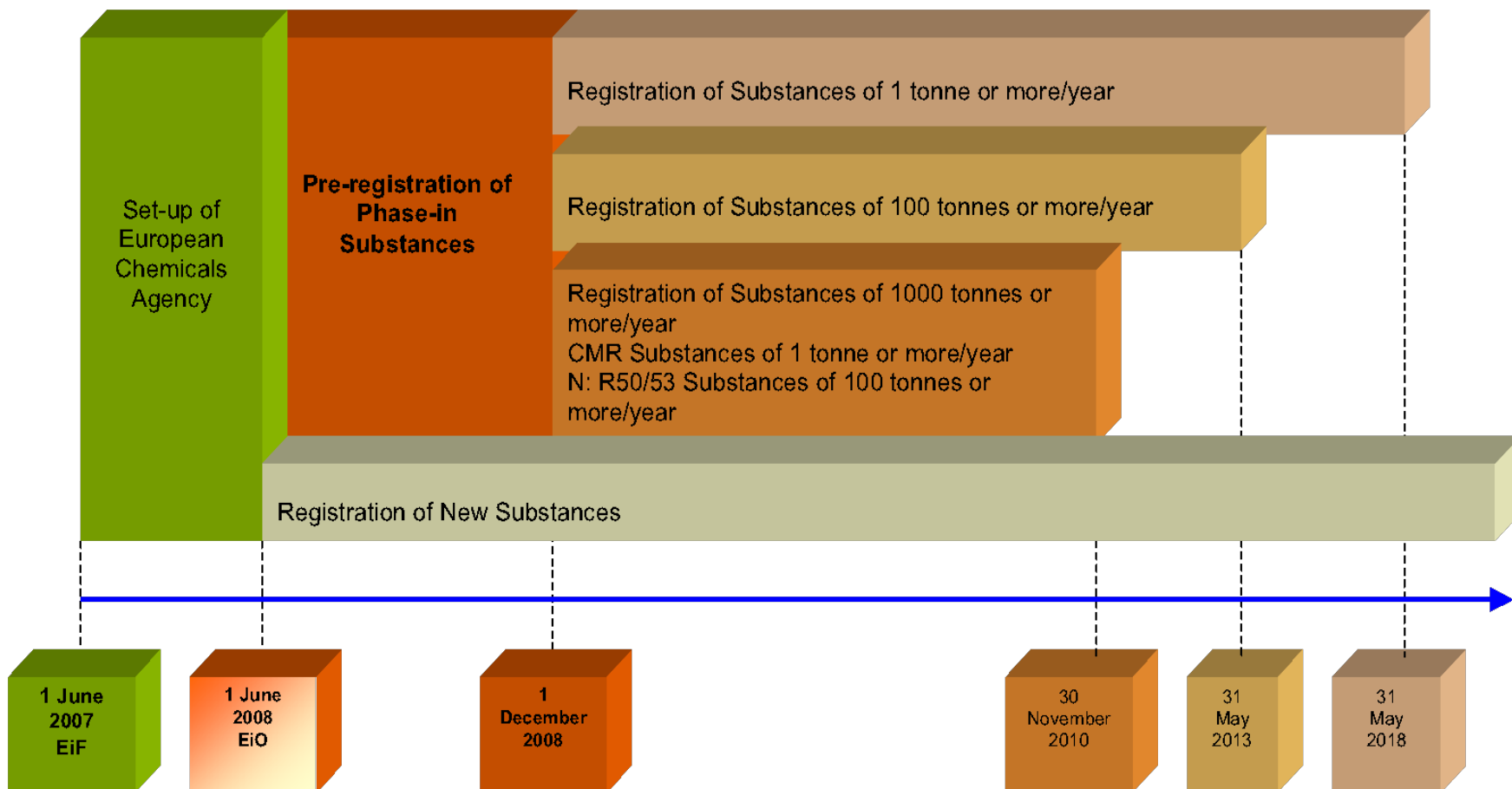
Aim and scope of REACH

- ☑ ensure a high level of *protection of human health and the environment*
- ☑ *promote alternative methods for hazard assessment*
- ☑ *free circulation of substances on the Internal Market*
- ☑ *enhance competitiveness and innovation*

Major Principles of REACH

- **Core elements**
 - Registration of substances ≥ 1 tonne/year: **one substance one registration**
 - Communication in the supply chain
 - Evaluation of some substances by Member States
 - Authorisation only for Substances of Very High Concern
 - Restrictions – to address unacceptable risks
 - **European Chemicals Agency, ECHA manages system**
 - Public access to key information
- **Focus on priorities**
 - Tiered information requirements by tonnages
 - Staggered registration timelines
- **Shift of responsibilities**
 - **from public authorities towards industry**

REACH Timelines



Registration – Key aspects

Substance Information Exchange Fora (SIEFs)

- Agreement on Sameness (pre-SIEF), Classification & Labelling, Data Sharing
- Preparation of the Joint Submission
- **Letter of Access, in case of an already registered substance**

Classification, Labelling & Packaging (CLP)

- Notification to ECHA CLP Inventory (no tonnage trigger)

Registration of substances of ≥ 1 t/y,

- Total tonnage determines obligations and timelines
- Chemical Safety Assessment/ Report (CSA/CSR)
 - Registered substances (≥ 10 t/y),
 - Downstream User may send its own Chemical Safety Report to ECHA (≥ 1 t/y)
 - Substances for Authorisation & Restriction (no tonnage trigger)



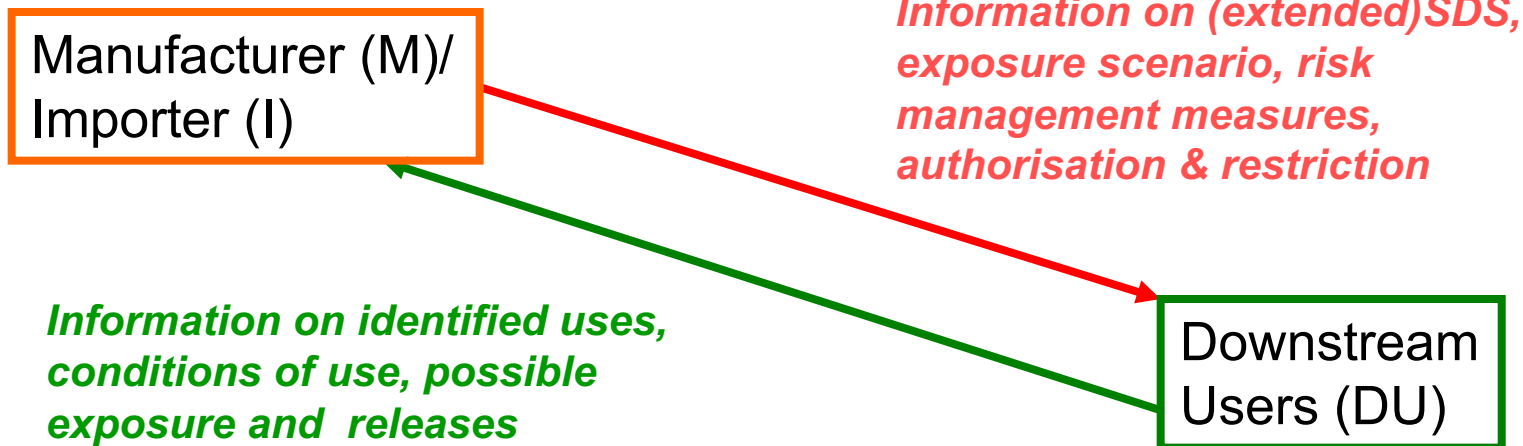
Between suppliers (M/I ↔ M/I)

- SIEF: Agreement of the sameness of a substance, Classification and labelling, Data sharing & Joint submission

Between users (DU ↔ DU)

- Uses and Conditions of use

Between Suppliers and Users (M/I ↔ DUs)



Between M/I and ECHA

- Registration, Evaluation and Authorisation/Restriction
- Notification to the C&L Inventory



Authorisation (hazard based)

Assuring that Substances of Very High Concern (SVHCs) are properly controlled and that SVHCs are progressively replaced by suitable alternatives where these are economically and technically viable.

- 1st step: Identification of SVHCs by ECHA
- 2nd step: Commission adopts list of substances subject to authorisation
- 3rd step: Companies apply for authorisation for given substances

173 SVHC identified so far (Candidate List)

43 substances subject to authorisation (Annex XIV)



Substances of Very High Concern (SVHCs)

- 173 SVHC identified so far (Candidate List): CMRs, PBT, EDs
- **SVHCs that can be found in textiles:** such as brominated flame retardants (e.g. hexabromocyclododecane and decabromodiphenyl ether), a number of phthalates, nonylphenol ethoxilates (NPEO) and their derivatives, and pentadecafluorooctanoic acid (PFOA).
- They are not prohibited but subject to information obligations:
 - **If >0.1 % duty to provide information for safe handling**
 - **Consumers right to know on request within 45 days**

Restrictions under REACH

- Restriction: one of the possible risk management actions under REACH, if risk is not sufficiently controlled
- Concerns manufacture, placing on the market or use of a substance, on its own or in mixtures and articles
- Restrictions can be: bans, use limitations, concentration limits in mixtures and/or articles
- Restriction can impose any relevant condition, such as requiring technical measures or specific labels.
- Restrictions listed in Annex XVII to REACH

Chemicals in textile/leather articles

- More than 2,400 chemical substances identified to be used in the production of textile articles.
- Approximately 10 % were considered to pose a risk to human health and 5 % to the environment.
- Leather articles restriction on chromium (VI) in leather in Annex XVII
- The purpose of the chemicals legislation is to prevent chemical risks to humans and the environment.
 - REACH Chemicals Regulation
 - CLP Regulation on the classification, labelling and packaging of chemical substances and mixtures

Enforcement

Enforcement is a responsibility of Member States
Imported goods are tested when entering the EU
RAPEX – Rapid Alert system for dangerous non-
food products

(https://ec.europa.eu/consumers/consumers_safety/safety_products/rape_x/alerts/?event=main.listNotifications)

The Forum for the Exchange of Information on
Enforcement = REACH ADCO (REACH Art 86)

Takes care of enforcement of CLP, PIC
(import/export of very hazardous chemicals) and
Biocides.

Enforcement

RAPEX notifications on textile articles 2015-2017

	2017	2016	2015
Azodyes	2	6	15
Chromium VI		1	1
Nickel		1	
Formaldehyde	1		

Serious risk A12/1281/17 Clothing, textiles and fashion items

Socks Linex Disney 'Frozen' Children's socks, 3-pack, sizes 22/24, 25/27, 28/30, 31/33, printed with characters from "Frozen" (Anna, Olaf, Elsa).

Origin: China

Chemical The socks with the 'Anna' character contain azo dyes releasing the aromatic amine 4,4-Methylenedianiline in a concentration of 54 mg/kg. When the product is in direct and prolonged contact with the skin, the Aromatic Amine may be absorbed by the skin. Aromatic Amines can cause cancer, cell mutations and affect reproduction.

https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/?event=viewProduct&reference=A12/1281/17

Thank you

For further information
please visit:

-
- <https://echa.europa.eu/regulations/reach/restriction>
 - <http://ec.europa.eu/growth/sectors/chemicals/reach/>
 - http://ec.europa.eu/environment/chemicals/index_en.htm



This presentation does not necessarily reflect the official opinion of the Commission.

Registration

Art. 7: Registration and notification of substances in articles

- Those manufacturing or importing chemical substances in amounts of at least one tonne per year shall register these with the European Chemicals Agency (ECHA).
- The obligation to register also applies to substances in articles such as textiles if the amount is at least one tonne per year.

"Normal" Restriction procedure

- Initiated by Commission or Member State (MS)
- Preparation of "Annex XV dossier" (MS or ECHA)
- Contains information on hazards and risks, alternatives, socio-economic assessment
- Public consultation
- Opinions by ECHA Committees for Risk Assessment and Socio-economic Analysis
- Unacceptable risk: Commission prepares proposal for amendment of Annex XVII

"Simplified" restriction procedure

- Article 68(2)
- Simplified procedure can be applied for substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), categories 1A and 1B on their own, in mixtures or in articles that could be used by consumers.
- Initiated by Commission
- No need for Annex XV dossier, public consultation, opinion by RAC and SEAC

Use of Article 68(2)

- Substances and mixtures: long-established practice, Entries 28-30 of Annex XVII ban marketing to and use by consumers
- Articles (new under REACH): Considerations whether to apply this provision to articles

Restriction of CMRs in textiles

- CMR substances present in textile articles were chosen as first case for the approach targeting categories of consumer articles
 - Widespread use (clothing, household, furniture)
 - Exposure: contact with skin
 - Concerns by Member States and certain industry associations
 - No comprehensive product specific legislation as regards chemical content

Restriction of CMRs in textiles

- Final consultation of other Commission Services on restriction proposal.
- Consultation of ECHA Forum on enforceability (on-going).
- Public consultation through feedback mechanism.
- Discussion and vote in the REACH Committee.

Other Restrictions in Annex XVII

Leather articles *restriction on chromium (VI) in leather*

Textiles articles

- **restriction on nonylphenol ethoxylates (NPE) in textiles**
- **Azocolourants and Azodyes**

Chromium (VI) in leather articles

- Annex XVII, Entry 47
- **Scope:** leather articles and leather parts of articles coming into contact with the skin
- **Upper limit of content:** 3 mg/kg of total dry weight
- **Entry into application:** 1 May 2015

Azocolourants and Azodyes

- **Annex XVII, Entry 43**
- Azodyes which, by reductive cleavage of one or more azo groups, may release one or more of the aromatic amines listed in Appendix 8, in detectable concentrations, i.e. above 30 mg/kg (0,003 % by weight) in the articles or in the dyed parts thereof, according to the testing methods listed in Appendix 10, shall not be used, in textile and leather articles which may come into direct and prolonged contact with the human skin or oral cavity, [..]
- 3. Azodyes, which are contained in Appendix 9, "List of azodyes" shall not be placed on the market, or used, as substances, or in mixtures in concentrations greater than 0,1 % by weight, where the substance or the mixture is intended for colouring textile and leather articles.
- **Scope: clothing, bedding, towels, hairpieces, footwear, gloves, chair covers, textile toys, yarn and fabrics intended for use by final consumer**

Nonylphenol ethoxylates (NPE) in textiles

- Annex XVII, Entry 46(a)
- Reason: risk to the environment, toxic to aquatic species living in surface water
- Scope: textile articles which can be washed in water
- Upper limit of content: concentrations greater than 0,01 % by weight of that textile article
- Entry into application: 3 February 2021

REACH Enforcement

REF4 EU enforcement project on REACH restrictions (14)

- Participants: **29 MS**
- The project entailed cooperation with customs
- Operational phase (i.e. inspections) in 2016
- 20% of products checked were sold on internet
- Higher non-compliance rates on products of unknown origin
- For products with known origin, the products from Asia were the ones with higher non-compliance rates

REACH Enforcement-analytical methods

Compendium of Analytical methods*

- Recommended by the Forum to check compliance with Annex XVII restrictions (March 2016)
- Includes analytical methods for 42 existing restrictions.
- Open for comments.
- Review is expected for 2019.

*https://echa.europa.eu/documents/10162/13577/compendium_of_analytical_methods_en.pdf/3807683c-5340-4638-b5bc-5554635cdc8a

Enforcement-The FORUM

- The Forum for the Exchange of Information on Enforcement = REACH ADCO
- Established body by the REACH regulation (Art 86)
- Takes care of enforcement of CLP, PIC (import/export of very hazardous chemicals) and Biocides.
- ECHA holds the secretariat of the Forum
- The Commission acts as observer.

REACH Enforcement

- Enforcement projects with MS participation
 - Big projects (so called REF projects): 26 to 29 MS
 - Small projects: 5 to 16 MS

REF4 EU enforcement project on REACH restrictions (14)

Substances	Products	Checks	Level of non-compliance (%)
Azocolourants and Azodyes	textile and leather articles	450	1.1
Chromium VI compounds	leather articles	467	13.3