



EUROPEAN  
ENVIRONMENTAL  
BUREAU

# **Eu regulatory framework for promoting substitution. REACH Authorisation.**

Dolores Romano  
Substitution Expert for the  
European Environmental Bureau

## **Content:**

Substitution Regulatory framework in the EU

REACH Authorisation process basics

REACH Authorisation process results

Example: DEHP used in PVC cables

# Substitution Policy Framework in the EU

World Summit for Sustainable Development 2002: EU commitment to achieve the sound management of chemicals throughout their life cycle by 2020.

Global chemicals strategy (Strategic Approach for Global Chemicals Management, SAICM) in Dubai 2006.

7<sup>th</sup> Environmental Action Program, adopted in 2013, commitment to develop by 2018 a Union Strategy for a Non-Toxic Environment.

# Substitution Regulatory Framework in the EU

- Worker Protection
- Environment protection
- Waste
- Specific articles/uses
- Marketing of chemicals: REACH

# Worker Protection



## Chemicals Agent Directive

Employers shall ensure that the risks from chemical agents are eliminated or reduced to a minimum. Substitution shall by preference be undertaken.

Substitution: replacing it with a chemical agent or process which, under its condition of use, is not hazardous or less hazardous to workers' safety and health.

## Carcinogens and Mutagens Directive

Obligation to substitute carcinogens and mutagens whenever technically possible.

# Environmental protection

## **VOC Solvents Directive**

Carcinogens, mutagens, or substances that are toxic to reproduction shall be replaced, as far as possible, with less harmful ones “within the shortest possible time”.

## **IPPC Directive**

Applications for permits shall include a description of ‘the main alternatives.

## **EU POP Regulation**

Member States have to elaborate action plans to eliminate the releases of POPs, including measures to substitute or modify materials, products and processes.



# Waste



## **ROHS Directive \_ electrical and electronic equipment**

Establishes substitution requirements for several hazardous substances by more environment-friendly alternatives.

## **End-of Life Vehicles Directive**

Limits the use of hazardous substances in vehicles.

## **Batteries and Accumulators Directive**

Requests Member States to encourage the development and marketing of batteries and accumulators which contain less polluting substances, in particular safer alternatives to mercury, cadmium and lead.

# REACH Regulation

Ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation.”

REACH intends to achieve these aims by:

- Improving generation of information on hazards, exposure and uses of substances
- Improving information throughout the supply chain and to consumers.
- Improving Risk Management Measures
- Encouraging replacement of SVHC





# REACH Regulation

- Registration: no data no market
- Evaluation
- **Authorisation**
- **Restriction**
- Information throughout the supply chain

# A global model?



- The EU is seen as a global frontrunner in regulating chemicals.
- South Korea, Malaysia, Turkey and China have adopted REACH-like legislations.
- Switzerland, Canada, Japan and New Zealand have shown a keen interest in learning from REACH
- Iceland, Liechtenstein and Norway, directly apply REACH

# REACH\_Restriction

Bans uses of certain substances that pose an EU wide risk to the health or the environment.

Covers also imported articles.

Proposals made by Commission or by Member states.

Includes analysis of alternatives.

Examples: Restriction of the use of BPA in thermal paper.  
Restriction of four phthalates in several uses.

# REACH\_Authorisation

The aim of authorisation is to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are **progressively replaced by suitable alternative** substances or technologies where these are economically and technically viable.” {REACH Art. 55}

# REACH\_Authorisation

Substances of very high concern (SVHC) can only be marketed or used in the EU if the Commission grants them an authorisation (does not cover imported articles).

Companies must apply for authorisation and demonstrate, that:

- Risks of the use are adequately controlled (threshold substances)  
or
- Socioeconomic benefits of the use outweigh the risks to human health or the environment and **there are no suitable alternatives**

# Steps

- 1.- Identification of SVHC
- 2.- Prioritisation.
- 3.- Submission of Applications for Authorisation.
- 4.- Public consultation on alternatives.
- 5.- ECHA Committees opinions (RAC and SEAC)
- 6.- Commission decision after consultation with MS.

# Identification of SVHC

## SVHC:

- Carcinogens, mutagens and reprotoxicans (CMR);
- Persistent, bioaccumulative and toxic (PBT), vPvB;
- and equivalent concern (sensitizers, endocrine disrupters).

## Candidate List with 173 substances.

Considered by chemical industry and downstream users the main driver for innovations towards safer alternatives.

Worldwide reference for substitution



# Authorisation List (Annex XIV)

Includes a sunset date, after which the SVHC can't be used or marketed in the EU.

31 substances in Annex XIV

Applications received for 7 of the 15 substances with expired sunset dates



Substance	Number of received <sup>1</sup> applications (applicants)	Number of uses	RAC-SEAC opinions per use <sup>2</sup>	RAC-SEAC opinions per use and per applicant <sup>3</sup>	Commission decisions per use and per applicant <sup>4</sup>
Bis(2-ethylhexyl) phthalate (DEHP)	5 (7)	10	10	14	7
Dibutyl phthalate (DBP)	2 (2)	4	4	4	4
Bis(2-ethylhexyl) phthalate (DEHP) and Dibutyl phthalate (DBP)	1 (1)	3	3	3	3
Lead sulfochromate yellow (C.I. Pigment Yellow 34) and Lead chromate molybdate sulphate red (C.I. Pigment Red 104)	1 (1)	12	12	12	12
Hexabromocyclododecane (HBCDD)	1 (13)	2	2	26	26
Diarsenic trioxide	4 (4)	5	5	5	5
Trichloroethylene	13 (15)	19	19	21	14
Lead chromate	1 (1)	1	1	1	
Chromium trioxide	26 (62)	43	24	81	2

Substance	Number of received <sup>1</sup> applications (applicants)	Number of uses	RAC-SEAC opinions per use <sup>2</sup>	RAC-SEAC opinions per use and per applicant <sup>3</sup>	Commission decisions per use and per applicant <sup>4</sup>
Sodium dichromate	19 (25)	25	18	30	1
Chromium trioxide, Sodium dichromate and Potassium dichromate	1 (6)	3	3	18	
Sodium chromate	2 (4)	3	1	2	4
1,2-Dichloroethane (EDC)	15 (17)	19	11	13	1
Potassium dichromate	4 (4)	7	6	6	
Ammonium dichromate	3 (5)	4	2	2	
Dichromium tris(chromate)	1 (2)	2	2	4	
Chromium trioxide; Dichromium tris(chromate);	1 (2)	4	4	8	
Strontium chromate	1 (10)	2	2	20	
Potassium hydroxyoctaoxodizincatedichromate	1 (5)	2	2	10	
Diglyme	8 (8)	9	2	2	
Arsenic acid	1 (1)	1			
Chromic acid	1 (1)	1	1	1	
Formaldehyde, oligomeric reaction products with aniline (technical MDA)	1 (1)	2			
2,2'-dichloro-4,4'-methylenedianiline (MOCA)	1 (1)	1			
<b>Total</b>	<b>114 (198)</b>	<b>184</b>	<b>134</b>	<b>283</b>	<b>79</b>

# Submission of Applications for Authorisation.

Shall include:

- Chemical Safety Report
- **Analysis of Alternatives**
- **Substitution plan**
- Socio-economic analyses

# **Public consultation on alternatives**

Third parties can submit information on available alternatives for the uses applied for.

Third parties may be invited to participate at dialogues with ECHA and applicants to discuss alternatives.

Comments are published at ECHA's website

# ECHA Committees opinions

## **RAC:**

- Are the risks adequately controlled (threshold)?
- Are the proposed risk management measures (RMM) appropriate and effective?
- Are the alternatives safer?
- RMM and operating conditions for granting authorisation.

## **SEAC:**

- Suitable alternatives?
- Do socio-economic benefits of uses outweigh risks?
- Proposed review period



# Commission decision



First consults Members states

Establishes conditions for granting authorisation and review period (RP)

In general: longer RP for specific uses

# **Restriction after authorisation sunset dates**

In order to protect health and the environment, from risks posed by articles, the Commission may propose the restriction of uses of SVHC once the sunset date has expired. Includes imported articles. [Article 69(2)]

Example: Restriction of four phthalates.

# Examples: use of DEHP in PVC cable production:

**RoHS Directive** restricts DEHP in PVC (including recycled PVC) in electrical and electronic equipment placed on the market from 22 July 2019. For some categories the restriction applies from 22 July 2021.

**Authorisation** for use of DEHP in recycled PVC materials granted until 21 February 2019.

Authorisation for use of DEHP in virgin PVC materials pending.

**Restriction** proposal for PVC articles containing four phthalates: DEHP, DBP, BBP and DIBP.





# Example: HBCDD

Use as flame retardant in expanded polystyrene (EPS)

Authorisation granted with a review period of 18 months (bridging authorisation until alternatives are fully available in the market).



# Example: trichloroethylene

COMPANY	USE	SCOPE	REVIEW PERIOD
VLISCO	Solvent for the removal and recovery of resin from dyed cloth	Narrow	12y
Microporous GmbH	Solvent in the manufacture of polyethylene separators for lead-acid batteries	Narrow	7y
SPOLANA	Use as an extraction solvent in caprolactam production	NARROW	4 Y

# Example: trichloroethylene

COMPANY	USE	SCOPE	REVIEW PERIOD
Chimicomplex	degreasing agent in closed systems	Broad	26 months
Blue Cube Germany Assets GmbH & Co. KG	Industrial Parts Cleaning by Vapour Degreasing in Closed Systems where specific requirements (system of use-parameters) exist	Narrow	7 years

# Example of operating conditions (Blue Cube)

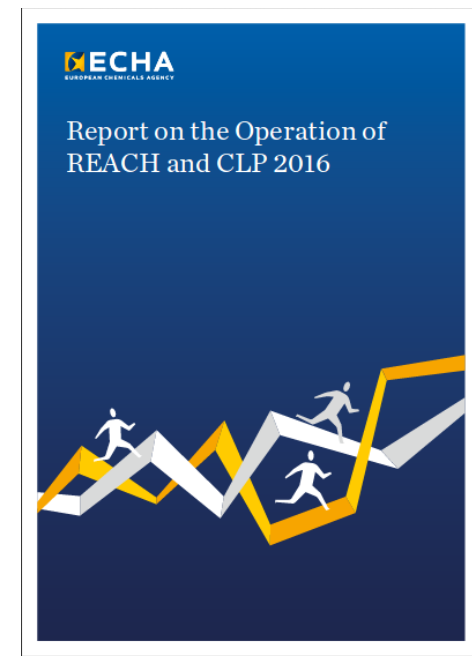
- Use of TCE for cleaning only where specific requirements exist.
- Prior to the first supply under the authorisation, all downstream users shall provide their supplier **with a written declaration that they carried out an analysis of alternatives and that no suitable alternatives exist.**
- Ensure that all downstream users are provided with an obligatory **training on alternative cleaning solutions and on the methodology for analysis of alternatives.**
- TCE is used exclusively in an ECSA Type IV or V machines
- The process must be performed under vacuum
- Training for downstream users as specified by the applicant in the CSR.

# Substitution is taking place

Even if applications for authorisation are received, there are indications that substitution is taking place. For instance, in the case of the plasticiser DEHP, originally 25 companies made a registration, however, only three manufacturers of DEHP applied for an authorisation.

During the application process, one company (Arkema, France) discontinued manufacturing DEHP.

The EU's production of three phthalates (DBP, DEHP and DIBP) has also reduced by more than 50 % during the period 2010-2015.



## Investor analysis of chemicals management increases thanks to ChemSec and RobecoSAM

**The Dow Jones Sustainability Indices (DJSI) provide investors with a more comprehensive assessment of corporate chemicals management following collaboration between ChemSec and RobecoSAM**

Corporate chemicals management will from now on play a greater role in evaluating performance in the RobecoSAM Corporate Sustainability Assessment (CSA), the research backbone for the Dow Jones Sustainability Indices (DJSI). The product stewardship section of the CSA has been updated in order to better reflect the growing interest from investors in issues surrounding chemical sustainability. The update is the result from a collaboration effort between [RobecoSAM](#) and chemical expert organization [ChemSec](#).

*"ChemSec is very satisfied that the world's leading rating index shows leadership and increases its attention towards chemicals. By looking more closely at corporate chemical management, the CSA and its products like the DJSI will now give investors a more complete picture in terms of sustainability, something we know many investors have been longing for,"* says Sonja Haider, Senior Investors Advisor with the International Chemical Secretariat, ChemSec.

**Read more: Why the stock market's increased attention on toxic chemicals is a big thing – Analysis by ChemSec Executive Director, Anne-Sofie Andersson**

# Conclusions

- Global commitment towards high level of protection of human health and the environment from chemicals
- EU legal framework is promoting substitution worldwide.
- No future for the production and use of Substances of High Concern.

# Thankyou

[Dolores.romano@eeb.org](mailto:Dolores.romano@eeb.org)

European Environmental Bureau

[www.eeb.org](http://www.eeb.org)