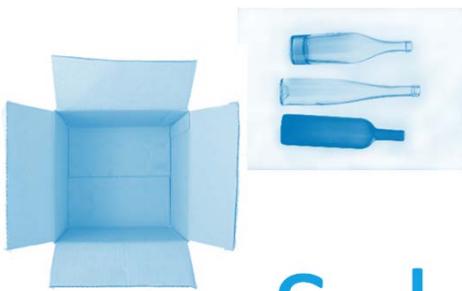




Substances (of concern) in Articles

Oona Freudenthal
REACH&CLP Helpdesk Luxembourg
Luxembourg Institute of Science and Technology

REACH&CLP Annual conference
6th December 2018



Substances are all around!



What is an article under REACH? (1)

"[...] an object of a special shape, such as a gr...



*Regulation (EC) 1907/2006, Article 3(3)
ECHA Guidance on substances in articles
https://echa.europa.eu/documents/10162/23036412/articles_en.pdf

What is an article under REACH? (2)



Paraffin wax



carrier for the pigment



Shape not more relevant for its function (to bring pigment to paper) than the chemical composition



mixture
(not an article!)

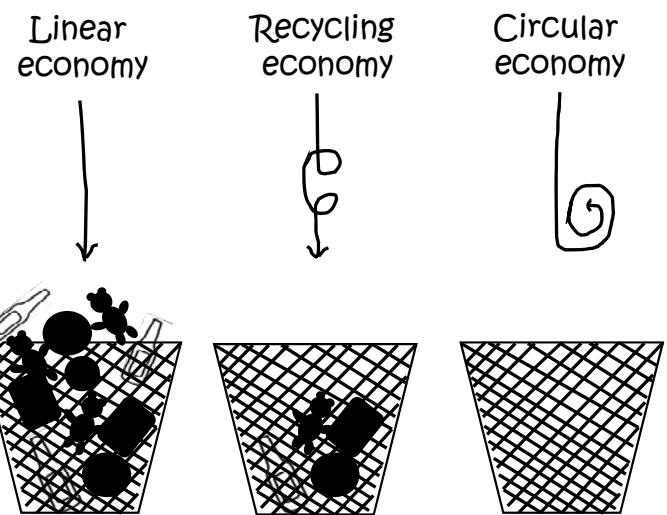


Who are article suppliers?

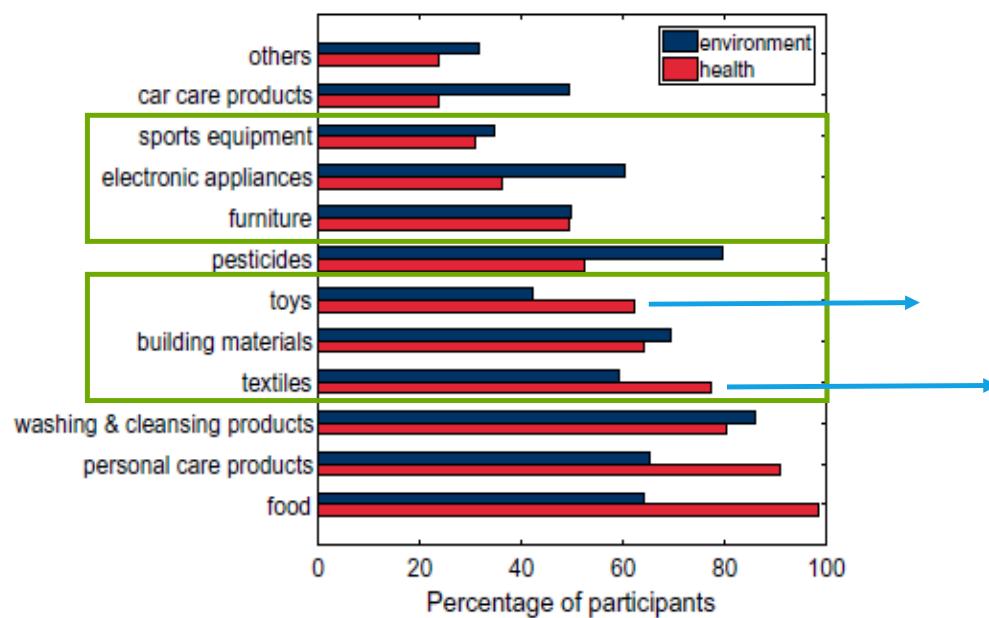
- Article producers e.g.
 - Toy industry
 - Furniture industry
 - Textile industry
 - Electronics industry (home appliances, computers, electrical circuit boards...)
 - Kitchen wear manufacturers (glassware, porcelain, cooking utensils...)
 - Artisans (jewellers, goldsmiths, dressmakers, shoemakers...)
 - Packaging industry (including food packaging!)
- Importers and distributors placing articles on the market
- Retailers selling all of the above mentioned articles (among others)

Substances in Articles (SiA)

- A growing concern!
- Trade of articles is an important part of global transport of chemicals.
- Generally consumers and businesses are not well aware.
- Increasing the availability of information on SiA -> crucial strategy in solving the problem of substances of concern and their impact on human health and the environment.
- Vital for the implementation of Circular Economy!



SiA – Consumer concerns



Majority of interest is for human health reasons!

Respondents interested in product groups for human health reasons (red) or for environmental reasons (blue). Total number of participants: 1030.

Hartmann and Klaschka Environ Sci Eur (2017) 29:29

Substances of concern – Where and why?

Substance	Characteristics/ purpose of use	Material/Article used in	Possible health impact
Metals (lead, chromium, cadmium, mercury)	Colouring, stabilization ^[1]	Enamelware, crayons ^[1] , Electronic appliances ^[2] , jewellery, toys ^[3]	Toxic, accumulative ^[1,3] , effect on renal function, carcinogenic and reproductive effects ^[3]
Phthalates (DCHP, BBA, DEP...)	Plasticisers ^[1, 2]	Plastics ^[2] (toys, packaging, PVC flooring ^[1]), coatings ^[4]	Reproductive effects and endocrine disruption ^[1]
VOCs (e.g. formaldehyde)	Solvents, Adhesives ^[1, 5]	Construction products e.g. wood panels ^[5] , chipboards ^[1]	Acute toxicity, neurotoxicity ^[1]
Perfluorinated compounds (PFCs)	Water/stain repellents ^[3]	Textile finishing: clothing, carpets ^[2, 3]	Persistent, bioaccumulative, toxic ^[3]
Brominated flame retardants (BFRs)	Increase fire resistance ^[6]	Electronic appliances ^[3] Construction products: insulation material (polystyrene/urethane), textiles ^[6]	Bioaccumulative ^[3]

[1] https://www2.mst.dk/udgiv/Publications/2001/87-7944-519-5/html/kap10_eng.htm#f85

[2] Hartman and Klaschka, Environ Sci Eur (2017) 29:29

[3] Toxic Substances in Articles: The need of information (<http://www.diva-portal.org/smash/get/diva2:701141/FULLTEXT01.pdf>)

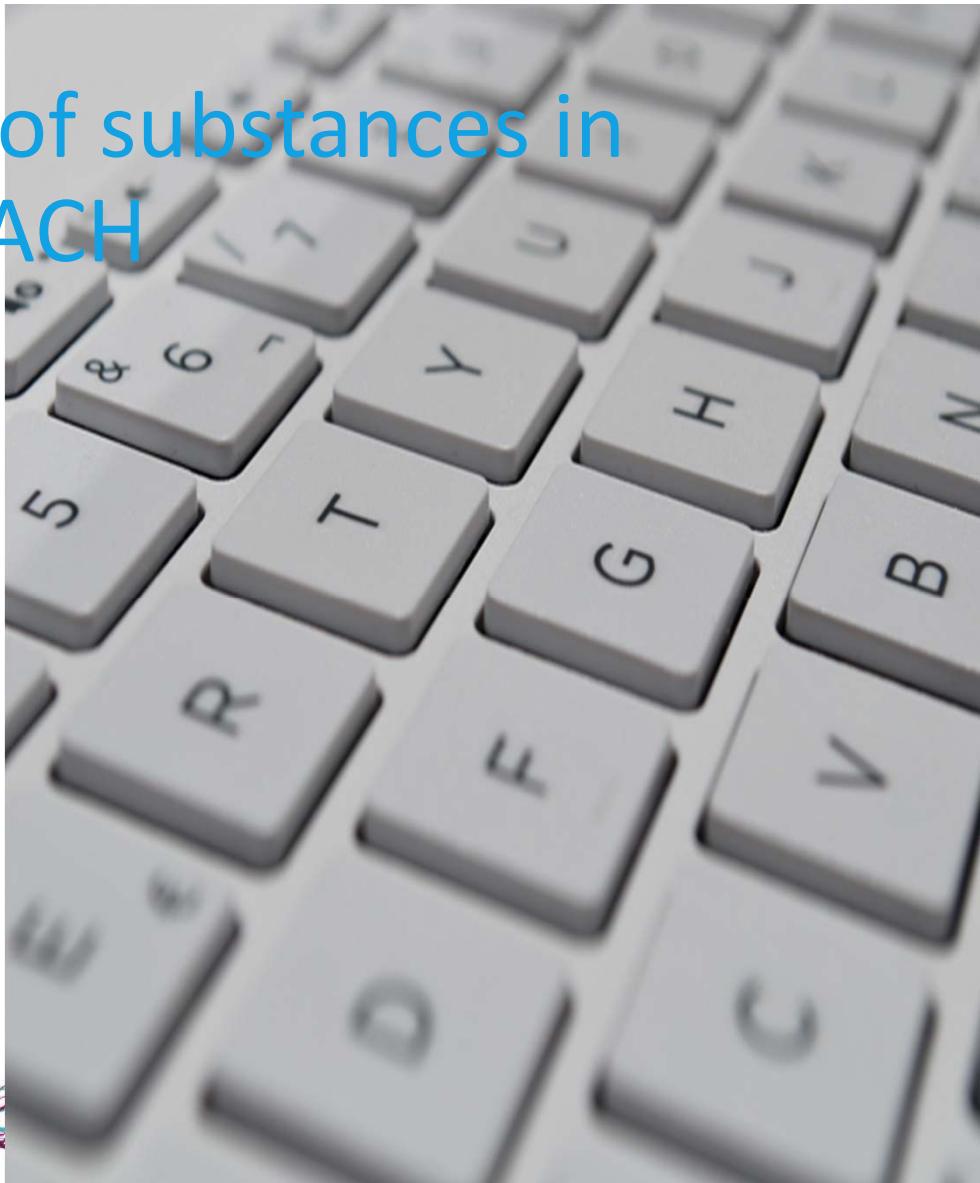
[4] ECHA data on DCHP: <https://echa.europa.eu/fr/substance-information/-/substanceinfo/100.001.405>

[5] Weigl et al., International Wood Products Journal (2014), 5:3

[6] Alaee et al., Environment International (2003), 29 pp 683-689

Registration of substances in articles – REACH

- Registration* of substances in articles is required from producers and importers when **both** conditions listed are fulfilled:
 - The substance is intended to be released under normal or reasonably foreseeable conditions of use.
 - The total amount of the substance present in all articles with intended release produced or imported by one actor exceeds 1 tonne per year.



Candidate List substances in articles – REACH

- 191 substances (of very high concern, SVHC) on Candidate List currently
- Notification* of Candidate List substances in articles is required from producers and importers of articles when **both** of the following conditions are met:
 - The substance is present in those articles in quantities totalling **over one tonne** per producer or importer per year
 - The substance is present in those articles **above a concentration of 0,1% (w/w)**
- Communication duty** on Candidate List substances (concentration > 0,1%, w/w) in articles -> **name** of substance and information on safe use!
 - Within the **supply chain** (provided by the supplier to the recipient)
 - To the **consumer** (upon request), within 45 days

Article producers: also consider the [Authorisation List](#) (Annex XIV) for possible authorisation requirements for SiA!

Restrictions – REACH

Annex XVII Entry 23, Cadmium and its compounds

10. Shall not be used or placed on the market if the concentration is equal to or greater than 0,01 % by weight of the metal in:

“A substance containing cadmium and/or its compounds used in articles”

- (i) metal beads and other metal components for jewellery making;
(ii) metal parts of jewellery and imitation jewellery articles and hair accessories, including:
— bracelets, necklaces and rings,
— piercing jewellery,
— wrist-watches and wrist-wear,
— brooches and cufflinks.

Annex XVII
market or



Is it an article?

What are the exemptions?

https://echa.europa.eu/documents/10162/23036412/articles_en.pdf

ECHA guidance



Is it a complex object?

*Is it a combination of an article
and substance/mixture?*



Un service du Luxembourg Institute of Science and Technology
En partenariat avec le Ministère du Développement durable et des Infrastructures
et le Ministère de l'Economie

SVHC Alert

Deutsche Fassung
Version française
[SVHC under regulatory assessment and scrutiny](#)



The following (potential) SVHC are under regulatory assessment and scrutiny:

>> Early warning: Substances of potential concern listed in the Public Activities Communication Tool (PACT)

Reminder: The Public Activities Coordination Tool (PACT) lists all substances for which an informal hazard assessment or a risk management option analysis (RMOA) is being developed or has been completed with the aim to identify potential SVHC. The listing of a substance in the PACT can be seen as a very early warning for companies allowing stakeholders to prepare for possible future requirements well in advance. New chemicals are added to the PACT on a regular basis. Please consult the [PACT list](#).

Details of the substance

Substance name	Amylase, α-
CAS/EC Number	9000-90-2/232-565-6
Status/activity	Risk Management Option Analysis (RMOA): Respiratory Sensitizer
Outcome	No need to initiate further regulatory risk management action at this time
Latest update	12/09/2018

Uses

This substance is used in the following products: washing & cleaning products and water treatment chemicals (consumer use).

This substance is used in the following products: paper chemicals and dyes, textile treatment products and dyes, laboratory chemicals, leather treatment products, washing & cleaning products, water treatment chemicals and pharmaceuticals.

This substance is used in the following areas: municipal supply (e.g. electricity, steam, gas, water) and sewage treatment and scientific research and development. This substance is used for the manufacture of chemicals, textile, leather or fur and pulp, paper and paper products (use at industrial sites).

Source of information ECHA (2018): Registration dossier: Brief profile: Amylase, α-, available at <https://echa.europa.eu/brief-profile/-/briefprofile/100.029.592>

Details of the substance

Substance name	Sodium perfluorooctanoate
CAS/EC Number	20109-59-5/243-518-4
Status/activity	Hazard assessment: Endocrine disruptor (ED)
Outcome	Under development
Latest update	10/08/2018

The REACH&CLP Helpdesk informs about Substances of Very High Concern (SVHC)

The goal of Article 55 REACH is to properly control the risks arising from substances of very high concern (SVHC) and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable.

The so-called [SVHC Roadmap 2020](#) aims to have all relevant and currently known included in the [Candidate List](#) by 2020. The planned steps to achieve this objective are in the [SVHC Roadmap implementation plan](#), foreseeing screening methods a management option analysis (RMOA) to identify potential SVHC and the best risk management measure.

The inclusion of a substance in the [Candidate List](#) already creates [legal obligations](#) for companies manufacturing, importing or using such substances, whether on their own, in mixtures or in articles. Manufacturers, importers or downstream users shall not place a substance on the market for use or use it themselves if that substance has been included in [Annex II \(authorisation list\)](#), unless an authorisation has been granted.

Companies should be aware of the impending regulatory constraints at an early stage in order to anticipate upcoming obligations and to start looking for possible alternatives. The REACH Helpdesk informs you regularly on the status of SVHC and potential new SVHC.

Subscribe via:

<http://www.reach.lu/en/support/resource-center/newsletter/>

LUXEMBOURG
INSTITUTE OF SCIENCE
AND TECHNOLOGY



LE GOUVERNEMENT
DU GRAND-DUCHÉ DE LUXEMBOURG
Ministère du Développement durable
et des Infrastructures

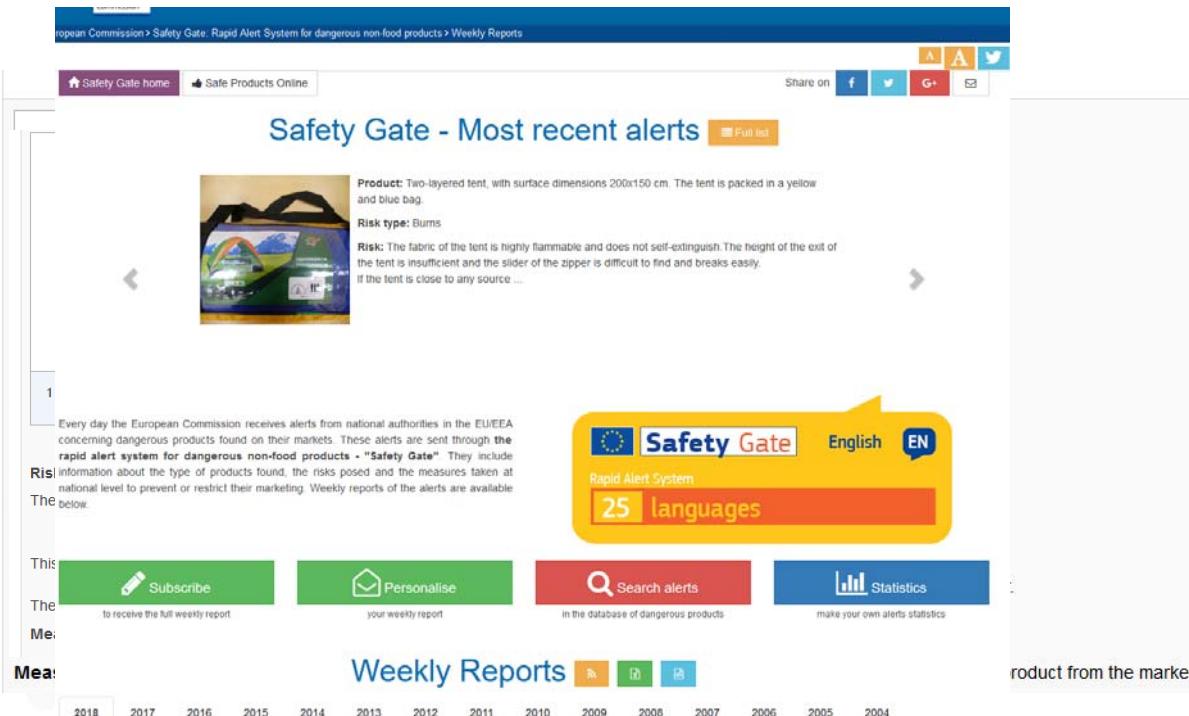


LE GOUVERNEMENT
DU GRAND-DUCHÉ DE LUXEMBOURG
Ministère de l'Economie

A selection of regulatory aspects beyond REACH

- **Waste Framework Directive (2008/98/EC)**
 - General framework of waste management requirements and sets the basic waste management definitions for the EU.
 - SVHC information of **articles** to ECHA database by January 2021! ((EU) 2018/851)
- **Toy Safety Directive (2009/48/EC)**
 - Safety criteria that toys must meet before they can be marketed in the EU.
- **Construction Products Regulation ((EU) No 305/2011)**
 - Harmonized rules for the marketing of construction products in the EU.
- **Restriction of Hazardous Substances Directive, RoHS (2002/95/EC)**
 - Restricting the use of hazardous substances in electrical and electronic equipment
- **General Product Safety Directive (2001/95/EC)**

Safety Gate - the rapid alert system for dangerous non-food products



The screenshot shows the European Commission's Safety Gate website. The main heading is "Safety Gate - Most recent alerts". Below it, there is a thumbnail image of a two-layered tent packed in a yellow and blue bag. The text next to the image reads: "Product: Two-layered tent, with surface dimensions 200x150 cm. The tent is packed in a yellow and blue bag." Underneath, it says "Risk type: Burns" and provides a detailed description of the risk: "Risk: The fabric of the tent is highly flammable and does not self-extinguish. The height of the exit of the tent is insufficient and the slider of the zipper is difficult to find and breaks easily. If the tent is close to any source ...". At the bottom of the page, there is a summary of the system: "Every day the European Commission receives alerts from national authorities in the EU/EEA concerning dangerous products found on their markets. These alerts are sent through the rapid alert system for dangerous non-food products - "Safety Gate". They include information about the type of products found, the risks posed and the measures taken at national level to prevent or restrict their marketing. Weekly reports of the alerts are available below." There are also buttons for "Subscribe", "Personalise", "Search alerts", and "Statistics".

https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/content/pages/rapex/index_en.htm

Thank you for your attention!

Oona Freudenthal, PhD

Regulatory Science Engineer

oona.freudenthal@list.lu

+352 275 888 5063

