

Für Mensch & Umwelt

Umwelt 
Bundesamt

**Strengthening REACH Provisions
Concerning (Imported) Articles**

Welcome and Introduction: Background of the project

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Motivation for the study

Regulation of substances in articles is done at different places

- **The „product area“:** Provisions on packaging, toys, cars, construction products, electronics, environmental labels, ...
- **The „chemical area“** Provision on substances, mixtures and articles in laws on industrial chemicals, persistent organic pollutants (POPs), biocides, ...

Situation sometimes results in

- gaps of regulation (nobody feels responsible)
- double work (same substances are discussed at different places)



Definition of Article (Art. 3, 3.): means an object which during production is give a special shape, surface or design which determines its function to a greater degree than does its chemical composition

Motivation for legal expertise on „REACH and articles“ (II)

- **Some basic provisions for articles should be implemented in one single legal act, not spread to many sector specific laws**

→ this can be done in REACH

(Issues specific for certain product groups should still be addressed in specific laws.)

- **Important to close gaps in REACH regarding articles**

- Substances of very high concern (SVHC) in imported articles are not subject to authorisation

- Communication duties for SVHC in articles (and maybe other substances) are not sufficiently precise and effective

→ check which options are reasonable regarding an amendment of REACH

(Non) existing provisions for articles in REACH, overview research project

Existing provisions for articles in REACH

- **Article 7 Registration and notification of substances in articles**
- **Article 33 Duty to communicate information on substances in articles**
- **Registration: Information concerning articles is also part of the registration**
(Article 10 together with Annex VI (technical dossier) and Annex I (chemical safety report))
- **Title VIII and Annex XVII: restrictions**
(in case restriction refers to the placing on the market of articles containing certain substances)
- **Not for articles: Title VII and Annex XIV on substances for authorisation**

Example for regulatory gap: Authorisation duty (I)

- Annex XIV contains a list of substances (SVHC) which are subject to authorisation.
- An authorisation is necessary for the use of a substance in the European Economic Area (EEA). It can be granted under certain conditions.
- Authorisation is only relevant for articles in an indirect way: When the use of a substance is not allowed in the EEA, it can't be contained in articles produced in Europe.
- Articles produced outside Europe are therefore not subject to the authorisation duty and the articles are allowed to contain SVHC.

Example for regulatory gap: Authorisation duty (II)

Product Examples:

Reprotoxic Phthalate-Plasticizers
in Annex XIV
(DEHP, BBP, DBP, DIBP)
with sunset date 21. February 2015



cable



textile print

Result of non-inclusion of imported articles into the authorisation duty:

- Incomplete protection of consumers, workers and the environment from SVHC.
- Serious disadvantage for producers of articles in Europe, often small and medium sized enterprises.
- But: The world trade legislations doesn't care about discrimination of domestic economic stakeholders, only about discrimination of economic stakeholders from outside of that area.

Example for other way of regulation:

RoHS directive on hazardous substances in electronics (2011/65/EU)

Combines restriction of placing on the market of articles which contain certain substances (independent of their production place) with the possibility to apply for exemptions.

Regulatory options investigated in the report

Part 1 of the report

- **Extended authorisation requirement: compatible with WTO principles?**

Part 2 of the report

- **Regulatory option 1: Introduction of a standardised communication format for articles**
- **Regulatory option 2: Labelling requirements for SVHC in articles**
- Regulatory option 3: Extension of communication requirements to other substances
- Regulatory option 4: Extension of registration requirements to unintended release
- **Regulatory option 5: Clarification of the information requirements for a registered use in an article**
- Regulatory option 6: Clarification of the reference point of the 0.1 % threshold stipulated by Art. 7 and Art. 33 REACH
- Regulatory option 7: Registry for articles containing SVHC

→ Only the bold ones will be presented today.

Substances of Very High Concern (SVHC)

Substances of Very High Concern (SVHC) - Properties

SVHC show their impact not immediately but after long time spans or at distant places.

SVHC have the following properties according to REACH art. 57:

a) carcinogenic category 1A or 1B	C	38	14
b) mutagenic category 1A or 1B	M	2	-
c) toxic for reproduction category 1A or 1B	R	64	6
d) persistent, bioaccumulative and toxic (PBT)	PBT	3	1
e) very persistent and very bioaccumulative (vPvB)	vPvB	5	1
f) equivalent level of concern (e.g. endocrine disrupting)	EC	7	-
	Multiple	<u>36</u>	<u>9</u>
		155	31

1. Step: Identification as SVHC and inclusion into the „candidate list“, currently 155 substances
2. Step: potentially inclusion in Annex XIV for substances for authorisation, currently 31 substances

Substances of Very High Concern (SVHC) – Grouping

Grouping of SVHC is also possible according to e.g. their

- **chemical composition or**
- **function**

Or grouping according to substances which remain / don't remain in the articles.

a) Process chemicals

e.g. solvents, surfactants, ...

b) Constituents of articles

e.g. plasticizer, flame retardants, pigments, ...

- We are talking today only about substances which remain in the articles.
- Substance which are used outside Europe as process chemicals and don't remain in the article can hardly be addressed by the authorisation duty.