

Ufoplan-project

# ANALYSIS OF THE REALISATION OF OBLIGATIONS FROM ARTICLE 7 AND 33 UNDER REACH FOR IMPORTED ARTICLES

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# 1 INTRODUCTION

The new European chemicals regulation REACH entered into force on 1st of June 2007. Thereby, obligations for substances in articles according to article 7 will be applied, which have not been regulated in chemicals legislation. Up to now substances in articles causing negative effects to human health or the environment were regulated at most by use of restrictions of directive 76/769/ECC. Further requirements especially for consumer products have been covered by product-specific regulations only. The new REACH requirements for articles can be summarised as follows.

## 1.1 Requirements for articles under REACH

### 1.1.1 Substances in articles with intended release, Article 7(1)

Producers and importers of articles will have to register substances in articles according to Article 7 (1), if they are intended to be released from the article and are present in an overall quantity of 1t/a and per producer or importer. This will not be necessary if the substance is already registered for that specific use (Article 7 (6)). This category of articles will be founded by a small amount of representatives as e.g. perfumed textiles.

### 1.1.2 Articles containing substances of very high concern, Article 7 (2) to Article 7 (4)

In case substances are incorporated to articles which fulfil the criteria of Article 57 (substances of very high concern; SVHC) and have been identified according to Article 59 (substances which have been included into the candidate list for authorisation), the European Chemicals Agency (ECHA) shall be notified if they are incorporated in quantities above 1t/a per producer / importer und are present in a concentration above 0.1% weight per weight (w/w) in the article. According to the text of the regulation the concentration of a substance refers to the article as placed on the market, not to single components or homogenous materials which are components of the article. However, a notification will not be necessary if the producer or the importer of an article can exclude an exposure or the substance is already registered for that use (Article 7 (6)).

### 1.1.3 Duty to communicate information on substances of very high concern in articles, Article 33

Producers and importers of articles containing SVHC in concentrations higher than 0.1% w/w have to supply the commercial recipient with sufficient

information on the safe use, but at least communicate the name of the substance in an active way.

This information has to be communicated to a consumer on request free of charge within 45 days. These obligations have to be fulfilled independently if the quantity of 1t/a is reached or the exposure can be excluded.

#### **1.1.4 Registration of substances in articles according to Article 7 (5)**

Producers and importers of articles containing substances which are not intended to be released from the articles can be requested by the ECHA to register those substances in case there are reasons for suspecting that the substance is released and resulting from that there is arising a risk for human health or the environment.

#### **1.1.5 Flow of information along the European supply chain**

Under REACH substances as such or in mixtures manufactured or imported in amounts >1t/a per legal entity have to be registered. For dangerous substances registered in amounts >10t/a the use has to be assessed and information for safe use during the whole life cycle has to be submitted to the downstream user together with the safety data sheet and the exposure scenario.

The downstream users are obliged to implement the recommendation received from their supplier. In case the use is not covered by the specifications of the suppliers the downstream user may communicate information about his use of the substance in articles and ask the supplier to make an assessment.

Producers of articles who incorporate substances into article matrices will receive information by the safety data sheet and exposure scenario about:

- Name of the substance(s);
- Registration number (if already registered);
- Classification and labelling of the substance or of the mixture;
- Range of concentration of the substances in the mixture if applicable<sup>1</sup>;
- Identified use, given either in form of the use descriptor system<sup>2</sup> or as free text;
- Substances which underlie authorisation or restriction;
- Information on safe use in chapter 8 of the safety data sheet together with information on use in consumer products (mixtures and articles) based on classification and labelling and / or the assessment of the use in the chemical safety report;
- Information on operational conditions of use, risk management measures and product-related demands (mixture and article) in the

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<sup>1</sup> This applies obligatory to components of mixtures if the concentration of the substance exceeds than the concentration limits given in Article 14(2)

<sup>2</sup> The Use Descriptor System is described in the Guidance documents „Guidance on information requirements and chemical safety assessment, Chapter R. 12: Use Descriptor System.“. It includes descriptors for substances in articles without intended release in chapter 12-5.6.

exposure scenario in case a chemical safety assessment was performed.

## **1.2 Import of articles from non-EU countries**

At first importers of articles have to comply with product-related regulations given in marketing and use restrictions according to Annex XVII of REACH (former Directive 76/769/EC) and specific requirements resulting from product regulation like the Directive on the Safety of Toys, the German Foods and Commodities Ordinance.

The same requirements on communication for producers of articles under REACH do not apply to actors in the non-EU supply chains. Normally importers of articles will not have to consider any communication requirements for substances used in articles if they market them within the EU. Therefore importers often are not in a position to receive the information they need from their non-EU suppliers.

# **2 OBJECTIVES AND TASKS OF THE PROJECT**

## **2.1 Objectives**

First there was done an analysis of the difficulties evolving from the import of articles. As the basis of the results 2-3 case studies were elaborated focusing on articles with a potentiality of containing PBT or vPvB substances.

By means of the case studies it is demonstrated which fields of problems have to be taken into account when implementing the new REACH requirements on articles and how importers can act to ensure and prove REACH-conformity. "Best practice examples" can demonstrate the approaches suited for an enhanced communication within the international supply chain.

In terms of an efficient control of Article 7 (2) by the federal state authorities a description of the current situation was generated and a regulatory evaluation of possible options for a control system was conducted. Originating from that, possible approaches for the development of efficient product rules and boundaries of regulatory control were shown.

The results should be interpreted with the focus of a potential suitability for an implementation in an international context, too.

## **2.2 Tasks**

It is assumed that REACH will provide sufficient information for producers of articles to accomplish the obligations of Article 7. This is ensured because of

the fact that hazardous substances, that will be registered in quantities > 10t/a, will be assessed according to the uses. Information for a safe use will be provided within the complete value-added chain. Therefore the national authorities have an opportunity to control the coverage of a use in an article of a producer by the material safety data sheet and the exposure scenarios of the raw material substances.

The communication requirements do not range over the non-European supply chains. On the one hand this fact causes difficulties to obtain the necessary information from their supplier to the importers of articles. This information is the prerequisite for them to derive their REACH obligations and to prove conform behaviour. On the other hand the national authorities have difficulties to control conformity at import. To both protagonists it is a need to develop feasible instruments for the proof of conformity and regulatory control.

The aim of Article 7 and 33 of the REACH regulation is to protect human health and the environment from risks occurring from hazardous substances in articles. A registration requirement only exists for substances with an intended release from articles. SVHC that shall remain in the article and which are included in the candidate list shall only be notified from June 2011 if they exceed a concentration threshold of 0.1% (w/w) and a total amount of 1t/a in all imported articles per importer.

The project focused on the import of articles which are covered by Article 7 (2) and Article 33. Following questions were examined:

- Which difficulties do occur to importers and which instruments are suited to solve them?
- Which opportunities do exist for the regulatory control of the federal state authorities and which are the necessary requirements?
- How can importers prove REACH-conform behaviour?

Furthermore implementation of market surveillance also plays a prominent role.

## 3 ONGOING EU-PROCESSES AND OTHER PROJECTS

### 3.1 Revision on Technical Guidance Document “Guidance on requirements for substances in articles”

As laid down in Article 77(g) and (h) ECHA is obliged to provide “technical and scientific guidance for the application of Article 7 by producers and importers of articles” and “on the operation of this Regulation for Member State competent authorities”. Hence in the REACH Implementation Project 3.8 the “Guidance on substances in articles” was developed. From the start of implementation ECHA collects information on the use of the guidance document to identify potential

problems on the implementation processes. This information is provided to stakeholders. The feedback received up to now on the Guidance on substances in articles shows that a revision is needed. As relevant topics that have to be covered in a revised document have been identified:

- Workability and implementation of the 0.1% concentration limit
- Exclusion from registration requirements for substances in articles which are already registered for that use – How can this be shown?
- Borderline cases: substances / mixtures – articles and substances / mixtures in a container / on a carrier material – How to differentiate?
- Documentation of the exemptions from notification according to Article 7(3)
- Communication requirements according to Article 33

The revision process still is going on<sup>3</sup>. Some relevant issues also touched by the work of this project are briefly described as follows.

a) Application of 0.1% concentration limit

Up to now it seems to be likely that there will not be a change in the interpretation of the 0.1% limit. Although new findings on the application of the 0.1% limit were provided by the project conducted by the Nordic Council of Ministers (see also chapter 3.2), the interpretation will remain to the whole complex article<sup>4</sup>. The legal opinion of the European Commission is determining to ECHA and will be kept unless overruled by a decision of the Court of Justice.

However, Section 4.4 of the Guidance on the determination of a SVHC on the candidate list in articles with different components explains that it might be necessary to check if a SVHC is contained in different concentration in different components of a complex article in order to be able to detect if the 0.1% (w/w) limit is exceeded in the whole article. This also illustrates the need of producers and importers to collect more information on substances in materials and parts or components in the future independently of how to apply the 0.1% threshold (see also chapter on case study work)<sup>5</sup>.

b) Support for importers

Some Member States recommended adding additional information on where SVHC of the candidate list potentially can be found in articles. ECHA agreed and announced to give more information on the guidance in Appendix 4: information sources on substances in articles. There a reference is made to

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<sup>3</sup> The draft Guidance can be obtained from [http://guidance.echa.europa.eu/guidance4\\_en.htm](http://guidance.echa.europa.eu/guidance4_en.htm), draft version 2.2 was send to CARACAL on 21 April 2010

<sup>4</sup> Summary of comments received during consultation of the Forum and the MSC, response by ECHA: "Concerning the interpretation of the 0.1% threshold the legal opinion of the European Commission is determining for ECHA unless overruled by a decision of the Court of Justice.

At the PEG meeting of 20/11/09 the Commission explained that the current interpretation of the 0.1% threshold was elaborated by the Commission's Legal Service and communicated to the Member State Competent Authorities in Doc. CASG(SiA)/04/2007. According to the Commission, if the legislator would have wanted the 0.1% threshold to apply to homogeneous materials only, the legislator would have explicitly mentioned this (like in certain provisions on restrictions in the REACH Regulation) and defined what is to be understood as a homogeneous material."

<sup>5</sup> Summary of comments received during consultation of the Forum and the MSC, response by ECHA: „In order to be able to conclude with certainty that a complex article does not contain above 0.1% (w/w) of a SVHC without having to know the specific SVHC concentration and the mass of each component, the concentration of the SVHC in each component has to be compared to the 0.1% threshold. This means it should be known for each component whether it contains above 0.1% (w/w) of a SVHC or not.“

publicly available very general information on substances in articles from different sectors. More information will be added for the final version.

Concerning potential difficulties for producers and importers of articles to decide on how to analyse substances in articles information on selected methods is given in Appendix 5: Methods for the sampling and analysis of substances in articles. The non-exhaustive list includes in particular methods for the determination of substances released from articles e.g. migrating from food contact material. This would support producers and importers mainly in identifying whether and which kind of safety instruction should be given to customers. Further support as proposed by some Member States to include the inventory collected by the Forum on analytical methods for the restricted substances in the Annex XVII was found as not appropriate by ECHA so far as this list would lead to the need of a Guidance update each time the candidate list was enlarged or the analytical methods would change.

c) Providing information to customers

A clarification was made on the issue who had to be considered a consumer as this term is not defined in the REACH regulation. As agreed on a discussion at its meeting on 20 November 2009 in the Partner Expert Group (PEG) ECHA decided not to add a definition but to leave the interpretation to the common sense. Nevertheless ECHA points out that Article 33 (2) does not require a consumer to purchase an article in order to request the Article 33 information.

It was further clarified that the deadline for article suppliers to provide information according to Article 33 to consumers should be 45 calendar days. As there is no general obligation to inform consumers on SVHC contained in an article a sticker was not seen as an appropriate way of providing information. So ECHA will replace the example of stickers by the example of standard answering letter. As other formats for providing information the Guidance now names:

- Instruction for use and packaging
- Information on labelling
- Link to a website with up-to-date information
- Standard communication formats developed by industry sector associations

All these formats have to be readily available to the recipient of the article or the consumer.

### **3.2 Project on the application of the 0.1% limit by the Nordic Council of Ministers**

Under REACH notification and communication obligations concerning SVHC included in the candidate list for authorisation apply if a concentration of 0.1% (w/w) in the article is exceeded. The question on how to apply this limit in case of complex articles is a main one to be solved on EU level because on this various opinions exist. On the one hand the current ECHA guidance “Guidance on requirements for substances in articles” points out that the limit has to be

applied to the whole complex article; this was also verified by the legal service of the Commission. On the other hand 6 Member States and Norway notified their dissenting views and question the application of the 0.1% limit to the whole complex article as dilution effects occur which would lead to a loss of information. Therefore a project “REACH trigger for information on substances of Very High Concern (SVHC) – as assessment of the 0.1% limit in Articles” was initiated by the Nordic Council of Minister (The Nordic Chemicals Group) during December 2008 – September 2009 supported by a reference group with members from Sweden, Denmark, Finland, Norway, Austria, Belgium, France and Germany. The main findings from the case study work of the project are briefly described here as similar findings were made also in this project.

a) Parts and components are addressed in other legislation

An analysis showed that substance-related legal requirements refer to different levels: parts and components are as well addressed as material. That leads to the conclusion that industry and enforcement currently apply legal thresholds to different parts of complex articles.

b) Requirements cease to apply during application

The current ECHA interpretation implies that different requirements will apply to the same article when sold separately and incorporated into a complex article (see also chapter 5.3.3 on electronics).

c) Information may get lost

The application to the whole complex article leads to the situation that considerable amounts of SVHC will be imported into the EU by large volume articles without triggering any safety information according to Article 7(2) or 33 (see also Chapter 5.3.3 on electronics).

d) Loss of information occurs at random

According to the current interpretation of the 0.1% limit the flow of information may stop when smaller articles containing SVHC are assembled into heavier articles as well as when SVHC are used in concentrations close to the 0.1% limit in smaller articles.

e) Access to SVHC-related information is key

Producer and importers will have to ask their suppliers for substance-related information if they want to ensure legal compliance. The workability depends on how easy producers and importers can get access to this information and how much effort they have to spend on. Moreover it was observed that the knowledge about substances used in articles is divers and quite poor in some supply chains.

f) Flow of substance-related information is feasible

The case studies conducted in the project showed that in some supply chains like toys, shoes, and electronics experience had been made already with implementing substance-related obligations and responsibilities. Also it has been shown that market actors are able to implement routines and tools on the level of parts and material.

g) Workability is driven by quality management

An overall conclusion from the project was that workability mainly depends on whether quality management systems are in place or not.

h) Interference with harmonized market is possible

Under the current interpretation articles imported to EU and produced in EU will meet different preconditions. In case the limit is applied to a complex article an EU producer who assembles complex articles will have access to more information on substances used in parts. This may put more pressure on EU producers to substitute SVHC than on importers.

i) Lack of information may cause business risks

The information according to Article 33 provides information on potential needs for seeking substitutes in case of the authorization process. If no information is provided producers have small chances to prepare for substitution.

j) Efforts for enforcement may increase

Currently substance-related obligations are mainly relating to parts or materials. This facilitates market surveillance especially when testing needs to be conducted.

### 3.3 Candidate list

The first candidate list with 15 substances was published on 28th October, 2008. Five of those substances (substance groups) were already identified as PBT/vPvB substances. The substances identified and the potential uses are shown in Table 1. ECHA suggest prioritised substances for authorization on 14th January, 2009.

Table 1: Extract from first candidate list, PBT/vPvB substances [ECHA 28 October 2008]

Substance identification		Reason for inclusion	Potential use
Substance name	EC (CAS No.)		
Anthracene	204-371-1	PBT (Article 57d)	Impurity in recycled extender oils or black pigments (carbon black)
5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	201-329-4	vPvB (article 57e)	Perfume in cosmetics and body care products
Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified:	247-148-4 and 221-695-9	PBT (Article 57d)	Flame retardant
Alpha-hexabromocyclododecane	(134237-50-6)		
Beta-hexabromocyclododecane	(134237-51-7)		
Gamma-hexabromocyclododecane	(134237-52-8)		

Substance identification		Reason for inclusion	Potential use
Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	287-476-5	PBT and vPvB (Article 57d - e)	Lubricant used in metal works, grease of leather, flame retardant in textiles, rubber, paints, fillers, adhesives
Bis(tributyltin)oxide (TBTO)	200-268-0	PBT (Article 57d)	In the past used as biocide in EU6

In the meantime further 14 substances were included in the candidate list. The Table below shows the PBT/vPvB substances extracted from the list and information on potential uses.

Table 2: Extract from second candidate list, PBT/vPvB substances [ECHA 13 January 2010]

Substance identification		Reason for inclusion	Potential use
Substance name	EC-No.		
Anthracene oil	292-602-7	Persistent, bioaccumulative and toxic; Very persistent and very bioaccumulative; Carcinogen, category 2	The substances are mainly used in the manufacture of other substances such as anthracene and carbon black. They may also be used as reducing agents in blast furnaces, as components in bunker fuel, for impregnating, sealing and corrosion protection.
Anthracene oil, anthracene paste, distn. lights	295-278-5	Persistent, bioaccumulative and toxic; Very persistent and very bioaccumulative; Carcinogen, category 2; Mutagen, category 2	
Anthracene oil, anthracene paste, anthracene fraction	295-275-9		
Anthracene oil, anthracene-low	292-604-8	Persistent, bioaccumulative and toxic; Very persistent and very bioaccumulative; Carcinogen, category 2; Mutagen, category 2	
Anthracene oil, anthracene paste	292-603-2	Persistent, bioaccumulative and toxic; Very persistent and very bioaccumulative; Carcinogen., category 2; Mutagen, category 2	
Pitch, coal tar, high temp.	266-028-2	Persistent, bioaccumulative and toxic; Very persistent and very bioaccumulative; Carcinogen, category 2	

<sup>6</sup> di-substituted Dibutyltin (DBT) and Dioctyltin (DOT) compounds are used as stabilizer in PVC and therefore may be contained in consumer articles. Further they are used as catalysts for the manufacture of polyurethane foams and silicone sealing materials. Source: BfR and UBA recommend further restricts to the use of Organotin compounds in consumer products, updated common statement No. 032/208 of UBA and BfR 05th February 2008

Substance identification		Reason for inclusion	Potential use
			paving, manufacturing of other substances and the production of clay targets.

### 3.4 Other activities and projects

#### 3.4.1 SIN-List and workers union list

In parallel to the ECHA process on identifying SVHC other organisations started to draft their own lists because the ECHA process was criticized as too slow from NGO's view. So at first ChemSec<sup>7</sup> published the so called SIN-List (**S**ubstitute **I**t **N**ow). The publication readily showed some effects within industry. Some companies integrated the list into their compliance management system as another "Black List" even though no legal requirements arise from it (see also chapter on case study electronics). The SIN-list contains 17 substances (substances groups) suspected or already identified as PBT/vPvB substances. Five of 17 are already included in the first candidate list (highlighted green in the table).

Table 3: Extract SIN-list, PBT (vPvB substances [ChemSec, October 2008]

Substance identification		Reason for inclusion
Substance name	EC-Nr.	
1,2,3-trichlorobenzene	201-757-1	PBT
1,2,4-trichlorobenzene	204-428-0	PBT
Alkanes, C10-13, chloro, SCCP	287-476-5	PBT
Cyclododecane	206-033-9	PBT
Diphenyl ether, octabromo derivative	251-087-9	PBT/ Classified CMR
Hexabromocyclododecane	247-148-4	PBT
hexachlorobuta-1,3-diene	201-765-5	PBT/vPvB
pentachlorobenzenethiol	205-107-8	PBT/vPvB
Tetramethyllead	200-897-0	PBT
Bis(tributyltin)oxide (TBTO)	200-268-0	PBT

<sup>7</sup> with support of: BEUC (the European Consumer's Organisation), CIEL (the Center for International Environmental Laws, U.S.); EEB (the European Environmental Bureau), Friends of the Earth Europe, The Greenpeace European Unit, HEAL (the Health and Environment Alliance), ISTAS (the Union Institute of Work, Environment and Health, Spain), WECF (Women in Europe for a common future) und WWF's European Policy Office, <http://www.sinlist.org/>

Substance identification		Reason for inclusion
Anthracene oil	292-602-7	PBT/ Classified CMR
Anthracene oil, anthracene paste	292-603-2	PBT/ Classified CMR
Anthracene oil, anthracene paste, anthracene fraction	295-275-9	PBT/ Classified CMR
Anthracene oil, anthracene paste, distn. Lights	295-278-5	PBT/ Classified CMR
Anthracene oil, anthracene low	292-604-8	PBT/ Classified CMR
Anthracene, pure	204-371-1	PBT
Musk Xylene	201-329-4	PBT

Another list was developed by The European Trade Union Confederation (ETUC) the so-called "Trade Union Priority List for REACH Authorisation (short: "TU list"<sup>8</sup>) in 2009. Into focus was brought the identification of substances which from a union's perspective should have priority for inclusion in the Candidate List and potentially in the Authorisation List. The list mainly focussed on substances having very dangerous properties for workers' health and which are produced in quantities in > 1.000 t/a. The SIN List has 89 substances in common with the TU List. The PBT/vPvB substances were identified from the list developed by OSPAR and EU's PBT/vPvB working group.

### 3.4.2 CMR-project

Another UBA project conducted in parallel of this project "Cancerogene, mutagene, reproduktionstoxische (CMR) und andere problematische Stoffe in Produkten - Identifikation relevanter Stoffe und Erzeugnisse, Überprüfung durch Messungen, Regelungsbedarf im Chemikalienrecht" (FKZ 3707 61 300) - short: CMR-Project focuses on issues regarding problematic substances in articles. It has started in December 2007 and will be finalised in autumn 2010. The project is carried out by Forschungs- und Beratungsinstitut Gefahrstoffe GmbH (FoBiG) and Öko-Institut, Freiburg.

The objectives of the project are

1. Identification of regulatory gaps in REACH and exemplification thereof
2. Identification of gaps in enforcement of SVHC requirements – illustration of relevance by providing examples
3. Checking of any difference on substances in articles between EU and non-EU articles
4. Discussion of potential approaches for identified problems

<sup>8</sup> <http://www.etuc.org/a/6023>

A first result from this project was the creation of a “master list” containing “problematic” substances with relevance for articles. This list will be used to identify branches, articles and materials in a first step and analyse some articles and materials for verification purposes secondly.

Table 4: Overview on substances included in „master list“

Reason for inclusion	Number of substances / substance group
CMR Cat. 1 or 2	274
CMR Cat. 3	154
Substances classified very toxic (T+)	145
Substances causing sensitisation by inhalation	83
Substances causing sensitisation by skin contact	14
Endocrine disrupters	61
PBT-substances and vPvB- substances; according REACH criteria Annex XIV	11
P-substances according REACH criteria Annex XIV	23
B- substances according REACH criteria Annex XIV	20
Substances dangerous for the environment	12
Total number of substances / substance groups	797

The list also contains 11 PBT- und vPvB-substances identified by EU-PBT-Working Group.

Table 5: PBT- and vPvB substances of EU-PBT- Working group

Name	CAS-Number
Anthracen	120-12-7
Bis(tributylzinn)oxid (TBTO)	56-35-9
Cyclododecan	294-62-2
Diphenylether, Octabrom-Derivate	32536-52-0
Endosulfan	115-29-7
Hexabromcyclododecan (HBCD)	25637-99-4
Hexachlorbuta1,3-dien	87-68-3
Pentachlorbenzothiol	133-49-3
Tetramethyllead	75-74-1
1,2,3-Trichlorbenzol	87-61-6
1,2,4-Trichlorbenzol	120-82-1

In a subsequent case study approach the following sectors were selected for an in-depth analysis:

- Electrical and electronic equipment

- Textiles
- Toys

Selected materials are:

- soft-PVC
- Polystyrene
- Leather

First results received from information publicly available found in the product category toys showed that about 70 problematic substances were found in toys. It is suspected that further substances can be also relevant but are not analysed at all or not sufficiently so far. About half of the substances identified (app. 32) are already regulated.

Other substances will be regulated in future under the new Directive on the safety of toys and others will be not, as e.g.

- endocrine disrupting substances with being classified toxic for reproduction
- PBT- and vPvB-substances.

The latter are potential candidates for the authorisation process under REACH and producers and importers will be subject to obligations under Article 7 and 33.

## 4 REGULATORY FRAMEWORK

### 4.1 Conformity with WTO rules

It has been evaluated whether Art. 7 REACH contravenes WTO rules. In particular specialist lawyers<sup>9</sup> scrutinized the requirements of Art. 7 REACH with respect to a violation of the TBT-Agreement (Agreement on Technical Barriers to Trade) and GATT (General Agreement on Tariffs and Trade). Even with different argumentations they have come to the conclusion that Art. 7 REACH is conformable with WTO; although a discrimination of non-European articles cannot be excluded due to potential higher registration costs<sup>10</sup>. This kind of discrimination, however, is regarded as justified as it only refers to substances which are released within the European Community.

In a statement of the UBA of 21-Jan 2004 it has been proposed to implement conformity certificates, which should be issued from the non-European suppliers and made available to the importers of articles in order to ensure the compliance with Article 7 REACH. Such an obligation would not violate WTO

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<sup>9</sup> Tietje, Rechtsgutachten zur WTO-rechtlichen Zulässigkeit einer möglichen Einbeziehung von Stoffen in Erzeugnissen aus Drittstaaten in die REACH Registrierungsspflichten (Art. 6 REACH), 2005; und Winter, Welthandelsrecht und Umweltschutz

<sup>10</sup> UBA Stellungnahme: Ordnung, Stephan, 28.12.2005.

rules; however, the obligation to issue conformity declarations should also affect European producers of articles which they should provide to their customers.

## **4.2 Legal basis for the supervision of companies**

The enforcement of Article 7 REACH requires a high-level exchange of information between the companies of the supply chain, between the company concerned and the monitoring authority as well as between all authorities involved. Each information requirement of an authority reduces the rights of the companies of confidentiality of their information.

The relevant task is how to find a solution for the conflicting interests of the parties concerned.

The ECHA has not got a direct right to ask non-European producers for information of their articles, as REACH -as European regulation- does not affect non-European companies.

Thus, the ECHA can only ask the importers of the articles to provide relevant information, as stated in Article 7 REACH. The enforcement of REACH will be done by the member states as Art. 126 REACH stipulates. There are two terms of relevance in Germany: § 21 ChemG as basis of authority for the competent federal state authorities responsible for the enforcement of REACH, and § 21a ChemG as basis of authority for the customs authority.

The competent federal state authorities have got the right to request all relevant information of the companies concerned. Furthermore, they are allowed to enter the factory premises and to check the working material as well as information sheets and documents. Even though this term restricts the constitutionally protected right of inviolability of the home (Art. 13 GG), it has to be accepted, as § 21 (4) explicitly states.

A limitation of the information requests can be found in § 21 (5) ChemG: a person may refuse information, if the person would take the risk to get prosecuted with respect to a criminal offence. Another limitation of the authorities' supervision of companies is the limited permission to collect data which have been asked due to the right of data protection of companies.

There is the need of exchange between the authorities, as more than one company is involved in the data acquisition. According to § 4 VwVfG there is a general obligation of authorities to help other authorities with relevant information (so-called "administrative assistance"). A limitation regarding this principle can be found in the following § 5 VwVfG: The authority is not obliged to cooperate if the operation has to be kept confidential. Confidentiality can be assumed for confidential business information. For the question which information is confidential business information coming under the protection of this term cannot be generalised, as a balance has to be found between the valuable interest of non-disclosure of business-relevant information and the right (and obligation) of the authorities to enforce the provisions of REACH.

### 4.3 Consequences

The discussions have shown that REACH implies many enforcement rules, which do not establish new permissions and rights of the authorities rather they are still based on the same basic rules for supervision; even the custom authorities have not received more rights in order to control importing companies. The difference is that the consequences for non-compliant companies have become more serious. It has become clear that a supervision of the companies concerned is not possible without any reliable cooperation between the authorities. Even though the cooperation cannot be forced in all legal issues, the cooperation can be advanced due to strategic enforcement projects and a computer-based information collection system. One proposal which is close to the acceptance by all European member states is the instrument of ICSMS<sup>11</sup>, an internet-supported information and communication system for the pan-European market surveillance which has already been implemented in Germany and other European countries with constructive results.

## 5 EXEMPLARY CASE STUDIES

### 5.1 Selection of case – product groups

First of all criteria for a selection of case studies were developed. As there were:

- The chosen articles should possibly contain SVHC of the candidate list. The focus was laid on PBT- or vPvB-substances to take into account the aspect of potential environmental effects.
- The selection should have covered one simple, more or less homogenous article and one complex article to proof potential impacts of the 0.1% concentration limit referring to the whole article, to a part of the article or to the (homogenous) material. The complexity was defined by means of:
  - Number of parts
    - Very high: > 1000 parts
    - High: 100 – 1000 parts
    - Middle: 10 – 100 parts
    - Low: < 10 parts
  - The structure of the supply chain: number of processing steps or trade levels
    - High: > 8
    - Middle: 3 – 8

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<sup>11</sup> European Market Surveillance System, <http://www.icsms.org>

- Low: 1 – 3 (manufacturer of substance – formulator – producer of article)
- Globality:
  - High: final article is imported
  - Middle: parts of article are imported
  - Low: at most raw material is imported
- The article is as well imported as product to illustrate difference in communication within the supply chain.
- The willingness of relevant market actors to provide information to the case studies was the prerequisite for a further case study work.

Another aspect in the selection process was to identify interfaces to other product oriented regulations.

In a first expert meeting with experts from industry, associations, consumers and authorities a selection of convenient products was done: gasket, awning, and electronic devices (printer). The criteria are given in an overview.

Table 6: Overview on criteria for case study selection

Article	SVHC	Complexity of parts	Structure of supply chain	Globality	Interfaces
Electric and electronic equipment - Printer - Parts	- Phtalates - Brominated Flame retardants - PFOS - (SCC, MCCP) - (Be in alloys) - Co(II)Cl in drying agents	100 – 1000 1 - 1000	Steps: 5 (high)  Suppliers: 10 – 100 (medium)	High: production nearly complete outside EU	- WEEE/ROHs - IEC 2012 - JIG – 04/9 - ELV - Non-EU regulations - Different existing tools, obligations or declaration - Internal standards - Customer requirements
Awning (Tents)	- Phtalates - Flame retardants - Impurities from transport, processing aids, process - Substances in packaging (DEHP, Co(II)Cl)	10 - 100	Steps: > 5 (high)  Suppliers: 10 – 100 (medium)	High, but refining often done inside EU (flame proofing)	- Fire protection requirements - CPD
Rubber-products: Gaskets	- PAH in Germany: GS certification only on voluntary basis) - Phtalates - FRS - MCCP	< 10	Steps: low  Suppliers: ?		- ELV - GADLS - Tool: IMDS - Food contact material - Voluntary GS certification

For the selection of the case studies SVHC of the candidate list should potentially be contained in the article. Therefore it was identified which substances could be contained in a specific material. A stepwise approach was

chosen to consider the SVHC-substance, the material and also the article as such.

- SVHC substance used as in a function of \_\_\_\_\_
- SVHC used in material \_\_\_\_\_
- Material used in article \_\_\_\_\_

**Fehler! Verweisquelle konnte nicht gefunden werden.** shows an overview on SVHC potentially used in Materials.

Table 7: Overview on SVHC used in materials

Substance used as	Material	Article	Comments
Decabromodiphenyl ether (Deca-BDE) Flame retardant	plastics, fibres	Electronics, textiles	Currently discussed as POP <sup>12</sup> substance, not classified, not included on candidate list. Emission into environment via articles is seen as low relevant compared to use of substance as such. According to RoHS <sup>13</sup> banned in electronics.
Hexabromocyclo-dodecane (HBCDD) Flame retardant	(rubber foam-) plastics, mainly Polystyrene <sup>14</sup> , fibres, isolating material	Insulation material, packaging, electronics textiles, seat upholstery (car)	Relevant for imported articles. Low release rates but high volume and widespread use of articles
Short Chain Chlorinated Paraffins (SCCPs) plasticizer, flame retardant	plastics, rubber, sealing material, textiles, adhesives, paints, coatings	Belt conveyor, coated textiles	Banned for metal and leather processing agents in concentration > 1%. Little number of special uses
poly-aromatic hydrocarbons (PAHs)	Constituent / impurity of plastiziser oils for rubber	Rubber products	PBT-substances, currently no included in candidate list as sum parameter, but Anthracene is. Restriction for extender oils used in the production of tyres or parts of tyres if they contain; no existing

<sup>12</sup> persistent organic pollutants

<sup>13</sup> RoHS-Directive (Directive 2002/95/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment)

<sup>14</sup> Insulation foams EPS (Expanded Polystyrene (EPS) hard foam) and XPS (extruded Polystyrene hard foam).

Substance used as	Material	Article	Comments
			concentration thresholds for consumer products <sup>15</sup>

## 5.2 Case study work

After selection of applicable article categories some companies were contacted in the single sectors which preferably represent different levels of the supply chain e.g. supplier of sub-parts, distributor, producer of final products. The companies were asked about their readiness to contribute to the project. Those companies who were ready to provide information were asked on further details in forthcoming case study description. Some companies asked for anonymisation in the study report.

The approach in the implementation of the REACH-requirements concerning imported articles was requested at several companies by personal or by telephone interviews. A list of central questions was use as a guidance that covered:

- What is the characteristic of the company and the article?
- Which kind of substance-related requirements to articles do already exist from other product related regulations?
- Which information is available to fulfil these requirements?
- Which information gap has to be closed to fulfil the REACH requirements? How could this be done?
- Which kind of practical experience exists with tools which could be used to ensure conformity?
- How should communication be organised with surveillance authorities?

At a workshop with contributing representatives from companies, associations, and authorities the results from the case study work were discussed. In the single case studies the focus was on the general proof of conformity („good/best practice“) for importers of articles that fits to show the implementation of the Article 7 (2) and 33 requirements. It became obvious that companies focused on Article 33 requirements as these communication obligations are already relevant since the first candidate list was published in October 2008.

## 5.3 Findings from case study work

### 5.3.1 Homogenous articles – Gasket

Gaskets were chosen as an example of a more or less homogenous article. Possible SVCH off the candidate list are Anthracene (PAHs<sup>16</sup> as impurities in

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<sup>15</sup> PAH in rubber grips were subject to surveillance in the German program 2008 published by The Federal Office of Consumer Protection and Food Safety (BVL)

<sup>16</sup> Polycyclic Aromatic Hydrocarbons

rubber), DEHP<sup>17</sup> (used as plasticiser in plastics), Hexabromocyclododecane (HBCDD) (used as flame retardant), and also MCCP<sup>18</sup>.

#### 5.3.1.1 Characteristics of company and article

The interviewed company U1 imports, deals and stores different kinds of gaskets for diverse uses e.g. in the sector of the automotive industry, food production, water pipes or machineries. The company don't produce article itself.

Typical kinds of gasket are for example O-ring gaskets and rotary shaft seals in a broad number of various types and sizes for different applications. The O-rings consist of elastomeric; the rotary shaft seals enclose a metal part additionally.

Table 8: overview on characterisation of articles

	1	2
Product name	O-Rings	Rotary shaft sealing
Colour / Form	black	Black or coloured
Weight	Depending on size few to multiple 100 grammes	Depending on size few to multiple 100 grammes
Number of parts	1	1
Composition	Elastomere like natural rubber, NBR <sup>19</sup> , EPDM <sup>20</sup>	Elastomere like natural rubber, NBR, EPDM Metal component: steel, stainless steel
Are spare parts or accessories available for the article?	Not applicable: articles are accessories for bigger and more complex articles like machinery	

The analysis of the material composition so far showed that one SVHC of the first candidate list - DEHP - is contained as plasticiser in the articles made from the raw material group of NBR and EPDM. The NBR- and EPDM-master batches (mixtures under REACH) of the pre-suppliers who provide to the direct supplier of company U1 contains according to the information DEHP in a concentration of 6-7%. It is not possible to calculate the exact concentration in the final article after processing, forming and vulcanization. As natural rubber is the main material of the articles it is assumed that the final articles contain a clear concentration > 0.1%; even if there is a dilution because of the metal fraction in the case of the rotary shaft sealing. Therefore the company informs their customers according to Article 33 about the content of DEHP.

Orders to the suppliers are made on a short-term (on-time, without storage) as well as on a long-term basis. The latter is done mainly for articles produced for a customer-specific storage. The company U1 purchases final articles from

<sup>17</sup> Bis (2-ethylhexyl)phthalate

<sup>18</sup> Middle Chain Chlorinated Paraffins

<sup>19</sup> NBR: Nitrile Butadien Rubber

<sup>20</sup> EPDM: Ethylen Propylen Dien Rubber

different suppliers inside and outside EU. The supply relationships are mainly based on a long-term basis. The origin of the raw material is not known in detail.

#### 5.3.1.2 Existing requirements, information gaps

The articles dealt by company U1 are covered by different industry-specific regulations regarding the chemical substances.

As examples the vehicle-specific regulation together with GADSL<sup>21</sup>-list and the database IMDS<sup>22</sup>) as well the WEEE-directive were mentioned. Articles used in the sector of food production are subject to the conditions from the Foodstuffs and Consumer Goods Law<sup>23</sup>. Products that are intended to come into contact with drinking water underlie the raw material certification according to DVGW<sup>24</sup>. Moreover for some of the articles company U1 orders a FDA-conformity certification from a laboratory. In these cases the laboratory proofs by analysis if the product complies with the requirements of the FDA-principles. According to the FDA-standards not only specifications for allowed ingredients are made but also further requirements exist. For example the compliance of migration limits have to be shown in simulation tests.

In the above-mentioned regulations exist requirements on substances in articles that are far in excess to those of REACH; much more knowledge about the containment of chemical substances is needed.

For articles already recorded in such a database containing information on material and substances because of other regulations another SVHC of the candidate list can be easily identified by means of the CAS-No.

With regard to the implementation of REACH at first it was difficult for the company to understand the new requirements under REACH Article 7 and 33 and to identify the relevance: What are SVHC of the candidate list and do they have any relevance for the products of the company? Therefore the company gathered information needed in public events and additionally charged a consultant.

The analysis of the company's concernment results in the fact that the products in particular due to those additives used in the processing of rubber may be affected by REACH requirements. At the same time the company can use the IMDS-database as a tool to collect information about chemical substances in articles. Before the entry into force of REACH, the IMDS database was only used to fulfil requirements arising from regulations in the automotive sector.

Only information on substances specified by the suppliers was collected. To fulfil REACH requirements it was needed to extend the data recording on

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<sup>21</sup> The Global Automotive Declarable Substance List (GADSL-list) contains substances used in vehicle parts, substances which are banned from use as well as declarable substances. It was developed as a communication tool to be used along the vehicle supply chain and for the implementation of existing regulations e.g. the Directive 2000/53/EC on End-Of-Life Vehicles.

<sup>22</sup> IMDS: "International Material Data System" – is a tool developed and used by the automotive industry. In this tool Information about substances and raw material used in subparts and parts is collected. Since February 2010 a separate REACH module was implemented. <https://www.mdssystem.com/magnoliaPublic/de/public/news.html>

<sup>23</sup> Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch (Lebensmittel- und Futtermittelgesetzbuch - LFGB). <http://www.gesetze-im-internet.de/bundesrecht/lfgb/gesamt.pdf>

<sup>24</sup> Deutsche Vereinigung des Gas- und Wasserfaches e.V.

materials in the IMDS database up to all products. This ensured that all SVHC of the candidate list had been gathered. Since company U1 does not produce products itself and its influence on the raw materials used by their suppliers is limited, it was necessary to integrate the suppliers. So all SVHC in all products could be identified by a material declaration of all products supplied to company U1 into the IMDS database.

Company U1 states that it is not efficient neither economical feasible to conduct a broad chemical analysis of all products as it is required for food contact materials.

#### 5.3.1.3 Practical experience with information tools

So far, the company used the database IMDS and the substance list GADSL from the automotive industry. As this is a collection of material data combined with a declaration list containing relevant SVHC, the company already had a useful tool readily available to fulfil Article 7 and 33 requirements. So the identification of concerned products was seen as little difficult. A remaining problem is that company U1 doesn't know the exact composition of the pre-mixtures used by the pre-suppliers for the production of gaskets. For this reason the composition in the final products has to be estimated.

The implementation functions very well in this way because the suppliers showed a strong willingness to provide information on the articles' composition and to feed the data into the IMDs data tool. It has to be mentioned that according to the experience of U1 in this sector the bigger Asian suppliers are more cooperative regarding information transfer than the EU suppliers are. These are more or less small and medium sized companies. This was justified with the size of the company and the organisational structure. The Asian commercial partners are often companies with global trade relationships. They act more professional and customer-oriented than the small and medium EU-companies. Further U1 concluded long term supply relationships very positive because the continuation of the trade relationship is a common objective of all trade partners. Therewith confidence, quality and prompt communication play an important role.

Company U1 describes another benefit in covering all products in their data base. So a quick response to enquiries on certain substances is much easier. As it happened in the past, customers are caused by press releases or ongoing changes in regulation to ask for information about specific substances in the products.

In the future these substances should be either covered by the SVHC candidate list or already substituted. Additionally company U1 can easily determine if and which products may be concerned.

As an example from the past company U1 gave the substance group PAH. Because of the ban of PAH-containing extender oils in tyres<sup>25</sup> similar requirements were introduced for other synthetic rubber products. At that time U1 had to answer many customer requests and the identification of relevant

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<sup>25</sup> REACH Annex XVII

products was complex and time-consuming. Already then the use of the IMDS-database was very helpful.

Nevertheless the process of collecting data is extensive and challenging because of the high amount of different products (more than 50,000). This is also already the fact with the first 15 SVHC on the candidate list. As the list will grow in the near future, it is important for companies to know early which potential SVHC are relevant in their products.

#### 5.3.1.4 Communication with surveillance authorities

So far surveillance by authorities is done two to three times a year for the control of the raw material certification for drinking water<sup>26</sup> according to DVGW respectively KTW. The requirements in this case are distinct: in case the required certificate can't be shown, the part is not compliant and it is not allowed to use it in the sector of drinking water.

Furthermore, the requirements of the ELV-directive and WEEE seem to be more distinctive than the REACH requirements because a limited number of substances have to be considered. In contrast the requirements of REACH Article 7 and 33 are less distinctive. There is neither a certification nor any reliable information available which products may be concerned because of possibly being SVHC-containing. The company is responsible to check this itself. As the existing trade system is based on cooperation and communication between the actors and a complete control by chemical analysis is not possible, there is a risk of undetected single articles from the non-sensitive sector with a concentration of > 0.1% SVHC.

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<sup>26</sup> A certificate proves that a part or a raw material fulfils the specified requirements of a DVGW-certification. For products made of non-metal raw materials like plastics or plastic coated or elastomeric material defined requirements exist with regard to durability and also from the sector of drinking water hygienic suitability e.g. according to KTW-recommendations for taste and olfactory impairments of the drinking water as well as the requirements from the Arbeitsblatt W 270 on microbiological harmlessness, see also: [www.dvgw-cert.com](http://www.dvgw-cert.com)

Proposal of company U1:

For a better and more efficient surveillance by authorities the company would welcome a kind of system audit. The competent authority e.g. could evaluate the (quality) system and tools built up by the company regarding the appropriateness to fulfil the requirements in general.

Comment by authorities:

A kind of system audit in the sense of an evaluation of the company's ability to identify and implement their REACH obligations would be conceivable in connection with the control of notification obligations.

Proposal of company U1:

Moreover it would be helpful to have more practical information and examples for the implementation by importers of articles. This was missing in the beginning of the REACH implementation.

Comment by authorities:

There will be more supporting documents provided by ECHA and the national helpdesks. Information more branch-specific has to be provided by associations.

### 5.3.2 Less complex articles - Awning

#### 5.3.2.1 Characteristics of company and article

The interviewed company U2 is distributor of consumer articles. These are partly imported. All in all 80,000 different articles are traded in the assortment, among them also mixtures. The orders to the suppliers are generally made according to the seasons and go out about 3 months in advance.

Company U2 made an internal negotiated agreement not to import articles containing potential SVHC whether they are already included to the candidate list or not. The compliance is ensured by using appropriate suppliers contracts. In doing so company U2 excludes to have notification or communication obligations from imported articles under REACH.

Company U2 also purchases articles from EU-suppliers even if they contain SVHC of the candidate list exceeding the concentration limit of 0.1% (w/w) and if the suppliers inform according to Article 33. In this case information is forwarded to the customers. As the EU-supplier is in charge of fulfilling REACH conformity, company U2 assumes that it can rely on the communication.

As an example for this case study an awning was chosen. The company orders about 3 to 5 models, each of them ordered by 500 pieces per order.

Table 9: Overview characterisation of article

<b>Product name</b>	<b>Awning</b>
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Product name	Awning
Colour / Form	Differs depending on the model
Total weight	Depending on size 30 to 50 kg
Number of parts	about 30-50, among them also parts that are assembled by other parts e.g. the crank
Composition	Scaffold made of diverse metal and plastic parts, textile canvas, varnish / powder coating
Spare parts / Accessories	cranks, gears, springs etc.

The awnings are imported as final product from non-EU-suppliers. Spare parts are normally ordered at specialized EU-suppliers. Detailed information about certain ingredients of the composition is not known. A content of that 0% of SVHC is assumed because of existing trading contracts.

#### 5.3.2.2 Existing requirements, information gaps

Awnings and other products of the company U2 are covered by the Construction Products Directive. But here only partly requirements concerning hazardous substances are defined and they rather refer to emissions than to ingredients as e.g. the German AgBB-scheme<sup>27</sup> for floorings<sup>28</sup>.

For clothings the voluntary Oeko-Tex 100 standard exists. It can be used to document that beside regulatory also voluntary thresholds are kept. But for industrial textiles like awnings no regulatory threshold doesn't exist yet.

As a SVHC from the candidate list actually contained in some of the EU ordered articles company U2 mentioned Hexabromocyclododecane (HBCDD) which is used as a flame retardant in thermal insulation material and electrical cable.

Although company U2 is aware of the fact that the inclusion of a substance to the candidate list does not mean a ban of the substance, it decided to make sure not to import any SVHC-containing article as the easiest strategy. Articles containing SVHC will not be imported from non-EU suppliers.

This requirement is communicated to suppliers as a criterion of potential exclusion of SVHC-containing articles from import.

The compliance with this trading requirement is part of the contracts. The suppliers have to ensure that no (potential) SVHC according to REACH Article

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<sup>27</sup> AgBB: Health-related Evaluation of Emissions of Volatile Organic Compounds (VOC and SVOC) from Building Products (2008\*), see also <http://www.umweltbundesamt.de/building-products/agbb.htm>

<sup>28</sup> An extensive analysis of interfaces between REACH and the Construction Product Directive and other product related regulations can be found in the final report of "Schnittstellen zwischen REACH und anderen produktbezogenen Stoffregulierungen Schwerpunkt Bauprodukte (FKZ: 206 67 460 / 04): [http://www.reach-info.de/dokumente/schnittstellen\\_endbericht.pdf](http://www.reach-info.de/dokumente/schnittstellen_endbericht.pdf) (only in german)

Another research project about interfaces between REACH and Construction Products Directive was done in the frame of the research programm „Zukunft Bau“ des Research in the Federal Ministry of Transport, Building and Urban Development and des Federal Institute for Research on Building, Urban Affairs and Spatial Development: „Auswirkungen europäischer Bestimmungen für Gesundheits- und Umweltschutz auf Bauprodukte und Bauwerke - Schnittstellen zwischen REACH und der BPR, 2009“, <http://d-nb.info/995751005/34> (only in german).

57 have been added. If in case of doubt no information is given by the supplier within 20 days, own analyses for checking will be initiated by company U1.

Concerning articles from EU-suppliers, information about SVHC of the candidate list is no criterion of exclusion to company U2, as according to REACH the information has to be given without request. So company U2 don't have to make an extra effort to comply with REACH obligations.

Proposals of company U2:

Public available information to identify relevant substances and the concerned products and materials is desirable.

As an example of good practice the Electromagnetic Compatibility Directive and the information given by national authorities on materials was mentioned. As a positive approach the information provided by the WKÖ (Wirtschaftskammer Österreich) was quoted. This information gives a general but practical advice in which kind of article or material a specific SVHC can be expected.

Comment of the authorities:

Meanwhile the ECHA give this kind of information together with the press release about the addition of new SVHC to the candidate list.

### 5.3.2.3 Practical experience with information tools

Company U2 don't have a specific tool for screening their product portfolio but use an internal product database similar to an inventory. For the import of articles no regulations or standards exist to make the receipt of information about substance content easier. Only private contracts can be used to impose some pressure to suppliers to receive necessary information about substance content or product qualities.

### 5.3.2.4 Communication with surveillance authorities

So far market surveillance takes place on occasion within the framework of general product safety or the checking of hazardous substances contained in products (according to REACH Annex XVII). This means an inspector visits one store and selects an article for controlling purposes. One article is sealed and left in the store and another identical one is taken away for the checking. After the analysis is finished the store will be informed about the result.

Currently in case of an inspection company U2 would show the trade agreements and delivery receipts. In some cases substitution can be demonstrated: e.g. some PVC-articles were substituted by PELD-articles<sup>29</sup> without plasticizer.

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<sup>29</sup> PELD = LDPE, Low density polyethylene

Proposal of company U2:

A centralised surveillance of trading companies at the central purchasing department would be more efficient than the current practice of checking of affiliated stores.

Comment of the authorities:

The ongoing practice to control single articles at affiliated stores results from the German Equipment and Product Safety Act (Geräte- und Produktsicherheitsgesetz (GPSG)). Surveillance of all product-related regulations and a centralised helpdesk are neither considered as workable nor compatible with federal structures.

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### 5.3.3 Complex article – Electrical and Electronic Equipment

#### 5.3.3.1 Characteristics of company and article

In the sector of complex articles different actors from different steps of the supply chain were interviewed:

- A distributor of parts U3
- A producer of electronic equipment (printers) U4
- A producer of servers U5

The different actors and their position within the supply chain are shortly characterised in an exemplified way as follows.

##### 5.3.3.1.1 Distributor of parts U3

Company U3 is importer and distributor of electronic parts, components, assembly parts, modules and devices in the commercial sector (Business to Business, B2B). The products are used to assemble more complex articles.

Products from more than 300 different producers are traded. This results in a quantity of more than 300,000 different articles being traded in single units (devices) up to a lot size of a million pieces (parts).

The notice of orders at the suppliers depends on the kind of article. Partly “high runner goods” are held in stock, partly products are only ordered in case of specific customer order.

The company does not produce itself. About 80% of the articles are imported from non-EU countries. All articles ordered by EU suppliers are also produced in non-EU countries. This means EU suppliers have to provide information according to Article 33. But this also means that for all imported articles the distributor will be responsible to identify if any information according to Article 33 has to be provided to European customers. This information is not needed

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<sup>30</sup> Approaches for an efficient implementation of market surveillance in the frame of GPSG, also the implementation of strong centralised framework are published in White Paper by the German central government and states (Ländern) (Gemeinsames Ministerialblatt 2009, S. 581ff.)

for customers in non-EU countries. The suppliers are manufacturer of raw materials, producer of parts and articles.

The following graphic shows an overview of the complex global supply chain, regarding to the role of the distributor and the potential loss of information in the supply chain in case of an assembling of parts to more complex articles.

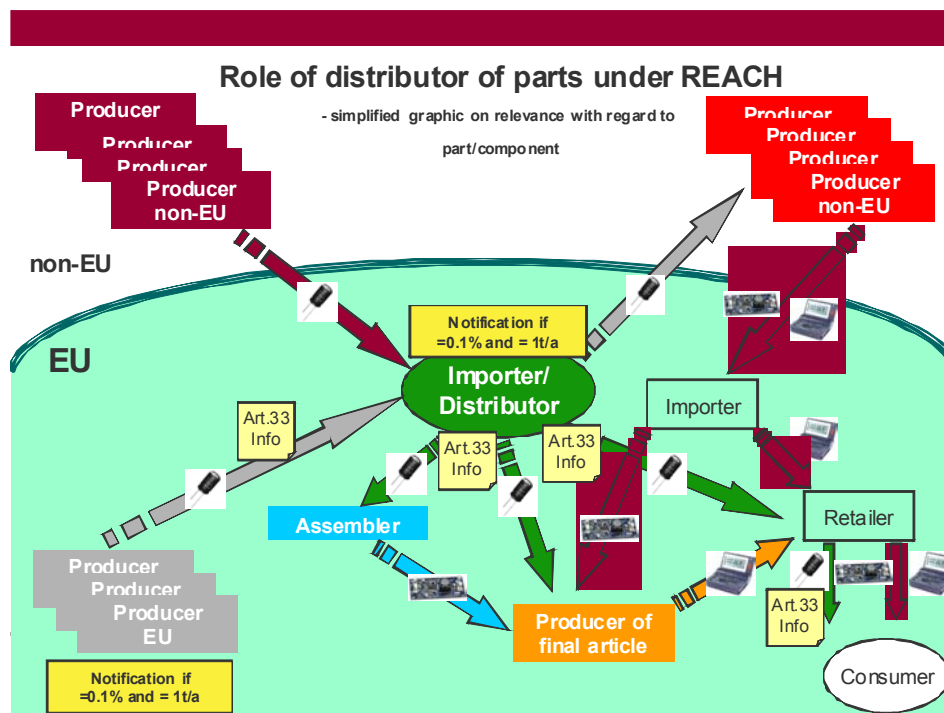


Figure 1: complex global supply chain und role of distributor of electronic parts

#### 5.3.3.1.2 Producer of printers – company U4

Company U4 is a producer of final complex articles (printers). The articles are only sold to commercial customers (retail) and next to private consumers. Production is done in a very complex and globally branched supply chain. Producer / suppliers of parts are normally located in non-EU countries. With the production of electrical and electronic equipment, a 5-7 stage supply chain is customary. The importer / producer of the final article doesn't know the actors of this chain down to the beginning (beginning = manufacturing of raw material).

Table 10: characterisation of exemplary article printer

Product	printer, about 115 different models
Whole weight	Approx. 6 kg
Number of parts	Approx. 300, each part is ordered from at least 2 suppliers
Composition	Metal and plastic
Spare parts or accessories available?	Yes, various as e.g. power cord, toner cartridge.

#### 5.3.3.1.3 Producer of servers – company U5

Company U5 has the role of a producer of servers and also importer of complete servers as well as components. Packaging is also identified as relevant under REACH. The company sells only to commercial customers (B2B: resale only in the commercial sector needs an active dissemination of information according Article 33 if relevant). End customers are e.g. manufacturing shops, banks, assurances, doctor’s surgeries.

The product line covers small servers, hardware used for cash desks and stores (retail store solutions) up to high capacity “super computers”. The number of server versions produced each year depends on the customer orders. All in all about > 100 versions are delivered to the customer. Normally the notice of orders at the supplier is about 15 days up to a month. The time of production normally needs 10 days, but in case of more complex systems accordingly needs longer.

The supplier of raw materials (e.g. metals, plastics) and parts are located both inside and outside EU. Producer of components are mainly located outside EU (USA, Asia).

#### 5.3.3.2 Existing requirements, information gaps

For electrical and electronic equipment requirements of legal regulations and also of customers have to be considered. The following list is not exhaustive; it gives an overview over some international requirements with regard to the chemical composition of articles. In addition other national requirements may be also relevant.

Table 11: overview on relevant legal requirements (list is not exhaustive)

Regulation	Description
Product Safety Directive	DIRECTIVE 2001/95/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 3 December 2001 on general product safety incl. Amendments
Battery Directive	DIRECTIVE 2006/66/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC incl. Amendments
Packaging Directive	EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE 94/62/EC of 20 December 1994 on packaging and packaging waste incl. Amendments
Marketing and use restriction of PFOS	DIRECTIVE 2006/122/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 December 2006 amending for the 30th time Council Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (perfluorooctane sulfonates) incl. Amendments
POP convention	REGULATION (EC) No 850/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC & COUNCIL REGULATION (EC) & No 1195/2006 of 18 July 2006 amending Annex IV to Regulation (EC) No 850/2004 of the European Parliament and

Regulation	Description
	of the Council on persistent organic pollutants incl. Amendments
REACH	REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC incl. Amendments Article 7 and 33 (regulate the containment of SVHC of the candidate list; substances are not banned but information has to be disseminated if the content exceeds 0.1%) REACH Annex XVII (former Marketing and use of substances Dir 76/769/EEC)
RoHS I	DIRECTIVE 2002/95/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment incl. Amendments regulated substances are banned from use, some RoHS-exemptions are claimed
RoHS II	Proposal COM(2008) 809/4
AECEIP	Chinese regulation concerning the prevention of environmental pollution because of EEE: Administration on the Control of Pollution Caused by Electronic Information Product« (ACPEIP) - "China-RoHS"
Suisse Chemical Regulation	Schweizer Chemikaliengesetz Bundesgesetz vom 15. Dezember 2000 über den Schutz vor gefährlichen Stoffen und Zubereitungen (Chemikaliengesetz, ChemG); Chemikalien-Risikoreduktions-Verordnung – Verbotsliste, Verwendungsbeschränkungen
End-of-Life-Vehicle-Directive ELV-Directive	Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles incl. Amendments
GADSL	Global Automotive Declarable Substance List <a href="http://www.gadsl.org">www.gadsl.org</a>
Medical devices	COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices incl. Amendments COUNCIL DIRECTIVE of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC)
POHS	Norwegian RoHS: Prohibition on Certain Hazardous Substances in Consumer Products (PoHS)
Product regulations	Norwegian product regulations act
Toys Directive	DIRECTIVE 2009/48/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 June 2009 on the safety of toys incl. Amendments

#### *5.3.3.2.1 Requirements concerning SVHC*

Although the inclusion of substances into the candidate list doesn't mean a banning of the substance, in practice this leads to the demand of some customers to substitute them and other potential SVHC. Thus a steering effect of the candidate list is visible even if the 0.1% concentration limit is not exceeded in the single products. If the customer demands can be met depends on the timing of the inclusion of new substances into the candidate list and also whether a substitution is technically feasible. Experience made so far with the RoHS Directive showed that a subsequent substitution is often difficult because of the complexity of the articles. Generally a longsome adaptation of the product design has to be made.

Requirements on EEE articles including materials, part and components are communicated by technical specifications. Under existing regulations like RoHS these can also be used to specify chemical requirements as for example "article, material must not contain substance X".

The companies mentioned that non-EU suppliers are often not willing to support their EU customer in fulfilling their legal requirements because they are not concerned themselves. The companies hold that their market power is not sufficient to push substitution. Companies of the EEE sector compared to those of the automotive sector are numerous and much smaller. As it is necessary to comply with numerous varying requirements it is a complex challenge for producers and distributors to ensure compliance with all international requirements definitely.

U4 holds that the SIN-list („Substitute It Now“) published by Chemsec<sup>31</sup> (<http://www.chemsec.org/>) intensifies the pressure to substitute (potential) SVHC especially in consumer products. The list may help companies in identifying relevant substances and start to look for substitutes.

The companies also recognize a global increase of requirements comparable to those from REACH e.g. in USA, Canada. In general a tendency to ask for positive declarations like "Article contains certain substances xyz" can be noticed.

#### *5.3.3.2.2 Determination of information about SVHC along the supply chain*

##### Determination about substances in materials / articles

The EEE sector has a long-lasting experience with known dangerous substances because of the requirements from RoHS-Directive and general product safety. Normally information about those substances is communicated by negative lists what means the substances must not contained in the article. A whole material declaration or positive lists are not available. There are approaches to identify SVHC-substances among substances actually used in EEE article resulted in company specific list with 80 up to 1000 substances. There is no further information about the amount of those substances in the respective material or part.

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<sup>31</sup> Chemsec: The International Chemical Secretariat is a NGO campaigning for a tox-free environment

The following problems were identified in creating lists which contain substances used in EEE and SVHC:

- The pre-suppliers often don't provide information about the substances contained in the articles.
- The information given by pre-suppliers is inaccurate.
- Often it is not possible to verify the information given by pre-suppliers and furthermore the chemical analysis of complex articles often is disproportional elaborate.

Among potential SVHC from the first candidate list phthalates especially DEHP used as plasticiser in plastics, mostly in PVC, and brominated flame retardants were identified as relevant for EEE articles. Currently DEHP is used in the plastic isolation material of power cords in amounts of about 30%. The power cord is definitely an article because of its intended function. This means an information obligation according to Article 33. Other substances like SCCP, MCCP, and PFOS may be contained, too. Beryllium can be found in alloys<sup>32</sup>.

Overall it seems to be realistic to expect another 100 substances used in EEE being included into the candidate list.

The companies receive information about SVHC by asking their suppliers. The suppliers usually give answers in writing electronically. It is often difficult for the European companies to gather this information. One company declared that it may take up to 3-6 months until an answer is received; the response rate is < 50%.

The following arguments were mentioned why suppliers do not provide information:

- Company secret: material composition is intellectual property of supplier.
- Patent pending: the patent process is not yet finished; the information is not given completely.
- The supplier is not the producer himself but orders from third parties and doesn't hold information on substances himself. This situation can be regarded as normal with non-EU suppliers.

The enquiry of information at the suppliers is also influenced by other factors as the structure and the organisation of the manufacturers. Furthermore it is influenced by the supplier's willingness and capability to follow and implement continuously legal changes originated from multiple international requirements and also to use suited standard formats for information transfer.

Companies stated that clear substance bans in the context of a restriction would cause a higher amount of acceptance from the suppliers as they clearly refer to the article's content. In addition such banned substances could be retrieved easily by distinct negative lists.

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<sup>32</sup> Cobalt(II)chlorid can be used as an indicator in silica gel which is used as a drying agent in the packaging. These are no articles but mixtures in a container

Currently within the sector there is a lack of a compilation of articles and materials possibly containing (potential) SVHC. There will be the need for e.g. a standardised platform for suppliers leading to such information. At the moment there are many separate descriptions but no consolidated description on a global basis. The limitations of such solutions can be summed up as following:

- Very often they refer to the final product (as available for consumers) instead of the actual single parts
- Products of highest relevance are covered very often but other possibly concerned products in many cases are not.

Proposals of the companies

An overall description for all sectors of potential SVHC used at the electronics sector and by its supplier industry is missing. A corresponding sector specific list provided by the associations would be helpful.

Comment of the authorities

The preparation of such a list is the duty of the industry.

Whether information from suppliers is easily to access or not depends on the role of the supplier and the supplier - purchaser relationship. Contractual agreements usually only exist one step down in the supply chain. Therefore it is relevant e.g. whether the basis for this cooperation is a long lasting cooperation or it is a supplier of important special products – in these cases information will be easier to access. To receive the information will be more difficult by far if suppliers are integrated in communication by a multi stage process. The same situation occurs if the purchased article is a mass product which composition and contained substances are basically determined by the price and several producers compete on the prices.

The companies do usually have information on materials in parts if the part supplier is directly supplying to the producer of the article. This does not reflect the normal situation within IT-industry. Suppliers of raw material for IT-articles are not known as there is no contractual relationship existing. To interlink a part with a function will also be very difficult to achieve as the decision will be made on an individual basis. There is a lack of criteria and definitions for deciding whether and when a part has a certain function.

It is not easy to get information on the import of articles from the supplier. Access of information on the articles' chemical composition is often restricted. From the company U3 point of view there is also a certain gap in understanding the legal requirements in Europe and the way and the completeness the information has to be submitted. The reference to existing legal requirements supports the request in such a way that at least basic information is provided. However, there is no overall view of all rules, legislations and standards available as they are originating from many fields as there are e.g. environmental protection, climate protection, consumers' protection, waste

legislation, etc. Furthermore they have been conceived for different markets e.g. medicine, automotive, toys, food industry, etc.

#### 5.3.3.2.3 *The 0.1 % concentration limit reference in information enquiry*

The efforts for the companies to enquire information exceeds due to the complexity of the products. Company U4 prepared a compilation of the information to be collected (assuming worst case: full declaration of all substances present in the articles) resulting from the complexity of the articles and the multitude of suppliers (at least 2 suppliers per part).

Table 12: Overview, reference unit und communication request

Reference unit	Number of reference units	communication
Notebook	1	1 article
Sub-assembly (e.g. motherboard)	10	Up to 10 parts containing up to 300 substances
Components (e.g. resistor)	1.000	Up to 1.000 components containing up to 300 substances
Homogenous material	> 1.000	over 1.000 materials in up to 1.000 components containing up to 300 substances

In case not the actual article is used as reference it is a problem to find a suited definition guaranteeing a comprehensible and legally compliant differentiation. What is a part, what a component or a sub assembly and what would be the relevant reference for the 0.1 % threshold in each case? In the electronics sector several articles can be sold separately and always fulfil the definition of an article as such, e.g. a memory extension. The differentiation of the reference unit by its functionality seems uncertain for the companies as this could end up in different interpretations in practice.

In WEEE<sup>33</sup> differentiation has been made by named categories. An external hard disk with an own case is an article whereas a single memory card is not. This approach is comprehensible for the companies.

The existing threshold of 0.1 % of a substance with reference to the homogenous material under RoHS is viewed critically by the companies. In their opinion, this approach is working for simple articles. It is not possible to implement this reference for complex articles which is shown in experiences and discussions up to now on the EU-level. The definition and the differentiation of the homogenous material is difficult e.g. in the case of metallic surfaces on circuit boards.

#### 5.3.3.2.4 *Communication of information*

The role of the interviewed companies primarily originates the obligation to communicate information according to article 33 to their commercial costumers

<sup>33</sup> WEEE: Waste Electrical and Electronic Equipment directive (directive 2002/96/EC)

(trader, retailer). The communication of information to private consumers is operated by specialised traders with handing over the final product<sup>34</sup>.

The following figure exemplifies the communication of information according to article 33 from a trader’s point of view of in the supply chain and the dilution effect on the integration of parts in more complex articles:

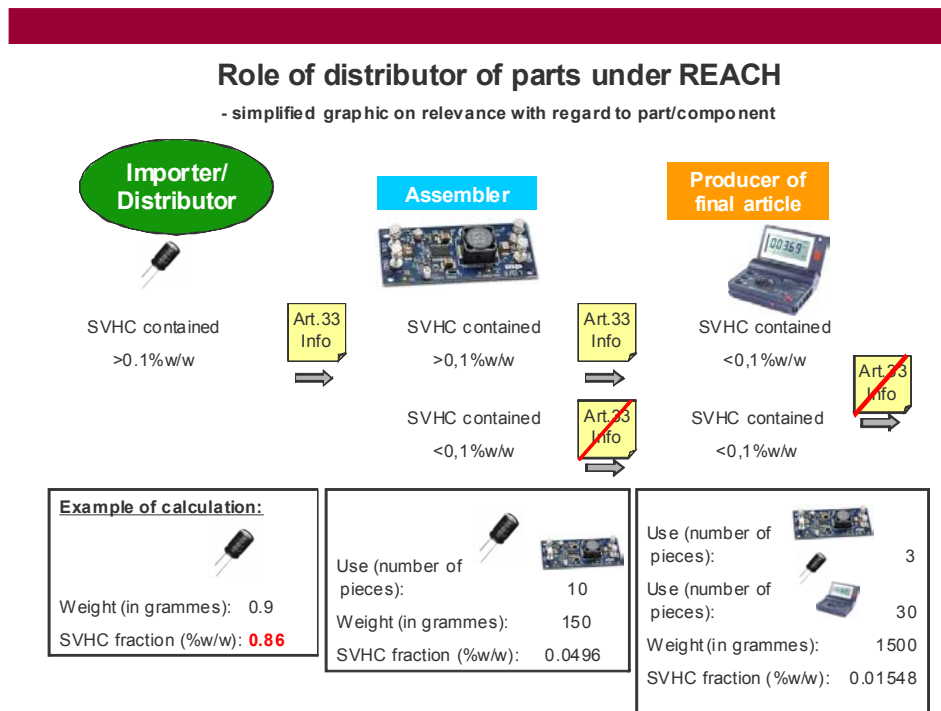


Figure 2: Role of the trader in the supply chain and communication according to article 33

In the sector a common apprehension concerning the communication on SVHC in articles is that companies fulfilling the REACH obligations and giving the information on the substances in their articles will be in a worse position than companies that do not, due to the presumption that a detailed declaration of substances means an exceptionally large amount of SVHC contained.

Especially to companies without trade or brand name (“no name products”) the pressure to comply with REACH obligations is not too strong as in case of an offence the economic loss by damage to the image is not seen as serious. This is considered as a disadvantage by the compliant companies that sell trade marks.

An overall observation of the companies is so far an only marginal request of information on SVHC of the candidate list by consumers. Company U4 is communicating the information to commercial recipients according to article 33 by the use of a link in the product documents and a central English internet website at the moment. It is possible to get information for the final product as well as for the accessories and (spare) parts. A communication in the product information at the moment is not implemented.

The information is related to the existing SVHC candidate list and contains:

<sup>34</sup> On an actual request from a consumer according to article 33(2)

- The name of the article, e.g. “power cable” and also of the packaging e.g. “original packaging toner cartridges”.
- A general note indicating a named SVHC of the candidate list e.g. DEHP may be contained in the article above 0.1 % (w/w). The exact concentration is not declared. The information is given in several languages.
- Name and CAS-number of the substance.

There is also information given that candidate substances are not included. Information on safe handling of the article is not included up to now.

Company U4 additionally provides a separate website with declarations of conformity. This website also contains a link to external websites from producers of parts and accessories also providing information on SVHC.

Problems can occur in case information on updates of the SVHC on the candidate list has to be provided:

- Spare parts are stored in stock for longer periods of time. On changes of the candidate list for these items possibly information updates can not be provided.
- Re-use of articles: there is no information available due to a break within the supply chain.

In the sector various communication and phrase exemplars exist for the communication within the supply chain and to consumers. The phrase exemplars of Bundesverband der deutschen Industrie e.V.<sup>35</sup>, of Zentralverband Elektrotechnik- und Elektronikindustrie e.V., ZVEI<sup>36</sup> and other industry and commercial associations provide sufficient support to formulate communication.

Proposal of companies:

The companies' don't find a need for further phrase exemplars provided by authorities. The major problem of the implementation process to be solved is the new communication requirement on substances in articles for retailer and trade. Still there is a lack of tools and also routine in the communication between the actors. This learning process should be supported by information events and brochures.

The development of a unique format or phrases to be used in different sectors is judged as not reasonable. Specific formats established by each sector are expected to be more fruitful.

The use of stickers giving information like “This article is conform to REACH” is refused by the companies because a REACH conformity is also given in case the article contains > 0.1% of SVHC from the candidate list. Therefore this kind of information is expected to be misinterpreted and would need extra explanations.

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<sup>35</sup> [http://reach.bdi.info/REACH-helpdesk\\_startseite.html](http://reach.bdi.info/REACH-helpdesk_startseite.html)

<sup>36</sup> ZVEI <http://www.zvei.org/index.php?id=3972>

The information supply by stickers stating „Article contains > 0.1% SVHC (substance ABC)“ is expected to be very laborious in practice as with each change of the candidate list an updating would be needed. Therefore an information supply by using an internet website is favoured. In this regard it is seen as problematic that the Guidance on substances in articles (version 1) classed information supply via internet as “not readily available”<sup>37</sup>. This wording is not part of the legal text in Article 33.

Comment by authorities:

Currently at EU level providing of information is interpreted as an activity. This is not the same as publishing information on a website. Thus provision of information in a written form is regarded as an activity. Providing additional information on the homepage of the company or by e-mail could be desirable (see also BAuA brochure REACH-info No. 6 on articles).

### 5.3.3.3 Practical experience with information tools

#### Communication instruments

To guarantee an efficient procedure, the supply chain communication has to be processed automatically. Similar to the automotive industry negative and positive lists<sup>38</sup> of substances are used. They could be part of trade contracts and adapted to the production process if required.

Generally several systems are used to show conformity with existing regulation. This might be first an IT-tool used for the processing of orders, second a merchandise planning and control management and further internal databases for gathering and analyzing suppliers' information. A data format for the transmission of REACH information between producer, retailer and customer is intended to be implemented in case the acceptance by producers is given.

Currently a large variety of different instruments from other sectors is used for information retrieval and retracing of substances, but they are always sector-specific or market-specific - in some cases even company-specific. A really useful solution which solves all needs is not available. Also some system

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<sup>37</sup> Guidance on requirements in substances in articles May 2008: Footnote 30 on page 59:

„As the candidate list is subject to change, a link to a website with up-to-date information could be provided in addition to a paper label. However, a link would not be sufficient since the information is then not readily available.“ The Guidance document is currently under revision. The currently draft version 2.2, from April 2010, specifies on pages 28/29:

The most appropriate format for provision of information may also vary, depending on the content and the addressee of the information. Standard answering letters might be a suitable medium to inform consumers, whereas a professional user might be better informed through separate use instructions.

REACH does not specify a format for providing information according to Article 33; possible formats could for example be:

- modification of existing documents, such as instructions for use and packaging
- information on labels
- link to a website containing up-to-date information
- standard communication formats developed by industry sector associations

In any case, you must choose a format that will ensure that the information is readily available to the recipient of the article or the consumer, always taking into account the particular situation of use.

<sup>38</sup> Explanatory note: Under RoHS, a negative declaration means the substance is used in the article, a positive declaration means the article is free of substances regulated under RoHS.

suppliers' offers exist but they are not harmonized according to the needs of the EEE industry.

Proposal of company U3:

For article-related information according to REACH the EEE industry needs tools. These tools should be characterised as follows:

- Acknowledged and usable on international level, considering all relevant regulations
- Standardised format but nevertheless variable
- Short and precise illustration on concernment, content of respective regulation, concrete examples, enabling legal compliance
- Standardised format for transmission of information
- Easy to use

Gathering of data on substances in articles

For the development and use of a standardized IT-Tool it has to be clarified previously:

- How has to be entered data?
- Which data has to be entered?

Company U5 uses an Excel-tool for the product content declaration. However this is no complete material declaration, but it classes substances as:

- legally banned
- banned from use because of company internal specifications
- reportable.

For the collection of information the following approaches seem to be applicable:

- a) The Joint Industry Guide<sup>39</sup> (JIG, JIG-list) is an industry standard which is not suitable for REACH requirements. Nevertheless it is very helpful to have a harmonized transmission format as provided in IPC 175x. With the extension of the JIG-list a universal data collection instrument will be established similar to the GADSL-list is in the automotive industry
- b) The IEC/PAS 61906:2005 „Procedure for the declaration of materials in products of the electrotechnical and electronic industry“ concerning the electronical transmission of information is valid until 2011 and seems feasible for substance declaration.

A approach comparable to the JIG-list is followed by the Japanese „Joint Article Management Promotion consortium“ (JAMP, <http://www.jamp->

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<sup>39</sup> <http://www.jedec.org/download/search/ACF276.pdf>

[info.com/english/](http://info.com/english/)). Compilation and implementation of these standards mean following requirements for companies:

- Costs for the implementation.
- Different lists are implemented, a harmonisation is missing.
- Some countries have specific lists to be considered (e.g. Bahrain, China, Norway).
- The substance lists used by the sector need a continuous adaptation because of legal changes and the ongoing discussion about substance restrictions.

The companies agree on the fact that the systems IMDS und GADLS are not applicable for the EEE industry.

Result on potential material declaration:

The companies' answers differ on the question of a full material declaration. On the one hand a full material declaration is considered as not workable in the supply chain. It would be impossible to protect company secrets and the amount of data to be collected is presently not manageable.

On the other hand it was admitted that a full material declaration would solve the need to comply with all existing regulations. So far high implementation costs hinder the development of such an international tool so that the implementation couldn't be accomplished so far. Another point to consider is that the interests and requirements within the sector are quite divers. Some companies intend to substitute dangerous substances up to a high degree. Others merely want to comply with the legal requirements.

Proposal of company U4::

In practice companies use a minimum of effort to comply with **REACH** requirements. So the SVHC of the candidate list are compared to substances declared by suppliers by using ordinary Excel-sheets.

For communication on chemical substances in articles along the supply chain, the development of a global format (e.g. xml-standard) is seen as a substantial need for the EEE industry.

#### 5.3.3.4 Communication with surveillance authorities

Declarations of conformity in many cases are not provided because the supplier is not able to confirm information in place of the pre-supplier. Therefore conformity can only be confirmed by process documentation.

A chemical analysis of complex articles is difficult, laborious and expensive. Thus chemical analyses can not be regarded as an alternative. They can be only done as spot check.

Company U5 declares that it means a high administrative effort to sum up the whole tonnage of SVHC because on the one hand many legal entities in EU exist but the import of products is centralized. For ordering, the employees use a common purchasing system. Product components or spare parts are often imported centrally and further distributed to the single legal entities. The centrally registered product information has to be given back into the respective legal entities to calculate the respective tonnage of substances in the articles for the single legal entities.

A control of REACH requirements by authorities currently is not enforced. But surveillance is done under different regulations e.g. Directive on the safety of toys. Documents, certificates of conformity and analysis certificates are not requested by authorities. In case of a conformity check of Article 7 and 33 company U3 would show:

- Producer's declaration
- Own documents like shipping notes, additional information from suppliers
- Documentation and proof of conformity, information according to Article 33, communication with consumers

Company U5 states the CE-conformity not suitable to prove REACH conformity. On the one hand it is used in the EEE sector for final products but not for components or parts. On the other hand conformity is addressed what means the product is considered as marketable. But under REACH in contrast information about SVHC content and on safe use is required.

The companies see it as unrealistic to disclose each violation of Article 33 requirements by enforcement. Single violation can only be disclosed by analysis of single articles. Probably this will be the fact not regarding the relationship between threshold level and entire product or smaller unit.

Therefore a strict self control is seen as the only feasibility to ensure REACH compliance by the companies. At the same time it is expected that competitors who do less efforts gain advantage at the market. Pressing of charges against competitors are not expected. As a relevant impetus for ensuring REACH compliance are seen substitution inquiries from customers and campaigning of NGOs.

From the companies' point of view the main point for enforcement is to examine if REACH requirements are covered by a management system.

Thus embedding REACH requirements entirely into the management system, especially at product purchasing and evaluation of suppliers, is seen as crucial. An option may be the suppliers' qualification as it is done already for product safety reasons.

## 6 SUMMARY

## **6.1 Summary of case studies**

### **6.1.1 Role of importer of homogenous articles**

The case study of homogenous articles illustrates a situation where requirements on the product are mainly defined by the customers (in this case: automotive industry) or by the sector of use (drinking water). Producers of articles have to fulfil these substance-related requirements in addition to technical specifications. This concerns the declaration and the ban of specified hazardous substances. The producer receives the information from his customer and passes it on to his suppliers located in EU and non-EU countries. Because of this communication way the producer of the articles has a limited knowledge about the material but he has no influence on the raw material. Thus he has to rely on the information given in the material database by his supplier. A verification and accurate testing of the concentration of SVHC of the candidate list in the final article could only be done by a chemical analysis. This especially concerns SVHC contained as impurities.

The most important job for the importer under REACH is to learn which SVHC of the candidate list might be contained in an article and whether action is required. It emerged that long lasting vendor relationships are helpful.

In particular the non-EU suppliers showed a strong willingness to cooperate in fulfilling legal requirements. Another advantage in the implementation process is a material database from the automotive sector already used by the company. This now could be used for other products, too. It is also used for internal and external documentation purposes. In case of control of REACH conformity by enforcement authorities the company would prefer a system check instead of a spot check of single articles.

### **6.1.2 Role of importer of less complex articles**

In the case of import and trade of less complex articles (awnings) the importer requires the specification “no SVHC from the candidate list in the articles” from his suppliers.

For awnings no substance-related specifications from other product-related regulations exist. Information gaps on potential SVHC contents are closed by direct request to non-EU suppliers. The distributor anticipates that information according to Article 33 is given by EU suppliers without further request. The company ensures compliance by purchase contracts and evidence of substitution. This would be shown to enforcement authorities. Additionally own analyses are made to verify the information received from suppliers. The documentation is made by the use of a company-owned database.

### **6.1.3 Role of importer of complex articles**

The substance-related requirements for complex articles arise from product-related regulations as well as from customer-specific demands.

A problem identified in the implementation process on SVHC from the candidate list in articles was the prospective growing candidate list. It is not obvious which substances would be added next, so components and parts need to be checked continuously. This requirement is seen as more laborious than requirements presently arising from WEEE and RoHS. The substance bans of these regulations include less substances and substance groups and are changed only in the course of a revision.

The access to information and the data collection in a 5-7 step supply chain with only non-EU suppliers is described as difficult and laborious. Additionally the importers indeed have influence on the technical specification but less influence on the material. Especially at the level of material the access to reliable information is difficult because the suppliers quote business secrets and patents. Because of this situation a detailed detection of SVHC in the final article is difficult. Currently the companies find it difficult to implement a full material documentation in the global supply chain. But a start is made by an international accepted standard for declaration.

In case of a checking by enforcement authorities the companies would show declarations of conformity from producers and analysis certificates.

For surveillance authorities declarations of producers would not be sufficient. From this point of view, importers never can be sure of having received the full information. If public available information foreshadow that SVHC of the candidate list may be contained, it can be reasonable to have run an own analysis to attend to the duty to take care<sup>40</sup>.

## **6.2 Conclusion**

### **6.2.1 General aspects**

In general it can be said that knowledge on the content and the precise concentration about dangerous substances and particularly SVHC of the candidate list is in the interest of producers and importers. The access to this information is essential to act legally compliant. This includes information on SVHC of the candidate list > 0.1% but also substances with defined thresholds regulated under RoHS or REACH Annex XVII. Apart from these regulations the information is needed to fulfil customer-specific requests or requirements which go beyond that.

Information on substances is also needed to define and implement internal company-specific environmental goals. In the consumer sector of brand products the knowledge about problematic dangerous substances is a prerequisite to avoid product recalls or scandals. The complexity of the article does not matter.

### **6.2.2 Information and communication along the supply chain**

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<sup>40</sup> See also reach-clp helpdesk, REACH –Info 6: Articles: Demands to producers, importers and retailers. [http://www.reach-clp-helpdesk.de/cdn\\_094/reach/de/Publikationen/REACH-Broschueren.html](http://www.reach-clp-helpdesk.de/cdn_094/reach/de/Publikationen/REACH-Broschueren.html)

The case studies and the discussions with different actors from different levels of the supply chain showed that a simplified supply chain communication as assumed under REACH is not real life practice so far. This results from globally branched supply chains, different requirements, and the companies' influence on the product design.

Basically dangerous substances can be brought into the article from different sources. They could be brought into as:

- Constituent of raw-materials or pre-products or
- Result from the production process or own synthesis steps or the use of process auxiliaries and as
- Impurity in pre-products, own synthesis steps or the use of process substance und auxiliaries.

As a source of information the producer's knowledge of the article on impurities, additives, chemical reaction during the production process can be used.

Another source would be the information given by pre-suppliers.

But even in case of an existing communication flow between importer and non-EU suppliers substance-related information may get lost. Most significant point is the transfer of substance respective mixture to an article: from here on the access to information on substances used is limited. Even within the EU supply chain difficulties exist because also under REACH safety data sheets are only generated for dangerous substances and mixtures, but not for articles.

Information is getting lost even the more the use in an article attenuates the SVHC: the use in a material, the integration into components and further into the final complex article. If a material or component is incorporated into a complex article and the concentration limit of 0.1% (w/w) relating to the whole article falls below this, information is no longer disseminated along the supply chain. The information on the single components about exceeding the 0.1% limits for example in case of a re-use of components is not available any more.

The kind of information depends on the requirements. It is essential to know if the 0.1% limit is exceeded. A detailed knowledge about the exact concentration is needed to be able to calculate a possible exceeding of the tonnage limit above all articles containing the respective SVHC (Article 7 (2) notification).

General information about the use of dangerous substances is needed to meet customer-specific demands and to prepare for the extension of the candidate list or for substitution.

Also now the dissemination of information on SVHC of the candidate list is closely associated with the obligation to provide customers with information on safe use. This necessitates collecting information about the substance's release behaviour to allow an exposure assessment. Up to now this is not yet in the focus of the companies.

The access to information is different with the companies interviewed in the case studies. Importers can only ask directly their direct suppliers. A supplier who is not resident in EU doesn't have to fulfil REACH requirements. A passable approach – in particular for retailers - is to source only articles

produced in the EU. That delegates responsibility to EU suppliers. In practice it would not be possible to implement this way of purchase area-wide. Also it is not considered as possible and sustainable by the companies.

The experience made by the companies interviewed so far showed that in the majority of cases there is no difference between European and Asian producers regarding the access to information on technical product quality and on SVHC content. The main difficulty mentioned was at retracing information on substances.

The kind of access companies have to get reliable information is crucial. This depends on the influence a company has on the product design, on the effort it needs to get the information and the costs to collect and document this information. This is independent of the issue on how to apply the 0.1% limit – on the material, the part or the complex article.

The findings of the case studies showed that access to get reliable substance-related information from non-EU suppliers depends on the situation in the supply chain. Two main categories have to be differentiated:

### **Producer with full design control**

This kind of producer is in the position to define product specification along the whole supply chain. This includes the ban of defined substances which is mainly communicated by “Black lists“. This approach demands a continuous check and updating of the lists about banned substances or at which concentration a declaration is needed according to the legal requirements and expert discussions. The use of „White lists“, denominating permitted substances needs a very detailed knowledge about production processes in the supply chain. In addition these producers can define the communication format or tool.

This approach also requires a quality management system which allows checking of the defined specifications. This may include a supplier certification or the analysis of products.

This kind of full design control only exists in very few cases e.g. the automotive sector or aviation industry. Currently full design control often ceases with the definition of technical specification. In particular mass production parts with low function requirements like screws are not covered.

### **Importer or producer buying off the shelf**

This kind of actors doesn't give any or only few specifications on the use of substances to suppliers. They have to gather information on content and concentration of SVHC by using chemical analysis or plausibility check. This is in particular needed if suppliers don't want to provide information or information given is not reliable. This often happens when non-EU suppliers have to be asked or production levels with low transparency and variable sources of parts and pre-products are involved. The check by using chemical analysis of articles needs a targeted approach concerning the frequency of spot checking and the

scope of testing e.g. the testing of mixed samples from components or specific parts of the article. This requires knowledge about a potential content of SVHC in certain parts or materials. The assessment of suppliers can be used supportively.

In practice a mixture of both positions can be found especially regarding the knowledge of substances used within the supply chain.

### **6.2.3 Conformity and surveillance**

Due to the complex communication, the multiplicity of traded goods and the complexity of legal requirements on the EU and the global market it appears impossible to the companies to confirm conformity of each single article and to check it by analytical means.

It is estimated more important to establish good or best practice processes in the company. This requires a good basis of knowledge about legal requirements in the companies and the awareness of individual responsibility as an essential prerequisite for REACH conformity. Only then also non-EU suppliers can be informed adequately and trained if necessary and the information flow can be developed effectively.

The implementation of full material declarations for all article categories is expected to be not realistic because it would be too laborious. The use of positive and negative lists is regarded as a practical instrument for communication purposes.

Another relevant aspect of REACH conformity is the company policy as well as the implemented quality management system. At this point the decision is made whether a company is going to identify its obligations and to act legally compliant and which tool it would use for this. Also it has to be decided whether the company will merely fulfil the REACH obligations – this means to identify relevant contents of SVHC and communicate them if higher than 0.1% – or if it will be going further. The latter requires the possibility to influence suppliers. Further requirements could mean to require always less than 0.1% SVHC in the article or a substitution with less dangerous substances. The catalyst for such a strategy often is the trade of branded consumer products.

Further market actors exist without influence on the product design who only buy off the shelf (no name products). In this sector neither pressure from selling a branded product exists nor there seems to be a realistic possibility of area-wide surveillance. Scandals as already known with brand products don't pressure this kind of actors to act conform to REACH.

In the opinion of authorities it can be assumed that in case of an offense against Article 7 or 33 no wilful misconduct would exist if documentation of good practice and a working management system were kept. By rectification of deficiencies conformity to REACH can be achieved.

On the other hand authorities don't have much room for manoeuvre than to report offences whether wilful or not. In case of wilful misconduct prosecution takes place.

## 6.2.4 Support for importers

It is fundamental for the implementation of REACH that companies have basic knowledge on REACH and product conformity. This requires trained staffs.

Especially for small and medium sized trading enterprises this often is difficult to manage. Also the legal text and the technical guidance documents of ECHA are difficult to understand for non-experts who did not have to deal with EU legislation about chemicals before.

For this reason further support is expected from authorities regarding information on compliance with legal standards. This concerns both interpretation on EU-level on the definition of an article and the enforcement of the application of the 0.1% threshold. Additional support is expected from associations in the respective sectors. A general guideline for all product lines is estimated as not yielding the desired results. Guidelines should be short and precise and also branch-specific. They should allow the actor to recognize his obligations easily.

As it is consensus between the actors that individual responsibility is the key guidance should give information on substances possibly contained in articles or materials and about communication with suppliers.

A general problem recognized both by authorities and companies is that relating SVHC of the candidate list to articles (or materials) often is difficult. This concerns as well actors who have to identify possibly relevant substances in the articles as authorities who need this information to disclose offences. Here both sides need information on the materials SVHC can be found in at all. This information is provided in the supporting documents or in Annex XV dossiers. These are not easy to understand for everyone though and therefore are often not useful in practice.

As a good approach to orientation on where to find possibly SVHC the companies mentioned the information provided by Wirtschaftskammer Österreich (WKÖ) in their leaflet „Infoblatt Anwendungsgebiete zur Zulassungskandidatenliste“<sup>41</sup>. Meanwhile also ECHA gives such kind of information together with the announcement on new entries into the candidate list<sup>42</sup>.

Table 13: example of an overview on uses and where to find possibly SVHC of the candidate list

Substance	Use (WKO <sup>43</sup> , ECHA <sup>44</sup> )
Bis (2-ethylhexyl)phthalate (DEHP)	Broadly used as plasticizer in PVC and other plastics (rubber, latex), in paints and varnishes, adhesives, fillers, toner paints and pigments, dielectric fluids in condenser, sealant and filler, lubricants, solvent specialties

<sup>41</sup> [http://portal.wko.at/wk/format\\_detail.wk?AngID=1&StID=399531&DstID=31](http://portal.wko.at/wk/format_detail.wk?AngID=1&StID=399531&DstID=31)

<sup>42</sup> See ECHA Press release 13. Januar, ECHA/PR/10/01

<sup>43</sup> Translated from: „Infoblatt Anwendungsgebiete zur Zulassungskandidatenliste“ der Wirtschaftskammer Österreich ([http://portal.wko.at/wk/format\\_detail.wk?AngID=1&StID=375582&DstID=31](http://portal.wko.at/wk/format_detail.wk?AngID=1&StID=375582&DstID=31))

<sup>44</sup> ECHA Press Release ECHA/PR/10/01: [http://echa.europa.eu/doc/press/pr\\_10\\_01\\_candidate\\_list\\_20100113.pdf](http://echa.europa.eu/doc/press/pr_10_01_candidate_list_20100113.pdf)

Substance	Use (WKO <sup>43</sup> , ECHA <sup>44</sup> )
	Use in articles: in soft PVC articles (about 30% w/w), cable coating, PVC profiles, foils of all kinds, in plastic toys (banned in concentrations of >0.1% of the material!!), floorings, artificial leather (car seats, furniture, shoes and boots, rain coats, plastic boots), cars (e.g. cavity sealing), medicinal devices (blood bag) and so on...
Hexabromocyclododecane (HBCDD) and all major diastereoisomers:  Alpha-hexabromocyclododecane Beta-hexabromocyclododecane Gamma-hexabromocyclododecane	Use as: flame retardant in polystyrene, expanded polystyrene (EPS, Styrofoam®), Extruded polystyrene foam (XPS, Styrodur®), high impact polystyrene (HIPS);  upgrading agent for textiles (flame retardant finishing)  Use in articles: especially article made of polystyrene e.g. insulation board; HIPS is often used as isolation of electrical components (telephone, TV) and also for commonly used articles like CD-cover

At large, regarding the correlation of SVHC to materials and articles laboratories are expected to play an important role on knowledge and experience about the relevance of SVHC. But also sector knowledge about substances used to produce materials and articles should be published. The allocation of substance to materials and articles currently done within the framework of a UBA project is regarded as very important for a future implementation<sup>45</sup>.

Table 14: example of an overview on an allocation of potential SVHC of the candidate list to materials

Material	SVHC
Plastic	Anthracen, 4,4'- Diaminodiphenylmethan (MDA), Bis(2-ethylhexyl)phthalat (DEHP), Benzylbutylphthalat (BBP), Dibutylphthalat (DBP), Cobaltdichlorid, Hexabromocyclododecan (HBCDD)
Metal	Cobaltdichlorid, Diarsentrioxid, Natriumdichromat

Bigger retail companies already make use of the service provided by laboratories by either assigning their own or charging external services. It has to be pointed out that as a prerequisite the actor has to be already aware of the fact that an analysis is necessary. Many products are already tested on technical performance or quality. A chemical analysis in some cases would mean only little additional work and expenses. Whether analysis is done at all mainly depends on the margin of profit (the difference between price of the good and production costs).

<sup>45</sup> UBA-Projekt: "Kanzerogene, mutagene, reproduktionstoxische (CMR) und andere problematische Stoffe in Produkten - Identifikation relevanter Stoffe und Erzeugnisse, Überprüfung durch Messungen, Regelungsbedarf im Chemikalienrecht", FKZ 3707 61 300

## 7 IMPLEMENTATION IN PRACTICE

In practice it seems hard for many companies importing or producing articles to establish a sustainable strategy for the implementation of the REACH requirements. Thus the next chapter should be used as a guideline for the first steps to implement the new obligation into the operative everyday life.

### 7.1 How can I - as a company - ensure REACH conformity?

The implementation of REACH conform behaviour regarding article handling can be seen as a multistage process in which the responsible person has to answer a set of questions. This could ensure to take up the resulting jobs and solutions into operative structures.

### 7.2 Roles and obligations in the context of articles under REACH

For the decision whether your company acts REACH conform, you first have to clarify unambiguously which responsibilities and obligations your company is subject to. In the beginning of such an analysis of concernment the identification of all REACH roles resulting from the company's activities has to be made. From the roles result responsibilities which are closely related to with corresponding obligations. The kind of these obligations depends on the products and their composition. With regard to substance-related requirements in articles the following activities and roles are relevant:

Table 15: article related role and requirements under REACH

Activity	Role	Potential requirements
Does the company produce articles within the EU? If so, does your company sell these articles to: <ul style="list-style-type: none"> <li>• Commercial customers (B2B)?</li> <li>• Consumers?</li> </ul>	Producer of articles	<ul style="list-style-type: none"> <li>• Notification of SVHC acc. Art. 7(2)</li> <li>• Registration of substances intentionally released from articles acc. Art. 7(1)</li> <li>• Information on SVHC acc. Art. 33(1)</li> <li>• Information on SVHC acc. Art. 33(2)</li> </ul>
Does your company buy articles or components or parts from non-EU suppliers? If so, does your company sell these articles to: <ul style="list-style-type: none"> <li>• Commercial customers</li> </ul>	Importer of articles	<ul style="list-style-type: none"> <li>• Notification of SVHC acc. Art. 7(2)</li> <li>• Registration of substances intentionally released from articles</li> </ul>

Activity	Role	Potential requirements
(B2B)? • Consumers?		acc. Art. 7(1) • Information on SVHC acc. Art. 33(1) • Information on. SVHC acc. Art. 33(2)
Does your company trade with articles within the EU (no non-EU import)? If so, does your company sell these articles to: • Commercial customers (B2B)? • Consumers?	Trader of articles	• Information on SVHC acc. Art. 33(1) • Information on. SVHC acc. Art. 33(2)

It seems to be obvious that obligations to register substances which are intentionally released from articles will only be relevant for few producers and importers of articles. This applies only in case of an intentional release of a substance according to Article 7(1) (example: perfumed textile). Some products generally regarded as article do not fulfil the definition of an article under REACH. A “release” from a container is no intentional release as described above but the use of a chemical (substance or mixture). The substances have to be registered according to Article 6 (example: writing pens).

This question has to be answered very carefully because an offence against this obligation as seen as a serious one.

In the following we focus on obligations according to Article 7(2) and 33 with regard to substances in articles without intentional release.

### 7.3 Exclusion of REACH obligations regarding substances in articles

As a producer or importer of articles you may be subject to notification or information obligations to ECHA and to the obligation to provide information to customers. As a seller of articles you bear the responsibility for the substances contained in your articles and are subject to the resulting obligation of giving information to your customers. Whether and to which extent the obligations have an effect depends on the products and the kind, the concentration and the number of constituents.

The challenge for the roles mentioned before regarding the REACH conformity includes the identification and implementation of the respective obligations or – and this would normally be the objective – the definite exclusion of article-related obligations.

Table 16: Question to exclude article related REACH obligations

	Question	Meaning	Recommendation
A	Do you know your role(s) under REACH?	Only if you have clearly identified the role of your company you can be sure to classify your responsibilities and obligations accurately. In particular distributors become importers by purchasing articles from non-EU suppliers with potential additional requirements.	Clarify and document role(s) accurately
B	Do you know the chemical composition of your articles and their components and spare parts?  Can you exclude that articles produced or imported contain SVHC from the candidate list in concentrations more than 0.1%?	The more details you know about the composition of your raw material and products the more certain you can identify SVHC resp. exclude the content of SVHC. But under REACH it is not necessary to know all ingredients and the exact concentration (except for registration obligations).	If you don't know the exact composition by means of other regulations or activities go on with questions D to G
C	Can you plausibly exclude due to the material composition that your products contain SVHC?	In general SVHC are added because they have to fulfil a specific function in the respective material e.g. plasticiser in PVC or rubber or brominated flame retardants in flame protected plastics. If these functionalities do not pertain to your article the SVHC may be only contained as an impurity.	Find out which functionalities and uses of SVHC may be relevant for your articles
D	Are you sure due to existing product related requirements which are kept already verifiable that no SVHC in concentrations of > 0.1% are contained?	Many products underlie already extensive legal or voluntary requirements which interfere with REACH requirements or even go beyond them e.g. Foodstuffs and Consumer Goods Law and voluntary label Oekotex 100. In this case the implementation ensures REACH conformity, too.	Ascertain which substance related requirements are fulfilled already and which interference with REACH requirements occurs
E	Can you positively exclude due to suppliers' information SVHC from the	The easiest way to ensure REACH conformity would be on the basis of supplier's information.	Include REACH requirements to your supply contracts

	Question	Meaning	Recommendation
	candidate list in concentrations > 0.1 % are contained in your articles?	But you have to decide on your own authority about the reliability of this information. Nobody can discharge you from your responsibility as a producer, importer, or supplier.	
F	Can you positively exclude due to chemical analysis SVHC from the candidate list in concentrations > 0.1 % are contained in your articles?	Analysis may be one option to ensure legal conformity but normally a comprehensive and complete control is too laborious and costly.	Have product analysis made as spot testing or in case of doubt about points C to F
G	Do you collect the amounts of articles produced or imported in a way that enables you to calculate the tonnage of ingredients per annum?	In case you are subject to obligation to register (B) or to notify (C-G) so this would apply from an amount of > 1 t/a per substance	If relevant, collect weight and number of all articles concerned

Only few companies would be able to answer question B with a clear „yes“. A complete documentation of the composition of complex articles of an extensive product portfolio would be very laborious. Often it would not even be feasible because information on composition from the supplier is not available or the information is declared as business secret. But it has to be noted that collecting complete information on the composition would not be needed for the implementation of requirements according to Article 7 (2) and 33. In many cases it would be sufficient to answer Question E in combination with C, D and F to ensure REACH compliance.

Generally declarations of supplier’s conformity (E) are standard in purchasing contracts inside and outside EU. But a supplier’s declaration in written form alone does not ensure REACH conformity sufficiently. A producer, trader or importer of articles will be responsible even in case of a false declaration. For to cope with this responsibility you have to occupy yourself with your suppliers, articles and material for the purpose of Questions C and D at least so far that you are able to evaluate the declaration’s plausibility and reliability. In case of doubt you would have to test (F) the article. But for this a decision has to be made about material to be tested and the substances to be analysed.

In this way European producers and traders purchasing their raw material or articles inside EU compared to non-EU importers can benefit because their European suppliers are subject to the same obligation of communication as themselves. Importers of articles can’t refer to such binding legal regulations but nevertheless have to comply with Article 7(2) and 33 even if they don’t have any access to information on used raw materials and production processes.

## **7.4 Requirements for management systems**

An analysis of companies' concrete obligations (producer, importer and trader) will often lead to the result that no action is necessary at the moment. Presently under the given conditions only few articles will be concerned because an analysis will lead to the conclusion that they fall below the 0.1% limit.

But even if at the moment there are no obligations to fulfil under Article 7(2) or 33 companies will have to comply also in future. Therefore it doesn't make sense at all to run an extensive analysis of all products regarding SVHC for only one time. The challenge would be to establish a system which is suited to check and document REACH conformity on a regularly or continuous basis. This would need a system that considers the changes of the candidate list as well as the changes in article composition or product portfolio.

Such a system has to fulfil the following requirements:

- Transfer of REACH obligations to requirements and objectives on articles and communication in the supply chain
- Definition of article-related specifications for purchase, research and development which are suited to achieve these objectives
- Collection of all relevant ingredients contained in articles and raw material (by information from suppliers or own analysis)
- Internal dissemination of information and documentation
- Gathering of incoming information on parts and materials of sold articles in order to implement product-specific obligations
- Development of formats or standards for purposes of communication with customers

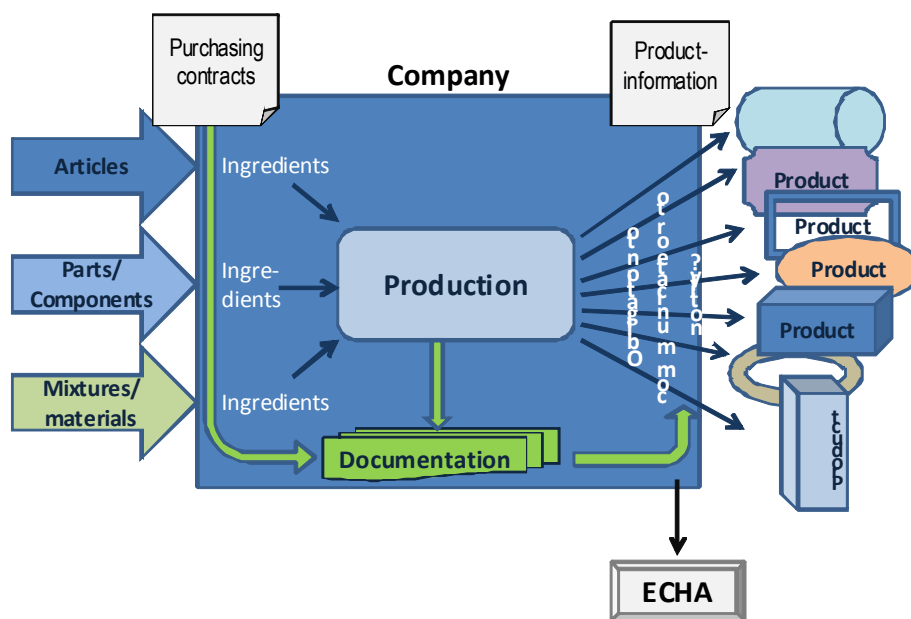


Figure 3: management of information on substances in articles

Most of those questions are not new. They are subject in many companies in the frame of product safety or quality assurance. Companies already have to collect substance-specific information because of legal requirements (e.g. substance restrictions) or customer requirements (e.g. list of declarable substances as used in the automotive industry).

The question arises how strongly a company wants to influence actively the composition of the raw materials or parts used in order to avoid any article-related obligations under REACH or to avoid refusal by customers because of substance content. Concerning the product it has to be sorted out whether such activities are communicated to the customers even though there is no obligation to do so.

The approaches to ensure REACH conformity can be found in management systems as e.g. quality management systems or environmental management systems already implemented in many companies. The way the collection and the further processing of substance-related information have to be done depends on different factors. Many tools as e.g. elementary Excel-data sets or complex databases are applicable and available.

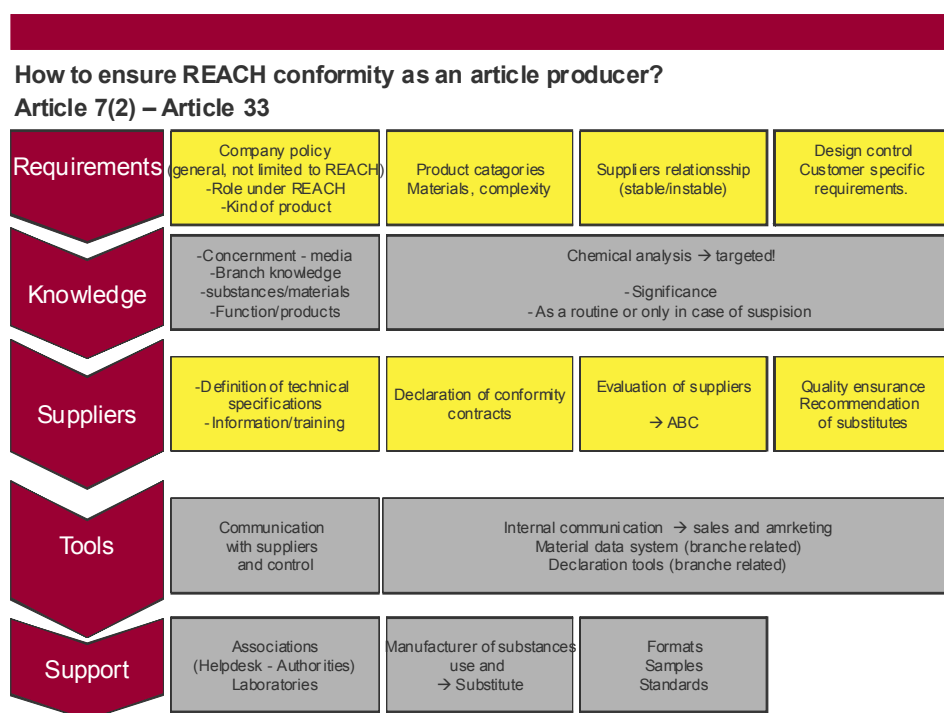


Figure 4: Overview on topics to consider in the development of a systematic building block approach

An important finding from the case study work of this project is certainly that a “one-size-fits-all approach” for all branches and companies does not exist. Moreover, each company has to find out for itself what is needed, what tools are at hand, and what is appropriate to ensure legal compliance and to assume the responsibility as article producer, importer or trader. Potential modules are shown in the figure above. These modules normally are not utilised by only one person in the company but by cooperating of responsible persons of purchase, sales and distribution, and product safety divisions.

1. Step: Evaluation of range and complexity of REACH requirements and concernment of articles

The range and complexity of requirements depend on the complexity of the products and the supply chain:

complexity	Very high	high	middle	low
Number of parts	> 1000	100-1000	10-100	< 10

Complexity article	high	middle	low
Steps of processing	>5	3-4	1-3 (M-F-DU <sup>46</sup> )
Number of pre-suppliers	>100	10-100	<10

<sup>46</sup> M = Manufacturer of substances, F = Formulator of mixtures, DU = Downstream User

<b>Complexity of supply chain</b>	<b>high</b>	<b>middle</b>	<b>Low</b>
globality	Import of final article	Import of components	Import of only raw material

Also the number and variability of product parts may increase the effort for the documentation. Short time product cycles will be a challenge for each update. The higher the complexity and the effort for documentation is estimated the higher are the needs for a suited documentation system.

For each type of article the potential relevance of SVHC for the functionality of the final product should be considered in an early stage of the product development (see also Question C above). Often an intended use of SVHC can be limited to few materials where they can be registered and analysed. SVHC contained as impurities for many materials can be excluded if the process is known and controlled.

## 2. Step: Analysis of tools available

In a second step a company should evaluate the existing procedures, requirements, documentation tools, and databases in order to fulfil the REACH requirements:

- Which substance-related requirements are already implemented and how can the procedure be adapted to REACH requirements with reasonable effort?
- How reliable is information provided by suppliers? How competent are the suppliers? Are the relationships with suppliers stable or rather changing? Which consequences do violations against contracts have for the suppliers? Which experiences were made in the past?
- Are there any ongoing discussions on substances used in the product which can be seen as a hint on problematic substances e.g. plastic additives already identified as CMR substances, additives used in lubricants which are persistent?
- Are merchandise management systems and control management systems or register of hazardous substances available that are applicable to map substance-related requirements for parts or materials? Can these systems be used for negotiations with suppliers?
- Are substance-related requirements or questions already implemented in the R&D process? A subsequent reduction, substitution or detection in the final products generally needs more effort!

## 3. Step: Completion by branch knowledge and branch methodology

In case the company does not hold own instruments or tools which are suited and reliable knowledge on materials and relevant substances is missing you should ask branch associations or other organisations for help and initialize an exchange of information. Your competitors and also your suppliers and customers have to answer the same questions. Also consultants and in some cases laboratories offer individual support. Associations and authorities, as

done in this project forums, offer support to find and develop fitting tools which will only be realized if a great number of companies share the process.

Often this would not lead to an overall solution in the first step but it should be helpful to identify the real problems and to achieve more safety in assessment and decision-making. It is obvious that, if you don't achieve at least to get an overview to the potential ingredients of your articles and consequential implications, in the long run you will not be able to ensure legal conformity neither with REACH nor with other product-related requirements.

## 8 ABBREVIATIONS

AgBB	Health-related Evaluation of Emissions of Volatile Organic Compounds (VOC and SVOC) from Building Products
B2B	Business to Business
BAuA	Federal Institute for Occupational Safety and Health, German: Bundesanstalt für Arbeitsschutz und Arbeitsmedizin
BBP	Benzyl butyl phthalate
CARACAL	Competent Authorities for REACH and CLP
CAS	Chemical Abstracts Service
ChemG	Act on the Protection against hazardous substances, German: Chemikaliengesetz
Chemsec	The International Chemical Secretariat
CMR	Carcinogenic, mutagenic or toxic to reproduction
CPD	Construction Products Directive
DBP	Dibutylphthalat
DEHP	Bis (2-ethylhexyl)phthalate
DU	Downstream User
DVGW	Deutscher Verein des Gas- und Wasserfaches e. V. - technisch-wissenschaftlicher Verein
ECHA	European Chemicals Agency
EEE	Electrical and Electronic Equipment
EPDM	ethylene propylene diene Monomer (M-class) rubber
EPS	Expanded polystyrene
ES	Exposure Scenario
ETUC	European Trade Union Confederation
EU	European Union
FDA	US Food and Drug Administration
FRS	Flame retardant substance
GADSL	Global Automotive Declarable Substance List
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GATT	General Agreement on Tariffs and Trade
GPSG	German Equipment and Product Safety Act, German: Geräte- und Produktsicherheitsgesetz
GS	Safety Tested, German: Geprüfte Sicherheit
HBCDD	Hexabromocyclododecane
HIPS	high impact polystyrene
IEC	International Electrotechnical Commission
IMDS	International Material Data System
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JAMP	Joint Article Management Promotion consortium
JIG	Joint Industry Guide
KTW	Kunststoffe im Trinkwasser (plastics in drinking water)
MCCP	Middle Chain Chlorinated Paraffins
MDA	4,4'- Diaminodiphenylmethane

NBR	Nitrile Butadien Rubber
PAH	Polycyclic Aromatic Hydrocarbons
PBT	Persistent, bio-accumulative and toxic substances
PEG	Partner Expert Group
PELD	LDPE, Low density polyethylene
PFOS	Perfluorooctanesulfonic acid, perfluorooctane sulfonate
POP	Persistent Organic Pollutants
PVC	Polyvinyl chloride
ROHs	„Restriction of the use of certain hazardous substances“; Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment 2002/95/EC
SCCP	Short Chain Chlorinated Paraffins
SDS	Safety data Sheet
SIN	Substitute It Now
SVHC	Substances of Very High Concern
TBT	Agreement on Technical Barriers to Trade)
TBTO	Bis(tributyltin)oxide
TU	Trade Union
UBA	Federal Environment Agency, German: Umweltbundesamt
vPvB	Very persistent and very bio-accumulative substances
VwfG	German: Verwaltungsverfahrensgesetz
WEEE	Waste Electrical and Electronic Equipment; Waste Electrical and Electronic Equipment Directive (WEEE Directive 2002/96/EC)
WKÖ	Wirtschaftskammer Österreich
WTO	World Trade Organisation
XPS	Extruded polystyrene foam
ZVEI	German: Zentralverband Elektrotechnik- und Elektronikindustrie e.V.