



Bundesanstalt für Arbeitsschutz
und Arbeitsmedizin

Federal Institute for Occupational Safety and Health (BAuA)

Articles under REACH - Information Flow from Producer to Consumer

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Webinar "Compliance Digital October 2021: Simplified corporate communications about SVHCs in articles", AskREACH, UBA, 21 October 2021

Articles under REACH - Information Flow from Producer to Consumer

Part 1 of the talk:

Basics of the information obligation

Article 33 (1) & (2):

Definitions

Scope of application

Information Obligation in the Supply Chain under REACH

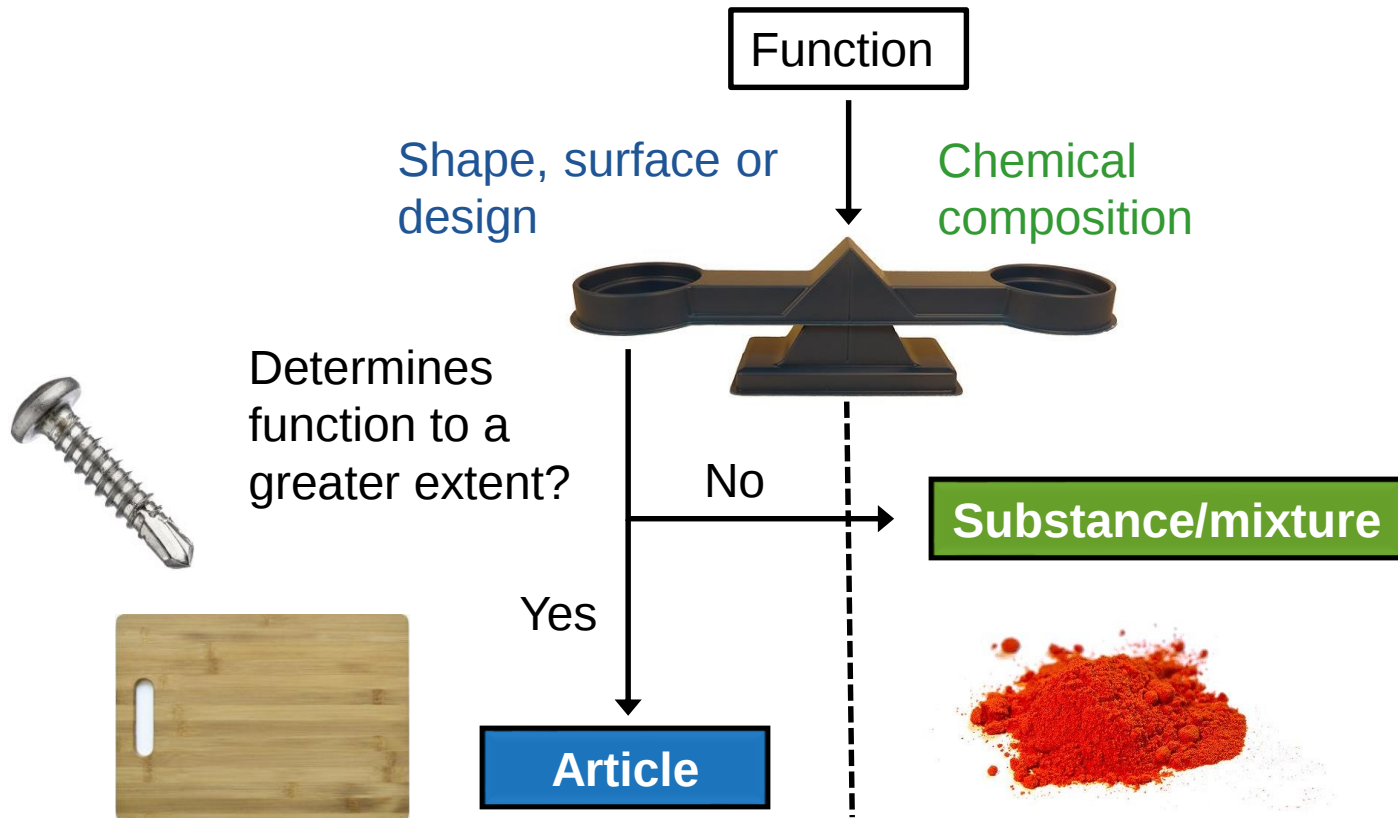
Article 33 (1), analogous

Any supplier of an article containing SVHC > 0.1 %, shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of the substance.

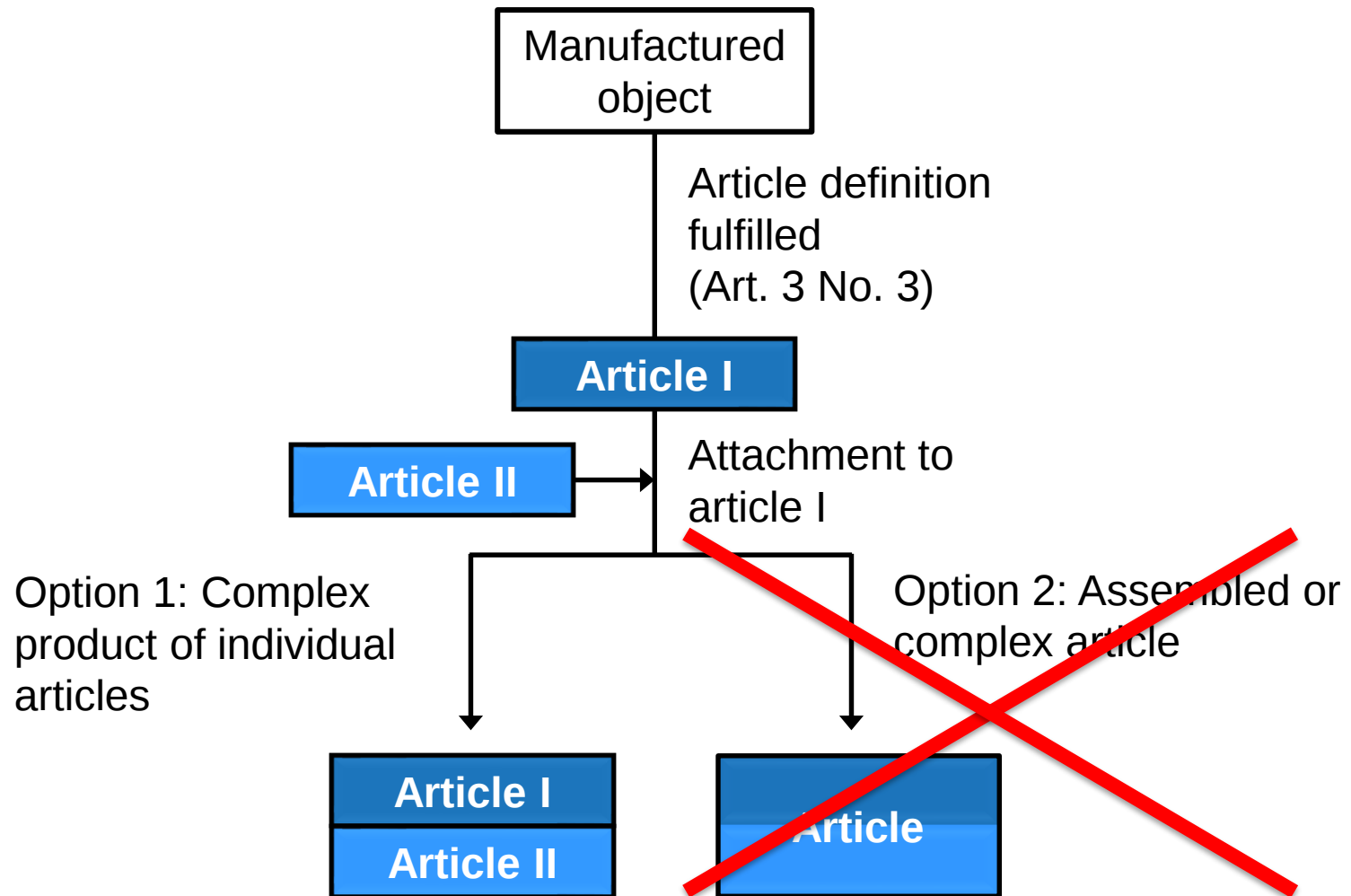


What is an Article?

Article 3 No. 3: means an object which during **production** is given a special **shape, surface or design** which **determines its function** to a **greater degree** than does its **chemical composition**



Articles in a Complex Product



Once an Article - always an Article

ECJ judgment case C-106/14:
"Once an article - always an article"

Object remains article, even if joined with others, unless...

1. Article becomes waste according to Directive 2008/98/EC

2. Article definition (Art. 3 No. 3) is no longer fulfilled

Article

Article?

End of article status



Candidate Substance (SVHC)

- Substance identified as being of very high concern (Art. 57):
 - Carcinogenic, mutagenic or toxic for reproduction (CMR) category 1A / 1B
 - Persistent, bioaccumulative and toxic (PBT)
 - Very persistent and very bioaccumulative (vPvB)
 - Equivalent level of concern single case substance
- Inclusion in candidate list according to Article 59 procedure



Candidate List

Page 1 of 5

50 Items per Page

Showing 1 - 50 of 209 results.

← First

Previous

Next

Last →

Substance name	EC No.	CAS No.	Date of inclusion	Reason for inclusion	Decision	IUCLID dataset	
Dibutylbis(pentane-2,4-dionato-O,O')tin	245-152-0	22673-19-4	25/06/2020	Toxic for reproduction (Article 57c)	D(2020)4578-DC		
Butyl 4-hydroxybenzoate	202-318-7	94-26-8	25/06/2020	Endocrine disrupting properties (Article 57(f) - human health)	D(2020)4578-DC		
2-methylimidazole	211-765-7	693-98-1	25/06/2020	Toxic for reproduction (Article 57c)	D(2020)4578-DC		
1-vinylimidazole	214-012-0	1072-63-5	25/06/2020	Toxic for reproduction (Article 57c)	D(2020)4578-DC		
Perfluorobutane sulfonic acid (PFBS) and its salts	-	-	16/01/2020	Equivalent level of concern having probable serious effects to human health (Article 57(f) - human health) Equivalent level of concern having probable serious effects to the environment (Article 57(f) - environment)	ECHA_01_2020.pdf		
Diisohexyl phthalate	276-090-2	71850-09-4	16/01/2020	Toxic for reproduction (Article 57c)	ECHA_01_2020.pdf		

Notes:

- Authentic version:** Only the Candidate List published on this website is deemed authentic. Companies may have immediate legal obligations following the inclusion of a substance in the Candidate List on this website including in particular Articles 7, 31 and 33 of the REACH Regulation.

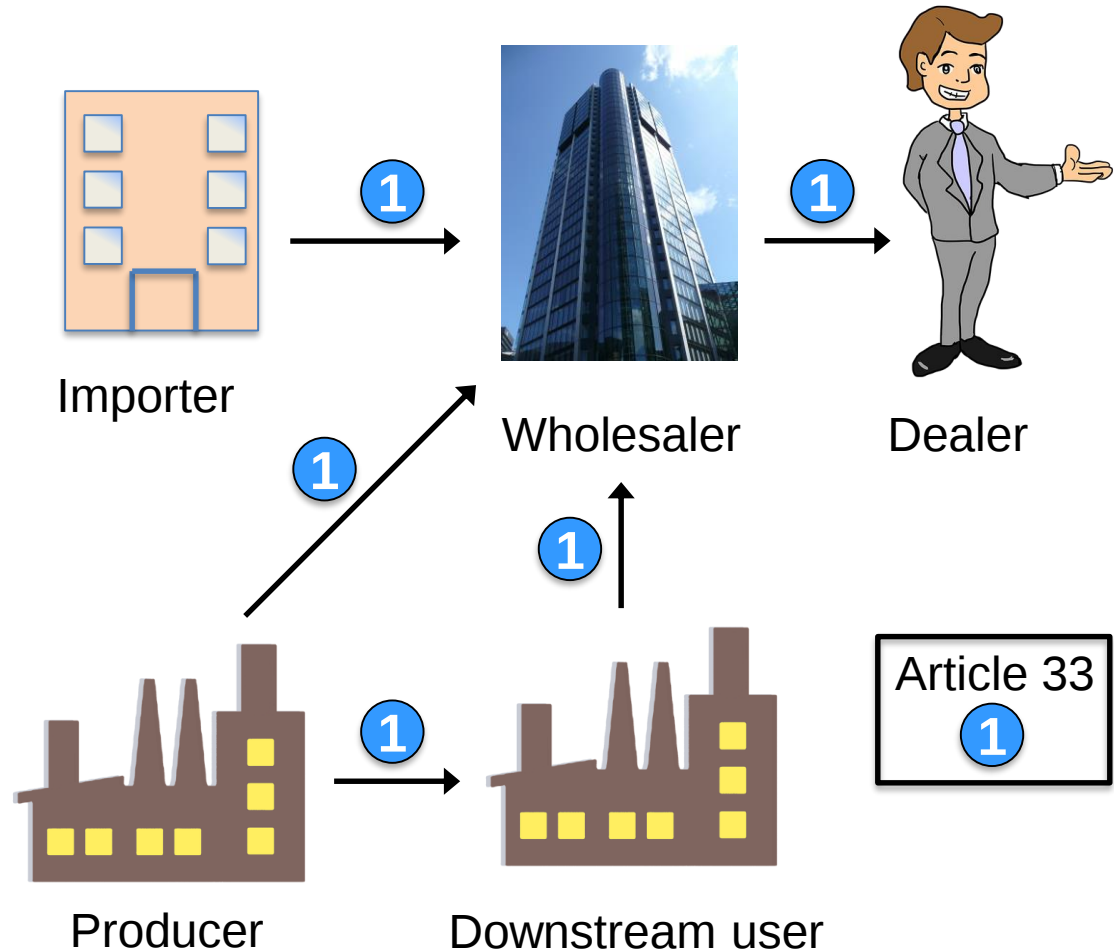
<https://echa.europa.eu/de/candidate-list-table>

Supplier & Recipient of an Article

Article 3:

Supplier...: any producer or importer of an article, distributor or other actor in the supply chain placing an article on the market

Recipient...: industrial or professional user, or a distributor, being supplied with an article but does not include consumers



Right to Information for Consumers - Art. 33 (2)

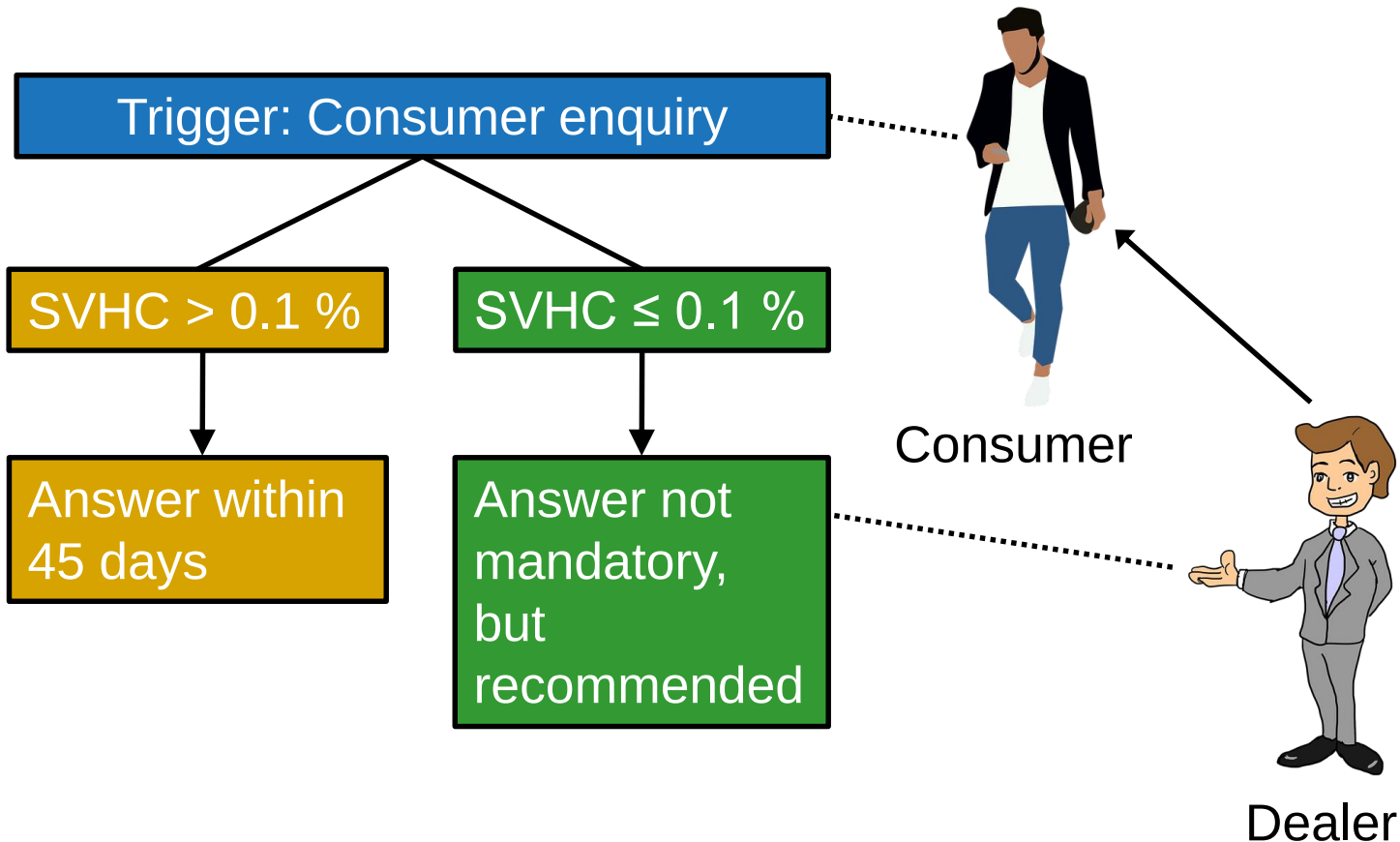
Deviations from
Art. 33 (1)

Article 33 (2), analogous

On request by a consumer any supplier of an article containing SVHC > 0.1 % shall provide the consumer with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.

The relevant information shall be provided, free of charge, within 45 days of receipt of request.

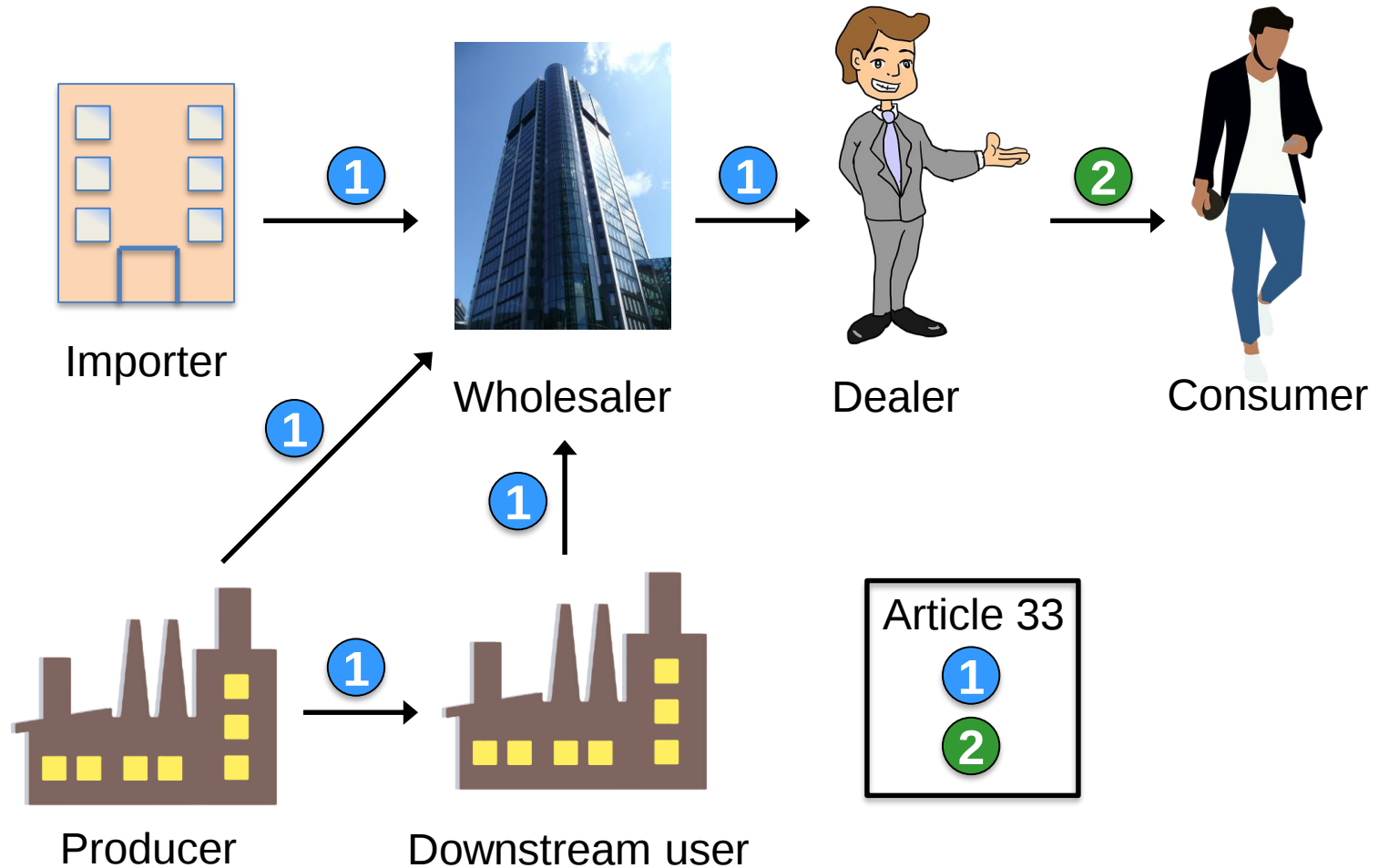
Right to Information Art. 33 (2)



No possession of the article necessary for enquiry

Information Obligation Art. 33 - Supply Chain

European Economic Area (EEA)



Content of Article 33 Information

Article 33 (1) & (2)

provide [...] with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.

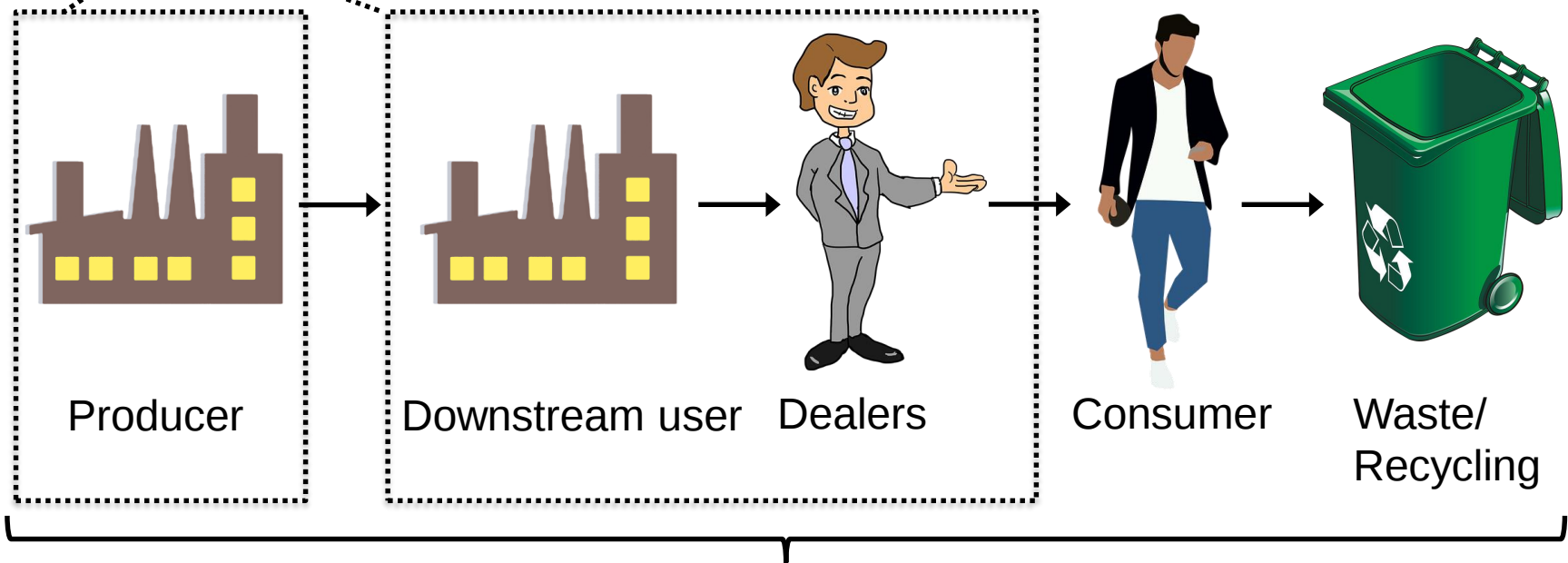


Content of Article 33 Information

1) SVHC name

2) Available, sufficient information on safe use:

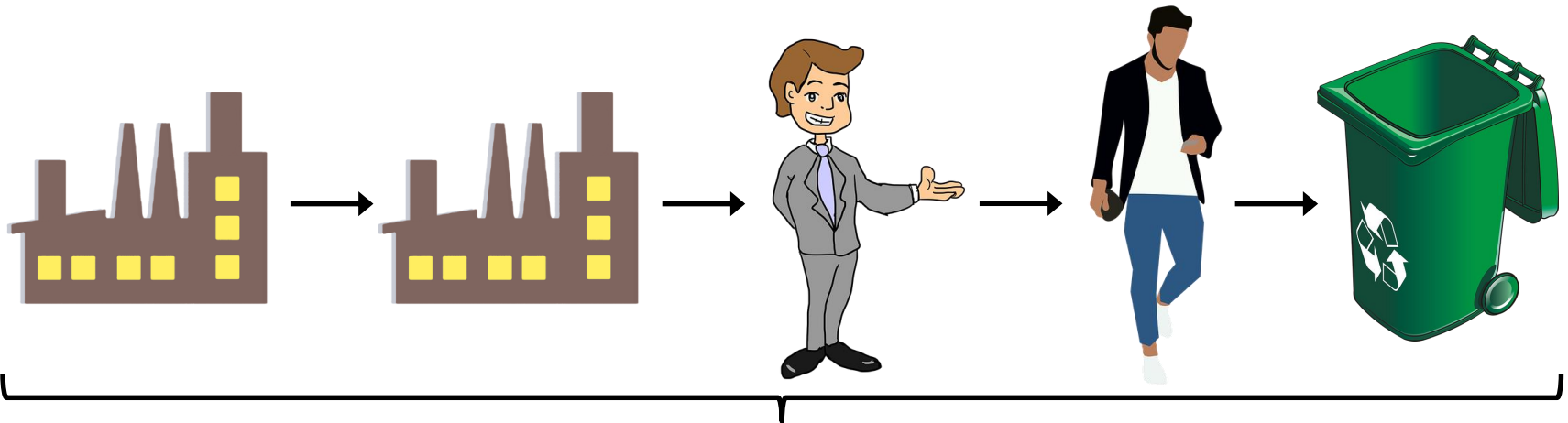
- First actor considers all foreseeable steps/activities
- Other actors supplement additional information



- Entire life cycle (e.g. further processing, storage, end use up to waste/recycling)

Content of Article 33 Information

- For each step in the life cycle, the following information may be included:
 - a) Conditions of use (temperature, frequency, duration...)
 - b) Risk reduction measures to avoid exposure
- Case-by-case consideration: the aim is safe use of the article (tailor-made information)
- Conclusion: **SVHC name is not necessarily sufficient**



- Entire life cycle (e.g. further processing, storage, end use up to waste/recycling)

Articles under REACH - Information Flow from Producer to Consumer

Part 2 of the talk:

Information obligation (Article 33) in practice:

Reference

Group entries

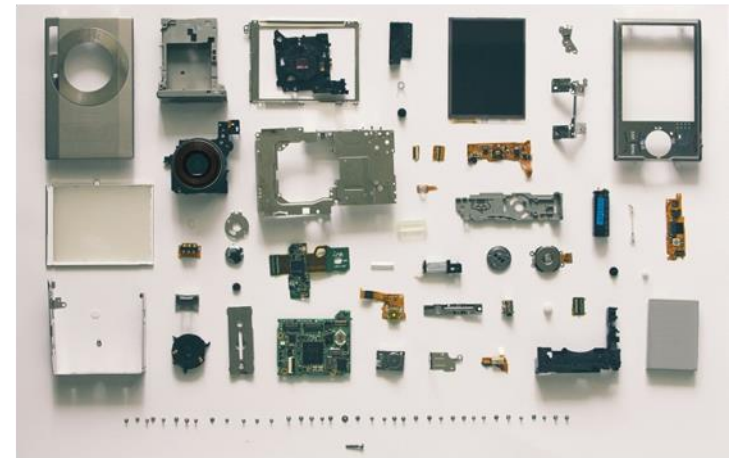
Communication channel & language

Recommended approach

Candidate list

Reference of SVHC Content

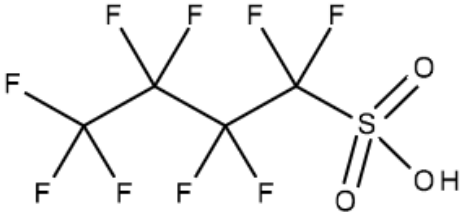
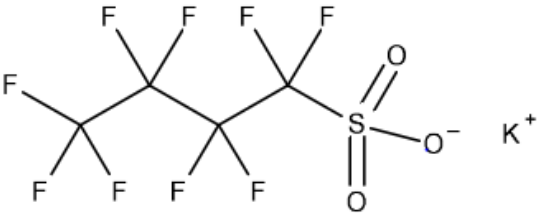
- ECJ judgement (2015): **Single article** is **reference value** for **SVHC content** and not complex product



- ⇒ Information on **each individual article** to recipient/consumer (if SVHC > 0.1%)
- ⇒ Information must clearly identify the article concerned: (e.g. screw "X" contains lead instead of camera "Y" contains lead)

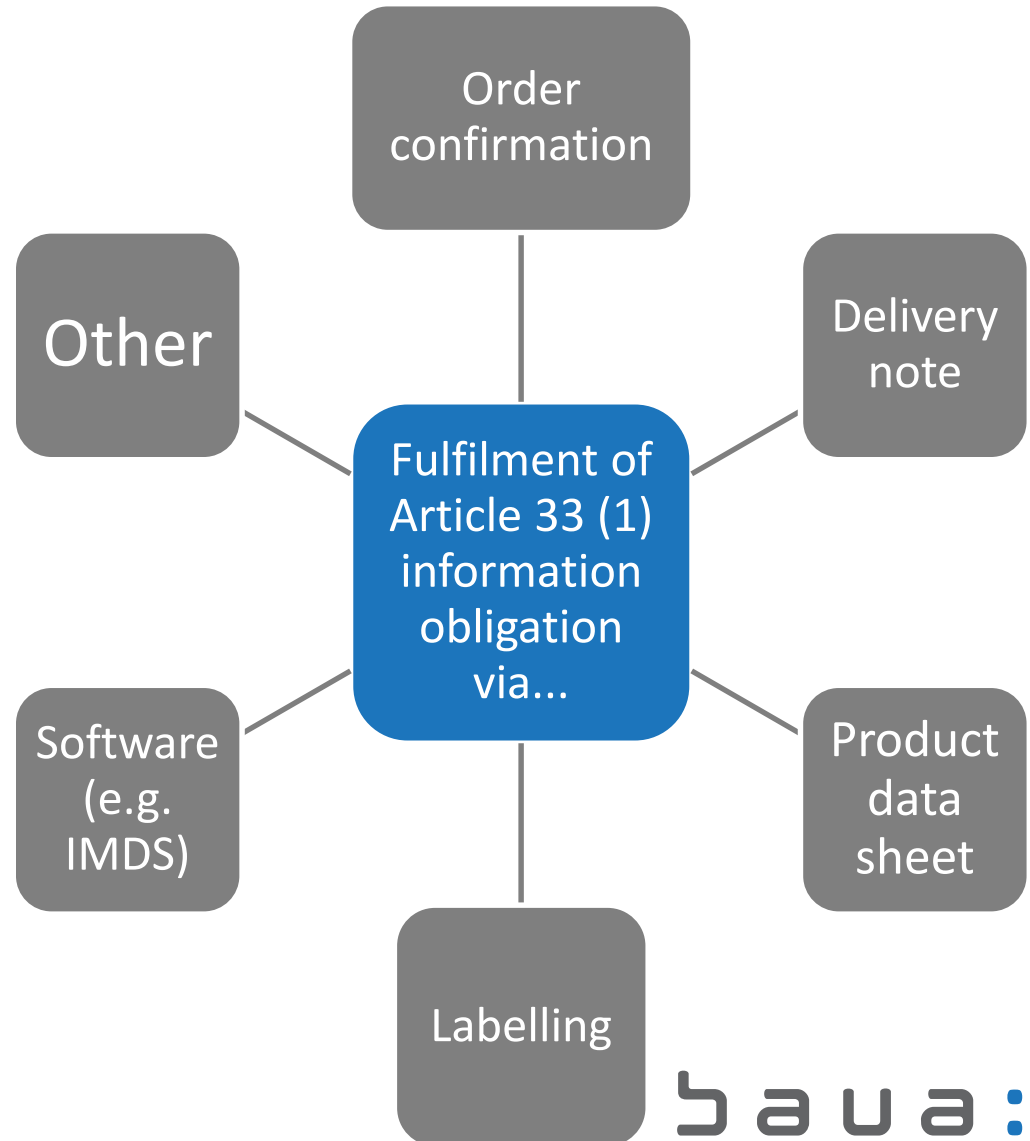
SVHC Group Entries & Limit Value

- Candidate list includes 219 entries, but **more substances covered by group entries**
- **Limit value of 0.1 % applies to individual substance**, no addition of the mass fractions of individual substances of a group
 - E. g. perfluorobutane sulfonic acid (PFBS) and its salts

PFBS		Case 1 0.6 % 	Case 2 0.06 % 	Case 3 0.06 % 
Potassium perfluorobutanesulfonate		0.06 % 	0.6 % 	0.06 % 
Art. 33 obligation?				

Communication Channel and Language

- REACH Regulation: no specification of communication channel & language
 - Publication on the Internet insufficient
 - For consumer: national language
 - For company: national language or language for regular correspondence



Recommended Approach in Supply Chain

- Duty applies from inclusion in candidate list, **no transition period**
- **No minimum number of articles**
- Example: Screw with > 0.1 % lead (SVHC inclusion **27.06.2018**)



EEA
producer



Dealer

- **Every actor in the supply chain must comply with the information obligation, even if the upstream supplier does not inform & SVHC > 0.1 %**

Supply:

28.06.2018

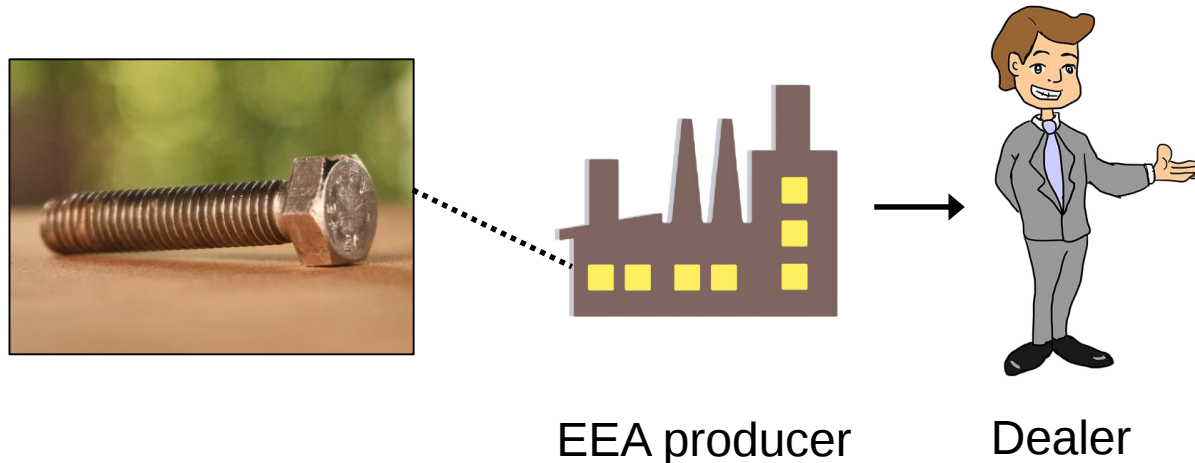
01.08.2018

Art. 33
obligation?

Yes

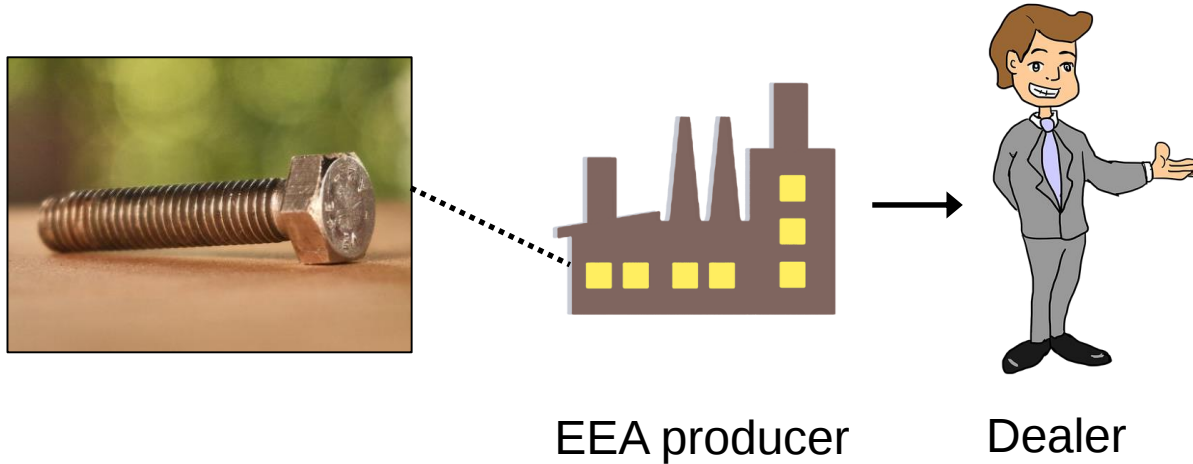
Yes

Recommended Approach in Supply Chain



- Ex. 1: Dealer purchases screws from EEA producer for the first time
 - Helpdesk recommendation: **Ask** EEA producers if **Art. 33 obligation is known**
 - Case-by-case examination: **Information** or non-transmission **plausible?**
 - Are there **SVHC suspicions**? E.g. SVHCs in similar articles, media reports, new scientific findings, etc.

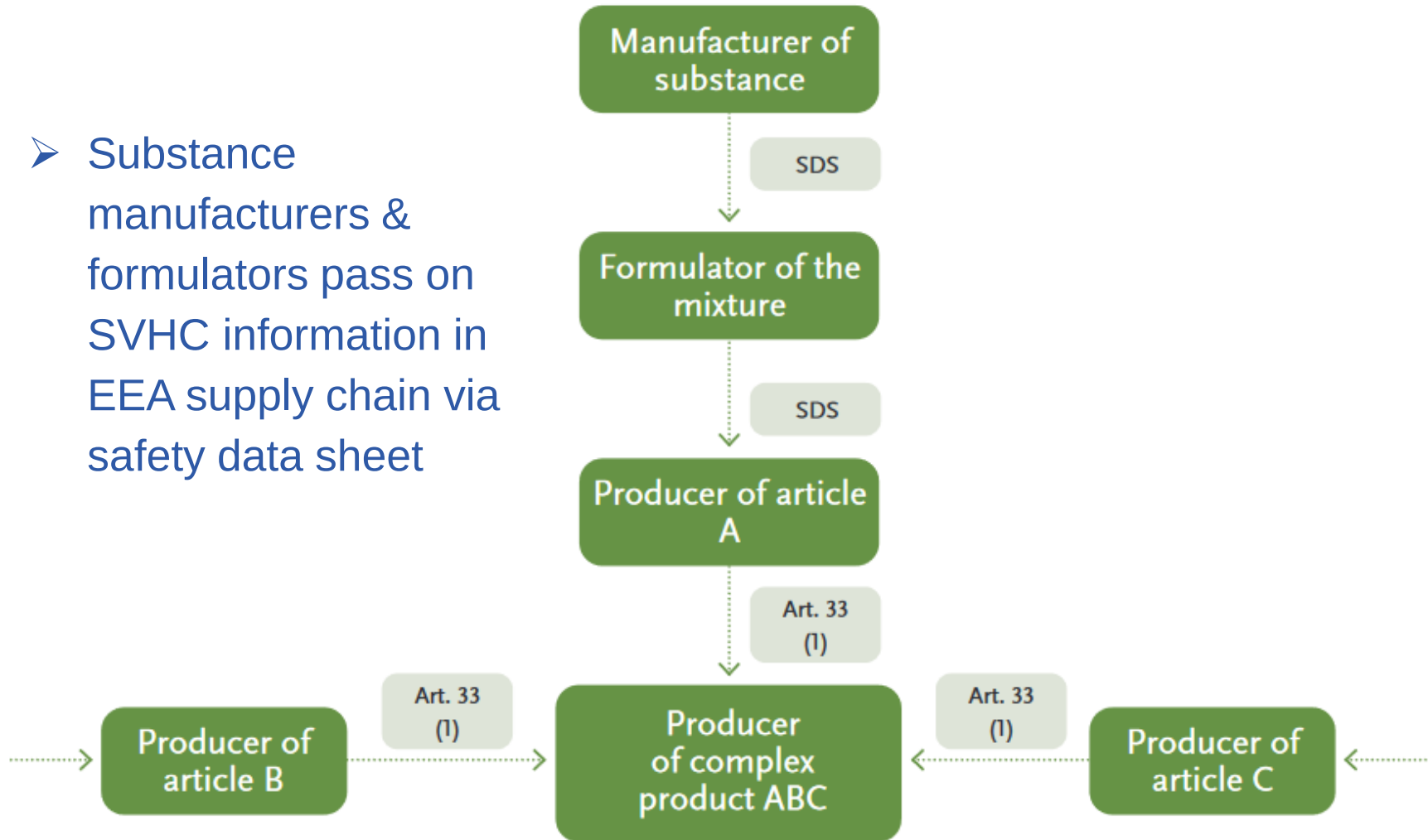
Recommended Approach in Supply Chain



- If EEA producer knows REACH obligations & there is no SVHC suspicion, no further action required
 - **Without suspicion, regular enquiries** with suppliers, who know REACH are **not recommended**
 - **Documentation useful** as proof for enforcement authorities

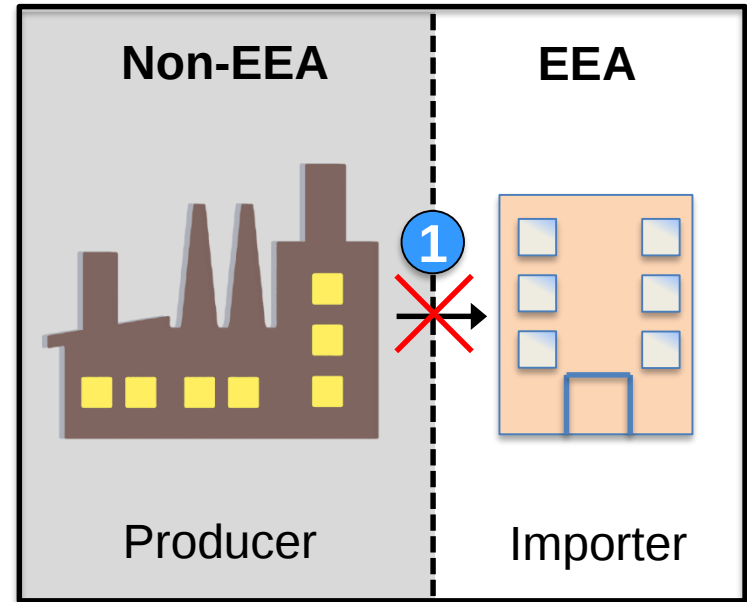
Recommended Approach in Supply Chain

- Substance manufacturers & formulators pass on SVHC information in EEA supply chain via safety data sheet



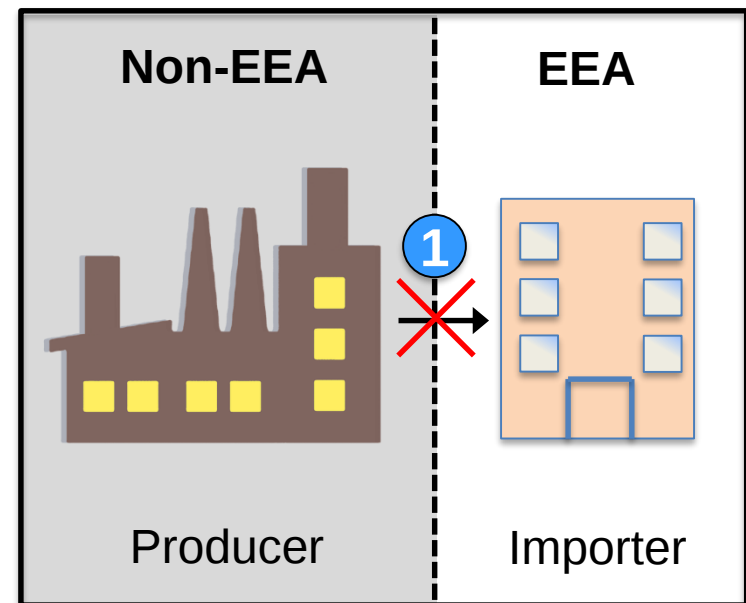
Recommended Approach in Supply Chain

- Ex. 2: Import from **non-EEA producer (not subject to REACH, but EEA importer)**
 - Recommendation: **Contact** non-EEA producer
- If no (helpful) information is received (including plausibility check & SVHC suspicions):
 - **Own considerations** on possible SVHC:
What materials are contained in the articles the product is made of?
Which SVHCs are to be expected? Check use areas of SVHCs:
<https://echa.europa.eu/de/information-on-chemicals>



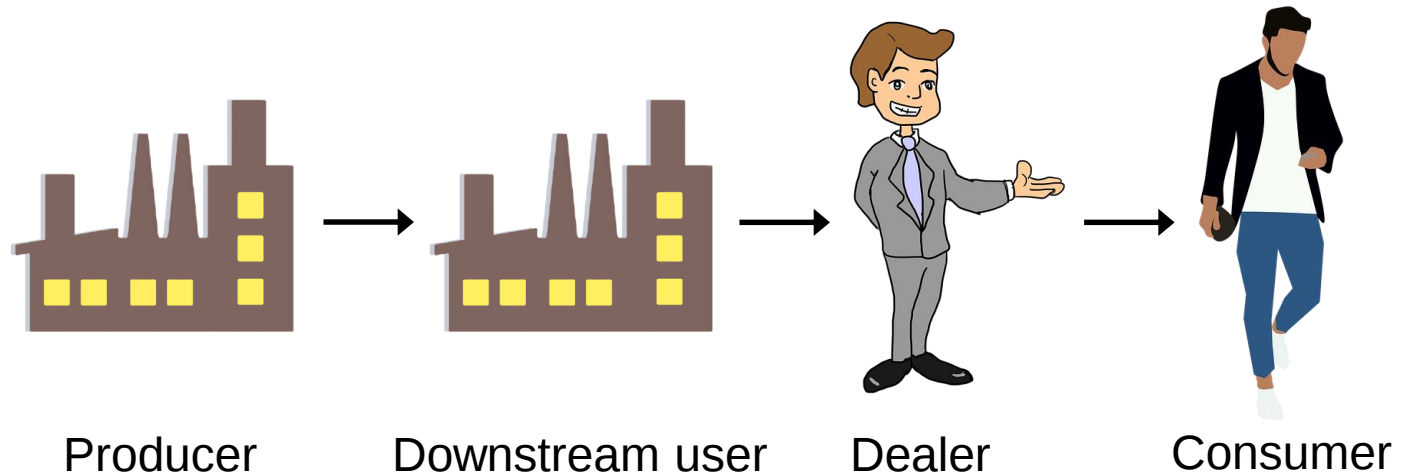
Recommended Approach in Supply Chain

- E. g. steel screw: Only a few SVHC are to be expected in concentration $> 0.1\%$ (e.g. lead)
- E. g. soft plastics: Plasticisers such as phthalates possible
- **Chemical analysis is last resort:**
Recommendation: Limit analysis to relevant SVHCs
- Alternative solution: **Contractual agreement with supplier** on SVHC information



Candidate List - Supply Chain Impact

Ex.: Lead (inclusion in candidate list 27.06.2018)



- **No retroactive duty to inform** after candidate list update
- Recommendation: Nevertheless inform
- Stock goods particularly affected

Candidate List - Consumer Enquiry

Ex.: lead (SVHC inclusion
27.06.2018), consumer submits
enquiry 01.09.2018

Duty to provide
information on
lead?

Reason

Case 1: Enquiry before purchase

Yes

Possession of the
article not required

Case 2: Enquiry after purchase
on 01.08.2018

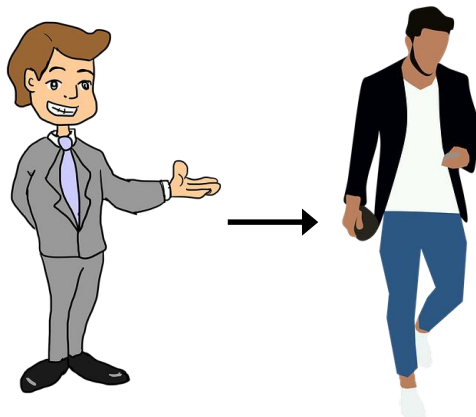
Yes

Enquiry after SVHC
inclusion

Case 3: Enquiry after purchase
on 01.12.2017,
dealer stopped sale 2017

No

As sale has been
discontinued,
relevant SVHC list
refers to time of
supply. Supply
before SVHC
inclusion



Article 33 (1) vs. (2) - Summary

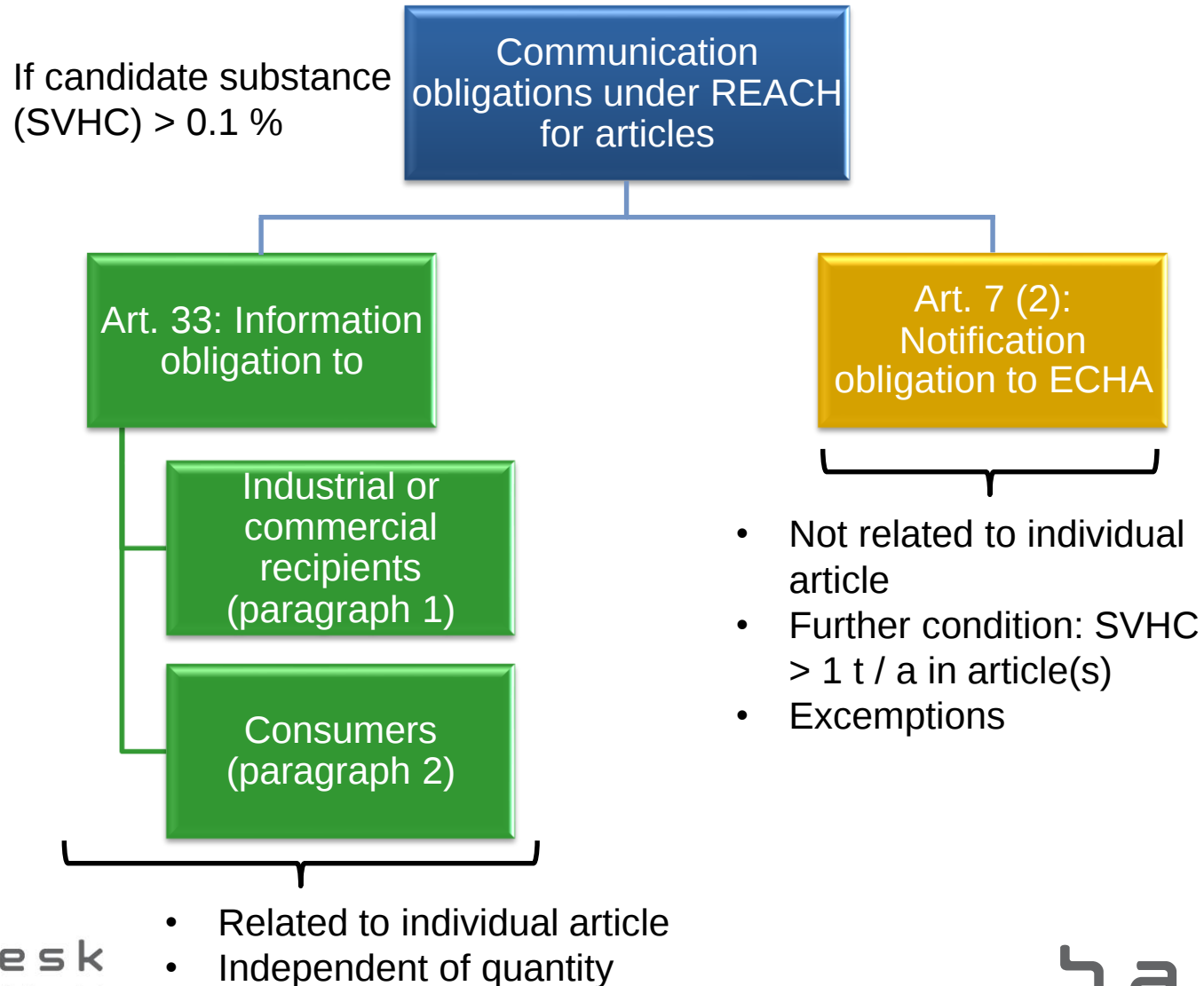
	Art. 33 (1)	Art. 33 (2)	Differences
Addressee	Industrial or commercial recipient	Consumer	
Trigger	Supply (at the latest with the first)	Enquiry (response within 45 days)	
Condition: SVHC content			Similarities
> 0.1 % (w/w) in the article			
Responsible			
Article supplier			
Content	SVHC name & available sufficient information for safe use		
Candidate list	Time of supply or enquiry (without supply)		
Transition period	None		
Number	No minimum number, i.e. from one article onwards		
Communication channel	Not specified		

Articles under REACH - Information Flow from Producer to Consumer

Part 3 of the talk:

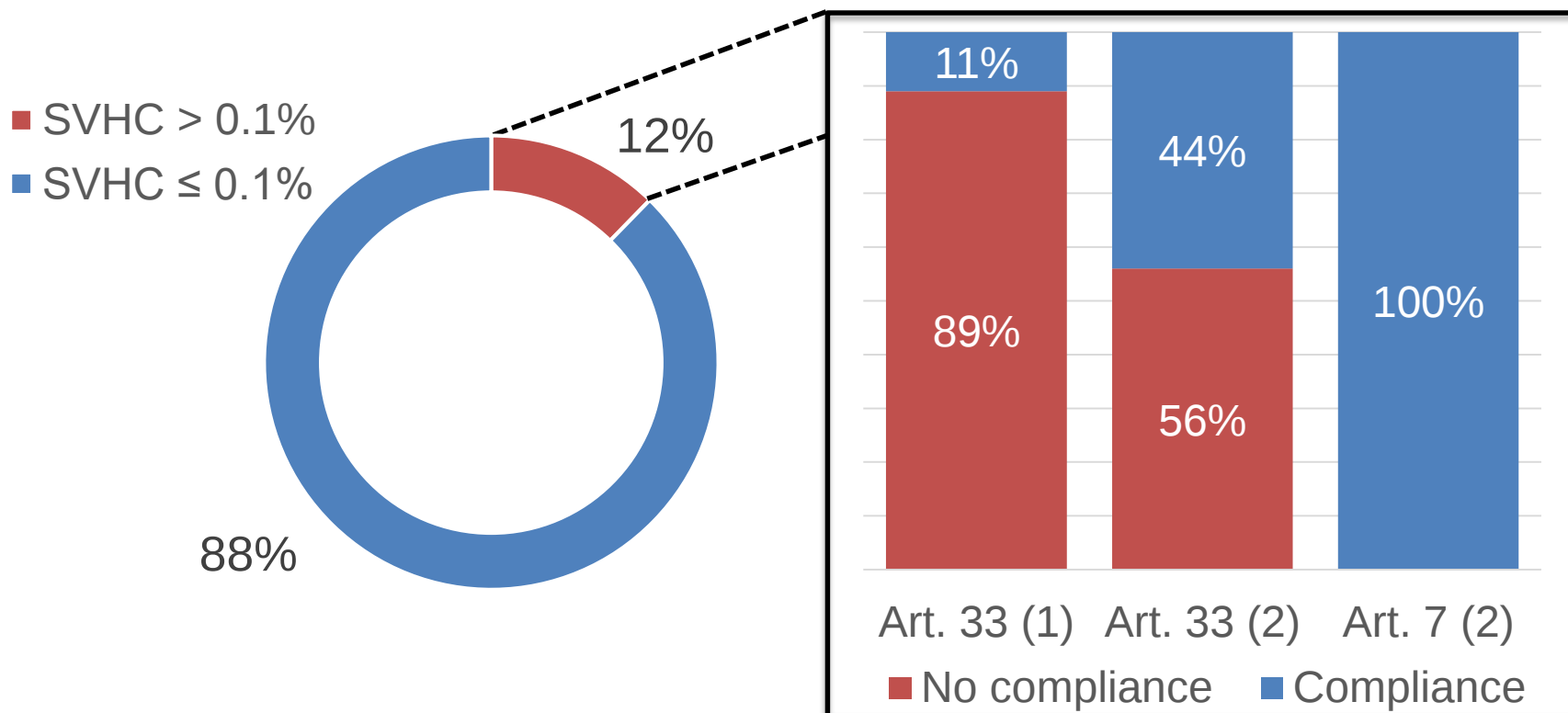
- **Further communication obligation for articles: Notification obligation Art. 7 (2)**
- **Results of the enforcement project**

Communication Obligations under "REACH"

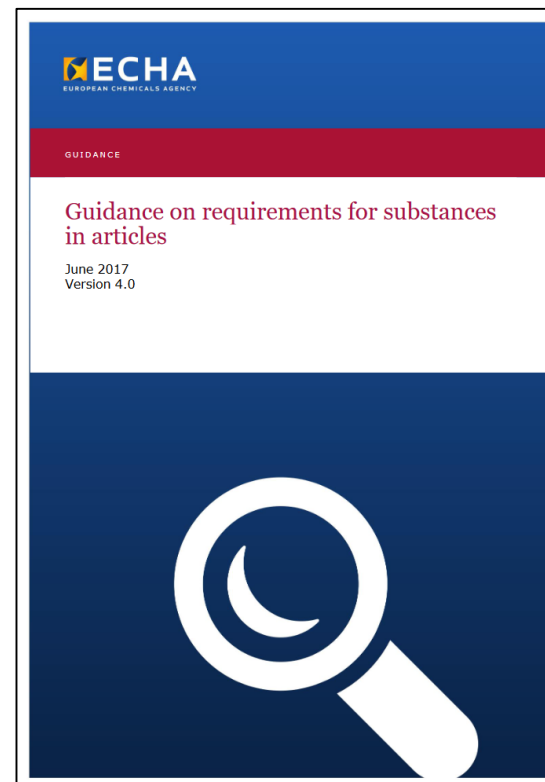
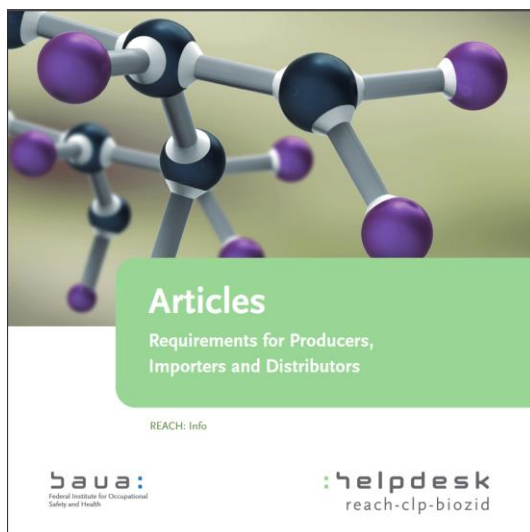


Enforcement Project on Communication Obligations for Articles

- Forum Pilot Project (10.2017 - 12.2018), focus on articles sold in the EU
- 682 consumer articles from 405 companies in 15 Member States reviewed



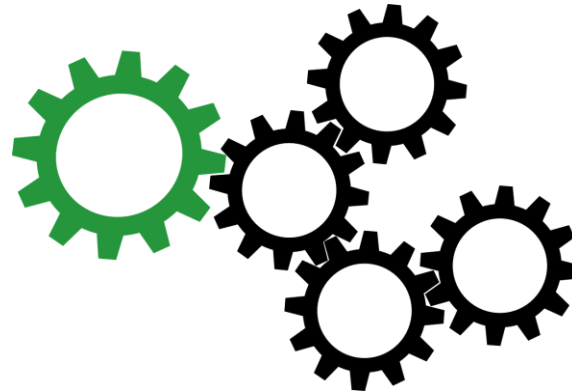
Information materials



https://www.reach-clp-biozid-helpdesk.de/SharedDocs/Publikationen/DE/REACH/BAuA/Broschueren/REACH-Info-Erzeugnisse_EN.html

Conclusion

- Forum **enforcement project shows deficits in supply chain communication** when $SVHC > 0.1\%$
- **Decisive for information flow to the consumer is the first actor** in the supply chain
- **Information obligation** under Article 33 **applies to every actor** in the supply chain and is **not dependent on information provided by the own supplier**
- **Critical is information flow between EEA importer and non-EEA supplier** by import
- **Success of the information obligation depends on the efforts of all actors**



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Thank you for your attention!