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What is an article?

- **“Article”**
  - An object which during production is given a *special shape, surface or design* which determines its function to a greater degree than its *chemical composition* (REACH Article 3(3))
- An article is composed of one or more substances or preparations.
- Specific substances may be added to give the article special properties.
- Examples → furniture, clothes, vehicles, toys

Borderline cases

<table>
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<th>Paint in pot</th>
<th>Spray can</th>
<th>Fire cracker</th>
<th>Car battery</th>
<th>Thermometer</th>
<th>Perfumed eraser</th>
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Substance Preparation Article
Relevant actors for substances in articles

- Importer (and producers) of articles in EU
  - Has to fulfil legal obligations in order to put an article on the EU market
- Only representative
  - can be appointed by a non-EU producer of article
  - takes the role of the importer
- Non-EU supplier/producer of article
  - Can/should support the importer by providing information
- Supplier of chemical substances
  - Can provide information to the non EU article producer

Obligations for importers of articles in the EU

1. Comply with existing restrictions (Annex XVII)
2. Register to ECHA substances in articles intended to be released (Article 7(1))
3. Notify ECHA of substances in articles under certain conditions (Article 7(2))
4. Communicate in the supply chain (Article 33)

-Please note that the authorisation procedure is not relevant for imported articles!
1. Restrictions

Existing restrictions in REACH annex XVII

• Substances in articles may be subject to restrictions
• Examples:
  – Cadmium content in plastic materials (entry 23)
  – Nickel in articles intended to come into direct and prolonged contact with the skin (entry 27)
  – Azocolourants in textile and leather articles (entry 43)
  – Penta- and octa-BDE in articles (entry 44-45)
  – 6 phtalates in toys and childcare articles (entry 51-52)
  – Dibutyl- and dioctyltin compounds in consumer articles (entry 20)
• Make sure your articles are in line with these restrictions!

2. Registration

Registration of substances in articles (Article 7(1))

➤ Substances in articles shall be registered when:
  ▪ The substance is present in the articles at a total of > 1 tonne per producer/importer per year, and
  ▪ The substance is intended to be released during normal and reasonably foreseeable conditions of use

➤ The obligation is for EU importers of articles – but they need information from their suppliers outside EU!

Example: perfumed eraser
3. Notification

Notifications of substances in articles (Article 7(2))

- **EU Producers and importers of articles** shall notify substances in articles to ECHA if
  - The substance is on the **Candidate List**, and
  - The substance is present in the articles at a total of **>1 tonne** per producer/importer per year, and
  - The substance is present in those articles above a concentration of **0,1%** weight by weight.

3. Notification

When to notify

- Companies shall notify to ECHA within 6 months of the inclusion of the substance on the candidate list.
- Substances that were included in the Candidate List by **1 December 2010** should be notified by **1 June 2011**.
- **1 December 2010** there were **38 substances** on the Candidate List
3. Notification

Derogations: Producers and importers of articles do not have to notify if…

- They can exclude exposure to humans or the environment during normal and reasonably foreseeable conditions of use including disposal, or
- The substances have already been registered for that use

What information should the notification contain? (article 7(4) of REACH)

- Identity and contact details of producer/importer
- Identity of the substance
- Classification of the substance
- Registration number, if available
- The tonnage range of the substance (also up to 3 years back in time)
- A brief description of use of the substance in the article (technical function) and of the uses of the article (eg. Consumer/professional use, indoor/outdoor use, high/low release, skin contact)
Communication requirements, Article 33

• Article 33(1): When there is >0.1% of a substance of very high concern (SVHC) in the article, the supplier of the article: “…shall provide the recipient of the article with sufficient information to allow safe use of the article including, as a minimum, the name of the substance”
  – Only for SVHC on the ‘Candidate List’
  – There is no exemption for uses already registered
  – No tonnage limit (i.e. also applies below 1 tonne/year)

• Article 33(2):
  – Consumers can request the same information. The information should be provided within 45 days, free of charge.

Article 33 communication

• Aim of Article 33: communicate sufficient information down the supply chain to allow the safe use of articles containing SVHC

• The safety information to be communicated depends on what a user needs to know to be able to use the article safely and not on how available this safety information is (potential routes of exposure, hazards of the SVHC, appropriate exposure control / personal protection measures, etc.)

• Always to be included: name of the SVHC
  It should, however, not be assumed that simply providing the name of the substance will in every case be sufficient to allow safe use of the article.
4. Communication

Format for Article 33 information

- REACH does not specify a format for providing information according to Article 33
- The format should ensure that the information is readily available to the recipient of the article or the consumer
- Standard communication formats developed by industry sector associations

0.1% threshold

- Interpretation of Articles 7 and 33 given in the Guidance on requirements for substances in articles:
  The 0.1% threshold applies to the entire article, i.e. to the article as produced/imported (for Article 7) or supplied (for Article 33);
- Based on this interpretation a larger article can be produced/assembled from smaller articles. The obligation applies to the finished article.
- On the same basis, parts that are disassembled from a larger article, for example to be sold, are to be treated as articles, provided the disassembled parts fulfill the article definition. The same applies to spare parts when sold separately.
- Companies which are collecting information not only on the whole article but also on parts thereof may, on a voluntary basis, prepare their notification to ECHA or their article 33 communication on this basis.
• Note that it is the *EU importer* who has the legal obligations under REACH
• The non-EU exporters can (and should) support the importer
• Consider the option of an Only Representative (Article 8)
  – Different notifications needed for different article manufacturers

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**How to prepare for customer requirements**

• Make an inventory of the articles you export
• Study possible obligations of your EU importer
  – Existing restrictions under REACH – Annex XVII
  – REACH registration requirements – Article 7(1)
  – REACH notification requirements – Article 7(2)
  – REACH requirements for information in the article supply chain – Art. 33
• Actively communicate with your EU clients to see how their needs can be met
• Actively communicate with your own suppliers
  – they may have the relevant information on the substances you incorporate into the articles
• Plan for the future
  – Do not wait - start collecting and assessing data now
  – Follow the development of the Candidate List and the Registry of Intentions (RoI)
  – Consider substitution of potential future Candidate List substances
What requests can be expected from EU importers in relation to possible registration:

- Is there intentional release of a substance from the article during normal and reasonable foreseeable conditions for use?
- If yes, how much of that substance is contained in the article?

• If registration is required
  - Substance Identity
  - Data on properties of substances (physicochemical, toxicity)
  - Note that you need legal access to data (RIP 3.4)
  - (Data for) Exposure assessment for relevant life cycle steps
  - Other data for the Chemical Safety Report

What requests can be expected from EU importers in relation to possible notification and Art 33 obligations:

- Does the article contain > 0.1% of a Substance of Very High Concern (SVHC) (i.e. Substances on the Candidate List)

• If notification or Article 33 communication is required
  - Substance Identity (name, EC or CAS number)
  - Amount and/or concentration of substance in the article
  - Other data necessary for safe handling of the article
  - Function of the substance in the article
  - (The location of the substance in the article)
Customer requirements going further than REACH...

- Does your article contain SVHC's (at all!)?
- Is your article 'REACH compliant'?

Further information and support

- Guidance on requirements for substances in articles
  - updated version published on 1 April
- The Candidate List
- The Registry of Intentions
- Web-page on substances in articles, including Q&A
- Data Submission Manual: How to prepare and submit a Substance in Articles Notification using IUCLID
- ECHA Helpdesk
Summary

• EU importers of articles have legal obligations
  – Non-EU producers of articles can/should provide information to meet their needs
  – Comply with existing restrictions
• EU customers may go further in their requirements
  – E.g. “No SVHCs in articles!”
• Be prepared
  – Make inventory
  – Keep track of Candidate List development
• Actively communicate up and down the supply chain