REGULATORY COMPLIANCE

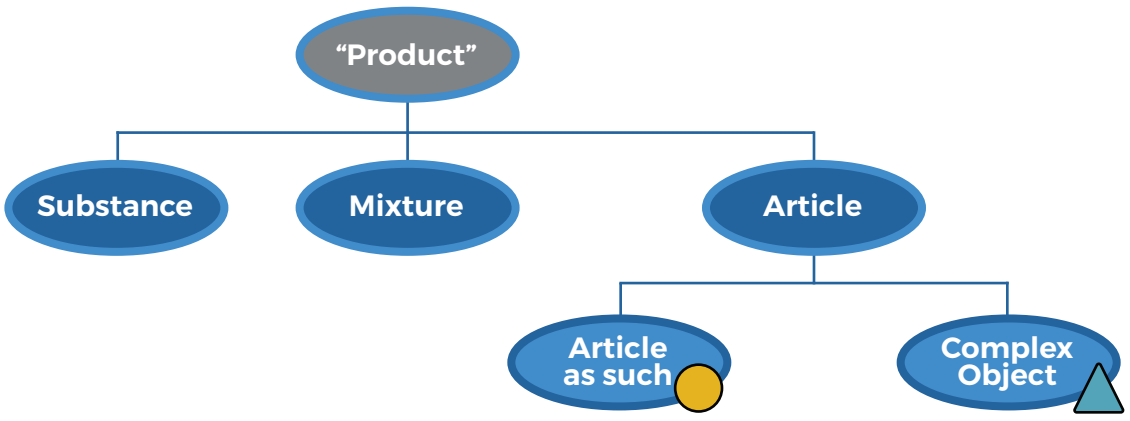
EU REACH

Overview

On **June 1, 2007**, the European Union and member states of the European Economic Area imposed new regulations for the **R**egistration, **E**valuation, **A**uthorization, and Restriction of **Ch**emical substances, commonly referred to as REACH. Any company that manufactures, imports, or distributes products in Europe must comply with REACH legislation.

Scope

The general parts of a product include substance, mixture and article. REACH regulation is only specific to the articles within a product. Articles include Article as Such or a Complex Object. Substance and Mixture are outside REACH scope until they are added to an article. Nearly all REACH obligations are related to substances as such or as part of a mixture but not to mixtures themselves.



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EU REACH

Confusion in REACH Article definition:

- Previously REACH regulation did not define how products that contain several articles (or components) should be interpreted. Given that weight by weight criteria could be applied to each article in a product separately OR the whole weight of the product applied, REACH obligations lent itself to individual interpretation.
- Member states have different views on these provisions. The Commission and the majority of member states support the application of the 0.1% threshold to the article as a whole while the opposing side campaigned for this threshold to apply to components.
- The EU Court of Justice was subsequently tasked with making final decision on if the 0.1% limit applies to the whole article or to each component separately.

Ruling Timeline and decision for Article definition:

April 2014

The EU Court of Justice was asked to decide if the 0.1% limit applies to the whole article or to each component separately.

February 2015

The Advocate-General published his opinion on this issue. The Advocate-General states that the definition does not distinguish between stand-alone and integrated articles and in such **agrees with the interpretation of the threshold applying to components**.

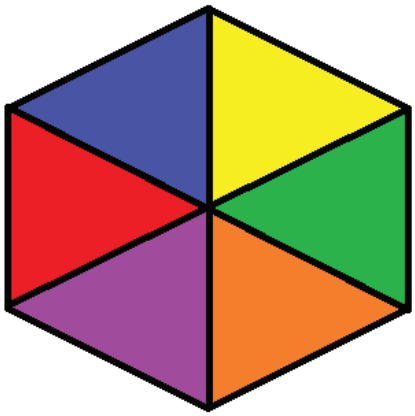
September 2015

The EU Court of Justice followed the advice of the Advocate-General and issued their judgement.

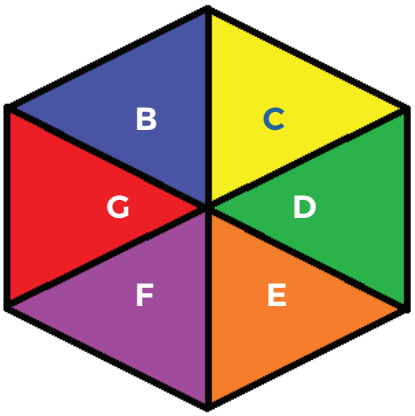
Ruling Impact:

- This ruling has important implications for the reporting obligations under REACH Article 7(2) and the information obligations of suppliers to customers under Article 33.
- **New Article Definition:** According to Article 3 of REACH, an article is 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.

Old Definition: A is the article



New Definition: A is a complex Product containing several articles and B, C, D, E, F, and G individual Articles



Articles as components must comply with REACH obligations when they contain an SVHC that exceeds 0.1% of the articles weight. Application of the 0.1% threshold to component parts will require more ECHA notifications and a higher number of supply chain communications.

EU REACH

New Article Definition vs Old Definition

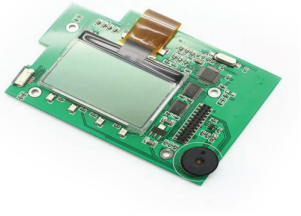
The following example of a truck will clarify the difference in REACH obligations required from manufacturers and importer per old definition and new definition.

Old Article Definition

Chip Capacitor contains SVHC >0.1% w/w

Chip Ceramic Capacitor weighs 4g and contains 5% w/w of an SVHC Lead "7439-92-1"

Motherboard doesn't contain SVHC >0.1 w/w of the article



Motherboard "new article" which weighs 600g and contains 0.03% w/w lead

Truck doesn't contain SVHC >0.1 w/w of the article

Truck "new article" which weighs 10 tons and contains 0.000002% w/w lead

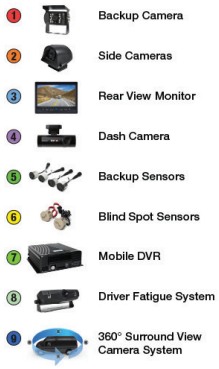


PHOTO CREDIT: HTTPS://FLEETS.REARVIEWSAFETY.COM/BACKUP-CAMERA/TRUCK-BACKUP-CAMERA-SYSTEMS.HTML

Insights and Consequences:

- Electrical parts represent 1% of typical car weight
- Car manufacturers could "ignore" SVHCs in electronics
- Electronics suppliers not asked to declare REACH candidate lists
- Manufacturers adopt a similar approach for their products e.g. heavy castings, large amounts of metal parts, etc.

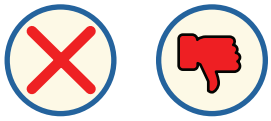
EU REACH

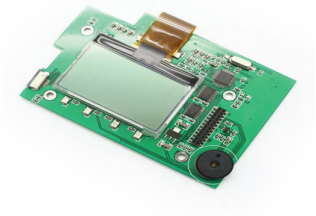
New Article Definition

Chip Capacitor contains SVHC >0.1% w/w

Chip Ceramic Capacitor weighs 4g and contains 5% w/w of an SVHC Lead "7439-92-1"

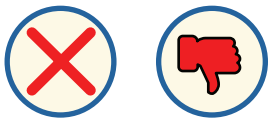
Motherboard contains an article which has an SVHC >0.1 %

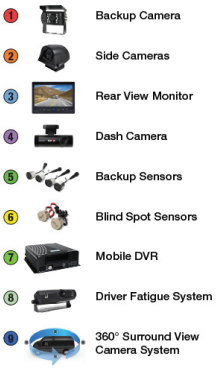




Motherboard includes a Ceramic Capacitor which contains >0.01 lead

Truck contains an article which has an SVHC >0.1%





Truck includes a Ceramic Capacitor which contains >0.01 lead

PHOTO CREDIT: HTTPS://FLEETS.REARVIEWSAFETY.COM/BACKUP-CAMERA/TRUCK-BACKUP-CAMERA-SYSTEMS.HTML

Obligation of Manufacturers and Importer

- Manufacturers and importers of an article "assembly or subassembly" containing SVHC above 0.1% w/w must notify ECHA by submitting a notification.
- Manufacturers no longer need to ask suppliers for the amount of the REACH Candidate list substance in the part because there is no need to calculate whether it is present > 0.1% by weight of the Product.
  - » Just need to ask Yes or No if the part includes an article which contains a REACH Candidate List substance above 0.1% by weight of that article.
- Must implement systems to collect any necessary information on safe use from suppliers whose parts include an article which contains > 0.1% of a REACH Candidate List Substance by weight of the article.
  - » In most cases, manufacturers should expect the supplier to indicate that there is no Safe Use information that needs to be communicated.

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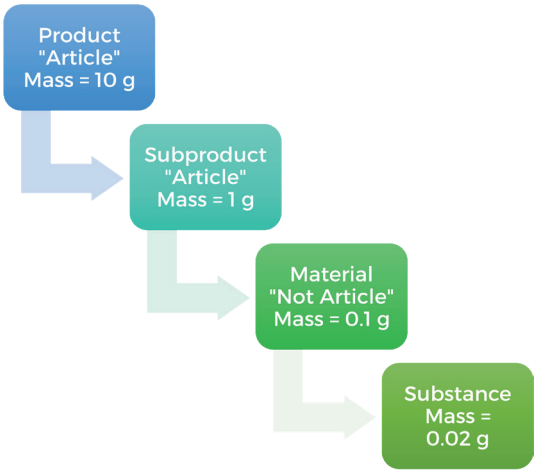
Substances Calculations according to the O5A principle

O5A: “Once an Article, Always an Article” ruling has changed the method for calculating Substances of Very High Concern (SVHC) levels under the EU REACH regulation.

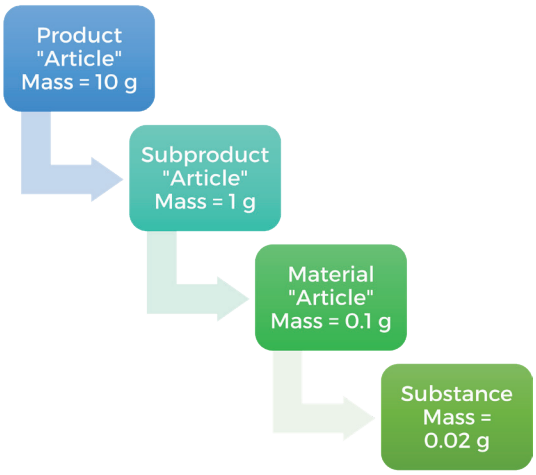
Substances Calculations according to the O5A principle

First determine the nearest article “article as such” that includes the SVHC.

In the next figure, the material is the nearest article to the substance. The Material mass equals .1g, so to calculate the substance mass percent in this article you divide 0.02 g b y 0.1 g, which equals 0.2 = 20%.



The material manufacturer will be affected and needs to notify ECHA and communicate to the supply chain the required information and safe use of the material.

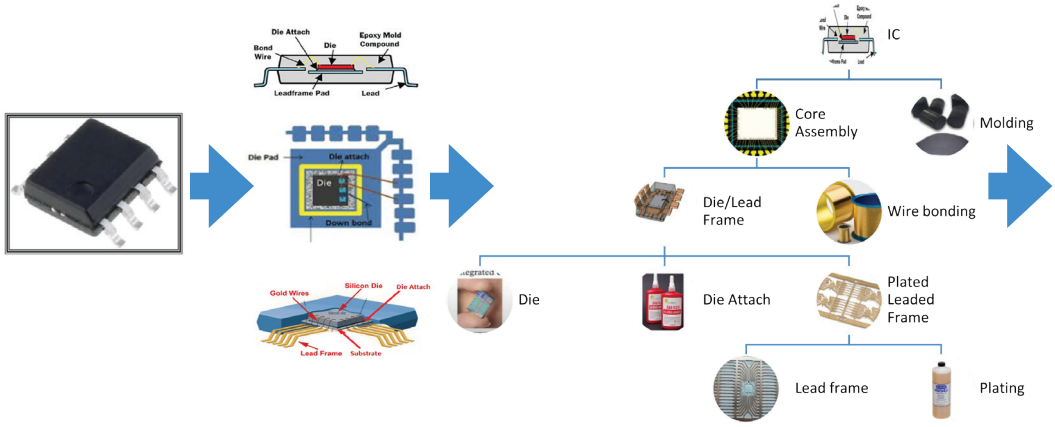


In the case of the subproduct, the mass is equal to 1g. Divide the substance mass percent of .02g by 1g and that equals 0.02 = 2%.

Subproduct manufacturer will be affected and needs to notify ECHA and communicate to the supply chain with required information and safe use of the material.

Calculation of the SVHC Status per Complex Article (IC)

Determine which materials meet the definition of an Article. For materials that do not, determine the relevant article concentration base to which they belong to.



Item/ Sub Item Name	Article/ Mixture
Mold Compound -Black	Mixture
Die	Article
Die Attach	Mixture
Leadframe	Article
Plating	Mixture
Wire Bond Cu	Article

Complex Article (IC) = A		Article/Mixture							
Item/Sub Item Name	Item/ Sub Item Mass (g)	Homogenous Material	Normalized Homogenous Material	Homogenus Material Symbol	Humogenous Material Mass (g)	Article Status	SVHC Concentration Base	SVHC Concentration	SVHC Status
Mold Compound -Black	0.02858	Mold Compound -Black	Molding Encapsulation	A1	0.02858	No, Mixture	A (IC)	SVHC(A1) = A1(SVHC)/A	**SVHC(A1)** = A1(SVHC)/A **<1000 PPM**
Die	0.00133	Die	Die	A2	0.00133	Yes, Article	A2	SVHC(A2) = A2(SVHC)/A2	**SVHC(A2)** = A2(SVHC)/A2 **<1000 PPM**
Die Attach	0.0024	Die Attach	Die Attach	A3	0.0024	No, Mixture	(A2+A3+A4+A5) Die Assembly	SVHC(A1+A3) = A2(SVHC)/ (A2+A3+A4+A5)	**SVHC(A1+A3)** = A2(SVHC)/ (A2+A3+A4+A5) **<1000 PPM**
Leadframe	0.03761	Leadframe	Leadframe	A4	0.03761	Yes, Article	A4	SVHC(A4) = A4(SVHC)/A4	**SVHC(A4)** = A4(SVHC)/A4 **<1000 PPM**
Plating	0.00189	Plating	Plating	A5	0.00189	No, Mixture	A4+A5	SVHC(A4+A5) = A5(SVHC)/A4+A5	**SVHC(A4+A5)** = A5(SVHC)/A4+A5 **<1000 PPM**
Wire Bond Cu	0.00018	Wire Bond Cu	Bond Wire	A6	0.00018	Yes, Article	A6	SVHC(A6) = A6(SVHC)/A6	**SVHC(A6)** = A6(SVHC)/A6 **<1000 PPM**

EU REACH

Enforcement of EU REACH

"REACH Article 126 requires that the penalties are "effective, proportionate and dissuasive"and the member states take all measures necessary to ensure that they are implemented. The commission continues to monitor closely the enforcement of REACH in member states.

With that though, every EU Member State enforcement authority differs on the level of inspection and enforcement of non-compliant products.

In general, penalties under EU REACH include:

- In case of continuation of the information, a penalty of 100 to 1000 EUR a day of infringement
- Upon conviction, there is a fine of up to 80000 EUR or imprisonment not exceeding 2 years or both
- Upon second conviction, there is a fine of up to 80000 EUR or imprisonment not exceeding 4 years, or both
- Where applicable, products can be removed from the marketplace.

Why Partner with SiliconExpert to Meet EU REACH Obligation

- SiliconExpert can designate materials within parts as articles, as well as combinations of materials as complex objects according to new O5A principle.
- Companies can use the SiliconExpert platform and complimentary services to manage REACH obligation
- SiliconExpert keeps you on schedule by evaluating, defining, and monitoring every data point of a product's constitution, making sure your REACH compliance is always up to date.

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