

Definition of Article

Article 3(3) of the REACH Regulation defines an article as **“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”**.

Substances of very high concern (SVHC)

SVHC are substances having hazardous properties of very high concern for human health and environment. These substances are categorized within REACH as under:

(a) Substances meeting the criteria to be considered as carcinogenic, mutagenic or toxic for reproduction (CMR categories 1 or 2).

(b) Substances meeting the criteria to be considered as persistent, bioaccumulative or toxic (PBT) or which are very persistent and very bioaccumulative (vPvB).

(c) Substances, such as those having endocrine disrupting properties, or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative (vPvB) properties or substances which are identified as causing serious and irreversible effects to humans or the environment which are equivalent to those of other substances listed under (a) or (b) on a case-by-case basis.

(d) Persistent organic pollutants (POPs) are vPvB substances and shall be included in authorisation process.

The SVHC list is finalized by the European Chemical Agency (ECHA) from time to time after extensive public consultation and deliberations. **As on date there are 46 SVHC substances identified by ECHA to be included in the candidate list. This list will grow by about 20-30 substance each year. It is anticipated that ultimately there shall be about 400 to 500 SVHC substances on the candidate list.**

Once a substance has been included in the candidate list it triggers various obligations for the exporters of articles to Europe¹. These obligations are listed below:

- Checking if any of the SVHC is present in the article being exported to Europe
- If an SVHC is likely to be present, whether there is a scope of intentional release of the substance from the article under normal or foreseeable conditions of use
- Checking if the intentional release of the SVHC substance or substances exceeds 1 ton per annum
- If the tonnage of 1 ton per annum is exceeded then REACH registration obligations shall apply to the article exporter
- If there is no intentional release, but any SVHC is present in the article being exported, the amount of the SVHC needs to be assessed. **However, in this case Registration will not be required.**
- If the SVHC exceeds 0.1%wt/wt in the article and the tonnage exceeds 1 ton per annum in the annual exports of articles to Europe, **then the article exporter has obligations for Notification**
- If the tonnage threshold of 1 ton per annum in the annual exports of articles to Europe is not exceeded, there is no obligation for Notification on the exporter

¹ 1. Austria, 2. Belgium, 3. Bulgaria, 4. Cyprus, 5. Czech Republic, 6. Denmark, 7. Estonia, 8. Finland, 9. France, 10. Germany, 11. Greece, 12. Hungary, 13. Ireland, 14. Italy, 15. Latvia, 16. Lithuania, 17. Luxembourg, 18. Malta, 19. Netherlands, 20. Poland, 21. Portugal, 22. Romania, 23. Slovakia, 24. Slovenia, 25. Spain, 26. Sweden, 27. United Kingdom

- **Notification on behalf of the non-European company can only be done by a European legal entity who is known as an the “only representative” of the non-European company**

Authorization procedure for SVHC substances

Based upon the candidate list of SVHC substances, ECHA will prioritize substances for the authorization procedure. Priority will be given to substances with PBT or vPvB properties, wide dispersive use or high volumes. The European Commission (EC) may decide to include candidate substances in Annex XIV (Authorisation List) of REACH. Registrants of these candidate substances as well as exporters of articles containing substances identified for authorization will then need to apply for authorization of their substances for specific use. An inclusion into the Annex XIV means that, after a transitional period, the substances may not be placed on the market or used unless authorization is granted for the specific use.

How to proceed with REACH compliance?

The compliance procedures enumerated in the guidance document of ECHA enumerates the following:

- **Obtaining information on substances in articles**

Preparing an inventory of all the chemicals that are used in the production of the articles. This may also require supply chain communication to include the substances that are used by other actors in the supply chain leading to the final production of article. This comprehensive list of chemicals can then be used to assess the presence or absence of the SVHC. It is also worthwhile to identify the export destination and the type of article being exported to Europe.

It is also important to quantify and analyze the SVHC using Non-analytical or Analytical methods.

If the non-analytical method proves that there is no SVHC present in the article, then the need for testing is eliminated altogether.

- **Chemical analysis of SVHC in articles**

Difficulties related to chemical analysis of substances in articles will be faced relating to the following issues and have to be kept in mind in case chemical analyses are conducted.

- Articles may be very complex and composed of different parts and materials. It is therefore difficult to create a sample for the analysis that represents the whole article.
- Substances that are included in the article matrix may have to be extracted from it
- The extraction may not be exhaustive, thus the full content of substances in the matrix may not be obtainable. This may result in chemical reactions that could “create” substances which do not exist in the article.

Thus, one has to exercise great caution before proceeding for the testing as it might still not yield the desired results

- **Documenting the results of the applicability assessment and testing (if conducted) for compliance check by the enforcement authorities**
- **Communication of the SVHC contained in the article and information for safe handling when the SVHC is below the limit of 0.1%wt/wt**

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