

Legal Definition of «Article»

ECJ Clarifies REACH Regulation

In its ruling of September 10, 2015, the European Court of Justice (ECJ) backs the view of several countries – including Germany – regarding the threshold of 0.1 percent by weight for substances of very high concern (SVHC) in products of complex composition. This ruling has far-reaching consequences for importers and retailers in the EU.

The REACH Regulation (EU 1907/2006) addresses the registration, evaluation, authorisation and restriction of chemicals in the EU. Depending upon their product portfolio, manufacturers and importers are affected by various points of the regulation and are obligated to submit data and information.

The regulation defines three categories of products: Substances, preparations, and articles (definitions in box). Article 33 of the regulation states that manufacturers and importers within the EU are required to notify downstream users (recipients) of the presence of any Substances of Very High Concern (SVHC) in their product (article) at concentrations exceeding 0.1% by weight. On request by a consumer, the end seller of an article must state whether the article contains an SVHC within 45 days.

In practice it became apparent that Article 33 of the regulation could be interpreted in various ways. It was unclear whether percent by weight calculations should be based on the total weight of a product or on the weight of each individual component of a complex product. The European Court of Justice has now clarified the situation in response to a case brought by a French company.

Shoes: Composite Products

Interpretation of the regulation was straightforward for simple products such as an EVA clog because the shoe is made of a single material. For complex products or articles consisting of several component articles, such as sport shoes, there were two conflicting views about the interpretation of the term “article” and application of the 0.1 percent by weight threshold.

Most of the EU member states and EChA were of the opinion that the 0.1 percent by weight limit referred to the total weight of a composite product. Just a few EU states, including Austria, France,

Definitions

Substance: A chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition

Preparation: A mixture or solution composed of two or more substances

Article: An object which during production is given a special shape, surface or design that determines its function to a greater degree than its chemical composition

Germany, and Sweden, interpreted the regulation with regard to the duty to inform in such a way that in the case of products made up of several component articles the 0.1 percent by weight limit should be calculated for each individual component article. The following example illustrates the differing interpretations.



Consideration of the complete shoe as an article:

Total weight of shoe: 372 g

Sole contains 0.33g of dihexyl phthalate

Amount of SVHC in shoe: $0.33 \text{ g} / 372 \text{ g} = 0.09 \%$ by weight

Interpretation 1 (EChA):

No duty to inform because there is only 0.09 wt. % of the SVHC in the composite article.

Consideration of the sole as a component article as shown on the left:

Weight of sole: 191 g

Sole contains 0.33g of dihexyl phthalate

Amount of SVHC in sole: $0.33 \text{ g} / 191 \text{ g} = 0.17 \%$ by weight

Interpretation 2 (e.g. Germany):

Duty to inform because the sole as a component article contains 0.17 wt. % of the SVHC.

The judgement handed down by the European Court of Justice has now clearly established that an article always remains an article and that the 0.1 percent by weight threshold applies to each individual component article of a composite article. The ruling has implications for all persons along the length of the supply chain.

Consequences for EU-based Manufacturers

Manufacturers who produce articles assembled in the EU already have to be informed by their suppliers about any SVHCs in an article, for example if the sole contains a listed phthalate at a concentration in excess of 0.1 percent by weight – as in the above example. As a rule, therefore, the manufacturer should already have all the relevant information for each component article. The new ruling means that for such a shoe this information has to be forwarded to the recipient, which was not necessary according to EChA's former interpretation. This also concerns retailers who now have to inform consumers on request whether a shoe contains an SVHC candidate at a concentration exceeding 0.1 percent by weight in the sole as a component.

Consequences for Importers

Importers who import composite products into the European Union now have to request information about the presence of SVHCs from suppliers of component articles or include the duty to inform as a clause in their procurement contracts. Since the duty to inform does not automatically apply outside Europe, the importer is responsible for acquiring the relevant information from his non-European suppliers.

Apart from the duty to inform downstream users, importers could also be affected by the duty to inform ensuing from the interpretation "Once an article – always an article". If products containing an SVHC in a concentration exceeding 0.1 percent by weight are imported into the EU and if the total amount of the SVHC in the articles exceeds one tonne per year then EChA must also be notified. In the above example, one pair of the shoes contains a total of 0.66 g of dihexyl phthalate. If 1.7 million pairs were to be imported into the EU, then the amount of dihexyl phthalate imported would be 1.12 tonnes. According to EChA's former interpretation, the SVHC constituted 0.09 percent by weight of the composite article. There would therefore have been no obligation to notify EChA, even though more than one tonne of the phthalate would have been imported. According to the ruling of the ECJ, however, the sole remains an article which, as described above, contains 0.17 percent by weight of the SVHC compound. Since more than one tonne of the SVHC candidate would be imported in a year in the case of 1.7 million pairs, EChA would have to be notified of the import.

In the near future EChA will revise its guidance on the REACH regulation to take account of the new ruling.

Since the court ruling is immediately effective and there is no transitional period, it is now up to manufacturers and importers to immediately establish whether any manufactured or imported articles are affected by the ECJ's interpretation, and if so to accordingly inform downstream users, in order to fulfil their obligations under REACH.

Further information:

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