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Impact of change of definition for REACH Article 33 requirements

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1. Executive summary

REACH Article 33 requires suppliers to inform their customers if a product contains >0.1% of an SVHC. This threshold was agreed between the 27 Member States and the ECHA (European Chemicals Agency). However, six States (Austria, Belgium, Denmark, France, Germany and Sweden) disagreed believing that the threshold should apply to "components". The exact reason for choosing 0.1% is not clear but is probably related to the safety data sheet threshold for hazardous substances in mixtures where these must be included if they are present at >0.1%. Changing the definition would have advantages and disadvantages to industry but overall there would be a very large increase in costs with very little apparent benefit to health or the environment. The likely impact of changing the definition as well as the possible effect of raising the threshold is described in this article.

2. Background

The REACH Regulation 1907/2006 imposes many different obligations on industry but the one that has the most significant impact on the electronics industry is from Article 33 which requires suppliers to inform downstream users if a Substance of Very High Concern (SVHC) is present in an article at 0.1% by weight or higher and provide safe use information if necessary. There are at the time of writing 53 SVHCs but more are added to the "Candidate List" every year. Obtaining reliable information from the supply chain about SVHCs is difficult and very time consuming. Currently this obligation is defined by official guidance provided by the European Chemical Agency (ECHA) which

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states that this information needs to be provided if the SVHC is at or above 0.1% by weight of the item being supplied. However, originally six (Austria, Belgium, Denmark, France, Germany and Sweden) and now up to nine EU Member States (plus Norway, Netherlands and possibly UK) disagree with this definition believing that the 0.1% limit should apply to each individual first article (i.e. a component) and not to complex articles as supplied that may contain hundreds of components. Their argument is that if a part contains >0.1% of an SVHC, and so information is required because the substance is hazardous, then this obligation should not stop when the substance is diluted by incorporating the component into a complex product. One of these Member States, France, has announced that it intends to use the alternative interpretation contrary to ECHA guidance. REACH is currently being reviewed and so it is possible that a new legally binding definition could be adopted and this might change to the one held by the nine dissenting member states, not the one in the ECHA guidance. This change would have a significant impact on the electronics industry, including all areas of the supply network and the implications are described here.

3. Basis of the 0.1% limit

Suppliers of hazardous chemicals are obliged to provide safety data sheets (SDS) that provide the information needed to use the substance safely. SDS are required if a mixture of substances contain hazardous substances at concentrations above certain threshold values which vary depending on the hazard. For the most hazardous chemicals the limit is 0.1% by weight but SDS would not required be if a mixture were to be diluted so that all hazardous substances are present below 0.1%. It is not clear what is the basis for the 0.1% limit for SVHC information but alignment with the concentration limits in SDS is comparatively logical.

If an SVHC is present at a high concentration, the potential risk to users is greater than when it is at a low concentration. If there is no need to provide safety information in a SDS on a hazardous substance present at 0.05% in a mixture however, why should it be necessary if the same substance is present at the same concentration in a complex article? Moreover, in the vast majority of cases an SVHC in article is much less mobile and accessible to the user than a substance in a mixture of chemicals.

As an example:

Mixture of substances – SDS requirements

- A mixture of chemicals includes DEHP at ~30% so an SDS is required;
- If the only hazardous substance present in a mixture is DEHP and this is present at 0.05% then an SDS is not required.

DEHP in a complex article at 0.05% by weight – Article 33 obligations:

- On the basis of ECHA's guidance, currently no SVHC information need be provided for articles as supplied containing DEHP at 0.05%. This is consistent with the SDS obligations

- Dissenting Member States interpretation; if DEHP were present at >0.1% in one component part (e.g. a short connecting PVC insulated wire) of a complex article, then SVHC information would be required even though the concentration in the complex article is <<0.1%. This is much more onerous than the SDS requirement.

4. Collecting SVHC data - current situation

REACH requires EU suppliers to inform their customers if an SVHC is present at >0.1% of an article as supplied. To meet this obligation, this data should ideally be obtained from their suppliers and the UK Health and Safety Executive who enforce REACH in the UK say that suppliers need to be proactive and need to try to obtain this information, at least by asking suppliers but by chemical analysis as a last resort. All electrical components and equipment distributors and many equipment manufacturers / systems integrators have contacted their suppliers for this data but with limited success. Most have not received 100% responses and many have less than 50%. Furthermore, as more SVHCS are regularly added to the list, there is a need to go back to suppliers each time to ask for more data.

In general, it appears that many suppliers are reluctant to admit that an SVHC is present and so do not reply even though this is only an information requirement, not a restriction. As a result, distributors find that most replies they receive state that parts contain no SVHCs whereas in reality, the actual percentage of parts with SVHCs is likely to be somewhat higher. Owing to these difficulties, databases of REACH SVHC information are usually incomplete and out of date.

Some distributors selling several hundreds of thousands of different products have collected SVHC data and typically found that about 0.5% of these contain SVHCs although there are still many gaps in their data. The cost of collecting SVHC data can be considerable for distributors that supply large numbers of products. Simply to request information from suppliers and collate data in a data base costs 10s of pence per item ("article") and if more extensive enquiries are made along the supply chain or chemical analysis carried out, the cost can easily exceed £1 per product. Furthermore, additional cost can be incurred every time that more SVHCs are added to the candidate list which can be twice per year. The annual cost to a large distributor for maintaining an up-to-date and credible database of SVHC information for electronic components and communication of SVHC information to customers is estimated to be typically £50,000 per year despite their large economies of scale. Smaller UK organisations (component and equipment manufacturers, smaller distributors and systems integrators) with a few hundred products will have proportionally higher costs per product.

As a result, manufacturers and systems integrators can have great difficulty determining whether their products contain >0.1% of SVHCs. This issue is exacerbated because, although suppliers will

admit to >0.1%, most will not give actual concentrations in the components they supply and so the manufacturer / systems integrators may not be able to calculate the concentration of SVHCs in their finished products and so whether they exceed the 0.1% threshold for the article they supply. This is however not always an unsolvable problem, e.g.

- Many SVHCs are process chemicals (e.g. solvents such as methoxy ethanol) and so can be ignored as they will not be present in articles.
- Many have specific uses and so it is possible to assume they will not be present (e.g. aluminosilicate refractory fibres are used only in heat shields, brake linings and thermal insulation).

Where a component does contain an SVHC, if this is small compared to the final product, it is often possible to assume that the final product SVHC concentration will be <0.1% due to the weights of the component and final product. For example, if 10 g of PVC wire is used in a 2kg product, the theoretical maximum concentration of DEHP or other plasticisers is:

- 10 g PVC wire = 50% PVC and 50% copper so 5 g of PVC polymer
- PVC typically contains ~30% plasticiser so 1.5 g DEHP.
- Therefore; 1.5 g in 2000 g = 0.075% DEHP maximum.

Note that if the final weight were 1kg, then the SVHC content may be >0.1%.

Even with minimal information from suppliers, it is often possible for equipment manufacturers and systems integrators to say with confidence that their products do not contain SVHCs but this is not always the case.

5. Management of risk

The reason for supplying SVHC information along the supply network is to provide any information that is needed by users to use the product safely. This risk is proportional to the SVHC concentration, for example:

- If PVC insulated wire with ~10% DEHP plasticiser is supplied to an assembler of electrical equipment, workers may frequently handle the wire and so will experience much larger quantities of DEHP than is normal in the general population. This is especially true if they hand solder without ventilation. Handling PVC containing DEHP is not thought to pose a risk but inhaling DEHP vapour when hand soldering could pose a risk and so ventilation is advisable.

- Once the finished product is complete and supplied to the user, they will handle the equipment but the level of exposure to DEHP is far lower and well within safe limits and safe use instructions would not be required under any normally foreseeable circumstances.

The example below illustrates the difference in handling a component that contains an SVHC with a finished product that contains this component:

Component contains **10% SVHC** and weighs 1 g	This component in equipment weighing 10kg – concentration of **SVHC = 0.001%** by weight

6. Implication of a change of definition

Changing the definition of what the 0.1% limit applies to will have several implications with advantages to some but disadvantages to most. The following examples illustrate these issues:

Scenario A: EU-based manufacturer/systems integrator of complex products – There are both advantages and disadvantages. A potential advantage of the alternative definition is that manufacturers and systems integrators of complex products would not need to determine if the final SVHC concentration of their products exceeds 0.1%, they simply pass on any SVHC data on components they receive from component suppliers to their customers. There are also disadvantages though, as is illustrated by the two following scenarios:

Approach	Data received	Does SVHC information need to be passed to customers?	Information to customers	Disadvantages
Current situation - 0.1% limit applies to articles	Data on all "parts" used is sought for SVHC data on those with >0.1% SVHC	Only if finished product contains >0.1% SVHC. Manufacturer needs to calculate final SVHC concentration using component data from suppliers to determine if >0.1%	Pass on SVHC data for product only if >0.1%	Difficult to determine if SVHCs exceed 0.1% in product without actual concentration of SVHC in supplied components
0.1% limit applies to components / simple articles	Data on all components with >0.1% SVHC needed including those in modules and sub-assemblies	Yes if any supplied components contain SVHCs at >0.1%, no need to calculate if complex article has >0.1%	Pass on all SVHC information obtained from suppliers (or from chemical analysis of components)	Customer may receive confusing data on many components but have no risk. May be impossible to obtain data on components in complex modules, etc. from non-EU suppliers

EU based distributors who import complex products into the EU will experience the same or more difficulties as those described above.

Scenario B: A distributor supplies a complex item of equipment from an EU based manufacturer/integrator for sale in the EU – the impact of the two alternative definitions are as follows:

Current situation - 0.1% limit applies to articles	**0.1% limit applies to components / simple articles**
The manufacturer is obliged to pass on SVHC data to the distributor who passes this on to their customers. Data is needed only for the equipment as a single entity and SVHCs are often diluted to an extent that SVHCs are usually <0.1%	The distributor would need to pass on the data on all components that contain SVHCs to customers. It is much more likely with this definition that SVHC data will need to be provided for a product. It is very unlikely that this information will be of any use to the end user as there is rarely going to be a risk or a need for safe use instructions for complex electrical equipment.

Scenario C: Distributor located in the EU imports complex electrical products from a non-EU manufacturer for sale in the EU – This could potentially be a similar situation to Scenario B above where the distributor obtains complex equipment from EU manufacturers. However, if the non-EU manufacturer is not willing to provide detailed SVHC information for all component parts, the distributor will find it almost impossible to comply and so may not be able to sell these products. There is no legal obligation for non-EU manufacturers to comply with EU legislation, this is the EU-based importers responsibility. It will probably be very difficult for EU importers to obtain detailed SVHC data on all constituent components in complex products from non-EU manufacturers and it may in many cases be impossible. In circumstances where they cannot obtain this information, there are only two potential alternatives (other than not importing), although both will often be impractical.

1. Examine product to identify constituent parts. Contact suppliers of all parts to determine SVHC content. This is unlikely to be possible for most parts as it will not be possible to identify the original manufacturer as they will not be labelled. Plastic mouldings for example will not state the name of the plastic supplier or the batch number that would be needed to determine its composition. There would also be great difficulty in persuading the original manufacturer to supply this information in many cases.

2. Chemical analysis of all parts. This would be extremely expensive, potentially over £100,000 for an average complexity product and is destructive and so impractical if the distributor is supplying only one.

Scenario D: Distributors who supply components – this could be no different to current situation – BUT! - this depends on how "component" is defined. It would be reasonable to define resistors, integrated circuit packages and transformers as components whereas graphic cards and power supply modules are complex products which contain many components. However, how would timer ICs with integral batteries be classified? Would the supplier need to obtain and then pass on to downstream customers SVHC data for both the IC and the battery separately? There are many other examples of "components" that have several parts such as:

- Compact fluorescent lamps that contain driver PCBs,
- Power-line filters – range from PCB mounted "components" to DIN rail mounted modules that contain capacitors, etc.
- Electric motors – some types contain internal controller PCBs.

How would these be classified?

If the distributor supplies only simple components such as actives and passives, then their workload should be unchanged.

If the distributor also sells sub-assemblies, modules and other complex products, then much more data is required on all components within the complex articles. The distributor would need to communicate with the manufacturer to obtain SVHC information on all component parts and as a result for some complex products could receive a long list of constituent components with SVHCs at >0.1% instead of a single statement referring to each finished product. The chances of a complex article containing at least one component with >0.1% SVHC will be higher than the concentration of a complex article exceeding 0.1% due to dilution. As a result, a much higher proportion of products will need to be supplied with SVHC information. Distributors report that they have identified only about 0.5% of their products with SVHCs at >0.1%, but with the alternative definition, this proportion is likely to be much larger.

6.1 Determining if a complex product requires SVHC data

Manufacturers / systems integrator currently need to determine whether their final complex products contain >0.1% of an SVHC if these contain components that have >0.1% of SVHCs. The manufacturer / systems integrator can calculate this only if he knows all of the following:

- Weight of component
- Weight of finished product
- Concentration of SVHC in component.

Usually, however the actual SVHC concentration is not provided by suppliers who merely state >0.1%. This is frequently insufficient information to determine whether after dilution, there will be >0.1% of SVHCs in the complex article although it may be estimated with knowledge of how SVHCs are used and their likely concentrations in components. With the alternative definition of the concentration limit applying to simple articles, there is no need to calculate the final concentration as what would be required is the data on individual components that can be passed along the supply chain.

However, under most circumstances, changing the requirement for supplying SVHC information from >0.1% in a complex product to >0.1% in components will result in a very large increase in workload with associated costs with no apparent benefit. This is because electrical equipment is assembled from a combination of:

- Materials – hazardous constituent concentrations are given in safety data sheets
- Components – most made outside EU so often difficult to obtain SVHC data
- Sub-assemblies and modules containing many components – most made outside EU and currently difficult to obtain SVHC data on module or sub-assembly so it will be many times more difficult to obtain data on all component parts.

6.2 Impact on costs to distributors

If an average complex product consists of 1000 components, instead of obtaining SVHC on the single complex article, it will be necessary to obtain information on all 1000 components, potentially at a thousand-fold increase in cost;

- Databases need to store data on many more items
- Need to collect more data from suppliers and transfer to database
- More SVHC data to be passed to customers

The cost could however be even larger if chemical analysis is needed where no information is available on some of the component parts as analysis costs for plastics, for example, will be >£200 per material. It is often possible to exclude the possibility that SVHCs exceed 0.1% in complex articles due to dilution but there is a risk of concentrations of several SVHCs in many types of components exceeding 0.1%, so they cannot be ignored. One large retailer has estimated that the cost of complying based on the alternative definition in one Member State could exceed €5 million per year (and this is with the current SVHC list only).

7. Options for industry

It is unclear why the six dissenting States oppose the current definition but this may be due to lobbying by environmental groups whose aim is to effectively ban all hazardous substances, irrespective of risk, cost or adequate consideration of the consequences regarding alternative materials and any change in the products' performance, safety and reliability. Several other Member States are reconsidering their positions but this appears to be based on the views of dissenting States and they may not yet have heard counter-arguments from industry.

REACH has several separate aims. The aim of Article 33 is to ensure that users are aware of the presence of SVHCs at concentrations that could pose a risk. At very low concentrations that do not pose a risk, there should be no need to provide this information. For very dangerous chemicals that pose a risk to health and the environment, REACH has a procedure to ban substances. Article 33 requirements are not intended to be a "ban" and the candidate list of SVHCs includes substances that may require authorisation for use as process chemicals within the EU but authorisation limitations do not affect these chemicals when they are present in articles that are imported into the EU. REACH restrictions (in Annex XVII) however can ban both the use of substances in processes and also in articles and so if a substance poses a risk when it is in an article, then the restriction process followed by a ban is the correct one to use.

It is clear that the alternative definition if adopted would have a very large cost impact on industry but no impact assessment has been carried out by the Commission or Member States to determine the cost and benefits (if any). It will be necessary for manufacturers, systems integrators, importers and distributors to lobby Member States (ministers, prominent MPs and relevant civil servants), the European Parliament, the ECHA and the Commission so that they understand the implications of changing the definition and so do not make changes that are very costly with minimal benefits to health and the environment. Arranging low key face to face meetings as an initial means of trying to open constructive discussions is often beneficial. Any communication either private or public should be as concise as possible, carefully honed to ensure they are intelligible to the intended recipient and rigorously checked for objectivity.

Lobbying is time consuming, expensive and requires special expertise and this is best coordinated and channelled through Trade Associations such as ECSN. France has already announced that it will interpret the Article 33 concentration limit to be based on components. REACH is being reviewed and changes will be made so now is the time to take action. Another possible option is for EU Trade Associations to make a formal complaint to the European Commission that the dissenting Member States are not compliant with REACH as they are incorrectly interpreting the definition. This would escalate the issue but would allow the European Court of Justice to decide but may take many months at least.

7.1 Raising the SVHC threshold

It has been suggested that the 0.1% threshold is too low. There is rarely a risk to users of articles that contain small amounts of SVHCs so that safe use instructions rarely need be supplied so only the identity of the SVHC must be provided as is required by Article 33. With safety data sheets, chemicals need to be included if they exceed threshold values but this is 0.1% only for the most dangerous substances and many types of chemicals have thresholds of 1%. It would not be unreasonable for ECHA to specify thresholds for each SVHC based on the concentrations in articles that might pose a risk to users so that they do need to be informed of their presence. Raising the threshold would not remove the need for suppliers to maintain a database of SVHC information but there will be many circumstances where dilution of parts in complex articles would guarantee that the SVHC could not exceed the higher threshold and so no effort to determine its presence would be needed, thereby reducing the burden on industry. Raising the threshold is unlikely to have a significant impact on health as the threshold should be set at a level where there is no risk. If a risk to the environment exists then ECHA should consider a restriction and not rely on low SVHC thresholds. Politicians are however greatly influenced by Green Groups and less so by industry and so the likelihood that thresholds would be raised is very small.

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