

Frequently Asked Questions on Article 33.1 of the REACH legislation.

Developed by Automotive Task Force-REACH

There is a legal requirement as part of the wider REACH legislation for a supplier of an article (see glossary for definition) to communicate with the next professional user when substances listed in the REACH Candidate List for Authorisation are present in a concentration exceeding 0.1% weight/weight of the article. The challenge is to firstly understand the chemical ingredients in all the articles that you produce, import, distribute or place on the market and then to devise an appropriate method to communicate the required information.

Further information can be obtained from the Automotive Industry Guideline
http://www.acea.be/index.php/files/aig_reach_v21_en_zip_updated_17_09_2008/

1. What are Candidate List Substances of Very High Concern (hereinafter CL-SVHC)?

SVHC is short for Substances of Very High Concern that are listed in the REACH Candidate List for Authorisation (hereinafter CL-SVHC). These are chemical substances that are considered to be Carcinogenic, Mutagenic or toxic to Reproduction (CMR) classified in category 1 and 2; Persistent, Bioaccumulative or Toxic (PBT) or very Persistent very Bioaccumulative (vPvB) according to the criteria in Annex XIII of the REACH Regulation and/or substances of equivalent concern to the aforementioned e.g. endocrine disruptors. The Candidate List for Authorisation is updated frequently. In a subsequent step CL-SVHC may be included in Annex XIV and undergo the authorisation process. See glossary for more details.

2. What type of material or product is within the scope of Article 33.1?

Article 33.1 encompasses all articles supplied; it can mean a whole car, truck, bus, spare and re-manufactured parts, marketing or promotional material, accessories and any article supplied to your customer.

When considering complex, heterogeneous or composite parts, the lowest unit of supply is the relevant article for communication of CL-SVHC. So, for example if a water pump is considered, the individual sub components or fixings are not relevant, rather it is the complete water pump that is assessed for CL-SVHC content. However, if the sub-components are supplied separately, the CL-SVHC concentration in the sub-components needs to be taken into consideration and possibly communicated. Furthermore, packaging is classed as a separate article.

3. How do I calculate the 0.1% threshold of an Article?

It is important to be clear about precisely where to apply the 0.1% threshold. The substance concentration threshold of 0.1 % (w/w) applies to the article produced, imported, distributed or placed on the market. It does not relate to the homogeneous materials of an article or to the individual weight of its sub-components. If an article is complex and composed of several different articles then the requirements have to be fulfilled by each producer of the complex article sub-components and also by the producer of the entire (complex) article. The obligation to communicate CL-SVHC applies to articles produced in the EU/EEA and to imported articles if certain criteria are met.

4. Who does Article 33.1 affect?

It applies to all actors in the supply chain that place articles on the market. This does not affect consumers as Article 33.2 covers this group.

5. As the articles I supply do not release any chemicals into the environment, does this mean I am exempt from the need to communicate CL-SVHC information?

No. The intended release issue is connected to the need to register the substance and is covered elsewhere in the REACH Regulation. All articles placed on the market in the EEA need to be checked for CL-SVHC content, and the information passed to the recipient of the article when they are present in reportable concentrations.

6. In some peripheral area of our business, we distribute promotional point-of-sale or marketing materials to our customers without financial recompense. Are these exempt?

Any article that is transferred to a recipient is placing it on the market and is therefore being supplied and made available. Therefore these examples are not exempt.

However, if the article is passed to the consumer by you or your customer it is covered by Article 33.2 of REACH.

7. To whom do I communicate the CL-SVHC information?

The CL-SVHC information is directed towards the immediate recipient of the article (see glossary for definition of article), or another way of saying this is the next entity in the supply chain that takes ownership of the product. The consumer is not included as this is a business-to-business transfer of information.

8. How do I communicate this information?

REACH does not specify how to communicate under Article 33. Thus it is up to each company to determine its own strategy. The more harmonised this approach is within a sector the better. For example, if an IT platform exists in which a product is sold via an on-line catalogue (e.g. an automotive parts catalogue used to purchase spare parts throughout a national dealer network), then a message should appear automatically when a particular item or part number is selected for purchase. CDs or DVDs that contain parts catalogue information may also include the CL-SVHC data at part number level.

The information should be positioned next to or linked to the individual part number so that it would be relatively difficult to avoid noticing. In other words, the normal means by which customers would usually order the item is the point at which the CL-SVHC information should be encountered.

It is unnecessary to create a system of acknowledgement so that evidence exists that your customer read and understood the information. It is the responsibility of the next entity in the supply chain to pass on the information in a similarly automatic and obvious fashion. For example a car manufacturer would have to notify his dealer network.

Simply making reference to a web address in sales literature or brochures is not suitable as this does not meet the automatic criterion, as it could easily be overlooked.

9. How much CL-SVHC detail do I have to provide?

The regulations use the words “as a minimum” and “information available” both of which are wide open to interpretation and there is little guidance published by ECHA or other authorities. In most cases, the CL-SVHC present in an article is bonded or combined during an industrial process with non hazardous materials. There is often information about the hazards of particular CL-SVHC, but only in their pure form and is often detailed in a Safety Data Sheet (SDS). This may be irrelevant information and possibly unduly alarming if it were to be distributed. So, on balance it is advised only to communicate the name of the CL-SVHC. It can be assumed that vehicle parts are not inherently hazardous unless specifically mentioned as such in an instruction manual.

10. Is there a template I can use so I get the wording correct?

Yes, e.g. the German Industry Association BDI has published a guidance document with a sample letter that can be used for communication along the supply chain (Annex I in the BDI document):

http://reach.bdi.info/REACH-Hilfestellungen/Musterformulierungen_Artikel_33_v220410e.DOC

11. How do I know whether the articles I supply contain CL-SVHC's? Is it expected that my supplier provides me with Article 33.1 information automatically, or do I need to ask?

ECHA emphasises that business- to- business communication of this type between European Economic Area (hereinafter EEA) based companies should be automatic and not as a response to prompts within the supply chain. Thus, in the first instance the professional customer can assume that they will be provided with the required information without the need to make any requests.

However, there is a difference between how to communicate with suppliers within and those located outside the EEA. Suppliers that are located outside the EEA do not have the legal obligation to automatically inform their EEA based customers. Therefore, it follows that EEA based companies may need to actively request information from non-EEA based suppliers and the question needs to be posed about CL-SVHC content. Including the obligation to communicate CL-SVHC information into the supplier contract or terms of trading is highly recommended (see also Q 18).

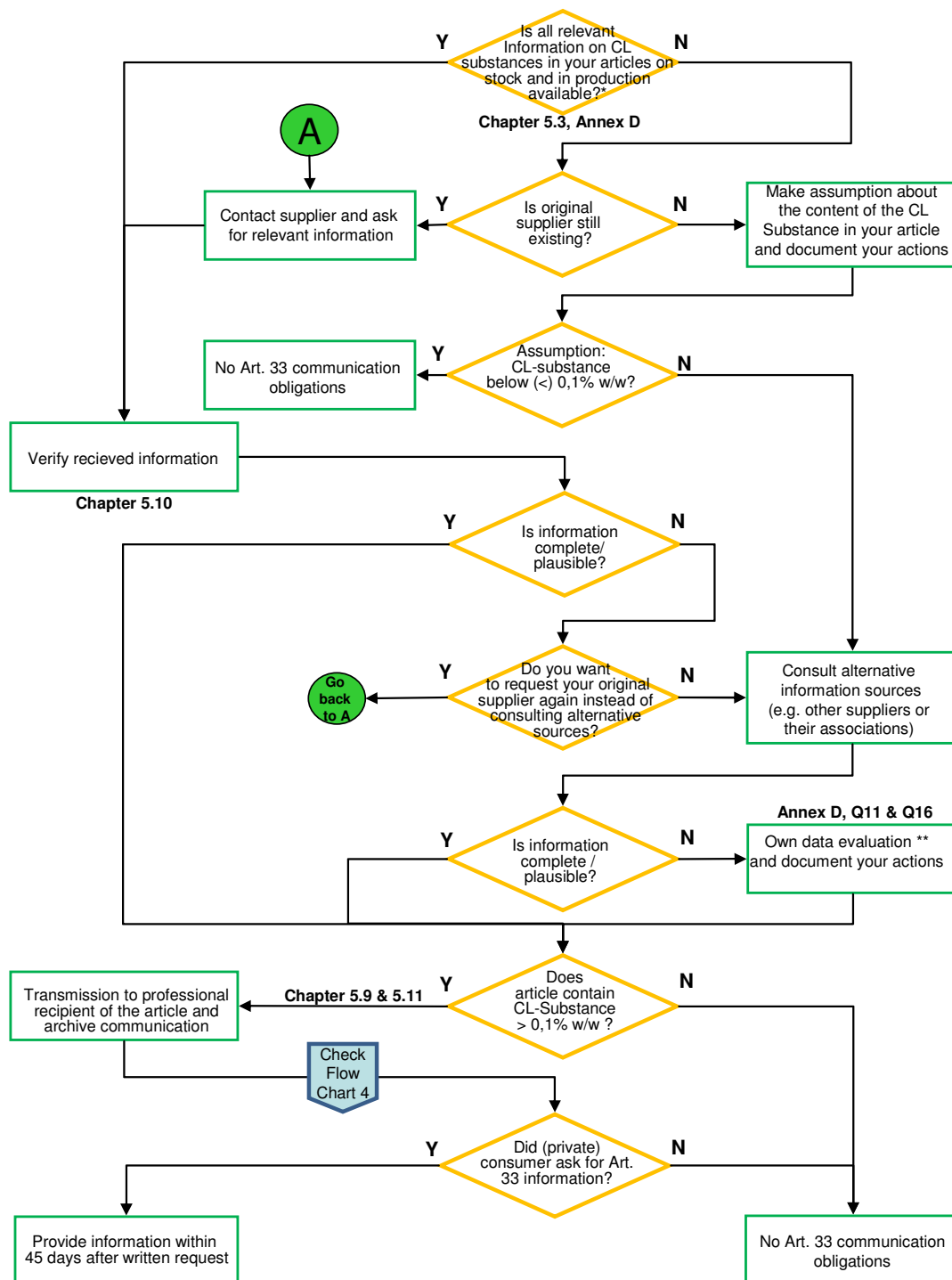
If generic databases exist such as the IMDS, then these are the chief source for collecting evidence that a CL-SVHC is present in an article. In the main, data provided by the IMDS or equivalent systems is what is referred to as "available" in the legislative text. Alternatively, if portions of your supply chain are not covered by these quantitative methods, a risk analysis exercise should be undertaken to search for CL-SVHC existence. An entirely passive approach is not advised; instead one has to raise the question in the supply chain.

In cases where data is not available a four-step approach is recommended;

- Ask your supplier (if not in business see answer to Q.16).
- Undertake a risk based survey analysis based on your in- house knowledge to arrive at the most likely areas of CL-SVHC existence
- Obtain robust and reliable data from similar product groups and then use those findings to extrapolate information for the articles where there is no information available. This may be called a "read across" process.
- As a last resort and in extreme circumstances, laboratory tests can be carried out. At present this is not foreseen as being necessary or appropriate.

This is a workable and practical framework and does not represent absolute scientific and legal certainty as it includes an element of subjectivity. Nevertheless it remains consistent with the themes and intentions of the REACH regulatory framework.

Flow Chart 8 :
REACH Art 33
Communication Process



- * • Information on CL-substance > 0.1 % w/w should be delivered automatically by your supplier with the article (e.g. IMDS Material Data Sheet)
• For in house manufactured parts the same information has to be available

- ** • Risk based survey analysis based on in-house expert knowledge
• Comparison with similar product groups (data bases)
• Ultima ratio: chemical analysis

12. What if a supplier voluntarily passes on detailed safe handling information about a particular substance present in an article, what action do I take?

As the impact of REACH filters through industry over time and the list of substances classified as CL-SVHC's expands, it may be expected that safe handling information will appear more regularly. If a supplier transmits this sort of information to you, it is always your duty to pass this on after verifying the information appears on the surface, to be accurate.

It is the Task Force's view that other areas of legislation or Health & Safety policies may be used to disseminate safe handling techniques as well as up-to-date instruction manuals.

In general, articles supplied by the automotive industry are considered safe.

13. What happens if information received is dubious or contradictory? For example, one particular supplier provides robust CL-SVHC data whilst another supplier of a very similar product claims that there is no CL-SVHC in reportable quantities.

It should be clearly understood that suppliers are responsible for the accuracy and authenticity of data provided. It is not necessary to undertake wholesale verification of suppliers' data; one must broadly accept the authenticity of data received. Data received in the main should be trusted.

However if obvious or clear-cut contradictions or errors in data submission occur, then the offending provider of this suspect data may be challenged.

This is a due diligence (n.b. no provision of due diligence in REACH) approach and evidence of communication should be archived and can be produced in the event of any enforcement activity.

This is regarded as the limit of proactive checks that are to be carried out when seeking to identify CL-SVHCs in a supply chain. Wholesale CL-SVHC checking would constitute a "double loop" of unnecessary and repetitive tasks.

14. Do I have to undertake expensive laboratory tests to determine at a molecular level whether specific obscure chemicals exist in articles that I supply?

Wholesale molecular analysis would be commercially unviable and possibly scientifically inexact given the complexity of most articles in the automotive industry. If this approach were adopted, then it would possibly lead to huge volumes of material being scrapped and even landfilled. This would clearly be in contradiction with the environmental spirit of REACH, as declared in the first page of the preamble of the legal text.

15. My suppliers are either unwilling or unable to tell me whether CL-SVHC's exist in reportable quantities, so it is impossible for me to be 100% certain about what I report. What action should I take?

As mentioned above, if your supplier no longer provides you an article and if the supplier is unwilling to provide CL-SVHC content, or requests payments for laboratory tests or other unreasonable responses, then you should adopt the four step risk analysis process (see answer to Q. 11). Trade associations may be able to act as a forum to promote best practice in this area.

16. Many of the parts I stock are for specialised vintage or classic cars and so no supplier exists as they ceased trading some years ago. How can I possibly adhere to these regulations?

The Commission has not adequately understood the significance of this scenario and considerable discussions have taken place on this subject amongst industry experts. In former times there was no sophisticated method for capturing or recording data on the chemical constituents in automotive parts, so only very limited data exists or it is not readily obtainable. As a consequence an innovative set of tasks have been devised to resolve this impasse and this is illustrated in Flowchart under Q 11. Each key step can be described as follows;

- Search the IMDS or equivalent systems for part numbers in which CL-SVHC content above 0.1% exists.
- Submit the description of parts affected to the Task Force-REACH SVHC Survey .
- The areas of inventory that are most likely to contain CL-SVHC's in communicable quantities can now be understood. One may then apply the findings from the SVHC survey to an individual supply chain using the in- house knowledge and expertise to target and identify likely suspect parts.

This way of approaching a seemingly impossible situation is considered a way of avoiding the need to undertake elaborate laboratory testing that may be of dubious accuracy. This method is only applicable in two specific circumstances;

- Firstly when there is no supplier in existence. The process outlined above in the answer to Q.11 is relevant for all other situations.
- and
- Secondly when there are serious reasons to suspect that CL-SVHCs exist in an article.

17. Do I have to translate the CL-SVHC information into all 23 EU languages?

No, as this is a business-to-business information flow the regular language that is used within each company is sufficient. In most cases English is appropriate.

18. Is there anything I can do to encourage suppliers to conform to Article 33.1?

Yes, there are two courses of action recommended. Firstly ensure that the contract between you and your supplier includes clauses that specify their obligations in respect of communicating CL-SVHC information.

Secondly, a periodic communication either by letter or e-mail to the supply base to encourage this type of data to be provided.

19. What are the key messages of Article 33.1?

- Packaging is an article, so the presence of a CL-SVHC needs to be communicated if it exceeds the 0.1% w/w limit
- Legacy parts are within the scope of Article 33.1
- Professional or industrial customers and distributors are to be notified of CL-SVHCs automatically
- Consumers are not considered a “recipient” and should not be notified within Article 33.1 (consumers are covered by Article 33.2)
- Article 33.1 affects you even if your parts do not discharge substances into the environment
- It is not sufficient to load all the data on the web and leave it up your customers to find this information
- You are not exempt from the duties to communicate if total CL-SVHCs in all articles is under 1 tonne/annum

FAQ Glossary

Articles

Means an object that during production is given a special shape, surface or design that determines its function to a greater degree than does its chemical composition.

Source: Reach legal text

Candidate List

List of substances of very high concern for potential inclusion in REACH Annex XIV which lists substances subject to authorisation of use (Article 59 REACH).

Substances fulfilling one of the criteria of Article 57 shall be included in the candidate list if agreement on the proposal for identification as a SVHC has been reached through the procedure specified in Article 59 of the REACH Regulation. Article 57 describes carcinogenic, mutagenic, toxic for reproduction and bio accumulative properties that are used to determine SVHC's.

Current/Serial Parts

Parts that are used in current production and whose supplier is therefore contractually bound to provide material data. In addition to parts supplied to the assembly plant or OEM production facility, this may include replacement or spare parts that are supplied to the aftermarket sector for vehicle models still being produced. These are normally distributed through dealer networks. These parts normally have a relatively high demand and supply is regular and constant. The OEM always determines the standards and specification of current/serial part

EEA

The European Economic Area (EEA) consists of the 27 European Union states plus Norway, Iceland and Lichtenstein.

GADSL

Stands for Global Automotive Declarable Substance List and is used by the automotive supply chain to facilitate communication and exchange of information throughout the supply chain. It provides a definitive list of substances requiring declaration and ensures the management of declaration along the complex supply chain

IMDS

The International Material Data System is a collective, computer-based material data system used by the Automotive Industry to manage substance & material relevant aspects of the different parts used in vehicles. Through this system, the automotive industry is able to reconstruct the complete material flow.

Legacy Parts

Non-current vehicle components whose original supplier has ceased trading due to liquidation or bankruptcy and therefore no longer exist as a legal entity. In this instance there is no data available on the materials involved or specifications or no entity to approach to obtain this information. Frequently, these parts have been subject to an all time buy that was arranged before the supplier disappeared.

Comment from US colleague that could be merged into the above paragraph

Legacy parts are old parts that a company has in its portfolio that are not part of its core business and also parts the company no longer wants to produce. The company usually tries to end production by not taking on any new business or by selling the business. A lot of times legacy parts occur when two or more divisions or companies merge and then the resultant entity no longer desires to produce some of the merged parts.

Non-current Parts

Aftermarket or spare parts for a particular model of vehicle that has ceased current production are what is described as non-current. The suppliers of those parts are contractually obliged to continue to provide replacement or spare parts to the agreed standards and quality for a specified period that extends for some years after the vehicle production as ceased. Parts may become non-current during the life of a particular model of a vehicle whilst still in production when face-lifts/make-overs/re-launches/redesigns occur. This is sometimes known as the supersession process. The supplier may change for commercial reasons, but the specifications and materials remain the same. Non-current parts may have an intermittent supply and demand which normally diminishes over time.

As is the case with current parts, the OEM always determines the standards and specification of non-current parts

OE (Original equipment) or Genuine parts

This means all parts originally supplied under contract to agreed and approved standards and specifications to the vehicle manufacturer. The OEM controls the quality and distribution channels of these certified spare parts. This can be both current and non-current.

OEM

Original Equipment Manufacturer/Manufacturing means the names of the vehicle manufacturers that produce the brands e.g. Toyota, Ford, BMW, Land Rover, Volkswagen, Hyundai etc.

Parts on Stock

All parts purchased and in stock or “on the shelf” before and after REACH Regulation came into force in December 2006. This term can mean either current or non-current parts.

Patented Parts

These are not approved by the OEM and are generally a lower cost option used in the independent market outside the dealer network. The OEM has no responsibility for the material, quality or specifications of these parts.

Placing on the market

Placing on the market: means supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market

Source: REACH legal text

Re- manufactured parts

In various circumstances, a third party supplier can be involved in reconditioning used parts that are then sold often at a reduced cost. Normally, this can be arranged by applying a surcharge to encourage the return of the used part. These may be called exchange units and can typically include engines, gearboxes, starter motors, clutch kits or alternators. Furthermore, a third party supplier, not the original manufacturer, can be used to upgrade, enhance, re-package or re-calibrate genuine/OE parts to a comparable and approved standard.

SDS

This stands for Safety Data Sheet. The SDS provides a mechanism for transmitting appropriate safety information on substances and mixtures.

Service exchanged parts

These are normally engines or gearboxes that are re-conditioned using approved OEM channels.

Spare parts

All components that are supplied after the vehicle has been purchased in order to replace parts through normal wear and tear, damage, failure or the decision to upgrade to an alternative component to enhance the appearance or performance. Spare parts include;

- OE (Original equipment) or Genuine parts
- Patented Parts
- Used parts
- Service exchanged parts
- Re- manufactured parts

There are a number of different definitions of vehicle components, parts, accessories or spares that need to be clearly established as each type of component may need to be treated differently when seeking to apply Article 33.1 in the automotive industry.

Supplier of an article

Means any producer or importer of an article, distributor or other actor in the supply chain placing an article on the market.

Source: REACH legal text

SVHC

A Substance of Very High Concern (SVHC) is a chemical substance that may have very serious and often irreversible effects on humans and the environment.

Substances on the Candidate List may subsequently become subject to authorisation of use in the EEA by decision of the European Commission.

Used parts

Used parts are obtained by recycling spares removed from a previously owned car and normally obtained from car breakers.