Candidate List substances in articles

Guidance on the duty to communicate information under REACH



- 2. Your duty to communicate information
- 3. Place demands on existing and new suppliers
- 4. Check supplier's declarations and test reports
- 5. Communicate information to professional users on delivery of products
- 6. Be prepared to respond to requests from consumers
- Annex A: Template for covering letter for suppliers
- Annex B: Template for Supplier's Declaration
- Annex C: Example of guideline for shop staff









1 About the guidance

This guidance concerns the requirements in EU legislation on chemicals for information about chemical substances of very high concern in articles (REACH article 33). The guidance was published by the Danish EPA, the Trade Association Danish Building Centres ("Brancheforeningen Danske Byggecentre"), the Danish Chamber of Commerce and the Confederation of Danish Industry, as part of a Partnership on the duty in article 33 for building centres and their suppliers. Even though the guidance was developed for building centres, it may be used by all suppliers of articles, procurement officers and distributors.

Articles is a REACH term for a wide range of products, such as electronic equipment, furniture, kitchen utensils, toys, clothes, shoes, bicycles and packaging. If the articles sold by your company contain chemical substances from the Candidate List, you have a duty to communicate this information to distributors and professional users when supplying the articles, while consumers only have to be informed if they ask. Candidate List substances are still legal in many products, but they are in the authorities' spotlight because they are considered to be of very high concern for human health and for the environment.

This guidance is intended as a help to collect and communicate adequate and accurate information about Candidate List substances in articles throughout the value chain. By following this guidance and using its templates, you may furthermore help to ensure that suppliers are faced with more uniform requirements, and thereby enhance the quality of the information and reduce the amount of documentation and quality control for all suppliers in the chain.

Information about Candidate List substances in articles makes it easier for producers and importers to identify substances that might benefit from being substituted with other less harmful alternatives. Furthermore, the information makes it easier for professional users and consumers to avoid products that contain substances of very high concern for human health or the environment.

Tool: Do your articles contain Candidate List substances?

As a supplement to this guidance, the Partnership has developed a special tool to help you check and inquire about information received from your suppliers about Candidate List substances in articles. The tool provides examples of Candidate List substances in article parts made of materials such as plastic, rubber, metal, wood, etc. It also gives access to databases providing an overview of Candidate List substances in selected materials.

Read more at the Danish EPA website (in Danish)





Know your duty to communicate information

If you are a supplier of an article containing more than 0.1% (weight by weight) of a Candidate List substance, you must communicate this information to your customers, and, if necessary, guide them on safe use. This applies irrespective of whether the article was produced in the EU or imported from a country outside the EU. The duty to communicate information applies to each individual part of a complex article.

Examples of complex articles which may contain Candidate List substances

Each part of a paint brush constitutes a separate article, and customers have the right to be informed of any content of Candidate List substances in each individual part. This rule ensures that no information about Candidate List substances in individual parts is lost along the supply chain, thus providing better protection for customers.



Note that the packaging of the paint brush constitutes a separate article.

Your duties to communicate information vary, depending on whether you supply to professional users or consumers:

- **Professional users** must be informed on delivery about the content of Candidate List substances in articles and all article parts.
- **If a consumer** asks whether an article or article part contains Candidate List substances, he/ she must receive a response within 45 days. Consumers are also entitled to information about Candidate List substances in articles they are not purchasing.

Simply directing the consumer to one's own supplier or the producer/importer of the article/article part is not sufficient. Each supplier is responsible for knowing whether the articles they sell contain Candidate List substances, and as a supplier, it is your duty to inform your customers. Similarly, however, your supplier (importer or producer) has a duty to communicate such information to you, if your supplier is established in an EU country.

REACH imposes no requirements on the format of information, i.e. whether it is to be in printed or electronic form, attached to the article or packaging, or enclosed with it, etc. The information may also be provided as a link to a website, as long as the information is easy to find.

How do you decide whether a product is an article?

As a rule of thumb, if the product has a permanent shape, it is probably an article. REACH 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 does its chemical composition. Therefore, when assessing whether a product is an article, you need to consider whether its shape determines its function. Objects that have been given a shape, e.g. a cup or a plastic chair, are articles. However, paint, cleaning agents and cosmetics are not articles. These are chemical mixtures. Similarly. even though they have a permanent shape, a bar of soap or a candle are not articles, because their chemistry, rather than their shape, determines their function. Packaging is considered an article because its shape, surface or design is more important than its chemical composition.

If you are in doubt about whether a product is an article, you may consult the European Chemicals Agency's Guidance on substances in articles. You may also contact your national REACH helpdesk.



What is the Candidate List?

The Candidate List is a list of chemical substances of Very High Concern (SVHC) for human health or the environment. These include substances that are carcinogenic or toxic for reproduction, or that are particularly hazardous to the environment. Endocrine disruptors may also be included on the list. The substances are candidates for inclusion on the list of substances requiring authorisation under REACH. Read about the authorisation scheme

The European Chemicals Agency (ECHA) updates its Candidate List twice every year with new substances, and the duty to communicate information applies from the date on which the substance is added to the Candidate List. In January 2018, there were 181 substances on the List. See the Candidate List

<u>Sign up for the ECHA newsletter</u> to receive regular updates on REACH and new substances on the Candidate List.

Notification obligation for Candidate List substances in articles

This guidance only concerns suppliers' duties to communicate information under article 33 of REACH. Therefore, you should be aware that you may have other obligations as well. Producers of articles in the EU and importers of articles from countries outside the EU may also be under an obligation to notify Candidate List substances in articles to the European Chemicals Agency if the total amount of substances present in all articles exceeds 1 tonne per year. Notification must be given by no later than six months after a substance has been included on the Candidate List. Read about the notification obligation





Place demands on existing and new suppliers

In order to meet your duty to communicate information, as a wholesaler or a retailer, you need to receive information from your suppliers about the content of Candidate List substances in the articles/article parts they supply to you. Consequently, you must ensure that your suppliers are familiar with the rules associated with the duty to communicate information, and it is advisable to incorporate the requirements in all your supplier agreements/contract specifications.

In particular, suppliers outside the EU may be ignorant or unaware of the fact that importers of articles need information about the content of Candidate List substances in order to comply with EU legislative requirements. If you import articles from a non-EU country, you are responsible for informing your suppliers about the requirements, and possibly for referring them to additional information about the requirements and an up-to-date Candidate List. If the article is supplied from an EU country, the European supplier has a duty to communicate information to you, without you having to ask for it. However, you have a duty to ensure that you receive the correct information.

If the article or the individual parts of a complex article contain more than 0.1% (weight by weight) of a Candidate List substance, the supplier must:

- State the chemical name of this substance
- Provide sufficient information to allow safe use of the article

If the article or the individual article parts do not contain more than 0.1% (weight by weight) of a Candidate List substance, it is advisable to make an agreement with your supplier to issue a declaration to this effect.



Annex A shows a template for a letter that can be used to describe the duty to communicate information to your suppliers, as well as the demands your company places on its suppliers. The wording of the letter makes it usable for suppliers within and outside the EU. **Annex B** shows a template for a supplier's declaration. This declaration also imposes an obligation on the supplier/importer to update the declaration when new substances are included on the Candidate List.

Using the templates is optional. If you use the supplier's declaration template when placing demands on your suppliers, you may help ensure that suppliers are faced with uniform requirements for information and documentation from all their Danish customers. This will make life easier for the suppliers and at the same time improve the quality of the declarations.

Supplier's declarations can be submitted to "ByggeBasen"

"ByggeBasen" is an online product catalogue for the Danish building centres' association. The catalogue includes approx. 600,000 product numbers. It is now possible for suppliers associated with Byggebasen to report supplier's declarations (annex B) to ByggeBasen.

Members of the Trade Association Danish Building Centres can access "ByggeBasen" and declarations by using a login or via their ERP systems. Furthermore, supplier's declarations will be accessible under the name "Product data" via apps run by the building centre chains, and customers can gain access via their DB-number or EAN-number.



Check supplier's declarations and test reports

As a distributor, you are responsible for any information you pass on to your customers, and consequently, you need to check that the information you receive from your suppliers is adequate and accurate. A declaration from a supplier stating simply that e.g. "The product is REACH-compliant" is not sufficient, because it does not say whether the article, or parts of the article, contain Candidate List substances.

If you receive no information that an article contains a Candidate List substance, you need to consider what is most likely: That the article does not contain any Candidate List substances, that the supplier does not have this information, or that the supplier is unaware of its duties or does not comply with these duties. A further reason may be that the supplier is unaware that the threshold value applies to each individual part of a complex article.

Note that a test report cannot take the place of a declaration concerning the content of Candidate List substances, unless such a declaration is included and clearly indicated in the report.

If you assess that the information is insufficient, you should ask follow-up questions to the supplier. In this connection, it may be beneficial to know which substances are usually present in various materials. You can use the website Er der kandidatlistestoffer i dine artikler? (in Danish), which has been developed by the Danish Partnership for article 33, to ask your suppliers more specific questions about the content of substances in the articles or article parts supplied.

The Candidate List is updated with new substances every six months, and as new substances are added to the list, more work will be required to keep track of the content of substances in articles. Consequently, you may consider how this work can be organised systematically, e.g. by incorporating REACH requirements into existing routines for quality control and supplier management..



Checklist for assessing supplier's declarations:

- Does the declaration specifically address compliance with article 33 of REACH on information on Candidate List substances in articles or article parts?
- Is the declaration less than six months old so that it concerns the most recently updated Candidate List?
- Does the declaration unambiguously concern the supplier and the articles supplied?
- Who prepared the declaration, and is this person authorised to sign the declaration on behalf of the supplier?
- Is there reason to doubt the validity of the declaration? If so, request that documentation be submitted to support the declaration, e.g. a test report.

Checklist for assessing test reports:

- Does the report state the name and address of the laboratory conducting the analysis?
- ✓ Does the report state the dates of receiving material and performing the test?
- ✓ Is the test less than six months old?
- Can the report be uniquely identified, e.g. through a case number and a date of issue?
- Does the report contain a unique identification code and a description of the material and the substance(s) that the test is designed to detect?
- Have the test preparation methods and analytical methods applied been described with reference to applicable standards and any deviations from such standards?
- Does the report state the limit of detection (LOD) or limit of quantification (LOQ) for the test method?
- ✓ Are test results shown with unit of measurement and indication of uncertainty?
- Has the report been signed, and possibly stamped, by a person authorised to do so?



When would it be relevant to carry out random checks?

REACH does not require chemical analyses, but analyses may be used as random checks supplementing insufficient information from suppliers. They may also be used if you suspect that the article/article parts contain a Candidate List substance, or if you want to make sure that the concentration of a substance in individual article parts is indeed below 0.1%.

Chemical analyses are costly, and therefore it may be a good idea to combine analyses to detect Candidate List substances with checks for compliance with other legislation or with product quality testing. There are no formal requirements on the methods and laboratories to be used for these checks and tests. However, it is a good idea to opt for an accredited laboratory and to apply standard methods. You can check the Er der kandidatlistestoffer i dine artikler? website (In Danish) to limit the number of substances to be analysed.

ECHA's guidance on substances in articles provides useful advice on how to organise chemical analyses

Communicate information to professional users on delivery of products

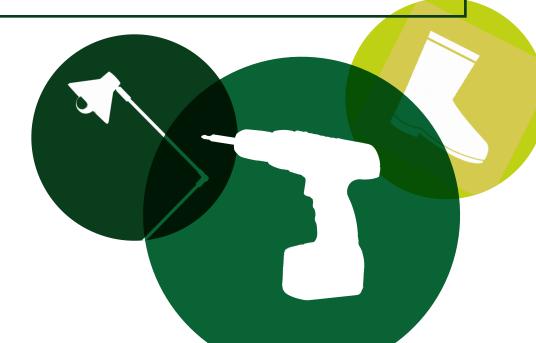
Professional customers must be informed on delivery about the content of Candidate List substances in the article/article parts. This applies to you as a recipient of the article from your supplier within the EU, as well as to your professional customers. You may consider whether information about the content of Candidate List substances can be included on product labels, instructions for use or other inserts accompanying the article. Another option is to send this information to the customer along with the invoice or the order confirmation, possibly as a link to a website from where the information can easily be accessed.

If an article contains Candidate List substances, you must provide the information that is available to you, and that is sufficient to allow safe use of the article, including, as a minimum, the name of the substance. There are no requirements on the format of the information, or how it is communicated. However, it is a good idea to explain to the customer that provision of the information is required by law, and that the chemical substances in question are considered to be of very high concern for human health or the environment.

How do you assess whether information on safe use is needed?

When deciding what information to communicate concerning safe use, you need to consider how the article will be used, and how this use may affect the environment or the health of individuals who come into contact with the article. You should also consider how the article will be handled and, ultimately, how it will be disposed of as waste once it is obsolete.

Information on safe use may include conditions of use, e.g. temperature, outdoor/indoor use, frequency and duration, as well as measures to reduce the impact on humans exposed to substances or release into the environment. Safety information may be based on the property causing the substance to have been included on the Candidate List. If the risk of impacts on humans or the environment is low for the relevant use, information about the name of the substance may be sufficient. However, you should keep in mind that the substances in question are considered to be of very high concern.



6

Be prepared to respond to requests from consumers

Few consumers are aware of their right to be informed whether an article contains Candidate List substances. However, this may be changing as organisations and authorities in several European countries are working to disseminate knowledge about this right through inspection and various information campaigns.

Furthermore, there are no requirements on the format of the information to which consumers are entitled, or how it is to be communicated. However, information on chemical substances is often hard to understand, and consequently, it can be considered good practice to explain why substances cause concern, and possibly their function in the article. Furthermore, consumers may find it difficult to understand if they have to wait for up to 45 days before they receive a response, so it is a good idea to be clear about this.

Companies with several retail shops may benefit from ensuring that all shops and employees follow the same routines for responding to requests from consumers. In this connection, it may be beneficial to draw up a guideline for shop staff, instructing them in how to respond to requests. **Annex C** shows an example of a guideline that may serve as inspiration.

Example of information about content of Candidate List substances

The handle bar of a bicycle may contain the substance bis (2-ethylhexyl) phthalate (DEHP), and the plastic cover on the saddle may contain the substance dibutyl phthalate (DBP). Both substances are covered by the duty to communicate information to consumers, because they are on the EU Candidate List of chemical substances considered to be of very high concern for human health and the environment. The substances are added as plasticisers in plastic, and their use in the bicycle is not currently forbidden or restricted.



Checklist: Are you fully up to date with the Candidate List substances?

- Have you received information about the content of Candidate List substances in articles/article parts supplied by all your suppliers?
- Do you have an overview of the Candidate List substances potentially present in different materials, and do you have routines in place to keep this overview up to date?
- ✓ Have you agreed with your suppliers that they should update information regularly?
- Do you have routines in place to ensure that you keep up to date on information about content of substances in articles and individual parts of complex articles?
- **✓** Have you checked whether information is required about safe use?
- ✓ Have all your customers received the information to which they are entitled?



Annex A: Template for covering letter for suppliers

Dear supplier,

According to article 33 of the EU REACH Regulation customers have the right to know whether the articles they purchase contain any chemicals from the REACH candidate list. These chemicals are also known as SVHC (Substances of very high concern) as they may have serious and irreversible effects on health or the environment. The candidate list contains at present (January 2018) 181 substances, which are subject to the information obligation. Without this information, the articles cannot be placed on the market within the EU.

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. Articles that are assembled or joined together in a new article (complex article) remain articles for REACH purposes.

Our suppliers must submit a Supplier's Declaration for each article or article part in a complex article using the enclosed template. If no SHVC are present in the article or any of the article parts in a concentration of more than or equal to 0.1%, one declaration is sufficient.

You are invited to enclose any documents (e.g. laboratory tests and reports) that can document the presence/absence of SVHC. However, such documents do not replace the declaration, which must always be completed.

Note, that packaging is considered as a separate article and is under the same obligations.

It is of utmost importance that data are up to date and verifiable and we expect our suppliers to continuously monitor the REACH candidate list and react when the list is amended. This happens two times a year. **The latest candidate list can be found here**

Add if in line with company policy:

We are aware that several of the substances on the candidate list are widely used in the production of articles, e.g. a range of phthalates are used in plastic components. We are also aware that if articles are used in accordance with the designated use, they do often not, to the best of present knowledge, pose a danger to health or to the environment and that the use of these substances is often in accordance with applicable law. However, in order to be proactive, we encourage our suppliers to phase out the use of SVHC in articles, as we prefer to source and distribute products not containing SVHC, wherever technically and economically viable.

Read more about the obligations to inform consumers of SVHC here:

https://echa.europa.eu/information-on-chemicals/candidate-list-substances-in-articles

https://echa.europa.eu/documents/10162/13563/leaflet_reach_2018_non_eu_en.pdf

Should you have any queries about the declaration, please, do not hesitate to contact us.

Kind regards,

Annex B: Template for Supplier's Declaration

Supplier's Declaration for articles / article parts

REACH and Substances of Very High Concern (SVHC), regulation (EC) No. 1907/2006

1. THE ARTICLE		
1.1 Article name and EAN number:		
1.2 Describe if the article is made up of more than one article part:		
1.3 Photo of article (optional)		
2. SUBSTANCE(S) IN THE ARTICLE		
2.1 Does the article or any parts of the article, that in it self meets the definition of an article, contain SVHC from the latest updated candidate list at a concentration above 0.1% (w/w)?		No Yes
2.2 If answer to 2.1 is "yes", the subs (insert more rows if necessary). Oth	tance(s) in question must be specified fo perwise, go to part 3.	or each article part
Name of article/article part and EAN number:	Chemical name/CTFA name/INCI name/ International abbreviation:	CAS no./EC no.:
2.3 Is information on safe use required? Consider how the article is used and which exposures and risks are relevant.		_ No _ Yes
	provide information to ensure safe use. ance X, which is harmful to environment Handle waste as hazardous waste.	or health.
The undersigned supplier accepts t documentation towards the author REACH article 33. The undersigned :	es that the information given in this decl hat the information in this declaration ca ities and for customer information obliga supplier take the full responsibility for upo or changes in the REACH Candidate List o	an be used for ation according to dating the declaration
3.1 Supplier's full formal name:		
3.2 REACH contact person:		
3.3 E-mail of contact person:		
3.4 Phone of contact person:		
3.5 Date:		
3.6 Signature:		

Annex C: Example of guideline for shop staff

Guideline for shop staff		
How to respond to requests from consumers concerning Candidate List substances in articles (REACH)		
What does the duty to communicate information mean?	If a consumer asks us whether a product contains chemical substances on the EU Candidate List of substances of very high concern, according to REACH, the EU legislation on chemicals, we have a duty to respond to this request within 45 days.	
	This duty to communicate information only applies to products defined as "articles". Articles is the REACH term for products with a permanent shape, such as electronic equipment, furniture, kitchen utensils, toys, clothes, shoes, bicycles and packaging.	
	The duty to communicate information applies to each individual part of a complex article. An example of a complex article is a bicycle, where the consumer has a right to information about substances in the saddle, frame, tyres, etc.	
	Consumers are also entitled to information about Candidate List substances in articles they are not purchasing.	
	The duty does not apply to chemical mixtures such as paint, pesticides and cleaning agents, but it does apply to their packaging.	
What is the Candidate List?	The Candidate List is the EU's list of chemical substances considered to be of very high concern for human health and the environment. Substances of Very High Concern are also frequently referred to by the abbreviation SVHC.	
	These include substances that are carcinogenic, toxic to reproduction or particularly hazardous to the environment.	
	The use of the substances is still legal in many products, but there is a duty to communicate information about the substances.	
What do you need to do?	If a customer asks whether a product contains substances from the Candidate List or SVHCs, you should do the following:	
	Tell the customer that they may expect a waiting time of up to 45 days.	
	2. Note down the date on which you received the request.	
	3. Register contact information for the customer (phone and/or email) so that we can get in touch with the customer when we have an answer to the question.	
	4. Register the EAN no. and product no. for the product.	
	5. If relevant, indicate which part of the product the customer's question concerns.	
	6. Give the customer an acknowledgement of receipt of the request (state how).	
	7. Submit the information above to xxxxxx on the date on which you received the request.	
Contact	If you have any questions or need additional information, please contact: xxxxxx	