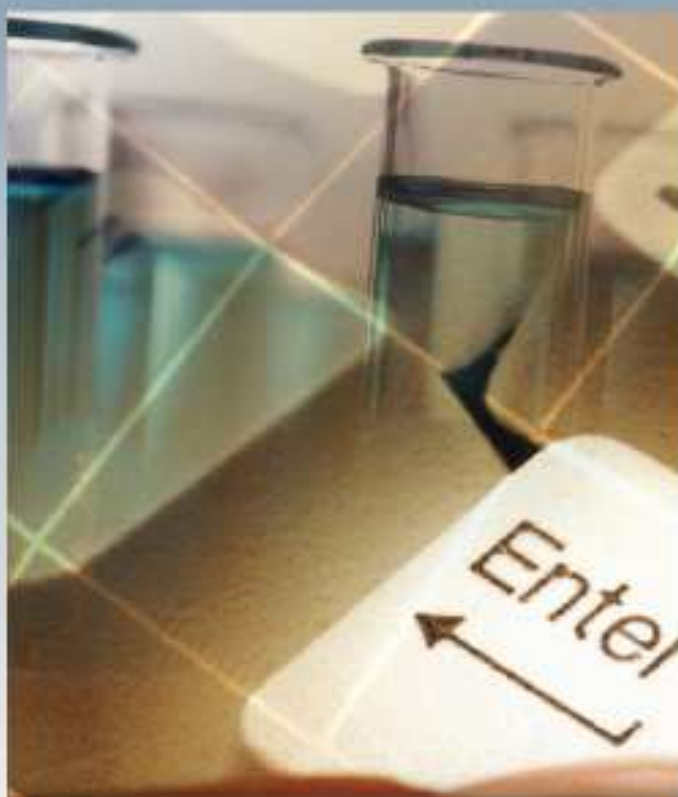


Questions and Answers on notifications on substances in articles



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The European Chemicals Agency (ECHA) is producing this document to inform interested readers about questions arising from the practical steps to submit a Substances in Articles notification touching upon basic provisions of Regulation.(EC) No 1272/2008.

If you have questions or comments in relation to this document please submit them using the information request form (quote the reference and issue date). The information request form can be accessed via the Contact ECHA page at: http://echa.europa.eu/about/contact-form_en.asp

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HOW TO DETERMINE IF THE NOTIFICATION OBLIGATION APPLIES

1. Do I have to notify?

Notification of substances in articles is required from producers and importers of articles when all the following conditions are met:

- The substance is included in the [Candidate List](#)
- The substance is present in articles produced and/or imported by you above a concentration of 0.1% (w/w).
- The total amount of the substance present in all articles produced and/or imported by you, which contain more than 0.1% (w/w) of the substance, exceeds 1 tonne per year.

In this context you are an article producer if you produce articles within the European Economic Area (EEA) whereas you are an article importer if you are established in the EEA and import from countries located outside the EEA.

2. How do I calculate the concentration of a Candidate List substance in my article?

One of the conditions that trigger the notification obligation is when the concentration of the Candidate List substance exceeds 0.1% (w/w) in the article. The concentration of the substance should be calculated on the whole article as imported or produced. Chapter 4.4 of the [Guidance on requirements for substances in articles](#) provides explanations and examples on how to do this calculation.

The substance concentration threshold of 0.1% (w/w) applies to the article as produced or imported. In practice however, companies may find it easier to collect concentration information not on the whole article but on parts thereof. Companies have the possibility to prepare their notification to ECHA on this basis. An example of when this may be preferred is if you are importing 10 different articles, each containing a common part (e.g. same rubber handle). You know the rubber handle contains the Candidate List substance in a concentration of 30% (w/w), which allows you to deduce that the concentration in each of the 10 imported articles will always be >0.1%. Again, it may be preferred to notify on the basis of the part containing the Candidate List substance rather than notifying the different articles and thereby avoiding more complex concentration calculations.

3. How do I calculate the total amount of the Candidate List substance in my article?

One of the conditions that trigger the notification obligation is when the total amount of the Candidate List substance present in all articles produced and/or imported exceeds 1 tonne per actor per year. The articles concerned should contain more than 0.1% (w/w) of the substance. If an article contains the substance at a concentration below 0.1 w/w, this article does not have to be included in the tonnage calculation

The 1 tonne per year limit applies to the total tonnage produced/imported, in the EEA by the same legal entity. The tonnage is not calculated separately for different EU member states if the legal entity is the same.

If you believe you are close to one of the thresholds but are unsure whether you exceed it or not, we recommend you to notify.

Chapter 4.5 of the [Guidance on requirements for substances](#) in articles provides explanations and examples on how to do this calculation.

4. How do I know that a Candidate List substance is present in my article?

This information should be made available to the notifier via the actors of his supply chain. The information needed can often be derived from standardised information that is obtained

from suppliers of substances/mixtures based in the EEA (e.g. Safety Data Sheets or, where a SDS is not required, safety information and regulatory requirements according to Article 32 of the REACH Regulation). Suppliers in the EEA of articles containing >0.1% of a Candidate List substance must provide available and relevant safety information according to Article 33 of the REACH Regulation, including, as a minimum, the name of that substance. Pro-active requests in the supply chain are often useful to obtain the necessary information, in particular when the supplier of the article is outside EEA. As a last resort, chemical analysis of the article could be considered. For more information see Chapter 5 of the [Guidance on requirements for substances in articles](#).

5. What practical steps can I take to find out if the notification obligation applies to me?

Some first considerations of the type of articles you import or produce, the materials they are made of and the imported/produced amounts may give you a hint on whether you have the obligation to notify due to the fact that the conditions > 1 tonne per year and concentration >0,1% are met. If you can not exclude that you could meet the notification requirements for any substance, you should contact your supplier.

You are obliged to notify the presence of all Candidate List substances in your articles. However there may be certain substances on the Candidate List that are more relevant for the article type you are producing or importing, or for the material(s) that the article is made of. If this is the case, you may wish to communicate with your supplier especially about these Candidate List substances or carry out tests for the presence of these Candidate List substances in your articles.

The following information will be needed in order to determine if the obligation to notify applies to you and also when making your notification. You can obtain this information via your supplier, via other information sources or possibly as a last resort by means of chemical analysis.

- the identity of any Candidate List substance in the article (i.e. chemical name or CAS number or EC number);
- the concentration of the substance in the article;
- where in the article the substance is present;

SUBMISSION OF THE NOTIFICATION DOSSIER

6. How can I submit a notification?

The notification is made using the IUCLID software (version 5.3), which can be downloaded free of charge from the [IUCLID 5](#) web page. It is then submitted via [REACH-IT](#). [The Data Submission Manual](#) provides detailed and illustrative assistance to successfully carry out the notification.

To facilitate the submission of the information required to complete a notification, ECHA has made available pre-filled substance datasets in IUCLID 5.3 format for substances on the Candidate List. These datasets contain information on substance identification, composition and classification and labelling. Each Candidate List substance has its own pre-filled dataset, which can be downloaded from the Candidate List webpage.

Once you have created your Substance in Articles notification dossier, it is recommended to use the Technical Completeness Check (TCC) tool. This IUCLID 5 plugin will detect any missing information in your dossier before exporting it and submitting it to ECHA through REACH-IT. You can download the latest version of the TCC plugin from the [IUCLID 5](#) web page.

7. What is the deadline for notification?

A notification of a substance in articles shall be made at the latest 6 months after the substance has been included on the Candidate List. The obligation started to apply from 1 June 2011.

8. What are the implications if one fails to submit a notification in time? Can it be done later?

If you have the obligation to notify a substance in your articles and the deadline has already passed you are encouraged to notify immediately.

You might face national enforcement sanctions if you fail to meet the deadline. Although ECHA accepts notifications after the legal deadline, this does not prevent your national enforcement authorities to impose sanctions on you.

9. What if I start to import the substance after it has been included in the Candidate List?

If the import of the substance starts after the notification deadline has expired (i.e. 6 months after the inclusion in the Candidate List), notifications must be made without undue delay as soon as the conditions related to the notification obligation are met, i.e. as soon as the 1 tonne per year threshold has been exceeded.

10. How many articles can I submit in one notification for the same substance?

One notification should be submitted for all the articles produced or imported containing the same substance by/to one legal entity. You are however requested to indicate the uses for each different type of article in your notification.

11. Is it possible to submit a single notification for different substances or different importers/manufacturers?

No, it is necessary to submit a separate notification for each substance and for each importer/manufacture.

12. Do I have to update my notification?

In order to be able to demonstrate compliance with your obligations, you are recommended to update your notification if the information included in the notification changes. Examples of important changes could be: change in tonnage range, production/import of different articles (with e.g. different use) containing the same substance etc.

If you stop importing or producing articles containing a candidate list substance you do not need to update your IUCLID 5 dossier, but you can inform ECHA directly via [REACH-IT](#).

For more information see Chapter 8 of the [Data Submission Manual](#).

GENERAL QUESTIONS

13. Where can I find the Candidate List?

The [Candidate List](#) and additional useful information is published on the website of ECHA.

14. What is the Candidate List?

Substances fulfilling one or more of the criteria specified in Article 57 of the REACH Regulation can be identified as “substances of very high concern” (SVHC) and put on the “Candidate List”. These SVHC can be:

- substances meeting the criteria for classification as carcinogenic, mutagenic or reprotoxic (CMR) category 1 A or B in accordance with section 3.6 of Annex I to Regulation (EC) No 1272/2008
- persistent, bioaccumulative and toxic (PBT) substances or very persistent and very bioaccumulative (vPvB) substances (according to the criteria of [Annex XIII](#) of the REACH Regulation)
- substances for which there is evidence for similar concern (Article 57(f) of the REACH Regulation), such as endocrine disruptors

Substances are identified as SVHC according to the procedure established by Article 59 of the REACH Regulation.

15. How is the Candidate List updated?

The [Candidate List](#) is updated when substances are identified as Substances of Very High Concern (see above). This is normally done twice per year (in June and December). To allow interested parties to be aware of substances which might be included in the Candidate List, a [Registry of Intentions](#) is published on the website of ECHA. As a producer or importer of articles, you are advised to regularly check the Registry of Intentions. This can help you to prepare for possible obligations that could arise when a substance is included in the Candidate List.

16. What is an 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*”. Chapter 2 of the [Guidance on requirements for substances in articles](#) provides information on how to determine if an object fulfils the above definition, including instructions on how to address borderline cases (Appendix).

17. Is packaging considered part of the article?

Packaging is considered a separate article under REACH. Please refer to section 2.3 of the [Guidance on requirements for substance in articles](#) for more information.

18. How do I calculate the concentration and the tonnage for a “set of objects”?

The notification obligation applies to the article as imported or produced. To make the distinction between producing a single article and producing a set of objects the way the article is supplied to the recipient is relevant. Hence, in case you supply an article in parts and it is the recipient who assembles the article from the parts, then this should be considered as a set of objects and the calculation of the 0,1% should be carried out separately for each part. On the other hand, if you supply an article assembled then only one article is supplied and not a set of objects. Please be aware that some Member States have

Questions and answers on notifications on substances in articles

expressed dissenting views on the calculation of the 0.1% of SVHC in articles, holding the opinion that "once an article always an article".

For imported articles it is the way the article is imported (in parts or assembled) that is relevant.

As described in question 2 of this document, companies always have the possibility to make their notification on the basis of parts, if so preferred.

19. Is there any notification fee?

There is no fee charged for the notification.

20. Can I indicate information as confidential?

You have the possibility to indicate part(s) of the information included in your notification as confidential. Chapter 5.7 of the [Data Submission Manual](#) provides guidance on how to indicate information as confidential and how to provide a justification.

21. I have stopped production/import of the article containing the Candidate List substance. Do I have to notify?

If the production/import ended before the substance was included in the Candidate List or before the notification obligation starts to apply (i.e. 1 June 2011 for substances placed on the Candidate List before 1 December 2010 or 6 months after a substance has been included in the Candidate List) then you do not have to notify.

Please note, however, that for the information requirements specified in Article 33 of the REACH Regulation the date of supply of the article is the relevant date, i.e. the obligations also apply to the producers and suppliers of articles which were produced or imported before the substance was included in the Candidate List and are supplied after the inclusion. Please refer to section 4.3 of the Guidance for additional information.

22. Do I have to take into account the tonnage of the substance in articles produced/imported before the substance was put in the Candidate List?

Once a substance enters the Candidate List you have to determine if you have the obligation to notify. One of the inputs needed to determine this is the tonnage of the substance in imported/produced articles per calendar year (or the average of the three previous years if the article has been imported/produced during three years before the start of the notification obligation). In this calculation, you have to include the tonnage in articles imported/produced for the full calendar year, i.e. if applicable, also before the date of the inclusion of the substance in the Candidate List. However, if the three year average is not available, the notifier will need to rely on the amounts of the previous calendar year.

23. Do I need to notify Candidate List substances in articles made from recycled material?

Article 7 of the REACH Regulation applies also to producers or importers of articles containing recycled material. The producers or importers must assess whether the articles they produce or import fall under the criteria of Article 7. It may be difficult to know the exact concentration of a [Candidate List](#) substance in e.g. recovered polymers where the concentration varies between each batch. If companies draw the conclusion that the articles contain less than 0,1% of the Candidate List substance, ECHA recommends companies to document their basis for drawing this conclusion to be prepared in case of enforcement.

24. Can I appoint an Only Representative (OR)? What can he do on my behalf?

The Only Representative is a natural or legal person established in the Community to fulfil the obligations of non-EU manufacturers under Title II of the REACH Regulation (see Article

8 of the REACH Regulation). The provision of article 7(2) on notification of Candidate List substances in articles is part of Title II of the REACH Regulation. Thus, an OR can be appointed by a producer of an article outside EU to submit a substance in articles notification.

25. Which use will be made of the notifications? Will they trigger new registration requirements?

The notifications will not trigger a decision to register the substance in articles, as such. However the notification information can be used in addition to several other sources (e.g. registration information) to support identification of further needs for risk management. ECHA may require producers or importers of articles to submit a registration if there are grounds for suspecting that the substance is released from the articles under normal or reasonably foreseeable conditions of use and such a release presents a risk to human health or the environment. These decisions will be taken on a case-by-case basis and are not restricted to Candidate List substances.

26. Which are the enforcement activities and the penalties foreseen? What about the dissenting views from some MS?

Enforcement of the REACH Regulation, including the type of penalties is the remit of the authorities of the individual Member States. The different interpretation of how the concentration limit triggering the obligation to notify is to be applied (concentration calculated based on the whole article or on parts of the article) may result in companies facing diverging enforcement practices in different Member States.

27. Who should I contact if I have further questions?

You should contact your [national REACH helpdesk](#).

If you have questions on technical issues on [REACH-IT](#) and [IUCLID 5](#) or you are not in the European Economic Area (EEA) you may contact the [ECHA helpdesk](#).

If you would like to determine your general obligations under the REACH Regulation and how to fulfil them you should use the [Navigator](#).

For general guidance on the provisions of the REACH Regulation that apply to Substances in Articles you should consult the [Guidance on requirements for substances in articles](#).

For guidance on how to submit a notification under Article 7(2) of the REACH Regulation you should consult the [Data Submission Manual](#).

DEROGATIONS

28. Am I exempted from notification?

You are exempted from notification if:

- You can exclude exposure of humans and the environment to the Candidate List substance in the articles during normal or reasonably foreseeable conditions of use, including disposal. Chapter 6.3 of the [Guidance on requirements for substances in articles](#) provides information on exposure based exemptions from notification.
- The substance is already registered for that use. Chapter 6.4 of the [Guidance on requirements for substances in articles](#) provides advice on how to find out if the substance is already registered for that use.

If you conclude that you are exempted from notification, in line with one of the two cases above, ECHA recommends that you document carefully the basis for and reasoning behind this conclusion in order to be prepared for any enforcement activities at national level.

Questions and answers on notifications on substances in articles

Please note that the second exemption applies if the substance is already *registered* for that use. If the substance is already *notified* in the same type of article by another company, the exemption does not apply.

29. How can I prove that there is no exposure to the Candidate List substance present in my article?

A producer/importer of an article wanting to demonstrate ‘exclusion of exposure’ has to ensure that the Candidate List substance does not come into contact with humans or the environment during the use and disposal of the article. For more information on exposure-based exemption from notification see chapter 6.3 of the [Guidance on requirements for substances in articles](#). Note that in practice it may be more difficult and costly to demonstrate “no exposure” than to make a notification.

30. How do I find out if the substance is already registered for a particular use? Can I use information that is disseminated on the ECHA website?

A substance has already been registered for a particular use, if two conditions are fulfilled:

- The substance in question has already been registered, and
- The use in question is the same as one of the uses described in an existing registration of this substance.

For more see chapter 6.4 of the [Guidance on requirements for substances in articles](#).

ECHAs [dissemination portal](#) contains information on registered uses, taken from section 3.5 of the IUCLID registration dossier and based mostly on the so called use descriptors. However due to the generic architecture of the use descriptors, this description is generally not sufficient to conclude on the sameness of two uses for the purpose of establishing whether an exemption on the basis of Article 7(6) of the REACH Regulation applies. The published information that a substance has been registered for use in the Article Category ‘Plastic articles’ does not necessarily mean the registration is made to cover all plastic articles. It could mean that use of the substance in production of some specific plastic articles is covered and described in the registration, while other plastic articles are not covered and assessed. The uses of two very different plastic articles may lead to very different exposures to humans and the environment. If the exposure related to the use of your article is not adequately assessed in a registration dossier, it cannot be considered a registered use.

Please note that there are limited possibilities to include information in section 3.5, apart from the use descriptors. Section 3.5 of the IUCLID registration dossier may however contain ‘free text’ information, which is not based on the use descriptor system. Whether such information is sufficient to conclude on the sameness of use has to be examined on a case by case basis.

Most producers of articles are also downstream users under the REACH Regulation and as such have certain obligations outlined in Title V of the REACH Regulation. Since most substances on the [Candidate List](#) are already registered, producers of articles should already have communicated their use to the registrant for the purpose of registrations. Producers of articles will therefore not have to notify in most cases.

Importers of articles may not have access to detailed information on registered uses. If you are not certain that your specific use is already registered you should notify.

31. I am using a CMR/PBT/vPvB in articles however this substance is not in the Candidate List. Do I need to notify?

Questions and answers on notifications on substances in articles

Notification requirements apply only to substances already included in the [Candidate List](#) and meeting the criteria in Article 7(2) of the REACH Regulation. Therefore, if a substance is not yet in this list there is no need to notify. However, please note that CMR/PBT/vPvB can be included in the Candidate List. It is advised to keep track of the use of these substances in your articles and to follow the development of the Candidate List via the Registry of Intentions. By signing up for the [ECHA e-News](#) you will be alerted every time the [Candidate List](#) or [Registry of Intentions](#) is updated with new substances.

INFORMATION REQUIREMENTS

32. How can I provide substance identity information?

This information should be provided in the IUCLID file. As a minimum it consists of the substance name and/or EC and CAS numbers. To facilitate the submission process ECHA publishes pre-filled substance datasets with substance identity information in the [Candidate List webpage](#). Substance identity information is also available in the “supporting documentation column” of the same webpage. Chapters 3 and 4 of the [Data Submission Manual](#) provide guidance on how to download and use these datasets.

33. How can I find the registration number?

If available, the registration number should be provided in the IUCLID file (section 1.3). The registration number only needs to be included in the notification dossier if the substance has already been registered and the registration number is available to the notifier. If the article is imported from outside the EU, this field does not need to be filled. Producers of articles, incorporating the Candidate List substance into the article themselves, should normally have access to the registration number via the Safety Data Sheet (SDS) for the substance. In this case, the article producer is likely to be exempt from the notification obligation however he should verify that his use is indeed covered by the registration. Chapter 5.5 of the [Data Submission Manual](#) provides guidance on how to enter this information in IUCLID.

34. How can I provide information on classification and labelling?

This information should be provided in the IUCLID file. To facilitate the submission process ECHA publishes pre-filled substance datasets with classification information in the Candidate List webpage. Classification information is also available in the “supporting documentation column” of the same webpage. Chapter 4 of the [Data Submission Manual](#) provides guidance on how to download and use these datasets.

35. How can I describe the use of the Candidate List substance in my article?

This information should be provided in the IUCLID file (section 3.4), by using the descriptor “Technical function of the substance”. Chapter 5.10 of the [Data Submission Manual](#) provides guidance on how to fill these IUCLID section.

36. How can I describe the use of my article?

This information should be provided in the IUCLID file. There you should give:

- a brief description of the article and its use(s) in free text (section 3.4 of IUCLID).
- a brief description of the use of the article during its service life using the use descriptor system (section 3.5 of IUCLID)

Similar articles with similar uses can be grouped under the same use description. Chapters 5.9 and 5.10 of the [Data Submission Manual](#) provide guidance on how to fill these IUCLID sections.

37. How can I provide the tonnage range?

This information should be provided in the IUCLID file (section 3.2). In this section, producers and importers of articles should indicate the tonnage of the Candidate List substance contained in the manufactured/imported articles. As a minimum requirement, the tonnage range is to be provided in section 3.2. In Section 3.4 you have the possibility to provide more detailed information if you so wish. Chapter 5.7 of the [Data Submission Manual](#) provides guidance on how to fill these IUCLID section, including which years to base the calculation on.

38. Which is the “per year” definition for notification purposes?

Article 3(30) of the REACH Regulation specifies that "per year" means "per calendar year", i.e. 1st January – 31st December. However, for the purpose of the tonnage calculation, if the article has been manufactured or imported for at least three consecutive years the average volume of the preceding three years is recommended to be used. However, if the three year average is not available, the notifier will need to rely on the amounts of the previous calendar year.

39. When do I have to submit information on my production site? Is it possible to include several sites in the same notification?

Only producers of articles who manufacture their articles in the European Economic Area (EEA) will have to enter their production sites. Article importers do not need to fill in this information. Please refer to section 5.8 of the [Data Submission Manual](#) for additional information. If a company has several sites producing articles, it can list all the sites in one notification. Different notifications should not be made for different sites if the sites belong to the same legal entity.

40. At which stage of the manufacturing process do I have to notify?

Notification is required from producers or importers of articles, therefore you have to notify only when the object manufactured/imported is an article. Please refer to Chapter 2 of the [Guidance on requirements for substances in articles](#) for additional information on the distinction between a substance/mixture and an article.

41. What are the pre-filled substance datasets?

To facilitate the submission of notifications ECHA has made available pre-filled substance datasets in IUCLID format (i5z files) for substances on the Candidate List. These datasets contain information on substance identification, composition and classification and labelling. Each substance has its own pre-filled dataset, which can be downloaded from the [Candidate List](#) webpage. Chapters 3 and 4 of the [Data Submission Manual](#) provide information on how to download and use the datasets.

Links

Candidate List:

http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp

Guidance on requirements for substances in articles:

http://guidance.echa.europa.eu/docs/guidance_document/articles_en.htm?time=1306157834

List of national helpdesks:

http://echa.europa.eu/help/nationalhelp_contact_en.asp

Questions and answers on notifications on substances in articles

ECHA helpdesk:

http://echa.europa.eu/help/echahelp_en.asp

REACH navigator:

<http://guidance.echa.europa.eu/>

IUCLID 5:

<http://iuclid.eu/>

REACH-IT:

http://echa.europa.eu/reachit_en.asp

Data Submission Manual, Part 20 - How to Prepare and Submit a Substance in Articles Notification using IUCLID:

http://echa.europa.eu/doc/reachit/dsm20/dsm_20_v1.0_en.pdf

Annex XIII of REACH:

http://echa.europa.eu/legislation/reach_legislation_en.asp

Registry of Intentions:

http://echa.europa.eu/chem_data/reg_intentions_en.asp

ECHA dissemination portal:

<http://apps.echa.europa.eu/registered/registered-sub.aspx>

ECHA e-News:

http://echa.europa.eu/news_en.asp

Questions and Answers on notifications on substances in articles:

http://echa.europa.eu/reach/sia/sia_faq_en.asp