Obligations of a downstream user in the context of nanoforms of a substance

Helpdesk Focus: REACH

While the main focus in the last two years has been on the registration of substances in nanoform, it is now on the obligations within the supply chain. There are specific requirements to the downstream users in this context.
If they produce a nanoform of a substance, no registration obligations arise. However, the obligations of the downstream user can vary depending on different conditions and may range from the preparation of a risk assessment, the adaptation and extension of the safety data sheet to the preparation of a separate chemical safety report. This brochure of the Helpdesk Focus series attempts to explain the different downstream user scenarios and to identify the obligations that arise in each case.

Content

1 Introduction

Following the publication of the Helpdesk Focus: "Registration of substances in nanoform", which was addressed to manufacturers and importers of substances in nanoform, this brochure of REACH Focus concentrates on the obligations of the downstream user (DU). The scope of these obligations depends on the hazardous properties of the substance in nanoform and the produced quantity.

First of all, however, it must be differentiated in which case the formation of a nanoform is a manufacture within the meaning of REACH Regulation (EC) No. 1907/2006 and when it is a use. Depending on this, either registration obligations or downstream user obligations arise.

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2 The production of the nanoform of a substance is not a manufacture under REACH

The term manufacture refers to the substance as such, as it is synthesised. It is therefore closely linked to the substance definition in Article 3 No. 1 of the REACH regulation (EC) no. 1907/2006. If a substance is manufactured in nanoform according to the definition in Annex VI of the REACH regulation, it must be addressed in the registration dossier in accordance with the requirements of Annexes VI-X. Analogously, this also applies to the import of the substance in nanoform. Detailed information on the obligations for manufacturers and importers of substances in nanoform can be found in the REACH Focus: Registration of substances in nanoform[1]. If a manufactured substance is transformed into a different form this constitutes a use[2], as the chemical identity of the substance does not change. To distinguish this use from substance manufacture, the term "production" is used in this focus document. Even if uses do not trigger any registration obligations, the downstream user must check which obligations he has to fulfill, inter alia according to Article 37 of the REACH regulation. These depend on the quantity used and any hazardous properties of the substance. The following chapter explains in detail, which obligations arise under different conditions.

3 Possible obligations of a downstream user

As already mentioned above, the scope of the obligations of a downstream user under Article 37 of REACH depends on various factors. Therefore, a distinction is made between four scenarios, which will be briefly described in the following pages and then explained step by step.

Some remarks to start with: practical detailed questions on how or by which means information has to be submitted are not addressed in this focus document. Information on this can be found in the relevant corresponding guidelines. This document focuses rather on the basic answer to the question: which obligations arise under which conditions? Furthermore, the scenarios outlined here follow a narrow interpretation of the legal text. In practice, there will be other or additional ways of sharing the information mentioned here. For example, safety data sheets are frequently prepared for non-hazardous substances and passed on in the supply chain.

In the following four scenarios, it is assumed that the substance that is transformed into a nanoform by a downstream user (DU) has been registered in the supply chain. Incidentally, in this context it does not matter whether this new nanoform is generated from a bulk form or another nanoform of the substance. Scenarios 1 and 2 describe the requirements for downstream users that apply when the registered substance has no hazardous properties. Scenarios 3 and 4 assume that the registered substance has hazardous properties. In the scenarios, only the use of the substance itself is taken into account. **Furthermore, for the sake of simplicity, it is assumed that the supplier is also the registrant of the substance**.

[1] Available in German only:
https://www.baua.de/DE/Angebote/Publikationen/Fokus/Stoffe-in-Nanoform.html

[2] Please refer to ECHAs Q&A no. 1838:
https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/ids/1838
https://echa.europa.eu/en/support/qas-support/browse/-/qa/70Qx/view/scope/REACH/Nanoforms+of+substances

3.1 Scenario 1: Substance has no hazardous properties, registration <10 t/a

General conditions

The substance from which the nanoform is produced is not classified as hazardous according to CLP Regulation (EC) No 1272/2008, is not persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) and has not been included in the candidate list as a substance of very high concern (SVHC).

This means that no safety data sheet (SDS) has to be provided in accordance with Article 31 of the REACH regulation. Furthermore, the substance has been registered by the manufacturer/importer in a quantity < 10 t/a. This means that no Chemical Safety Report (CSR) according to Article 14(1) has to be prepared in this supply chain. This applies regardless of whether the substance was also registered by another manufacturer or importer in a higher tonnage and he has to prepare a CSR. The supplier of the substance shall provide the downstream user, if necessary, the available and relevant information in accordance with Article 32(1). The downstream user now produces a new nanoform from this substance.

What are the obligations of this downstream user?

The downstream user needs to clarify whether the nanoform has hazardous properties in contrast to the supplied substance. If this is the case, the nanoform must be classified. This means that the downstream user must prepare a safety data sheet in accordance with Article 31, if he intends to supply the substance in nanoform to another recipient. Furthermore, from the point of view of ECHA it is necessary to pass the new information on the hazardous property in accordance with Article 34 to the supplier.[3] However, ECHA does not provide any guidance on how the registrant will deal with this information. In addition to this communication, a notification to ECHA in accordance with Article 38(4) is required, as a downstream user classifies the substance differently from its supplier.

If the downstream user concludes that there is still no need to prepare a safety data sheet for the newly produced nanoform, he shall only pass on to his recipient the information available to him in accordance with Article 32(1), if necessary. If the nanoform produced is only used in-house, the downstream user principally does not need to prepare a safety data sheet, but must fulfil his obligations under REACH according to Article 35 and carry out a risk assessment at the workplace (on the basis of the Hazardous Substances Ordinance). Additional obligations, such as the preparation of a separate chemical safety report, do not exist.

[3] Please refer to ECHAs Q&A no 1833, which can be found in section I. Downstream user under: *https://echa.europa.eu/en/support/qas-support/browse/-/qa/70Qx/view/scope/REACH/Nanoforms+of+substances*

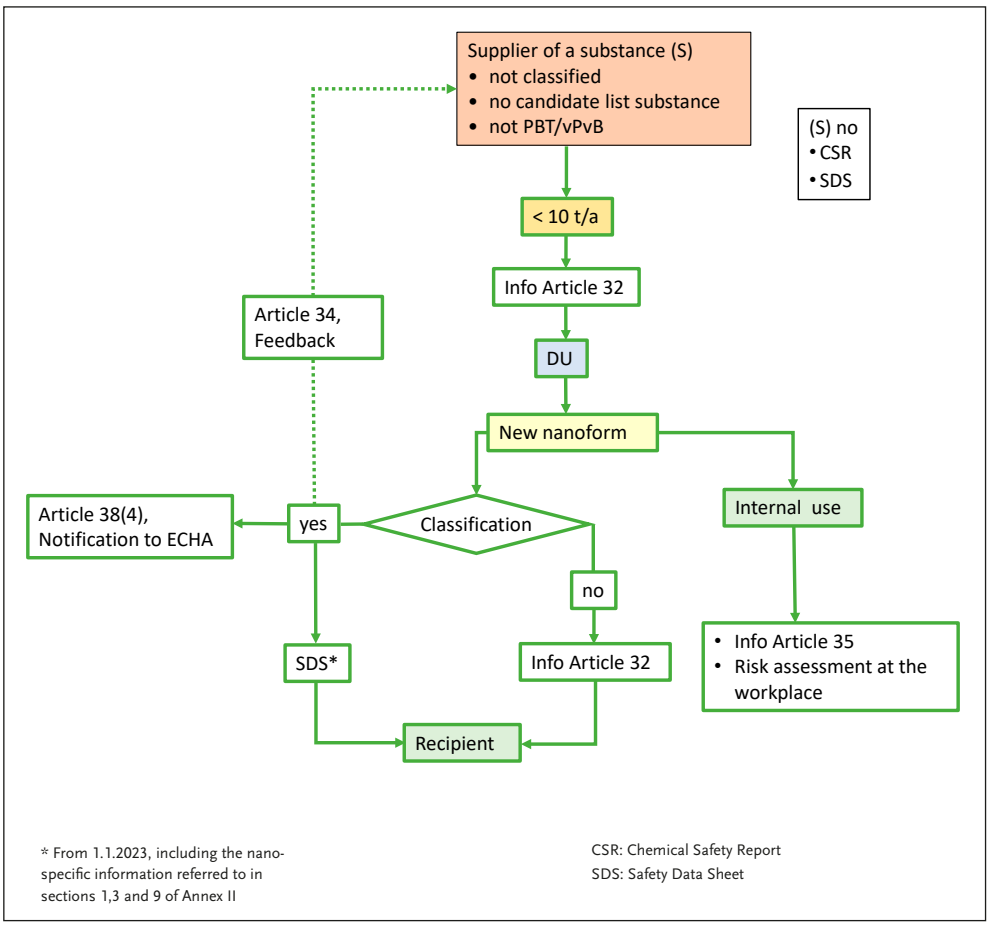

Fig. 1 Scenario 1: the substance is not hazardous and has been registered in this supply chain in quantities below the 10 tonne per year treshold.

3.2 Scenario 2: Substance has no hazardous properties, registration ≥10 t/a

General conditions

The substance from which the nanoform is produced, is not classified as hazardous according to CLP Regulation (EC) No. 1272/2008, is not persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) and has not been included in the candidate list as a substance of very high concern (SVHC).

This means that no safety data sheet has to be provided in accordance with Article 31 of the REACH regulation. Furthermore, the substance has been registered by the manufacturer/importer in a quantity ≥ 10 t/a. This means that a chemical safety report (CSR) must be prepared in this supply chain in accordance with Article 14(1). However, exposure scenarios do not have to be developed.
The supplier of the substance shall provide the downstream user, if necessary, the available and relevant information in accordance with Article 32(1). The downstream user now produces a new nanoform from this substance.

What are the obligations of this downstream user?

As in scenario 1, the downstream user has to verify of whether the new nanoform has hazardous properties in contrast to the supplied substance. If this is the case, the nanoform must be classified and a safety data sheet prepared in accordance with Article 31 if the substance in nanoform is supplied to another recipient. Furthermore, from ECHA's point of view, it

is necessary to pass the new information on the hazardous property to the supplier in accordance with Article 34[4]. However, ECHA does not give any guidance on how the registrant will deal with this information. In addition to this communication, a notification to ECHA in accordance with Article 38(4) is required, if a downstream user classifies the substance differently from its supplier.

However, if the downstream user concludes that a safety data sheet still needs not to be prepared for the newly produced nanoform, he shall only provide, if necessary, the information available to him in accordance with Article 32(1) to his recipient. In the case of only in-house use, the downstream user must fulfil his obligations according to Article 35 and carry out a risk assessment at the workplace.

Interim conclusion:
In both cases the downstream user does not receive a safety data sheet or any exposure scenarios.

The only difference between the two scenarios described is, that in the 2nd scenario the registrant of the substance must prepare a chemical safety report. However, this does not result in any different obligations for the downstream user. Rather, as described above, he must clarify whether the nanoform has deviating hazardous properties and, if so, take the necessary measures.

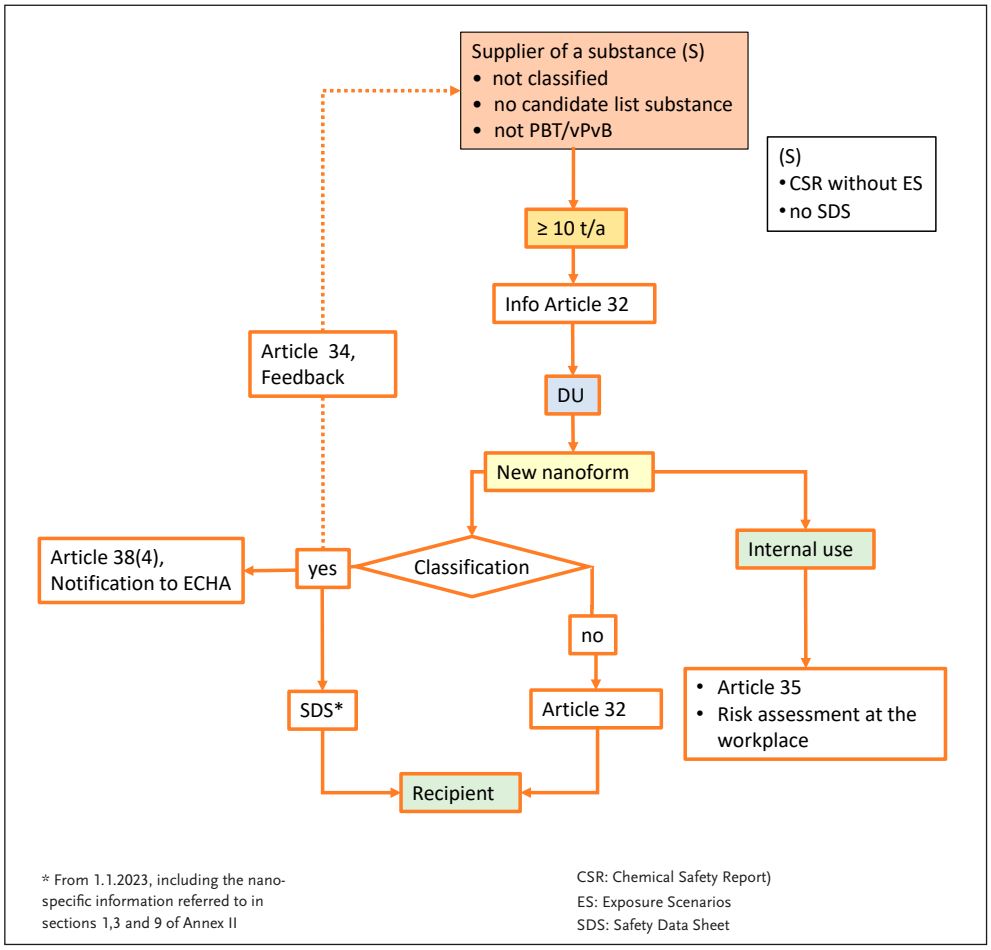

Fig. 2 Scenario 2: the substance is not hazardous and the quantity used reaches or exceeds the 10 tonne threshold per year.

[4] Please refer to ECHAs Q&A no 1833, which can be found in section I. Downstream user under:
https://echa.europa.eu/en/support/qas-support/browse/-/qa/70Qx/view/scope/REACH/Nanoforms+of+substances

3.3 Scenario 3: Substance has hazardous properties, registration <10 t/a

General conditions

The substance from which the nanoform is produced is either classified as hazardous according to CLP Regulation (EC) No. 1272/2008 or is persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) or has been included in the candidate list as a substance of very high concern (SVHC).

Furthermore, the substance has been registered by the manufacturer/importer in a quantity < 10 t/a. This means that no Chemical Safety Report (CSR) has to be prepared according to Article 14(1) in this supply chain. This applies irrespective of whether the substance was registered by another manufacturer or importer in a higher tonnage and he has to prepare a CSR including exposure scenarios. The supplier of the substance shall provide a safety data sheet (SDS) to the downstream user in accordance with Article 31, which, however, does not contain any exposure scenarios (no extended SDS, eSDS). The downstream user now produces a new nanoform from the substance.

What are the obligations of this downstream user?

The downstream user needs to verify whether the nanoform has an additional or different hazardous property compared to the supplied substance. If this is the case, the classification of the nanoform must be adapted accordingly. This means that the downstream user must revise the safety data sheet in accordance with Article 31, if he wishes to supply the substance in nanoform to another recipient. By Regulation (EU) 2020/878 amending Annex II of the REACH Regulation (EC) No. 1907/2006, information on nanoforms of substances will also be required from January 1, 2023, e.g. in sections 1, 3 and 9 of the safety data sheet. Furthermore, from the point of view of the ECHA, it is also necessary to provide the information on the deviating hazardous properties to the supplier in accordance with Article 34.[5] However, ECHA does not provide any guidance on how the registrant should deal with this information. In addition to this communication, a notification to ECHA must be carried out in accordance with Article 38(4) when a downstream user classifies the substance differently from its supplier.

If, however, the downstream user concludes that the newly generated nanoform does not pose a new or an additional risk, he only has to provide his own contact details as a supplier and can otherwise simply pass on the other contents of the safety data sheet. In addition, from 1 January 2023 at the latest, he has to include the information on nanoforms in sections 1, 3 and 9 of the safety data sheet. If the nanoform produced is only used in-house within the company, the downstream user does not have to revise or pass on a safety data sheet, but he must comply with his obligations in accordance with Article 35 and carry out a risk assessment at the workplace.
Additional obligations, such as the preparation of a separate chemical safety report, still do not exist.

[5] Please refer to ECHAs Q&A no 1833, which can be found in section I. Downstream user under:
https://echa.europa.eu/en/support/qas-support/browse/-/qa/70Qx/view/scope/REACH/Nanoforms+of+substances

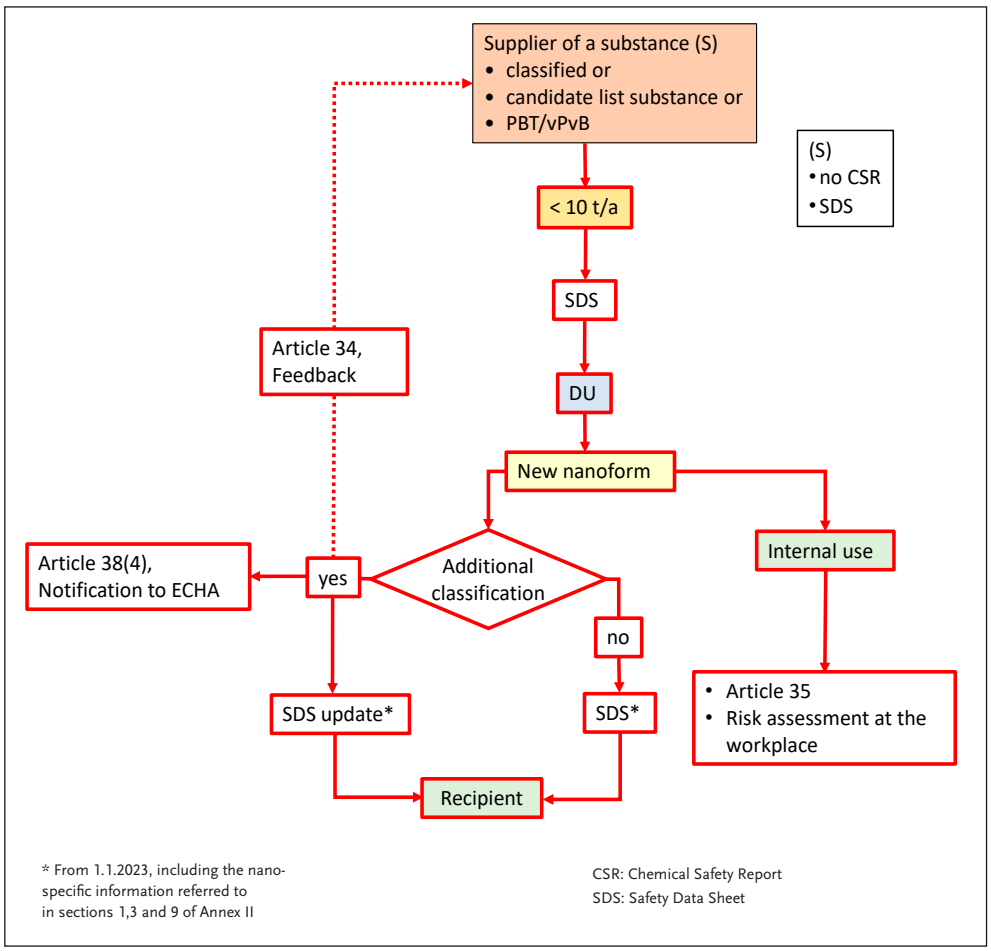

Fig. 3 Scenario 3: the substance is hazardous and has been registered in the supply chain in quantities below the 10 tonne threshold per year.

3.4 Scenario 4: Substance has hazardous properties, registration ≥10 t/a

General conditions

The substance from which the nanoform is produced is either classified as hazardous according to CLP Regulation (EC) No. 1272/2008 or is persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) or has been included in the candidate list as a substance of very high concern (SVHC).

The supplier manufactured 10 t or more of the substance per year. This means that the supplier has to prepare a Chemical Safety Report (CSR) including exposure scenarios according to Article 14 for the different identified uses of the substance.

With the first delivery of the substance, the supplier must provide the recipient with a safety data sheet and the exposure scenarios included in the chemical safety report (extended safety data sheet, eSDS). The downstream user now produces a new nanoform from the substance.

What are the obligations of this downstream user?

The downstream user needs to check on the basis of the identified uses in chapter 1 of the safety data sheet as well as on the attached exposure scenarios, whether his activity, i.e. the production as well as the further use(s) of a (new) nanoform, is covered by the conditions of use and risk management measures in the supplier's exposure scenarios.

This is the case if its use(s) can be carried out safely by applying the risk management measures described, i.e. the **Risk Characterisation Ratio** (RCR) is below 1.[6]

The examination of the downstream user may lead to the following results:

1. the use "production of a substance in nanoform" is covered by the information in the eSDS of the supplier.

The use of the downstream user can then be considered as an identified use.

In addition, the downstream user must check whether the (new) nanoform has any additional or different hazardous properties and whether an additional or modified classification is required compared to the substance supplied.

If the classification of the new nanoform of the substance has not changed, the downstream user can pass on the contents of the eSDS, which was sent to him by the supplier, to the recipient of the new nanoform of the substance. He only has to provide his own contact details as a supplier and, from 01 January 2023 at the latest, the information on nanoforms in sections 1, 3 and 9 of the safety data sheet, among others.

If the new nanoform of the substance has additional hazard characteristics compared to the information in the eSDS submitted to him, the downstream user must adapt the classification of the nanoform accordingly. This means that the downstream user must revise the safety data sheet in accordance with Article 31, if he wishes to supply the substance in nanoform to another recipient. Next to this, the downstream user must, from ECHA's point of view, inform the supplier on the basis of Article 34(1).[7] In addition to this communication, a notification to ECHA in accordance with Article 38(4) must also be made, if a downstream user classifies the substance differently from its supplier.

2. the use "production of a substance in nanoform" is not covered by the information in the eSDS of the supplier.

If the downstream user's uses are not included in the supplier's eSDS or the conditions of use are different from those described, the downstream user can report the "new" uses to the supplier (registrant) so that he can include them in the CSR as identified uses. The information required and provided by the downstream user for this must be detailed enough to allow the registrant to create appropriate exposure scenarios.

If the downstream user uses the substance in quantities of at least 1 t/a, he can alternatively prepare his own chemical safety report including the appropriate exposure scenarios and keep this information available for possible enforcement activities. The downstream user must also prepare his own CSR if the registrant does not take up the new uses notified to him in his CSR. This obligation can only be waived if the downstream user can benefit from one of the exemptions referred to in Article 37(4).

[6] Guidance on Information Requirements and Chemical Safety Assessment, Part E: Risk Characterisation
https://echa.europa.eu/de/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
As well in "Guidance for downstream users", Chapter 5.4.4
https://echa.europa.eu/documents/10162/2324906/du_en.pdf/9ac65ab5-e86c-405f-a44a-190ff4c36489

[7] Please refer to ECHAs Q&A no 1833, which can be found in section I. Downstream user under:
https://echa.europa.eu/en/support/qas-support/browse/-/qa/70Qx/view/scope/REACH/Nanoforms+of+substances

In addition, according to Article 38(1), the downstream user must notify ECHA of the preparation of his own chemical safety report, in this context he must also report i.a. the uses and conditions of use.

In any case, the downstream user must prepare his own eSDS with the changed conditions of use, which he passes on to his recipient. This must also include the changed classification of the substance in nanoform as well as, from 1.1.2023, the information about the nanoform according to sections 1, 3 and 9 of the eSDS, among others.

From ECHA's perspective, if the new nanoform of the substance has additional hazard characteristics compared to the information in the eSDS submitted to him, the downstream user must inform the supplier thereof according to Article 34[7]. In addition to this communication, a notification to ECHA according to Article 38(4) must be made, if a downstream user classifies the substance differently from its supplier.

If, in either case, the new nanoform continues to be used exclusively in-house, the provisions of Article 35 must be complied with (risk assessment at the workplace, operating workplace, operating instructions).

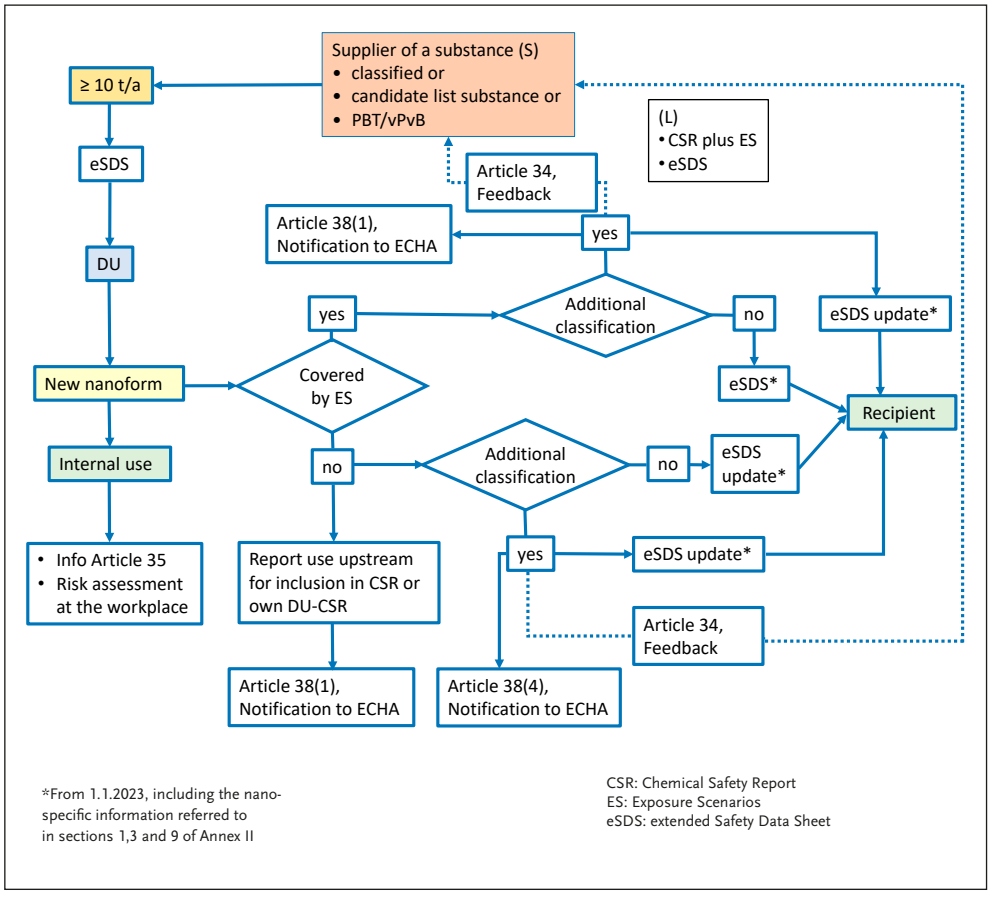

Fig. 4 Scenario 4: the substance is hazardous and the quantity reaches or exceeds the 10 tonne threshold per year.

In summary, the following applies: In deviation from the obligation described under point 2 of this section to prepare a separate chemical safety report, the downstream user may, in accordance with Article 37(4), invoke the following exceptions and refrain from preparing a chemical safety report, if

- no safety data sheet is submitted (scenarios 1 and 2)
- no chemical safety report needs to be prepared by the registrant (scenarios 1 and 3)
- his exposure scenarios are covered by those described in the eSDS (case one of scenario 4)

Furthermore, the downstream user does not have to prepare his own chemical safety report (these points are not discussed in detail in the brochure), if

- he only uses the substance for product- and process-oriented research and development
- he uses the substance below 1 t/a
- the concentration of the substance in a mixture is below certain concentration values (see Article 14(2))

If the downstream user for the first or second of the above reasons does not prepare a chemical safety report, he shall inform ECHA in agreement with Article 38(1b) accordingly.

4 Conclusion

The scenarios described here are intended to help downstream users to be aware of their existing obligations when producing substances in nanoform. In doing so, there is no claim to completeness in the sense that all possible scenarios are mentioned and completely covered.

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Gender-neutral language is used in this publication. Where this is not possible or would detract from the readability of the text, terms used to refer to persons include all genders.

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