ECHA
EUROPEAN CHEMICALS AGENCY

Examples for application of the Annex III inventory

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1. Introduction

This document gives recommendations and examples to illustrate in which situations a registrant of a 1-10 tonne phase-in substance can benefit from **reduced** information requirements (data on physicochemical properties only), and in which cases **standard** information (requirements listed in Annex VII) is required for registration under REACH.

2. General considerations for the information gathering

- ECHA publishes the Annex III inventory to help you with your registration tasks. It is unlikely that substances in the inventory can be registered with reduced information requirements. However, in addition to checking the Annex III inventory, you should gather your own information to see if your substance meets one or both of the Annex III criteria. Tools like the eChemPortal (http://www.echemportal.org/) and the C&L Inventory are particularly useful in this regard. QSAR tools like the Danish QSAR database can also be helpful.

- When gathering information on the properties of your substance, you should take into account all of its main constituents, impurities and additives. For instance, if you search ECHA's Annex III inventory or the registration database, you should use the identifiers for your substance and all the main constituents, impurities and additives you can identify.

- When you search for your substance, its main constituents, impurities and additives, use all available identifiers: EC number, CAS numbers and names.

- If there is an active SIEF for your substance, and a registration has already been submitted, you need to join the SIEF to be in line with the 'one substance, one registration' principle of REACH. In this case, you should normally be able to get the necessary information on whether the Annex III criteria apply to your substance from the SIEF.

- If you do not qualify for the reduced information requirements, you need to submit a 1–10 tonnes dossier with full Annex VII information. A fee waiver is not applicable in this case.

3. Things to consider when deciding if your substance qualifies for reduced information requirements (data on physicochemical properties only)

When assessing the situation of your substances, consider the following:

- The Annex III inventory is an advisory tool. Even if your substance is listed there, you may still be able to submit a dossier with reduced information requirements. In this case, however, you will need to document in your IUCLID dossier why the indications for concern found in the Annex III inventory can be disregarded.

- If you have a substance without dispersive or diffuse uses, it will qualify for reduced information requirements if the following conditions are fulfilled:

- it is not likely to meet the criteria for category 1A or 1B classification in the hazard classes carcinogenicity, germ cell mutagenicity or reproductive toxicity;
- it is not likely to meet the criteria for the identification of persistent, bioaccumulative and toxic (PBT) substances , and very persistent and very bioaccumulative (vPvB) substances.

In this case, you do not need to take into account indications referring to other hazard endpoints.

- The justification needed to disregard an indication for your substance and to submit with reduced information requirements depends on the type of indication found in the Annex III inventory, for example:
  - One of the impurities of your substance is listed in Annex VI to CLP as a skin sensitiser. As this is a harmonised classification, a very good justification would be needed to claim reduced information requirements in this case. For instance, this indication could be disregarded if the impurity is only present in a concentration below the limit for classification (<0.1 % w/w).
  - The indication found in the Annex III inventory states that your substance is predicted as toxic through the oral route. If you have access to good quality information indicating the contrary, you could consider disregarding this information. For instance, you may own an experimental study stating that the LD50 is >2 000 mg/kg bw, and because the experimental study is considered more reliable than the QSAR prediction, you have good reason to disregard the indication from the Annex III inventory.
  - One of the main constituents of your substance is recommended in IMAP as mutagen 1A or 1B. As this recommendation is based on an assessment by a regulatory body, a very good justification would be needed to disregard this indication. It is unlikely that you can submit your registration with reduced information requirements.
  - Your substance appears as a predicted skin irritant in the Annex III inventory. It has not been registered and does not have a notification in ECHA's C&L Inventory. The absence of information in the C&L Inventory is not very strong evidence, so you should not disregard the indication from the Annex III inventory. A full Annex VII information set is needed for your substance.
- If your substance is likely to meet only a hazard class related to a physical hazard (e.g. explosiveness, flammability, etc.), you are still entitled to reduced information requirements.
- When you conclude that your substance can benefit from the reduced information requirements, the registration dossier has to be submitted in the specific dossier template for 1-10 tonnes with physicochemical information only. Section 14 of IUCLID allows you to justify why the substance does not meet the criteria set in Annex III.
- If there is no indication that the substance may meet an environmental or human health hazard class, we recommend that you use the free text fields "Remarks" in section 14 of IUCLID. There, you can explain your approach to ECHA and potentially avoid being picked up for further regulatory scrutiny at a later point.

- To determine whether your substance benefits from reduced information requirements, you have to consider whether dispersive or diffuse uses are expected. For instance, the following uses are considered dispersive/diffuse uses:

    a) consumer uses;

    b) uses by professional workers (i.e. uses by professionals outside industrial sites);

    c) article uses, unless these are only limited to industrial sites;

    d) uses at industrial sites (including uses of articles), if not limited to a few sites only and carried out under rigorous containment (with minimisation of environmental emissions).

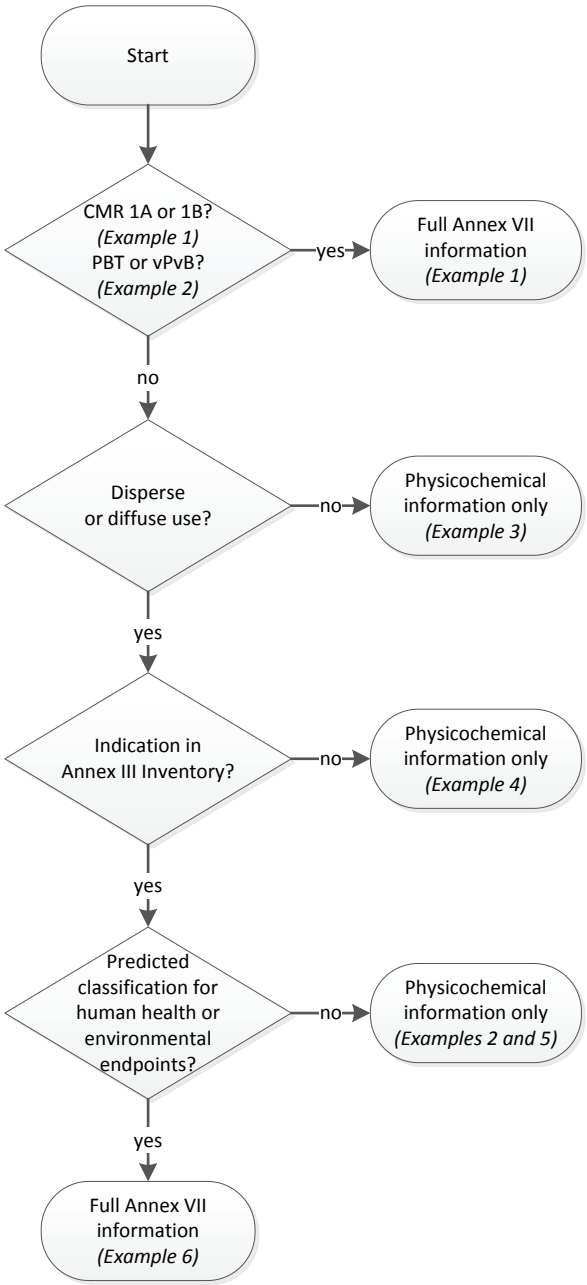
- If your substance is listed in the Annex III inventory as likely to meet criteria for human health or environmental hazards, but no dispersive or diffuse uses are expected (see above), you can submit a registration dossier with data on physicochemical properties only together with an explanation stating that you do not have dispersive and diffuse uses.

- The REACH guidance on information requirements and chemical safety assessment, chapter R.12 (December 2015) gives more information on the use descriptor system, which can be useful when determining whether your substance has dispersive or diffuse uses.

4. Examples for Annex III applications

The six examples in this document illustrate different scenarios you may come across: how you can gather and use information to understand if you can submit your dossier with information on physicochemical properties only or if full Annex VII requirements apply.

Figure 1: The flowchart indicates the scenarios applying to the six examples.



4.1. Example 1: Substance found in the Annex III inventory – full Annex VII registration required

This example describes a case for a mono-constituent substance. To identify whether reduced information requirements for your substance apply, you follow these steps:

Step 1: You gather all available information on your substance, including communication in the SIEF and a search on eChemPortal (www.echemportal.org/echemportal/). You want to explore whether the data on physicochemical properties would be sufficient for your registration.

Step 2: You search for your substance in ECHA's Annex III inventory. You will find your substance using the CAS number and substance name.

Step 3: The information in ECHA's inventory indicates that your substance is suspected to be mutagenic 1A or 1B. This means that you have an indication that your substance fulfils the Annex III criterion a) on CMR or PBT/vPvB substances. You no longer need to consider the uses of your substance, as mutagenicity 1A or 1B on its own is sufficient to require full Annex VII information.

Step 4: You decide not to investigate further other sources, but to submit a 1–10 tonne dossier with full Annex VII information. Keep in mind that you may need to generate missing data. This data covers all information requirements listed in Annex VII and not only the data related to the endpoint for which the Annex III inventory indicated a concern. A fee waiver is not applicable because there is an indication that at least one Annex III criterion is met.

4.2. Example 2: Substance found in the Annex III inventory – reason to disregard indications for bioaccumulation

For this example, we assume that your substance is an organic, mono-constituent substance with a log Kow of around 5-6. It has diffuse or dispersive use. To identify whether reduced information requirements for your substance apply, you follow these steps:

Step 1: You gather all available information on your substance, including communication in the SIEF and a search on eChemPortal (www.echemportal.org/echemportal/). You want to explore whether the data on physicochemical properties would be sufficient for your registration.

Step 2: You search for your substance in ECHA's Annex III inventory. You will find your substance using the EC number and CAS number.

Step 3: The information in the inventory indicates that your substance is suspected to be bioaccumulative. The Annex III criterion a) says that if your substance has the potential for being persistent, bioaccumulative and toxic (PBT) or very persistent, very bioaccumulative (vPvB) properties, you need full Annex VII information for your REACH registration. ECHA's inventory says that a BCF of 3.44 log(L/kg), i.e. 2 754 L/kg, is predicted. The next step is to compare the predicted BCF value with the criteria for PBT and vPvB identification in Annex XIII to the REACH Regulation. The threshold value for the bioconcentration factor is 2 000 (or in log units 3.3). This means your substance may fulfil the B criterion (bioaccumulative) but not the vB criterion (very bioaccumulative, for which the threshold is 5 000).

To identify the PBT characteristics of your substance, the persistent and toxic properties have to be assessed as well. You have no degradation data. Therefore, you look at the screening information that can be used for assessing persistency. ECHA's inventory indicates if a substance is predicted as not readily biodegradable. For your substance, there was no such indication. You run a valid QSAR to further assess the biodegradability and conclude that it is

likely to be readily biodegradable and therefore not persistent.

ECHA's inventory also gives an indication if a substance is predicted to be toxic. For your substance, there was no such indication. You use QSAR tools following the instructions in ECHA's Practical Guide: How to use and report (Q)SARs to check whether your substance is predicted to be toxic. You find no indication for a classification need.

In conclusion, you have an indication for bioaccumulation from the Annex III inventory, but you have reasons to disregard this information as you predict that your substance is not persistent in the environment and not toxic and, therefore, likely not to be a PBT substance.

Step 4: You check further information sources including ECHA's chemicals database. You find no REACH registration for your substance and the C&L Inventory does not list your substance or any of its impurities under the sections harmonised classification or notified classification and labelling according to CLP criteria for a human health or environmental effect.

Step 5: You search for your substance in the QSAR Toolbox (www.qsartoolbox.org). You find no additional experimental data or other information, such as structural alerts (profiling), which would indicate PBT/vPvB properties or the need for classification according to the CLP Regulation. There is also no such information for any of the identified impurities. You have already used QSAR tools in step 3 and found no indication for PBT/vPvB properties or the need for classification according to the CLP Regulation. Based on all the information gathered, you conclude that you can benefit from reduced information requirements under REACH.

Step 6: You decide to submit your REACH dossier with data on physicochemical properties only. You do not want to claim a fee waiver as otherwise you will need to submit full Annex VII information.

Step 7: You record the following information in your dossier in IUCLID 6, Section 14 - Annex III criteria:

1. The substance is on the list of substances likely to meet the REACH Annex III criteria, published by ECHA: **Yes**

2. Do any of the submitted REACH registrations or C&L notifications suggest a potential for C or M or R (category 1A or 1B) or PBT or vPvB properties for the substance? **No**

3. Do any of the other regulatory data available for the substance (e.g. Annex VI of CLP) suggest a potential for C or M or R (category 1A or 1B) or PBT or vPvB properties for the substance? **No**

4. Do any of the experimental data already available (e.g. in QSAR Toolbox) suggest a potential for C or M or R (category 1A or 1B) or PBT or vPvB properties for the substance? **No**

5. Do any of the alternatives to test data (e.g. QSAR, read-across, in-vitro) suggest a potential for C or M or R (category 1A or 1B) or PBT or vPvB properties for the substance? **No**

   Remarks **<not filled>**

6. Wide dispersive use(s), diffuse use(s) or use(s) by consumers for the substance itself, in mixtures or articles can be excluded. **No**

Remarks **<not filled>**

7. Do any of the submitted REACH registrations or C&L notifications suggest that the substance is likely to meet the classification criteria for any health or environmental hazard classes or differentiations? **No**

8. Do any of the other regulatory data available for the substance (e.g. Annex VI of CLP) suggest that the substance is likely to meet the classification criteria for any health or environmental hazard classes or differentiations? **No**

9. Do any of the experimental data already available (e.g. in QSAR Toolbox) suggest that the substance is likely to meet the classification criteria for any health or environmental hazard classes or differentiations? **No**

10. Do any of the alternatives to test data (e.g. QSAR, read-across, in-vitro) suggest that the substance is likely to meet the classification criteria for any health or environmental hazard classes or differentiations? **No**

    Remarks **<not filled>**

11. Justification for disregarding any indication of meeting the criteria of Annex III as declared above: **The substance is listed in the ECHA inventory as "suspected bioaccumulative", with a BCF value of 3.44 log(L/kg). However, it is likely that the substance is not a PBT because valid QSARs have shown that the substance most likely is not persistent and not toxic. Therefore the Annex III criterion a) is not met. Furthermore, the substance likely does not meet the classification criteria for any health or environmental hazard properties and therefore Annex III criterion b) is also not met.**

4.3. Example 3: Substance found in ECHA's inventory but no CMR or PBT/vPvB properties and no dispersive or diffuse uses exist – reduced information requirements apply

In this example, your company manufactures a substance which is hazardous but the substance is used only at a few industrial sites under conditions with low release/exposure potential to workers and the environment (i.e. strictly controlled conditions including rigorous containment and minimisation of emissions to the environment). To identify whether reduced information requirements for your substance apply, you follow these steps:

Step 1: You gather all available information on your substance, including communication in the SIEF and a search on eChemPortal (www.echemportal.org/echemportal/). You want to explore whether the data on physicochemical properties would be sufficient for your registration.

Step 2: You search for your substance in the ECHA Annex III inventory. You will find your substance using the EC number and substance name.

Step 3: The information in ECHA's inventory indicates that your substance is suspected to be a skin irritant. You do not have any indications for CMR or PBT/vPvB properties.

The Annex III criterion b) say that if your substance is likely to be classified as hazardous and has diffuse or dispersive uses, then full Annex VII information is required. Therefore, you look at the uses of the substance in your supply chain. You know that you sell your substance only to a small number of customers, and from downstream sector organisations you learn that your substance is only used at a small number of industrial sites. In conclusion, you have an

indication that your substance likely meets a classification criterion for a health hazard but your substance may not fall under the category dispersive or diffuse use. You have the possibility to submit your dossier with data on physicochemical properties only, but you have to collect further evidence.

Step 4: You search for your substance in ECHA's chemicals database. The brief profile indicates "Warning! According to the classifications notified by companies to ECHA, this substance is harmful if swallowed and causes serious eye irritation". You conclude that your substance is likely to be hazardous for human health and fulfils one part of the Annex III criterion b). You decide to investigate further whether the *use* part of the criterion is fulfilled or not.

Step 5: You check the REACH Guidance document on registration. You find there that only closed (rigorously contained) uses at industrial sites qualify as non-dispersive and non-diffuse uses. Your substance is not used by consumers as such, in mixtures or in articles, there are no widespread uses by professional workers and no widespread industrial uses or industrial uses outside rigorous containment (including minimisation of environmental emissions). You are able to concretely describe the conditions of use ensuring rigorous containment and minimisation of releases in your registration dossier. Examples of substances with these types of uses may be special catalysts, solvents or process regulators used at a few chemical manufacturing sites in Europe.

You also have data available from your customer sites or from a suitable modelling tool, which shows that releases to air, water and soil and the exposure to workers during use are insignificant. You conclude that your substance has no dispersive or diffuse use, and therefore the Annex III criterion b) requiring a full Annex VII registration is not fulfilled.

Step 6: To benefit from reduced information requirements, you have to verify that your substance has no CMR or PBT/vPvB properties. You have already checked ECHA's chemicals database and there was no indication for these kinds of properties. You search for your substance in the QSAR Toolbox (www.qsartoolbox.org) and find no experimental data or other information, which would indicate CMR or PBT/vPvB properties. There is also no such information for any of the identified impurities. You use QSAR tools following the instructions in ECHA's Practical Guide 5: How to use and report (Q)SARs. You get confirmation for skin and eye irritation, but no indication for CMR or PBT/vPvB properties. Based on all the information gathered, you conclude that you can benefit from reduced information requirements under REACH.

Step 7: You decide to submit your REACH dossier with data on physicochemical properties only. You do not want to claim a fee waiver as otherwise you would need to submit full Annex VII information.

Step 8: You record the following information in your dossier in IUCLID 6, Section 14 - Annex III criteria:

1. The substance is on the list of substances likely to meet the REACH Annex III criteria, published by ECHA: **Yes**

2. Do any of the submitted REACH registrations or C&L notifications suggest a potential for C or M or R (category 1A or 1B) or PBT or vPvB properties for the substance? **No**

3. Do any of the other regulatory data available for the substance (e.g. Annex VI of CLP) suggest a potential for C or M or R (category 1A or 1B) or PBT or vPvB properties for the substance? **No**

4. Do any of the experimental data already available (e.g. in QSAR Toolbox) suggest a potential for C or M or R (category 1A or 1B) or PBT or vPvB properties for the substance? **No**

5. Do any of the alternatives to test data (e.g. QSAR, read-across, in-vitro) suggest a potential for C or M or R (category 1A or 1B) or PBT or vPvB properties for the substance? **No**

   Remarks **<not filled>**

6. Wide dispersive use(s), diffuse use(s) or use(s) by consumers for the substance itself, in mixtures or articles can be excluded. **Yes**

   Remarks **The use of the substance is limited to four sites. The use at industrial sites takes place under closed (rigorously contained) conditions leading insignificant exposure to humans and insignificant release to the environment on the various routes. The substance is not used by consumers as such, in mixtures or in articles and there are no disperse or diffuse uses by professional workers.**

7. Justification for disregarding any indication of meeting the criteria of Annex III as declared above **The substance is listed in the ECHA inventory as "suspected skin irritant". However, dispersive and diffuse use can be excluded and there is no indication that the substance has CMR or PBT properties.**

4.4. Example 4: Substance not found in ECHA's inventory or any other source – reduced information requirements apply

This example describes a case for a simple mono-constituent substance for which your company does not have any indications for hazardous properties. To identify whether reduced information requirements for your substance apply, you follow these steps:

Step 1: You gather all available information on your substance, including communication in the SIEF and a search on eChemPortal (www.echemportal.org/echemportal/). You want to explore whether the data on physicochemical properties would be sufficient for your registration.

Step 2: You search for your substance in ECHA's Annex III inventory. You cannot find your substance using the EC number, CAS number or substance name. You also cannot find identified impurities/additives of your substance in the inventory.

Step 3: You search for your substance in ECHA's chemicals database. You find no REACH registration for your substance and the C&L Inventory does not list your substance or any of its impurities under the sections harmonised classification or notified classification and labelling according to CLP criteria for a human health or environmental effect.

Step 4: You have not found experimental data or other information, which would indicate the need for a classification or hint towards persistent or bioaccumulative properties. There is also no such information for any of the identified impurities. You use QSAR tools following the instructions in ECHA's Practical Guide: How to use and report (Q)SARs and you find no indication for a classification need or persistent or bioaccumulative properties. Based on all the information gathered, you conclude that you can benefit from reduced information requirements under REACH.

Step 5: You decide to submit your REACH dossier with data on physicochemical properties only. You do not want to claim a fee waiver as otherwise you would need to submit full Annex VII information.

Step 6: You record the following information in your dossier in IUCLID 6, Section 14 - Annex III criteria:ation:

1. The substance is on the list of substances likely to meet the REACH Annex III criteria, published by ECHA: **No**

2. Do any of the submitted REACH registrations or C&L notifications suggest a potential for C or M or R (category 1A or 1B) or PBT or vPvB properties for the substance? **No**

3. Do any of the other regulatory data available for the substance (e.g. Annex VI of CLP) suggest a potential for C or M or R (category 1A or 1B) or PBT or vPvB properties for the substance? **No**

4. Do any of the experimental data already available (e.g. in QSAR Toolbox) suggest a potential for C or M or R (category 1A or 1B) or PBT or vPvB properties for the substance? **No**

5. Do any of the alternatives to test data (e.g. QSAR, read-across, in-vitro) suggest a potential for C or M or R (category 1A or 1B) or PBT or vPvB properties for the substance? **No**

   Remarks **<not filled>**

6. Wide dispersive use(s), diffuse use(s) or use(s) by consumers for the substance itself, in mixtures or articles can be excluded. **No**

   Remarks **<not filled>**

7. Do any of the submitted REACH registrations or C&L notifications suggest that the substance is likely to meet the classification criteria for any health or environmental hazard classes or differentiations? **No**

8. Do any of the other regulatory data available for the substance (e.g. Annex VI of CLP) suggest that the substance is likely to meet the classification criteria for any health or environmental hazard classes or differentiations? **No**

9. Do any of the experimental data already available (e.g. in QSAR Toolbox) suggest that the substance is likely to meet the classification criteria for any health or environmental hazard classes or differentiations? **No**

10. Do any of the alternatives to test data (e.g. QSAR, read-across, in-vitro) suggest that the substance is likely to meet the classification criteria for any health or environmental hazard classes or differentiations? **No**

    Remarks **<not filled>**

11. Justification for disregarding any indication of meeting the criteria of Annex III as declared above **<not filled>**

4.5. Example 5: Substance found in the Annex III inventory – reason to disregard indications for aquatic toxicity

For this example, we assume that your substance is a soluble organic, mono-constituent substance. It has diffuse or dispersive use. To identify whether reduced information requirements for your substance apply, you follow these steps:

Step 1: You gather all available information on your substance, including communication in the SIEF and a search on eChemPortal (www.echemportal.org/echemportal/). You want to explore whether the data on physicochemical properties would be sufficient for your registration.

Step 2: You search for your substance in ECHA's Annex III inventory. You cannot find your substance using the EC number or CAS number but you find it by the substance name.

Step 3: The information in the inventory indicates that your substance is suspected to be hazardous to the aquatic environment. More specifically, it says that LC50 and EC50 values are predicted to be higher than 10 but less than 100 mg/l. The Annex III criterion b) says that if your substance is likely to be classified as hazardous and has diffuse or dispersive uses, then full Annex VII information is required.

You compare the toxicity values with the criteria for classification (CLP Regulation). Category Acute 1 does not apply (threshold for LC50 and EC50 values ≤1mg/l). Categories Chronic 1 and 2 also do not apply (thresholds for LC50 and EC50 values are ≤1mg/l and 1-10 mg/l, respectively). For Category Chronic 3, the criteria for LC50 and EC50 are 10 to 100mg/l. This would be in line with the predicted values found in the Annex III inventory. However, the criteria furthermore say that this applies only for substances which are not rapidly degradable and/or the experimentally determined BCF ≥ 500 (or, if absent, the log Kow ≥ 4). Your substance has a log Kow of 3, and therefore does not fulfil the latter part of the classification criterion. However, you have no data on the degradability. ECHA's inventory indicates if a substance is predicted as not readily biodegradable. For your substance, there was no such indication.

In your substance portfolio, you have a similar substance, which has been shown in an experimental study to be readily biodegradable. You run a QSAR for your substance to further assess the biodegradability and conclude that your substance is likely to be readily biodegradable. You can demonstrate rapid degradation according to the Guidance on the Application of the CLP Criteria (June 2015), which states that "*[a] weight of evidence approach based on read-across provides convincing evidence that a given substance is rapidly degradable*". In conclusion, it means that you have an indication for a hazardous property from the Annex III inventory, however, you have reasons to disregard the information as the predicted aquatic toxicity does not likely lead to a classification based on the Log Kow <4 and predicted ready biodegradability.

Step 4: You check further information sources including ECHA's chemicals database. You find no REACH registration for your substance and the C&L Inventory does not list your substance or any of its impurities under the sections harmonised classification or notified classification and labelling according to the CLP criteria for a human health or environmental effect.

Step 5: You search for your substance in the QSAR Toolbox (www.qsartoolbox.org). You find no additional experimental data or other information, which would indicate the need for a classification. There is also no such information for any of the identified impurities. You use QSAR tools following the instructions in ECHA's Practical Guide: How to use and report (Q)SARs and find no indication for a classification need. Based on all the information gathered, you conclude that you can benefit from reduced information requirements under REACH.

Step 6: You decide to submit your REACH dossier with data on physicochemical properties only. You do not want to claim a fee waiver as otherwise you would need to submitfull Annex VII information.

Step 7: You record the following information in your dossier in IUCLID 6, Section 14 - Annex III criteria:information:

1. The substance is on the list of substances likely to meet the REACH Annex III criteria, published by ECHA: **Yes**

2. Do any of the submitted REACH registrations or C&L notifications suggest a potential for C or M or R (category 1A or 1B) or PBT or vPvB properties for the substance? **No**

3. Do any of the other regulatory data available for the substance (e.g. Annex VI of CLP) suggest a potential for C or M or R (category 1A or 1B) or PBT or vPvB properties for the substance? **No**

4. Do any of the experimental data already available (e.g. in QSAR Toolbox) suggest a potential for C or M or R (category 1A or 1B) or PBT or vPvB properties for the substance? **No**

5. Do any of the alternatives to test data (e.g. QSAR, read-across, in-vitro) suggest a potential for C or M or R (category 1A or 1B) or PBT or vPvB properties for the substance? **No**

   Remarks **<not filled>**

6. Wide dispersive use(s), diffuse use(s) or use(s) by consumers for the substance itself, in mixtures or articles can be excluded. **No**

   Remarks **<not filled>**

7. Do any of the submitted REACH registrations or C&L notifications suggest that the substance is likely to meet the classification criteria for any health or environmental hazard classes or differentiations? **No**

8. Do any of the other regulatory data available for the substance (e.g. Annex VI of CLP) suggest that the substance is likely to meet the classification criteria for any health or environmental hazard classes or differentiations? **No**

9. Do any of the experimental data already available (e.g. in QSAR Toolbox) suggest that the substance is likely to meet the classification criteria for any health or environmental hazard classes or differentiations? **No**

10. Do any of the alternatives to test data (e.g. QSAR, read-across, in-vitro) suggest that the substance is likely to meet the classification criteria for any health or environmental hazard classes or differentiations? **No**

    Remarks **<not filled>**

11. Justification for disregarding any indication of meeting the criteria of Annex III as declared above: **The substance is listed in the ECHA inventory as "suspected hazardous to the aquatic environment". The predicted LC50/EC50 is above 10 mg/l. However, it is likely that no classification is needed because it has a log**

Kow <4 and a valid QSAR and a similar substance (CAS yyy-yy-y) in our portfolio indicates that the substance most likely biodegrades rapidly. We conclude that the Annex III criteria are not met.

4.6. Example 6: UVCB substance with constituents found in ECHA's inventory – reduced information requirements do not apply

For this case, we assume that your substance is a UVCB substance of biological origin, but for which some constituents can be identified. A typical example could be a fragrance. The substance is used in consumer articles, so dispersive or diffuse use is expected.

The substance is a UVCB, so there is an EC number and CAS number that can be used to identify the whole substance. As the composition is not fully defined, only the major constituents have an EC number, CAS number or systematic name assigned.

Therefore, for this case, you try to collect information on the constituents of your substance, by querying the numerical identifiers of a) the whole substance and b) all the constituents you can identify.

Step 1: You gather all available information on your substance, including communication in the SIEF and a search on eChemPortal (www.echemportal.org/echemportal/). You want to explore whether the data on physicochemical properties would be sufficient for your registration.

Step 2: You search for your substance in ECHA's Annex III inventory. You cannot find your substance using the EC number, CAS number or substance name. You search the EC numbers of two constituents and see the substances listed in the inventory.

Step 3: The information in the inventory indicates that the two constituents are suspected skin sensitisers, which means that the substance may need to be classified as hazardous to human health. Together with the information on the use, i.e. the substance is used in consumer articles and has dispersive or diffuse uses, it means that you need to submit a registration dossier covering full Annex VII information - unless you can justify that the indication for skin sensitisation is not valid. You decide to further investigate the properties of your substance.

Step 4: You check for more information in ECHA's chemicals database. You find no REACH registration for your substance and the C&L Inventory does not list your substance or any of its defined constituents under the sections harmonised classification or notified classification and labelling according to CLP criteria for a human health or environmental effect. You have not found any experimental data or other information, which would indicate the need for a classification or hint towards persistent or bioaccumulative properties.

Step 5: The only information on the hazard properties of your substance are the indications found in the Annex III inventory for two of the constituents. You have no other information that allows you to disregard these indications, so you need to submit your REACH dossier with full Annex VII information.

Step 6: As you cannot qualify for the reduced information requirements, you need to submit a 1–10 tonne dossier with full Annex VII information. In this case, you do not need to fill in IUCLID section 14 – Annex III criteria. A fee waiver is not applicable because there is indication that at least one Annex III criterion is met.